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REPORT OF THE FOURTH SESSION  
OF THE  
CODEX COMMITTEE ON FOODS FOR SPECIAL DIETARY USES

Cologne  
3-7 November 1969

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FOURTH SESSION OF THE  
CODEX COMMITTEE ON FOODS FOR SPECIAL DIETARY USES  
Cologne, 3-7 November 1969

Introduction

1. The Codex Committee on Foods for Special Dietary Uses held its Fourth Session by courtesy of the Government of the Federal Republic of Germany from 3-7 November in Cologne. On behalf of the Federal Ministry of Youth, Family and Health, Mrs. H. Merkel welcomed the participants and stressed the importance of this Committee within the framework of the Codex Alimentarius Commission. The Chairman of the Committee was Mr. H. P. Mollenhauer. Delegates and observers from 17 countries and observers from 7 international organizations attended the meeting. The List of Participants is attached as Appendix I to this Report.

Adoption of the Provisional Agenda and Appointment of Rapporteur

2. The Committee decided to amend the provisional agenda slightly by considering the three standards listed under Agenda Item 6, "Proposed Draft Standards for Foods for Infants and Children", (namely, (a) Infant formula, (b) Dry pre-cooked cereal for infants and (c) Canned baby food) before Agenda Item 4, "Proposed Draft General Principles for Foods for Infants and Children,"
3. The Committee unanimously elected Mr. L.M. Beacham of the U.S. delegation to act as rapporteur of the meeting.

Cooperation of the International Union of Nutritional Sciences (IUNS) in the Work of the Committee

4. Prof. IT, Gounelle de Pontanel informed the Committee that the International Union of Nutritional Sciences had set up a Committee composed of medical experts to give its views on the texts of standards prepared by the Codex Committee. The Committee expressed its appreciation of the help offered and agreed that the draft standards elaborated by the Committee would be sent to the IUNS for comments in the course of the normal Procedure for the Elaboration of Codex Standards. The expert advice given by IUNS would be taken into account when reviewing the standards.

Proposed Draft Standard for Infant Formula (Mothers' Milk Substitute)  
Document CCDP/69/7, September 1969)

5. After the delegate of the author country (U.S.) had made an introductory statement on the above document, the Committee considered whether the requirements of foods for infants and children should be contained in three separate standards as proposed by the author country, or whether one standard would be sufficient. The Committee decided that the Standard for Infant Formula should cover those foods which would serve as a complete substitute for human milk in respect of the nutritional requirements of infants. The Committee therefore decided to delete the reference to partial substitution contained in the Scope section of the standard, and also to delete references to normal milk. The Committee noted that the title "Infant Formula" might not be sufficiently clear and agreed that this should be amended to read "Infant Formula (Mothers' Milk Substitute)". In considering the Description section of the standard the

Committee decided that the reference to the addition of carbohydrates should be deleted since the food covered by the standard was a complete and not a partial substitute for human milk. The Committee agreed that the subsidiary definitions referring to "infant" and "calorie" should be retained in this section.

6. During the discussion of the section dealing with Essential Composition and Quality Factors, the U.S. delegation informed the Committee that in the preparation of infant formula foods, protein sources such as meat, fish and soya beans were also used to meet the needs of infants suffering from milk allergies. The Committee agreed that these raw materials should be retained as constituents of infant formula foods.
  7. Regarding the inclusion of vitamins and minerals in infant formula foods, several delegations were of the opinion that the vitamin and mineral contents of infant formula foods should be similar to those contained in human milk. It was pointed out that even the diet of breast-fed children often needed to be supplemented by vitamin D and iron, and that the requirements for adding vitamins varied according to regional, climatic and other conditions. The Committee thought it would be necessary to express a range of minimum and maximum amounts of added vitamins, especially for the liposoluble vitamins, and minerals, rather than to state only a minimum amount. It was decided to ask governments to comment specifically on these ranges. The delegation of the U.S. informed the Committee that the amounts appearing in the standard had been taken from recommendations of the Committee on Nutrition of the American Academy of Paediatrics. The Committee agreed to express vitamin A in accordance with the recommendation of a Joint FAO/WHO Expert Group on Requirements of Vitamin A, Thiamine, Riboflavine and Niacin <sup>1</sup> in terms of the nomenclature of the International Union of Pure and Applied Chemistry, i.e. as retinol in mcg for the vitamin A-Alcohol and as beta-carotene-equivalents in mcg for all other compounds having vitamin A activity. The Committee discussed whether the vitamin content should be expressed in relation to calories of the food as had been done in the draft standard or whether they should be expressed in other ways, such as the daily needs of the infants, in metric or other measurements (e.g. vitamin A expressed as I.U.), It was pointed out that requirements for certain vitamins sometimes depend on regional conditions (e.g. vitamin D) and that government comments would be requested on this matter.
- <sup>1</sup> Requirements of Vitamin A, Thiamine, Riboflavine and Niacin. Report of a Joint FAO/WHO Expert Group. Rome, Italy, 6-17 September 1965. FAO, Rome, 1967. (FAO Nutrition Meetings, Report Series No. 41 - WHO Technical Report Series No. 362.)
8. Regarding the quality of the protein to be used in these products, some delegations held the view that this should be related to whole-egg protein as reference protein, as recommended by a Joint FAO/WHO Expert Group on Protein Requirements. <sup>2</sup> The delegation of the U.S. informed the Committee that caseine was used as a reference protein for practical purposes. The Committee decided to add "whole-egg protein" and "cow's milk protein" as alternatives for "caseine" and to include them in the standards in square brackets. The Committee also decided to put the proposed figures - 1.8 grams and 70% for protein quantity and quality-in square brackets, and to request comments on the type of reference protein to be chosen and on the figures given, noting that the quality and the quantity of the proteins to be used depended on the reference protein. As regards linoleates and total fat content of infant formula foods, some

delegations thought that the figures suggested were too low and would have to be reconsidered in the light of government comments.

<sup>2</sup> Protein Requirements. Report of a Joint FAO/WHO Expert Group, Geneva, 8-17 October 1963. FAO, Rome, 1965. (FAO Nutrition Meetings, Report Series No. 37.)

9. In considering the section dealing with Purity Requirements, the Committee was of the opinion that those requirements dealing with meat, poultry and other food derivatives of animal origin, including fish ingredients, should be mentioned under the heading "Hygiene". Regarding the other requirements, the Committee thought it preferable to list these in conformity with the format of Codex standards. In respect of Pesticide Residues, the Committee considered that the levels permitted in infant formula foods should be lower than those acceptable for adults. It was recommended that the Joint FAO/WHO Meeting on Pesticide Residues, with paediatricians in attendance, should examine the problem of pesticide residues in foods for infants and children.
10. The Committee noted that the text of the standard as presented by the author country contained a statement to the effect that infant formula foods would have to be demonstrated as being safe and suitable for their intended purposes by clinical tests. After some discussion, the Committee decided that it would not "be necessary to include such a statement in the standard and that the fact that the food would have to be suitable was already contained in the Scope section of the standard. A number of delegations thought that a specific statement as to the suitability of such foods established on the basis of clinical tests would be desirable.
11. The Committee slightly reworded the paragraph dealing with the consistency and particle size of infant formula food.
12. The Committee recognized that the section dealing with Hygiene Requirements referred principally to bacteriological purity rather than to the raw materials used during manufacture. The reference to heat treatment in this section was suitably amended and transferred to the Description section of the standard. At the suggestion of the delegation of the Federal Republic of Germany, the Committee decided to ask the Codex Committee on Food Hygiene to prepare a Code of Hygienic Practice for Foods for Infants and Children giving it a certain priority. The delegation of the Federal Republic of Germany offered to prepare a working paper on this subject and to provide figures on bacteriological count and for toxic substances produced by micro-organisms for discussion by this Committee (CCDF) at its next session.
13. The Committee reiterated its previous decision that the use of additives should be restricted in foods for infants and children as compared to foods for adults. It was pointed out that the ADI figures given by the Joint FAO/WHO Expert Committee on Food Additives related to the average adult population and not to infants and children. It was decided that any additives to be permitted in infant formula foods would be given in a positive list. The U.S. delegation offered to prepare a first draft of such a list. The Committee understood that the restriction on additives did not refer to additions to increase the nutritive value of infant formula foods but only to additives used for technological purposes.
14. The Committee decided to follow the provisions of the Recommended General Standard for the Labelling of Prepackaged Foods (document CAC/RS 1 (1969)) and discussed those provisions of the General Standard which allowed options to

be exercised (section 3 - "Mandatory Labelling of Prepackaged Foods"). The Committee decided that ingredients should be listed in descending order of proportion, but that in the case of vitamins and minerals each of these substances should be listed consecutively. The Committee noted that further requirements in respect of ingredients also appeared among the special additional provisions for labelling in the Standard for Infant Formula (Mothers' Milk Substitute).

15. Several delegations considered it important to state on the label, together with the name of the food, whether the principal constituent was milk, or whether milk was present only in small amounts, or not at all. The Swiss delegation considered that where an infant formula food was based principally on milk the name of the product appearing on the label should carry an additional statement indicating that fact. In products not derived from milk, a statement such as: "contains no milk products" would be appropriate. The delegation of the Netherlands pointed out that the list of ingredients already provided all the necessary information as regards the composition of infant formula. Moreover, since several of the common ingredients of original milk might not be present in all cases (e.g. electrolysed whey, caseine, lactose), it might be difficult to determine when a statement could be made to the effect that the product did or did not contain milk. Whilst the statement on the label "contains no milk products" might be of use for a quick assessment by the paediatrician, a statement in the name of the product "on milk basis" would require further quantitative delimitation. The Committee decided to place the reference to milk content in square brackets and to draw this specifically to the attention of governments when requesting comments.
16. The Committee decided that the declaration of net content of infant formula foods should be expressed by weight, or by volume in the case of liquid products, and that the country of origin of the product should be declared on the label except when the product was sold in the country of origin.

As regards the additional specific labelling provisions for infant formula foods the Committee noted that a label declaration was required for moisture, protein, fat, available carbohydrates, ash and crude fibre contents expressed as percentage weight by weight or weight per unit volume and that this information referred to the product as sold. The Committee further noted that the statement of the number of available calories supplied by a specified quantity of the food as customarily or usually prepared for consumption referred to the product after dilution as prescribed. The Committee decided to add to this statement, and subject to government comments, also a statement regarding the quantity of protein, fat, available carbohydrates, ash and crude fibre in the product after dilution.<sup>1</sup>

<sup>1</sup> Note by the Secretariat: The second part of paragraph 16 was re-edited by the Secretariat to bring it into line with the provisions of the standard.

17. At the request of the delegation of Ghana, the Committee discussed the possibilities of special labelling which would indicate storage requirements in various climatic zones. It was thought that storage instructions were particularly important for foods for infants and children, although this was a problem of a general nature relating to all foods. The Committee believed that when infant formula was shipped to countries where special storage conditions were

required, the necessary information would be contained in the commercial documents accompanying the product.

18. A number of delegations thought that dates of manufacture or expiration dates for consumption should be declared on the label. Other delegations pointed out that this information could be misleading since the quality of the product could be affected more by unsuitable storage or manufacturing conditions than by the duration of storage. In respect of coding in lot identification for control purposes, it was proposed that such coding should also indicate date of manufacture and country of origin. Most of the delegates thought that this additional coded information was not necessary but decided to request comments from governments on this point. In respect of the distribution of infant formula, the Committee decided that this product should be freely available not only where foods were sold but also through other channels, such as drugstores or pharmacies without special licensing requirements.
  19. The Committee was informed that methods of analysis for determining moisture, total protein, fat, ash, crude fibre, minerals and vitamins were available in the "Suggested Guidelines for Sampling Identification and Analytical Procedures for Food" prepared by U.S. government authorities.<sup>2</sup> The Committee thought that this would be a useful document to be considered by the Codex Committee on Methods of Analysis and Sampling. The chemical methods included in these Guidelines should be compared with the methods of analysis already being used in different laboratories for foods for dietary uses, such as those of the Swiss "Lebensmittelbuch" - Chapter 22 - Dietetic Foods. The delegation of France mentioned that certain determinations, such as vitamin determinations, would be more difficult to make in foods for dietary uses than in common foods. The delegation of the U.S. agreed to provide the members of the Codex Committee on Methods of Analysis with the above-mentioned Guidelines.
- <sup>2</sup> Suggested Guidelines for Sampling, Identification and Analytical Procedures for Foods. Distributed by Nutrition Section, Office of International Research, National Institute of Health, Bethesda, Maryland 20014, USA, November 1965. (Project supported by the Advanced Research Projects Agency (Project AGILE) under ARPA Order No. 580.)
20. The Committee agreed that methods of analysis should be developed for nutrients such as amino-acids, including tryptophan, pantothenic acid, vitamin B<sub>6</sub>, vitamin E, vitamin B<sub>12</sub>, magnesium, copper, and certain carbohydrates, and also that biological methods such as the quantitative determination of the utilizable protein, had to be submitted to the Codex Committee on Methods of Analysis and Sampling for endorsement,
  21. When considering the calorie conversion factors and the specific factors for converting nitrogen into protein, the Committee agreed to propose those used for the preparation of the most recent food composition tables, prepared by FAO in collaboration with the Nutrition Program of the U.S. Department of Health, Education and Welfare.
  22. The standard as revised is attached to this report as Appendix II. Points on which government comments are specifically sought are placed in square brackets.

Proposed Draft Standard for Canned Baby Food (Document CCDF/69/9, September 1969)

23. The Committee agreed to consider the Standard for Canned Baby Food immediately following discussion on the Standard for Infant Formula since there

- were certain similarities in the two standards. During the discussion the question arose as to whether there was a need for such a standard, or whether its provisions could not eventually be covered by a General Standard for Foods for Infants and Children. It was stressed that the General Principles which were also on the agenda of the meeting were not intended to become a standard. The Committee decided that a separate standard for canned baby foods in liquid or semi-liquid form was necessary to cover those foods which were required during the normal infant's weaning period and for the progressive adaptation of infants and children to ordinary food. One delegation stated that there were also available on the market foods for this purpose which were in dry or semi-solid form.
24. In order to clarify that the standard applied only to canned foods the Committee decided to make reference in the Scope section to heat processing. In the section on "Essential Composition and Quality Factors" the Committee took the view that it was sufficient to mention only food constituents of animal or plant origin, to which vitamins and minerals could be added, but that the addition of these substances would have to be carefully scrutinized with reference to individual products. The list of optional ingredients was reduced to contain only spices, salt and protein concentrates. Governments were invited to state the maximum amounts of salt which could be added to these products. In respect of the consistency of the food, some delegations suggested that the expression "homogenized" should be used. However, it was pointed out that this expression referred in English-speaking countries to a particular process of manufacture which was not used for this food. The Committee agreed to deal with the provisions under the heading "Purity Requirements" in the same way as had been agreed upon in the Standard for Infant Formula (Mothers' Milk Substitute). Some delegations thought there should be a provision to the effect that canned baby food, when containing fish ingredients, should be practically free of pieces of bones.
  25. In view of the fact that the Standard for Canned Baby Food covered foods in which there was a wide variety of major components or characterizing ingredients, the Committee thought that the generic name "canned baby food" would not be appropriate for use as a name of the product. In this connection, reference was made to clause 3.1(a) of the Recommended General Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969) namely "that the name shall indicate the true nature of the food and normally be specific and not generic". It was pointed out that canned baby food would be designated by the major components or characterizing ingredients contained in the food, accompanied by suitable word(s) referring to the consistency of the food or to its intended use. A number of delegations did not agree with this concept and stated that, in their view, the name of the food, which was "canned baby food" should always be declared on the label.
  26. In view of the decision of the Committee, as stated in paragraph 2.4, that the addition of vitamins and mineral nutrients to the product should be scrutinized product by product, no firm decision as to the statement to appear on the label, referring to vitamin and mineral nutrients, could be made at this stage. Governments were invited to comment specifically on this matter.
  27. It was decided that the remaining sections of the standard concerning "Packaging", "Distribution" and "Methods of Analysis and Sampling" should be

dealt with in the same way as had been done in the standard for Infant Formula (Mothers' Milk Substitute). With regard to the section on Weights and Measures. The Committee decided that the minimum fill of container should be 85% for products weighing less than 250 g (8 ozs.) and 90% for products weighing more than 250 g (8 ozs.).

28. The standard as revised is attached to this report as Appendix III. Points on which government comments are specifically invited are placed in square brackets.

#### Proposed Draft Standard for Dry Pre-cooked Cereal, Rusks and Biscuits for Infants and Children (Document CCDF/69/8-September 1969)

29. The Committee briefly examined the above document and decided to amend this standard in conformity with the standard for Infant Formula (Mothers' Milk Substitute), as appropriate. The Committee considered that no provision was necessary for a maximum fluoride concentration. The standard as revised is attached to this Report as Appendix IV. Points on which government comments are specifically invited are placed in square brackets.

#### Status of Standard for Foods for Infants and Children

30. The Committee decided to advance the Standard for Infant Formula (Mothers' Milk Substitute), the Standard for Canned Baby Food and the Standard for Dry Pre-cooked Cereal, Rusks and Biscuits for Infants and Children to Step 3 of the Procedure for the Elaboration of World-wide Standards.

#### Food Additives and Pesticide Residues in Foods for Infants and Children

31. During the session the U.S. delegation provided three proposed positive lists of food additives for use in the Standards for Infant Formula (Mothers' Milk Substitute), Canned Baby Food and Dry Pre-cooked Cereal, Rusks and Biscuits for Infants, and these were distributed as Conference Room documents. (Please see paragraph 13 of this report.) The Committee did not consider the lists in detail at this stage but decided to consider them as proposals, to attach them as Annexes to the respective standards and to ask governments for comments. During a brief perusal of the lists, reservations were made by several delegations against the inclusion of monosodium glutamate, artificial colours, caramel colour, curing agents in meat, and zinc salts. With regard to the latter, the delegation of the U.S. explained that these salts were used to make up deficiencies in soya-based products.
32. In respect of the levels of pesticide residues permitted in the standards for foods for infants and children, the Committee decided that it would itself evaluate the recommendations of the Codex Committee on Pesticide Residues as soon as they became available, with special reference to the need to have the lowest possible residue levels in these foods.

#### Proposed Draft General Principles for Foods for Infants and Children

33. The Committee had before it Appendix II of document ALINORM 69/26 containing the above General Principles and document CCDF/69/5 - Synopsis of Government Comments. Some delegations were of the opinion that the General Principles had served their purpose and that they were no longer necessary since individual standards for foods for infants and children were being

elaborated. The Committee decided to discuss the General Principles briefly in the light of government comments received.

34. The Committee slightly amended the document and decided to hold it at its present step (Step 3) of the Procedure until more individual standards for foods for infants and children had become available. The Committee would then review the need for the General Principles. It was not thought necessary to circulate the document for further government comments. The Proposed Draft General Principles for Foods for Infants and Children are attached to this Report as Appendix V.

#### Proposed Draft Standard for Special Dietary Foods with Low Sodium Content (including Salt Substitutes)

35. The Committee had before it Appendix III of ALINORM 69/26 containing the above standard which had been sent out for comments at Step 3; a synopsis of government comments - document CCDF/69/5, and Methods of Analysis and Sampling - document CCDF/69/6.
36. During the discussion of the standard, it appeared that the standard did not only deal with special dietary foods with low sodium content but also contained provisions for salt substitutes which were considered to be foods per se. It was therefore thought appropriate to amend the title of the standard accordingly. Following a proposal by the Danish delegation, the Scope section of the standard was changed in order to clarify the fact that this standard would refer only to the special dietary purpose related to the sodium content of the food and to salt substitutes.
37. As suggested by a number of delegations, the Committee agreed that the following three requirements would have to be met in foods with low or very low sodium contents. Low sodium dietetic foods are those:
  - (a) which have been processed without any addition of sodium salts,  
and
  - (b) the sodium content of which is not more than one half of that of the comparable normal product,  
and
  - (c) the sodium content of which is not more than 120 mg/100 g of the final product as normally consumed.

The same criteria were to apply to foods with very low sodium content except that the limit for sodium content was set at 40 mg/100 g. The Committee was informed that there were justifiable technological reasons for stipulating a reduction of 50% of the sodium content. It was pointed out that the reduction of 50% referred to the final product as consumed. The delegation of Canada informed the Committee that in that country regulations concerning very low sodium foods set a limit of 10 mg per serving.

38. Concerning the composition of salt substitutes, it was decided that the limits given for magnesium were related to the mass of the total cations present in the mixture and that the limits for choline referred to the salt substitute mixture as such. It was not considered necessary to apply limits for the other substances in the finished product since their use would be self-limiting because of the taste of

- these substances. The Committee agreed to include provisionally in the standard references to ammonium salts and salts of glutamic and phosphoric acids. The Committee agreed to add to the list salts of succinic acid. The Committee also decided to include provisionally free succinic, free glutamic and free citric acids in the standards. France and the Federal Republic of Germany reserved their positions against the inclusion of a provision in the standard for ammonium salts, even provisionally. The Committee was informed that the substances appearing in the list of salt substitutes would be submitted to the Codex Committee on Food Additives for endorsement.
39. Regarding the labelling section of the standard, the Committee agreed that the provisions of the Recommended International Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969) would not apply directly to this standard but would apply only to the particular food concerned. The Committee considered the specific labelling provisions of the standard concerning the sodium content of the low sodium foods and agreed that mention on the label of carbohydrates, proteins and fat in low sodium food would be optional because this would be of interest in certain instances in the use of these foods. It was suggested that the use of a class name for salt substitutes in the labelling of foods produced with such salt substitutes would suffice. A number of delegations considered that the quantities of the cations should be declared. In view of the division of opinion on this point," the Committee decided to leave the provisions in square brackets for further comments. The Committee added a paragraph for the labelling of salt substitute mixtures themselves to the effect that all ingredients would be listed and the cations would be declared on this product in percentage mass per mass (m/m). The Committee also considered that it would be necessary for this product to have provisions for anticaking agents and was informed that the Codex Committee on Food Additives was presently dealing with these substances. Pending the establishment of such a list, the Committee decided to add colloidal silica in the standard.
40. The Committee expressed its appreciation for the paper prepared by the Secretariat regarding methods of analysis for sodium and decided to send this document for examination and endorsement by the Codex Committee on Methods of Analysis and Sampling.
41. The Committee decided to delete the reference from the draft standard to the Guidelines for the Elaboration of Codex Standards for Foods for Special Dietary Uses because this standard only referred to the sodium content of foods.
42. The Committee decided to advance the standard to Step 5 of the Procedure for submission to the Seventh Session of the Codex Alimentarius Commission. The standard as revised is attached to this report as Appendix VI.

#### Proposed Draft Standard for Foods for Use in a Diet for Diabetics

43. The Committee had before it documents CCDF/69/3 containing the above standard and CCDF/68/6 - "Labelling of Special Foods Suitable for Diabetics".
44. Some delegations were opposed to the elaboration of such a standard because they maintained that no foods should be offered for sale as suitable for diabetics. There was some agreement that special provisions were needed for the labelling of these products but that the expression "for diabetics" should not be used. It was pointed out that there were various types of diabetes and that each type

required a different diet which should be prescribed by a medical practitioner. Other delegations who favoured the standard thought that diabetics were in need of and used to special dietary foods of a composition which was suitable for their purpose and appropriately labelled. Attention was also drawn to the fact that a variety of these foods were on the market and that from the point of view of public health control it was desirable to have a standard which would include provisions for the composition and presentation of these foods. Although the views of the delegations were divided, the Committee decided to send the Proposed Draft Standard for Food for Use in a Diet for Diabetics at Step 3 of the Procedure to governments for comments, after it had been editorially revised and recast in Codex Format. The standard, as revised, is attached to this Report as Appendix VII. (See also paragraph 49).

45. During the meeting, a variety of prepackaged foods intended for use by persons suffering from diabetes, and coming from various countries, were exhibited and examined by the participants.

#### Gluten-Free Foods

46. The Committee considered document CCDF/68/9-"Proposed Draft Standard for Foods with low Gluten Content", prepared by the delegation of the United Kingdom, together with a Conference Room document summarizing governments' comments on the standard. The Committee decided to change the title of the standard to read: "Proposed Draft Standard for Gluten-Free Foods", because these products were commonly known under the denomination "gluten-free". The Committee stressed the fact that certain foods in the trade were based on "gluten-free" cereals and that others were made from cereals from which the gluten had been removed. It was pointed out that the gluten extraction processes did not allow absolute freedom from gluten for the latter category of cereals. Considering the difficulties of accurately determining the residual gluten content in these processed foods, the Committee saw no possibility for setting a maximum permissible level for gluten residue. It was concluded that the only possibility at this stage was to evaluate the residual gluten content through clinical tests, and decided to introduce a definition based on this consideration into the standard. The delegation of France observed that medical practitioners, when considering a food labelled as "gluten-free" should be informed whether or not it was absolutely free from gluten.
47. The Committee decided to introduce a mandatory provision for the declaration of the carbohydrate, protein and fat contents, and of the energy value into the standard. The delegations of Canada and Poland reserved their positions on this point; they recognized that this declaration was desirable but thought it should be optional.
48. The Committee decided to circulate the amended Proposed Draft Standard for Gluten-free Foods for comments at Step 3 of the Procedure. The text of the standard appears as Appendix VIII to this Report.

#### Foods with Low Carbohydrate Content (Carbohydrate Reduced Foods)

49. The Committee had before it document CCDF/69/4 - "Proposed Draft Standard for Foods with Low Carbohydrate Content (Carbohydrate Reduced Foods)"; document CCDP/68/10 - "Foods with Low Starch Content"; and CCDF/69/5 - Synopsis of Government Comments. The Committee decided to base its

discussions on document CCDF/69/4 because this had superseded the previous draft on foods with low starch content. In a general discussion it was pointed out that this standard for Foods with Low Carbohydrate Content (Carbohydrate Reduced Foods) could possibly replace the standard for Foods suitable for a Diet for Diabetics. After a full discussion of the contents of the former standard, it was decided to send out both standards at Step 3 of the Procedure to governments for comments not only on the contents of the two standards but particularly on the question of whether both standards were needed, whether either of them was needed, or whether they could be combined into one standard. The delegation of the Federal Republic of Germany pointed out that the sole fact of low carbohydrate content was insufficient for making this food particularly suitable for diabetics because carbohydrates include sucrose. Furthermore in a diet for diabetics, not only carbohydrate content but the fat content may also be of decisive importance.

50. Concerning the individual sections of the standard for Foods with Low Carbohydrate Content (Carbohydrate Reduced Foods), the following amendments were suggested. It was decided to adapt the Scope section to that of the standards on Low Sodium Foods and Gluten-Free Foods. Concerning Composition, it was decided that the standard was only to refer to products: containing not more than 50% by weight of the carbohydrate content of a comparable normal food. With reference to food additives, the majority of the Committee was in favour of having a positive list of the additives which were to be used in these products. This list would be supplied at a later stage. At the request of the delegation of the Federal Republic of Germany, a clause was inserted in square brackets that the labelling and presentation of the product should in no way imply that it was suitable for a diet for diabetics. It was pointed out that although the carbohydrate content was reduced it could still contain sucrose and other carbohydrates which would be harmful to diabetics.
51. The Committee decided to circulate the amended Proposed Draft Standard for Foods with Low Carbohydrate Content (Carbohydrate Reduced Foods) for comments at Step 3 of the Procedure. The text of the standard appears as Appendix IX to this Report. (Please see also paragraph 44).

#### Body-Building Foods

52. The Committee was informed by the Chairman that the Sixth Session of the Codex Alimentarius Commission had noted (ALINORM 69/67, paragraph 112) that a majority of this Committee had then expressed the opinion that the subject of body building foods should not be dealt with. The Committee decided that no further work should be contemplated on this subject.

#### Proposed Draft Standard for Protein Concentrates for Human Consumption (Document CCDF/69/2)

53. The above document, which had been prepared by the Nutrition Division, FAO, was introduced by a member of the Division. He drew the attention of the Committee to the difficulty in establishing a single comprehensive standard for protein concentrates derived from such different sources as oilseeds, fish or single cell organisms. It was therefore proposed to have one individual standard for each category of raw products. The FAO representative mentioned that FAO, WHO and UNICEF had been advised by their Joint Protein Advisory Group of the

urgency of undertaking such a study and accordingly a report on this matter should be available by the end of 1970.

54. The delegation of the Federal Republic of Germany had prepared substantial comments on the above-mentioned draft standard, aiming at widening the definition and description of protein concentrates, as well as introducing the concept of processed protein-rich foods, including those enriched by a single amino-acid. The Committee expressed its appreciation for the work done by the Federal Republic of Germany and recommended that FAO and WHO should elaborate guidelines for protein concentrates which are suitable for adding to foods for human consumption. It was stressed that priority should be given to standards for existing or proposed commercial foods enriched in protein. The delegation of the Federal Republic of Germany accepted a request to prepare a draft standard for consumer-packaged protein rich foods or for foods on the label of which special reference would be made to the protein content. The representatives of FAO and WHO indicated that they were preparing specifications for raw protein concentrates which could be made available for the next session of the Committee for information. The delegations of Ghana and Switzerland agreed to furnish the delegation of the Federal Republic of Germany with information on the type and quantities of such foods offered for sale to the consumer.

#### Guidelines for the Elaboration of Codex Standards for Foods for Special Dietary Uses

55. The Secretariat informed the Committee of the decision of the Sixth Session of the Codex Alimentarius Commission on the Guidelines. These Guidelines and the verbatim extract of the Report of the Commission appear in Appendix X of the Report.

#### Other Business

56. The Secretariat mentioned to the Committee that Sampling Plans for Prepackaged Foods had been elaborated by the Codex Committee on Processed Fruits and Vegetables (Document ALINORM 69/27). It was pointed out that these Sampling Plans would be applicable to quality factors of large lots of prepackaged foods and that the Committee should consider whether it was also applicable to foods for special dietary uses.
57. During the discussion, it was pointed out that the provisions and criteria for foods for special dietary uses as elaborated by this Committee could not be compared with ordinary quality criteria. Attention was drawn to paragraph 183 of the Report of the Sixth Session of the Codex Alimentarius Commission, according to which the U.S. delegation had offered to prepare a Sampling Plan which could be applied to criteria concerning the health aspects. The Committee decided not to send out at this time the Sampling Plans for government comments as to suitability for foods for special dietary uses but to wait for the new U.S. document on this matter.

#### Ascorbic acid in spinach

58. The Secretariat informed the Committee that the Joint Group of Experts on Quick Frozen foods had referred to this Committee the problem of possible interaction of ascorbic acid and the nitrates in some quick frozen foods such as spinach, especially in baby foods. Since the members of the Committee were not in a

position to consider this problem at such short notice, it was decided to include this among the subjects on which comments were to be requested.

#### Future work

- 59, The Committee decided not to make any plans for further work at the present in view of the heavy work load for its next meetings.

#### Date and place of the next session

60. Concerning the date of the next session, it was stated that no date could be fixed at present because this would depend on the general timetable of all Codex meetings to be determined by the Codex Alimentarius Commission at its Seventh Session. However, the next session should not be held before October 1970 in order to allow enough time to prepare for the meeting. The Chairman indicated that the place for the next session would probably remain unchanged.

## Summary of Status of Work

Prepared by the Secretariat

### A. STANDARDS

1. Proposed Draft Standard For Special Dietary Foods with Low Sodium Content (including Salt Substitutes.) Appendix VI and paragraph 42 of the Report

Advanced to Step 5 of the Procedure for submission to the Seventh Session of the Codex Alimentarius Commission

#### Proposed Draft Standards for

2. - infant Formula (Mothers' Milk Substitute)  
Appendix II and paragraph 30 of the Report
3. - Canned Baby Foods  
Appendix III and paragraph 30 of the Report
4. - Dry Pre-cooked Cereal, Rusks and Biscuits for Infants and Children  
Appendix IV and paragraph 30 of the Report
5. - Foods for Use in a Diet for Diabetics  
Appendix VII and paragraph 44 of the Report
6. - Gluten-free Foods  
Appendix VIII and paragraph 48 of the Report
7. - Foods with Low Carbohydrate Content (Carbohydrate Reduced Foods)  
Appendix IX and paragraph 51 of the Report

Proposed Draft Standards listed above advanced to Step 3 of the Procedure for circulation to governments and interested international organizations for comments.

### B. GENERAL PRINCIPLES AND GUIDELINES

1. Proposed Draft General Principles for Foods for Infants and Children  
Held at Step 3 and attached to the Report as Appendix V for information as per paragraph 34 of the Report.
2. Guidelines for protein concentrates suitable for adding to foods for human consumption  
FAO and WHO to provide information as per paragraph 54 of the Report.
3. Guidelines for the Elaboration of Codex Standards for Foods for Special Dietary Uses. Attached to the Report as Appendix X for information and reference papers.

### C. ASSIGNMENTS UNDERTAKEN BY AUTHOR COUNTRIES

1. Methods of Analysis for determining moisture, total protein, fat, ash, crude fibre, minerals and vitamins. The U.S. to provide the Codex Committee on Methods of Analysis with the "Suggested Guidelines for Sampling, Identification and Analytical Procedures for Food" prepared by the Nutrition Program, U.S. Department of Health, Education and Welfare (please see paragraph 19 of the Report).

2. Consumer-packaged protein rich foods. Federal Republic of Germany to prepare a draft standard for this product. Ghana and Switzerland to provide the Federal Republic of Germany with information on the type and quantities of such foods offered for sale to the consumer (please see paragraph 54 of the Report).
3. Code of Hygienic Practice for Foods for Infants and Children. Federal Republic of Germany to prepare a working paper for the next session of the Codex Committee on Foods for Special Dietary Uses (please see paragraph 12 of the Report).

D. REFERRALS TO OTHER COMMITTEES

1. Joint FAO/WHO Meeting on Pesticide Residues to examine the problem of pesticide residues in foods for infants and children (please see paragraph 9 of the Report).
2. Codex Committee on Food Hygiene to prepare a Code of Hygienic Practice for Foods for Infants and Children on the basis of information to be provided by the Codex Committee on Foods for Special Dietary Uses (please see paragraph 9 of the Report).

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PROPOSED DRAFT STANDARD FOR INFANT FORMULA (MOTHERS' MILK  
SUBSTITUTE)

(At Step 3 of the Procedure)

1. SCOPE

Infant Formula (Mothers' Milk Substitute) 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 major part of those partially breast-fed.

2. DESCRIPTION

2.1 Infant Formula (Mothers' Milk Substitute) 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 bacterial spoilage under all normal conditions of handling, storage and distribution.

3. DEFINITIONS

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 FACTORS

4.1 Composition

4.1.1 Infant Formula (Mothers' Milk Substitute) is a product based on milk of cows or other animals and/or on other edible constituents of animal, including fish, or plant origin.

4.1.2 Infant Formula shall contain the following minimum and maximum levels of vitamin, mineral, protein and fat per 100 calories of intake:

4.1.2.1 Vitamins Minimum and Maximum  
Amounts  
per 100 available calories

Min. Max.

Vitamin A expressed as

- Retinol OR

-  $\beta$ -Carotene OR

- Vitamin A

Vitamin D

Vitamin E

75 mcg

450 mcg

250 I.U.

40 I.U.

0.3 I.U.

Ascorbic Acid (Vitamin C)	8 mg
Thiamine (Vitamin B <sub>1</sub> )	25 mcg
Riboflavin (Vitamin B <sub>2</sub> )	60 mcg
Niacin	800 mcg equivalents *
Vitamin B <sub>6</sub>	35 mcg
Folic Acid	4 mcg
Pantothenic Acid	300 mcg
Vitamin B <sub>12</sub>	0.15 mcg

4.1.2.2 Minerals

Minimum and Maximum  
Amounts per 100 available  
calories

		<u>Min.</u>	<u>Max.</u>
Calcium	Ca	50 mg	
Phosphorus	P	25 mg	
Magnesium	Mg	6 mg	
Iron	Fe	1 mg	
Iodine	I	5 mcg	
Copper	Cu	60 mcg	

\* 60 mcg L-tryptophane is considered to be equivalent to 1 mcg niacin.

4.1.2.3 Protein (per 100 available calories): Not less than [1.8 g] of protein of nutritional quality [as Protein Efficiency Ratio] equivalent to that of [whole egg protein] [cow's milk protein] [caseine] or, of an amount and quality of protein such that the quality of the protein expressed as a fraction of that of [whole egg protein] [cow's milk protein] [caseine] multiplied by the gram weight of the protein per 100 calories, is not less than [1.8 g] and, the protein is of a quality not Less than [70%] of that of [whole egg protein] [cow's milk protein] [caseine].

4.1.3 Fat and linoleate (per 100 available calories)

The product shall contain linoleate (in the form of a glyceride) at a level not less than [2%], and fat at a level not less than [15%], of the total available calories.

4.2 Optional ingredients

The product may contain such added optional nutrients as proteins or amino acids, protein hydrolysates, carbohydrates, ingredients supplying essential fatty acids, and water.

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, including optional 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 shall not be exposed to ionizing radiation.

### 5. FOOD ADDITIVES

5.1 Vitamins and minerals in addition to those listed under 4.1.2.1 and 4.1.2.2 of this standard may be added, if required, in order to provide nutrients ordinarily found in human milk and to ensure that the formulation is suitable to serve as the sole source of nutrition of the infant.

5.2 The food additives which may be used in this product are those which are listed in Annex A to this standard. These additives are subject to endorsement by the Codex Committee on Food Additives.

### 6. 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 extent possible. Acceptable residue levels as established by the Codex Committee on Pesticide Residues may have to be lower for Infant Formula (Mothers' Milk Substitute) than for foods for adults.

### 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 comply with the Code of Hygienic Practice for Foods for Dietary Uses. (To be prepared by the Codex Committee on Food Hygiene.)<sup>1</sup>

<sup>1</sup> Note by the Secretariat: When the Code is available it may be necessary to include end product specifications in this paragraph.

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

7.3 Fish ingredients shall be the products of edible species of fish 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 Fish and Fishery Products.)

### 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.

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

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 "Infant Formula (Mothers' Milk Substitute)" [accompanied by "on milk basis" or "contains no milk products" as appropriate.]

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 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 of animal or plant origin and for food additives.

10.3 Declaration of nutritive value

10.3.1 The percent weight by weight or weight per unit volume of [moisture], protein, fat, available carbohydrates, ash and crude fibre contained in the food shall be declared on the label.

10.3.2 A statement of the number of available calories [and the quantity of [moisture], protein, fat, available carbohydrates, ash and crude fibre] supplied by a specified quantity of the food as customarily or usually prepared for consumption shall appear on the label.

[10.3.3 A statement of the total quantity of each vitamin and mineral as listed in paragraphs 4.1.2.1 and 4.1.2.2 of this standard shall appear on the label.

10.3.4 A statement of the quantity of each vitamin and mineral added to the food shall appear on the label.]<sup>1</sup>

<sup>1</sup> Secretariat Note: A provision regarding the declaration of vitamin and mineral contents was included in the original draft of the author country. The Committee briefly discussed this matter but a text was not agreed upon and did not appear in the adopted draft version of the standard. The Secretariat has therefore added paragraphs 10.3.3 and 10.3.4 above and placed them in square brackets for government comments.

10.4 Net contents

The net contents of Infant Formula. (Mothers' Milk Substitute) foods 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" unite) or in a system of measurement as required by the country in which the food is sold, or in both systems. <sup>1</sup>

<sup>1</sup> Secretariat Note: During the adoption of this section it was pointed out that the avoirdupois system is only applicable to the expression of weight, but not of volume.

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

The country of origin of the food shall be declared unless it is sold within the country of origin, in which case the country need not be declared.

10.7 Lot identification

Bach 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 and the country of origin.]

10.8 Utilization information

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.

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.

11.2 Sampling

Sampling shall be carried out according to the Sampling Plans for Prepackaged Foods, ALINORM 69/27.

11.3 Methods of Analysis

Methods of Analysis and test procedures to be developed on the basis of the "Suggested Guidelines for Sampling, Identification and Analytical Procedures for Food" prepared by the U.S. authorities. Other microbiological and biological methods to be developed.<sup>2</sup>

<sup>2</sup> Suggested Guidelines for Sampling, Identification and Analytical Procedures for Foods. Distributed by Nutrition Section, Office of International Research, National Institute of Health, Bethesda, Maryland 20014, USA, November 1965. (Project supported by the Advanced Research Projects Agency (Project AGILE) under ARPA Order No. 580).

INFANT FORMULA (MOTHERS' MILK SUBSTITUTE)

(Preliminary tentative alphabetical list of proposed 'additives and additions)  
Subject to endorsement by the Codex Committee on Food Additives

Amino Acids
Calcium Salts
Carrageenans
Copper in available forms
Iron in available forms
Magnesium Salts
Malto Dextrine
Manganese Salts
Mono and Di-glycerides
Potassium Salts
Sodium Ascorbate
Sodium Bicarbonate
Sodium Citrate
Sodium Phosphates
Vitamins
Zino Salts

PROPOSED DRAFT STANDARD FOR CANNED BABY FOODS

(At Step 3 of the Procedure)

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 Infant Formula (Mothers' Milk Substitute).
- 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 "calorie" means a kilocalorie or "large calorie".

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Composition

Canned baby food is a product prepared from the edible constituents of animal including fish, or plant origin with or without the addition of milk and milk products.

3.2 Optional Ingredients

- spices
- salt [percentage or range to be added]
- protein concentrates suitable for human consumption

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 Colour, Flavour and Odour

The product shall have a colour, flavour and odour normal for its component parts. It shall be free from objectionable flavours and odours.

3.6 Specific Prohibition

The product shall not be exposed to ionizing radiation,

4. FOOD ADDITIVES

The food additives [including vitamins and minerals] which may be used in this product are those which are listed in Annex A to this standard. These additives are subject to endorsement by the Codex Committee on Food Additives.

5. 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 extent possible. Acceptable residue levels as established by the Codex Committee on Pesticide Residues may have to be lower for Canned Baby Foods than for foods for adults.

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 comply with the Code of Hygienic Practice for Foods for Dietary Uses. (To be prepared by the Codex Committee on Food Hygiene.)<sup>1</sup>

<sup>1</sup> Note by the Secretariat: When the Code is available it may be necessary to include end product specifications in this paragraph.

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

- 6.3 Fish ingredients shall be the products of edible species of fish 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 Fish and Fishery Products.)

7. PACKAGING

The product shall be packed in hermetically sealed containers which will safeguard the hygienic and other qualities of the food.

8. WEIGHTS AND MEASURES

8.1 Fill of Can

The fill of can shall be 85% for products weighing less than 250 g (8ozs) and 90% for products weighing more than 250 g (8ozs) of the water capacity of the can measured at 20 C.

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 characterizing ingredient(s) accompanied by words suitable to indicate the consistency or intended use. The words "canned baby food" may also appear on the label.

### 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 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 of animal or plant origin and for 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, ash 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

The country of origin of the food shall be declared unless it is sold within the country of origin, in which case the country need not be declared.

### 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 and the country of origin.]

10.8 Utilization information

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.

11. METHODS OF ANALYSIS AND SAMPLING

11.1 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.

11.2 Sampling

11.2.1 Sampling shall be carried out according to the Sampling Plans for Prepackaged Foods, ALINORM 69/27.

11.3 Methods of Analysis

[Methods of Analysis and test procedures to be developed on the basis of the "Suggested Guidelines for Sampling, Identification and Analytical Procedures for Food" prepared by the U.S. authorities. Other microbiological and biological methods to be developed.]<sup>1</sup>

<sup>1</sup> Suggested Guidelines for Sampling, Identification and Analytical Procedures for Foods. Distributed by Nutrition Section, Office of International Research, National Institute of Health, Bethesda, Maryland 20014, USA, November 1965. (Project supported by the Advanced Research Projects Agency (Project AGILE) under ARPA Order No. 580.)

CANNED BABY FOODS

(Preliminary tentative alphabetical list of proposed additives and additions)  
Subject to endorsement by the Codex Committee on Food Additives

Artificial Flavours
Ascorbic Acid (as antioxidant)
Available Iodine
Beta Carotene
Calcium Salts
Caramel
Carrageenans
Citric Acid
Curing Agents in meat as approved by the Codex Committee on Meats and Meat Products
Fumaric Acid
Gelatin
Hydrolyzed Vegetable Protein
Iron in available forms
Modified Starch
Monosodium Glutamate
Natural and Artificial Colours
Natural Flavours
Potassium Salts
Sodium Caseinate
Sodium Phosphates
Spices
Vegetable Gums
Vitamins

PROPOSED DRAFT STANDARD FOR DRY PRE-COOKED CEREAL  
RUSKS AND BISCUITS FOR INFANTS AND CHILDREN

(At Step 3 of the Procedure)

1. SCOPE

Dry pre-cooked cereal, rusks and biscuits for infants and children are foods intended to supplement human milk or Infant Formula (Mothers' Milk Substitute) during the weaning period of normal infants or to supplement the diet of children.

2. DESCRIPTION

2.1 Dry pre-cooked cereal for infants and children is a cereal grain-based food which, after cooking, is dried or baked to a low moisture content and then so fragmented as to permit reconstitution with water, milk or Infant Formula (Mothers' Milk Substitute).

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 Infant Formula (Mothers' Milk Substitute). 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.

4. ESSENTIAL COMPOSITION AND QUALITY FACTORS

4.1 Composition

Dry pre-cooked cereal, rusks and biscuits are prepared primarily from one or more flours of cereals, such as wheat, rice, barley, oat, maize and also soybean (defatted or low fat). Milk biscuits may consist primarily of whole milk solids, or other solids of milk, with the addition of one or more flours or fractions of cereal grains.

4.2 Optional ingredients

- protein concentrates suitable for human Consumption (including amino acids)
- other high protein content ingredients
- fruits
- nutritive sweeteners
- malt
- milk or milk products
- fats and oils
- bone meal
- salt (including iodized salt)
- spices

4.2.1 Ingredients for which Codex standards exist shall comply with the provisions of these standards.

4.3 Consistency and Particle Size

When reconstituted according to the label directions for use, dry precooked 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 Colour, flavour and odour

The products shall have a colour, flavour and odour normal for their component parts. They shall be free of objectionable flavours and odours.

4.6 Moisture content

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

4.7 Specific prohibition

The products shall not be exposed to ionizing radiation.

5. FOOD ADDITIVES

The food additives [including vitamins and minerals] which may be used in this product are those which are listed in Annex A to this standard. These additives are subject to endorsement by the Codex Committee on Food Additives.

6. 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 extent possible. Acceptable residue levels as established by the Codex Committee on Pesticide Residues may have to be lower for these products than for foods for adults.

7. HYGIENE

7.1 The products shall be clean and free of poisonous or deleterious substances which may render them injurious to health. They shall be prepared, packed and held under sanitary conditions and comply with the Code of Hygienic Practice for Foods for Dietary Uses (to be prepared by the Codex Committee on Food Hygiene).<sup>1</sup>

<sup>1</sup> Note by the Secretariat: When this Code is available it may be necessary to include end. product specifications in this paragraph.

8. PACKAGING

8.1 The products shall be packed in containers which will safeguard the hygienic and other qualities of the food.

8.2 The containers including packaging materials 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 materials, 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

The container should be well filled with the product. In the case of dry pre-cooked cereal the contents when removed from and re-introduced into the container [according to a standard method to be outlined] shall occupy not less than \_\_\_\_\_% of the total cubic volume of the container. [Percentage to be added].

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

The name of the food shall be: "Dry Pre-Cooked Cereal for Infants (and/or Children)", "Rusks for Infants (and/or Children)" or Biscuits (or "Milk Biscuits") for Infants (and/or Children)".

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 of animal or plant origin and for 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, ash 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

The country of origin of the food shall be declared unless it is sold within the country of origin, in which case the country need not be declared.

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 and the country of origin.]

11.8 Utilization information

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.

12. METHODS OF ANALYSIS AND SAMPLING

12.1 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.

12.2 Sampling

12.2.1 Sampling shall be carried out according to the Sampling Plans for Prepackaged Foods, ALINORM 69/27.

12.3 Methods of Analysis

[Methods of Analysis and test procedures to be developed on the basis of the "Suggested Guidelines for Sampling, Identification and Analytical Procedures for Food" prepared by the U.S. authorities. Other microbiological and biological methods to be developed.]<sup>1</sup>

<sup>1</sup> Suggested Guidelines for Sampling, Identification and Analytical Procedures for Foods. Distributed by Nutrition Section, Office of International Research, National Institute of Health, Bethesda, Maryland 20014, USA, November 1965. (Project supported by the Advanced Research Projects Agency (Project AGILE) under ARPA Order No. 580.

DRY PRE-COOKED CEREALS, RUSKS AND BISCUITS FOR INFANTS AND CHILDREN

(Preliminary tentative alphabetical list of proposed additives and additions) Subject to endorsement by the Codex Committee on Food Additives

Amino Acids
Ammonium Bicarbonate
Available Iodine
Calcium Salts
Diastase
Glyceryl Monostearate
Iron in available forms
Lecithin
Mono and Di-glycerides
Sodium Bicarbonate
Sodium Caseinate
Sodium Phosphates
Vitamins

PROPOSED DRAFT GENERAL PRINCIPLES FOR FOODS FOR INFANTS AND CHILDREN \*

(Held at Step 3 of the Procedure and attached for reference and information only)

\* This text is a slightly revised version of the text appearing in ALINORM 69/26, Appendix II, Report of the Third Session of the Codex Committee on Foods for Special Dietary Uses, October 1968. The Committee's discussion is recorded in paragraphs 4 to 33 of ALINORM 69/26

1. SCOPE

These General Principles should apply to all foods which are described directly or by implication, by words or by pictures or other means, as being foods which are suitable for feeding infants and children.

2. DESCRIPTION

2.1 Definition

Foods for infants and children are intended to serve as food during the first periods of life and for the progressive adaptation of the infant or child to normal food.

2.2 Subsidiary Definitions

Infants in this context are children up to the age of 12 months

Children in this context are children from the age of more than 12 months up to the age of three years.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Composition (to be amended as specific standards for foods for infants and children become available)

The products concerned are based on the following categories or mixtures thereof:

- milk, milk products, milk constituents, vegetable protein, vegetable fat or other suitable proteinaceous or fatty substances
- cereals, carbohydrates
- vegetables, fruit, meat, fish, eggs, cereal products

3.2 Purity Requirements

Foods intended for infants and children should meet the following requirements:

3.2.1 They should contain only wholesome ingredients, suitable and appropriate for ingestion by infants and/or children.

[3.2.2 Raw materials should conform with their normal quality requirements such as colour and flavour.]

3.2.3 The finished products should be practically free of residues from hormones and antibiotics and pesticides.

### 3.3 Hygiene Requirements

3.3.1 Bacteriological Requirements. According to the Code of Hygienic Practice for Foods for Infants and Children. (This code will be developed by the Codex Committee on Food Hygiene.)

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

3.3.3 The Recommended International Code of Practice containing the General Principles of Food Hygiene (CAC/RCP-1(1969) should apply; however, with certain foods for infants and children special requirements may be imposed.

### 3.4 Specific Prohibition

Foods intended for infants and children shall not be exposed to ionizing radiation.

## 4. FOOD ADDITIVES AND ADDITIONS

4.1 Suitable substances may be added for technological or special dietary uses to the extent required for foods for infants and children.

4.2 With regard to type and quantity, the special food requirements of infants and children should be taken into consideration. The additives should not impair the biological utilization of the nutrients and should only be added in the minimum of the quantity required for obtaining the intended effect.

4.3 The additives should be in conformity with the specifications of identity and purity established by the Codex Alimentarius Commission.

It may sometimes be necessary to prescribe stricter specifications for an additive which is to be used in foods covered by these "General Principles".

4.4 Only those additives may be used which are appended as positive lists to the individual standards.

4.5 As a general rule, artificial colouring substances, chemical preservatives and artificial antioxidants should not be used.

## 5. LABELLING

5.1 The appropriate provisions of the Recommended International General Standard for the Labelling of Prepackaged Foods (CAC/RS-1(1969)) "shall apply.

The following specific information, as appropriate, may also be given subject to endorsement by the Codex Committee on Food Labelling;

5.1.1 the special dietary use the food is supposed to serve; the type or purpose of product, e.g. "strained", or "junior", etc.

5.1.2 Date of production in clear or code or time limit for consumption, [limiting date for guarantee], in cases where this provision is especially warranted.

5.1.3 Content of carbohydrate, protein, fat, according to the type or specific purpose of the product. \*

\* Tolerances for upper and lower limits of content to be established.

- 5.1.4 Calorie content of the product.
- 5.1.5 The type and quantity of the additions for special dietary uses. Declaration of the quantity contained in the case of mineral substances and/or vitamins is only required where essential for the dietary purpose.
- 5.1.6 Instructions for use, including indication of age group for which the product is intended.
- 5.1.7 Reference should be made, where appropriate, to keeping quality and storage conditions after opening of the container.

6. PACKAGING

Foods for infants and children should 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

Foods for infants and children should be freely available wherever foods are sold as well as from speciality stores and drugstores or pharmacies without licensing requirements not imposed on foods generally.

8. METHODS OF ANALYSIS AND SAMPLING

The methods of analysis and sampling which will be elaborated for individual products are international referee methods which are to be endorsed by the Codex Committee on Methods of Analysis and Sampling.

9. APPLICATION OF THE GENERAL GUIDELINES FOR FOODS FOR SPECIAL DIETARY USES

In addition to the special provisions of these "General Principles for Foods for Infants and Children" the "General Guidelines on Foods for Special Dietary Uses" should apply to all foods for infants and children.

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

(Advanced to Step 5 of the Procedure for submission to the Seventh Session  
of the Codex Alimentarius Commission)

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 include 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
    - 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.
  - 3.2 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 finished product.

3.2.2	The following provisions in respect of salt substitutes and their specifications are subject to <u>endorsement by the Codex Committee on Food Additives.</u>	
3.2.2.1	Potassium sulphate; potassium, calcium or [ammonium] salts of adipic, [glutamic], carbonic, succinic, lactic, hydrochloric, tartaric, citric, acetic, or [phosphoric] acids.	No limitation
3.2.2.2	Magnesium salts of adipic, [glutamic], carbonic, citric, succinic, acetic, [phosphoric], lactic, hydrochloric or tartaric acids, mixed with other Mg-free salt substitutes.	Mg <sup>++</sup> to be not more than 20% m/m (mass per mass) of the total cations (K <sup>+</sup> , Ca <sup>++</sup> , Mg <sup>++</sup> and [NH <sub>4</sub> <sup>±</sup> ]) present in the mixture.
3.2.2.3	Choline salts of acetic, -carbonic, lactic, hydrochloric, tartaric or citric 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 total mixture.
3.2.2.4	Free adipic, [glutamic] and citric acids	No limitation
3.2.3	Anticaking agents: colloidal silica -	Not more than [...% m/m] of the final product.

#### 4. LABELLING

- 4.1 In addition to the appropriate provisions of the Recommended International General Standard for the Labelling of Prepackaged Foods (CAC/RS-1(1969)) relating to the particular food concerned, the following specific provisions for the labelling of special dietary foods with low sodium content shall apply. These provisions are subject to endorsement of the Codex Committee on Food Labelling:
- 4.2 Special dietary foods with low sodium content, excluding salt substitutes as such
- 4.2.1 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.
- 4.2.2 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. [In addition, the fact that no sodium salts have been added may be declared.]
- 4.2.3 The average carbohydrate, protein and fat content in 100 g of the product as normally consumed, as well as the calorie value may be declared on the label.
- 4.2.4 [The fact that salt substitute(s) listed in paragraph 3.2 of this standard have been added and the maximum amount of potassium, calcium, magnesium, [ammonium] and choline expressed as mg cation per 100 g of the food as normally consumed shall be declared on the label.]

4.3 Salt substitutes as such

4.3.1 The name of the product is "salt substitute"

4.3.2 The amount of the cations (i.e. potassium, calcium, magnesium, [ammonium], and choline)/100 g m/m in the final product shall be declared on the label.

5. 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;

(a) Determination of sodium content:

- (i) LINDNER K., and DWORSCHAK E. - Zeitschr. f Lebensm. Unters. u Forsch. 131, p. 207-215 (1966) Flame photo metric method for determination of potassium, sodium, calcium and magnesium in foods (in German).
- (ii) Centre technique de l'Union interjudiciale des industries françaises de bisuiterie, biscotterie, entremets, desserts instantanés, aliments diététiques et de régime. Dosage du sodium par voie humide. Méthode par photométrie de flamme. Bulletin d'information technique, CTU, No. 1, Annexe 2 (25 September 1968)

(Both methods are included in document CCDP 69/6, September 1969)

(b) Determination of potassium, calcium, magnesium, [ammonium] and choline:

- (i) in foods other than salt substitutes
  - (ii) in salt substitutes
- (To be developed.)

PROPOSED DRAFT STANDARD FOR FOODS FOR USE IN A DIET FOR DIABETICS

(At Step 3 of the Procedure)  
(Editorially revised and recast by the Secretariat, Rome)

1. SCOPE

This standard applies to foods which are represented, directly or indirectly or by implication as intended for use in a diet for diabetics by reason of their special composition and/ or physical, chemical, biological or other modification resulting from processing.

2. DESCRIPTION

The composition of foods for use in a diet for diabetics is based on the fact that the metabolism of carbohydrates, and, in certain cases of diabetes, the metabolism of fats is disturbed. Therefore the intake of such carbohydrates as D-glucose, invert sugar, disaccharides, starch and starch degradation products, and where necessary, the intake of fat shall be reduced to the necessary minimum. The calorie intake of such foods as against comparable normal foods (listed in Annex I) is reduced as far as possible. Fructose, and polyalcohols such as Sorbitol, Mannitol and Xylitol are considered as being capable to replace sugars which would be harmful in a diet for diabetics.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Limitation of the content of carbohydrates:

- |       |   |  |
|-------|---|--|
| 3.1.1 | Bread, other baked foods, farinaceous foods including noodles, ready-mixed flours | Carbohydrates reduced by a minimum of 3/10 as against comparable normal foods                  |
| 3.1.2 | Marmalades, jams, confitures, fruit jellies and fruit juices                      | Not more than [8 grammes per 100 grammes] of harmful sugars in the food ready for consumption. |
| 3.1.3 | Fruit preserves   | Not more than [8 grammes per 100 grammes] of harmful sugars in the food ready for consumption. |
| 3.1.4 | Other foods   | Carbohydrates reduced by a minimum of 1/2 as against comparable normal foods.                  |

3.2. Sugars

- 3.2.1 The addition Of the following sugars is not permitted: D-glucose, invert sugar, disaccharides, glucose syrup.
- 3.2.2 The addition of fructose is permitted.

3 3 Fat content

- 3.3.1 The content of fat calories in foods for use in a diet for diabetics shall not exceed that of comparable normal foods.

3.3.2 The content of fat calories shall not exceed [.....]% of the total calorie content of the food for use in a diet for diabetics ready for consumption [with the exception of chocolate].

#### 4. ADDITIVES

4.1 Food additives used for technological purposes are listed in Annex II. (To be elaborated.)

##### 4.2 Sweeteners

4.2.1 Sugar replacing substances <sup>1</sup>

Sorbitol  
Mannitol  
Xylitol

<sup>1</sup> Standards for those substances to be elaborated.

4.2.1.1 The use of these substances in foods for use in a diet for diabetics shall not increase the calorie value of the foods above that of comparable normal foods.

4.2.2 Non-nutritive sweeteners <sup>2</sup>

Saccharine, sodium, potassium and calcium  
[Cyclamate, sodium, potassium and calcium]

<sup>2</sup> Specifications and purity requirements according to the Joint FAO/WHO Expert Committee on Food Additives.

#### 5. CONTAMINANTS

5.1 Pesticide residue tolerances

5.2 Others

(To be elaborated.)

#### 6. HYGIENE

It is recommended that the products covered by the provisions of this standard be prepared in accordance with the appropriate sections of the Recommended International Code of Practice containing the General Principles of Food Hygiene (CAC/RCP 1-1969).

#### 7. PACKAGING

Foods to which this standard applies, may be only offered for sale in packages, except for foods which are offered for consumption on the premises.

#### 8. LABELLING

8.1 In addition to the appropriate provisions of the Recommended International General Standard for the Labelling of Prepackaged Foods (CAC/RS-1(1969)) relating to the food concerned the following specific provisions for the labelling of foods for use in a diet of diabetics shall apply. These provisions are subject to endorsement by the Codex Committee on Food Labelling.

8.2 Products which are represented directly, indirectly or by implication as foods for use in a diet for diabetics shall conform to the provisions of this standard.

- 8.3 On the label of products to which this standard applies there shall be an indication that a diet of diabetics requires the supervision of a medical doctor.
- [8.4 Nothing on the label of products to which this standard applies shall infer that the advice from a medical doctor is not needed.]
- 8.5 The terms "diabetes" or "diabetic", also in combination with other words or similar expressions on the label of these products shall not infer that by using these products a diabetic could be cured or increase his intake of food (nutriments) or that his health condition could be improved by increased consumption of these products.
- 8.6 Products to which this standard applies shall carry the following declarations on the label:
- 8.6.1 The content of carbohydrates, fat, protein and the total available calorie value per 100 g of the food ready for consumption.
- 8.6.2 The quantity of the food which has similar effect on the metabolism of a diabetic person as 12 g of D-glucose (= 1 bread unit).
- 8.6.3 The quantity of fructose and the name and quantity of the sugar replacing substances as listed in 4.2.1.
- 8.6.4 The name and quantity of non-nutritive sweeteners as listed in 4.2.2.
- 8.7 Sweeteners offered for sale as such
- 8.7.1 The names of sweeteners as listed under 4.2.1 and 4.2.2 shall be "sugar replacing substances" or "non-nutritive sweeteners" [or "artificial sweeteners"] or "sugar replacing substances containing non-nutritive [artificial] sweeteners", as appropriate.
- 8.7.2 The label shall indicate the quantity of fructose, the name and quantity of sugar replacing substances as listed under 4.2.1 and the name [and quantity\_7 of non-nutritive sweeteners listed under 4.2.2.
- 8.7.3 In the case of sugar replacing substances listed in 4.2.1 and also in mixtures with non-nutritive sweeteners as listed in 4.2.2, the available calorie value per 100 g shall be declared.
- [8.7.4 Labelling prescriptions for alcoholic beverages designed for use in a diet for diabetics. (To be elaborated.)]
- [8.8 The date of manufacture or the date after which the food may not be used.]
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. METHODS OF ANALYSIS AND SAMPLING
- (to be developed)

ANNEX I

1. Normal foods which may also be manufactured as "foods for use in a diet for diabetics":
  - Bread and other baked foods
  - Farinaceous foods including noodles
  - Ready-mixed flours
  - Sugar confectioneries, pastry
  - Chocolate
  - Marmalades, jams, confitures, fruit jellies
  - Fruit preserves
  - Soups including sweet soups
  - Custard powders
  - Soft drinks (non alcoholic)
  - Alcoholic beverages: beer, wines, sparkling wines
  - Ready-to-eat dishes
  - [To be completed]
2. Normal foods which may not be manufactured as "foods for use in a diet for diabetics" nor claimed to be such:
  - Mineral waters
  - Tea surrogates
  - [To be completed]

ANNEX II

List of additives used for technological purposes. [To be elaborated]

PROPOSED DRAFT STANDARD FOR GLUTEN-FREE FOODS

(At Step 3 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 by reason of being free from gluten.
  - 1.2 The standard refers only to the specific provisions related to the special dietary purpose for which these foods are intended.
2. DEFINITION
  - 2.1 For the purpose of this standard, gluten includes such protein fractions of wheat, rye, barley and oats which are capable of causing gluten induced enteropathies.
  - 2.2 Gluten-free food is a food so described, containing wheat, rye, barley or oat flour, from which the gluten has been extracted or in which ingredients not containing gluten have been substituted for the wheat, rye, barley or oat flour normally used in foods of that kind.
  - 2.3 For the purpose of this standard "gluten-free." means that the gluten content, if any, does not cause signs of intolerance when consumed by persons allergic to gluten under clinical testing conditions.
3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

A low gluten food shall be based on or shall contain

  - (i) wheat, rye, barley or oat flour from which all gluten has, so far as is practicable, been extracted, or
  - (ii) ingredients which do not contain gluten in substitution for what, rye, barley or oat flour normally used in a food of that kind, or
  - (iii) any mixture of two or more such ingredients.
4. LABELLING
  - 4.1 In addition to the appropriate provisions of the Recommended International General Standard for the Labelling of Prepackaged Foods (CAC/RS-1(1969)) relating to the particular food concerned, the following specific provisions for the labelling of gluten-free foods shall apply. These provisions are subject to endorsement by the Codex Committee on Food Labelling.
  - 4.2 The description of "gluten-free" shall be given in immediate proximity to the name of the product.
  - 4.3 The label shall also bear an indication of (a) the carbohydrate, protein and fat contents, and (b) calorie value of an average helping of a specified size or, where appropriate, of a unit (e.g. one biscuit) of the product.
5. PACKAGING

A gluten-free food shall only be sold in a container.

6. 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.

7. METHODS OF ANALYSIS AND SAMPLING

Methods for the determination of carbohydrate, protein, fat and calorie content. . [To be developed.]

PROPOSED DRAFT STANDARD FOR FOODS WITH LOW CARBOHYDRATE  
CONTENT (CARBOHYDRATE REDUCED FOODS)

(At Step 3 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 by reason of their low carbohydrate content.
  - 1.2 The standard refers only to the specific provisions related to the special dietary purpose for which these foods are intended.
2. DESCRIPTION

Foods low in carbohydrate content are foods from which a. considerable proportion of the carbohydrate content present in comparable normal foods has been removed or omitted.
3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

A low carbohydrate food shall have not more than 50% by weight of the carbohydrate content of a comparable normal food.
4. ADDITIVES:
  - 4.1 Food additives used for technological purposes are listed in Annex I. (To be elaborated.)
  - 4.2 Minerals and vitamins in quantities necessary to make up for losses caused by processing.
  - 4.3 Non-nutritive sweeteners \*

\* Specifications and purity requirements according to Joint FAO/WHO Expert Committee on Food Additives.

    - 4.3.1 Saccharine, sodium, potassium and calcium  
[Cyclamate, sodium, potassium and calcium]
5. CONTAMINANTS
  - 5.1 Pesticide residue tolerances. (To be elaborated.)
  - 5.2 Others. (To be elaborated.)
6. HYGIENE

It is recommended that the products covered by this standard be prepared in accordance with the appropriate sections of the General Principles of Food Hygiene of the Codex Alimentarius.
7. LABELLING
  - 7.1 In addition to the appropriate provisions of the Recommended International General Standard for the Labelling of Prepackaged Foods (CAC/RS.1(1969)) relating to the particular food concerned the following specific provisions for the labelling of foods with low carbohydrate content (Carbohydrate reduced

foods) shall apply. These provisions are subject to endorsement by the Codex Committee on Food Labelling;

- [7.2 The description "low in carbohydrates" or similar description shall be given in immediate proximity to the common or usual name of the product.]
- [7.3 Nothing in the labelling of the foods to which this standard applies shall imply that the advice from a medical doctor is not needed.]
- [7.4 The label shall not contain any description, statement or picture which is calculated to indicate directly or by ambiguity, omission or inference that the food is an aid to slimming, unless the label also bears a clear, legible and conspicuous statement to the effect that the food cannot aid slimming unless it forms part of a diet in which the total intake of calories is controlled.]
- 7.5 The words "low carbohydrate content", or other words having or implying a similar meaning shall not be used to describe a foodstuff which in its normal form does not contain starch or carbohydrate.
- [7.6 In the labelling or presentation of the product there may be no implication that it is suitable for the diet of diabetics.]
- 7.7 Foods to which this standard applies shall carry the following declarations on the label:
- 7.7.1 The content of carbohydrates, fat, protein and the total available calorie value per 100 g of the food ready for consumption.
- 7.7.2 In addition, the declaration of the total available calorie value may also be given per average helping of a specified size, or where appropriate, per unit (e.g. one biscuit) of the product.
- 7.7.3 The names of the non-nutritive sweeteners used as listed in 4.3.
- 7.7.4 The names and quantities of vitamins and/or minerals used.
- [7.8 The date of manufacture or the date after which the food may not be used.]

## 8. PACKAGING

Foods which are covered by this standard shall not be sold except in a container.

## 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. METHODS OF ANALYSIS AND SAMPLING

[To be elaborated.]

ANNEX I

List of Food Additives  
(to be elaborated)

Guidelines for the Elaboration of Codex Standards for  
Foods for Special Dietary Uses

(included for information and reference purposes) <sup>1</sup>

<sup>1</sup> Extract from the Report of the 6th Session of the Codex Alimentarius Commission (4-14 March 1969, Geneva, document ALINORM 69/67, paragraph 113): "The Commission also examined the Guidelines for the Elaboration of Codex Standards for Foods for Special Dietary Uses (ALINORM 69/48) and agreed that they were suitable as Guidelines for the Committee. It was also agreed that when reference to appropriate sections of these Guidelines was made in standards, this should be done by quoting such sections in extenso."

I. PREAMBLE

1. Scientific and technical progress and an improved standard of living have provided conditions under which products, suitable for correct special dietary use, can be developed. Regulations concerning foods for special dietary uses are, both internationally and regionally within Europe, at varying stages of development and it is for this reason that legislation in the field of foods for special dietary uses must be coordinated according to international criteria.
2. In the elaboration of world-wide standards it would be appropriate in view of varying dietary customs to consider also regional conditions.
3. The principle should be applied that foods for special dietary uses, including foods for infants and children, which are not medicines but by reason of their composition and character especially appropriate to meet the nutritive requirements resulting from special physiological conditions.
4. Foods for special dietary uses should, as a general rule, comply with the provisions of national legislation for comparable ordinary foods; where Codex-Standards for such foods already exist, these standards should be followed except for such variations as are laid down by Codex Standards for foods for special dietary uses.
5. Foods for special dietary uses should be freely available wherever foods are sold and without licensing requirement not imposed on foods generally.

II. DESCRIPTION

1. Definition

Foods for special dietary uses are those foods which are distinguished from ordinary foods by their special composition and/or by their physical chemical, biological or other modification resulting from processing. For this reason they meet the particular nutritive need of persons whose normal processes of assimilation or metabolism are modified or for whom a particular effect is to be obtained by a controlled intake of foods. They are foods and not medicines.

2. Categories of foods for special dietary uses

The following groups represent examples of foods for special dietary-uses as defined under 1. above.

A.\* Foods which meet the special nutritive physiological needs of healthy persons, such as:

\* The Codex Committee on Foods for Special Dietary Uses at its 2nd Session (6-10 November 1967, Freiburg/Breisgau document ALINORM 68/26) agreed that foods to which components are added or subtracted are not necessarily foods for dietary uses unless such addition or subtraction serves a special dietary purpose and is so stated on the label.

- i) Foods for infants and children
- ii) Foods for pregnant and breast-feeding women
- iii) Foods for the aged
- iv) Foods supplying supplementary nutrients including foods for special diets required by intensive physical exertion or special environmental conditions.

B. Foods for persons suffering from abnormal physiological conditions, such as:

- a) Foods with low sodium content including salt substitutes
- b) Foods with low gluten content
- c) Foods with low content of certain amino acids
- d) Foods with low calorie content
- e) Foods with high calorie content
- f) Foods with low fat content
- g) Foods with low carbohydrate content
- h) Foods with low protein content
- i) Foods with high protein content
- j) Hypoallergenic foods.

III. LABELLING AND CLAIMS

The provisions of the Recommended International General Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969) together with the following provisions for the labelling of foods for special dietary uses and subject to endorsement by the Codex Committee on Food Labelling:

- a) The labelling of a food for special dietary use should include:
  - i) the dietetic purpose it is supposed to serve where appropriate and according to the respective provisions in the individual standards,
  - ii) an indication of the suitability of any food offered for a special dietary purpose.
- b) Only those foods should be designated with the terms "special dietary", or words conveying the same meaning, which correspond to the definition in these guidelines.

IV. DISTRIBUTION OF FOODS FOR SPECIAL DIETARY USES

Foods for special dietary uses should only be distributed in packages or containers with the exception of meat and cheese products when distributed to the ultimate consumer, and products which are to be consumed on the premises. This exception does not affect the labelling provisions.