

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

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ALINORM 83/26

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

15th Session

Rome, 4-15 July 1983

REPORT OF THE 13TH SESSION OF THE

CODEX COMMITTEE ON FOODS FOR SPECIAL DIETARY USES Bonn-Bad Godesberg, 20-24 September 1982

INTRODUCTION (Agenda Item 1)

1. The Codex Committee on Foods for Special Dietary Uses held its 13th Session from 20 to 24 September 1982 in Bonn-Bad Godesberg by courtesy of the Government of the Federal Republic of Germany. The meeting was chaired by Dr. H. Drews, Ministerialrat in the Federal Ministry of Youth, Family and Health. Professor Dr. D. Eckert, Chief of the Division for Consumer Protection of the Ministry for Youth, Family and Health and Chairman of the Codex Alimentarius Commission, opened the session on behalf of the Federal Minister for Youth, Family and Health, Mrs. A. Fuchs. Dr. Eckert welcomed the delegates and especially those who were present for the first time. He drew attention to the increasing number of countries attending the sessions of this Committee, a fact which reflected the growing interest in the work of this Committee. Dr. Eckert also outlined the achievements of the Commission in the twenty years of its existence and emphasized also that the Committee was now embarking on an entirely new field concerning nutritional aspects in Codex work. The full text of Professor Dr. Eckert's address is contained in Appendix II to this report.

2. The Session was attended by delegates and observers from the following 27 countries:

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|-----------------------|--------------------------|
| Argentina | Korea, Rep. of |
| Australia | Netherlands |
| Austria | New Zealand |
| Brazil | Norway |
| Canada | Panama |
| Cuba | Paraguay |
| Czechoslovakia | Portugal |
| Denmark | Spain |
| Finland | Sweden |
| France | Switzerland |
| Germany, Fed. Rep. of | Thailand |
| Greece | United Kingdom |
| Italy | United States of America |
| Japan | |

Observers were present from the following country and International Organizations:

- German Democratic Republic
- Association of Official Analytical Chemists (AOAC)
- European Economic Community (EEC)
- International Association for Cereal Chemistry (ICC)
- Association of Dietetic Foods Industries of the EEC (IDACE)
- International Federation of Glucose Industries (IFG)
- International Federation of Margarine Association (IFMA)
- International Secretariat for the Industries of Dietetic Food Products (ISDI)
- Marinalg International

A list of participants, including officers from FAO and WHO, is included in Appendix I to this report.

3. The Session was preceded on 16-17 September 1982 by the meeting of an ad-hoc Working Group on Follow-up and Supplementary Foods for Older Infants and Young Children. A summary report of the meeting, including a list of participants, is contained in Appendix VIII to this report (see also paras 107-114).

ADOPTION OF THE AGENDA (Agenda Item 2)

4. The Committee noted that the ad-hoc Working Groups on Methods of Analysis and on the Advisory Lists for Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children would meet during the session and would report back to the Committee (see paras 115-119 and 120-126).

5. The Committee unanimously adopted the Provisional Agenda (CX/FSDU 82/1) without change.

APPOINTMENT OF RAPORTEURS (Agenda Item 3)

6. Dr. R.W. Weik and Mr. L.M. Beacham of the delegation of the United States and Messrs A. Duran and J.L. Allain of the delegation of France kindly agreed to serve as rapporteurs for the session.

MATTERS ARISING FROM THE FOURTEENTH SESSION OF THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES (Agenda Item 4)

7. The Committee had before it document CX/FSDU 82/2 which contained references to and information on a number of matters arising from other Codex activities on which some action was required. The Committee was informed that several of the items mentioned were related to other agenda items and agreed therefore that they should be discussed in connection with those items (Parts B, C, D, E, F). Further information on the consideration by the 29th Session of the Executive Committee to matters related to the WHO Code on the Marketing of Breastmilk Substitutes was provided in CX/FSDU 82/11, Add.1 (CRD); document CX/FSDU 82/8, Add. 1 (CRD) was entitled: "The Problem facing the Developing Countries in Asia in accepting the Codex Standard for Infant Formula (CAC/RS 72-1976)", prepared by Thailand on behalf of the Coordinating Committee for Asia. For discussion of the latter two matters please see paras 127-131 and 133-140.

Amendment of Procedure for the Elaboration of Codex Standards

8. Based on the recommendations of the Codex Committee on General Principles the Commission had agreed on a revised Procedure for the Elaboration of Codex Standards. The major changes were as follows:

- (a) Steps 1, 2 and 3 have been combined, whereby subsidiary bodies may decide on the elaboration of a standard and request Government comments on the proposed draft standard, pending the subsequent approval by the next session of the Commission.

Where the timing of the sessions so requires, comments at Step 6 may be requested prior to the adoption of the relevant standard at Step 5 by the Commission. These amendments should eliminate undue delays arising from the timing of sessions.

(b) At Step 8 the Commission adopts the standards as Codex standards, the previous Steps 9-11 and 9-12 respectively were taken outside the Step Procedure. The Codex Alimentarius consists of the Codex standards and related texts and of a tabulation of acceptances.

The 5th Edition of the Procedural Manual has been prepared to take into account the above and other amendments. A number of volumes of the Codex Alimentarius have already been published. Volume IX on Foods for Special Dietary Uses including the Code of Hygienic Practice for Foods for Infants and Children and related microbiological criteria will be available in a few months time. A revised summary on acceptances will be produced for the 15th Session of the Commission.

Date Marking

9. The Committee was informed that the Commission had, at its 14th Session, adopted the revised text of the Guidelines on Date Marking for Use by Codex Committees (Vol. VI of the Codex Alimentarius). The Committee recalled that it had introduced provisions on date marking and storage instructions into the Codex Standards for Foods for Infants and Children and for Gluten-free Foods. These provisions had been adopted by the 13th Session of the Commission with the proviso that they would be revised as soon as the relevant guidelines became available.

10. The Committee considered the revised text for provisions on the date of minimum durability and storage instructions and concluded as follows:

(a) The Committee decided to retain date marking in the form of the date of minimum durability and appropriate storage instructions in the standards for Foods for Infants and Children and for Gluten-free Foods.

(b) The provisions were amended in accordance with the Guidelines on Date Marking to read as follows:

"Date Marking

The date of minimum durability (preceded by the words "best before") shall be declared by the day, month and year in uncoded numerical sequence except that for products with a shelf-life of more than three months, the month and year will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer. In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.

Storage Instructions

In addition to the date, any special conditions for the storage of the food shall be indicated if the validity of the date depends thereon.

Where practicable, storage instructions shall be in close proximity to the date marking."

(c) The Committee decided to amend the Codex Standard for Low-Sodium Food to include the above provisions. The Secretariat was requested to take the necessary action.

Sampling Plans for the Determination of Contaminants in Foods (CX/FA 82/8)

11. The Committee was informed that the above document had been discussed at the 15th Session of the Committee on Food Additives as a Conference Room Document. Comments had been requested from Codex Committees and Governments. It was recommended that delegations should remind the appropriate authorities in their countries to submit such comments.

Microbiological Criteria - Annex to the Code of Hygienic Practice or Foods for Infants and Children

12. The Committee was informed that the above criteria had been finalized by the Committee on Food Hygiene (Appendix VII to ALINORM 81/13) and adopted by the Commission. To emphasize the advisory nature of the document, an appropriate preamble had been added. Technical comments had been referred to the 18th Session of the Committee on Food Hygiene (paras 52-62 of ALINORM 83/13). The document is in the course of being published in Volume IX of the Codex Alimentarius.

CONSIDERATION OF REVISED TERMS OF REFERENCE AND OF APPROACH BY CCFSDU TO WORK ON NUTRITIONAL ASPECTS IN CODEX STANDARDS AND TEXTS (Agenda Item 5)

13. The Committee had before it Working Paper CX/FSDU 82/3 which had been prepared by a consultant, Dr. M.C. Cheney of Canada. The Chairman expressed the appreciation of the Committee for the paper and congratulated Dr. Cheney for having prepared an excellent document.

14. The Chairman gave a brief resumé of the facts which had led to the proposals contained in the document with regard to revised terms of reference, modes of operating under these revised terms of reference and the timing of the additional work. The Commission had, at its 14th Session, considered document ALINORM 81/7 entitled "Nutrition and the Work of the Codex Alimentarius Commission", prepared by Professor Dr. R.J.L. Allen. The document had contained a review of the Codex activities related to nutritional aspects in food standards on a Committee by Committee basis. Whilst it had been recognized that nutritional aspects had not been neglected in Codex work it had been recommended that a procedure be developed by which the work of the individual Committees could be coordinated and centralized, to avoid inconsistencies of approach and differences of emphasis. This Committee had been determined to be the best qualified to undertake such work.

15. It had also been noted by the Commission that this Committee had already requested the Commission to extend its responsibilities in order to discuss the Guidelines on Nutrition Labelling and on the revision of PAG Guideline No. 8 (Protein-rich mixtures for use as supplementary foods).

16. The 14th Session of the Commission had agreed in principle with the recommendations set forth in ALINORM 81/7 (para. 54) and had requested this Committee to report back to its 15th Session on the following matters: (a) the extent to which it could undertake new responsibilities under the revised terms of reference; (b) modus operandi and timing of additional work; (c) priorities of work and (d) consideration of amending the name of the Committee. The Secretariat had been requested to consult with the host government to determine the conditions under which additional work could be carried out.

17. The Secretariat informed the Committee that it had been agreed in discussions with the host government that annual sessions would not be possible for administrative and financial reasons, even if the amount of work could justify more frequent sessions. It was also pointed out that the preparation of documentation for the Committee which was of a highly technical nature would require a longer cycle than one year. The host government had, however, expressed its willingness to convene and host a two-day Working Groups prior to Sessions of this Committee which could evaluate working papers and comments on specified items and prepare appropriate recommendations for the plenary.

18. In introducing the document, Dr. Cheney pointed to the Commission's decision, namely: to request its subsidiary bodies to consider, as need arose, nutritional aspects in drawing up standards for foods, particularly foods having a significant role in the diet of developing countries. Dr. Cheney felt that CCFSU had always complied with that request and had also the expertise to advise other Committees on nutritional aspects in food standards and related texts. She considered therefore that the elaboration of appropriate guidelines, as drafted in Appendix I to the paper, should be given the highest priority. As indicated in para. 40 of the paper it was not envisaged that CCFSU would have full endorsement functions, but would endorse provisions in specific standards when requested to do so by the originating Committees. Committees would determine in accordance with the above mentioned guidelines which provisions should be referred to CCFSU for examination and endorsement. She suggested that the terms of reference be modified accordingly. Other documents, which the Committee might consider developing, could include advisory texts of a more general nature e.g. on general principles of nutritional qualities or guidelines on fortification. She mentioned that the type of nutritional aspects suitable for inclusion in Food Standards included the addition of nutrients to foods, quality aspects and effects of processing.

19. The Committee agreed with the points outlined by Dr. Cheney and concurred that it would not be possible to establish a precise timetable. It was agreed that working through specific Working Groups would be the most flexible means to achieve good results. The subject matters for future sessions of the Working Group would have to be determined according to an evaluation of priorities.

However, in view of the urgency attached to developing further the guidelines for the Use of Codex Committees on the Inclusion of Provisions on Nutritional Quality in Food Standards and other Codex Texts, it was considered that these would be the theme of the Working Group preceding the 14th Session of this Committee. It was also agreed that, since those Codex Committees which developed standards were the main users of these guidelines, good liaison should be maintained with those Committees.

20. The Committee established the above Working Group which would operate under the coordination and the chairmanship of the Federal Republic of Germany. The following countries are members of the Working Group: Brazil, Canada, Fed. Rep. of Germany, Finland, France, Netherlands, Norway, Sweden, Thailand, United Kingdom, United States, EEC (as observer). Interested countries which were not present at this session were invited to inform the Chairman of the Committee in writing of their wish to participate at the Working Group.

21. The Committee agreed to place the guidelines into the Step Procedure in order to emphasize their importance, and to consider them to be at Step 3, subject to approval by the Commission. The Secretariat was requested to take appropriate action.

22. The Committee discussed fully as to whether the name of the Committee should be amended to reflect the new responsibilities of the Committee. It was pointed out by the Chairman that a change at the present time might be premature and that an amendment of the name should be considered at a future session when the Committee was more familiar with its new tasks. The Secretariat stated that also the terms of reference had a bearing on the name of the Committee which should, in general, reflect the functions of the Committee. The delegation of Norway supported by the delegations of the Netherlands, France and Denmark proposed to name the Committee "Committee for Nutrition and Foods for Special Dietary Uses". The delegation of the Netherlands expressed the opinion that at a later stage this might be amended to read "Committee for Nutrition". The delegation of the Federal Republic of Germany felt that the name should only be changed if necessary and if it were changed it should be done adding "and nutritional quality" to the present name. This view was supported by Switzerland. The Committee decided to request the Working Group to examine this matter and make recommendations to the next session of this Committee.

23. The Committee concluded as follows:

- (a) The Committee agreed with the following revised terms of reference and is willing to take on the new responsibilities outlined therein:
- To develop guidelines, general principles and standards for foods for special dietary uses, alone or in cooperation with other Committees, and to endorse provisions for special dietary purposes contained in commodity standards. The standards should be elaborated on a worldwide basis except where this is not found to be possible, in which case, the standards could be elaborated on a regional or group of countries basis.
 - To study specific nutritional problems assigned to it by the Commission.
 - To draft provisions concerning the nutritional aspects of all foods.
 - To advise the commodity and general subject Codex Committees on the nutritional aspects of the standards for which they are responsible and to elaborate guidelines for this purpose.
 - To consider, amend if necessary, and endorse provisions on nutritional aspects contained in draft standards or other Codex texts prepared by other subsidiary bodies of the Codex Alimentarius Commission and referred to the Committee.
- (b) The Committee does not recommend yearly sessions since this would create administrative and financial difficulties and since a longer period of time is needed for the cycle required for effective preparation of working documents of a highly technical nature.
- (c) As outlined in paras 19 and 20 above the Committee has determined the subject matter, its mode of operating and the composition of the Working Group which will meet prior to its next session (14th). A similar exercise will be followed for future working groups when new topics arise.
- (d) The Committee requests the Commission to approve that the "Guidelines for the Use by Codex Committees on the Inclusion of Provisions on Nutritional Quality in Food Standards and other Codex Texts" be placed into the Step Procedure to emphasize their importance (at Step 3).
- (e) Comments from Governments, Interested International Organizations and Codex Committees will be requested on the above guidelines as contained in Appendix IV to this report.
- (f) The Committee requested the Working Group to give further consideration to a possible amendment of the name of the Committee with the view that it should fully reflect the new terms of reference and responsibilities in an unequivocal way.
- (g) The Committee will inform the Commission at future sessions of its priorities since it is not possible to establish a long-term time-table.

CONSIDERATION OF THE DRAFT GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES AT STEP 7 (Agenda Item 6)

24. The Committee had before it the above Draft General Standard (Appendix II to ALINORM 81/26) and comments from Governments thereon (CX/FSDU 82/4). In introducing this item, the Chairman of the Committee expressed the opinion that the Committee should discuss not only the various sections of the General Standard, but should also address the scope of the standard in order to determine whether it should cover only prepackaged foods for special dietary uses.

Section 1 - Scope

25. The Secretariat informed the Committee that the Codex General Standard for the Labelling of Prepackaged Foods was under revision and the terms "prepackaged" and "consumer" were redefined in such a way as to include products intended for catering purposes. The delegation of Argentina pointed out that special dietary foods could only be marketed in that country in the prepackaged form.

26. Following a discussion as to whether the standard should include a statement that special dietary foods should at all times be presented in the prepackaged form, the Committee decided to leave the scope section of the standard essentially unchanged. However, it agreed to include foods intended for sale for catering purposes as provided for in the General Standard for the Labelling of Prepackaged Foods under revision.

Section 2.1 "Foods for Special Dietary Uses"

27. The delegation of the USA was of the opinion that it should not be mandatory that "foods for special dietary uses" should have a composition which differed significantly from the composition of comparable ordinary foods, pointing out that in its opinion ordinary foods might be represented as for special dietary use. Should the Codex Standard contain such a mandatory requirement the USA would have to indicate a deviation when accepting the General Standard. It was noted in this respect that Section 6.1.3 on Claims required such a compositional difference for a food to be designated "special dietary".

28. The delegations of the Netherlands and Norway were of the opinion that Section 2.1 did not distinguish sufficiently between ordinary foods and special dietary foods and that, therefore, it would be desirable to list those foods which could be considered to fall under the definition for the purpose of making claims or listing claims. A number of delegations were of the opinion that any list developed could not be exhaustive and, if developed, would have to be advisory and subject to frequent revision.

29. The Committee decided not to proceed as suggested by Norway and the Netherlands.

Section 2.4 - Advertising

30. The delegation of the United States, supported by Thailand, suggested that the words "except those mentioned under 2.2 and 2.3" should be deleted, since label declarations were a form of advertising. The Committee noted that the Codex Committee on Food Labelling would consider the question of advertising; for this reason it was decided to leave section 2.4 unchanged.

Section 2.5 - Claims

31. The delegation of Switzerland suggested that this section should be brought into line with the General Labelling Standard by deleting the text following the word "quality". The Secretariat, supported by Thailand, pointed out that reference to nutritional and special dietary aspects would be essential in relation to claims concerning foods for special dietary uses. It was agreed to leave the text of section 2.5 unchanged.

General Remarks

32. The representative of the EEC suggested that the definitions of terms should be those included in the General Labelling Standard, which could be included by reference. It was noted that there may be a need to depart from the General Labelling Standard and that the latter was still under revision. It was agreed to return to this matter in the future when the General Labelling Standard has been finalized.

33. It was also agreed, on the suggestion of the Secretariat, that the CCFL be requested to consider including in the Scope Section of the General Labelling Standard for Prepackaged Foods a reference to the General Standard under discussion, in addition to the reference to individual Codex Standards in Section 4, on the basis of which the labelling of prepackaged foods may depart from the General Labelling Standard.

Section 4 - Mandatory Labelling of Prepackaged Foods for Special Dietary Uses

Section 4.1.1.2

34. In the opinion of the delegation of Argentina the term "common or usual name" required further explanation. In order to make the meaning of this term clear the Committee decided to adopt the text as given in section 4.1.1.2 of the General Labelling Standard in Appendix VI to ALINORM 83/22.

Section 4.3 - Nutritional Labelling

35. The delegation of the United Kingdom suggested that minerals and vitamins should be declared as a proportion of the daily recommended intake per 100 g or, preferably, per one serving of the product. It was noted that section 4.3(c) related to characterizing ingredients, whether nutritional or not, and, therefore, should read "specific nutrients foodstuffs". It was also noted that reference to minerals and vitamins should be made elsewhere in the standard in relation to nutritional labelling. The Committee agreed that a better term was "specific nutrients and/or other components", since not all components were nutritive and since those components which characterized the special dietary nature of the food required declaration.

Section 4.7 - Lot Identification

36. The delegation of Argentina indicated that sub-section 4.1 was not mandatory in that country, but that products labelled in accordance with this section would be permitted entry.

Section 4.8 - Date Marking

37. The Committee agreed that the text adopted earlier during the session (para. 10) should replace section 4.8.1. The delegation of France was of the opinion that where the product contained unstable vitamins, a date limit should be declared on the label. The delegation of Thailand also was of the opinion that for foods for infants and children an expiry date should be indicated.

Section 4.9

38. The Committee agreed that the text adopted earlier during the session for storage instruction should be used for the unopened food in sub-section 4.9.1 (para. 10) with sub-section 4.9.2 remaining unchanged.

Section 5.1 - General

39. The delegation of Switzerland was of the opinion that it would not always be possible to include statements on that portion of the label which were presented to the consumer at the time of sale. For this reason the last sentence of Section 5.1 should be deleted. Noting that this requirement was included in the General Labelling Standard which was still subject to discussion by the CCFL, it was decided to leave Section 5.1 unchanged.

Section 5.2 - Language

40. In order to make it quite clear that supplementary labels should not be such as to be easily separated from the container, it was agreed to change the wording to "an attached supplementary label".

Section 6.1.1

41. The question was raised as to whether advisory texts could be included in Codex Standards as mandatory provisions. The Committee noted its previous decision (para. 40, ALINORM 81/26) that the Codex General Guidelines on Claims should indeed be mandatory, when incorporated in this standard.

Section 6.1.3

42. The delegation of the Federal Republic of Germany suggested an additional change in order to make it clear that it was not the intention that only the terms "special dietary" or "special dietetic" should not be used under certain circumstances, but that reference, in any way, to the special dietary nature of the product was not permitted. The Committee agreed to make the necessary editorial changes to Section 6.1.3.

Section 6.2 - Irradiated Foods

43. The Committee noted that this question was under discussion by the CCFL and the CCFA and that it would be amended in due course.

Status of the Standard

44. The Committee decided unanimously to advance the Draft General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses to Step 8 of the Codex Procedure. The text of the standard is given in Appendix III to this report.

CONSIDERATION OF A PROPOSED DRAFT STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS CLAIMED TO BE SUITABLE FOR INCORPORATION IN A PRESCRIBED DIETARY REGIMEN FOR DIABETICS AT STEP 4 (Agenda Item 7)

45. The Committee had before it the above proposed draft standard contained in Annex II, Appendix III to ALINORM 81/26 and Government comments thereon (CX/FSDU 82/5).

General Discussion

46. The Committee discussed the need to continue with the elaboration of this general standard. The question also arose as to whether only questions relating to labelling and claims should be covered or whether there was a need to include also some compositional criteria.

47. The delegation of the United Kingdom pointed out that medical opinion had changed over the years as regards the dietary management of diabetes. Current thinking in the UK was directed to a need for diabetics to reduce their intake of readily absorbable carbohydrates and to control body weight. While this could be achieved through a selection of normal foods it was recognized that foods existed on the market which claimed to be suitable for diabetics. These foods should be controlled in terms of their mono- and disaccharide content while maintaining a fat and energy content so that they did not exceed that of comparable foods. Provisions for "glucoplastic" sugar substitutes such as fructose and sorbitol could also be subject to regulations. The delegation of New Zealand, supported by the delegation of Japan, was of the opinion that there was no need to elaborate a standard on diabetic foods since the General Standard for the Labelling of and Claims for Special Dietary Foods could be expanded to take such foods into account. This was also supported by the fact that there were different forms of diabetes (e.g. among Polynesian groups of population) which required different types of management. While agreeing with these views, the delegation of France was of the opinion that some reference to certain compositional criteria was essential. The delegation of the Netherlands pointed to the need to agree internationally on the suitability of the various sweeteners as well as on questions relating to labelling and claims.

48. The delegation of Canada supported the views expressed by New Zealand and pointed to the need to describe these products in terms of objective criteria rather than as being "suitable for diabetics". The delegations of Denmark, Australia and Czechoslovakia expressed the view that it was premature to establish an international standard for foods for diabetics in view of differences in scientific opinion concerning the management of diabetes. Standards should be first established at the national level. The delegation of Australia expressed concern about the suitability of fructose in the diet of diabetics.

49. The delegation of the Fed. Republic of Germany expressed the view that there was a need to regulate foods for diabetics since these existed on the market and since these products represented a part of a life-long diet.

50. It was agreed that the standard should, in any event, be discussed since there was a clear need to agree on labelling and claims. Questions of composition could be tackled at a later stage. The question of whether a separate standard should be developed or whether the General Standard should be expanded was an editorial one which could also be discussed later.

Section 1 - Scope

51. The delegation of the Netherlands stated that any food could be suitable for diabetics provided the dietary regimen was chosen carefully by the person concerned. However, artificially sweetened foods could be regarded as foods suitable for diabetics. This was a question of labelling. The delegation of France was of the opinion that foods for diabetics should be restricted to compositionally modified foods. As such foods needed to be controlled, one approach would be to leave the matter to national legislation or alternatively, to cover the matter in the general labelling and claims standard as it was important for diabetics to know the composition of foods recommended for them. The delegation of the United Kingdom agreed with the view of the Netherlands but suggested that the standard should not be restricted only to artificially sweetened products.

52. The Committee agreed to leave the section on scope unchanged.

Section 2.1 - Diabetics

53. The delegation of Denmark, supported by Norway, was of the opinion that the definition of a "diabetic" should be redrafted since such a definition should not be based on a requirement for special dietary foods.

54. The Committee decided to place the definition in Section 2.1 in square brackets so that it could be rediscussed at the next session.

Section 2.2 - Qualified Person

55. The delegation of the USA suggested that only physicians should be referred to as qualified persons. It was agreed to make editorial changes to make it clear that qualified persons also included other persons such as qualified dietitians as suggested by the existing text.

Section 2.5 - Nutritive Sweeteners

56. Several delegations suggested that fructose should not be included in a definition of "nutritive sweeteners" by deleting the words "/ except fructose /", in view of uncertainties concerning the suitability of this substance for diabetics. This view was supported by several delegations. Other delegations were not of the view that a limited intake of fructose by diabetics would be acceptable. It was agreed that the words "except fructose" be deleted. It was noted that sorbitol was converted to fructose during metabolism.

Section 2.6 - "Glucoplastic" Sugar Substitutes

57. The Canadian delegate questioned whether fructose should not be deleted in this section. It was agreed to leave fructose in as a permitted component for the time being.

Section 3 - Mandatory Labelling

58. Section 3.2.2(a) was corrected by adding the word "low" in relation to "molecular". In Section 3.2.2(b) it was agreed that the quantity of "glucoplastic sugar substitutes" referred to individual quantities of these substances rather than combined weight. In this respect it was noted that analytical difficulties would be met when hydrogenated glucose syrup was used since this material contained sorbitol and other sugar alcohols.

59. As regards sorbitol and other polyols a mandatory declaration of possible laxative properties was thought to be necessary by the delegations of the Federal Republic of Germany and the Netherlands.

Section 4 - Claims

60. The delegation of the Netherlands, supported by Norway, suggested that an additional clause be inserted prohibiting reference to properties leading to reduction of weight both for products made with artificial sweeteners and with glucoplastic sugar substitutes. The Committee decided not to include such a provision at this time.

Section 4.1

61. The delegation of the United Kingdom suggested that the text of Section 4.1(a) should be amended by introducing a maximum limit of 5% for mono- and disaccharides. This was desirable to control the presence of total sugars from all sources, which would be present in the product as a result of the use of ingredients such as fruits and milk. This represented an approach recommended by the British Diabetic Association. The delegations of the United States and Sweden questioned the basis of the proposed limit of 5%, while the delegation of the Netherlands was of the opinion that the presence of 5% sugars in soft-drinks would represent a large intake of sugars from that source.

62. The Committee decided not to follow the suggestion of the delegation of the United Kingdom since it was not considered to be feasible to control effectively dietary sugar intake through setting upper limits in standards.

63. The delegation of the Netherlands suggested that lactose, which was a sugar not requiring insulin, should be exempted from 4.1(a). Noting that lactose was slowly digested and metabolized to glucose and would fall under the definition of glucoplastic sugar substitute, the Committee decided not to accept the suggestion of the Netherlands.

64. The delegations of Denmark, Sweden and the United States were of the opinion that fructose should be included in 4.1(a) for reasons given in para. 56 above. The Committee took no action on the proposal.

65. The delegation of the Netherlands expressed the opinion that the glucoplastic sugar substitutes indicated in Section 4.1(b) should be used in restricted amount since they yielded energy and because of their possible laxative effect. The delegation of the United States was of the opinion that more information was needed on these glucoplastic sugar substitutes, including information relating to the safety of certain of them, and that maximum levels may have to be set for glucoplastic sugar substitutes. The delegations of Denmark and Norway were of the opinion that 4.1(b) should either be deleted or a maximum limit set for glucoplastic sugar substitutes since their beneficial properties were in doubt.

66. The Committee adopted a text proposed by the Secretariat which required that the presence of sugar substitutes should be restricted as far as possible. The Committee also decided to delete the square brackets in 4.1. It was agreed that Governments should be requested to comment on the question of setting limits for sugars and their substitutes.

67. The delegation of the Federal Republic of Germany, supported by a number of delegations, proposed that 4.3(f) be deleted since it did not correspond to modern concepts of management of diabetes. The delegations of the United Kingdom and the Netherlands suggested that in 4.3(f) "carbohydrate" should read "readily absorbable insulin-requiring carbohydrates".

These delegations were against the deletion of 4.3(f) and considered that, if deleted, even sugars would be permitted to be marketed as being suitable for diabetics. The delegation of the Netherlands proposed to exempt fructose from this deletion.

68. The Committee agreed with the proposals of the delegations of the United Kingdom and the Netherlands except that the words "insulin requiring" were deleted and the term "fructose" was placed in square brackets.

69. The Committee discussed a proposal of the Netherlands that the claim "sugar-free" should be generally prohibited. The Canadian delegate indicated that only energy-free foods could be described as "sugar-free" in Canada and proposed the inclusion of the following text in the standard:

"that a food which contains little or no sugar is also reduced in energy value or that such a food may be useful in weight-reduction diets when such is not the case".

The delegations of the Federal Republic of Germany, Czechoslovakia and the USA supported the delegation of Canada.

70. The Committee adopted the text proposed by Canada. The delegation of the Netherlands was strongly in favour of a total prohibition of the claim "sugar-free".

Status of the Standard

71. The Committee agreed that the standard required further consideration and was not ready to be submitted to the Commission. The Proposed Draft Standard, as amended, was returned to Step 3 for further comments. The revised text of the standard is given in Appendix V to this report.

CONSIDERATION OF PROPOSED DRAFT GUIDELINES ON THE LABELLING OF AND CLAIMS FOR "MEDICAL FOODS" (Agenda Item 8)

72. The Committee had before it Working Paper CX/FSDU 82/6 containing the above guidelines which had been prepared by the delegation of the United States. The Chairman thanked the delegation of the United States for the valuable document which deals with an important type of foods for special dietary uses, i.e. a new concept of foods which had to be administered under very specific conditions, under strict supervision of medically qualified persons, and which required therefore appropriate labelling.

73. Dr. J. Chopra, speaking for the delegation of the United States, introduced the paper and pointed out that the present guidelines represented a first draft of provisions for labelling and claims and did not contain compositional criteria. The developments of these foods were influenced by rapid advances in science, nutrition and medicine and required therefore reliable and accurate labelling and well understood definitions.

74. Dr. Chopra highlighted the specific characteristics as contained in Sections 2.1 and 2.2 (Definitions) and drew attention to Section 3.6 which outlined the types of foods for special dietary uses which were not to be considered medical foods. She further indicated that reference to the disease for which the food was suitable could either be of specific or generic nature (e.g. PKU or malabsorption).

75. Great importance was attached to appropriate warnings on the label in order to avoid certain of these foods being consumed by healthy persons for whom they might be harmful. Concerning the use of claims, Dr. Chopra pointed out that it was important to avoid, through the appropriate regulation of claims, the marketing of such foods which were not based on sound scientific and medical principles.

76. Several delegations, including those of Switzerland, Austria, France, Italy, Federal Republic of Germany and Portugal expressed their appreciation for the document which dealt with a new type of products for which often comprehensive national regulations were not available.

77. Concerning the name of the product, it was stated by a number of delegations that the term "medical" food could be misleading and indicated that products so designated were drugs. The proposed alternatives included: "dietary foods for prescription" (Switzerland),

"dietetic foods for medical prescription" (France), "foods to be used only under medical supervision" (Federal Republic of Germany), "health food" (Thailand), "foods for patients" (Netherlands). The Committee agreed therefore to place the term "medical" in square brackets.

78. The delegations of Austria and of Spain expressed the view that the guidelines should contain provisions which would distinguish these medical foods more clearly from foods for special dietary uses as defined in the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses. The delegation of Austria felt that for this purpose it might be useful to replace "product" by "food" throughout the guideline. The delegation of Argentina indicated that in Argentina these foods are considered to be drugs.

79. The delegation of France stated that it could agree with the principle contained in the guidelines and outlined the relevant regulations for such foods in force in France. Medical foods should not be considered to be drugs, and therefore the term "medical food" should not be used; furthermore the definition should make a clear distinction from foods for special dietary uses.

80. Several delegations commented on the usefulness of retaining the detailed provisions contained in Section 2.2. The delegations of France, Thailand, and the United Kingdom explained the reasons why they wished to delete especially Section 2.2(a) dealing with nutritionally complete foods. The delegation of France was opposed to the principle as such; i.e. to medical foods supplying all nutrients, since these foods should be adapted to their intended purpose. The delegation of the United Kingdom informed the Committee that such foods were used in the United Kingdom, e.g. for treating digestive up-sets and sold without prescription.

81. The delegation of the Federal Republic of Germany, supported by Denmark, emphasized the importance of such nutritionally complete foods which were used for tube-feeding of very ill people. They should therefore contain all nutrients and should be subject to careful control.

Status of the Guidelines

82. The Committee agreed, in principle, with the draft guidelines in its revised version as contained in Appendix VI and decided to place them into the Step Procedure at Step 3 subject to approval by the 15th Session of the Commission.

83. It was further agreed to request comments on the terms in square brackets and on the whole text of the guidelines. These comments should be submitted at an early date to the delegation of the United States which offered to prepare two papers (a) a collation of comments received and (b) a text of guidelines revised in the light of those comments.

84. The Committee also agreed that a Working Group consisting of delegates from the United States, France, Federal Republic of Germany, Switzerland, Netherlands, United Kingdom, Thailand and Canada would meet during the next session of this Committee in order to examine the documentation and prepare recommendations for the Plenary. (See para. 154).

CONSIDERATION OF PROPOSED DRAFT STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED LOW ENERGY REDUCED FOODS (Agenda Item 9)

85. The Committee had before it working paper CX/FSDU 82/7 containing the above standard which had been prepared by the delegation of the United States. The Chairman expressed the Committee's appreciation for the paper and thanked the delegation of the United States for preparing the redrafted version of the standard, which had taken into account Government comments on this matter. The delegation of Australia stated that great importance was attached in Australia to the products covered by the standard and regulations for them.

86. The Committee agreed that it was important to delineate the scope of this standard clearly and to distinguish clearly the products covered by this standard from other foods for special dietary uses by means of appropriate definitions. Special attention should be paid to those sections which concerned either ordinary unmodified foods low in energy or foods suitable for use by diabetics. These latter ones were already covered by another standard. The Committee decided to take these considerations into account when discussing the draft section by section.

Section 1 - Purpose

87. The Secretariat was requested to give advice as to whether this section should appear in a standard. It was pointed out that the guide on the Format of Codex Standards (see Procedural Manual) did not specifically mention such a section. The Committee might, however, decide to include a section "purpose", if the nature of the standard concerned would make that desirable. Sections on "purpose" were often included in guidelines. The Chairman proposed as an alternative to enclose the content of Section 1 in a preamble since it was important for the understanding of the standard. It was decided to leave Section 1 unchanged.

Section 2 - Scope

88. It was decided to clarify the scope by indicating that the standard applied to the labelling of and to claims for the foods concerned.

89. Several delegations expressed doubts as to whether reference to body weight and the use of the terms "maintaining" or "reducing" were appropriate since considerations on body weight were related to a diet as such and not to a single food. It was agreed to delete reference to body weight. For similar reasons it was agreed to replace the term "maintaining" by "controlling".

90. Attention was drawn to the Proposed Draft Standard for the Labelling of and Claims for Prepackaged Foods claimed to be suitable for Incorporation in a Prescribed Dietary Regimen for Diabetics (see paras 45-71) which covered foods for use in a diet for diabetics. Whilst it was recognized that many diabetics were obese and could benefit from energy reduced foods, the Committee decided, nevertheless, to separate entirely the two standards and to delete all references and provisions related to foods for use in a diet for diabetics from the scope as well as from the other sections of this standard.

Section 3 - Definitions

Definition of "Low Energy Foods" (Section 3.1)

91. The Committee discussed extensively the above definition and, in particular, whether it should apply to foods for special dietary uses only or whether the definition should include also foods which are naturally low in energy. It was pointed out that this Committee was dealing with foods for special dietary uses. During the discussion of the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses, the Committee had already decided to limit the scope of these labelling standards to foods for special dietary uses, i.e. specially modified foods. The Committee had also included in the general standard under the section on claims (Section 6.1.3) a provision for appropriate claims concerning foods naturally low in certain nutrients. It was decided to amend "food" to read "foods for special dietary uses".

92. The Committee also discussed the numerical value in the criteria which justified the use of the name "low energy food". Dr. Chopra, in introducing the paper, informed the Committee that these values reflected the regulations of the United States. The delegation of the United Kingdom was of the opinion that these figures should be further discussed. They might also not be appropriate if the Committee decided that the standard should also cover meal replacers which provided about 4 Kcal per gramme of dry matter and about 200 Kcal per serving. The delegation of Switzerland, supported by France, suggested the maximum

be raised to 50 Kcal. Other delegations, including the delegation of the Federal Republic of Germany, pointed out that lower maximum levels of 20 Kcal should be introduced for soups and drinks since the portion of the foods normally consumed was much larger. Reference was also made to very low calories drinks which were well-known by consumers. It was also suggested that the final text might even contain different values for different types of foods. It was decided to place the numerical values in square brackets and request comments thereon.

93. The delegation of the Federal Republic of Germany was of the opinion that the term "serving" and reference to household measures were too vague, since they varied with the eating habits in different populations and countries. It proposed to relate all criteria to metric units. This view was supported by the other delegations; especially since a Codex Standard was intended to be an internationally acceptable document.

94. The delegation of Canada pointed out that the provision on sugar substitutes required clarification, since the products concerned were artificial sweeteners extended with starch or lactose, which were used in very small amounts and per serving provided about 4 Kcal, derived from the carrier material. These products needed therefore a specific exemption from the requirements of 0.4 Kcal per gramme as stipulated in this definition. This was supported by the United Kingdom. It was agreed to delete the present second sentence of 3.1 and to request the United States to redraft the provision.

Definition of "Reduced Energy Food" (Section 3.2)

95. The Delegation of Denmark proposed to express the energy reduction by metric weight units instead by serving. The delegation of the United Kingdom proposed a reduction by 25% of the energy value and that consideration be given to whether the reduction should be in the product as sold or as served. It was decided to place "one third" in square brackets. Several delegations were of the opinion that a large number of minimally processed foods could not be modified so as to become either "low energy" or "energy reduced" since their nature did not make feasible any considerable modification of their energy content (e.g. fruit, meat). Therefore the use of these terms could result in an undue emphasis on processed or fabricated foods.

Sections 3.5 to 3.7

96. For reasons indicated in para. 93 these sections were placed in square brackets to emphasize the need for comments on the appropriateness of using terms such as serving or portion. The delegation of Australia stated its opposition to permitting the use of these products for infants and children up to four years. The delegation of Italy drew attention to the recommendation by JECFA not to use artificial sweeteners for young children. It was agreed to place the relevant part of Section 3.5 in square brackets.

Section 4 - Labelling

97. It was agreed that in the redraft of the standard particular attention should be given to the provisions contained in Section 4 to avoid any conflict with other labelling standards for foods for special dietary uses and especially with the General Standard and with the other provisions contained elsewhere in this standard. It would also be necessary to distinguish clearly between labelling provisions for inclusion in Section 4 and claims which should be included in Section 5.

98. Some editorial amendments were made to bring the provisions in line with the definition in Section 3.

Section 4.2 was deleted since a similar provision was already covered in Section 4.5.

99. The delegation of Sweden suggested to consider in Section 4.6 more detailed requirements with regard to the normal foods which were considered to be comparable with those modified foods. Also the delegation of Italy felt that the approach to these requirements in Section 4.6 was not scientifically sound. It was agreed that different approaches might have to be considered.

100. In connection with considering Section 4.8, the delegation of Denmark was of the opinion that Section 3.1 should not apply to foods naturally low in energy but only to modified foods and that Section 4.8 should therefore be deleted. The delegation of the United States proposed that this section be replaced with Section 6.1.3 of the General Standard. The Committee agreed to place the section in square brackets, since it was agreed that more thoughts had to be given to this matter.

Section 5 - Claims

Sections 5.1 and 5.3

101. The Committee agreed that Section 5.1(a) would have to be redrafted since it was confusing in its present version. Consideration should be given not only to sugars but also to the need for similar provisions for fat. In accordance with the Committee's decision on foods for use in a diet for diabetics (see para. 90) the Committee decided to delete Section 5.3 entirely.

102. The delegation of the Netherlands explained that it was opposed to the use of the term "diet" or "dietetic" for foods or drinks simply because these were low or reduced in calories.

Status of the Standard

103. The Committee decided to advance the Proposed Draft Standard for the Labelling of Prepackaged Low Energy and Reduced Energy Foods to Step 3 of the Procedure. The revised text is contained in Appendix V to this report.

104. It was also decided to follow the same procedure in the further elaboration of the standard as outlined in paras 83 and 84. Special attention should be paid to complete the editorial changes concerning the use of the term "energy" through out the standard.

Meals and Meal Replacers

105. The delegation of Denmark supported by the Federal Republic of Germany stated that no specific provisions for meal replacers (slimming foods) had been included in the above standard. They drew attention to the urgent need to regulate these foods since they could represent a hazard to health if not properly used. The Chairman confirmed that those foods played an important role in weight control. The delegation of Norway felt that these products should not be called "slimming foods" at all.

106. The Committee decided that the Circular Letter which would accompany the final version of this report should request Government comments on the important aspects of slimming foods including the need for and feasibility of a standard for these products.

CONSIDERATION OF THE REPORT OF THE AD-HOC WORKING GROUP ON FOLLOW-UP AND SUPPLEMENTARY FOODS FOR INFANTS AND CHILDREN (Agenda Item 10)

107. The Committee had before it the following documents: CX/FSDU 82/10, Addenda 1 and 3 thereto and the Report of the ad-hoc Working Group (Appendix VIII to this report) which was introduced by the Chairman of the Working Group, Prof. J. Rey (France). He outlined the major issues discussed by the Working Group, including the need for a standard for follow-up foods. Such fundamental questions as the need for a standard and the position regarding "milk-based" follow-up foods and the starting age for which follow-up foods were intended, still needed to be resolved.

(a) Follow-up Foods for Older Infants and Young Children

General

108. The delegation of Switzerland traced the development of the Proposed Draft Standard as contained in CX/FSDU 82/10, Add. 1. The European Society for Pediatric Gastroenterology and Nutrition (ESPGAN) had defined follow-up formula to be a formula suitable for feeding

of infants from 4-6 months of age. This period corresponded to the weaning period during which the diets of infants vary considerably. The delegation pointed out these foods constituted only part of such diets and that there was a large international trade in these products.

109. It was also noted that the subject of infant formula and follow-up foods was being examined within the EEC and that no conclusions had as yet been reached, since this work was at present at an early stage.

110. The delegation of Norway, supported by a number of delegations, suggested that the standard be returned to Step 3 for further comments. The delegation of Switzerland was of the opinion that going forward to Step 5 was preferable since, in any event, the Committee would still have ample opportunity to consider the standard in the light of comments.

Status of the Standard

111. The Committee decided to return the Proposed Draft Standard for Follow-up Foods to Step 3 of the Codex Procedure. The text of the standard is given in Appendix IX to this report.

(b) Guidelines for Development of Supplementary Foods for Older Infants and Children

3. Definitions

112. The representative of WHO expressed the opinion that the present definition of the drafts gave the impression that these supplementary foods were equivalent to breastmilk or Infant Formula as they were defined as being suitable at the age of 4-6 months. The Committee agreed to return to this matter at its next session.

Status of the Guidelines

113. It was agreed that little would be gained from further discussion of the guidelines which had been considered in detail by the ad-hoc Working Group. The Committee, therefore, decided to advance them to Step 3 of the Procedure. The text of the guidelines is given in Appendix X to this report.

(c) Establishment of a New Ad-hoc Working Group

114. The Committee thanked the Chairman and members of the Working Group for the work they had done and decided that the ad-hoc Working Group should be reestablished. It would meet during the next session of the Committee (see para. 154).

CONSIDERATION OF THE REPORT OF THE AD-HOC WORKING GROUP ON METHODS OF ANALYSIS FOR FOODS FOR INFANTS AND CHILDREN (Agenda Item 11)

115. The Committee had before it a report of the above ad-hoc Working Group which met during the session of the Committee (see Appendix XI to this report). The Chairman of the Working Group, Professor Dr. W. Krönert, informed the Committee of the conclusions of the Group. It was expected that certain methods, such as the determination of iodide, in standards for foods for infants and children, would be finalized at the next session. The Working Group had also discussed the need to review the various standards for special dietary foods already elaborated or under elaboration in order to make sure that appropriate methods of analysis and sampling were available. This would involve a change in the mandate of the Working Group and at least a one day meeting during the next session of the Committee.

116. The delegation of Italy referred a question to the Working Group concerning a HPLC-method for the determination of Vitamin A and other vitamins and a method to distinguish between cis- and trans-fatty acids. The Committee agreed that the Working Group should also follow the development of a method for the determination of gluten in "gluten-free" foods.

117. The Secretariat informed the Committee that the Codex Committee on Food Labelling had set up an ad-hoc Working Group to develop methods for the verification of nutrients declared on the label. The Chairman of that Working Group would contact Prof. Krönert in order to coordinate work.

118. The Committee accepted the conclusions of the Working Group as given in its report (Appendix XI to this report) and agreed that the Working Group should also consider the questions in para. 116.

Establishment of a New Ad-Hoc Working Group

119. The Committee thanked the Chairman and members of the Working Group and decided that the ad-hoc Working Group be reestablished and should meet during the next session of the Committee (see para. 154).

CONSIDERATION OF MATTERS RELATED TO MINERAL SALTS AND VITAMIN COMPOUNDS FOR USE IN FOODS FOR INFANTS AND CHILDREN (Agenda Items 11 and 12)

A. Report of the Ad-hoc Working Group on Mineral Salts and Vitamin Compounds

120. As indicated in para. 4 the above Working Group met during the session and the meeting was attended by representatives from the Federal Republic of Germany, France, Switzerland, United Kingdom and the United States. Dr. R.W. Weik of the United States acted as Chairman and presented the following report:

(a) The Working Group considered comments from Governments contained in CX/FSDU 82/9-Part II, Add. 1, and CX/FSDU 82/8 and the proposal from Switzerland contained in CL 1981/57 (FSDU).

(b) Switzerland proposed the addition of (i) dextrines; (ii) modified starches (as included in List A(1) of the Guide to the Safe Use of Food Additives); (iii) Guar Gum; and (iv) Carob Bean Gum (Locust Bean Gum) to the Advisory List of Vitamin Compounds.

(c) The Working Group agreed to the addition of (i) and (ii) above but at a level of 0.1 g/kg of ready to use food with a combined total of 0.2 g/kg.

(d) The Working Group noted that the gums (iii) and (iv) were already permitted in the Infant Formula Standard as thickening agents and agreed to include them in the Advisory List at a combined use level not to exceed the level in that standard.

(e) The Working Group considered a request from the United States to add guar gum to canned baby food. Since the standard currently provided for Locust Bean Gum at the level of 0.2/100 g, the Working Group agreed to the proposed amendment of providing for guar gum at the level of 0.2 g/100 g.

(f) The Working Group agreed to add to the "C" list ferrous ascorbate and the lysine/copper complex as requested by France and pyridoxine palmitate and pyridoxine di-palmitate as requested by Italy. Both Governments are requested to supply the required information to meet the Criteria for Amendments of the Advisory List.

121. The Committee agreed with the report and the proposals contained therein and requested the Secretariat to take the necessary action with regard to the amendments to the Codex Standards for Foods for Infants and Children (see para. 122) and the Advisory List for Vitamin Compounds. The revised texts are contained in Appendix XIII to this report. Appropriate amendments were also made to List C (Proposals for Inclusion into the Advisory List). List C, as well as the relevant list for mineral salts and the criteria for amendment of the approved lists as published in Volume IX of the Codex Alimentarius, are attached to this report as Appendix XII. Interested Governments were invited to supply data for an evaluation of these proposed substances in accordance with the established criteria.

B. Proposed Amendment to Codex Standard for Infant Formula (CODEX STAN 72-1981) at Step 4

122. The above amendment was contained in para. 87 of ALINORM 81/26. An editorial amendment was made in the numbering (5.3 became 5.5). It was also agreed to include into 5.5(b) reference to the maximum levels for carrier substances as contained in para. 120 above.

Status of the Amendment

123. The Committee agreed that the revised text of the Amendment, as contained in Appendix XIII to this report, be advanced to Step 5 and that it be recommended to the Commission to omit Steps 6 and 7 and adopt, at its next session the amendment at Step 8, in view of its non-controversial nature.

C. Proposal for Amendment of Maximum Level of Vitamin D in Codex Standard for Infant Formula (CODEX STAN 72-1981)

124. The delegation of the Netherlands recalled that the Committee had decided that the Proposed Draft Standard for Follow-up / Food / should contain in square brackets a maximum level of 120 I.U. per 100 available Kcal (30 I.U. per 100 available kJ) and proposed that also in the Codex Standard for Infant Formula the maximum should be raised to the same limit.

125. The delegation of France supported this view and pointed out that the supply of Vitamin D was basically a problem related to the daily dose from all sources. Up to six months the Vitamin D content of Infant Formula covered the requirements (after that age this was not the case). Also for other reasons infant formula had to be complemented by other foods after the age of six months.

126. The Committee agreed with the Chairman's view that Governments should be requested to comment on this matter, which would be further discussed at the Committee's next session. The Secretariat was requested to elaborate appropriate wording for inclusion into an appendix which would contain all proposals for additional amendments submitted by the Committee to the Commission (see para. 121 and Appendix XIII).

D. Problems Concerning the Acceptance of the Standard for Infant Formula by Developing Countries in the Region of Asia

127. The delegation of Thailand introduced a paper prepared at the request of the 3rd Session of the Coordinating Committee for Asia (CX/FSDU 82/8-Add. 1- CRD), outlining the reasons why developing countries in the region of Asia were not in a position to give full acceptance to the Codex Standard for Infant Formula. In view of the rather complex technology required to produce a product which would meet the requirements of the Codex Standard and of the cost of the final product in relation to income, infant formula conforming with the Codex Standard was not likely to be produced locally in Asia.

128. The delegation of Thailand recommended that:

(a) The Codex standards for infant formula and other foods for infants and children should represent minimum nutritional requirements consistent with adequate growth of normal infants and children;

(b) the Codex standards should reflect existing local technology and locally available raw materials so that a product can be made available to the majority of the people; and

(c) there should be an increase in technical and economic cooperation between developed and developing countries leading to the development of nutritionally adequate food products for proper growth and development at a reasonable price.

129. The Committee discussed recommendation (a) above. It noted that the Codex standard represented a standard containing minimum nutritional requirements and that scientific and medical principles of infant nutrition had to be taken into account when considering any significant changes in the composition of the product.

130. As regards recommendation (b) above, the delegation of New Zealand expressed the view that a large portion of people in developing countries would not be able to afford to buy infant formula as now produced. Codex standards should be regarded as representing a quality at which to aim. This applied also to follow-up and supplementary foods. Efforts should be made to develop supplementary food products which could be prepared by the mother from locally available materials.

131. Regarding recommendation (c) above, the delegations of France and the United Kingdom were of the opinion that developing countries themselves should make proposals to this Committee when in possession of sufficient technical information. It was hoped that industry would take appropriate steps in assisting the development of appropriate foods for infants and children at a reasonable price. The Committee noted that the Australian Dairy Corporation had offered to participate in a collaborative study to develop an infant formula based on indigenous materials. The hope was expressed that other such organizations would also offer practical assistance. The Secretariat indicated that FAO would welcome requests for technical assistance in this area and also suggested that the Committee may wish to recommend to the Agencies concerned that action be taken leading to a technical cooperation which would alleviate the problem mentioned by the delegation of Thailand.

132. The Committee noted the paper prepared by Thailand and accepted the conclusions contained therein. It was agreed that Governments be invited to send comments and information specifically in relation to the problems raised in the Thai paper concerning the acceptance of the Codex standards for infants and children. The need for revising these Codex standards would be considered in the light of information received.

(A) CONSIDERATION OF IMPLICATIONS FOR THE WORK OF THIS COMMITTEE ARISING FROM THE WHO INTERNATIONAL CODE ON MARKETING OF BREASTMILK SUBSTITUTES IN THE LIGHT OF GOVERNMENT COMMENTS

AND

(B) CONSIDERATION OF EFFECTS OF STORAGE TIME AND CONDITIONS ON NUTRITIONAL VALUE OF FOODS FOR INFANTS AND CHILDREN IN THE LIGHT OF GOVERNMENT COMMENTS (Agenda Item 13)

133. In its 14th Session the Codex Commission had recommended that the Committee for Foods for Special Dietary Uses review the sections of the standards for foods for infants and children dealing with labelling, advertizing and instructions for use with regard to relevant sections of the WHO International Code. The Commission had further suggested for consideration by the Committee matters relating to the nutritional value of products, and especially effects of storage time and conditions on nutritional value. Member countries were invited to submit comments on this matter to the next session of this Committee (ALINORM 81/39, para. 423). Progress in these issues had been reviewed by the Executive Committee in its 29th Session and the Executive Committee had expressed its continued support to WHO in the achievement of the aim of the International Code (ALINORM 83/3, paras 87-91).

134. Following up on the recommendations of the Commission the Secretariat in a Circular Letter (CL 1981/52) had invited comments from member countries on these issues for the 13th Session of the Committee. The Committee had before it document CX/FSDU 82/11, Parts I, II and III, which summarized the comments received on both (a) implications of the WHO International Code of Marketing of Breastmilk Substitutes on Codex standards; and (b) the effects of storage time and conditions on the nutritional value of foods for infants and

children, as well as comments regarding certain health aspects of feeding bottles and teats falling under the scope of the code.

135. After this introduction the Chairman called on Dr. Shubber, the Representative of the Office of the Legal Counsel, WHO, to explain the implications for the work of the Committee on Foods for Special Dietary Uses arising from the International Code of Marketing of Breastmilk Substitutes. Dr. Shubber pointed out that a general and significant implication for the Committee probably arose, from a legal point of view, from the link created between the International Code and Codex standards. Article 10, paragraph 2, of the former provided for the application of standards recommended by the Codex Alimentarius Commission to food products falling within the scope of the code, when such products were sold or otherwise distributed. Hence, the need would arise for harmonizing the requirements of the relevant Codex standards with those of the International Code. Dr. Shubber referred to three main areas, namely, advertising and promotion, information, and labelling. To illustrate the point about harmonization, he gave the example of the conflict between the International Code and certain provisions of the Codex Code of Ethics for International Trade in Food (CAC/RCP 20-1979). He stated that this question was considered by the Executive Committee of the Codex Alimentarius at its 29th Session held in Geneva on 12-16 July 1982. The Executive Committee requested FAO and WHO to prepare a paper containing whatever amendments were thought to be necessary to the Code of Ethics and the reasons for the amendments. The paper should be circulated to Governments for their comments and the paper and such comments would be considered by the Codex Alimentarius Commission (see ALINORM 83/3, para 7, para. 38).

136. He also referred to the concern expressed by the representatives of WHO vis-à-vis Section 2.4 ("Advertising") of the Draft General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (see ALINORM 81/26, Appendix II) to the Chairman of the Committee when the Draft Standard was under consideration by the Committee earlier during the session. This concern was motivated by the possibility of interpreting Section 2.4 as permitting the advertising and promotion of products falling within the scope of the International Code as well as the terms of reference of the Committee. Such an interpretation would not be compatible with the provisions of the International Code, which did not permit advertising and promotion of such products. He concluded by expressing his readiness to answer any question any delegate might wish to raise with respect to the International Code.

137. In the discussion it was widely felt that both the Codex standards and the WHO Code of Marketing could and should exist side by side, a view that had also been expressed by the EEC in its written comment. There was uncertainty about a need at this stage for modification of certain provisions in the standards to bring them in line with the WHO Code and the view was expressed to await experience by countries in the application of the standard as well as the code before deciding on eventual modifications. The Legal Counsel of WHO pointed out that both the Codex standards and the WHO Code were essentially recommendations to Governments, and although both could exist side by side they needed to be compatible. Regarding modifications in the WHO Code that might be considered desirable Governments had been invited to commit such comments and suggestions to the Director-General of WHO who would report on progress regarding the code to the next World Health Assembly. The Codex Secretariat reminded the Committee that the Commission had recommended a review rather than a revision of the relevant standards. Such a review might also include legal advice on certain foods covered by other Committees and recommendations to those Committees. In further discussion the possibilities of appointing a consultant to prepare such a review paper and of the Committee forming an ad-hoc Working Group on the matter were considered. The Joint Secretariat was urged to explore the possibility to appoint a consultant for preparation of a review paper for the next session of the Committee.

138. Regarding the effects of storage time and conditions on the nutritional value of foods for infants and children a very limited number of comments had been received in response to CL 1981/52. Of the countries from which comments had been received, only New Zealand had recently initiated studies on possible effects of this kind. The Chairman, therefore, reiterated to the Committee the invitation to submit comments that had been made in the Circular Letter. In response to a question from the delegation of the United Kingdom, the WHO member of the Secretariat gave an account of the steps that had so far been taken by WHO in implementing the resolution of the World Health Assembly in this regard (CX/FSDU 82/11-Parts I and II, Annex 1). Following a consultation on the Design of Studies to investigate the Nutritional Value of Baby Foods under Adverse Climatic Conditions whose report was before the Committee (CX/FSDU 82/11-Part III), steps had been taken to ascertain, in collaboration with respective Governments, the prevailing condition of storage, transport and packaging of the products in question as well as existing food quality and food safety control mechanisms in a selected number of countries concerned. In addition, laboratory studies on changes in nutritional value and safety under controlled conditions were being initiated. In both cases collaboration with the International Council of Infant Food Industries (ICIFI) had been established. Progress would be reported by the Director-General of WHO to the next World Health Assembly.

139. In further discussion the importance of storage conditions at the household level was emphasized in view of the fact that expiry dates on packages often apply only down to retail level. The Committee requested that information on progress and design of studies should be as detailed as possible and that documentation for the World Health Assembly should be also supplied to Codex Contact Points. The Secretariat confirmed that this would be done. In repeating his initial request for additional information from members of the Committee the Chairman asked that such information be transmitted directly to WHO.

140. Regarding possible health hazards from feeding bottles and teats the Swiss delegation informed the Committee that a regulation on maximum levels of N-nitrosamine migrated from teats and pacifiers had been elaborated in Switzerland and had recently become effective.

FUTURE WORK (Agenda Item 14)

141. The Committee agreed that the following items should be placed on the Agenda of its (14th) Session:

- (a) Proposed Draft Standard for Labelling of and Claims for Prepackaged Foods claimed to be suitable for Incorporation in a Prescribed Dietary Regimen of Diabetics at Step 3.
- (b) Proposed Draft Standard for Follow-up [Food] at Step 3.
- (c) Proposed Draft Standard for the Labelling of and Claims for Prepackaged Low Energy and Energy-Reduced Foods at Step 3.
- (d) Proposed Amendment to Standard for Infant Formula (CODEX STAN 72-1981) at Steps 5/8.
- (e) Proposed Draft Guidelines for the Use of Codex Committees on the Inclusion of Provisions on Nutritional Quality in Food Standards and other Codex Texts at Step 3.
- (f) Proposed Draft Guidelines on Supplementary Foods for Older Infants and Young Children at Step 3.
- (g) Proposed Draft Guidelines on [Medical Food] at Step 3.
- (h) Proposed amendments to certain provisions in Codex Standard for Foods for Special Dietary Uses.

142. The delegation of the United States recalled that the Committee had listed at a previous session the elaboration of General Principles of Fortification of Foods as an item in its programme of work. It had also been mentioned in the consultant's paper CX/FSDU 82/3. The delegation suggested that the Committee should place this matter as a high priority item in the programme of work.

The delegation of Canada agreed with the view expressed by the United States and kindly offered to prepare a working paper on the subject for the next session. She also indicated that the Food Standards Committee of IUNS might provide some assistance in the development of the paper. The Committee accepted this kind offer.

OTHER BUSINESS

Use of the Spanish Language

143. The delegation of Argentina, speaking on behalf of the delegations of Cuba, Panama, Paraguay and Spain, stated that it would be appreciated if consideration could be given to the translation of working documents into Spanish and the providing of simultaneous interpretation into Spanish during the session of the Committee. This would increase attendance by Spanish speaking countries.

144. The Committee noted the request of the Spanish speaking delegations.

Use of Ammonium Salts in Cereal-based Foods for Infants and Children

145. The delegation of the United Kingdom recalled that in 1977 the Working Group on Food Additives in Baby Foods had recommended the inclusion of ammonium carbonate and bicarbonate in cereal-based foods for infants and children as chemical leavening agents. At that time the delegation of the United Kingdom undertook to provide residue and other appropriate data to the Joint FAO/WHO Expert Committee on Food Additives (JECFA) so that the safety of these additives could be assessed. This was done and the 1982 JECFA had cleared the use of the ammonium salts in question subject to limitation by good manufacturing practice. In view of these developments the delegation of the United Kingdom recommended that the salts in question be included in the Codex Standard for Cereal-based Foods for Infants and Children.

146. The Committee, after discussion, agreed that this represented a material change which should be dealt with through the Codex Amendment Procedure. The question was raised whether the conclusions of JECFA applied to infants and children. The delegation of the United Kingdom informed the Committee that data submitted to the JECFA revealed that no evidence of the presence of residues of the additives in question appeared in the finished product. The Secretariat informed the Committee that the proposed addition of ammonium carbonate and bicarbonate to the Standard for Cereal-based Foods for Infants and Children would be referred to the Codex Committee on Food Additives which could consider questions relating to health such as residues of the additives in food and possible interaction with products in the light of conclusions of JECFA.

147. The Committee agreed that the following proposed amendment be sent to Governments for comments at Step 3 subject to agreement by the 15th Session of the Commission:

Section 5 - Food Additives in Codex Standard No. 74-1981

Add the following:

| | | |
|-------|-----------------------------|--|
| 5.6 | <u>Leavening Agents</u> | |
| 5.6.1 | Ammonium carbonate | } Limited by Good Manufacturing Practice |
| 5.6.2 | Ammonium hydrogen carbonate | |

Amendment of Codex Standards for Canned Baby Foods and Processed Cereal-based Foods for Infants and Children (CODEX STAN 75-1981 and 74-1981) - Definition of "Children"

148. The Committee recalled that it had agreed, in principle, to amend the definitions "child" and "children" to read "young child" and "young children" (see para. 5 of the Report of the Working Group in Appendix VIII).

149. The Committee agreed that, as a consequence, similar amendments should be made in Section 2.2 of the Codex Standard for Canned Baby Foods, and of Section 3.3 of the Codex Standard for Processed Cereal-based Foods for Infants and Children. It was agreed that the Secretariat should take the appropriate action. The wording of the amendment is contained in Appendix XIII.

Comments on Draft Guidelines on Nutrition Labelling (ALINORM 83/22, Appendix IV)

150. The Committee noted that the above guidelines which were under elaboration by the Committee on Food Labelling would be considered by the next session of that Committee at Step 7. A small working group was established to elaborate specific comments for submission to the Committee on Food Labelling. Members of the delegations from Canada, Finland, Federal Republic of Germany, Norway, Switzerland, United Kingdom and the United States participated in the Working Group which was chaired by Dr. J. Chopra.

151. The Committee agreed to submit the following comments to the Codex Committee on Food Labelling:

3.2.2 In view of the many types of carbohydrates which may be present in foods with differences in absorption and metabolism, such as oligosaccharides and polydextrose, declaration of only starch and sugar alcohols may not be sufficient. Provisions for the declaration of other forms of carbohydrates should be added to the second sentence of that provision as follows "... and other components of carbohydrates where present may also be listed."

3.2.3 Add: "The amount of cholesterol may also be listed".

3.2.4.1 Add: (e.g. sodium and potassium).

3.2.8.1 Add: "If the factor for the energy value of a substance differs significantly from the above factors the specific factor should be used (e.g. medium chain triglycerides).

3.3.1 The term "average value" as used is not clear and therefore must be explained.

3.3.4 Add: "Naming the sugar alcohol ... g"
"Oligosaccharides ... g"
"etc".

Definition: A definition of starch is needed to insure that only high molecular weight material is included. Specific methodology may be needed."

152. The delegation of the Netherlands indicated that it would like to make additional comments with respect to dietary fibre, but agreed to submit them as Government comments directly to CCFL.

DATE AND PLACE OF THE NEXT SESSION

153. The Chairman informed the Committee that the fourteenth session of the Committee will be held in Bonn-Bad Godesberg either in April or, preferably, October 1984. Governments will be notified of the exact date in due course.

154. The ad-hoc Working Group on Nutritional Aspects will meet for two days on Thursday and Friday prior to the session to consider the "Draft Guidelines for the Use of Codex Committees on the Inclusion of Provisions on Nutritional Quality in Food Standards and Other Texts". The morning of the first day of the fourteenth session of the Committee will be devoted to meetings of other Working Groups with the plenary session commencing during the afternoon of the first day.

SUMMARY STATUS OF WORK

| Standard/Code/Document | Status Step | To be dealt with by | ALINORM/App. Document |
|--|-------------|---------------------|--------------------------------|
| Standard for Foods with Low Sodium Content (including salt substitutes) | 9 | Governments | CODEX STAN 53-1981 1/ |
| Standard for Infant Formula | 9 | Governments | CODEX STAN 72-1981 1/ |
| Standard for Canned Baby Foods | 9 | Governments | CODEX STAN 73-1981 1/ |
| Standard for Processed Cereal-based Foods for Infants and Children | 9 | Governments | CODEX STAN 74-1981 1/ |
| Advisory List of Vitamin Compounds for Use in Foods for Infants and Children | - | Governments | CODEX ALIMENTARIUS Vol. IX |
| Advisory List of Mineral Salts for Use in Foods for Infants and Children | - | Governments | |
| Standard for Gluten-free Foods | 9 | Governments | CODEX STAN 118-1981 1/ |
| Draft General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses | 8 | 15th CAC | ALINORM 83/26 Appendix III |
| Proposed Draft Standard for the Labelling of and Claims for Prepackaged Foods Claimed to be suitable for Incorporation in a Prescribed Dietary Regimen for Diabetics | 3 | 14th FSDU | ALINORM 83/26 Appendix V |
| Proposed Draft Standard for Follow-up Foods | 3 | 14th FSDU | ALINORM 83/26 Appendix IX |
| Proposed Draft Standard for Low Energy and Energy-Reduced Foods | 3 | 14th FSDU | ALINORM 83/26 Appendix VII |
| Proposed Draft Guidelines for Use by Codex Committees on the Inclusion of Provisions on Nutritional Quality in Food Standards and other Codex Texts | 3 2/ | WG and 14th FSDU | ALINORM 83/26 Appendix IV |
| Proposed Draft Guidelines for "Medical Foods" | 3 2/ | 14th FSDU | ALINORM 83/26 Appendix VI |
| Proposed Draft Amendment to Codex Standard for Infant Formula CAC/RS 72-1976 | 5 3/ | 15th CAC | ALINORM 83/26 Appendix XIII |
| Proposed Draft Amendments to Codex Standards for Foods for Infants and Children | 3 2/ | 14th FSDU | ALINORM 83/26 Appendix XIII |

1/ Included in Codex Alimentarius, 1st Ed., Vol. IX.

2/ Subject to approval by the 15th Session of the Commission.

3/ It is recommended to omit Steps 6 and 7 and adopt the provision at Steps 5/8.

SUMMARY STATUS OF WORK (Cont.)

| Standard/Code/Document | Status Step | To be dealt with by | ALINORM/App. Document |
|---|-------------|--|----------------------------|
| Review of Implications of WHO International Code of Marketing of Breastmilk Substitutes and Related Products on Codex Standards Concerned | - | 14th FSDU | CX/FSDU 84/... |
| WG on Methods of Analysis | - | 14th FSDU | ALINORM 83/26 Appendix XI |
| WG on Vitamin Compounds and Mineral Salts | - | 14th FSDU | ALINORM 83/26 Appendix XII |
| General Principles concerning the Fortification of Foods | - | 14th FSDU | ALINORM 84/... |
| Proposed Draft Standard for Consumer-Packaged Protein Foods | 4 | ALINORM 78/26 see para. 86 | ALINORM 71/26 Appendix VII |
| Cholesterol-reduced Foods | - | Postponed, ALINORM 78/26 see para. 83 | - |
| Medium-chain Triglycerides | - | Postponed, ALINORM 78/26 see para. 84 | - |
| Low-lactose Products | - | Postponed, ALINORM 78/26 see para. 100 | - |

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OPENING ADDRESS

13th Session of the Codex Committee
on "Foods for Special Dietary Uses"

20 September 1982

Bonn-Bad Godesberg

Ladies and Gentlemen,

On behalf of the Government of the Federal Republic of Germany I should like to welcome you most sincerely to the 13th Session of the Codex Committee on "Foods for Special Dietary Uses".

The Federal Minister for Youth, Family Affairs and Health, Mrs. Anke Fuchs, asked me to convey to you her greetings and best wishes for a successful session.

I am very happy to see that you answered our invitation so numerously. Whilst representatives of 9 member countries and 3 International Organizations took part in the 1st Session of this Committee in 1966 I can today welcome representatives of 32 states and 10 International Organizations. The delegations of Greece, the People's Republic of Korea and of Paraguay as well as a representative of the German Democratic Republic as a consultant take part for the first time. I should particularly like to welcome these new representatives. The highly increased number of participants illustrates the importance of the work of your Committee on an international level.

My welcome is also directed again to the representatives of FAO and WHO. We are happy to see here Dr. Ladomery deputizing for Mr. Kermode, Chief of the Joint FAO/WHO Food Standards Programme, and should like to ask him to give Mr. Kermode our best wishes for a complete recovery. We also welcome our competent and much appreciated Mrs. Dix as well as Dr. Keller and Dr. Shubber. I am sure that the personal effort of Mrs. Dix in preparing and executing this session is a guarantee for success.

Ladies and Gentlemen,

As President-in-Office of the Codex Alimentarius Commission I should like to say a few words about the importance of the Codex Alimentarius.

The Codex Alimentarius Commission which was jointly set up in 1962 by FAO and WHO, has now been in existence for 20 years. In these two decades much has been achieved and in 14 plenary sessions about 115 standards and 30 codes of practice have been adopted. Furthermore about 50 standards for dairy products, 6 series on maximum levels of pesticide residues as well as numerous methods of analysis were developed. Yet it is not only a question of technical results. Above all the spirit, the will and the willingness to international cooperation play a decisive role.

In international food legislation the Codex standards whether adopted or under elaboration - are doubtlessly of considerable importance. For many developing countries this was the basis for a food legislation of their own. The Codex standards are intended to put these countries in a position to participate in the international trade in food by way of manufacturing finished products rather than providing raw materials. In this however the fundamental aim of the standardizing activities will be a constant guidance, that is the protection of the consumer against risks for his health caused by food and the application of fair manufacturing and trade practices.

Ladies and Gentlemen,

In so far 12 sessions the Codex Committee on "Foods for Special Dietary Uses" has done valuable work. This doubtlessly is a field of activities, which presented a number of difficulties and opened up new horizons. Nevertheless the Committee found solutions

in often strenuous consultations and elaborated a number of important standards for foods for infants and young children as well as specific nutritional needs.

In this coming session important questions will again be under discussion. I should like to name in particular the continuation of the consideration of the Draft General Standard for the Labelling of and Claims for Prepackaged Foods Claimed to be Suitable for Incorporation in a Prescribed Dietary Regimen for Diabetics at Step 4. It would be desirable to advance these particular two draft standards decisively so that the Committee could then turn to other fields of action.

Further I name:

- the extension of the terms of reference in view of the questions concerning nutritional aspects of food standards;
- the Draft Standard for Follow-up and Supplementary Foods for Infants and Young Children; and
- the consideration of the implications of the International WHO/Codex for the Marketing of Breastmilk Substitutes on the Work of the Committee.

Those matters concerning the nutritional aspects of food standards were already in principle assigned to the Committee by the Commission. It has the task to examine the planned terms of reference which bring about an extension of the responsibilities of your Committee in order to enable the Commission to come to a final decision at its 15th Session. The Draft Standard for Follow-up and Supplementary Foods for Infants and Young Children is a standard the necessity of which is not universally agreed upon.

The International Codex for the Marketing of and Advertising for Breastmilk Substitutes elaborated by WHO and UNICEF as reaction to recent developments will now play an important part in this Committee because of its factual relatedness with the Standards for Foods for Infants and Young Children. I hope the Committee will also have a fruitful discussion on this topic.

Ladies and Gentlemen,

The coming consultations will again make great demands on you all. I hope, however, that beside the technical discussions you will find time for talking and cultivating sometimes long-standing mutual relationships. I hope you will enjoy your stay and sometimes remember the beauty of these last summerdays on the Rhine.

For the session I wish you all the best and hope it will be harmonious and successful.

DRAFT GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS
FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES
(advanced to Step 8)

1. SCOPE

This standard applies to the Labelling of all Prepackaged Foods for Special Dietary Uses as defined in Section 2.1, including those intended for sale for catering purposes, and to claims made for such foods.

2. DEFINITION OF TERMS

For the purpose of this standard:

- 2.1 Foods for Special Dietary Uses are those foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such. ^{1/} The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist.
- 2.2 Label includes any tag, brand, mark, pictorial or other descriptive matter written, printed, stencilled, marked, embossed or impressed, on, or attached to a container of food.
- 2.3 Labelling includes the label and any written, printed or graphic matter relating to and accompanying the food.
- 2.4 Advertising includes any statement written, visual or oral, related to the food, including in promotional literature except those mentioned under 2.2 and 2.3.
- 2.5 Claims means any representation which states, suggests or implies that the food has particular qualities relating to its origin, nutritional properties, nature, processing, composition or any other quality which render it suitable for a special dietary use. The inclusion of substances mentioned only on a list of ingredients or as part of nutritional labelling shall not constitute a claim.
- 2.6 Container means any form of packaging of food for sale as a single item whether by completely or partially enclosing the food in such a way that the contents cannot be altered without opening or changing the packaging and includes wrappers.
- 2.7 Prepackaged means packaged or made up in advance, ready for retail sale in a container.
- 2.8 Ingredient means any substance, including a food additive, used in the manufacture or preparation of a food and present in the final product.

3. GENERAL PRINCIPLES

- 3.1 Prepackaged Foods for Special Dietary Uses shall not be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding their character in any respect.
- 3.2 Nothing in the labelling and advertising of foods to which this standard applies shall imply that advice from a qualified person is not needed.

^{1/} This includes foods for infants and young children.

4. MANDATORY LABELLING OF PREPACKAGED FOODS FOR SPECIAL DIETARY USES

The label of all prepackaged foods for special dietary uses shall bear the information required by sub-sections 4.1 to 4.9 of this section as applicable to the food being labelled, except to the extent otherwise expressly provided in specific Codex Standards for Foods for Special Dietary Uses. (See Annex I).

4.1 The Name of the Food

4.1.1 The name of the food shall indicate the true nature of the food and normally be specific and not generic.

4.1.1.1 Where a name or names have been established for a food in a Codex Standard, at least one of these names shall be used.

4.1.1.2 In other cases, a common or usual name shall be used, if one exists, by common usage or is prescribed in national legislation.

4.1.1.3 Where no common or usual name exists, an appropriate descriptive name shall be used.

4.1.1.4 A "coined" or "fanciful" name, however, may be used provided it is not misleading and is accompanied by an appropriate descriptive term.

4.1.2 The designation "special dietary", "special dietetic" or an appropriate equivalent term, may be used in conjunction with the name only where the product corresponds to the definition of such foods in section 2.1

4.1.3 The characterizing essential feature but not the condition for which the food is intended, shall be stated in appropriate descriptive terms in close proximity to the name of the food.

4.2 List of Ingredients

4.2.1 A complete list of ingredients shall be declared on the label in descending order of proportion by weight, except that in the case of dehydrated foods which are intended to be reconstituted by the addition of water or milk, the ingredients may be listed in order of proportion in the reconstituted product provided that the list of ingredients is headed by a statement such as "Ingredients when reconstituted in accordance with the directions on the label".

4.2.2 Where an ingredient of a food is itself the product of two or more ingredients, the latter shall be declared in brackets, in descending order of proportion by weight (m/m), following the name of the actual ingredient of which they form a part.

4.2.3 A specific name shall be used for ingredients in the list of ingredients except that class titles for ingredients may be used in accordance with General Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969).

4.3 Nutritional Labelling

4.3.1 The declaration of nutritional information on the label shall contain the following:

(a) The amount of energy per 100 grammes or 100 ml of the food as sold and where appropriate per specified quantity of the food as suggested for consumption, expressed in kilocalories (kJ) and kilojoules (kCal).

(b) The number of grammes of protein, carbohydrate and fat per 100 grammes or 100 ml of the food as sold and where appropriate per specified quantity of the food as suggested for consumption.

(c) The total quantity of those specific nutrients or other components which provide the characterizing essential feature for the special dietary use for which the food is intended per 100 grammes or 100 ml of the food as sold and, where appropriate, per specified quantity of the food as suggested for consumption.

4.4 Net Contents

4.4.1 The net contents shall be declared in either the metric ("Système International" units) or avoirdupois or both systems of measurement as required by the country in which the food is sold. ^{1/} The declaration shall be made in the following manner:

- (a) for liquid foods, by volume;
- (b) for solid foods, by weight, except that when such foods are usually sold by number a declaration by count may be made;
- (c) for semi-solid or viscous foods, either by weight or volume.

4.4.2 Foods packed in a liquid medium normally discarded before consumption shall carry a declaration of the drained weight of the food.

4.5 Name and Address

The name and address of the manufacturer, packer, distributor, importer, exporter, or vendor of the food shall be declared.

4.6 Country of Origin

4.6.1 The country of origin of the food shall be declared.

4.6.2 Where a food undergoes processing in a second country which changes its nature, the country in which the processing is performed shall be considered to be the country of origin for the purpose of labelling.

4.7 Lot Identification

Each container shall be embossed or otherwise permanently marked, in code or in clear, to identify the producing factory and the lot.

4.8 Date Marking

4.8.1 The date of minimum durability (preceded by the words "best before" shall be declared by the day, month and year in uncoded numerical sequence except that for products with a shelf-life of more than three months, the month and year will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer. In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.

4.9 Storage Instructions and Directions for Use

4.9.1 Storage of Unopened Food

In addition to the date, any special conditions for the storage of the food shall be indicated if the validity of the date depends thereon.

Where practicable, storage instructions shall be in close proximity to the date marking.

4.9.2 Storage of Opened Food

Storage instructions of opened packages of a food for special dietary uses shall be included on the label if necessary to ensure that the opened product maintains its wholesomeness and nutritive value. A warning should be included on the label if the food is not capable of being stored after opening or is not capable of being stored in the container after opening

^{1/} Governments communicating acceptance of this standard are requested to indicate specifically their country's requirements concerning the system of measurement.

4.9.3 Directions for Use

Directions for use shall be included on the label if necessary to ensure correct utilization. In particular, directions for reconstitution shall be included on the label if applicable.

5. PRESENTATION OF MANDATORY INFORMATION

5.1 General

Statements required to appear on the label by virtue of this standard or any other Codex Standard shall be clear, prominent and readily legible by the consumer under normal conditions of purchase and use. Such information shall not be obscured by designs or by other written, printed or graphic matter and shall be in contrasting colour to that of the background. The letters in the name of the food shall be in a size reasonably related to the most prominent printed matter on the label. Where the container is covered by a wrapper, the wrapper shall carry the necessary information, or the label on the container shall be readily legible through the outer wrapper or not obscured by it. In general, the name and net contents of the food shall appear on that portion of the label normally intended to be presented to the consumer at the time of sale.

5.2 Language

The language used for the declaration of the statements referred to in para. 5.1 shall be a language acceptable to the country in which the food is intended for sale. If the language on the original label is not acceptable, an attached supplementary label containing the mandatory information in an acceptable language may be used instead of relabelling.

6. ADDITIONAL REQUIREMENTS

6.1 Claims

6.1.1 Any claims made for the foods covered by this standard shall be in accordance with the General Guidelines on Claims elaborated by the Codex Alimentarius Commission.

6.1.2 Where a claim is made that the food is suitable for "special dietary uses" that food shall comply with all provisions of this standard except otherwise provided in a specific Codex Standard for Foods for Special Dietary Uses.

6.1.3 A food which has not been modified in accordance to Section 2.1 but is suitable for use in a particular dietary regimen because of its natural composition shall not be designated "special dietary" or "special dietetic" or any other equivalent term. However, such a food may bear a statement on the label that "this food is by its nature X" (X means the essential distinguishing characteristic) provided that such statement does not mislead the consumer.

6.1.4 Claims as to the suitability of a food as defined in Section 2.1 for use in the prevention, alleviation, treatment or cure of a disease, disorder or particular physiological condition are prohibited unless they are:

- (a) in accordance with the provisions of Codex standards or guidelines for foods for Special Dietary Uses, and following the principles set forth in such standards or guidelines;
- (b) or, in the absence of an applicable Codex standard or guideline, permitted under the laws of the country in which the food is distributed.

6.2 Irradiated Foods

Foods which have been treated with ionizing radiation, shall be so designated.

6.3 Nothing in this standard shall preclude the adoption of additional or different provisions in a Codex Standard for Foods for Special Dietary Uses, in respect of labelling, where the circumstances of a particular food would justify their incorporation in that standard.

7. OPTIONAL LABELLING

Any information or pictorial device may be displayed in labelling provided that it is not in conflict with the mandatory requirement nor would mislead or deceive the consumer in any way whatsoever in respect of the food.

ANNEX TOAPPENDIX III

LIST OF CODEX STANDARDS FOR FOODS
FOR SPECIAL DIETARY USES

The following standards have been adopted by the Codex Alimentarius Commission and sent to Member Governments for acceptance:

| | |
|--|---------------------|
| (a) Food with Low Sodium Content (including Salt Substitutes) | CODEX STAN 53-1981 |
| (b) Infant Formula | CODEX STAN 72-1981 |
| (c) Canned Baby Foods | CODEX STAN 73-1981 |
| (d) Processed Cereal-based Foods for Infants and Children | CODEX STAN 74-1981 |
| (e) "Gluten-free" Foods | CODEX STAN 118-1981 |

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APPENDIX IV

PROPOSED DRAFT GUIDELINES FOR THE USE OF CODEX COMMITTEES ON
THE INCLUSION OF PROVISIONS ON NUTRITIONAL QUALITY IN FOOD
STANDARDS AND OTHER CODEX TEXTS

(At Step 3) 1/

1. PURPOSE

- 1.1 To ensure that nutritional quality aspects are included in food standards and other Codex texts when appropriate.
- 1.2 To provide guidance to Codex Committees in their consideration of the need for provisions on nutritional quality in food standards and other Codex texts.
- 1.3 To assist Codex Committees in developing appropriate provisions on nutritional quality.

2. SCOPE

These guidelines are intended to be used by all Codex Committees in the development of food standards or other texts.

3. DEFINITIONS

For the purpose of these guidelines:

- 3.1 Fortification means the addition of one or more essential nutrients to a food for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients.

1/ Subject to approval by the 15th Session of the Commission.

- 3.2 Nutrient means any substance normally consumed as a constituent of food:
- (a) which provides energy; or
 - (b) which is needed for the growth, development and maintenance of life; or
 - (c) in the absence of which, characteristic biochemical or physiological changes occur.
- 3.3 Essential nutrient means any substance normally consumed as a constituent of food which is needed for growth and development and the maintenance of life.
- 3.4 Nutritional equivalence means of equal nutritive value in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients.
- 3.5 Nutritional quality as applied to food means the presence of essential macro-nutrients, micronutrients and all energy-yielding substances and to those aspects of foods, consideration of which is traditionally considered as part of the science of nutrition. These other aspects include non-essential amino-acids; specific types of fatty acids and carbohydrates; dietary fibre (plant material not digested by human enzymes); cholesterol; lipotropic substances; all components of human milk; the quantity and quality of fats and proteins; nutrient bioavailability; nutrient requirements and recommended dietary intakes; nutrient interactions with other nutrients, food additives, natural toxicants, environmental contaminants and drugs; nutrient excesses and the effects of food processing both positive and negative, on such nutritional quality.
- 3.6 Restoration means the addition to a food of nutrient(s) which have been lost during the course of good manufacturing practice, in amounts which will result in the presence in the food of at least the pre-processed levels of the nutrient(s).
- 3.7 Substitute food is a food which resembles a common food particularly a food of animal origin in appearance, texture, flavour and odour and is intended to be used as a complete replacement or partial replacement (extender) for the food it resembles.

4. INSTRUCTIONS TO CODEX COMMITTEES

- 4.1 Committees should be aware of the broad range of factors which influence the nutritional quality of foods to ensure that their consideration of nutritional aspects takes into account all relevant matters.
- 4.2 Provisions and advisory information on nutritional aspects of foods should be included in food standards and other Codex texts in the following circumstances:
- (a) the food is a major source of nutrients in the diets of populations;
 - (b) the food has sustained significant and unavoidable losses of nutrients during processing;
 - (c) the food is destined for use as a substitute for, or the principal ingredient in a substitute for, a common food, particularly of animal origin;
 - (d) the food's nutritional quality is dependent upon the amount and/or characteristics of the principal ingredient present in the food;
 - (e) a variety of methods of processing with varying degrees of impact on nutritional quality is available.

4.3 Addition of Nutrients to Foods

4.3.1 Provision for the addition of nutrients to foods should be made where appropriate for the following purposes:

4.3.1.1 Restoration of Processing Losses

Essential nutrients which are present in the pre-processed food in amounts equal to or greater than 2% of the recommended intake in a serving or in the case of a staple food, in a reasonable daily intake should be restored.

4.3.1.2 Nutritional Equivalence of Substitute Foods

Essential nutrients which are present in the food being substituted or partially substitute in amounts equal to or greater than $\frac{1}{2}\%$ of the recommended intake $\frac{1}{}$ in a serving or in the case of a staple food in a reasonable daily intake $\frac{1}{}$, should be present in equivalent amounts in the substitute food or extended food.

4.3.1.3 Fortification

4.3.2 When provision is made for the addition of nutrients for the purpose of fortification, advisory information for the guidance of national Governments should be included. It should identify nutrients which have been or may be added to the food and suggest that countries where deficiencies of these nutrients exist and are of public health significance should consider the feasibility and effectiveness of fortifying the food with one or more of these nutrients. As a general rule, the advisory information should not identify quantities of nutrients to be added as these will depend upon the conditions of the country concerned.

4.3.3 Provisions in food standards and other Codex texts respecting the addition of nutrients to foods for the purposes of fortification should be of an advisory nature and subject to national legislation.

4.3.4 When provision is made in food standards and other Codex texts, for the addition of nutrients for the purposes of restoration and/or nutritional equivalence, advisory information for the guidance of national governments should be included. It should identify the nutrients to be considered for restoration or nutritional equivalence and the levels at which they should be present in the food to achieve restoration or nutritional equivalence.

4.3.4.1 Where general agreement exists regarding the need for restoration or nutritional equivalence and particularly where risks to health may be involved, a mandatory provision should be included requiring that the food contains the nutrient(s) in specified amounts.

4.3.4.2 Where general agreement exists on the specific nutrients and amounts required, an optional provision should be included providing for the addition of these nutrients and specifying the amounts to be contained in the food.

4.3.4.3 Where general agreement does not exist, an advisory provision should be included permitting the addition of nutrients to the food in accordance with national legislation. Advisory information identifying the nutrients and the levels needed for restoration or nutritional equivalence should be included in an annex to the standard and should not be subject to acceptance.

4.3.5 In adding nutrients to foods for any purpose, the following conditions should be fulfilled:

4.3.5.1 The nutrient must be stable in the food under customary conditions of storage, distribution and use.

4.3.5.2 The nutrient must be physiologically available from the food.

4.3.5.3 The nutrient should not impart undesirable characteristics to the food (colour, taste, flavour, texture, cooking properties).

4.3.5.4 The technology should be available to permit the addition of the nutrient in a satisfactory manner.

4.3.5.5 The additional cost should be reasonable for the intended consumer.

4.3.6 Advisory lists of vitamin compounds and mineral salts for particular foods or classes of foods should be drawn up for the guidance of national Governments.

4.4 Quality criteria which influence nutritional quality such as minimum quantities of either the principal or characterizing ingredients or macronutrients from these ingredients should be included in the body of the standards whenever appropriate.

4.5 Advisory information on choice of processing methods to minimize adverse effects on established and recognized nutritional quality should be included where appropriate.

4.6 Should Codex Committees decide to include provisions pertaining to the nutritional aspects of foods in standards and other texts, they should submit these provisions to the Codex Committee on Foods for Special Dietary Uses for endorsement. / Should they decide not to submit their provisions for endorsement, full justification for not doing so should be submitted to the Commission /.

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APPENDIX V

PROPOSED DRAFT STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKGED FOODS CLAIMED TO BE SUITABLE FOR INCORPORATION IN A PRESCRIBED DIETARY REGIMEN FOR DIABETICS
(Returned to Step 3 of the Procedure)

1. SCOPE

This standard applies to the labelling of all those foods for special dietary uses, as defined in the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses, which are claimed to be suitable for incorporation in a prescribed dietary regimen for diabetics, and to claims made for such foods.

2. DEFINITION OF TERMS

For the purpose of this standard:

2.1 Diabetics are those diabetic individuals who have been advised, by a qualified person, that particular prepackaged foods specifically modified for diabetics and marketed for this purpose, may be included in their dietary regimen within the limits prescribed by the qualified person.]

2.2 Qualified Person means a medically qualified person or other person appropriately authorized to advise diabetics regarding their dietary regimen as part of the treatment and control of their diabetes.

2.3 Prescribed Dietary Regimen is that dietary regimen prescribed by a qualified person to meet the specific nutritional requirements of an individual diabetic.

2.4 Carbohydrates means metabolisable carbohydrates and include nutritive sweeteners and starches.

2.5 Nutritive Sweeteners are those sugars which are defined by the Codex Alimentarius Commission and "glucoplastic" sugar substitutes.

2.6 "Glucoplastic" Sugar Substitutes are substances such as sorbitol, mannitol, xylitol and other polyols, and fructose which are intended to replace glucose, sucrose and other glucose containing low molecular weight carbohydrates.

2.7 Non-nutritive Sweeteners are sweetening substances which are not utilized in the metabolism as a source of energy or which are contributing only a negligible amount of energy as normally consumed.

3. MANDATORY LABELLING

3.1 Foods to which this standard applies shall be labelled in conformity with the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses, except that the condition for which the food is intended may be stated in close proximity to the name of the food, provided that it is accompanied by the following statement, or some similar statement:

"May be suitable for diabetics, subject to advice from a qualified person".

3.2 The following additional material shall also be shown on the labels of foods to which this standard applies:

3.2.1 Sugar substitutes and non-nutritive sweeteners shall be identified in the List of Ingredients by their specific names together with the appropriate classname in brackets in descending order of proportion.

3.2.2 In addition to the declaration of nutritional information required to be shown on the label in compliance with Section 4.3.1 of the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses, the following nutritional information shall be given on the label:

- (a) the total combined weight in grammes of glucose, sucrose and other glucose containing low molecular weight carbohydrates; and
- (b) the individual weights of "glucoplastic" sugar substitutes per 100 grammes of the food, and where appropriate, per specified quantity of the food as suggested for consumption. The amounts of these substances present in the food shall also be included in the calculation of the total amount of carbohydrate present in the food, and this should be made clear in the labelling.

4. CLAIMS

4.1 No claim that a food is suitable for incorporation in a prescribed dietary regimen for diabetics shall be made unless the food is a special dietary food as defined in the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses and which is prepared in accordance with the following principles:

- (a) no glucose, sucrose or other glucose containing low molecular weight carbohydrates are added as ingredients in these foods;
- (b) added sweeteners may be derived from "glucoplastic" sugar substitutes and/or non-nutritive sweeteners;
- (c) these foods are prepared in accordance with good manufacturing practice and the use of glucoplastic sugars having a laxative effect is limited as much as feasible in order to minimize the laxative effect of these substances.

4.2 Any claims made for foods covered by this standard shall be in accordance with the General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses.

4.3 Nothing in the labelling or advertising of foods covered by this standard shall claim, either expressly or by implication:

- (a) that such foods may be taken by diabetics without reference to the limits of a dietary regimen prescribed by a qualified person;
- (b) that such foods are suitable for the use of all diabetics;
- (c) that the nutritive needs of diabetics cannot be met by proper selections from ordinary food;

- (d) that a particular ingredient or component has a particular suitability for incorporation in a dietary regimen for diabetics in general or for any particular type of diabetic;
- (e) that the use of such foods is essential or necessary for incorporation in a dietary regimen for diabetics in general or for any particular type of diabetic;
- (f) that a food has been specially modified and is suitable for incorporation in a dietary regimen for diabetics in general or for any particular type of diabetic if the food does not contain substantially less readily absorbable carbohydrates, /except fructose/, than a similar food for normal consumption.
- (g) that a food which contains little or no sugar is also reduced in energy value or that such a food may be useful in weight-reduction diets when such is not the case.

4.4 In the labelling and advertising of foods to which this standard applies, statements or claims may be made that such foods may afford a greater variety of foods for the diabetic within the limits of the dietary regimen prescribed by a qualified person.

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APPENDIX VI

PROPOSED DRAFT GUIDELINES FOR THE LABELLING OF AND CLAIMS FOR /MEDICAL/ FOODS

(At Step 3) 1/

1. Purpose

1.1 To ensure that /medical/ foods, marketed worldwide are safe and suitable for the intended purpose and properly labeled.

1.2 To provide the physician and the patient with necessary information about the product and its safe and suitable use including indications, contraindications and precautions.

1.3 To ensure that labelling of /medical/ foods is accurate and reliable.

2. Definition

2.1 /Medical/ foods are specially formulated or processed products, represented for the dietary management of a specific diseases(s), disorder(s), or medical condition(s), consumed or administered enterally, and represented for use under the supervision of a physician. The formulations are based on well-recognized nutritional and medical principles established by experts appropriately qualified by scientific training and experience, and the use of these formulations has been shown by appropriate evidence to be safe and beneficial in meeting the nutritional requirements of individuals suffering from the specific diseases(s), disorder(s), or medical condition(s).

2.2 To provide maximum information on composition and nutritional efficacy, /medical/ foods are classified in terms of nutritional adequacy rather than medical use. Many types of /medical/ foods have multiple uses and their usefulness would be dictated by nutritional needs of the patient which can be determined after medical evaluation.

1/ Subject to approval by the 15th Session of the Codex Alimentarius Commission.

For this reason medical foods are categorized as:

- (a) Nutritionally complete
 - (b) Nutritionally incomplete
 - (c) Nutritional components
- (a) Nutritionally complete medical foods supply all the known essential nutrients for normal growth, development, and maintenance of health. These medical foods are formulated to supply adequate quantities of essential nutrients in terms of daily requirements when fed in reasonable volumes each day.
 - (b) Nutritionally incomplete medical foods supply all the known essential nutrients for normal growth, development, and maintenance of health (as defined by Recommended Dietary Allowance or Recommended Dietary Intake (RDA/RDI)), except for lack or decrease in specific nutrients formulated on the basis of specific metabolic needs (e.g., a medical food low in phenylalanine to meet the nutritional requirements of patients with phenylketonuria)
 - (c) Nutritional components - medical foods supply one or more essential nutrients intended for further formulation to meet special nutrient requirements for specific metabolic needs.

3. Scope

These guidelines cover products which are formulated for use as described in the definition and its label or labelling represents that the product:

- 3.1 May be used for nutritional support through tube feeding.
 - 3.2 May be used as the sole source of nutrition, or may be combined with other products or substances, for use as the sole source of nutrition, and is represented for use in specific medical conditions requiring the supervision of a physician.
 - 3.3 Is a dietary supplement represented for use to meet nutritional requirements in specific medical conditions requiring the supervision of a physician.
- or
- 3.4 Is an infant formula formulated and represented to meet special dietary needs of infants with a specific disease or disorder.

The types of products which are not considered to be medical foods are:

- 3.5 Infant formulas for feeding normal healthy infants and
- 3.6 Foods for special dietary use not represented to meet nutritional requirements for a specific disease(s), disorder(s) or medical condition(s) requiring the supervision of a physician, such as:
 - (a) Hypoallergenic foods.
 - (b) Foods represented as useful in reducing or maintaining caloric intake or body weight.
 - (c) Foods used to regulate sodium intake.
 - (d) Foods declaring fat and fatty acid and cholesterol content.
 - (e) Dietary supplements of vitamins and/or minerals not represented to meet nutritional requirements in a specific disease(s), disorder(s), or medical condition(s) requiring the supervision of a physician.

3.7 Products or formulations whose label or labeling contain nutritional claims (such as low cholesterol, high fiber, low lactose, etc.) but do not represent the product or formulation to meet the nutritional requirements for a specific disease(s), disorder(s), or medical condition(s) requiring the supervision of a physician. These types of products are utilized by individuals that wish to modify nutrient(s) intake, do not require the supervision or monitoring of a physician, merely contain increased or reduced amounts of a particular nutrient(s) that can be consumed safely by the general public, and bear no disease-related claims on their labels or in labeling.

4. Principles for /medical/food labeling

4.1 The labels, package inserts, and other labeling for all types of medical foods (nutritionally complete, nutritionally incomplete, nutritional components) bear sufficient information for the explicit intended use. Certain detailed and explicit information is needed by the physician, pharmacist, and the nutritionist. The supervising dietitian requires complete directions on the preparation of certain /medical/foods, and nurses and technicians require carefully designed instructions on methods of administration, particularly for tube feeding. The patient-consumer needs information about the nature and purpose of /medical/foods and directions and precautions in their use. The consumer information is aimed at those with average reading ability and comprehension and is based in part on the assumption that the consumer will wish to rely primarily on the attending physician, nutritionist, or dietitian for detailed professional guidance.

Information for professional personnel and patient-consumers of relatively complex /medical/foods are outlined below:

5. Labeling requirements

The following information (except for items 5.1, 5.2, 5.3, 5.11 and 5.12) may be provided on a consumer package insert rather than the label if the package label is too small to accommodate the information or the manufacturer prefers providing the information on a package insert. All information must be given in lay terms as much as possible (e.g., contraindications = when not to use).

5.1 Information required by food labeling and the General Standard for the Labeling of and Claims for Prepackaged Foods for Special Dietary Uses, as appropriate.

5.2 A prominent statement on the principal display panel: (a) "For the dietary management of _____," where the blank is filled in with the disease(s), disorder(s), or medical condition(s) for which the product is safe and efficacious. (b) USE ONLY UNDER THE SUPERVISION OF A PHYSICIAN.

5.3 If the /medical/ food meets one of the three criteria (5.3 (a), (b), or (c)), a prominent statement on the principal display panels: Warning: THIS PRODUCT MAY BE HAZARDOUS TO INDIVIDUALS NOT HAVING THIS (THESE) MEDICAL CONDITION(S).

The criteria for determining that a product must bear a warning statement are:

- (a) /Medical/foods which pose a health hazard when consumed by individuals that do not have the disease(s), disorder(s) or medical condition(s) for which the product is intended. For example, a product which contains an excess, deficiency, absence, or imbalance of nutrients and is recommended as sole source of nourishment.
- (b) /Medical/foods which adversely affect breast milk quality or quantity.
- (c) /Medical/foods which may adversely affect pregnant women or the foetus.

5.4 Purpose of product - indication condition(s), disorder(s), or disease(s) in which the product is known to be useful and beneficial, the rationale for its use, and a description of the product. For example - a special preparation for the dietary management of patients who need an easily digested, readily absorbed, low-residue diet. Uses include preoperative bowel preparation, short bowel syndrome, and gastrointestinal fistulae.

5.5 A statement indicating that the product is nutritionally complete or incomplete, or altered. If the product is nutritionally incomplete and the directions for use indicate that the product may be used as a sole source of nutrition for specific medical conditions, the label or labeling must also state what nutrient(s) is deficient and why it is deficient or nutritionally altered and why it was altered.

5.6 Complete nutrition information per 1000 kcal (or kJ) or 100 ml (or per 100 gm) of the food and where appropriate per specified quantity of food as suggested for consumption, RDA/RDI (for those nutrients that have an established RDA/RDI and in absolute amounts). Infant formulas that are also medical foods would provide complete nutritional information per 100 kcal (or kJ) and per 100 ml as suggested for consumption. The source of ingredients such as acid modified starch from corn, osmolality (mOsm/kg of water) when appropriate, and information on product tolerance and level of intended use should be given.

5.7 Feeding instructions including methods of administration and serving size.

5.8 A complete statement concerning adequate precautions, side effects, contraindications, and product-drug interactions or a statement that there are no known precautions, side effects, contraindications, or product-drug interactions, if none are known.

5.9 If the product is an infant formula for use by an infant with a specific disease or disorder it is considered a medical food. Such infant formulas are labelled for use solely for clinically serious or unusual diseases or conditions, which are also life-threatening. The product will contain all the nutrients required by infant formula standard (at the levels required therein) except for the nutrient(s) specifically intended for reduction, deletion or increase as specified on the label or labeling of the product and why the nutrient(s) is reduced, deleted, or increased.

5.10 Storage directions before and after opening the product and adequate directions for preparation, if appropriate, and use.

5.11 An expiration date indicating the "use by" or "use before" date prior to which all nutrients specified on the label or labeling will meet or exceed the level specified and product quality is assured.

The following information is voluntary and may be provided in brochures, pamphlets, or by other means.

5.12 Scientific references and clinical data to support nutritional adequacy.

5.13 Source of information for diet counseling.

5.14 Information for obtaining supplies of the product.

Duplication of some information may be necessary because the information necessary for physicians must be given in greater detail so that the appropriateness of administering a product can be decided.

6. Claims

6.1 The definition of /medical/food (section 2.1) assists in narrowing the labelling claims of /medical/foods which will be permitted under this guideline. The label claim permitted for /medical/foods should be limited to the statement "For the dietary management of _____," where the blank is filled in with the disease(s), disorder(s), or medical condition(s) for which the product is safe and efficacious. This label claim would only be permitted for /medical/foods. This aspect of /medical/food labelling is extremely delicate and claims to be permitted must be clearly defined to avoid confusion that could result when regulatory agencies are attempting to determine when manufacturers are making /medical/food claims or drug claims.

6.2 A manufacturer of a /medical/food shall maintain records of clinical or other scientific studies or other evidence, upon which this manufacturer based its conclusion that the product is safe and effective for its labelled use. Upon receipt of a written request from the importing country the manufacturer shall submit full reports of such studies promptly.

6.3 Where a claim is made that the food is suitable for the dietary management of a disease or disorder that food shall comply with all provisions of this guideline.

6.4 Claims as to the suitability of a food as defined in section 2.1 for use in the prevention or treatment of a disease or disorder, are prohibited unless they are:

- (a) In accordance with the provisions of Codex Guidelines for the Labelling of and Claims for /Medical/ Foods and follow the principles set forth in such Guidelines.
- (b) In the absence of an applicable Codex guideline, permitted under the law of the country in which the food is distributed.

7. General Considerations

7.1 All ingredients used in the formulation of a /medical/food must be safe and suitable (approved by Codex Food Additives Committee).

7.2 A manufacturer of a /medical/food shall maintain records of clinical or other scientific studies, or other evidence, upon which the manufacturer based its conclusion that the product is safe and effective for its labelled use(s).

8. Periodic review of /medical/food labelling

/Medical/foods labelling should be sufficiently flexible to allow for scientific advances and innovative approaches. Labelling should be reviewed periodically and updated in accordance with scientific facts about nutrition and disease.

PROPOSED DRAFT STANDARD FOR LABELLING OF AND
CLAIMS FOR PREPACKAGED LOW ENERGY AND REDUCED ENERGY FOODS 1/

(At Step 3)

1. Purpose

1.1 To fully inform purchasers of the value of foods for special dietary uses that purport to be or are represented as useful in maintaining or reducing energy intake or body weight.

1.2 To prevent purchasers of foods for special dietary uses in maintaining or reducing energy intake or body weight from being misled about foods which are not of special dietary usefulness for such purpose.

1.3 To restrict the use of label statements and to require certain disclosures on foods which are not of special dietary usefulness in maintaining or reducing energy intake or weight.

1.4 To provide a standard appropriate for labelling of and claims for "low energy" and "reduced energy foods".

2. Scope

The standard applies to the labelling of and claims for prepackaged foods for special dietary uses, including those intended for sale for catering, in controlling or reducing energy intake.

3. Definitions

3.1 "Low energy food": A food for special dietary uses may purport to be or be represented as "low energy" only if a serving of the food contains no more than [40] kcal/ 19.6 kj and the food has an energy density of no more than 0.4 kcal/0.1 kj per gm.

3.2 A "reduced energy food": a food may claim to be "reduced energy" only if a comparison of the energy content of a specified serving of the food with the energy content of an equivalent serving of the same food without fabrication or alteration of special dietary significance, reveals a energy reduction of at least [one-third]. A "reduced energy" food must not be nutritionally inferior, except with respect to energy, to the food for which it substitutes or the same food without the fabrication or alteration of special dietary significance.

3.3 "Non-nutritive sweeteners" are sweetening substances which are not utilized in the metabolism as a source of energy or which are contributing only a negligible amount of energy as normally consumed.

3.4 "Non-nutritive ingredient", means an ingredient not utilized in normal metabolism as a source of energy.

3.5 One kj is equivalent to 0.239 kcal.

1/ Low calorie and reduced calorie food.

3.6 Serving size: The term "serving" means that reasonable quantity of food suited for or practicable of consumption as part of a meal by an adult male engaged in light physical activity, [or by an infant or child under four years of age when the article purports or is represented to be for consumption by an infant or child under four years of age.]

3.7 Portion size: The term "portion" means the amount of a food customarily used only as an ingredient in the preparation of a meal component (e.g., one-half cup flour, one-half table-spoon cooking oil or one-quarter cup tomato paste).

3.8 A label statement regarding a serving (portion) shall be in terms of a convenient unit of such food or a convenient unit of measure that can be easily identified as an average or usual serving (portion) and can be readily understood by purchasers of such food (e.g., a serving (portion) may be expressed in slices, cookies, or wafers; or in terms of ounces, fluid ounces, teaspoonfuls, tablespoonfuls, or cupfuls.)

4. Labelling ^{1/}

4.1 Foods to which this standard applies shall be labelled in conformity with the appropriate sections of the "General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses" except that:

4.2 Any "low energy" or "reduced-energy" food which uses a non-nutritive sweetener must declare on its label the presence of that non-nutritive sweetener. If the food contains both nutritive and non-nutritive sweeteners the presence of both must be declared.

4.3 A "low energy" or "reduced-energy" food which uses another non-nutritive ingredient to achieve its dietary usefulness must declare on its label the presence of that non-nutritive ingredient and its percentage by weight.

4.4 The term "low energy" or a "low energy food", may be used on the principal display panel to characterize products that are "low energy" within the meaning of the definition of section 3.

4.5 The label of a "reduced energy" food must describe the comparison upon which the special dietary usefulness claim is based either by identifying a specific food having at least [one and a half times] as many kcal/kj per serving for which the reduced energy food can substitute, or by indicating that the reduced energy claim is based on a comparison with the same food without the fabrication or alteration of special dietary significance. This statement must include a comparison between the energy content of a specified serving of the food and an equivalent serving of the compared food, e.g., artificially sweetened peaches packed in water, 38 kcal/9.1 kj per one-half cup serving, 62 percent less than peaches in heavy syrup.

^{1/} See para. 97.

4.6 A "reduced energy" food similar in all its organoleptic properties to the food it is representing or substituting for, or to the food without fabrication or alteration of special dietary significance, may be labelled a "reduced energy food". However, if the "reduced energy" food is not similar in all its organoleptic properties to the compared food, e.g., canned pears packed in unsweetened water, in comparison with pears in heavy syrup, it may be labelled with appropriate terms to indicate its dietary usefulness, but in immediate proximity such labelling shall indicate material difference in organoleptic properties between it and the food to which it is compared. The food shall not bear terms in juxtaposition with its name or in the labelling that represent or suggest that the food is essentially the same as the other food in all its organoleptic properties except for a reduction in calories.

4.7 Foods that are low energy within the meaning of the definition of section 3, as naturally occurring, without having any fabrication or alteration, may be labelled as a low energy food, e.g., celery, "a low energy food". They may not be labelled with the term "low energy" immediately preceding the name of the food, because such terminology would imply that the food has been altered to lower its energy with respect to foods of the same type.

5. Claims

5.1 Label terms suggesting usefulness as low energy or reduced energy foods:

(a) Consumers may reasonably be expected to regard terms representing that the food contains no sugars, or sweeteners, e.g., "sugar free", "sugarless", "no sugar", as indicating a product which is low in energy or significantly reduced in energy. Consequently a food not in accordance with the definition of section 3 may not be labelled with such terms unless:

Immediately accompanied each time it is used by a statement "not a reduced energy food", or "not a low energy food", or "not for weight control", or "useful only in not promoting tooth decay", or other terms indicating that the sole special usefulness of the food is for a specific purpose, other than weight control.

Paragraph (a) of this section shall not apply to a factual statement that a food is unsweetened or contains no added sweeteners in the case of a food that contains apparent substantial sugar content, e.g. fruit juices.

(b) A food may be labelled with terms such as "diet", "dietetic", "artificially sweetened", "sweetened with non-nutritive sweetener", or other terms representing or suggesting that the food is low in energy or reduced in energy, or that the food may make a comparative claim of a special dietary usefulness only if:

The food is labelled "low energy" or "reduced energy" or bears a comparative claim of special dietary usefulness in compliance with the criteria established for "low energy" or "reduced energy" foods.

5.2 Paragraph 5.1 (a) and (b) of this section will not apply to:

(a) Any use of such terms that is specifically authorized by a Codex standard governing a particular food.

(b) Any use of the term "diet" which clearly shows that the food is offered solely for dietary use(s) other than regulating energy intake or body weight e.g., "low sodium diets."

(c) Any use of such terms on a formulated meal replacement, low energy meal, or other food that is represented to be of special dietary use as a whole meal, pending the issuance of a codex standard governing the use of such terms on such foods.

6. General considerations

It may not be technologically feasible to manufacture a "reduced energy" food under the criteria set forth in section 3 for all foods that are significant dietary sources of energy and for which it would be useful, to those on energy-restricted diets, to have a reduced energy substitute. Accordingly, the Committee on Foods for Special Dietary Uses, may establish (by standard) an acceptable alternative criteria for a "reduced energy" food. Under no circumstances shall a food be permitted to be labelled as "reduced energy" food unless:

- (a) the proposal demonstrated that it is not feasible to attain a greater energy reduction than that for which approval is sought.
- (b) The proposal demonstrated that the use of the food with the energy reduction attained, will result in a significant reduction in energy in the diet, and be useful to those on weight control programmes.

ALINORM 83/26

APPENDIX VIII

REPORT OF THE AD-HOC WORKING GROUP ON FOLLOW-UP AND
SUPPLEMENTARY FOODS FOR INFANTS AND CHILDREN

Introduction

1. The 12th Session of the Codex Committee on Foods for Special Dietary Uses had established an ad-hoc Working Group to meet prior to its 13th Session to consider the following:

(a) The Proposed Draft Standard for Follow-up and Supplementary Foods for Older Infants and Children with the aim to amend it in such a way as to apply to follow-up foods only, taking into account further information from governments on the type of product, and

(b) The PAG Guideline No. 8 with a view to a possible up-dating in the light of recent scientific and technological developments in infant and child feeding (para. 54 of ALINORM 81/26).

2. By CL 1980/45 governments were requested to provide data and comments on the above two matters. Comments were received from France, Finland, New Zealand, Netherlands, Norway, Poland, Sweden, Thailand (CX/FSDU 82/10. Add. 2) and Switzerland (CX/FSDU 82/10, Add. 1).

3. In order to facilitate the discussion of the WG a consultant (Dr. G.D. Kapsiotis) was engaged to prepare a working paper which contained an evaluation of the comments received and proposed texts for a revised standard for Follow-up Foods and an up-dated guideline on Supplementary Foods based on PAG Guidelines No. 8 (CX/FSDU 82/10, Appendices I and II). The paper contained furthermore sections on nutritional requirements of the infant during weaning, dietary allowances, nutrient density, terminology and definitions, current infant feeding patterns as well as explanatory notes on the two appendices. In

opening the session the Chairman of the Committee expressed the Committee's appreciation of the paper.

4. The session of the Working Group took place on 16/17 September 1982 and was chaired by Prof. J. Rey of France. The following countries and international organizations were represented: Argentina, Australia, Brazil, Canada, Germany Fed. Rep. of, Finland, France, Netherlands, Norway, Sweden, Switzerland, Thailand, United Kingdom, United States, EEC, ISDI. (For details see Appendix I to this paper).

5. The Working Group agreed to concentrate mainly on the discussion of the two appendices containing the revised texts for (a) a draft standard for follow-up formula and (b) draft guidelines on supplementary foods. The Committee also agreed, in general, that the definition for "child" be amended to read "young child".

PROPOSED DRAFT STANDARD FOR FOLLOW-UP FORMULA FOR OLDER INFANTS AND YOUNG CHILDREN
(Appendix 1 to CX/FSDU 82/10)

Name of the Standard

6. The Working Group agreed to change the name of the standard to 'Follow-up [Food] ...' since it was thought that the word 'Formula' implied a complete infant food to the consumer. It was agreed to make this consequential amendment throughout the standard.

Section 2.1.1 - Definition of "Follow-up Food"

7. The point was made that the definition as drafted in Appendix I to CX/FSDU 82/10 did not sufficiently distinguish between the product covered by the standard and Infant Formula since follow-up foods did not serve as substitutes for Infant Formula, especially at an age of less than 6 months. This was so since follow-up foods were designed for infants who received nourishments from other sources and since nutrient requirements were different during the weaning period.

8. The Working Group adopted a new text for Section 2.1.1 as given in Appendix II to this report. In adopting the new text, the Working Group agreed that the standard should cover products based on milk as well as other constituents of animal and/or plant origin. The delegation of Switzerland supported by the delegation of France stated that they would prefer to have the following definition:

"2.1.1 Follow-up [food] means a food intended for the use as a liquid part of the weaning diet [replacing] partially or wholly breastmilk or infant formula for the infant from the age of [4-6 months] on and for the young child."

Section 3.2.1 - Protein per 100 Available Calories (or Kilojoules)

9. The Working Group considered a proposal of the Chairman to lower the minimum protein requirement to 2.25 g per 100 available calories as recommended by experts within the EEC. The Working Group decided to place the minimum protein provision of 3 g in square brackets so that it would be rediscussed in the light of the proposed new figure at a later stage.

Section 3.2.1.3 - Milk-based Products

10. It was decided to delete this section describing the requirement for a milk-based product, as it was considered to be sufficiently covered in sections 3.3.1.2 and 9.1.3.

Section 3.2.2.2 - Requirement for Linoleic Acid

11. It was pointed out that the requirement for linoleic acid, an essential fatty acid, may not be met through the use of milk products and that, therefore, the restriction of this requirement to follow-up foods made with vegetable fats was not appropriate. The Working Group decided to delete the words 'where the product contains vegetable fats' and also decided to lower the requirement to 300 mg per 100 Calories to bring it into line with Infant Formula.

Section 3.2.3 - Carbohydrates

12. In order to permit the use of carbohydrates other than sugars, i.e. other than 'nutritive carbohydrate sweeteners', the Working Group decided to change the wording to read 'nutritionally available carbohydrates'. It was pointed out that this would permit the addition of starches which required cooking and that follow-up foods would not necessarily be cooked prior to consumption. This was thought to be covered by the requirement that such carbohydrates would have to be "suitable for the feeding of the older infant and the young child". It was also suggested that mono- and disaccharides should be subject to a maximum limit. This was thought to be adequately covered by Section 3.1 dealing with the energy content of the product.

Section 3.2.4 - Vitamins other than Vitamin E

Vitamin D

13. In order to take into account countries where, through lack of adequate sunlight enabling the natural formation of vitamin D, some recurrence of rickets had been observed, it was agreed that the maximum level should be tentatively increased to 120 I.U. The provision was placed in square brackets so that any possible implications of this increase could be discussed at a later stage.

Riboflavin (Vitamin B₂)

14. The need for a higher minimum requirement than that for Infant Formula for this vitamin in follow-up foods was thought to be necessary, since milk which is one of the main sources of riboflavin in the diet is consumed to a lesser extent during the weaning period. Some delegations thought that this reasoning was not consistent with the fact that Infant Formula was recommended for consumption beyond six months of age. The delegation of the United States expressed the view that since the standard provided for protein sources other than milk, the vitamin and mineral levels should either reflect the values in the Codex Standard for Infant Formula or be increased proportionally for all vitamins and minerals and not only for riboflavin, calcium and phosphorus. The Working Group decided to place the provision for minimum riboflavin content of 150 µg in square brackets.

Vitamin B₆

15. It was noted that the minimum requirement of 45 µg for this vitamin was related to a minimum requirement of 15 µg vitamin B₆/g protein used. As the minimum requirement for protein of 3 g had been placed in square brackets the Working Group decided to do likewise with this requirement.

Section 3.2.6 - Minerals

Chloride

16. It was agreed to change the minimum requirement for chloride to 55 mg in order to bring it into line with the Infant Formula Standard.

Calcium (Ca) and Phosphorus (P)

17. For reasons similar to those stated in connection with riboflavin above, the Working Group agreed to retain the higher minimum requirements than those in Infant Formula in square brackets. As regards the minimum requirements for other minerals, it was thought that these would be adequately covered from other foods consumed during the weaning period.

Section 4 - Food Additives

18. The Working Group noted that the use of food additives was optional but that only those additives which are listed in Section 4 may be used. The Secretariat pointed out that a suitable explanatory note would be prepared for the relevant volume of the Codex Alimentarius to make this point clear. The Secretariat was requested to ensure that the preamble to Section 4 in the French text was appropriate.

Section 5 - Contaminants

19. The delegation of Argentina was of the opinion that Section 5.1 was not sufficiently strict as it permitted the presence of pesticide residues which were technically unavoidable. Argentinian regulations required the absence of such residues as well as other residues such as indicated in Section 5.2.

20. The delegation of France was of the opinion that a maximum limit for mycotoxins should be established.

Section 9.1.3 - Labelling of Milk-Based Products

21. The opinion was expressed that this section did not adequately define a milk-based product. Furthermore, the question was raised by the delegation of Switzerland as to whether the provisions 3.2.4 and 3.2.6 for vitamins (except vitamin E) and minerals respectively should be mandatory in their entirety for products made from milk. The proposals of Switzerland was that vitamins, other than vitamins A, D, C and E and minerals, other than Na, Ca and Fe, should be optional for follow-up foods based on milk.

22. In the discussions that followed the point was made that the use of milk as a source material would ensure that the product would be nutritionally adequate with respect to the above vitamins and minerals. The proposal of Switzerland was supported by the delegations of the UK and France. On the other hand it was pointed out that Section 3.2 was operative which required the presence of the nutrients enumerated in Sections 3.2.4 - 3.2.6. Furthermore, there was no adequate definition of a milk-based product which, both from a point of view of the ingredients and the methods of processing used, would ensure a nutritionally adequate product. The delegations of Sweden, Canada, Fed. Rep. of Germany, Finland, Norway, USA and Thailand as well as the representative of FAO favoured, therefore, the inclusion of the same mandatory provisions for nutrient content irrespective of the raw material used.

23. As regards the definition of a product based on milk, the Working Group agreed that both for labelling purposes and in order to deal with the question raised by Switzerland above, it would be necessary to arrive at a satisfactory text of Section 9.1.3. The following revised text was put forward tentatively for consideration by the CCFSDU:

"only those products which are prepared from whole or skimmed milk as such or with minor modification that does not substantially impair the vitamin and mineral content of the milk may be labelled "follow-up milk"."

The delegations of the Netherlands and Australia indicated that they could not take a position on the Swiss proposal or the labelling of milk-based products as above until a clear distinction is made in the Standards between products based on milk and products based on non-milk raw materials.

Section 9.3 - Declaration of Nutritive Value

24. The question was raised as to how the inclusion of optional provisions for nutrients for milk-based products would relate with Section 9.3(b) which required the declaration of vitamins and minerals. The Secretariat was of the opinion that nutrients which were subject to optional provisions as listed in Sections 3.2.4 and 3.2.6, would not necessarily have to be declared on the label. It was noted that such a different approach to nutrient labelling could lead to misinformation of the consumer and might even imply that a milk-based product is of lesser nutritional value.

Need for Elaboration of a Standard for Follow-up Foods

25. At the end of the Session the delegation of Norway raised the question whether there was a real need to elaborate a Codex standard for follow-up foods. The delegation of Switzerland recalled that such a decision had already been reached by the Committee some considerable time ago. A show of hands revealed that five delegations were for the elaboration of a standard, seven against with two delegations abstaining. The matter was referred to the CCFSDU for decision

GUIDELINES FOR THE DEVELOPMENT OF SUPPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN

26. The Committee noted that the above guidelines were intended to advise on important nutritional and technical aspects of Supplementary Foods for Older Infants and Young Children. At earlier sessions of CCFSDU and of the Coordinating Committees it had been recognized that there was a need to provide for guidance on low-cost foods for low income populations prepared from adequate raw materials locally available in developing countries. Requirements for such products would vary according to the specific nutritional needs of the infants concerned, the types of nutrients provided by the basic staple foods and the types of suitable raw materials available. The Working Group agreed that under these circumstances, guidelines were more flexible and appropriate than a standard.

Section 1 - Purpose

27. Several delegations felt that the guidelines should contain a provision which would clearly outline the above principle to avoid that the foods covered by these guidelines were used together with other protein-rich types of infant foods. It was pointed out that this could be achieved through appropriate labelling which would be more informative for the consumer.

Section 2 - Scope

28. Attention was drawn to the fact that under the present definition for supplementary foods also follow-up foods were covered. Since the standard for follow-up foods stipulated requirements different from those contained in the guidelines, this might create confusion. The Working Group noted that a standard would always have precedence over a guideline. This had already been recognized in section 2.2. It was decided to amend Section 2.2 by including reference to the standard for follow-up foods.

29. The Working Group also noted the opinion that the Scope section should be more specific in order to achieve a clear distinction between the different weaning foods.

Section 3 - Definitions

30. As agreed in connection with the revised definition for follow-up foods, the Working Group accepted the following definition for supplementary foods:

"Supplementary Foods for Older Infants and Young Children" means a food for use from the beginning of the infant's weaning period from [4-6 months] on as a supplement to breastmilk or to breastmilk substitutes and to other foods available in the country where the product is sold. [These products should provide such nutrients which are lacking in the basic staple food]."

31. The latter sentence was placed in square brackets since it was felt that more thought had to be given to that aspect and specific comments were required on this matter.

Section 4 - Raw Materials Used in Supplementary Foods

32. The question was raised, as to whether the extensive provisions of this section should be retained or whether a simplified version containing general headings only was preferable.

33. The Secretariat pointed out that it had been the intention to provide for a wide range of informative data, i.e. to draw also attention to the need for appropriate or specific processing of certain cereals, pulses and other raw materials. This would enable the authorities to get advice on more aspects concerning the development of weaning foods.

34. It was also suggested that milk and milk products should be included in the section on main ingredients in view of their high nutritional value. It was, however, also pointed out that these products were in many instances either not available or too expensive to be included on a regular basis to these types of food.

35. Objections were also raised against the use of nutritive sweeteners. However, it was recognized that their value for increasing the energy density of the product was, in this case, more important than the nutritional considerations of nutritive sweeteners in infant food.

36. The Working Group also agreed to include as Section 4.2.4 a new provision which would permit the use of other ingredients, provided they had been proven to be suitable for use in these products.

37. In connection with Sections 4 and 5 the Working Group agreed that governments should be invited to study the guidelines and provide comments either direct or through the coordinating Committees.

38. The delegation of Brazil expressed the opinion that the guidelines would not help to make available really low cost foods only by proposing the use of local and/or non-conventional raw materials since there are some industrial and commercial factors which always make the products too costly for the real poor. The existence of industrially produced products could also divert from the possibilities to promote home prepared foods. Therefore the delegation of Brazil felt that the guidelines should only deal with the general principles for weaning foods.

Section 6 - Formulation of Supplementary Foods

39. The Working Group felt that the provisions under "General Aspects" - Section 6.1 should be used as the basis for nutritional calculations only and should be added as explanatory notes to Table 1 - Proposed Model Composition for Supplementary Foods. Several delegations advised that they had more detailed technical comments on the provisions in Section 6 which would be submitted again to the Committee prior to its next session (related to water content, proteins, fats, etc.). It was also agreed to delete the first half of the sentence of Section 6.3.3 and to reduce the value for linoleic acid to 300 mg.

40. The Working Group noted the following proposal by Switzerland for Section 6.2.21: "In order to cover 75% of the recommended daily protein intake (i.e. 12 g per day) with 100 g of supplementary foods (corresponding to 400 calories), the food shall not contain less than 3.0 g per 100 available calories (or 0.7 g per 100 available Kilojoules) of protein of nutritional quality equivalent to that of casein or a greater quantity of other protein in inverse proportion to their biological value. The quality 3/ of the protein shall not be less than 70% of that of casein. The total quantity of proteins shall not be more than 5.5 g per 100 available calories (or 1.3 g per 100 available Kilojoules). The minimum value established for the quality and the maximum value established for the quantity of proteins may be modified by the national authorities in accordance with their own legal provisions and/or local conditions."

41. It was also proposed that the values for nutrients given in Table 1 should be replaced by ranges since variations in nutrient content were envisaged in any case in view of the different local conditions.

42. With regard to the guidelines the Working Group concluded as follows:

(a) A large majority of the working group decided to recommend to the Committee to continue the elaboration of guidelines on the development of supplementary foods for older infants and young children.

(b) The Working Group agreed that the text as contained in Appendix III to this Report was a suitable basis for further discussions.

(c) The Working Group recommended that comments should be requested on the guidelines from all countries and that, in addition, the guidelines should be submitted to the Codex Coordinating Committees.

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APPENDIX VIII
 Annex 1

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PROPOSED DRAFT STANDARD FOR FOLLOW-UP FOOD FOR OLDER
INFANTS AND YOUNG CHILDREN

(At Step 3)

1. SCOPE

- 1.1 This standard applies to foods defined in Section 2.1.1 below.
- 1.2 This standard does not apply to foods covered by the Codex Standard for Infant Formula (CODEX STAN 72/81).

2. DESCRIPTION

2.1 Definitions

2.1.1 Follow-up Food means a food intended for use as a liquid part of the weaning diet replacing breastmilk or Infant Formula for the infant from the age of 6 months and for the young child.

2.1.2 The term "infant" means a person of not more than 12 months of age.

2.1.3 The term "young child" means a person of 1-3 years of age.

2.1.4 The term "Calorie" means a kilocalorie (1 kilojoule is equivalent to 0.239 calories).

2.2 Follow-up Food is prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin, which have been proved to be suitable for infants from the age of 6 months and for young children.

2.3 Follow-up Food is so processed by physical means only as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution.

2.4 Follow-up Food when in liquid form, is suitable for use either directly or diluted with water before feeding, as appropriate. In powdered form it requires water for preparation. The product shall be nutritionally adequate to contribute to normal growth and development when used in accordance with its directions for use.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Energy Content

When prepared in accordance with the instructions for use, 100 ml of the ready-to-eat product shall provide not less than 60 and not more than 85 calories (or 250 and 355 kilojoules per 100 ml).

3.2 Nutrient Content

Follow-up Food shall contain the following nutrients at minimum and maximum levels indicated below:

3.2.1 Protein per 100 Available Calories (or Kilojoules)

3.2.1.1 Not less than 3.0 g^{1/} per 100 available Calories (or 0.7 g) per 100 available kilojoules) of protein of nutritional quality equivalent to that of casein or a greater quantity of other protein in inverse proportion to its nutritional quality. The quality 2/ of the

1/ [2.25 g and 0.5 g respectively proposed for consideration].

2/ Protein quality shall be determined provisionally using the PER method as laid down in the section dealing with methods of analysis.

protein shall not be less than 85% of that of casein. The total quantity of protein shall not be more than 5.5 g per 100 available Calories (or 1.3 g per 100 available kilojoules).

3.2.1.2 Essential amino-acids may be added to Follow-up [Food] only to improve its nutritional value. Essential amino-acids may be added to improve protein quality, only in amounts necessary for that purpose. Only L forms of amino-acids shall be used.

3.2.2 Fat per 100 Available Calories (or Kilojoules)

3.2.2.1 Not less than 3 g and not more than 6 g per 100 Calories (0.7 and 1.4 g per 100 available kilojoules).

3.2.2.2 The level of linoleic acid (in the form of a glyceride) shall not be less than 300 mg per 100 Calories (or 84 mg per 100 available kilojoules).

3.2.3 Carbohydrates

The product shall contain nutritionally available carbohydrates suitable for the feeding of the older infant and the young child in such quantities as to adjust the product to the energy density in accordance with the requirements set out in Section 3.1.

3.2.4 Vitamins other than Vitamin E

| | <u>Amounts per 100</u> <u>available Calories</u> | | <u>Amounts per 100</u> <u>available kilojoules</u> | |
|---|---|--|---|---|
| | <u>Minimum</u> | <u>Maximum</u> | <u>Minimum</u> | <u>Maximum</u> |
| Vitamin A | 250 I.U. or 75 ug expressed as retinol | 500 I.U. or 150 ug expressed as retinol | 60 I.U. or 18 ug expressed as retinol | 120 I.U. or 36 ug expressed as retinol |
| Vitamin D | 40 I.U. or 1 ug | [120] I.U. or [3] ug | 10 I.U. or 0.25 ug | [30] I.U. or [0.75] ug |
| Ascorbic acid (Vitamin C) | 8 mg | N.S. <u>1/</u> | 1.9 mg | N.S. <u>1/</u> |
| Thiamine (Vitamin B ₁) | 40 ug | N.S. <u>1/</u> | 10 ug | N.S. <u>1/</u> |
| Riboflavin (Vitamin B ₂) | [150] ug | N.S. <u>1/</u> | [35] ug | N.S. <u>1/</u> |
| Nicotinamide | 250 ug | N.S. <u>1/</u> | 60 ug | N.S. <u>1/</u> |
| Vitamin B ₆ <u>2/</u> | [45] ug | N.S. <u>1/</u> | [11] ug | N.S. <u>1/</u> |
| Folic acid | 4 ug | N.S. <u>1/</u> | 1 ug | N.S. <u>1/</u> |
| Pantothenic acid | 300 ug | N.S. <u>1/</u> | 70 ug | N.S. <u>1/</u> |
| Vitamin B ₁₂ | 0.15 ug | N.S. <u>1/</u> | 0.04 ug | N.S. <u>1/</u> |
| Vitamin K ₁ | 4 ug | N.S. <u>1/</u> | 1 ug | N.S. <u>1/</u> |
| Biotin (Vitamin H) | 1.5 ug | N.S. <u>1/</u> | 0.4 ug | N.S. <u>1/</u> |

1/ N.S. = Not specified.

2/ Formulas should contain a minimum of 15 µg Vitamin B₆ per gramme of protein. See Section 3.2.1.1.

| | <u>Amounts per 100</u> <u>available Calories</u> | | <u>Amounts per 100</u> <u>available kilojoules</u> | |
|--|--|----------------|---|----------------|
| | <u>Minimum</u> | <u>Maximum</u> | <u>Minimum</u> | <u>Maximum</u> |
| 3.2.5 <u>Vitamin E</u> (α -tocopherol compounds) | 0.7 I.U./ g linoleic acid <u>2/</u> but in no case less than 0.7 I.U./100 available calories | <u>N.S. 1/</u> | 0.7 I.U./ g linoleic acid <u>2/</u> but in no case less than 0.15 I.U./100 available kilojoules | <u>N.S. 1/</u> |
| 3.2.6 <u>Minerals</u> | | | | |
| Sodium (Na) | 20 mg | 85 mg | 5 mg | 21 mg |
| Potassium (K) | 80 mg | 200 mg | 20 mg | 50 mg |
| Chloride (Cl) | 55 mg | 150 mg | 14 mg | 35 mg |
| Calcium (Ca) <u>3/</u> | <u>[90]</u> mg | <u>N.S. 1/</u> | <u>[22]</u> mg | <u>N.S. 1/</u> |
| Phosphorus (P) <u>3/</u> | <u>[60]</u> mg | <u>N.S. 1/</u> | <u>[14]</u> mg | <u>N.S. 1/</u> |
| Magnesium (Mg) | 6 mg | <u>N.S. 1/</u> | 1.4 mg | <u>N.S. 1/</u> |
| Iron (Fe) | 1 mg | 2 mg | 0.25mg | 0.50 mg |
| Iodine (I) | 5 μ g | <u>N.S. 1/</u> | 1.2 μ g | <u>N.S. 1/</u> |
| Zinc (Zn) | 0.5mg | <u>N.S. 1/</u> | 0.12mg | <u>N.S. 1/</u> |

1/ N.S. = Not specified.

2/ Or per g polyunsaturated fatty acids, expressed as linoleic acid.

3/ The Ca:P ratio shall be not less than 1.0 and not more than 2.0.

3.3 Ingredients

3.3.1 Essential Ingredients

3.3.1.1 Follow-up [Food] shall be prepared from the milk of cows or of other animals and/or other protein constituents of animal and/or plant origin which have been proved suitable for infants from the age of [6 months] and of young children and of other suitable ingredients necessary to achieve the essential composition of the product as set out in Sections 3.1 and 3.2 above.

3.3.1.2 Follow-up [Food] based on milk shall be prepared from ingredients as set out in Section 3.3.1.1 above except that a minimum of 3 g per 100 available Calories (or 0.7 g per 100 kilojoules) of protein shall be derived from whole or skimmed milk.

3.3.2 Optional Ingredients

3.3.2.1 In addition to the vitamins and minerals listed under 3.2.4 to 3.2.6, other nutrients may be added when required in order to ensure that the product is suitable to form part of a mixed feeding scheme intended for use from [6 months] on.

3.3.2.2 The usefulness of these nutrients shall be scientifically shown.

3.3.2.3 When any of these nutrients is added, the food shall contain significant amounts of these nutrients, based on the requirements of older infants and children.

3.4 Purity Requirements

3.4.1 General

All ingredients shall be clean, of good quality, safe and suitable for ingestion by older infants. They shall conform with their normal quality requirements, such as colour, flavour and odour.

3.4.2 Vitamin Compounds and Mineral Salts

3.4.2.1 Vitamin compounds and mineral salts used in accordance with Sections 3.3.1 and 3.3.2 should be selected from the Advisory Lists for Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children approved by the Codex Alimentarius Commission.

3.4.2.2 The amounts of sodium and potassium derived from vitamin and mineral ingredients shall be within the limits for sodium and potassium in Section 3.2.6.

3.5 Consistency and Particle Size

When prepared according to the directions for use, the product shall be free of lumps and of large, coarse particles.

3.6 Specific Prohibition

The product and its components shall not have been treated by ionizing radiation.

4. FOOD ADDITIVES

The following additives are permitted:

| | <u>Maximum Level in 100 ml of Product</u> |
|------------------------------|---|
| | <u>Ready-to-drink</u> |
| 4.1 <u>Thickening Agents</u> | |
| 4.1.1 Guar gum | } 0,1 g |
| 4.1.2 Locust bean gum | |

| | | <u>Maximum Level in 100 ml of Product</u> <u>Ready-to-drink</u> |
|--------|--------------------------------------|--|
| 4.1.3 | Distarch phosphate | } 0,5 g singly or in combination in soy-based products only |
| 4.1.4 | Acetylated distarch phosphate | |
| 4.1.5 | Phosphated distarch phosphate | |
| 4.1.6 | Hydroxypropyl starch | |
| 4.1.7 | Carrageenan | } 0,03 g in milk and soy-based products only |
| | | } 0,1 g in hydrolyzed protein and/or amino acid-based liquid products only |
| 4.2 | <u>Emulsifiers</u> | |
| 4.2.1 | Lecithin | 0,5 g |
| 4.2.2 | Mono- and Diglycerides | 0,4 g |
| 4.3 | <u>pH-Adjusting Agents</u> | |
| 4.3.1 | Sodium hydrogen carbonate | } Limited by Good Manufacturing Practices within the limits for Na and K in Section 3.2.6. |
| 4.3.2 | Sodium carbonate | |
| 4.3.3 | Sodium citrate | |
| 4.3.4 | Potassium hydrogen carbonate | |
| 4.3.5 | Potassium carbonate | |
| 4.3.6 | Potassium citrate | |
| 4.3.7 | Sodium hydroxide | |
| 4.3.8 | Potassium hydroxide | |
| 4.3.9 | Calcium hydroxide | |
| 4.3.10 | L (+) Lactic acid | |
| 4.3.11 | L (+) Lactic acid producing cultures | |
| 4.3.12 | Citric acid | |
| 4.4 | <u>Antioxidants</u> | |
| 4.4.1 | Mixed tocopherols concentrate | } 1 mg in all types of Follow-up Formulas |
| 4.4.2 | L-Ascorbyl palmitate | |
| 5. | <u>CONTAMINANTS</u> | |
| 5.1 | <u>Pesticide Residues</u> | |

The product shall be prepared with special care under good manufacturing practices, so that residues of those pesticides which may be required in the production, storage or processing of the raw materials or the finished food ingredient do not remain, or, if technically unavoidable, are reduced to the maximum extent possible.

5.2 Other Contaminants

The product shall be free from residues of hormones and antibiotics, as determined by means of agreed methods of analysis, and practically free from other contaminants, especially pharmacologically active substances.

6. HYGIENE

6.1 To the extent possible in good manufacturing practice, the product shall be free from objectionable matter.

6.2 When tested by appropriate methods of sampling and examination, the product:

- (a) shall be free from pathogenic microorganisms;
- (b) shall not contain any substances originating from microorganisms in amounts which may represent a hazard to health; and
- (c) shall not contain any other poisonous or deleterious substances in amounts which may represent a hazard to health.

6.3 The product shall be prepared, packed, and held under sanitary conditions and should comply with the relevant provisions of the Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979).

7. PACKAGING

7.1 The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. When in liquid form, the product shall be packed in hermetically sealed containers; nitrogen and carbon dioxide may be used as packing media,

7.2 The containers, including packaging materials, shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply.

8. FILL OF CONTAINERS

In the case of products in ready-to-eat form, the fill of container shall be:

- (i) not less than 80% v/v for products weighing less than 150 g (5 1/2 oz.);
- (ii) not less than 85% v/v for products in the weight range 150-250 g (5 1/2 - 9 oz.); and
- (iii) not less than 90% v/v for products weighing more than 250 g (9 oz.) of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20°C which the sealed container will hold when completely filled.

9. LABELLING

In addition to Sections 1, 2, 4 and 6 of the Codex General Standard for the Labelling of Prepackaged Foods (Ref. CODEX STAN 1-1981), the following specific provisions apply:

9.1 The Name of the Food

9.1.1 The name of the product shall be "Follow-up [Food] for Older Infants and Young Children". In addition thereto any appropriate designation may be used in accordance with national usage.

9.1.2 The sources of protein in the product shall be clearly shown on the label in proximity to the name of the food.

9.1.3 Only those products which are prepared from whole or skimmed milk as such or with minor modification that does not substantially impair the vitamin and mineral content of the milk may be labelled "Follow-up Milk".

9.1.4 A product which contains neither milk nor any milk derivative may be labelled "contains no milk or milk products" or an equivalent phrase,

9.2 List of Ingredients

9.2.1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and added minerals, these ingredients shall be arranged as separate groups for vitamins and minerals, respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.

9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate class names for these ingredients and additives may be included on the label.

9.3 Declaration of Nutritive Value

The declaration of nutrition information shall contain the following information in the following order:

(a) the amount of energy, expressed in Calories (Kcal) and/or kilojoules (Kj), and the number of grammes of protein, carbohydrate and fat per 100 grammes of the food as sold as well as per specified quantity of the food as suggested for consumption;

(b) the total quantity of each vitamin, mineral and any optional ingredient, as listed in Sections 3.2 and 3.3.2 of this Standard per 100 grammes of the food as sold as well as per specified quantity of the food as suggested for consumption. In addition,

(c) the declaration of nutrient content per 100 Calories (or per 100 kilojoules) is permitted.

9.4 Net Content

The net content of the product shall be declared by volume if it is in liquid form, or by weight if it is in powdered form. The declaration of weight or volume shall be made in either the metric ("Système International" units) or in a system of measurement as required by the country in which the food is sold, or in both systems.

9.5 Name and Address

The name and address of the manufacturer, packer, distributor, importer, exporter or vendor of the food shall be declared.

9.6 Country of Origin

9.6.1 The country of origin of the food shall be declared if its omission would mislead or deceive the consumer.

9.6.2 When the food undergoes processing in a second country, which changes its nature, the country in which the processing is performed shall be considered to be the country of origin for the purposes of labelling.

9.7 Lot Identification

Each container shall be embossed or otherwise permanently marked, in code or in clear, to identify the producing factory and the lot.

9.8 Date Marking and Storage Instructions

9.8.1 The "date of minimum durability" (preceded by the words "best before") shall be declared by the day, month and year in uncoded numerical sequence except that for products with a shelf-life of more than three months, the month and year will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer. In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.

9.8.2 In addition to the date, any special conditions for the storage of the food shall be indicated if the validity of the date depends thereon.

9.8.3 Where practicable, storage instructions should be in close proximity to the date marking.

9.9 Information for Utilization

9.9.1 Directions as to the preparation and use of the food, and its storage and keeping after the container has been opened shall appear on the label or on the accompanying leaflet.

9.9.2 The labelling of a follow-up [Food] shall include a statement that Follow-up [Food] should not be introduced before the end of the [sixth month] of age.

9.9.3 Information that infants and children fed follow-up formula shall receive supplemental foods in addition to the food shall appear on the label.

GUIDELINES FOR DEVELOPMENT OF SUPPLEMENTARY FOODS
FOR OLDER INFANTS AND YOUNG CHILDREN
(At Step 3) 1/

1. PURPOSE

To provide guidance, on nutritional and technical aspects, for the development of supplementary foods for infants from 4-6 months onwards and young children, including:

- Formulation of supplementary foods, based on the nutritional requirements of older infants and young children,
- Processing techniques
- Instructions for use
- Hygiene, packaging and labelling

2. SCOPE

2.1 The provisions of the guideline apply to supplementary foods as defined in Section 3.1 below.

2.2 Foods covered by the Codex Standards for Cereal-based Foods (CODEX STAN 74-1981) and for Follow-up [Foods] (Appendix IX), should comply with these standards in the first instance. However, additional requirements may be recommended in accordance with the appropriate provisions of these guidelines.

3. DEFINITIONS

3.1 "Supplementary Foods of Older Infants and Young Children" means a food for use from the beginning of infant's weaning period from [4-6 months] on as a supplement to breastmilk or, breastmilk substitutes, or other foods available in the country where the product is sold. [These foods should provide such nutrients which are lacking in the basic staple food].

3.2 The term "infant" means a person up to 12 months of age.

3.3 The term "young child" means a person of 1-3 years of age.

4. RAW MATERIALS USED IN SUPPLEMENTARY FOODS

4.1

4.1.1 Cereals

4.1.1.1 All milled cereals used as foodstuffs may be used in the formulation of supplementary foods.

4.1.1.2 Cereals such as: oats, barley, sorghum, millet and teff which by simple milling yield flours with high crude fibre content not suitable for infant feeding, should be processed in such way as to reduce their fibre content.

4.1.1.3 Besides carbohydrates (mainly starch) cereals contain a non negligible quantity of protein (8-12%). Whereas rice presents a satisfactory essential amino acid composition, other cereals are as a rule deficient in lysine.

4.1.2 Pulses

4.1.2.1 Pulses, including chick peas, lentils, peas, cow peas, green gram (Cajanus cajan), mung beans, kidney beans, appropriately processed, have been found suitable for feeding older infants and young children.

1/ Subject to approval by the 15th Session of the Commission.

4.1.2.2 Pulses are a good source of protein (20-24%) with high content of lysine. They are, however, deficient in methionine. Depending on the nature of the other ingredients in the formulation, the addition of L-methionine might be desirable in order to improve the protein quality of the product.

4.1.2.3 Anti-nutritional factors present in edible pulses are mainly lectins (haemagglutinins) as well as trypsin and chymotrypsin inhibitors. While lectins can be destroyed by heating (boiling, toasting), trypsin inhibitory activity can be reduced at higher temperatures (pressure cooking), or through prolonged boiling.

4.1.2.4 Faba beans (*Vicia fava*), while having a very good nutritional quality and being a high yield crop, should not be used in the formulation of supplementary foods because of the danger of favism. Heating (boiling, pressure cooking, toasting) does not inactivate the toxic principles vicin and co-vicin.

4.1.3 Oil Seeds and Oils Seed Protein Products

4.1.3.1 Oil seed flours, protein concentrate and protein isolates which have been found suitable for feeding older infants and young children include:

Soya bean: flour (full fat and defatted), concentrate, isolate
 Groundnuts: defatted flour and isolate
 Sesame: whole ground and defatted flour
 Cottonseed: defatted flour
 Sunflower seed: defatted flour

4.1.3.2 Oils seed flours and protein products are a rich source of protein (50% for flours to 95% for isolates). Produced under appropriate conditions they can constitute the main protein component in the formulation of supplementary foods.

4.1.3.3 Appropriate conditions for the production of edible flours from soya beans, groundnuts, cottonseed and sesame are proposed in the PAG Guidelines No. 5, No. 2, No. 4 and No. 14 respectively. 1/

4.1.4 Fish and Fish Protein Concentrates

4.1.4.1 Dried, ground edible fish species and edible fish protein concentrates, produced under appropriate conditions have been found very suitable for the feeding of infants and young children. Such conditions are proposed in the PAG Guideline No. 9. 1/

4.1.4.2 Fish protein concentrates have a protein content of 70-80% of high quality and high lysine content.

4.1.5 Fats

4.1.5.1 Fats and especially vegetable fats and oils are added in the formulation of supplementary foods both for increasing the energy density of the food and for meeting physiological requirements of the older infant and the young child.

4.1.5.2 Vegetable oils and fats containing polyunsaturated fatty acids are to be preferred to those containing large amounts of saturated fatty acids.

4.2 Other Ingredients

4.2.1 Milk and Milk Products

Milk and Milk Products, when available, contribute to improving the nutritional quality of the product.

1/ PAG Guideline No. 2: Preparation of food quality groundnut flour; PAG Guideline No. 4: Preparation of edible cotton seed protein concentrates; PAG Guideline No. 5: Guideline for heat processed soy grits and flours; PAG Guideline No. 9: Fish protein concentrates for human consumption; PAG Guideline No. 14: Preparation of defatted edible sesame flour.

4.2.2 Sweeteners

Sugar and other nutritive sweeteners enhance acceptability of the food and contribute to reducing the bulkiness.

4.2.3 Flavours

Vanilla and traditional flavours may be added to supplementary foods to enhance acceptability.

4.2.4 Others

Other ingredients may be used, provided they have been proven to be suitable for their intended purpose.

5. PROCESSING

5.1 General Aspects

Regardless of the type and level of processing the raw materials should be preliminarily treated to obtain a wholesome and clean starting material. Such treatments include:

5.1.1 Cleaning and washing to eliminate dirt, damaged grains, insects and insect excreta and any adhering material.

5.1.2 Dehulling. Pulses and oilseeds should be dehulled as completely as feasible. Dehulling reduces the crude fibre content of the product to acceptable levels and eliminates tannins and other phenolic materials which can lower the protein digestibility. The same applies to certain cereals and in particular to those mentioned in Section 4.1.1,2.

5.2 Simple Processing

5.2.1 Milled Products

5.2.1.1 Ingredients suitable for the formulation of supplementary foods without further processing may be milled together or individually followed by the addition of other ingredients for the required formulation of the product.

5.2.1.2 Supplementary foods based on dry milled ingredients require thorough boiling in the prescribed quantity of water in order to sterilize the product, to destroy toxic substances and anti-nutritional factors which may be present, to gelatinize starch and generally improve the digestibility and absorption.

5.2.1.3 The bulkiness of preparations of feeds from supplementary foods consisting of dry milled ingredients, can be reduced by adding during the formulation adequate amounts of α -amylase which, during the slow heating to boiling, pre-digests partially the starch and reduces the amount of water needed for the preparation of the food.

5.2.2 Toasting (Roasting)

5.2.2.1 Pulses as well as oilseeds (soya, groundnuts and sesame) can be toasted as whole grains directly or after pre-soaking. Pre-soaking results in puffed grains with a light texture. Toasting enhances the flavour and the taste of the product, through dextrinization of starch, improves digestibility and contributes to reducing bulkiness.

5.2.2.2 The toasted ingredients, after dehulling, are milled and mixed with the other ingredients required for the formulation of the product.

5.2.2.3 The supplementary food based on toasted and milled ingredients require adequate boiling in the prescribed quantity of water prior to feeding.

5.2.3 Sprouting and Malting

5.2.3.1 Cereals and pulses can be induced to germinate by soaking or humidifying. The seed coat of the grains splits during the process and is removed by washing. The malted product after drying is milled and mixed with the other ingredients of the supplementary foods.

5.2.3.2 The action of natural amylases results in the predigestion of the starchy component (dextrinization), thus in a reduction of bulk and increase of the nutrient density of the products.

5.3 Advanced Processing Technology

5.3.1 Extrusion Cooking 1/

5.3.1.1 The milled main ingredients (cereals, pulses, oilseed flours) mixed together may be processed by extrusion-cooking in one step. The extruded product after drying (if necessary) is milled to the desired particle size and formulated by addition of the minor ingredients.

5.3.1.2 The effects of this technology are: gelatinization of the starchy component of the mixture with minimal quantities of water; inactivation of lectins and simultaneous reduction of trypsin inhibitor activity; need of reduced quantities of water for preparation i.e. increase in nutrient density.

5.3.1.3 The extrusion-cooking processed supplementary foods do not require, for nutritional reasons, boiling during reconstitution in water.

5.3.2 Enzymatic Pre-digestion 1/

5.3.2.1 The milled main ingredients (cereals, pulses, oilseed flours) with 1-2 volumes of water and 0.05-0.1% of the dry mixture of α -amylase are heated, under continuous stirring, in a converter slowly up to 60-70° C until the mixture acquires the desired fluidity, which indicates the splitting of the starch molecule into dextrins and reducing sugars. Then the temperature is raised to 85-90° C to inactivate the enzyme, and the resulting slurry is drum dried and reduced to flour or to small flakes. Then the minor constituents and fat are added to complete the formulation.

5.3.2.2 The product when reconstituted with the prescribed quantity of water does not require boiling.

5.3.2.3 The product displays improved organoleptic characteristics, higher digestibility, good solubility and requires minimal quantities of water for preparation thus having a high nutrient density.

6. FORMULATION OF SUPPLEMENTARY FOODS

1/ These products are also covered by the Codex Standard for Processed Cereal-based Foods. However, the standard does not include detailed provisions on nutrient content.

6.1 Nutritional Aspects

6.1.1 Energy

6.1.1.1 The energy content of the main components of supplementary foods (cereals, pulses, defatted oilseed flours) is relatively low.

6.1.1.2 The energy density can be increased by: adding fat and/or nutritive sweeteners and/or by processing the main ingredients as proposed in Sections 5.2 and 5.3.

6.1.1.3 100 g of supplementary food should provide about 400 kcal.(1.7 Mj).

6.1.2 Protein

6.1.2.1 The amino acid score of mixtures of cereals, legumes and/or oilseed flours should be adjusted to at least 65 and correspondingly to PER values not less than 2.1 and preferably above 2.3 (casein; 2.5).

6.1.2.2 The protein quality can be improved by the addition at adequate but safe levels of methionine or lysine in their L-form.

6.1.2.3 In order to cover 75% of the protein recommended intake through the supplementary food, its protein content should be adjusted at $16 \times 0.75 = 12$. With an amino acid score of 65 its protein content should be $12:65 \times 100 = 18,5$ g or 20g/100 g.

6.1.3 Fat

6.1.3.1 Incorporation of adequate quantities of fat, as technologically feasible is recommended in order to increase the energy density of the product. A level of 25% of energy deriving from fat would be desirable. This corresponds to 11 g in 100 g of supplementary food.

6.1.3.2 Where this is economically not feasible in the formulation of the supplementary food, the instructions for use on the label should recommend the addition of a specified quantity of fats and oils during the preparation of the food.

6.1.3.3 The level of linoleic acid (in the form of a glyceride) should not be less than 300 mg per 100 Kcal or 1.4 g per 100 g of product.

1/ The safe level of protein intake is the amount of protein considered necessary to meet the physiological needs and maintain the health of nearly all persons in a specified group. (This level is higher than the average requirement for protein).

2/ The energy requirement of persons is the energy intake that is considered adequate to meet the energy needs of the average healthy person on a specified category.

6.1.4 Carbohydrates

6.1.4.1 Carbohydrates, in the form of nutritive sweeteners, increase the energy density, are easier digested and absorbed than starch, and enhance acceptability.

6.1.4.2 Where this is economically not feasible in the formulation of the supplementary food, the instructions for use on the label should recommend the addition of a specified quantity of sugars, syrups or similar sweeteners during the preparation of the food.

6.1.4.3 As dietary fibres are slowly absorbed and fermented by the intestinal flora, thus causing laxative effect, the crude fibre content of the product should not exceed 5% per 100 g of product. Higher levels may be acceptable, although it would require clinical testing.

6.1.5 Vitamins and Minerals

6.1.5.1 The addition of vitamins and minerals should be conditioned by local nutrition and health problems as well as by national legislation.

6.1.5.2 The vitamin and mineral content of the ingredients of the supplementary foods should be taken into account when deciding on the type of vitamin-mineral premix to be added during the formulation.

6.1.5.3 In cases that older infants and young children are given vitamins and minerals through MCH centres or other health agencies, their addition in supplementary foods may be redundant.

6.1.6 Proposed Model Composition for Supplementary Foods

6.1.6.1 On the basis of the above considerations Table 1 proposes a model composition of supplementary foods for older infants and young children.

6.1.6.2 The model might not be applicable under all conditions prevailing in different countries and appropriate modifications can be made for adapting it to specific socio-economic conditions. (See also Sections 6.1.3.2, 6.1.4.2 and 6.1.5).

7. PREPARATION FOR USE

7.1 Products consisting of non-heat processed mixtures of raw ingredients should be adequately boiled during preparation in the prescribed quantity of water.

7.2 Products consisting of heat-processed mixtures may be prepared by addition cold or warm water and mixing. Boiling may not be required.

7.3 Where for technological and economic reasons the addition of high energy ingredients - fats, nutritive sweeteners - was not feasible their addition during preparation may be desirable and recommended.

8. HYGIENE

8.1 To the extent possible in good manufacturing practice, supplementary foods for older infants and young children should be free from objectionable matter.

8.2 When tested by appropriate methods of sampling and examination, the product: 1/

1/ Further consideration should be given to these sections.

Table 1. Proposed Model Composition for Supplementary Foods

| | Amounts per 100g. | Amounts per 100 kcal. | Amounts per 100 Kj |
|---|-------------------|-----------------------|-----------------------|
| Protein <u>1/</u> g. | 20 | 5.2 | 1.21 |
| Fat, g. | 10 | 2.6 | 0.6 |
| Crude fiber <u>2/</u> g. | 5 | 1.3 | 0.3 |
| Acid-insoluble ash, g. | 0.05 | - | - |
| 4.6.4. <u>Vitamin Content</u> <u>3/</u> | | | |
| Vitamin A, as retinol, μg | 400 | 100 | 24 |
| Vitamin D, (cholecalciferol), μg | 10 | 2.5 | 0.6 |
| Vitamin E, (α -tocopherol), μg | 5 | 1.25 | 0.3 |
| Ascorbic acid, mg | 20 | 0.52 | 0.12 |
| Thiamine, μg | 500 | 125 | 32 |
| Riboflavin, μg | 800 | 200 | 48 |
| Niacin, mg | 9 | 2.20 | 0.57 |
| Vitamin B ₆ , μg | 900 | 220 | 57 |
| Folic acid, μg | 100 | 27 | 6 |
| Vitamin B ₁₂ , μg | 2 | 0.52 | 0.12 |
| 4.6.5. <u>Minerals Content</u> | | | |
| Calcium, mg | 800 | 200 | 48 |
| Phosphorus, mg | 800 | 200 | 48 |
| Iron, mg | 10 | 2.7 | 0.6 |
| Iodine, μg | 70 | 18 | 4.5 |

1/ Protein with a Score of 65 and PER 2.2 (Casein: 2.5)

2/ Crude fiber higher than this may be acceptable, although it would require clinical testing

3/ The values for vitamins and minerals are considered minimal, except in the case of Vitamin D, where no further increase is desirable. The excess of each vitamin added during processing should be no greater than that needed to maintain label requirements over the expected shelf-life of the product.

General Aspects

- (a) For the purpose of calculating the energy and nutrient requirements, the child of one year of age is taken as a reference.
- (b) The recommended daily protein intake 1/ is 16 g of egg/milk quality.
- (c) The energy requirement 2/ is 1200 kcal. (5 MJ)/day.
- (d) 100 g of supplementary food in powder, grits or flake form, when prepared with the prescribed quantity of water, is considered a reasonable quantity that an older infant or young child can ingest easily in two or more feedings.
- (e) This quantity can provide only about one third of the energy requirements, but it can provide 75-100% of the recommended protein intake.

- (a) Should be free from pathogenic microorganisms;
- (b) should not contain any substance originating from microorganisms in amounts which may represent a hazard to health;
- (c) should not contain any poisonous or deleterious substances in amounts which may represent a hazard to health.

8.3 The product should be prepared, packed and held under sanitary conditions.

9. PACKAGING

9.1 The product should be packed in containers which will safeguard the hygienic and other qualities of food,

9.2 The containers, including packaging material, shall be made only of materials which are safe and suitable for their intended uses.

10. LABELLING

10.1 The Name of the Food

10.1.1 The name of the product should be "Supplementary Food for Older Infants and Young Children". In addition thereto any appropriate designation which may be used in accordance with national usage,

10.1.2 The sources of protein in the product should be clearly shown on the label in proximity to the name of the food, 1/

10.2 List of Ingredients

10.2.1 A complete list of ingredients should be declared on the label in descending order of proportion. The added vitamins and minerals should be arranged as separate groups for vitamins and minerals.

10.3 Declaration of Nutritive Value

The declaration of nutrition information should contain the following information in the following order: 1/

(a) The amount of energy, expressed in Kilocalories and/or Kilojoules, and the number of grammes of protein, carbohydrates and fat per 100 g of the food as sold.

(b) The total quantity of each vitamin and mineral per 100 g of the food as sold.

10.4 Net Content

The net content of the product should be declared by weight, in either the metric ("Système International" units) or in a system of measurement as required by the country in which the food is sold, or in both systems.

10.5 Name and Address

The name and address of the manufacturer, packer, distributor or vendor of the food should be declared.

10.6 Date Marking and Storage Instructions

10.6.1 The "date of minimum durability" (preceded by the words "best before") should be declared by the day, month and year in uncoded numerical sequence except that for products with a shelf-life of more than three months, the month and year will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer.

1/ Further consideration should be given to these sections.

In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.

10.6.2 In addition to the date, any special conditions for the storage of the food should be indicated if the validity of the date depends thereon.

10.6.3 Where practicable, storage instructions should be in close proximity to the date marking.

10.7 Information for Utilization

10.7.1 Directions as to the preparation and use of the food should appear on the label, preferably accompanied by appropriate sketches. These directions for use should include appropriate information in accordance with Section 7.

10.7.2 Instructions for the storage and keeping of the food after the container has been opened should appear on the label.

10.7.3 The label should include a statement that the food should not be introduced before [four to six months] of age.

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APPENDIX XI

REPORT OF THE THIRD MEETING OF THE AD HOC WORKING GROUP
ON METHODS OF ANALYSIS FOR FOODS FOR INFANTS AND CHILDREN

Participants:

Delegates from: Germany, Fed. Rep. of (Chairmanship)
Thailand
United Kingdom
United States of America
AOAC
FAO

(1) Determination of Ash (Type I Method)

The AOAC method (Official Methods of AOAC, XI, 1970, 7.010 Ash) has been endorsed by the CCMAS (see ALINORM 78/23).

(2) Loss on Drying (Type I Method)

The AOAC method XI, 1970, 7.003, Moisture, drying in Vacuo at 95-100°, has been endorsed by the CCMAS (see ALINORM 78/23).

(3) Crude Fibre

The opinion expressed during the second meeting of the ad hoc Working Group (1980), that no methods were necessary for crude fibre in Infant Formula and most of the other baby foods, was approved by the CCMAS. The Working Group recommended the ISO methods (ISO/DIS 5498 - Agricultural food products - Determination of crude fibre content - General method and ISO/DIS 6541 Agricultural food products - Determination of crude fibre content - Modified Scharrer method) for baby foods with high amounts of cereals as a correction in the determination of available carbohydrates. The combination of methods used to arrive at available carbohydrate content was considered to correspond to a Type I method situation.

(4) Vitamin E

A GLC-method has been tested collaboratively by AOAC in an international study. AOAC was asked to make this method available to the chairman of the Working Group and to the FAO Secretariat. The Secretariat should circulate this method to governments and interested international organizations for comments as a Type II method.

(5) Linoleic Acid

The final draft of a IUPAC method was distributed to members of the Working Group. This method will be published by IUPAC possibly in 1983. The IUPAC method has to be used in conjunction with IUPAC method 2.209. The Chairman of the Working Group agreed to ask IUPAC for permission for FAO Secretariat to send the final draft together with method 2.209 to governments and international organizations for comments as a Type II method.

(6) Sodium and Potassium

The method mentioned in the standard has been endorsed by the CCMAS for special dietary food with low sodium content. However, no special study had been performed with baby foods using this method. The Working Group recommended that interested International Organizations be requested to undertake such a study leading to the confirmation of this method as a Type II method.

(7) Iodide

A Danish method was distributed to the members of the Working Group for comments. The method will be rediscussed at the next meeting of the Working Group.

(8) Future Work

The Working Group discussed the necessity to work on methods of analysis for the various provisions in all standards on food for special dietary uses, not only for baby foods. This will be a considerable task and will need more time for meetings of the Working Group during the sessions of the Committee. Therefore, the Working Group proposed to have a meeting during the Plenary Session of the Committee for at least one day. The Chairman of the Working Group, together with the FAO Secretariat, were asked to prepare a list of the various methods required. This list should be sent to the appropriate International Organizations, asking them for methods suitable for the purpose of the Codex.

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APPENDIX XII

MATTERS RELATED TO THE ADVISORY LISTS FOR MINERAL SALTS
AND VITAMIN COMPOUNDS FOR USE IN FOODS FOR INFANTS
AND CHILDREN

- A. The Advisory Lists for Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children approved by the Codex Alimentarius Commission are included in Volume IX.
- B. CRITERIA FOR AMENDMENTS OF THE ADVISORY LIST OF MINERAL SALTS FOR USE IN FOODS FOR INFANTS AND CHILDREN
- (i) Mineral salts may be added to the list only if:
- (a) they are shown to provide technological and/or nutritional improvements;

- (b) the anion of the salt (or the acids from which the anion is derived) is an approved additive and its use would not exceed the ADI;
- (c) it is demonstrated by appropriate studies in animals and/or infants that the mineral element is biologically available from the salt;
- (d) the purity requirements for the mineral salt are established in an internationally recognized specification.

(ii) Mineral salts shall be deleted from the list if they are found no longer to meet the above criteria or if there is no evidence of their continued commercial application.

C. LIST OF PROPOSED MINERAL SALTS TO BE INCLUDED IN THE ADVISORY LIST OF MINERAL SALTS FOR USE IN FOODS FOR INFANTS AND CHILDREN

The following substances have been proposed for inclusion in the Advisory List of Mineral Salts for Use in Foods for Infants and Children. They have not been included due to lack of data required by the criteria set out above:

| Source of | Salts | Use in Foods for Infants and Children |
|----------------|--|--|
| Calcium (Ca) | Calcium glucuronate Calcium malate Calcium tartrate | |
| Magnesium (Mg) | Magnesium acetate Magnesium gluconate | Infant formula, processed cereal-based foods |
| Iron (Fe) | Ferrous ascorbate Ferrous glucuronate Ferrous glycerophosphate <u>1/</u> Ferrous phosphate Ferrous saccharate Ferric lactate <u>2/</u> Ferric tartrate | |
| Copper (Cu) | Cupric acetate Lysine/copper complex | Baked products, protein supplement formulae |
| Iodine (I) | Calcium iodostearate Sodium iodine <u>1/</u> | Milk-based, milk substitute protein hydrolysate formulae |
| Zinc (Zn) | Zinc lactate | |
| Manganese (Mn) | Manganese lactate | |
| Sodium (Na) | Sodium glucuronate Sodium glycerophosphate Sodium malate | |
| Potassium (K) | Potassium ascorbate Potassium glucuronate Potassium malate | |
| Chloride (Cl) | Zinc chloride <u>1/</u> | |

1/ Used in animal feeding studies.

2/ Not allowed in powdered formulae, cereals or baby foods.

D. CRITERIA FOR AMENDMENTS OF THE ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR INFANTS AND CHILDREN

(i) Vitamin Compounds may be added to the list only if:

- (a) they are shown to provide technological and/or nutritional improvements;
- (b) the anion of the compound (or acids from which the anion is derived) is an approved additive and its use should not exceed the ADI;
- (c) it is demonstrated by appropriate studies in animals and/or infants that the vitamin element is biologically available from the compound;
- (d) the purity requirements for the vitamin compound are established in an internationally recognized specification.

(ii) Vitamin Compounds shall be deleted from the list if they are found no longer to meet the above criteria or if there is no evidence of their continued commercial application.

E. LIST OF PROPOSED VITAMIN COMPOUNDS TO BE INCLUDED IN THE ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR INFANTS AND CHILDREN

The following substances have been proposed for inclusion in the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children. They have not been included due to lack of data required by the criteria set out above:

| Vitamin | Vitamin Compound | Purity Requirements |
|------------------------|---|---------------------|
| Provitamin A | Beta-apo-8'-carotenal Vitamin A Alcohol | FAO/WHO USP, FCC |
| Vitamin B ₂ | Riboflavin tetrabutryate | JSFA |
| Vitamin B ₆ | Pyridoxal 5'-phosphate Pyridoxine palmitate Pyridoxine di-palmitate | |
| Pantothenic Acid | Sodium pantothenate | |
| Vitamin C | Potassium ascorbate Ascorbyl stearate | JSFA |
| Choline | Choline hydrogen citrate | |

PROPOSED AMENDMENTS TO CERTAIN PROVISIONS OF THE CODEX
STANDARD FOR FOODS FOR SPECIAL DIETARY USES

I. PROPOSED AMENDMENTS TO CODEX STANDARDS FOR FOODS FOR INFANTS AND CHILDREN AT
STEP 3 1/

A. Leavening Agents

Standard concerned: Codex Standard for Processed Cereal-based Foods for Infants and Children (CODEX STAN 74-1981). It is proposed to include the following provisions in Section 5:

"5.6 Leavening Agents

- | | | | |
|-------|-----------------------------|---|---|
| 5.6.1 | Ammonium carbonate | } | Limited by Good Manufacturing Practice" |
| 5.6.2 | Ammonium hydrogen carbonate | | |

B. Definition of "Children" 2/

Standards concerned: Codex Standards for Canned Baby Foods (CODEX STAN 73-1981) and Processed Cereal-based Foods for Infants and Children (CODEX STAN 74-1981). To make the following amendment to Sections 2.3 and 3.3 of the above standards:

"2.3 - 3.3

The term "young children" means persons from the age of more than 12 months up to the age of three years." (Amendment underlined).

C. Guar Gum

Standard concerned: Codex Standard for Canned Baby Foods (CODEX STAN 73-1981). It is proposed to include the following provision into Section 4:

| | |
|----------|---|
| "4.1.2 | <u>Maximum level in 100 g of ready-to-eat product</u> |
| Guar Gum | 0.2 g" |

D. Maximum Levels for Vitamin D Content

Standard concerned: Codex Standard for Infant Formula (CODEX STAN 72-1981). It is proposed to amend Section 4.1.2 (a) as follows:

| | | | |
|-----------|---------------------------------------|----------------|--|
| | "Amount per 100 available Calories | | Amount per 100 available Kilojoules |
| | <u>Minimum</u> | <u>Maximum</u> | <u>Minimum</u> <u>Maximum</u> |
| Vitamin D | 40 I.U. | / 120 / I.U. | 10 I.U. / 30 / I.U." |

II. PROPOSED AMENDMENTS TO CODEX STANDARD FOR INFANT FORMULA (CODEX STAN 72-1981)
AT STEP 5 3/

"5.5 No food additives shall be present as a result of carry-over from raw materials and other ingredients with the exception:

- (a) of the food additives listed under 5.1 to 5.4 of this standard within the limits of the maximum levels stipulated in this standard; and

1/ Subject to approval by the 15th Session of the Commission.

2/ Consequential amendment.

3/ It is proposed to recommend to the 15th Session of the Commission to omit Steps 6 and 7 and to adopt the amendment at Steps 5 and 8.

(b) of the carrier substances mentioned in the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children within the limits of the maximum levels stipulated in that List.

III. AMENDMENT OF THE SECTION "SPECIAL VITAMIN FORMS" IN THE APPROVED ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR INFANTS AND CHILDREN

It is proposed that the amended text of this Section read as follows:

"Special Vitamin Forms

For reasons of stability and easier handling, some vitamins have to be converted into suitable preparations, e.g. stabilized oily solutions, gelatine coated products, fat embedded preparations. For this purpose, the edible materials and the additives included in the respective Codex Standard and the following substances may be used:

| | <u>"Maximum Level in ready-to-use food</u> |
|--|--|
| (a) Dextrins | 60 mg/kg |
| (b) Modified Starches as included in List A (1) of the Guide to the Safe Use of Food Additives (CAC/FAL 5-1979)" | 100 mg/kg |

IV. PROPOSED AMENDMENT OF CODEX STANDARD FOR FOODS WITH LOW SODIUM CONTENT (INCLUDING SALT SUBSTITUTES) 1/

It is proposed to include into the above standard a section on date marking to read as follows:

"4.1.6 Date Marking

The date of minimum durability (preceded by the words "best before") shall be declared by the day, month and year in uncoded numerical sequence except that for products with a shelf-life of more than three months, the month and year will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer. In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.

4.1.7 Storage Instructions

In addition to the date, any special conditions for the storage of the food shall be indicated if the validity of the date depends thereon. Where practicable, storage instructions shall be in close proximity to the date marking."

1/ Consequential amendment.
