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

Freiburg/Breisgau, 6 - 10 November 1967

INTRODUCTION

1. The Codex Committee on Foods for Special Dietary Uses held its Second Session from 6 - 10 November 1967, in Freiburg/Breisgau, under the chairmanship of Dr. h.c. Edmund Forschbach.

The following countries were represented:

Austria; Canada; Denmark; France; Federal Republic of Germany;
The Netherlands; Sweden; Switzerland; United Kingdom and
United States of America.

The Session was also attended by observers from the following international organizations:

IACC; EEC Glucose Association and UNICEF

A complete list of Participants, including Representatives of FAO and WHO, is set out in Appendix I.

AGENDA

2. The Provisional Agenda was adopted by the Committee without amendment.

APPOINTMENT OF RAPORTEURS

3. The Committee was of the opinion that there was no need to appoint a rapporteur and charged the Secretariat with the responsibility of producing the draft report.

TERMS OF REFERENCE

4. The Committee took note of the decision by the Codex Alimentarius Commission (paragraph 6 (h) page 16 of the Report of the Fourth Session) that:

"The Codex Committee on Dietetic Foods should be authorized to elaborate world-wide standards but that where it was not found possible by the Committee to reach agreement on a world-wide standard it would retain its authority to proceed with the elaboration of regional standards."

5. The Secretariat brought to the attention of the Committee the re-commendation of the Joint FAO/WHO Expert Committee on Nutrition that:

"... the Codex Committee on Dietetic Foods should concentrate on foods which are strictly speaking dietetic foods, the use of which is connected with morbid conditions of the human body, for example, food for diabetics, or foods low in various dietetic compounds, such as sodium, gluten phenylalanine, ...".

6. The Committee's attention was also drawn to paragraph 22 of the document ALINORM 68/4, Report of the 10th Session of the Executive Committee of the Codex Alimentarius Commission in which it was stated that in the light of the comments of the Joint FAO/WHO Expert Committee on Nutrition, a new name should probably be sought for the Codex Committee on Dietetic Foods to indicate that its Terms of Reference cover both special foods for certain individuals and also dietary foods, the use of which was connected with morbid conditions of the human body.
7. The Committee after a thorough discussion came to the conclusion that both groups of foods referred to in paragraph 5 above, including foods for special dietary uses for certain groups of healthy people, were adequately covered by the present Terms of Reference. The Committee decided that the expression "dietetic foods" should be replaced by "foods for special dietary uses".
(See also paragraph 27)

GUIDELINES

8. The Committee had before it Appendix II of ALINORM 66/4 (1), Report of the First Meeting of the "Codex Committee on Dietetic Foods" and CCDF 67/2, containing government comments on the above Appendix. These comments, including those from countries not represented at the meeting, were discussed in detail. An amended version of the previous "Guidelines for the elaboration of Standards on Dietetic Foods" is given in Appendix II. The following matters were raised in connection with the Guidelines:
9. The Secretariat of FAO pointed out that the Guidelines, although of great importance generally and for the work of the Committee, should not be regarded as a Codex standard whose elaboration must follow strictly the Rules of Procedure for such standards.
10. The Committee agreed to amend paragraph 1) of the preamble as shown in Appendix II upon the proposal of the Delegation of the USA who pointed out that it was desirable to facilitate the distribution of foods for special dietary uses because of their widespread use and need for their immediate availability.
11. The Committee agreed that sub-paragraphs (a), (b) and (c) of the section dealing with definition should be omitted since they were of an explanatory nature covered by section III dealing with the various categories of foods for special dietary uses.
12. In connection with foods for infants the Representative of WHO pointed out that the term "infant" referred only to children up to the age of 12 months. The Committee decided to amend the title to indicate that children older than 12 months of age be also included (see Appendix II). It was considered that there was no need to specify an age limit for children. The Committee agreed to omit reference to the various types of food for infants and children based on composition, since these would be dealt with when the respective standards were being elaborated.
13. The question was discussed whether there was a need for special foods for pregnant or breast-feeding women and for the aged. Some delegations emphasized that these groups of foods should not be included under the definition foods for special dietary uses. However, the majority of the Committee agreed that they should be retained because there was a need for the Committee to consider these products. It was understood that details of composition would be discussed as working papers on these individual subjects became available. The Delegation of Canada reserved its position since in its opinion foods for healthy people should not be classed as foods for special dietary uses. The Representative of WHO pointed out that it has not yet been possible to show scientifically that pregnant women needed specific foods. (Report of the WHO Expert Committee on Nutrition on Pregnancy and Lactation; Wld Hlth Org. techn. Rep. Ser., 302)

14. Upon the proposal of the Delegation of the United States of America the Committee agreed to insert an additional category of foods supplying supplementary nutrients. The Committee, however, decided that this new category should be combined with the original part B as shown in II 2) A iv, Appendix II of this Report. The Delegation of the U.S.A. reserved its position with respect to the inclusion of the original part B under this category of foods for special dietary uses and was also of the opinion that foods like enriched bread were foods for special dietary uses. The Delegation of the Netherlands objected to the inclusion of foods other than foods for infants and children under categories 2) A of the Appendix.
15. The Representative of the EEC Glucose Association raised the question whether in the light of this categorization dextrose would be considered a dietetic food, if claims were made that it provided readily available energy. It was generally felt that dextrose would not be considered a food for special dietary use.
16. After discussing at length the question whether "foods for special dietary uses for persons suffering from abnormal physiological conditions" (Appendix II, 2) B) should be renamed "..... patho-physiological conditions", the Committee decided to retain the present wording. The Delegation of the Netherlands was of the opinion that the expression "abnormal physiological" is a contradiction of terms and proposed the use of the designation "patho-physiological".
17. The Committee amended the list of foods under II, 2) B of Appendix II as follows:
 - a) It considered the category of foods for diabetics and proposed that this group should be named according to its composition rather than to its application. In view of the complexity of this type of food some delegations thought that foods for diabetics should be selected from the individual groups of compositional types of foods and it was concluded that this designation should be eliminated from this list. The Delegation of the Federal Republic of Germany reserved its position with reference to this elimination.
 - b) With respect to foods claimed to be of low content in gluten it was pointed out that it may be desirable that they be absolutely free from this material. It was pointed out to the Committee, however, that it may not be possible to achieve this in practice.
 - c) Regarding foods with low sodium content, it was considered that this category would include salt substitutes.

d) The designation "foods with low phenylalanine content" was replaced by "foods with low content of certain amino acids".

e) The Committee agreed to add to the list (Appendix II):

- Foods with high calorie content,
- Foods with high protein content,
- Foods with low protein content,
- Hypo-allergenic foods

18. The Representative of WHO pointed out to the Committee that foods for special dietary uses for persons suffering from abnormal physiological conditions should be justified on medical grounds and that the mode of use, which is under medical supervision, should be specified. The Delegation of France indicated that this notion should be enlarged to "justification on scientific grounds" because, besides physicians, there are specialists in the field of nutrition, whose work can be taken into consideration for the justification of foods for special dietary uses.

19. The Committee noted the following statement made by the Codex Committee on Food Labelling:

"The Committee (on Labelling) agreed to retain the present text contained in the Guidelines dealing with special dietary foods. The Committee (on Labelling) noted that the Codex Committee on Dietetic Foods would be submitting labelling proposals for endorsement by the Labelling Committee. Among many statements of detail made by delegations, the Delegate of Poland was of the opinion that quantities of added or eliminated substances which result in a special value of the food should also be declared. The Labelling Committee recommended that the Codex Committee on Dietetic Foods should pay particular attention in its proposals to the labelling of those special dietary foods where the addition or removal of substances resulted in the food having special properties. Such properties should be declared in order to inform the consumer of the true nature of the food."

20.a) With regard to the provisions for labelling and claims in the Guidelines the following amendments were made:

It was agreed to insert a statement that: "the provisions of the General Standard on Food Labelling apply 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".

The special provisions for the labelling of foods for special dietary uses were amended as shown in Appendix II. The Delegate of Canada pointed out that instead of deleting the provision for statements of testimonials or expert opinions to appear in the labelling, it would be more appropriate to state that no reference to such testimonials and expert opinions should appear in the labelling.

- b) Regarding the distribution of these foods the Committee decided to insert a sentence to point out that when foods for special dietary uses are distributed unpackaged the provisions for labelling should still apply.
21. At the proposal of the Delegate of Austria it was decided to explain in the report certain linguistic difficulties regarding the use of the word "diet". It was pointed out that in the English language, the word "diet" meant the normal intake of food, whereas in other languages this word had a more restricted use, referring to "foods for special dietary uses".
22. The Committee adopted the proposed Guidelines as shown in Appendix II and referred them to the Codex Alimentarius Commission for consideration.

FOODS WITH LOW SODIUM CONTENT

23. The Committee had before it document CCDF 67/5, a working paper prepared by the French Delegation, and a document SP 10/83-1 "Proposed Draft Provisional Standard for Foods of Low Sodium Content", based on the French working paper, prepared by the Secretariat of FAO. After a brief discussion it was decided that the latter document be amended by the Secretariat of FAO in the light of the paper prepared by the Delegation of France and of written comments from delegations which should reach the Secretariat in Rome not later than 15th February 1968. The amended paper should then be sent to the participants of this meeting and Codex Contact Points as a working paper for discussion at the next session of this Committee.
24. It was considered whether the proposals for the method of analysis for sodium in these foods should originate from this Committee. It was decided to request the Codex Committee on Methods of Analysis and Sampling to elaborate methods of analysis for sodium (see para. 40).

FOOD FOR NURSING MOTHERS, INFANTS AND THE AGED

25. The Committee had before it document CCDF/67/3, "Proposed Draft Provisional Standard for Foodstuffs destined for Babies and Infants", including Annex I which was distributed during the session, and also CCDF/67/3-1, a note by the Delegation of the United Kingdom on the above subject. The Delegation of the U.S.A. made available to the meeting drafts of standards for three types of foods for infants and children: infant formula, dry pre-cooked cereal for infants (babies) and canned baby food.
26. During the discussion of the paper CCDF/67/3 the Committee decided to restrict itself to the consideration of those provisions which involved basic principles:
27. Regarding the paragraph on "Definition", it was felt that in this section specific matters referring to composition should not be dealt with. However, as a general rule foods for infants should be standardized so that their composition is shown and is suitable for the infant or child. The Delegations of France and Switzerland were of the opinion that manufacturers should take all possible measures to ensure that the composition of food marketed by them comply as strictly as possible with both qualitative and quantitative indications on the label.
28. With regard to paragraph 2 (a) of CCDF/67/3, the Delegation of France was of the opinion that the text should be reworded in a more general way in order to cover all possible sources of contamination of the raw materials used and of the finished product.

Regarding tolerances for various toxic residues it was pointed out that so-called zero-tolerances would be meaningless. The question was raised whether there may be a need to distinguish between tolerances for infants and children as against those for adults. The majority was of the opinion that this was the case. Following a brief report on the findings of the Joint FAO/WHO Expert Committee on Food Additives it was suggested that this report 1/ be made available to the delegates.

29. Regarding paragraph 2(b) of CCDF/67/3, dealing with impurities that may occur in cereals, it was decided to eliminate this paragraph as it referred only to one particular group of foods and because these matters will be discussed in detail when the individual standards are being elaborated.

1/ FAO Nutrition Meetings Report Series, No.31, 1962, p.6.
See also the Seventh Report of the Joint FAO/WHO Expert Committee on Nutrition (in press).

30. With reference to bacteriological requirements contained in Annex I to the working paper (CCDF/67/3), the Delegation of U.S.A. suggested that the same hygienic requirements should apply as for normal foods according to the General Standard elaborated by the Codex Committee on Food Hygiene. Other delegations pointed out that the requirements should be more stringent.
31. The question of the elaboration of methods of analysis for bacteriological requirements was raised. The Committee's attention was drawn to the fact that the Joint FAO/WHO Committee of Government Experts on Milk and Milk Products was dealing with similar methods. It was also pointed out that the Joint FAO/WHO Expert Committee on Food Hygiene was occupying itself with bacteriological methods.
- Annex I of CCDF/67/3 dealing with bacteriological methods is to be referred to the Codex Committee on Methods of Analysis and Sampling.
32. Regarding paragraph 2 (d) of CCDF/67/3, the Delegation of the Netherlands expressed the view that the words "dietetic additives" should be replaced by "ingredients" or some other appropriate terms.
33. The majority of the Committee was of the opinion that the provisions laid down in paragraph 2 (e) of CCDF/67/3, regarding the prohibition of artificial antioxidants should be retained since such prohibition was an important provision for this type of food. The Delegations of the U.S.A. and of Canada were in disagreement with the content of this paragraph.
34. With reference to paragraph 4 of CCDF/67/3 "Packaging", the Delegation of the Netherlands was opposed to the distribution of unpackaged meat and cheese products for special dietary uses even when only distributed to the ultimate consumer.
35. With respect to the general character of the paper it was decided that its contents should serve as general principles for the elaboration of special dietary foods for infants and children and that compositional and other details would be dealt with in individual standards. It was suggested to amend its title to read "Proposed General Principles for Foods for Infants and Children". The Committee requested the Delegation of The Federal Republic of Germany to redraft the document in the accepted Format in the light of Comments received so far, together with points raised during the Session and any further written comments received from Participants. Such comments should be sent to the Delegation of the Federal Republic of Germany with copies to the Chief, Food Standards Program, Rome, not later than the end of February 1968. The Delegations of the United Kingdom and Switzerland agreed to cooperate further in this work. The amended and redrafted paper should be sent to the Secretariat of the Codex Committee on Foods for special dietary uses with copies to the Chief, Food Standards Program, FAO, Rome, not later than the end of June 1968 and to the Delegation of the U.S.A. at the earliest possibility.

The Delegation of the U.S.A. offered to prepare drafts for specific standards based on their documents made available at the Session in the light of the general discussion of this topic and further written comments from Participants, which should reach the Delegation of the U.S.A. not later than by the end of February 1968. Papers prepared by the author countries should reach the Secretariat of this Committee, with copies to the Chief, Food Standards Branch, FAO, Rome, by the end of June 1968.

FOODS FOR DIABETICS, INCLUDING SUGAR SUBSTITUTES

36. The Committee had before it a paper prepared by the Delegation of The Netherlands, entitled "Dietetic Foodstuffs for Diabetics" distributed to the Participants at the beginning of the Session. The Committee agreed that the examination of foods for diabetics was important and requested The Netherlands Delegation to prepare a working paper on the possibility for labelling foods for special dietary uses as suitable for diabetics for discussion at the next Session of this Committee. Such paper should be sent to the Secretariat of the Codex Committee on Foods for special dietary uses by the end of June 1968 with a copy to the Chief, Food Standards Program, FAO, Rome.

STARCH-REDUCED FOODS, GLUTEN-FREE FOODS, STRENGTHENING AND BODY-BUILDING FOODS

37. The Committee had before it papers on these subjects prepared by the Delegations of the United Kingdom and Switzerland. In view of the shortage of time the contents of these papers were not discussed. The author countries offered to redraft them in the accepted Format taking into consideration any comments received from participants.

FUTURE WORK ASSIGNMENTS AND OTHER BUSINESS

38. The Committee discussed the possibility of additional future work assignments. It was considered that there was sufficient work in progress, and hence priority lists would have to be established. The Delegation of the U.S.A. pointed out that it was doubtful whether the work already in preparation could be dealt with at the next Session. The Secretariat of FAO suggested that it will be necessary to consider the agenda for the next Session in order to ensure that all items can be discussed adequately.

39. With reference to the fact that some of the papers prepared for this meeting could not be dealt with, it was generally accepted that the transformation of the originally regional terms of reference into world wide ones would cause a temporary set-back which must be accepted in fairness to those delegations who were attending this Committee for the first time.
40. The question of methods of analysis and sampling of foods for special dietary uses was raised by the Delegate of Austria. It was pointed out that proposals for such methods should come from this Committee and that draft standards should contain such proposals. It was also envisaged that in some cases, this Committee could request the Codex Committee on Methods of Analysis and Sampling to recommend applicable methods which have been proposed by other Committees or make new recommendations.

DATE AND PLACE OF NEXT SESSION

41. Regarding the date and place of the next Session, it was proposed to hold the Session during the second week of October for one full week. The host country stated that they would indicate the meeting place at a later date.

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Guidelines for the Elaboration of Codex-Standards for
Foods for special dietary uses

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 licencing 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:

- 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 General Standard on Food Labelling apply 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:
 - 1) the dietetic purpose it is supposed to serve where appropriate and according to the respective provisions in the individual standards,
 - 2) 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.

*/ The Committee 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.

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.
