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(CX 5/20.3)  
November 1968

ALINORM 69/26

JOINT FAO/WHO CODEX ALIMENTARIUS COMMISSION  
Sixth Session  
(Geneva - 4-14 March 1969)

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

Cologne  
14-18 October 1968

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INTRODUCTION

1. The Codex Committee on Foods for Special Dietary Uses held its Third Session from 14-18 October 1968 in Cologne under the chairmanship of Dr h.c. Edmund Forschbach. Delegations from the following sixteen countries were present: Argentina, Australia, Austria, Canada, Denmark, France, Federal Republic of Germany, Hungary, Netherlands, Norway, Portugal, Sweden, Switzerland, Thailand, United Kingdom and United States of America. The Session was also attended by observers from the following six international organizations: Association des Industries des Aliments Diététiques de la C.E.E. (I.D.A.C.E), Commission of the European Communities General Direction of Agriculture, International Federation of Glucose Manufacturers, Federation Européenne des Importateurs de Fruits secs, Conserves, Epices et Miel (FRUCOM), International Association for Cereal Chemistry, Union des Industries de la Communauté Européenne (UNICE). Among the delegates present there were eight members of the medical profession. A complete list of participants, including officers of FAO and WHO, is set out as Appendix I.

ADOPTION OF THE AGENDA

2. The Committee discussed the Provisional Agenda (CCDF/68/1) and noted that no working papers had been submitted for the specific standards for foods for infants and children. It was agreed, therefore, that this point of the Agenda should be only briefly discussed. The Committee also decided to postpone discussion of item 8 until after Agenda item 11.

APPOINTMENT OF RAPORTEURS

3. Mr L.C. Gaskell from the United Kingdom and Mr Charles Gross from France agreed to act as rapporteurs and were so appointed by the Chairman.

PROPOSED GENERAL PRINCIPLES FOR FOODS FOR INFANTS AND CHILDREN

4. The Committee had before it the following working documents:
- (i) Proposed General Principles for Foods for Infants and Children - CCDF/68/2
  - (ii) Note by the Secretariat on the above, including comments from the United Kingdom - CCDF/68/2(1)
  - (iii) Comments from Switzerland - CCDF/68/2(4)
  - (iv) Comments from the United States of America - CCDF/68/2(3)
  - (v) Proposed General Principles for Foods for Babies and Infants (draft prepared by the Secretariat) - CCDF/68/2(2).

Since the draft prepared by the Secretariat had taken into account, as far as possible, the comments from various delegations, the Committee agreed that this document should serve as the basis for detailed discussions.

During the discussion the following observations and decisions

were made. a/

SCOPE

5. The Committee agreed not to include reference to 'weanlings' under this section since this would only create linguistic and other difficulties, but to refer instead to infants and children. It was considered that the term infant (i.e. child under the age of 12 months) would cover weanlings.

DESCRIPTION

6. Definition

As regards the sentence in square brackets, concerning standardization with respect to quantity and quality, the Committee noted an explanation that the intended meaning was to require standardization of the composition of such foods. The Committee agreed to omit the sentence in square brackets.

7. Subsidiary Definition

In conformity with the decision under SCOPE, it was agreed that for the purposes of these General Principles the word 'infant' would be taken to mean a child up to the age of 12 months and the word 'child' would be taken to apply from above 12 months to 3 years.

ESSENTIAL COMPOSITION AND QUALITY FACTORS

8. The Committee noted that the delegation of the USA was envisaging specific standards for more categories of raw materials than the three groups listed in this paragraph. It was pointed out by the delegation of the Federal Republic of Germany that the categories of raw materials were drawn up keeping in mind specific hygienic requirements in their preparation. The Committee agreed that the three categories of raw materials did not represent a final classification, but only an enumeration of raw materials and that this list could be further enlarged as required.

CONSISTENCY

9. The Committee agreed that a description of the consistency of the food concerned should be considered at the time when specific standards are discussed. Therefore paragraph 3.2 was deleted.

PURITY REQUIREMENTS

10. The Committee agreed that subparagraph 3.3.1 should be expressed in a more general way to embrace all components of foods for infants and children, and that the word 'wholesome' in respect of this sort of product should be related to the groups of consumers, viz. the infant or the child.

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a/ Read paragraphs 5 to 29 in conjunction with document CCDF/68/2(2) (see also para.4)

11. With respect to subparagraph 3.3.2, dealing with residues in these foods, the Committee agreed in principle that ideally both the raw materials used as well as the final product should be free from residues of hormones, antibiotics and pesticides. The Committee envisaged that the pesticide tolerances permitted in foods for infants and children might have to be lower than those set by the Codex Committee on Pesticide Residues for foods generally. It was pointed out in this connection that in certain cases tolerances were being elaborated by the Pesticide Residues Committee to take into account unintentional contamination of food and that in these cases it would be difficult to reduce the proposed levels.
12. The Committee agreed that subparagraph 3.3.4 should be interpreted to mean that the raw materials used in the preparation of foods for infants and children should possess their original characteristic properties regarding colour and flavour since this was an indication of the quality of the raw material used. The officer representing WHO pointed out that in some instances it would be desirable to change the original organoleptic characteristics of the materials used, viz. deodorizing fish meal and yeast.
13. The Committee was in agreement that the treatment with ionizing radiation of food for infants and children should not be permitted since very little was known about the effects of such irradiation on the wholesomeness of the food. Two delegations were against the use of ultraviolet irradiation since in their opinion this type of radiation may have effects on certain foods (e.g. the activation of pro-vitamin D to an unknown extent). These delegations proposed that ultraviolet radiation should be included in the prohibition. The majority of the Committee was not in favour of such an inclusion but agreed that this matter should be examined by the Codex Committee on Food Additives.

#### HYGIENE REQUIREMENTS

14. The Committee discussed whether or not subparagraph 3.4.2 should be retained. It was agreed that this matter be given consideration at a later date since the possibility existed that stricter hygienic requirements may have to be imposed on foods for infants and children. The Committee therefore decided to redraft this section in more general terms.

#### FOOD ADDITIVES AND ADDITIONS

15. In connection with subparagraph 4.3, the Committee agreed that in some instances a stricter specification may have to be prescribed for a particular food additive when used in foods for infants and children to take into account impurities such as lead.
16. Some delegations wished to have subparagraph 4.4 deleted since, in their opinion, these matters could be dealt with in the individual standards. The Swiss delegation suggested that the colouring of these foods artificially should be prohibited in order to preclude the use of colours which are not characteristic of the ingredients used.

The Committee reconfirmed its decision at the Second Session not to permit the use of artificial colouring substances, chemical preservatives and artificial antioxidants in this type of food but agreed to insert the words 'as a general rule' in order not to prohibit the occasional use of such additives when this was absolutely necessary.

### LABELLING

#### General Remarks

17. The Committee discussed the applicability of the 'General Standard for Labelling of Prepackaged Foods' <sup>a/</sup>, as detailed in paragraph 51 of these General Principles, to foods for infants and children. It was pointed out that this draft general labelling standard had been amended by the last session of the Codex Committee for Food Labelling and that the Commission would be discussing that standard at its next session at Step 8. The Committee therefore agreed that paragraph 51 should be drafted in such a way that the matter would be left open to reconsideration at the next session of the Committee.
18. With respect to the specific labelling requirements listed in paragraphs 5.2 to 5.8 of these General Principles, the Committee agreed that they may be required as a general rule in the specific standards for foods for infants and children, but that there may be exceptions. The delegation of Switzerland was of the opinion that the specific labelling requirements should be divided into two groups: one containing provisions which would always be mandatory and the other containing those provisions which would sometimes be required. The delegation of France was of the opinion that a declaration of food additives or additions on the label was necessary and that there should be a paragraph to this effect. The delegations of Australia and Canada were of the opinion that it was unrealistic to have mandatory requirements in a document which was intended to serve as guidelines.

#### Specific Remarks

19. The Committee agreed that the provisions for net weight declaration in subparagraph 5.2 were already covered by the general labelling standard (see paragraph 17). It was decided that a declaration of the number of meals would not be practical.
20. In connection with subparagraph 5.3, it was pointed out that the Guidelines for the Elaboration of Codex Standards for Foods for Special Dietary Uses (Appendix II, ALINORM 68/26) already required that the dietetic purpose be declared on the label. The Committee considered that a restatement of this fact was nonetheless useful.
21. During the discussion of subparagraph 5.4, a member of the delegation of the Federal Republic of Germany spoke on behalf of the consumers and stated that various national consumers' organizations had strongly requested the declaration of at least the date of manufacture and that in fact such a provision was in force in a number of countries. Other

delegations expressed the view that this information could create a false sense of security because declaration of a date was no guarantee of the keeping quality which would largely depend on storage conditions. The Committee decided that with foods for infants and children, declaration of a date was required only in certain cases.

22. In view of the fact that subparagraph 5.5 contained labelling provisions which were only of a general nature, the Committee agreed that the provisions for declaration of carbohydrates, protein, fat and calorie content should not be restricted to those cases where nutritional claims were made. The delegations of Australia, Canada and the United States of America were in favour of such a restriction and also were of the opinion that a declaration as above would be required with special formula products. The delegation of Argentina proposed adding the exact denomination and percentage of the raw materials used.
23. The Committee agreed that the declaration of calorie content in subparagraph 5.5 was required for foods for infants and children and that this should not be restricted to those products where specific nutritional claims were made. The delegations of Australia, Canada and the United States of America were not in agreement and desired a restriction as above.
24. In connection with subparagraph 5.7, the delegation of France was of the opinion that all additions should be declared since this information was important from a nutritional point of view.
25. The Committee agreed that the second sentence of subparagraph 5.8 would be covered if in the previous subparagraph the word 'indication' were changed to 'declaration'. The Committee agreed that because the quantities of food consumed by infants and children varied, a declaration of the number of servings should not be prescribed.
26. Upon the suggestion of the delegation of Switzerland, supported by France and the Netherlands, the Committee agreed to insert a provision requiring a reference to the keeping quality of the product, after opening the container, under the storage conditions specified.

#### PACKAGING

27. The Committee decided on slight editorial changes in this section in order to make it clear that the packages or containers for these types of food should be of a quality which would safeguard the wholesomeness, including the hygienic and special dietary value, as far as this was possible.

#### MANUFACTURE AND DISTRIBUTION

28. Concerning the provision that foods for infants and children should be freely available and not restricted to certain types of marketing, it was decided to insert the relevant text from the "Guidelines for Foods for Special Dietary Uses." The Committee noted that there may

be occasions when official control measures in the distribution were necessary, as for instance in the case of free distribution by governments.

#### METHODS OF ANALYSIS

29. It was noted that in these "General Principles", no specific methods of analysis and sampling were required. They will be elaborated in conjunction with the special standards for individual foods for infants and children.

#### CONCLUSIONS

30. The Committee adopted the proposed draft provisional General Principles for Foods for Infants and Children, as amended at Step 2 of the Codex Procedure, although the Committee was of the opinion that these General Principles should not be elaborated into formal Codex Standards. The draft is to be sent by the Commission's Secretariat to Member Countries and Associate Members of FAO and WHO and to the International Organizations concerned at Step 3 in order to obtain their comments.

#### STATEMENT BY PROFESSOR H. GOUNELLE

31. With reference to the General Principles for Foods for Infants and Children, Professor H. Gounelle, speaking personally and expressing also the opinion of the delegation of France, wished to draw attention to the fact that the categories of foods for special dietary uses were of particular concern to the medical profession, which prescribes or recommends them.
32. He was therefore of the opinion that, before the draft standards, etc. are sent to governments, it would be desirable that they be submitted to a homogeneous group of physicians and clinicians dealing with public health, for their opinion. The advice of this medical group could facilitate subsequent agreement by governments.
33. This medical committee could be set up by the Codex Committee for Foods for Special Dietary Uses, or alternatively by the World Health Organization. If it were impossible to organize such a meeting for instance for financial and other reasons, it would be possible for the International Union for Nutritional Sciences to take the responsibility, officially or unofficially, of such an international medical meeting.

#### PROPOSED DRAFT PROVISIONAL STANDARDS FOR FOODS FOR INFANTS AND CHILDREN

34. The delegation of the USA explained that the individual standards for foods for infants and children were not submitted because the whole question of foods of this type was being investigated in that country. The Committee agreed that individual standards for infant formula, dry pre-cooked cereal for infants and canned baby food would be considered at the next session. Delegations were again requested to send comments on the documents distributed at the last session



to the delegation of the USA<sup>a/</sup>, with copies to the Secretariat of the Committee b/ and the Chief, Food Standards Programme, FAO, Rome.

LABELLING OF SPECIAL FOODS SUITABLE FOR DIABETICS

35. The delegation of the Netherlands introduced a document entitled "The Designation 'Suitable for Diabetics' on Dietary Foods" (CCDF/68/6) which was distributed at the beginning of the session. In this paper the Netherlands recommended the following :

- (a) The diet for diabetics should be prescribed by a physician
- (b) It would be useful, for other than specifically medical reasons, to bring dietary products on the market which may be used by diabetics. To prevent misunderstanding, these products should be designated according to their type (e.g. 'for a diet poor in carbohydrates') and composition (e.g. fat, protein, and carbohydrate content). Their calorific value should also be stated.
- (c) The packing should not bear the words 'suitable for diabetics' because this designation is, in general, either incorrect or too restrictive. The products often are not suitable for all diabetics. Furthermore, such products (e.g. drinks low in calories) are also suitable for other purposes such as the control of obesity.

36. Some delegations stressed the need for a range of foods suitable for the diet of diabetics, but agreed that these foods were not specific to diabetics and had other applications (e.g. foods with low carbohydrate content, foods with low calorie content, etc.). Other delegations pointed out that in their countries there were products on the market labelled as being 'suitable for diabetics'. The medical members of the Committee were in general agreement that certain foods were not necessarily suitable for all diabetics and not all diabetics were in need of special foods. Such an indication on the label was not desirable since the control of diabetics should be done on an individual basis by qualified medical persons. The delegations of the UK and Switzerland maintained that this designation was useful to persons who were not in a position to interpret compositional designation such as 'low-calorie', 'low-carbohydrate', as implying suitability as a food for diabetics and that there might be foods (e.g. artificial sweeteners) which would be suitable for all diabetics. The majority of the Committee was in agreement with the principles and philosophy contained in the paper by the delegation of the Netherlands.

37. The delegation of the Federal Republic of Germany proposed to prepare a paper giving examples of groups of foods which were suitable for labelling as 'suitable for diabetics' and to make proposals for the labelling of such foods. The delegation of the United Kingdom undertook to assist in their work.

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a/ Dr Ralph Phillips, Director, International Organizations Staff, Office of Assistant Secretary, Department of Agriculture, Washington DC 20520

b/ Mrs Helga Merkl, Head of Division II, Federal Ministry of Health, Fincklenburgstrasse 5320, Bad Godesberg

PROPOSED DRAFT PROVISIONAL STANDARD FOR FOODS WITH LOW SODIUM CONTENT

38. The Committee discussed document CCDF/68/1, entitled "Preliminary draft of a Standard for Foods with Low Sodium Content" at Step 2 of the Procedure. The following comments and decisions were made in connection with the various sections of the draft standard :

TITLE

39. There was a discussion whether this product was to be renamed "foods with reduced sodium content" or "foods suitable for low sodium diet". The Committee decided to leave the title unchanged at present and review it later in the light of comments.

SCOPE

40. The Committee fully discussed the question whether this standard should apply to all foods which are labelled as having a low sodium content, including foods with a naturally low sodium content. A majority was against the inclusion of the naturally low sodium foods. It was stated that such foods would not be covered by the definition of foods for special dietary uses a/ because they were not distinguished from ordinary foods by their special composition.

41. The delegations of Australia, Switzerland and the United Kingdom, however, pointed out that the labelling of foods with naturally low sodium content should also be controlled and that this would not be the case if the Standard excluded them entirely. Some delegations thought that a special provision of the labelling section could deal with such foods. The delegate of Denmark suggested that the following amendment would clarify the relation of this standard to commodity standards for individual foods: "This standard does not apply to the composition of foods other than their sodium content and certain labelling requirements". The Committee decided to retain the text of the SCOPE section, thus excluding naturally low sodium foods, and to add reference to salt substitutes.

DEFINITION

42. The Committee then discussed the question of whether there should be one or two categories of low sodium foods, viz. 'low-sodium' and 'very-low-sodium'. It was pointed out that the total sodium intake of the consumer needing a low-sodium diet would be determined by the physician and that the diet could be composed of various foods with a 'low-sodium' content. The majority, however, was of the opinion that two categories were needed for practical reasons, as some foods could only be reduced to a certain level of sodium and that the total sodium intake would have to be corrected by some foods with 'very-low-sodium' content and also because there was a need for a complete 'very-low-sodium' diet.

SALT SUBSTITUTES

43. The Committee discussed the additives proposed for inclusion in a list for salt substitutes. It was pointed out that this Committee was to

a/ See "Guidelines for the Elaboration of Codex Standards for Foods for Special Dietary Uses", Appendix II, ALINORM 68/26

approve of the substances from the point of view of technological necessity and usefulness for that purpose, and that the Joint FAO/WHO Expert Committee on Food Additives, through the Codex Committee on Food Additives was responsible for toxicological evaluation. The delegation of the Netherlands stated that for toxicological reasons it was opposed to the inclusion of ammonium salts. The Secretariat undertook to draw the attention of the Joint Expert Committee to the special condition of the consumers of salt substitutes and low sodium foods.

#### LABELLING

44. Besides making various editorial changes in this section, the Committee discussed whether the calories, and the carbohydrate, protein and fat content should be declared on these foods. The representative of WHO pointed out that low-sodium foods would often be offered for slimming diets and should carry the full relevant information required. In the absence of a general consensus, the Committee took no firm decision on various points. Those points which are to be particularly reviewed in the light of government comments are indicated in square brackets.
45. The Committee adopted the proposed draft provisional standard for Foods with Low-Sodium Content at Step 2 of the Codex Procedure and requested the Secretariat of the Commission to distribute it to governments for comment at Step 3. The draft, as amended, is shown in Appendix III.

#### FOODS WITH LOW GLUTEN CONTENT

46. The Committee discussed a paper prepared by the delegation of the United Kingdom entitled "Proposed Draft Provisional Standard for Foods with Low Gluten Content" (CCDF/68/9).
47. According to medical opinion in the Committee, in some cases of hypersensitivity, complete absence of the allergenic factor in the food was required. In other cases, persons less sensitive to gluten, could tolerate small amounts of the allergenic factor. It was pointed out that it would be impossible to produce food entirely free of gluten and that, therefore, the level which could be permitted in foods claiming to be 'gluten free' should be established.
48. It was pointed out that the chemical nature of gluten was not well understood and that this was also true of the components possessing allergenic properties. For this reason the estimation of gluten would give considerable difficulties. The Committee agreed that more information was needed on this subject.
49. It was pointed out that there were products available which were being used successfully in hospitals for the feeding of persons sensitive to gluten. The Committee agreed that information should be obtained on the method of manufacture of 'gluten-free' foods and methods used to remove gluten.
50. The Committee agreed to submit the paper prepared by the United Kingdom

to governments for preliminary comments. The delegation of the United Kingdom agreed to redraft the present paper in the light of information received from Governments for the next session of the Committee.<sup>a/</sup>

#### FOODS WITH LOW STARCH CONTENT

51. The Committee had before it a paper prepared by the delegation of the United Kingdom entitled "Foods with Low Starch Content" (CCDF/68/10). The delegations of Australia, Canada, and the USA were of the opinion that such foods did not fall within the definition of foods for special dietary uses. The delegation of the Netherlands proposed that the present standard be enlarged to embrace all foods low in carbohydrate content. The delegation of the Federal Republic of Germany undertook to prepare such a draft standard with the help of the United Kingdom.

52. The Committee agreed that the present draft standard should be sent to governments for preliminary comments <sup>a/</sup> and that information should be sought particularly on the following points:

- (a) the desirability, or otherwise, of enlarging the standard for low-starch foods into a standard for low-carbohydrate foods and, in the affirmative, relevant data to achieve this end,
- (b) whether or not this type of food is to be regarded as food for special dietary uses.

#### STRENGTHENING AND BODY BUILDING FOODS

53. The Committee had before it document CCDF/68/11 prepared by the delegation of Switzerland. The document, in English, had been received by the Secretariat one week before the meeting and a French translation had been produced during the meeting. Following a proposal by the delegation of Canada, a majority of the Committee was of the opinion that the subject of body building foods should not be dealt with by this Committee because this group of products does not represent foods for special dietary uses. Some of these products could be used for dietary purposes, but there was no need for a special standard. The following delegations opposed this majority decision: Federal Republic of Germany, France, Hungary, Norway, Sweden and Switzerland.

#### MATTERS REFERRED BY CODEX COMMITTEES AND OTHER MATTERS

54. The Committee had before it document CCDF/68/8 containing a summary of various matters referred to the Committee by other committees.

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<sup>a/</sup> Comments should be sent to Mr L.C. Gaskell, Chief Executive Officer, Ministry of Agriculture, Fisheries and Food, Great Westminster House, Horseferry Road, London SW1, with copies to the Secretariat of the Committee, c/o Frau H. Merkl (footnote <sup>b/</sup> p. 10) and the Chief, Food Standards Programme, FAO, Rome.

Working Procedures

55. The Committee noted that the Commission at its Fifth Session had declared that the foods which were covered by other standards should only be dealt with by this Committee with reference to aspects of special dietary nature and that, conversely, such aspects were to be referred to this Committee for endorsement. The Committee should work in collaboration with other commodity committees if required.
56. The Committee also took note of a statement by the Executive Committee contained in the report of its Twelfth Session, regarding the further use of the "Guidelines for Foods for Special Dietary Uses".

Terms of Reference

57. The Secretariat proposed a text summarizing the Committee's terms of reference as adopted by the Commission at various sessions. The Committee adopted the new text contained in Appendix IV together with definition of "Foods for Special Dietary Uses" as adopted previously.
58. The delegate of Argentina stated that in his country a distinction was made between dietetic and special dietary foods. Dietetic foods were available only from pharmacies and on the prescription of a physician.

FUTURE WORK ASSIGNMENTS

59. The Committee agreed not to take on any new work assignments before the drafts being dealt with at present were finalized.

DATE AND PLACE OF NEXT SESSION

60. The Chairman stated that, subject to confirmation by the Codex Alimentarius Commission, the Federal Republic of Germany would hold the next meeting in or near Cologne. Regarding the date, the Committee proposed October or November to the Commission. The delegate of Australia requested that meetings should be scheduled in such a way that delegates travelling long distances could use their time to the best advantage.

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LISTE DES PARTICIPANTS  
LISTA DE PARTICIPANTES

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APPENDIX I

ANNEXE I

APENDICE I

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APPENDIX I

ANNEXE I

APENDICE I

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ANNEXE I

APENDICE I

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Frl. Solange RENAUX, Berlin

Frau Elisabeth VEIT,

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PROPOSED DRAFT PROVISIONAL GENERAL PRINCIPLES  
FOR  
FOODS FOR INFANTS AND CHILDREN  
(At Step 3 of the Procedure)

1. SCOPE

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

2. DESCRIPTION

2.1 Definition

Foodstuffs 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 \*

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

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

3.2 Purity Requirements

Foodstuffs 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.

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\* to be amended, as specific standards for foods for infants and children become available.

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- 3.2.2 Raw materials should conform with their normal quality requirements such as colour and flavour.
- 3.2.3 Meat ingredients should only be derived from animals in good health at time of slaughter and fit for human consumption as judged by a competent authority recognised by national legislation\*; other food components of animal origin should only be derived from healthy animals.
- 3.2.4 The finished products must be completely free from hormones and antibiotics and practically free from pesticide residues.
- 3.2.5 Irradiation: they should not be exposed to ionizing radiation unless such treatment is in accordance with a process of irradiation which may be approved by the Codex Alimentarius Commission.

3.3 Hygiene Requirements

- 3.3.1 Bacteriological Requirements (to be developed later and referred to the Codex Committee on Food Hygiene for endorsement).
- 3.3.2 The General Principles of Food Hygiene (approved by the Codex Alimentarius Commission, Appendix II.GP, ALINORM 68/13) should apply; however with certain foods for infants and children special requirements may be imposed.

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

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\* This text is used by Codex Committee on Fats and Oils in standards for animal fats.

5. LABELLING

5.1 The appropriate provisions of the General Standard for Labelling of Prepackaged Foods a/ shall apply.

The following specific provisions in respect of foods for infants and children are subject to endorsement by the Codex Committee on Food Labelling :

5.2 Foods for infants and children may, as a general rule, be required to carry the following specific information on the package or container:

- 5.2.1 Special dietary uses; type or purpose of product, e.g. "strained", or "junior", etc.
- 5.2.2 Date of production in clear or code or time limit for consumption, [limiting date for guarantee], in cases where this provision is especially warranted.
- 5.2.3 Content of carbohydrate, protein, fat, according to the type or specific purpose of the productb/.
- 5.2.4 Calorie content of the product.
- 5.2.5 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.
- 5.2.6 Instructions for use, including indication of age group for which the product is intended.
- 5.2.7 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. MANUFACTURE AND DISTRIBUTION

Foods for infants and children should be freely available wherever foods are sold and without licencing requirements not imposed on foods generally.

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a/ see paragraph 17 of this Report  
b/ tolerances to be established



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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 PROVISIONAL STANDARD

FOR SPECIAL DIETARY FOODS WITH LOW SODIUM CONTENT

(At Step 3 of the Procedure)

1. SCOPE

This standard applies to special dietary foods which are described, directly or indirectly or by implication, by words or by pictorial device or other means, as having a sodium content which is considerably lower than the sodium content of the normal food of that kind, and also includes salt substitutes.

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 Definition

'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(a) and (b) of this standard.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Special dietary foods with low sodium content

(a) Sodium content of 'low-sodium' foods - not more than  
 $\frac{120 \text{ mg}}{100 \text{ g}}$   
of the product  
as normally  
consumed

(b) Sodium content of 'very low-sodium' foods - not more than  
 $\frac{40 \text{ mg}}{100 \text{ g}}$   
of the product  
as normally  
consumed

3.2 Salt Substitutes

The following provisions in respect of salt substitutes and their specifications are subject to endorsement by the Codex Committee on Food Additives:

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- (a) Potassium sulphate; potassium calcium or ammonium salts of adipic, glutamic, carbonic, lactic, hydrochloric, tartaric, citric, acetic or phosphoric acids )  $\sqrt{0.5\%}$  by weight, singly or in combination, expressed as  $K^+$ ,  $Ca^{++}$ ,  $Mg^{++}$  or  $NH_4^+$  as appropriate
- (b) Magnesium salts of adipic, glutamic, carbonic, citric, acetic, phosphoric, lactic, hydrochloric or tartaric acids ) Mixed with mg-free salt substitutes; not more than  $\sqrt{20\% Mg^+}$  of the total amount of  $K^+$ ,  $Ca^{++}$  and/or  $NH_4^+$  used.
- (c) Choline salts of acetic, carbonic, lactic, hydrochloric, tartaric or citric acids ) Mixed with choline-free salt substitutes; the choline content not to exceed  $\sqrt{3\%}$  of the total amount of  $K^+$ ,  $Ca^{++}$ ,  $Mg^{++}$  and/or  $NH_4^+$  used.

4. LABELLING

- 4.1 The appropriate provisions of the General Standard for the Labelling of Prepackaged Foods shall apply.<sup>a/</sup>

The following specific provisions in respect of foods with low sodium content are subject to endorsement by the Codex Committee on Food Labelling :

- 4.2 The following specific provisions in respect of labelling of special dietary foods with low sodium content shall apply :

4.2.1 The sodium content shall be declared on the label, to the nearest multiple of 5 mg, per 100 g or per a specified serving of the food as normally consumed.

4.2.2  $\sqrt{\text{The label shall bear the description 'low-sodium' or 'very low-sodium' in accordance with paragraphs 2 and 3 of this standard}}$

4.2.3 The average carbohydrate, protein and fat content in 100 g of the product is normally consumed, as well as the calorie value shall be declared on the label.

4.2.4  $\sqrt{\text{The addition of salt substitute(s) listed in paragraph 3.2 of this standard and the amount added, expressed as mg cation (i.e. potassium, calcium, magnesium, ammonium or choline)/100 g of the food as normally consumed shall be declared on the label.}}$

<sup>a/</sup> see paragraph 17 of this Report

5. METHODS OF ANALYSIS AND SAMPLING

The methods of analysis and sampling described hereunder are international referee methods which are to be elaborated by the Codex Committee on Methods of Analysis and Sampling (see paragraphs 24 and 40 of the report of the Second Session, ALINORM 68/26).

6. OTHER REQUIREMENTS

The general provisions laid down in the "Guidelines for the elaboration of Codex Standards for Foods for Special Dietary Uses" shall apply.

TERMS OF REFERENCE OF THE  
CODEX COMMITTEE ON FOODS FOR SPECIAL DIETARY USES (\*)

To develop guidelines, general principles and standards for "foods for special dietary uses", alone or in cooperation with other Committees, and to endorse provisions for special dietary purposes contained in commodity standards. The standards should be elaborated on a world-wide basis except where this is found not to be possible, in which case the standard could be elaborated on a regional or group of countries basis.

Definition of "Foods for Special Dietary Uses"

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.

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(\*) References :

- (a) Paragraph 7(d), Report of the Third Session of the Codex Alimentarius Commission
- (b) Paragraph 6(b), Report of the Fourth Session of the Codex Alimentarius Commission
- (c) Paragraph 120, Report of the Fifth Session of the Codex Alimentarius Commission
- (d) Paragraphs 4, 5 and 6, Report of the Second Session of the Codex Committee on Foods for Special Dietary Uses, ALINORM 68/26
- (e) Guidelines for the elaboration of Codex Standards for Foods for Special Dietary Uses (Appendix II, ALINORM 68/26)