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OF THE

CODEX COMMITTEE ON FOODS FOR SPECIAL DIETARY USES

Bonn

30 November, 4 December 1970

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ALINORM 71/26
January 1971

FIFTH SESSION OF THE CODEX COMMITTEE ON FOODS FOR SPECIAL DIETARY USES

Bonn, 30 November - 4 December 1970

INTRODUCTION

1. The Codex Committee on Foods for Special Dietary Uses held its Fifth Session by courtesy of the Government of the Federal Republic of Germany from 30 November to 4 December in Bonn. The Chairman of the Committee was Mr. H.P. Mollenhauer, Ministerialrat, Federal Ministry of Youth, Family and Health. In opening the session, the Chairman expressed his satisfaction that interest in the work of the Codex Committee on Foods for Special Dietary Uses was growing. This was evident from the increased participation at this session. The session was attended by government delegates from the following 21 countries: Australia, Belgium, Canada, Denmark, France, Finland, Germany (Fed. Rep.), Hungary, Ireland, Italy, the Netherlands, Norway, Philippines, Poland, Portugal, Sweden, Switzerland, Tunisia, United Kingdom, United States of America and Venezuela. The following international organizations were also represented: Association of Official Analytical Chemists (AOAC), European Economic Community (EEC), FRUCOM, International Association for Cereal Chemistry, International Federation of Glucose Industries (IFG), UNICE-IDACE, International Union of Nutritional Sciences and International Organization of Consumers Unions. A list of participants, including officers from FAO and WHO, is attached as Appendix I to this Report.

ADOPTION OF THE PROVISIONAL AGENDA AND APPOINTMENT OF RAPPORTEUR

2. The Committee agreed with a proposal made by the delegation of the Federal Republic of Germany that agenda item 9 (Ascorbic Acid in Spinach) be taken immediately after the appropriate subject matter under agenda item 6 (Foods for Infants and Children) as these dealt with closely related problems.

3. On the proposal of the delegation of the Federal Republic of Germany, Mr. L.M. Beacham of the delegation of the U.S.A., agreed to act as Rapporteur and was so appointed.

MATTERS OF INTEREST TO THE COMMITTEE

4. The Chairman informed the Committee that the Codex Alimentarius Commission at its 7th session had adopted the Draft Standard for Special Dietary Foods with Low Sodium Content (including Salt Substitutes) at Step 5 of the Procedure and requested comments at Step 6. The Secretariat briefly described the decisions of the Codex Committees on Food Hygiene, Methods of Analysis and Sampling, and Food Additives. The Committee agreed that these matters be discussed at the appropriate points during the consideration of the various standards before the Committee.

PROPOSED DRAFT STANDARD FOR SPECIAL DIETARY FOODS WITH LOW SODIUM CONTENT (including Salt Substitutes)

5. The Committee had before it the above draft standard (Appendix VI, ALINORM 70/26) and papers containing comments from governments (CX/FSDU 70/2 and Add. 1 and 2). In considering the section dealing with Essential Composition and Quality Factors, a number of delegations were of the opinion that sub-section 3.1.1 (b) should be deleted from the standard. It was pointed out by these delegations that this provision was too restrictive and that the important provision was contained in sub-section 3.1.1(c) which required that a food presented as having a low sodium content shall not contain more than 120 mg/100 g sodium. For example, bread was sometimes prepared without the addition of salt and, for such bread to conform to the provision laid down in 3.1.1, an additional reduction of the normal sodium content of the ingredients used in bread-making would be necessary. A similar problem existed with fruit products to which sodium salts were not added during processing. In this connection it was pointed out that the standard dealt with foods which were normally not low in sodium content and that therefore this difficulty would not arise. After discussion, the Committee decided not to amend the standard as proposed.

6. The Committee agreed with the proposal of the Secretariat that, in a new section 3.1.3, reference be made to the use of salt substitutes in foods presented as "low sodium" or "very low sodium" and agreed to the following text:

"The addition of salt substitutes to a special dietary food with low sodium content is permitted and shall be limited by good manufacturing practice."

7. During the discussion of the sub-section dealing with salt substitutes as such, the general question arose as to whether or not the actual salts used as salt substitutes be listed instead of referring to a possible combination of cations and anions. It was agreed that, while such a procedure might have advantages, the present draft allowed for a greater flexibility in choosing appropriate substances for the formulation of salt substitutes. The Committee noted that the Codex Committee on Food Additives had endorsed the provisions for salt substitutes in their present form, with the exception of choline derivatives which had not yet been toxicologically evaluated and would be re-examined at a later date. It was understood by that Committee that eventually specifications of identity and purity would be drawn up for those substances which were in fact being used in the formulation of salt substitute preparations. The Committee considered proposals to delete ammonium from the list of permitted ions as the use of ammonium compounds was not desirable from a medical point of view in a diet of persons requiring low sodium foods. The delegations of Hungary, Sweden and Portugal were in favour of deleting the amino acid (glutamic acid and its salts), in view of the fact that persons requiring a diet with restricted sodium content often showed difficulty in excreting nitrogen. The question was raised as to what phosphates were of interest as salt substitutes. It was pointed out that only some ortho-phosphates had proper taste properties for the purposes of salt substitute formulations. The Committee noted that there would be little difficulty as regards the total load of phosphate for the diet resulting from the use of phosphates, but that the ratio of calcium:phosphorus was of significance. It was agreed that the delegations of the Netherlands, Federal Republic of Germany and U.S.A. should form a small working group and report to the Committee at a later stage during the session on the use of phosphates and ammonium as salt substitutes, as well as on permitted diluents and anti-caking agents.

Discussion of the recommendations of the Working Group on the use of ammonium salts and phosphates

8. The Committee considered a proposal of the above working group that the decision to delete the ammonium salts as compounds of dietary salt substitute be reconsidered on the grounds that:

- (a) these dietary salt substitutes were only used up to a level of about 5 g a day;
- (b) with a quantitative limitation of the ammonium ion content of 3% in the total mixture the health risks seemed to be negligible for those patients who were allowed to use these salts.

The Working Group further proposed that, in view of the fact that some soluble phosphates may have desirable taste properties, it would be desirable to permit the use of ortho-phosphates. On the other hand, it was desirable to restrict the total phosphate intake in the diet by limiting the total amount of ortho-phosphates in the salt substitute to a level not exceeding 4% P in the salt substitute. As diluents, the Working Group proposed to permit all safe and suitable nutritive foods as normally used (e.g. sugars, cereal flour). As anti-caking agent, the Working Group proposed colloidal silica to a maximum of 1% of the salt substitute in view of the fact that some other anti-caking agents were already permitted under sections 3.2.2.1 and 3.2.2.2 or under the ortho-phosphate provision. The delegations of France and Poland were opposed to the use of ammonium salts as components of dietary salt substitutes. On the proposal of the delegation of the U.K. the Committee agreed to add calcium silicate as an additional anti-caking agent up to 1% individually or in combination with colloidal silica.

9. The Committee agreed with the proposals of the Working Group and decided to amend the standard accordingly.

10. As regards section 3.2.2, the Committee did not agree with a proposal of the delegation of France to include potassium formate in the list of salt substitutes. On the proposal of the delegation of the Federal Republic of Germany, the Committee agreed to include free lactic and malic acids under 3.2.2.4. It was noted that the above additional substances would need endorsement by the Codex Committee on Food Additives. As regards sub-section 3.2.2.2, the Committee agreed to the following text to limit the proportion of magnesium in relation to other cations:

"Mg⁺⁺ to be not more than 20% of the total of the cations K⁺, Ca⁺⁺ and NH₄⁺ present in the salt substitute mixture."

11. The delegation of the U.S.A. was of the opinion that the iodization of salt substitutes was desirable since in many regions salt was used as a vehicle for the purpose of supplying iodine. A number of delegations were of the opinion that the iodization of salt or salt substitutes represented a regional problem and that it would be therefore undesirable to provide for the iodization of salt substitutes in an international standard. It was also questioned whether salt substitutes were the proper vehicle for this purpose since many persons requiring a diet with low sodium content did not use salt substitutes for reasons of palatability. The Committee agreed that the iodization of salt substitutes be left to national health authorities and adopted the following text in a new section 3.2.4:

"The addition of iodine-containing compounds shall be in conformity with national legislation of the country where the product is sold."

12. In considering the Labelling section, the Committee agreed that reference to the "appropriate provisions" of the Recommended International General Standard for the Labelling of Prepackaged Foods, as was the case in the present draft, was not sufficiently precise. It was therefore agreed that the section on labelling in this standard should deal only with specific requirements applicable to low sodium foods and salt substitutes, it being understood that more general labelling provisions were or would be laid down in the standard for the particular food concerned. The following text was agreed upon:

"In addition to any labelling provisions applying to the particular food concerned, the following specific provisions for the labelling of special dietary foods with low sodium content shall apply."

13. The Committee agreed to delete the sentence in sub-section 4.2.2 dealing with the optional declaration that no sodium salts had been added, with the understanding that section 6.1 of the Recommended International General Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969) would normally be attracted to the section on labelling in the particular standards concerned.

14. The delegation of France was of the opinion that it was necessary to make mandatory on the label indication of available carbohydrate, protein and fat content as well as the calorie value in relation to 100 g of the product ready for consumption. However, they were of the opinion that where the calorie value was less than 10 calories per 100 g of the product, as for example in the case of certain condiment mixtures, all the indications provided for in this section should be replaced by the declaration "without calorie value". Other delegations were of the opposite view and stated that this standard should only deal with provisions relating to sodium content and that the choice of a proper diet in respect of carbohydrate, protein and fat content should be dealt with elsewhere. The Representative of WHO was of the opinion that the declaration of the carbohydrate, protein and fat content as well as calorie value was of particular importance in the case of very low sodium foods. The Committee agreed to retain the present text of section 4.2.3 but to make it mandatory by replacing the word "may" by the word "shall". The delegations of the Netherlands and the U.S.A. were strongly opposed to this decision.

15. In considering section 4.2.4, the Committee discussed the way in which salt substitutes added to food should be declared. Some delegations were in favour of a complete listing of the ions and compounds while others were of the opinion that the declaration of the addition of salt substitutes to the food was sufficient. The Committee adopted the latter view but agreed that the quantitative declaration of total potassium in the food was important since this ion could be increased well above normal levels in low sodium foods. The following text was agreed upon:

"The addition of salt substitutes listed in paragraph 3.2 of this standard shall be declared on the label. The maximum total amount of potassium expressed as mg cation per 100 g of the food as normally consumed shall be declared on the label."

16. Regarding the labelling of salt substitutes as such (Section 4.3) the Committee agreed that reference should be made to the Recommended International General Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969). The delegation of the United Kingdom was of the opinion that the name of the product "salt substitute" was not in conformity with paragraph 3.1(a) of the Recommended International General Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969) since it did not describe the product adequately. The Committee agreed to amend the term "salt substitute" to "low sodium salt substitute". The delegation of Belgium was of the opinion that the word "dietetic" should appear in the name of the product. This proposal was supported by the delegations of France and Italy. The Committee agreed to the alternative name "low sodium dietetic salt" and further agreed that the standard be amended accordingly.

17. As regards the Methods of Analysis and Sampling section, the Committee was informed that the determination of sodium content would be on the agenda of the Sixth Session of the Codex Committee on Methods of Analysis and Sampling. The Committee agreed that methods of analysis were required for determination of potassium in foods with low sodium content as well as in salt substitutes, and also for the determination of calcium, magnesium, ammonium and choline in salt substitutes. The Committee requested the Secretariat to propose a method of analysis for NH_4^+ content ^{1/}The Committee agreed that the methods of analysis listed in Appendix III, section 5 to this report, should be submitted to the Codex Committee on Methods of Analysis and Sampling for endorsement. A proposal was made by the delegation of France to submit to the Committee for consideration sampling plans specially drafted for foods for special dietary uses. These sampling plans were distributed during the session, but the Committee considered it premature to discuss the plans at this stage

1/ Note by the Secretariat: As a maximum has been now adopted for phosphorus, calcium silicate and colloidal silica, methods of analysis are needed for these minerals. (See Appendix III para 5.2(b)).

and agreed that a working paper on this subject, based on the document prepared by France, should be prepared by the Secretariat for the next session of this Committee. This paper should deal with the need for these plans and the criteria to which the proposed sampling plans should apply and should also take into account the general decisions which would be taken by the Executive Committee at its forthcoming meeting with respect to the question of statistical sampling plans in relation to Codex standards. (See also para 83 of this Report).

Advancement of the Standard to Step 8

18. The Committee decided to advance the Standard for Special Dietary Foods with Low Sodium Content (including Salt Substitutes) to Step 8 of the Procedure for the Elaboration of Worldwide Standards, for submission to the Eighth Session of the Codex Alimentarius Commission. The standard as amended is attached as Appendix III to this Report.

PROPOSED DRAFT STANDARD FOR COMPLETE INFANT FOOD (COMPLETE INFANT FORMULA) (ex- Proposed Draft Standard for Infant Formula (Mother's Milk Substitute))

19. The Committee had before it the above draft standard (Appendix II, ALINORM 70/26) and papers containing comments from governments (CX/PSDU 70/3 and Add. 1 to 3). The title of the standard was amended according to the decision taken by the Committee regarding the name of the product (see para 57).

20. In discussing the Scope section, the general question arose as to whether the standard should cover only those products which were intended for use as a complete substitute for human milk or whether the standard should include other products which represented only a partial substitute for human milk. Some delegations were of the opinion that both types of product could be covered by the same standard, while other delegations were of the opinion that the standard under discussion should be restricted only to the former type of product and that separate standards should be elaborated for preparations which were only partial substitutes for human milk. The Committee agreed to restrict the standard to complete human milk substitutes as stated in the first sentence of the Scope section. The delegation of Switzerland pointed out that the products described by the standard could constitute any portion of the dietary intake of infants and that for this reason the word "major" should be deleted. Other delegations were of the view that the whole sentence was redundant as it implied in which way the preparation would be used and had no relevance to the scope of the standard. The Committee agreed to retain the second sentence and to delete the word "major". As regards the establishment of a standard for products other than those complying with the provisions of this standard, the Committee accepted the offer of the delegation of Switzerland to prepare a draft standard for the next session in close collaboration with the delegation of the Netherlands. The delegation of Denmark drew the Committee's attention to certain criteria which would have to be answered to justify the establishment of a standard for these products. These criteria should include the volume of international trade, the types of products which would be covered by the standard, etc. (See Procedural Manual of the Codex Alimentarius Commission, 2nd edition, page 45).

21. As regards the Description Section, the delegation of Canada stressed the importance of clinical trials to demonstrate the nutritional adequacy of human milk substitutes and proposed the addition of the following text at the end of section 2.2:

"..... and shown to be so by clinical trials."

A number of delegations were in agreement with this proposal. It was pointed out that it was difficult to conduct clinical trials on human babies, such as those involving growth studies, but that the examination of narrower aspects of a nutritional nature such as digestibility had been carried out; the Canadian proposal would lead to difficulties concerning the

acceptance of slight modifications of well-established formulations since these would have to be subjected to clinical trials before they would be in conformity with the standard. It was also pointed out that section 2.2 as drafted already inferred that nutritional adequacy of the product had been subjected to investigation. The Committee decided not to make any amendments to this section.

22. The delegation of Switzerland proposed that the words "by physical means" be deleted from section 2.3 since methods of processing, other than chemical means, could be envisaged in the future (e.g. biological methods), and that, furthermore, the word "bacterial" should be deleted since spoilage could be caused by other than this means. The Committee agreed that, at the present time, only physical means of treatment were recognized to prevent spoilage of this product and decided not to make any changes to the present text except for the deletion of the word "bacterial" and the addition of the words "and contamination".

23. As regards the definition of "Calorie" in the Definitions Section (3.2), the delegation of Denmark was of the opinion that reference should be made to the conversion factors to be used to calculate the metabolizable energy value. The Committee agreed that this matter be dealt with under the section on methods of analysis.

24. In considering the sub-section 4.1.1 of the Composition Section, the delegation of Switzerland was of the opinion that reference to fish was redundant since the provision relating to animal sources already covered products derived from this source. The Committee decided not to change the text. The delegation of Norway proposed to include also edible constituents from micro-organisms. The delegations of Tunisia and Switzerland were in support of this proposal. The representative of WHO pointed out that section 4.1.1 as drafted, and particularly with the amendment as proposed by Norway, offered the possibility of producing substitutes for human milk from any raw material, the composition of which was not sufficiently known or recognized as suitable for the feeding of infants. The Committee decided not to so amend the text of section 4.1.1 but agreed to specify that the addition of carbohydrates and potable water were permitted.

25. The Committee agreed that when recommending minimum or maximum values for vitamins and other nutritional factors, it was understood that the figures referred to the available form of the food factors concerned. It was therefore decided to amend section 4.1.2 accordingly.

Vitamins (per 100 available Calories)

26. In considering the sub-section 4.1.2.1 (Vitamins), the delegation of Switzerland was of the opinion that the Committee should clarify whether the vitamins and minerals listed were recommendations or provisions of a mandatory nature. The Committee agreed that these were mandatory provisions and noted that the vitamins and their minimum levels were based on the recommendations of the Nutrition Committee of the National American Academy of Pediatrics. These in turn had been based on levels actually found in human milk as well as on experience gained in the field of pediatrics.

27. The Committee decided not to change the minimum quantity laid down for Vitamin A in the standard, noting that the standard provided for the addition of Vitamin A as such and that reference to minimum quantities of retinol and beta-carotene were only for the purpose of expressing the analytical results in other ways. Some delegations were of the opinion that retinol was the only form of Vitamin A which should be permitted for use in this product.

28. Some delegations were of the opinion that the minimum level proposed for Vitamin D was somewhat high. Other delegations were of the opinion that in certain areas minimum levels higher than 40 I.U. were needed for the prophylaxis of rickets, but that this matter should be dealt with on an individual country basis. Some delegations were of the opinion that

products not containing Vitamin D should also be provided for as long as this fact was declared on the label. The Committee decided not to change the minimum level provided for in the standard and deferred decision on products without Vitamin D.

29. Regarding the level of Vitamin E, the delegation of Denmark pointed out that tocopherols other than the alpha-form, because of their relatively lower potency, may be disregarded in dietary calculations and evaluations; consequently, and for the sake of analytical simplicity it was preferable to provide for a minimum quantity of alpha-tocopherol expressed in mg, pointing out that the same numerical value per 100 Cal. would still apply. Some delegations were not in agreement and were of the opinion that the standard should rather specify the minimum physiological activity required. The delegations of Denmark, the Netherlands, Poland and the Federal Republic of Germany were of the opinion that the minimum activity of Vitamin E should be set in relation to the amount of poly-unsaturated fatty acids; the delegation of Denmark proposed a level of 1 I.U. /g linoleic acid.

30. Some delegations were of the opinion that lower minimum limits for ascorbic acid were adequate, while other delegations considered that the addition of greater amounts of this vitamin was required in view of losses incurred during processing and storage, as well as to take into account higher requirements by premature infants. It was agreed that the standard should take into account only normal infants and that the minimum level specified was related to the amount in the product as offered for sale, not the amount to be added. For these reasons, the Committee agreed not to make any changes to this provision.

31. Some delegations were of the opinion that a higher minimum amount of Thiamine (Vitamin B₁) was required in view of the fact that intestinal synthesis of Vitamin B₁ cannot be taken into account in the very young infant and furthermore because the average content in human milk is approximately 40 mcg. Other delegations were of the opinion that 25 mcg was an adequate minimum provision. The Committee decided not to make any changes to this provision.

32. The Committee confirmed the provision for a minimum level of 60 mcg of Riboflavin (Vitamin B₂).

33. It was pointed out that the term Niacin might lead to the addition of nicotinic acid, which had certain undesirable physiological effects. For this reason, it was desirable to provide for the addition of nicotinamide only and that a minimum level of 250 mcg would be required. It was pointed out that the extra requirement of niacin would always be provided by tryptophane present in the protein. The Committee agreed to this change and also agreed to delete the footnote referring to the equivalent of L-tryptophane to niacin.

34. The delegation of the Federal Republic of Germany pointed out the need to relate the minimum quantity of Vitamin B₆ to the protein content and was of the opinion that the minimum level of 35 mcg was too low. The Committee agreed to increase the minimum level to 50 mcg.

35. Regarding the level of Folic Acid, the delegations of the Federal Republic of Germany and Italy were of the opinion that the minimum level of 4 mcg was too high and that the mode of action of this vitamin was still a matter of controversy. The Committee noted that this minimum level had been recommended by the Joint FAO/WHO Expert Committee on Nutrition for infants between the age of 0 to 6 months. It was also pointed out that the addition of higher levels was needed in view of the high instability of this vitamin to elevated temperatures. In view of these doubts, the Committee agreed to place this provision in square brackets and to discuss it in the light of further information and comments at the next session.

36. As regards Pantothenic Acid and Vitamin B₁₂, the Committee confirmed the provision for minimum levels of 300 mcg and 0.15 mcg respectively.

37. The delegation of Canada was of the opinion that a minimum level of 4 mcg and a maximum level of 10 mcg of Vitamin K should be provided for. It was pointed out that human milk contained approximately 0.5 mcg/100 g of this vitamin and that, therefore, the proposed level of 4 mcg was too high. It was further pointed out that Vitamin K was needed only in certain cases which should be left to control by the physician. The Committee agreed to insert the Canadian proposal in square brackets and to discuss this matter at the next session in the light of comments received.

38. The Committee considered proposals to include Biotin and Choline in the standard. Doubt was expressed as to the need for these substances as their physiological activity was still a matter of controversy. The Committee decided not to make specific provision for these substances. It was also noted that the addition of vitamins other than those listed in section 4.1.2.1 was covered in section 5.1 of the standard, where this matter would be further considered.

Minerals (per 100 available Calories)

39. The delegation of Norway stressed the need to relate the amounts of Calcium and Phosphorus to the calcium : phosphorus ratio and proposed that this should be not less than 1.2 and not more than 2.0. The Committee agreed that the proposal of the delegation of Norway be included in the standard in square brackets and confirmed its previous minimum levels for these substances.

40. As regards Magnesium and Iron, the Committee confirmed the provisions for minimum levels of 6 mg and 1 mg respectively.

41. The delegations of the Federal Republic of Germany and Switzerland were of the opinion that the requirement for Iodine represented a medical problem and that therefore iodine should be deleted from the standard. The delegation of the U.S.A., supported by other delegations, was of the opinion that infant foods based on non-milk constituents required the addition of trace amounts of iodine for nutritional purposes. The Committee confirmed the provision for a minimum level of 5 mcg.

42. The delegations of the Federal Republic of Germany and Switzerland were of the opinion that the proposed level of 60 mcg of Copper was too high and proposed minimum levels of 30 mcg and 20 mcg respectively. The Committee adopted the proposal for a minimum level of 30 mcg to be placed in square brackets.

43. The delegation of Canada proposed the addition to the standard of provisions for Potassium and Sodium, Manganese and Zinc at the minimum levels of 80, 20, 0.2 and 0.5 mg respectively. The Committee agreed to insert the above proposed minerals and minimum levels in the standard in square brackets and to discuss this matter at the next session in the light of comments received. It was understood that the above values represented normal natural levels which the infant food should contain.

Discussion of the Maximum Amounts for Vitamins and Minerals

44. In discussing what the maximum levels should be the Committee considered various proposals to multiply the minimum levels by factors between two and four and also proposals for maximum levels for Vitamins A and D. The Committee agreed tentatively that the maximum levels should be twice the minimum levels with the exception of Vitamin D, which should be present in the product at a level of 40 I.U. Some delegations pointed out that a certain

tolerance should be permitted with regards to this figure of 40 I.U. It was agreed to discuss the maximum levels at the next session in the light of comments received. As regards minerals, the delegation of Canada proposed maximum levels of 80 mg for sodium and 200 mg for potassium. The Committee tentatively agreed that the maximum levels should be double the minimum levels. It was further decided that the provision of Ca : P ratio agreed to for the minimum level should also apply to the maximum levels of calcium and phosphorus. The delegation of the U.S.A. was of the opinion that, if the standard provided for the label declaration of only the minimum contents of vitamins and minerals, no need would exist for the establishment of maximum levels, since there would be no competitive incentive for manufacturers to add higher amounts. Some delegations were of the opinion that maximum levels were required only for Vitamins A and D. Other delegations were in favour of establishing maximum levels for all vitamins and minerals since, for example, where no maxima were laid down, the temptation would exist for manufacturers to add excess quantities without maintaining proper analytical control of the product. It was pointed out that the maxima should be set in such a way as to permit the addition of sufficient quantities of vitamins to deal with regional problems of vitamin deficiency (e.g. rickets).

Protein (per 100 available Calories)

45. The representatives of FAO made a general statement, informing the Committee about the next Meeting of a FAO/WHO Ad Hoc Expert Committee on Energy and Proteins : Requirements and Recommended Intakes, to be held in Rome in June 1971. In relation to this, it was mentioned that studies were under way in FAO to have a better knowledge of the amino acid composition of hen's egg protein in view of its use as a reference protein. It was also mentioned that the improvement of the NPU and PER evaluation methods were under consideration. The delegation of Switzerland pointed out that, since FAO and WHO were to discuss the matter of reference protein and methodology of protein efficiency at the meeting in June 1971, it was advisable to wait for their recommendations. The delegate of the U.K. proposed that the wording of section 4.1.2.3 be amended to "not less than [.....] g of protein, of nutritional quality equivalent to that of whole egg protein, or a greater or lesser quantity of other protein in proportion to its nutritive value" and suggested the deletion of the reference to the quality of protein being not less than 70% of hen's egg whole protein. The delegation of the Netherlands was of the opinion that it was necessary to maintain the requirement for a minimum quality level of 70% in order to avoid an undesirable large amount of low quality protein in the food. The delegation of the U.S.A. proposed that the minimum quantity of protein (expressed in terms of the reference protein) should be 1.5 g per 100 Cal. instead of 1.8 g since the figure of 1.8 related to casein as reference protein. This view, however, was not supported by the majority of delegations. The delegation of the Federal Republic of Germany expressed the view that a maximum amount of protein should be established in view of the risk of overloading the infant's organism with nitrogen and proposed a maximum of 3 g per 100 Cal. This maximum level was accepted by the Committee. After discussion of item 4.2 (optional ingredients, see para 48 of this Report), it was agreed that this section should be deleted but that reference to the addition of synthetic amino-acids should be made under section 4.1.2.3 with a view to raising the quality of the protein. The Committee agreed to the text proposed by the U.K. delegation amended as follows:

"Protein (per 100 available calories): 4.1.2.3.1: shall be not less than 1.8 g of protein of nutritional quality equivalent to that of whole egg protein or a greater quantity of other protein in proportion to its biological value. The quality of the protein shall be not less than 70% of that of whole egg protein. The total quantity of protein shall not be more than 3 g. 4.1.2.3.2: The addition of only essential isolated amino-acids is permitted, and only for the purpose of improving the nutritional quality of the protein, in conformity with the provisions specified in sub-section 4.1.2.3.1."

Linoleate (per 100 available Calories)

46. The delegate of Portugal stated that recent scientific work pointed to a blockage of fat metabolism and possibly protein metabolism by linoleic acid and that, therefore, the proposed level of linoleate should be kept in square brackets (Section 4.1.3). The delegation of Denmark was of the opinion that no maximum limit for the content of linoleic acid should be set, provided it was decided that the minimum content of Vitamin E should be related to the linoleic acid content. The delegation of Australia was of the opinion that it would be preferable to express the percentage of linoleic acid in terms of Calories only. Some delegations were in favour of levels between 500-600 mg/100 Calories. It was decided that the minimum level be increased to 300 mg/100 Calories and that there was no need to set a maximum level.

Fat

47. As regards fat, the Committee agreed to set a range of 25-50% of the total Calories in Section 4.1.3 and also agreed that these figures be placed in square brackets, subject to further consideration at the next session.

Optional Ingredients

48. In discussing the Section 4.2, it was noted that some of the optional ingredients were already covered by Sections 4.1.1 and 5.1 of the standard. As regards protein hydrolysates, a number of delegations were of the opinion that these should only be added to improve the nutritive value of protein. Similar arguments were advanced in respect of amino acids as optional ingredients. The delegate of Tunisia was of the opinion that reference should only be made to essential amino-acids and that maximum levels should be laid down for them. The delegation of the United Kingdom was of the opinion that this section should be deleted. The Committee agreed with this proposal and decided to consider the question of optional ingredients under Section 5.1, which should replace the present section 4.2. As regards the addition of amino acids, it was decided that reference to these should be made under Section 4.1.2.3 (see para 45 of this Report).

49. As regards Section 5.1, the delegation of Norway was of the opinion that the addition of vitamins and minerals in addition to those listed in Sections 4.1.2.1 and 4.1.2.2 be made mandatory, if it is shown that such an addition is essential. The delegation of the Netherlands was of the opinion that, if the addition of certain vitamins and minerals was desirable, these should be listed in Sections 4.1.2.1 and 4.1.2.2, whereas if doubt existed regarding their nutritional value, their addition should not be permitted since this would open the door to unfair advertizing. The delegation of the U.S.A. was of the opinion that the standard should not be drafted in such a way as to prevent the addition of factors which might be shown to be essential in the future and that the problem of promotional claims would be covered by appropriate labelling requirements. The Committee agreed that it was necessary to redraft Section 5.1 to permit the addition of vitamins and minerals listed in Sections 4.1.2.1 and 4.1.2.2 within the limits specified, as well as the addition of other nutrients to ensure that the food is suitable as the sole source of nutrition of the infant. As regards the addition of "other nutrients" it was pointed out that it would be difficult to control this provision, since it was not certain as to what authority would establish the need for and safety of such additions. The delegation of France was of the opinion that reference should be made in the standard to the levels of nutrients present in mother's milk. The Committee agreed that the text of Section 5.1(b) be placed in square brackets pending further consideration at the next session.

Consistency and Particle Size and Purity Requirements

50. The Committee decided not to change the text in Sections 4.3 and 4.4 as per the present standard.

Specific Prohibition

51. The delegation of France was of the opinion that, while there should be a prohibition of the use of ionizing radiation (Section 4.5), it might be desirable to permit the exposure of these products to small doses of radiation not exceeding 25 Rads, resulting from the use of processing and packing equipment that employ a low level radioactivity. The Committee decided not to make such an exception in the prohibition on the use of ionizing radiation but agreed that the text be amended to make clear that components which were used in the preparation of infant food should be included in the prohibition. It was further agreed to amend the text to refer to "treatment" rather than "exposure" by ionizing radiation.

Food Additives

52. The Committee considered a proposal by the delegation of Switzerland to divide the additives section into two classes, one dealing with nutritive substances and the other with additives for technological purposes. The Committee was informed that the Joint FAO/WHO Expert Committee on Food Additives had not yet dealt with the problem of the toxicity of additives in relation to infants but that this matter would be considered in the near future. It was pointed out that, in principle, only those substances should be dealt with under this section which were used for technological purposes and that the use of such substances should be justified. It was essential to establish maximum levels and specify the additives in greater detail. The delegations of Canada and the U.S.A. agreed to prepare a working paper for the next session, with the help of FAO and WHO, listing all the additives which were required.

Pesticide Residues

53. The Committee noted that, while the first sentence of this section represented an exhortation to produce food for infants free of pesticide residues as far as this was possible, the second sentence envisaged legal tolerances for pesticide residues not yet established for this product. It was pointed out that in many countries it was not feasible to produce agricultural raw commodities which were subject to lower tolerances than those which applied to these commodities generally. Furthermore, tolerances established for pesticide residues in foods took into account the very young child. The delegation of France suggested that infant food should be practically free of pesticide residues and free of residues of antibiotics and hormones. It was brought to the attention of the Committee that the standard should also provide for maximum levels of toxic elements such as lead and arsenic as well as toxins and solvent residues. The Committee agreed with the suggestion of the delegation of Denmark that the Code of Hygienic Practice for Infant Foods should take these problems into account. It would then be possible to select pertinent parts of the Code to be made mandatory in the standard. It was agreed that the second sentence of this section be deleted and a provision be added in square brackets, to the effect that the product be free of hormonal and antibiotic substances as well as practically free of pesticide residues.

Hygiene

54. The Committee had before it a working paper prepared by the delegation of the Federal Republic of Germany at the request of the Committee (ALINORM 70/26, para 12), entitled "Bacteriological Requirements and Microbiological Methods of Analysis for Baby and Infant Foods" (CX/FSDU 70/7, June 1970). The papers were taken note of and it was decided to send them out to governments for comments. The Committee requested the delegation of the Federal Republic of Germany to amend their paper if necessary in the light of such comments in collaboration with WHO, for a further examination at the next session. With respect to the request which the Committee had made to the Codex Committee on Food Hygiene concerning a Code of Hygienic Practice for Foods for Infants and Children (ALINORM 70/26, para 12), it was decided to ask that Committee to wait for the draft on "Bacteriological Requirements" to reach a more advanced stage before beginning with this work.

Packaging

55. The Committee agreed with a proposal of the delegation of Denmark to provide for the use of carbon dioxide and inert gases as packing media in Section 8.

Distribution

56. The Committee did not make any amendment to this section.

Labelling

57. The delegation of the United Kingdom was of the opinion that the Name of the Product (Section 10.1) was not sufficiently specific and proposed that an appropriate descriptive name be used indicating the true nature of the product, followed, if desired, by the present generic names. The delegation of Switzerland proposed the name "Preparation for Infants" followed by a more specific description of the product. The delegation of the Netherlands proposed the name "Complete Infant Food". The representative of WHO stressed the importance of agreeing on a name which did not imply that the preparation was a complete substitute for human milk and that it contained all protective elements. This was particularly true for countries with a developing economy. The Committee, after a long discussion, agreed that the standard should provide for appropriate descriptions permitted by national legislation and also decided to delete reference to "mothers' milk substitute". Two names, currently in use, were inserted in the standard, viz: "complete infant food" and "complete infant formula". It was agreed that these names would also be the name of the standard.

58. As regards the declaration of the presence or absence of milk, it was pointed out that the declaration of the absence of all derivatives of milk was important for the prevention of allergic reactions. Some delegations were of the opinion that the use of the designation "on milk basis" should be restricted to products which contained milk products as the major component of the food. The Committee agreed to retain the former declaration and to delete the latter. The delegation of Switzerland wished to record their disagreement with the decision not to require the use of designations indicating that the product was based on milk.

List of Ingredients

59. The Committee did not make any changes to the existing text in Sections 10.2.1 and 10.2.2.

Declaration of Nutritive Value

60. The Committee agreed to delete paragraph 10.3.1 and combine the provision therein into 10.3.2.

61. The Committee decided to remove the square brackets in paragraph 10.3.2 and to include the declaration of moisture after it was pointed out that in some instances the prepared product might be the sole source of moisture for the infant. The Committee further agreed to change the term "ash" to "mineral matter". Some delegations were of the opinion that the declaration of crude fibre and mineral matter did not represent useful information on the label. The representative of WHO was of the opinion that the declaration of crude fibre would be useful and that a WHO Expert Committee had set limits for this material. The delegation of the U.S.A. was of the opinion that crude fibre was of some significance only in products prepared from soya bean. The Committee agreed not to delete reference to mineral matter and crude fibre.

62. The delegation of Canada proposed to delete section 10.3.4 and to add to Section 10.3.3 after the words "quantity", the words "per 100 g of food as customarily or usually prepared for consumption or per serving food". The delegation of the U.S.A. suggested that the label should bear a statement that the food was in conformity with the requirements of the Codex standard for minimum quantities of vitamins and minerals. The Committee agreed to the amendment proposed by Canada.

Net Contents, Name and Address

63. The Committee did not make any changes to Sections 10.4 and 10.5.

Country of Origin

64. The delegation of the United Kingdom was of the opinion that the existing text in Section 10.6 should be replaced by that contained in the Recommended International General Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969) so as to afford governments the opportunity to judge whether or not the omission of the declaration of the country of origin would mislead the consumer. The Committee agreed by a small majority to so amend this section.

Lot Identification

65. The delegation of Tunisia proposed that the expiry date as well as the date of manufacture of the product should be declared in clear on the label. The Committee agreed by a small majority to so amend Section 10.7.

Information for Utilization

66. The delegation of Denmark suggested that instructions be given for the use of boiled water on the label (Section 10.8). It was pointed out that such an instruction would not be appropriate when the terminal heating procedure was used in the preparation of infant bottle feeds. It was however agreed that the words "or accompanying leaflet" be added to the section.

Advancement of Standard to Step 5

67. The Committee agreed that the proposed Draft Standard for Complete Infant Food (Complete Infant Formula) be submitted to the Commission at Step 5 of the Procedure for the Elaboration of Worldwide Standards (see Appendix IV). The delegations of the Federal Republic of Germany, Switzerland and the United Kingdom were opposed to this decision, since, in their opinion, the standard was not yet sufficiently complete to be sent to the Commission.

PROPOSED DRAFT STANDARD FOR CANNED BABY FOODS

68. The Committee had before it the above draft standard (Appendix III, ALINORM 70/26 and government comments in document CX/FSDU 70/3, 4, 5. On a proposal made by the delegation of the United Kingdom several delegations were in favour of amending the standard to include dehydrated foods and fruit juices intended for infant and children feeding. Other delegations pointed out that the standard already included a considerable number of foods of different types, the main common characteristic of which was a similar consistency of the products concerned, and that it would be desirable to elaborate other standards for dehydrated baby foods, freeze-dried baby foods and other products. After discussion, the Committee agreed to amend the Title and the Scope section, on the understanding that, at a later stage, other products could be included in this standard if appropriate. The Committee agreed that the French text of Section 1.2 should read "garantir leur conservation".

Definitions

69. The Committee decided to add the definition of "children" taken from the "Draft General Principles for Foods for Infants and Children" (Section 2)

Essential Composition and Quality Factors

70. The Committee agreed to a proposal of the Canadian delegation to amend Section 3.1 to read:

"Canned baby food is a product prepared from any nutritive material that is used, recognized or commonly sold as an article or ingredient of food".

The representative of WHO pointed out that Section 3.1 as drafted offered the possibility of producing canned baby food from any raw material, the composition of which was not sufficiently known or recognized as suitable for the feeding of infants. As regards optional ingredients, the Committee agreed to a provisional limit of 0.25 g/100 g for added salt, in Section 3.2. After a discussion on whether the wording "practically free of pieces of bones" could be amended in Section 3.4 (Purity Requirements), the Committee agreed to leave the text unchanged. The Committee decided to delete Section 3.5 (Colour, Flavour and Odour). The Committee agreed that the decisions taken for the Standard for Complete Infant Food should also apply to this standard, including the procedure to be applied to the drawing up of a list of food additives (Sections 3.6 to 7). It was pointed out that the paper containing a revised list of food additives should also include those which are used in the technology of dehydrated products.

Fill of Can

71. The Committee agreed that the requirement for fill of can should be understood to mean "not less than 85%" and "not less than 90%" of the can, "when completely filled", as appropriate.

Labelling

72. The Committee considered that the last sentence in Section 10.1 (Name of Food) was redundant and decided to delete it. With reference to its decision regarding the Food Additives section, the Committee considered that vitamins and minerals naturally present in the products would not need to be declared and decided to amend the text to read "added" vitamins and minerals in Section 10.2 (List of Ingredients). As regards the Food Additives section (4), the Committee agreed that vitamins and minerals added to the products for the purpose of restoring nutrients lost during processing need not be declared. As regards vitamins and minerals added with a view to enriching the products, the Committee agreed to a proposal made by the Canadian delegation to read "vitamin and mineral nutrients may be added in accordance with the legislation of the country in which the food is sold" (para 3.2). The Committee agreed to delete reference to "plant or animal origin" from Section 10.2.2. The delegation of the U.S.A. was in favour of declaring the levels of fat, protein and other nutrients where products were claimed to be of a special nutritive value (Section 10.4). The WHO representative stated that, as these products were intended for use as weaning foods for infants between the age of three to six months, it was essential that both the physician and the mother be informed about their nutritive value. He also pointed out the special importance of this kind of information for mothers in developing countries, where nutritional deficiencies were developing at an increasing rate. The Committee agreed to leave the text unchanged and to ask governments to comment on Section 10.4. As regards Section 10.6 (Country of Origin), the Committee decided to apply the text of the Recommended International General Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969). The Committee agreed to delete the square brackets in Section 10.7 (Lot Identification) and the reference to the country of origin.

73. The Committee decided to amend the texts of Sections 10.8 and 11 as in the standard for Complete Infant Food.

74. The Committee decided to return the Proposed Draft Standard for Canned Baby Foods to Step 3 of the Procedure, for further comments (see Appendix V).

PROPOSED DRAFT STANDARD FOR PROCESSED FOODS FOR INFANTS AND CHILDREN BASED ON CEREALS

75. The Committee had before it the Proposed Draft Standard for Dry Pre-cooked Cereal, Rusks and Biscuits for Infants and Children (Appendix IV, ALINORM 70/26) and government comments in document CX/FSDU 70/3, 4, 5. A proposal was made by the delegation of Norway to amend the Title and Scope section of the standard in order to cover weaning foods based on cereals, such as Incaparina and Colombiarina. The delegations of Tunisia and Venezuela emphasized that cereals used as food for infants and children were generally supplemented with soya, peanut or sesame flours, or with beans or peas. In order to cover these products, and other products such as pasta for infants and children as proposed by the delegation of Italy, the Committee agreed to change the title of the standard to read "Proposed Draft Standard for Processed Foods for Infants and Children based on Cereals". As several of these products would not be pre-cooked before they were offered for consumption, the Committee also agreed that all reference to pre-cooking of cereals should be deleted from the standard.

Description

76. The Committee agreed to amend the text in the Description section (2.1) as follows:

"Dry cereal for infants and children is a cereal grain-based food which is dried or baked to a low moisture content and then so fragmented as to permit reconstitution with water, milk or Complete Infant Food or, as in the case of pasta, used after cooking in boiling water. Dry cereal may contain legumes (pulses)".

Composition

77. The Committee decided to amend the first sentence of the text in Section 4.1 to permit the use of cereals such as millet, sorghum and buckwheat and of legumes (pulses). It also agreed that the second sentence should read "Milk biscuits consist primarily of whole milk solids, or other solids of milk, with the addition of one or more flours". The Committee decided to delete reference to fractions of cereal grains on the understanding that indigestible fractions such as bran should not be a normal component of these products.

Optional Ingredients

78. A general statement was made by the WHO representative regarding the use of non-conventional foods. He pointed out that the digestive physiology of infants was vulnerable and that foods which had not yet been proved as fully safe for infants should not be used for infant feeding. The wording regarding "protein concentrates" and "other high-protein content ingredients" were amended to make reference to their suitability for use by infants and children. The Committee agreed to delete reference to "bone meal" and to put the whole text of 4.2 in square brackets pending further comments from governments.

Weights and Measures

79. The delegation of Switzerland proposed to delete Section 10 dealing with filling the container with the product. The delegation of the U.S.A. was of the opinion that the section should be retained as it was a safeguard against oversize packages. The delegation of France pointed out that the minimum fill provision was not appropriate as it did not take into account the density of such products as dry cereals in powder form, the volume of which could be changed after transport. The Committee agreed to put this section in square brackets after redrafting by the Secretariat according to the above comments made by the delegations.

The Name of the Food

80. The Committee agreed to put Section 11.1 in square brackets pending further proposals by governments.

81. As regards all other sections, the Committee agreed to make the same changes as already decided for the Standard for Canned Baby Food and to follow the same procedure as regards the elaboration of the section on food additives.

82. The Committee decided to return the Standard to Step 3 of the Procedure for a further round of comments from governments (see Appendix VI).

METHODS OF ANALYSIS AND SAMPLING IN FOODS FOR INFANTS AND CHILDREN

83. The Committee agreed to delete any reference to Sampling Plans in the three standards, pending further developments concerning the need for tolerances for defects or other criteria. It also agreed to consider the proposal for Sampling Plans drafted for dietetic foods by the delegation of France, as already mentioned in paragraph 17 of this Report. The Committee was informed about recent developments in the field of methods of analysis of general application to foods for infants and children "Suggested Guidelines for Sampling, Identification, and Analytical Procedures for Food", prepared by the U.S. authorities which had already been commented on by governments. Several proposals had also been made for methods of analysis for the determination of nutrients other than those included in the Guidelines.

84. The Committee agreed that it would examine, at its sixth session, a paper prepared by the Secretariat according to the comments received, so as to be able to propose methods to be considered by the Codex Committee on Methods of Analysis at its 7th session.

85. The Committee also agreed to discuss the Sampling Plans at its next session on the basis of the working paper to be prepared by the Secretariat (see para 17 of this Report).

STATEMENT BY THE OBSERVER FROM THE INTERNATIONAL ORGANIZATION OF CONSUMERS' UNIONS

86. The observer from the IOCU, whilst appreciating the services given by the food industry in promoting good nutrition in infants, drew attention to the possibility of infant malnutrition, especially in developing countries, resulting from the influence of certain types of promotional activity. These promotional activities included all forms of advertising, direct mailing and direct contact with the consumer at home. The effect of these activities was to encourage premature weaning and reliance on manufactured foods which some mothers could not afford to buy in sufficient quantity, or which were often unsuitable because of the prevailing hygiene conditions, especially with respect to the purity of water supplies.

87. The observer from the IOCU suggested that the Codex Committee on Food Labelling should be requested to consider what controls might be exercised over these promotional activities to protect the consumer.

88. The delegation of Sweden informed the Committee of the voluntary agreement between the public health authorities and infant food manufacturers that "infant foods" should not be advertized directly to the lay public. The Committee agreed to refer this problem to the Codex Committee on Food Labelling.

ASCORBIC ACID IN SPINACH USED AS BABY FOODS

89. At its 5th session, the Joint ECE/Codex Alimentarius Group of Experts on Standardization of Quick-Frozen Foods had drawn the attention of both the Codex Committee on Foods for Special Dietary Uses and the Codex Committee on Food Additives to the question of the addition of ascorbic acid to spinach. The addition of ascorbic acid would be of particular interest in spinach used as baby food in connection with its possible effect on nitrates (ALINORM 70/25, para 39). At its 4th session, the Codex Committee on Foods for Special Dietary Uses had not been in a position to consider this problem and had decided to include it among the subjects on which comments were to be requested (ALINORM 70/26, para 58). Such a request was sent to governments by the Secretariat.

90. The Committee had before it a paper prepared by the Secretariat "Nitrates and Ascorbic acid in Spinach used as Baby Foods" (CX/FSDU 70/11) and comments from one government (CX/FSDU 70/11 Add. 1) on this subject. The paper summarized the problems posed by the presence of high quantities of nitrates in certain fresh or frozen vegetables, from which toxic effects were reported as regards spinach. This phenomenon is generally explained by reduction of nitrates into nitrites which may cause methaemoglobinemia and be particularly harmful to young infants. This paper included some suggestions regarding how to prevent such accidents among which is the proposed use of ascorbic acid in the prevention of reduction of nitrates into nitrites by micro organisms. Questions dealing with processed spinach were also dealt with in this paper, i.e. the corrosive effect of nitrates on cans, the presence of tin in the food in connection with levels of nitrates, and the oxalic acid content of spinach.

91. The delegation of the Federal Republic of Germany drew the attention of the Committee to a paper published in 1970, mentioning also the presence of carcinogenic substances (nitrosamines) in spinach with high nitrate content. The delegation of France reported some cases of methaemoglobinemia in infants fed with freshly prepared carrot soups and suggested the use of contracts between growers and manufacturers for vegetables with lower nitrate contents obtained through a limited use of fertilizers. This delegation also recommended that very young infants should not be fed with spinach. The delegation of the U.S.A. mentioned a report prepared by a Committee of Pediatricians on this subject and pointed out that a considerable number of cans of baby spinach had been sold in Canada and the U.S.A. over a period of twenty years without causing any methaemoglobinemia. The delegation of Denmark pointed that the cases of methaemoglobinemia observed in their country were only due to home-made foods and not to canned baby foods.

92. The Committee recognized that this subject was important but rather controversial and agreed that the paper prepared by the Secretariat should be sent to governments with a request for comments. The Committee also agreed that the question asked by the ECE/Codex Group of Experts on Standardization of Quick-Frozen Foods could not be replied to at this stage and the subject would be rediscussed at one of its next sessions when comments were available.

PROGRAMME OF FUTURE WORK

93. The Proposed Draft Standards for Consumer Packaged Protein Foods, at Step 2 of the Procedure, for Gluten-Free Foods, for Foods for Use in a Diet for Diabetics, and for Foods with Low Carbohydrate Content were not discussed for lack of time. It was decided to hold these drafts at their present level; the Committee agreed that the Proposed Draft Standard for Consumer Packaged Protein Foods was to be sent out for government comments (see Appendix VII) while the other drafts were to be given a low priority, until the more advanced standards have been completed.

DATE OF THE NEXT SESSION

94. Concerning the time and place of the next session, it was pointed out that the Codex Alimentarius Commission, at its 7th session, had given consideration to increasing the period between its sessions to more than one year and that the scheduling of sessions of most Codex Committees was also envisaged on an 18 months basis. In view of the considerable amount of unfinished work on hand, it was thought that this Committee could profitably meet more often. It was agreed that the next session should be held within approximately 12 months, but not later than early spring 1972.

SUMMARY OF STATUS OF WORK
(Prepared by the Secretariat)

A. STANDARDS

Standard at Step 8

Special Dietary Foods with Low Sodium Content (including salt substitutes) - Appendix III of this Report

Standard at Step 5

Complete Infant Food (Complete Infant Formula) - Appendix IV of this Report

Standard at Step 4

Foods for use in a diet for Diabetics - Appendix VII of ALINORM 70/26

Gluten-free Foods - Appendix VIII of ALINORM 70/26

Foods with Low Carbohydrate Content (Carbohydrate Reduced Foods) - Appendix IX of ALINORM 70/26

Standard at Step 3

Canned Baby Foods - Appendix V of this Report

Processed Foods for Infants and Children based on Cereals - Appendix VI of this Report

Standard at Step 2

Consumer Packaged Protein Foods - Appendix VII of this Report

B. GUIDELINES, GENERAL PRINCIPLES, CODE OF HYGIENIC PRACTICE

Guidelines for the Elaboration of Codex Standards for Foods for Special Dietary Uses (for information and reference purposes) - Appendix X of ALINORM 70/26

General Principles for Foods for Infants and Children held at Step 3 of the Procedure (for information and reference purposes) - Appendix V of ALINORM 70/26

Code of Hygienic Practice for Foods for Infants and Children (to be prepared by the Codex Committee on Food Hygiene after revision of the paper on Bacteriological Requirements. See para 54 of this Report).

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LIST OF DOCUMENTS

<u>Document No.</u>	
CX/FSDU 70/1	Provisional Agenda
CX/FSDU 70/2 and) Addenda 1 and 2)	Synopsis of Government Comments on Draft Standard for Special Dietary Foods with Low Sodium Content (including salt substitutes) at Step 7
CX/FSDU 70/3, 4, 5	Summary of Government Comments to Proposed Draft Standards at Step 3 - Infant Formula (Mothers' Milk Substitute) - Canned Baby Foods - Dry Pre-cooked Cereal Rusks and Biscuits for Infants and Children
CX/FSDU 70/3 Add. 1	Proposed Draft Standard for Infant Formula (Mothers' Milk Substitute) Government Comments on Vitamins
CX/FSDU 70/3 Add. 2	Swiss Government Comments to the Proposed Draft Standard for Infant Formula (Mothers' Milk Substitute)
CX/FSDU 70/3 Add. 3	Comments of the Netherlands on document ALINORM 70/26
CX/FSDU 70/7	Bacteriological Requirements and Microbiological Methods of Analysis for Baby and Infant Foods (prepared by the delegation of the Federal Republic of Germany)
CX/FSDU 70/8	Microbiological Specifications for Foods for Children (Information supplied by WHO)
CX/FSDU 70/9	Proposed Draft Standard for Consumer Packaged Protein Foods at Step 2 (prepared by the delegation of the Federal Republic of Germany)
CX/FSDU 70/9 - 1	Produits Riches en Proteines (Texte préparé par la délégation de la Suisse)
CX/FSDU 70/10 and Addenda 1 and 2	Synopsis of Government Comments on Proposed Draft Standards at Step 3 for: a) Foods for Use in a Diet for Diabetics b) Foods with Low Carbohydrate Content c) Gluten-free Foods
CX/FSDU 70/11	Nitrates and Ascorbic Acid in Spinach used as Baby Food (Note prepared by the FAO Secretariat)
CX/FSDU 70/11 Add 1	Nitrates and Ascorbic Acid in Spinach used as Baby Food. Comments by the Argentine Republic on ALINORM 70/26, paragraph 39
CX/MAS/70/B/6	Synopsis of Government Comments on Methods of Analysis and Sampling for Foods for Infants and Children

Conference Room Document 1

Plans d'Echantillonnage Aliments Diététiques
(prepared by the French delegation)

Other Conference Room
Documents

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United Kingdom
Comments on Methods of Analysis for Foods for
Special Dietary Uses

U.S. Working Paper 35 to CL 1970/18
The Determination of Sodium

DRAFT STANDARD FOR SPECIAL DIETARY FOODS WITH LOW SODIUM CONTENT
(INCLUDING SALT SUBSTITUTES)

(Submitted to the Commission at Step 8 of the Procedure for the Elaboration of Worldwide Standards)

1. SCOPE

- 1.1 This standard applies to foods which are represented, directly or indirectly or by implication, as intended for special dietary uses by reason of their low sodium content, and also includes salt substitutes.
- 1.2 The standard refers only to the specific provisions related to the special dietary purpose for which these foods are intended.

2. DESCRIPTION

2.1 Definition

Special dietary foods with low sodium content are products whose special dietary value results from the reduction, restriction, or removal of sodium.

2.2 Subsidiary definitions

'Low sodium' and 'very low sodium' foods are foods conforming to the respective provisions with regard to maximum sodium content laid down in paragraphs 3.1.1 and 3.1.2 of this standard.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Special dietary foods with low sodium content, excluding salt substitutes as such

3.1.1 A special dietary food with "low sodium" content is a food

- (a) which has been processed without the addition of sodium salts,
and
(b) the sodium content of which is not more than one half of that of the comparable normal product as consumed,
and
(c) the sodium content of which is not more than 120 mg/100 g of the final product as normally consumed.

3.1.2 A special dietary food with "very low sodium" content is a food in conformity with 3.1.1(a) and (b) above and the sodium content of which is not more than 40 mg/100 g of the final product as normally consumed.

3.1.3 The addition of salt substitutes to a special dietary food with low sodium content is permitted and shall be limited by good manufacturing practice.

3.2 Salt substitutes as such

The composition of salt substitutes is as follows:

3.2.1 The sodium content of salt substitutes shall be not more than 120 mg/100 g of the salt substitute mixture.

- 3.2.2 Unless otherwise indicated, the following provisions in respect of salt substitutes and their specifications have been endorsed by the Codex Committee on Food Additives.
- 3.2.2.1 Potassium sulphate; potassium, calcium or ammonium salts of adipic, glutamic, carbonic, succinic, lactic, tartaric, citric, acetic, hydrochloric or ortho-phosphoric acids) Not limited, except that P not to exceed 4% m/m and NH_4^+ 3% m/m of the salt substitute mixture)
- 3.2.2.2 Magnesium salts of adipic, glutamic, carbonic, citric, succinic, acetic, tartaric, lactic, hydrochloric or ortho-phosphoric acids, mixed with other Mg-free salt substitutes as listed in 3.2.2.1, 3.2.2.3 and 3.2.2.4) Mg^{++} to be not more than 20% m/m of the total of the cations K^+ , Ca^{++} and NH_4^+ present in the salt substitute mixture and P not to exceed 4% m/m of the salt substitute mixture)
- 3.2.2.3 Choline ^{1/} salts of acetic, carbonic, lactic, tartaric, citric or hydrochloric acids, mixed with other choline-free salt substitutes as listed in 3.2.2.1, 3.2.2.2 and 3.2.2.4) The choline content not to exceed 3% m/m of the salt substitute mixture)
- 3.2.2.4 Free adipic, glutamic, citric, lactic, ^{2/} or malic acids) Not limited)
- 3.2.3 Colloidal silica or calcium silicate) Not more than 1% m/m of the salt substitute mixture individually or in combination)
- 3.2.4 The addition of iodine-containing compounds shall be in conformity with the national legislation of the country where the product is sold.
- 3.2.5 Diluents: safe and suitable nutritive foods as normally consumed (e.g. sugars, cereal flour).

4. LABELLING

The following provisions for labelling are subject to endorsement by the Codex Committee on Food Labelling:

- 4.1 Special dietary foods with low sodium content, excluding salt substitutes as such
- 4.1.1 In addition to any labelling provisions applying to the particular food concerned, the following specific provisions for the labelling of special dietary foods with low sodium content shall apply:

^{1/} To be endorsed by the Codex Committee on Food Additives pending toxicological evaluation.

^{2/} To be endorsed by the Codex Committee on Food Additives.

- 4.1.2 The sodium content shall be declared on the label to the nearest multiple of 5 mg per 100 g and, in addition, per a specified serving of the food as normally consumed.
- 4.1.3 The label shall bear the description "low sodium" or "very low sodium" in accordance with paragraphs 3.1.1 and 3.1.2 of this standard.
- 4.1.4 The average carbohydrate, protein and fat content in 100 g of the product as normally consumed, as well as the Calorie value shall be declared on the label.
- 4.1.5 The addition of the salt substitutes listed in paragraph 3.2 of this standard shall be declared on the label.
- 4.1.6 The maximum total amount of potassium, expressed as mg cation per 100 g of the food as normally consumed shall be declared on the label.

4.2 Salt Substitutes as such

In addition to Sections 1, 2, 3.3, 3.4, 3.5, 4 and 6 of the General Standard for the Labelling of Prepackaged Foods (Ref. CAC/RS 1-1969) the following provisions shall apply:

- 4.2.1 The name of the product shall be "low sodium salt substitute" or "low sodium dietetic salt".
- 4.2.2 A complete list of ingredients shall be declared on the label. The amount of the cations (i.e. potassium, calcium, magnesium, ammonium and choline)/100 g m/m in the salt substitute mixture shall also be declared on the label.

5. METHODS OF ANALYSIS

The methods of analysis described hereunder are international referee methods which are to be endorsed by the Codex Committee on Methods of Analysis and Sampling.

5.1 Determination of sodium content:

- (a) LINDNER K., and DWORSCHAK E. - Zeitschr. f. Lebensm. Unters u. Forsch. 131, p. 207-215 (1966)
Flame photometric method for determination of potassium, sodium, calcium and magnesium in foods (in German)
- (b) Centre technique de l'Union intersyndicale des industries françaises de biscuiterie, biscotterie, entremets, desserts instantanés, aliments diététiques et de régime. Dosage du sodium per voie humide. Méthode par photométrie de flamme.
Bulletin d'information technique, CTU, No. 1, Annexe 2 (25 September 1968).
(Ref. document CCDF 69/6 and Appendix to CCDF 69/6).

5.2 Determination of potassium, calcium, magnesium and choline:

(a) in foods other than salt substitutes:

- Potassium: according to LINDNER K. and DWORSCHAK E. (see 5(a)(i) above)

(b) in salt substitutes:

- Potassium: according to LINDNER K. and DWORSCHAK E. (see 5(a)(i) above)
- Calcium: AOAC, XI, 14.014. Precipitation as oxalate and MnO_4^- titration recommended
- Magnesium: AOAC, XI, 2.097-2.102. Atomic absorption method recommended
- Choline: extraction, precipitation with ammonium reineckate, followed by measurement of the absorption at 526 nm: Methods of Vitamin Assay - 3rd Ed. 1966 - Assoc. of Vitamin Chemists Inc. Interscience Publishers (New York, London, Sydney)
- Ammonium: AOAC, X, 2.050, (XI, 2.057 ^{1/})
- Phosphorus: AOAC, XI, 7.025 - 7.028 (XI, 8.025 - 8.028) ^{2/} - Results expressed as P% m/m
- Silica: AOAC, X, 34.037 (XI, 35.049) ^{2/} - Results expressed as Si O₂

Note: Potassium, calcium, magnesium, ammonium and choline in a salt substitute shall be determined by comparison with a standard preparation the composition of which is similar to this salt substitute.

1/ Method proposed by the Secretariat (see para 17 of this Report) on the basis of U.S. proposals.

2/ Method proposed by the Secretariat, but not discussed during the session (see footnote on page 4 of this Report).

PROPOSED DRAFT STANDARD FOR COMPLETE INFANT FOOD (COMPLETE INFANT FORMULA)

(Submitted to the Commission at Step 5 of the Procedure for the Elaboration of Worldwide Standards)

1. SCOPE

Complete Infant Food is the food in liquid or powdered form intended for use as a complete substitute for human milk in meeting the normal nutritional requirements of infants. It may constitute the sole dietary intake of infants who are not breast-fed, or a part of those partially breast-fed.

2. DESCRIPTION

- 2.1 Complete Infant Food when in liquid form may be used either directly or diluted with water before feeding as appropriate. In powdered form it requires water for preparation.
- 2.2 The product shall be nutritionally adequate to promote normal growth and development when used in accordance with its direction for use.
- 2.3 The product is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution.

3. DEFINITION

- 3.1 The term "infant" means a person not more than 12 months of age.
- 3.2 The term "Calorie" means a kilocalorie or "large calorie".

4. ESSENTIAL COMPOSITION AND QUALITY FACTORS4.1 Essential Composition

- 4.1.1 Complete Infant Food is a product based on milk of cows or other animals and/or on other edible constituents of animal, including fish, or plant origin. It may contain carbohydrates and potable water.
- 4.1.2 Complete Infant Food shall contain, per 100 available Calories of intake, the following minimum and maximum levels of vitamins and minerals in an available form, protein, fat and linoleate:

4.1.2.1 Vitamins

Vitamin A

Amounts per 100 available CaloriesMinimumMaximum ^{1/}

250 I.U. or 75 mcg
expressed as retinol or
450 mcg expressed as
beta-carotene

[]

^{1/} The maximum levels have been tentatively agreed as twice the minimum levels, with the exception of Vitamin D (see para 44. Discussion of the maximum amount for vitamins and minerals).

<u>Vitamins</u>	<u>Amounts per 100 available Calories</u>	
	<u>Minimum</u>	<u>Maximum</u> ^{1/}
Vitamin D	40 I.U.	40 I.U.
Vitamin E	($\sqrt{0.3 \text{ I.U.}}$ or ($\sqrt{0.3 \text{ mg}}$ expressed as alpha tocopherol	[]
Ascorbic Acid (Vitamin C)	8 mg	
Thiamine (Vitamin B ₁)	25 mcg	
Riboflavin (Vitamin B ₂)	60 mcg	
Nicotinamide	250 mcg	
Vitamin B ₆	50 mcg	
Folic Acid	$\sqrt{4 \text{ mcg}}$	
Pantothenic Acid	300 mcg	
Vitamin B ₁₂	0.15 mcg	
$\sqrt{\text{Vitamin K}}$	$\sqrt{4 \text{ mcg}}$	

4.1.2.2 Minerals

	<u>Minimum</u>	<u>Maximum</u> ^{1/}
Sodium (Na)	$\sqrt{20 \text{ mg}}$	[]
Potassium (K) ^{*/}	$\sqrt{80 \text{ mg}}$	
Calcium (Ca) ^{*/}	50 mg	
Phosphorus (P) ^{*/}	25 mg	
Magnesium (Mg)	6 mg	
Iron (Fe)	1 mg	
Iodine (I)	5 mcg	
Copper (Cu)	$\sqrt{30 \text{ mcg}}$	
Zinc (Zn)	$\sqrt{0.5 \text{ mg}}$	
Manganese (Mn)	$\sqrt{0.2 \text{ mg}}$	

^{*/} The Ca: P ratio shall be not less than $\sqrt{1.2}$ and not more than $\sqrt{2.0}$

4.1.2.3 Protein (per 100 available Calories):

4.1.2.3.1 Shall be not less than $\sqrt{1.8}$ g of protein of nutritional quality equivalent to that of whole egg protein or a greater quantity of other protein in proportion to its biological value. The quantity of the protein shall be not less than 70% of that of whole egg protein. The total quantity of protein shall not be more than 3 g.

4.1.2.3.2 The addition of only essential isolated amino-acids is permitted, and only for the purpose of improving the nutritional quality of the protein, in conformity with the provisions specified in sub-section 4.1.2.3.1.

^{1/} See footnote on page 3

4.1.2.4 Fat and Linoleate

The product shall contain linoleate (in the form of a tri-glyceride) at a level not less than 300 mg per 100 available Calories and fat at a level not less than [25%] and not more than [50%] of total available Calories.

4.2 Optional Ingredients

[In addition to the vitamins and minerals listed under 4.1.2.1 and 4.1.2.2, other nutrients may be added when required in order to provide nutrients ordinarily found in human milk and to ensure that the formulation is suitable as the sole source of nutrition of the infant.]

4.3 Consistency and Particle Size

When prepared according to the label directions for use, the product is free of lumps and of large coarse particles and suitable for being fed through a soft rubber or plastic nipple.

4.4 Purity Requirements

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

4.5 Specific Prohibition

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

5. FOOD ADDITIVES

(List to be established)

6. CONTAMINANTS

6.1 Pesticide Residues

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 do not remain, or, if technically unavoidable, are reduced to the maximum extent possible. [The product shall be practically free from pesticide residues.]

6.2 Other Contaminants

[The product shall be free from hormonal and antibiotic substances.] ^{1/}

^{1/} It is envisaged that the Code of Hygienic Practice for Foods for Infants and Children will contain recommendations for maximum levels for such contaminants as toxins, trace elements, heavy metals and solvents. These may eventually form mandatory provisions under this section.

7. HYGIENE

- 7.1 The product shall be clean and free of poisonous or deleterious substances which may render it injurious to health. It shall be prepared, packed and held under sanitary conditions and should comply with the Code of Hygienic Practice for Foods for Infants and Children. (To be prepared by the Codex Committee on Food Hygiene.)^{2/}
- 7.2 The ingredients of animal origin shall be obtained from animals in good health, or should be obtained from such animals as have been slaughtered and prepared according to the Code of Hygienic Practice for Fresh Meat. (This Code is being elaborated by the Codex Committee on Meat.)
- 7.3 Fish ingredients shall be the products of edible species of fish, which should be obtained and prepared according to the Codes of Hygienic Practice for Fish and Fishery Products. (These Codes are being elaborated by the Codex Committee on Food Hygiene)

8. PACKAGING

- 8.1 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. Suitable inert gases and carbon dioxide may be used as packing media.
- 8.2 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.

9. DISTRIBUTION

The product should be freely available wherever foods are sold as well as from speciality stores and drug stores or pharmacies, without licensing requirements not imposed on foods generally.

10. LABELLING

- 10.1 In addition to Sections 1, 2, 4 and 6 of the Recommended International General Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969), the following specific provisions apply, (subject to endorsement by the Codex Committee on Food Labelling.)
- 10.2 The Name of the Food
- 10.2.1 The name of the product shall be either "Complete Infant Food" or "Complete Infant Formula" or any appropriate designation indicating the true nature of the food, in accordance with national usage.

^{2/} When the code is available it may be necessary to include end-product specifications in this paragraph.

- 10.2.2 In addition, a product which contains neither milk nor any milk derivative shall be labelled "free from milk and milk products".
- 10.3 List of Ingredients
- 10.3.1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of vitamins and minerals each of these ingredients shall be listed in consecutive order.
- 10.3.2 The specific and not the class name shall be declared for ingredients of animal or plant origin and for food additives.
- 10.4 Declaration of Nutritive Value
- 10.4.1 A statement of the levels of moisture, protein, fat, available carbohydrates, mineral matter and crude fibre supplied by a specified quantity of the food as customarily or usually prepared for consumption shall appear on the label. Alternatively, this declaration may be made in percent by weight or as weight per unit volume.
- 10.4.2 A statement of the number of available Calories and total quantity of each vitamin and mineral as listed in paragraphs 4.1.2.1 and 4.1.2.2 of this standard, per 100 g of food as customarily or usually prepared for consumption or per serving of food, shall appear on the label.
- 10.5 Net Contents
- The net contents of Complete Infant Food 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.
- 10.6 Name and Address
- The name and address of the manufacturer, packer, distributor, importer, exporter or vendor of the food shall be declared.
- 10.7 Country of Origin
- 10.7.1 The country of origin of the food shall be declared if its omission would mislead or deceive the consumer.
- 10.7.2 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.
- 10.8 Lot Identification
- Each container shall be embossed or otherwise permanently marked in a code which identifies the manufacturer and the lot. The date of manufacture or the date of expiry shall be declared in clear.

10.9 Information for Utilization

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.

11. METHODS OF ANALYSIS AND SAMPLING

The methods of analysis and sampling described hereunder are international referee methods (which are to be endorsed by the Codex Committee on Methods of Analysis and Sampling).

(Methods of Analysis including microbiological and biological methods and test procedures to be developed on the basis of government comments on the "Suggested Guidelines for Sampling, Identification and Analytical Procedures for Food" prepared by the U.S. authorities and other methods proposed by governments).

PROPOSED DRAFT STANDARD FOR CANNED BABY FOODS

(Returned to Step 3 of the Procedure for further Comments)

1. SCOPE

- 1.1 Canned baby food is a food in liquid or semi-liquid form intended for use during the normal infant's weaning period and for the progressive adaptation of infants and children to ordinary food. It does not include Complete Infant Food.
- 1.2 Canned baby food is so processed by heat before or after being sealed in the container as to prevent spoilage.

2. DEFINITIONS

- 2.1 The term "infant" means a person not more than 12 months of age.
- 2.2 The term "children" means children from the age of more than 12 months up to the age of three years.
- 2.3 The term "Calorie" means a kilocalorie or "large calorie".

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS3.1 Composition

Canned baby food is a product prepared from any nutritive material that is used, recognized or commonly sold as an article or ingredient of food.

3.2 Optional Ingredients

- spices
- added salt [maximum: 0.25 g/100 g]
- protein concentrates suitable for human consumption
- vitamin and mineral nutrients may be added in accordance with the legislation of the country in which the food is sold.

3.3 Consistency and Particle Size

Canned baby food is homogeneous or comminuted in the following forms:

- (a) strained - food of a fairly uniform, small particle size which does not require and does not encourage chewing before being swallowed;
- (b) junior - food that ordinarily contains particles of a size to encourage chewing by infants and children.

3.4 Purity Requirements

All ingredients, including optional ingredients shall be clean, of good quality, safe, and with excessive fibre removed where necessary. Fish ingredients shall be practically free of pieces of bones.

3.5 Specific Prohibition

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

4. FOOD ADDITIVES

(List to be established)

5. CONTAMINANTS

5.1 Pesticide Residues

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 do not remain, or, if technically unavoidable, are reduced to the maximum extent possible. [The product shall be practically free from pesticide residues].

5.2 Other Contaminants

[The product shall be free from hormonal and antibiotic substances]. 1/

6. HYGIENE

6.1 The product shall be clean and free of poisonous or deleterious substances which may render it injurious to health. It shall be prepared, packed and held under sanitary conditions and should comply with the Code of Hygienic Practice for Foods for Infants and Children. (To be prepared by the Codex Committee on Food Hygiene) 2/

6.2 The ingredients of animal origin shall be obtained from animals in good health, or should be obtained from such animals as have been slaughtered and prepared according to the Code of Hygienic Practice for Fresh Meat. (This Code is being elaborated by the Codex Committee on Meat)

6.3 Fish ingredients shall be the products of edible species of fish which should be obtained and prepared according to the Codes of Hygienic Practice for Fish and Fishery Products. (These codes are being elaborated by the Codex Committee on Food Hygiene)

7. PACKAGING

The product shall be packed in hermetically sealed containers which will safeguard the hygienic and other qualities of the food. Suitable inert gases and carbon dioxide may be used as packing media.

1/ It is envisaged that the Code of Hygienic Practice for Food for Infants and Children will contain recommendations for maximum levels for such contaminants as toxins, trace elements, heavy metals and solvents. These may eventually form mandatory provisions under this section.

2/ When the Code is available it may be necessary to include end-product specifications in this paragraph.

8. FILL OF CAN

The fill of can shall be not less than 85% for products weighing less than 250 g (8 oz) and not less than 90% for products weighing more than 250 g (8 oz) of the water capacity of the can measured at 20°C when completely filled.

9. DISTRIBUTION

The product should be freely available wherever foods are sold as well as from speciality stores and drug stores or pharmacies, without licensing requirements not imposed on foods generally.

10. LABELLING

In addition to Sections 1, 2, 4 and 6 of the Recommended International General Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969) the following specific provisions apply (subject to endorsement by the Codex Committee on Food Labelling):

10.1 The Name of the Food

The name of the product shall be that of the major component(s) or characterising ingredient(s) accompanied by words suitable to indicate the consistency or intended use.

10.2 List of Ingredients

10.2.1 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 minerals each of these ingredients shall be listed in consecutive order.

10.2.2 The specific and not the class name shall be declared for ingredients and food additives.

10.3 Net Contents

The net contents of Canned Baby Food shall be declared by volume if it is in liquid form or by weight or volume if it is in semi-liquid 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.

/10.4 Declaration of Nutritive Value

10.4.1 A statement of the number of available Calories and the percent weight by weight or weight per unit volume of moisture, protein, fat, available carbohydrates, mineral matter and crude fibre contained in the food shall be declared on the label.

10.4.2 A statement of the quantity of each vitamin and mineral present in the food shall appear on the label.]

10.5 Name and Address

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

10.6 Country of Origin

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

10.6.2 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.

10.7 Lot Identification

Each container shall be embossed or otherwise permanently marked in a code which identifies the manufacturer and the lot. The code shall also include the date of manufacture.

10.8 Information for Utilization

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.

11. METHODS OF ANALYSIS AND SAMPLING

The methods of analysis and sampling described hereunder are international referee methods (which are to be endorsed by the Codex Committee on Methods of Analysis and Sampling):

11.1 Methods of Analysis

Methods of Analysis, including microbiological and biological methods and test procedures to be developed on the basis of government comments on the "Suggested Guidelines for the Sampling, Identification and Analytical Procedures for Food" prepared by the U.S. authorities and other methods proposed by governments.

PROPOSED DRAFT STANDARD FOR PROCESSED FOODS FOR INFANTS AND CHILDREN BASED ON CEREALS

(Returned to Step 3 of the Procedure for further comments)

1. SCOPE

Processed foods for infants and children based on cereals are foods intended to supplement human milk or Complete Infant Food (Complete Infant Formula) during the weaning period of normal infants or to supplement the diet of children.

2. DESCRIPTION

2.1 Dry cereal for infants and children is a cereal grain-based food which is dried or baked to a low moisture content and then so fragmented as to permit reconstitution with water, milk or Complete Infant Food (Complete Infant Formula) or, as in the case of pasta, used after cooking in boiling water. Dry cereal may contain legumes (pulses).

2.2 Rusks and biscuits are cereal grain-based foods for infants and children, produced by baking process, which may be used either directly or after pulverization with the addition of water, milk or Complete Infant Food (Complete Infant Formula). The biscuits may also be "milk biscuits", based primarily on milk products.

3. DEFINITIONS

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

3.2 The term "children" means young children from the age of more than 12 months and up to the age of three years.

3.3 The term "Calorie" means "kilocalorie" or "large calorie".

4. ESSENTIAL COMPOSITION AND QUALITY FACTORS4.1 Composition

Dry cereal, rusks and biscuits are prepared primarily from one or more flours of cereals, such as wheat, rice, barley, oat, maize, millet, sorghum and buckwheat and also arachis, sesame, soybean (defatted or low fat) or other legumes (pulses). Milk biscuits consist primarily of whole milk solids, or other solids of milk, with the addition of one or more flours.

4.2 Optional Ingredients

- 4.2.1 [- protein concentrates suitable for consumption by infants and children (including amino acids)
- other high protein content ingredients suitable for consumption by infants and children
 - fruits
 - nutritive sweeteners
 - malt
 - milk or milk products
 - fats and oils
 - salt (including iodized salt)
 - spices

- Ingredients for which Codex standards exist and complying with the provisions of these standards

4.2.2 Vitamins and minerals may be added in accordance with the legislation of the country in which the food is sold.^{1/}

4.3 Consistency and Particle Size

When reconstituted according to the label directions for use, dry cereal is of a soft, smooth texture, free of lumps and chewable particles and is suitable for spoon feeding of infants and children. It does not require and does not encourage chewing before being swallowed. Rusks and biscuits shall be of a consistency so as to permit and encourage chewing.

4.4 Purity Requirements

All ingredients, including optional ingredients, shall be clean, safe, suitable and of good quality.

4.5 Moisture Content

The moisture content of the products shall be reduced to a level at which microorganisms cannot multiply.

4.6 Specific Prohibition

The product and its components shall not have been exposed to ionizing radiation.

5. FOOD ADDITIVES

(List to be established).

6. CONTAMINANTS

6.1 Pesticide Residues

The products 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 do not remain, or, if technically unavoidable, are reduced to the maximum extent possible. ^{1/}The product shall be practically free from pesticide residues.^{1/}

6.2 Other Contaminants

^{1/}The product shall be free from hormonal and antibiotic substances.^{1/}

^{1/} It is envisaged that the Code of Hygienic Practice for Foods for Infants and Children will contain recommendations for maximum levels for such contaminants as toxins, trace elements, heavy metals and solvents. These may eventually form mandatory provisions under this section.

7. HYGIENE

- 7.1 The product shall be clean and free of poisonous or deleterious substances which may render it injurious to health. They shall be prepared, packed and held under sanitary conditions and should comply with the Code of Hygienic Practice for Foods for Infants and Children (to be prepared by the Codex Committee on Food Hygiene). ^{1/}

8. PACKAGING

- 8.1 The product shall be packed in containers which will safeguard the hygienic and other qualities of the food.
- 8.2 The containers including packaging material shall be made only of substances which are safe and suitable for their intended uses. When the Codex Alimentarius Commission has established a standard for any such substance used as packaging material, that standard shall apply.

9. DISTRIBUTION

The products should be freely available wherever foods are sold as well as from speciality stores and drug stores or pharmacies without licensing requirements not imposed on foods generally.

10. WEIGHTS AND MEASURES (Safeguard against oversize packages)

^{1/}The container should be well filled with the product. In the case of dry cereal in powder form the contents when removed from and re-introduced into the container (according to a standard method to be outlined) shall occupy not less than $\left[\dots \right] \% \text{ } ^{2/}$ of the total cubic volume of the container. ^{2/}

11. LABELLING

In addition to Sections 1, 2, 4 and 6 of the Recommended International General Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969) the following specific provisions apply, (subject to endorsement by the Codex Committee on Food Labelling):

11.1 The Name of the Food

^{1/}The name of the food shall be: "Dry Cereal for Infants (and/or Children)", "Rusks for Infants (and/or Children)" or "Biscuits (or "Milk Biscuits") for Infants (and/or Children)". ^{2/}

^{1/} When this Code is available it may be necessary to include end-product specifications in this paragraph.

^{2/} Percentage to be added and method to be proposed: see also para 79 of this Report.

11.2 List of Ingredients

11.2.1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of vitamins and minerals each of these ingredients shall be listed in consecutive order.

11.2.2 The specific and not the class name shall be declared for ingredients and food additives.

11.3 Net Contents

The net contents shall be declared by weight except that when rusks and biscuits for infants (and/or children) are usually sold by number a declaration of count may be made. The declaration of weight shall be made 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.

11.4 Declaration of Nutritive Value

11.4.1 A statement of the number of available Calories and the percent weight by weight, or weight per unit volume of moisture, protein, fat, available carbohydrates, mineral matter and crude fibre contained in the food shall be declared on the label.

11.4.2 A statement of the quantity of each vitamin and mineral present in the food shall appear on the label.

11.5 Name and Address

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

11.6 Country of Origin

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

11.6.2 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.

11.7 Lot Identification

Each container shall be embossed or otherwise permanently marked in a code which identifies the manufacturer and the lot. The code shall also include the date of manufacture.

11.8 Information for Utilization

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.

12. METHODS OF ANALYSIS AND SAMPLING

The methods of analysis and sampling described hereunder are international referee methods (which are to be endorsed by the Codex Committee on Methods of Analysis and Sampling).

12.1 Methods of Analysis

[Methods of Analysis, including microbiological and biological methods and test procedures to be developed on the basis of government comments on the "Suggested Guidelines for Sampling, Identification and Analytical Procedures for Food" prepared by the U.S. authorities and other methods proposed by governments].

PROPOSED DRAFT STANDARD FOR CONSUMER PACKAGED PROTEIN FOODSINTRODUCTORY NOTE

The standard is intended for foods for special dietary uses which are based on their protein content. The draft refers solely to the protein content of the foods.

Concerning the protein content, two categories are proposed, namely ordinary "Protein Foods" (i.e. foods where the protein content is especially mentioned on the label but which are not particularly rich in protein) and "Protein-rich Foods", containing an elevated quantity of protein. The protein requirements are based on the assumption that an adult needs daily about 3000 kcal under average working conditions. For the special type of food referred to in this standard, his daily diet should contain 100 grammes of biologically complete protein, taking also into consideration special conditions such as protein malnutrition, gravidity, breast feeding, or disease and convalescence. Ordinary special dietary protein foods should contain sufficient protein to satisfy the daily protein requirement with a daily intake of the food concerned. Under these conditions 3000 kcal should contain not less than 100 grammes protein.

Special dietary protein-rich foods should contain enough protein to satisfy the daily requirement in one meal, i.e. if 3000 kcal are consumed in 3 meals of 1000 kcal each, 1000 kcal of the product should contain 100 grammes of protein. Such foods would also satisfy the protein requirements of children, if they consume adequate quantities according to age and size. It is understood that these products are mainly intended to combat protein malnutrition or deficiency, keeping in mind that any such standards must be somewhat arbitrary. Because of the widespread occurrence of metabolic disturbances owing to lactase deficiency, it is advisable to limit the amount of lactose in these foods.

PROPOSED DRAFT STANDARD FOR PROTEIN FOODS FOR SPECIAL DIETARY USES

(At Step 2 of the Procedure)

1. SCOPE
 - 1.1 This standard applies to foods which are represented, directly or indirectly or by implication as intended for special dietary uses (protein deficiency) by reason of their protein content.
 - 1.2 The standard refers only to the specific provisions related to the special purpose for which the foods are intended concerning the protein content. They do not affect the respective regulations concerning the foods as such (especially milk, eggs, and meat products).
2. DESCRIPTION
 - 2.1 Protein foods and protein-rich foods are foods whose special dietary value results from their protein content. They are ready for consumption needing no other than ordinary preparation in the household.

- 2.2 They are intended to satisfy the protein requirement of man partly or entirely with biologically complete protein.
- 2.3 They are normal foods or foods in the production of which a defined ^{1/}, safe and harmless protein source of animal or vegetable origin has been used; natural or synthetic peptides or amino acids may also be used, if required to make biologically complete the protein component of the product.
- 2.4 Protein-rich foods are foods conforming to the provisions of paragraph 3.2 with reference to the protein component.
3. ESSENTIAL COMPOSITION AND QUALITY FACTORS
- 3.1 Protein foods contain not less than 3 grammes of available (digestible) protein per 100 kcal according to paragraph 3.3, and not less than 350 kcal per 100 grammes of the food.
- 3.2 Protein-rich foods contain not less than 10 grammes of available (digestible) protein per 100 kcal, and not less than 350 kcal per 100 grammes of the food.
- 3.3 The required protein component of the product contains essential amino acids in a quantity which will make its biological value equivalent to 80% of the reference whole egg protein.
- 3.4 The lactose content of the protein component of the product may not exceed 0.5%; lactose may not be added.
- 3.5 The content of indigestible residues including crude fibre may not exceed the technologically unavoidable quantities contained in the raw materials used.
- 3.6 The mineral matter content may not exceed ..%.

4. LABELLING

In addition to the appropriate provisions of the Recommended International General Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969), and of any special provisions of a Codex standard relating to the particular food concerned, the following additional special provisions for the labelling of special dietary protein foods including special dietary protein-rich foods shall apply, (subject to endorsement by the Codex Committee on Food Labelling):

- 4.1 Reference shall be made on the label to a special dietary use of the product with reference to its protein content in accordance with the provisions of paragraphs 1 to 3 of this standard. The addition of a protein source not normally present in the food shall be declared.
- 4.2 The protein content of the product as normally consumed shall be declared on the label in % by weight in grammes per 100 kcal in grammes per serving.

^{1/} Standards and purity requirements for protein raw materials for special dietary protein foods will be elaborated in collaboration with FAO.

- 4.3 The average calorie value of the product [as normally consumed] per 100 grammes of the product [per serving] shall be declared.
- 4.4 The average carbohydrate and fat content of the product [as normally consumed] per 100 grammes of the product [per serving] shall be declared.
- 4.5 No reference may be made to any slimming effect or to a slimming or weight reducing diet unless the composition and labelling of the product warrant such claims in other respects than its protein content and in accordance with appropriate standards or legislation.

5. HYGIENE

- 5.1 It is recommended that the product is manufactured according to the appropriate provisions of the Code of Hygienic Practice for Prepackaged Foods.
- 5.2 The protein raw materials shall comply with the hygienic requirements to be laid down in special standards. 1/

6. PACKAGING

Special dietary protein foods shall be offered for sale in packages or containers which will safeguard the wholesomeness of the product including its hygienic and special dietary quality.

7. DISTRIBUTION

The foods covered by this standard shall be freely available wherever foods are sold as well as from speciality stores and drug stores or pharmacies without licensing requirements not imposed on foods generally.

8. METHODS OF ANALYSIS AND SAMPLING

Methods for determination of protein content and biological value including essential amino acids (to be developed).

1/ To be elaborated in collaboration with FAO.