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

Bonn
6-10 December 1971

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SUMMARY OF STATUS OF WORK

1. Status of Standards

Standard at Step 8

Draft Standard for Infant Formula (Appendix III to this Report).

Standard at Step 5

Proposed Draft Standard for Canned Baby Foods (Appendix IV to this Report).

Standard at Step 4

Foods for use in a diet for Diabetics - Appendix VII to ALINORM 70/26
Gluten-Free Foods - Appendix VIII to ALINORM 70/26

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

Standards at Step 3

Processed Foods for Infants and Children based on Cereals - Appendix V to this
Report.

Consumer Packaged Protein Foods - Appendix VII to ALINORM 71 /26.

2. Status of Guidelines, General Principles, Code of Hygienic Practice

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

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

Code of Hygienic Practice for Foods for Infants and Children (to be prepared by
the Codex Committee on Food Hygiene (see para 17 of this Report).

3. Matters of interest to the Codex Alimentarius Commission

- Examination of Standards at Steps 8 and 5 (paragraphs 78 and 94 and
Appendices III and IV to this Report).
- Request for a consultant for sampling foods for special dietary uses (para.
124)

4. Matters of interest to General Subject Committees

	Paragraphs in the Report	Reference in Standards
Food Hygiene	17, 20	Appendix III page 4 (endorsement), and Appendix VIII
Pesticide Residues	67	
Food Additives	12-13, 69, 78, 84	Appendix VII Appendix III
Methods of Analysis and Sampling	112-120	

Food Labelling

72-76, 90

Appendix III, pages
5-6 (endorsement).

REPORT OF THE SIXTH SESSION OF THE CODEX COMMITTEE ON FOODS
FOR SPECIAL DIETARY USES
Bonn, 6-10 December 1971

INTRODUCTION

1. The Codex Committee on Foods for Special Dietary Uses held its Sixth Session by the courtesy of the Government of the Federal Republic of Germany, in Bonn. The session was opened by the Chairman of the Committee, Mr. H.P. Mollenhauer, Ministerialrat, Federal Ministry of Youth, Family and Health, who welcomed the delegations on behalf of the Federal Minister for Youth, Family and Health. The session was attended by government delegations from the following 19 countries: Australia, Belgium, Cameroon, Canada, Denmark, Finland, France, the Federal Republic of Germany, Ghana, Italy, the Netherlands, Norway, Philippines, Sweden, Switzerland, United Kingdom, United States of America, Uruguay and Venezuela. The following International Organizations were also represented: Association of Official Analytical Chemists (AOAC), European Economic Community (EEC), International Association for Cereal Chemistry (IACC), International Federation of Glucose Industries (IFG), International Organization of Consumers Unions (IOCU), Institut Européen des Industries de la Pectine (IEIP), Union des Industries de la CEE (UNICE) and Association des Industries des Aliments Diététiques de la CEE (IDACE). A list of participants, including officials from FAO and WHO, is attached as Appendix I to this Report,

ADOPTION OF THE PROVISIONAL AGENDA

2. The Committee adopted the provisional Agenda without rearrangement of items.

APPOINTMENT OF RAPPORTEURS

3. Mr. N.K.S. Baker from the United Kingdom and Dr. H. Prost from France agreed to act as rapporteurs and were so appointed. Mr. L.M. Beacham from the U.S.A. agreed to assist in the drafting of the technical aspects of the Report.

MATTERS ARISING FROM SESSIONS OF THE CODEX ALIMENTARIUS COMMISSION AND CODEX COMMITTEES

4. The Committee took note of para. 128 of the Report of the eighth session of the Codex Alimentarius Commission requesting the Committee to examine the entirety of the label declarations of dietetic foods and further elaborate the Guidelines for the Elaboration of Codex Standards for Foods for Special Dietary Uses, contained in Appendix X of ALINORM 70/26, so that reference could be made to them in the various standards. The delegation of Australia repeated its offer to prepare a working paper for the seventh session of the Committee on the subject of labelling and claims in relation to foods for special dietary uses, based on the above Guidelines. The delegation of the United Kingdom stressed the importance of coordination with the Codex Committee on Food Labelling. The Committee accepted the offer of the delegation of Australia.

5. The Committee took note of para.-177 of the Report of the eighth session of the Codex Alimentarius Commission on the subject of labelling of milk substitutes to distinguish them from products based on milk. The Committee had also before it a working paper prepared by the Nutrition Division of FAO entitled "Processed Infant Foods, Imitation Milks and the Role of the Protein Advisory Group (PAG)" (MDS 70/19),

as well as a paper submitted by Dr. N.A. de Heer, Vice-chairman of the Codex Alimentarius Commission, entitled "Milk Substitutes".... (CX/FSDU 71/16).

6. The Representative of FAO drew the attention of the Committee to Art. 4 of the Code of Principles concerning Milk and Milk Products (Sixth edition, 1963), which governs the use of the term "milk" in respect of milk imitation products. According to Art. 4, the term "milk" should not be used for such products unless preceded by the word "imitation" or otherwise qualified to indicate the materials used. The Committee agreed that it would give special consideration to this labelling problem when discussing standards for products for special dietary uses, such as milk-based foods for infants and children. The Committee also recognized the need to label foods adequately so as to describe their true nature and was of the opinion that this problem, and the problem of food control generally, could be profitably discussed by the Food Standards Conference in Africa proposed to be held under the aegis of the Codex Alimentarius Commission in 1973. As far as non milk based foods, were concerned which were not intended for special dietary uses (i.e. milk substitutes or imitation milk products) the Committee was of the opinion that they did not fall within its terms of reference.

7 The Committee took note of para. 39 of the Report of the eighth session of the Codex Committee on Food Hygiene, ALINORM 72/13, and of the fact that the Codex Committee on Food Hygiene had postponed the elaboration of a Code of Hygienic Practice for Foods for Infants and Children until a later date, when the paper on the bacteriological requirements and microbiological methods of analysis for baby and infant foods reached a more advanced stage of elaboration. The Committee agreed that this matter would be dealt with under Agenda Item 6.

8. The Committee took note of para. 80 of the Report of the seventh session of the Codex Committee on Food Additives, ALINORM 71/12, in which the Codex Committee on Food Additives had requested this Committee to give special consideration to the full declaration of components of salt substitutes. The Committee requested the Secretariat to look into the implications of this proposal as regards possible amendments of the standard for low sodium foods and to report to its seventh session.

MATTERS ARISING FROM THE 15th REPORT OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES

9. The Committee had before it an extract of the 15th Report of the Joint FAO/WHO Expert Committee on Food Additives (CX/FSDU 71/9), which contained recommendations regarding the use of additives in baby foods. The Committee noted the recommendation of the Expert Committee to limit, as far as possible, the use of food additives in foods for infants and children and, as a general rule, not to permit the use of food additives for technological purposes in foods for children up to 12 weeks of age. The Committee agreed that the question of additives would be examined on a case by case basis in relation to specific standards in the light of recommendations of the Expert Committee.

NITRATES IN SPINACH USED AS FOODS FOR INFANTS

10. The Committee had before it a synopsis of government comments and the paper prepared for its fifth session regarding the possible hazards for young infants, arising from nitrates present in fresh or frozen spinach (CX/FSDU 70/11 and 71/11). Several delegations were in favour of prohibiting the use of these foods for infants less than 3 months of age. The Representative of the International Organization of Consumers Unions (IOCU) stated that, in the public's belief, spinach was a valuable food and that,

for this reason, adequate warning on the label concerning the unsuitability of this product for the very young infant was necessary. Other delegations proposed that the label of such products should indicate how to use and store these products once the container had been opened. The Committee agreed to set up a drafting group to meet during the Session consisting of delegates from Canada, Switzerland and the Federal Republic of Germany to propose a text for insertion into the standard.

11. The Drafting Group presented written recommendations for discussion by the Committee. Several delegations and the Representative of IOCU were of the view that recommendations regarding spinach should cover all types of processed spinach. The delegation of the U.S.A. pointed out that canned spinach had been in use for several generations in their country and that there appeared to be no problem concerning nitrates or nitrites in relation to this product. The delegation of Canada emphasized that the Drafting Group had met to make recommendations as regards frozen spinach only. The majority of the delegations was in favour of the recommendation made by the Drafting Group that spinach should not be fed to infants under 12 weeks of age. The delegation of the U.S.A. was strongly opposed to this view. The Committee agreed with the view of the Drafting Group that a high nitrate content of spinach carried a potential danger of causing methaemoglobinaemia in early infancy, and noted that the problem of reduction of nitrate to nitrite would also apply to other vegetables with a high nitrate content. This danger arises because of the possible reduction of nitrate to nitrite if the product is not handled according to the following recommendation:

Recommendation:

- Should be consumed immediately after preparation or opening of the container; unused portions should be discarded.

FOOD ADDITIVES IN FOODS FOR INFANTS AND CHILDREN

12. The Committee had before it a paper prepared by the delegations of Canada and the U.S.A. on food additives in the standards for Infant Formula, Canned Baby Foods and Cereal-based Foods for Infants and Children (CX/FSDU 71/2 and Addendum I). The delegation of Canada pointed out that not all the additives contained in the working papers were actually in use, i.e. some were no longer in use while others were envisaged for future use in foods for infants. A number of delegations were of the opinion that a Sub-Committee should be set up to discuss technological additives in baby foods. The Chairman pointed out that the setting up of a Sub-Committee would have to be authorized by the Codex Alimentarius Commission and that, therefore, it might be more expeditious to carry on work on food additives by correspondence between some interested participating countries. The Committee was of the opinion that the term "technological additives" should include substances such as colours and flavours and furthermore that the consideration of the two groups of substances, i.e. additives for technological and nutritional purposes should be separated. The delegation of the United Kingdom pointed out that it was also necessary to specify and list the substances actually added for nutritional purposes.

13. The delegation of Italy drew the attention of the Committee to the fact that the European Economic Community (EEC) was considering the question of food additives, pesticide residues and microbial toxins in foods for infants and children. The delegation of the Federal Republic of Germany was of the opinion that this Committee, through a Sub-Committee or some other arrangement, should also study the problem of contaminants and pesticide residues. The Committee agreed that, for the time being discussions should be restricted to additives used for technological purposes and that

the following countries should collaborate with Canada as the rapporteur country, in considering all aspects of technological additives in the three standards for foods for infants and children indicated above: Canada, the Federal Republic of Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States of America. This group would meet briefly during the Session and then correspond with Dr. T.K. Murray of Canada, who would have the responsibility of producing a working document for the next session of the Committee. The Committee received a verbal report from Dr. T.K. Murray of Canada which is reproduced as Appendix VII to this Report. The Committee was in agreement with the plan of work suggested by the meeting of the collaborating countries.

BACTERIOLOGICAL REQUIREMENTS IN STANDARDS FOR FOODS FOR INFANTS AND CHILDREN

14. The Committee considered a paper prepared by the delegation of the Federal Republic of Germany on bacteriological requirements in standards for foods for infants and children (CX/FSDU 71/3) as well as on pathogenic micro-organisms in foods, divided into four groups according to methods of preservation and/or methods of preparations for serving. This document had been amended in the light of comments made by governments and WHO.

15. In particular, the question was raised whether or not a special provision should be made concerning tests for Clostridium botulinum and, in the affirmative, whether such tests should be routinely applied only to products containing fish protein. Another point raised was whether specific sampling plans for the bacteriological standards of such foods should be elaborated. Several delegations were in favour of making such provisions mandatory in the standards, while other delegations were of the opinion that they should not be mandatory, but included in the Code of Hygienic Practice for Foods for Infants and Children to be prepared by the Codex Committee on Food Hygiene. The Committee noted that other Codex standards, such as those for processed fruits and vegetables, fruit juices and other products contained hygiene provisions which had already been examined in detail by the Codex Committee on Food Hygiene and adopted by the Codex Alimentarius Commission.

16. The Committee noted that the International Committee on Microbiological Specifications for Foods was elaborating sampling plans for microbiological examination of foods and agreed that no decision could be taken at this stage pending recommendations made by that Committee. It also agreed that the standards for foods for infants and children should include a mandatory provision which reads as follows:

"when tested by appropriate methods of sampling and examination, the product:

- (a.) shall be free from pathogenic micro-organisms and
- (b.) shall not contain any substances originating from micro-organisms in amounts which may be toxic."

17. The Committee further agreed that comments should be requested from governments on paper CX/FSDU 71/3, (reproduced as Appendix VIII to this Report) and, in particular, on the question as to whether precise bacteriological standards, such as those in the above document should or should not be included in the standards as mandatory provisions. It also agreed that the preparation of a Code of Hygienic Practice was within the competence and terms of reference of the Codex Committee on Food Hygiene and that the paper prepared by the Federal Republic of Germany and comments received from governments should also be sent to that Committee for consideration.

DRAFT STANDARD FOR COMPLETE INFANT FOOD (COMPLETE INFANT FORMULA) (At Step 7)

18. The Committee had before it Appendix IV of ALINORM 71/26 containing the above draft standard, a synopsis of government comments contained in document CX/FSDU 71/14 and a Proposed Draft Standard for Basic Preparations for Teat Feeding contained in document CX/FSDU 71/10 prepared by the delegations of Switzerland and the Netherlands. In discussion, the following amendments were made and points raised:

THE NAME OF THE PRODUCT

19. Recognizing that the elaboration of a standard for a complete infant formula . would be limited by existing knowledge in the field of nutrition, the Committee agreed to delete the word "complete" from the title of the standard. It also agreed to rename the standard "Infant Formula" in order to avoid any possible confusion with other infant foods. It was understood that the necessary consequential amendments to the name "Complete Infant Food" would be made throughout the standard, in line with the amended name of the product.

SCOPE

20. The Committee discussed the basic question as to whether the standard should include only those foods which were intended to constitute the sole dietary intake of infants who were not breast fed or whether basic preparations for infant feeding for the purpose of supplementing the diet should also be included (See paper CX/FSDU 71/10).

21. The delegation of the U.S.A. was of the opinion that this was feasible provided adequate labelling provisions were included in the standard to distinguish between the two products. The delegation of Canada and Sweden were of the opinion that there was no justification for the use of infant formulae which were nutritionally not complete. The delegation of the United Kingdom expressed strongly the view that the fortified milk products which had been in use for many years in their country had been shown by experience to be adequate infant foods even though they would not comply fully with the Draft Standard for Infant Formula. The delegation of Australia held the view that if both such products were included in one standard, this could lead to confusion.

22. The Committee agreed that the standard should not include basic foods, for the feeding of infants, which were nutritionally not adequate, requiring the intake of nutrients from other sources than the infant formula, but agreed that the standard originally elaborated by Switzerland and the Netherlands would be taken into consideration during the discussion of the standard for Infant Formula.

23. The delegation of the U.S.A., supported by the delegations of Switzerland, Sweden and Italy, proposed the addition of the words "including those with special physiological conditions" at the end of the first sentence, so as. to include products intended for special conditions, such as allergies to certain proteins, low tolerance to lactose or gluten, but not to include products such as low-phenylalanine preparations, which were regarded by these delegations as medicines.

24. The delegation of the Federal Republic of Germany pointed out that the standard already covered such products, since the selection of suitable ingredients, which would serve special circumstances, was permitted under Section 4.1.1. This delegation, supported by the delegations of France and the Netherlands, was of the opinion that the standard should be drawn up to meet the nutritional requirements of normal, healthy infants.

25. The Committee agreed with the view that the Scope Section should make it clear that this standard also applied to infant formula which required a special choice of ingredients or of composition to serve a specific purpose for infants who require food with special dietary modifications, except for other provisions laid down for dietary management of those conditions. The Committee, therefore, adopted the amendment proposed by the U.S.A. with a slight modification as follows: "This standard applies to food in liquid or powdered form intended for use as a substitute for human milk in meeting normal nutritional requirements of infants. It also applies to those foods intended for infants with special nutritional requirements, except with regard to other provisions concerning these special requirements".

DESCRIPTION

26. The delegation of Ghana proposed that a reference should be made to specific conditions of handling, storage and distribution as stated by the manufacturer rather than to "normal" conditions. The Committee recognized that storage depended largely on climatic conditions which varied greatly and that, therefore, the word "normal" might not be sufficiently precise. It agreed to add at the end of the sentence the following text: "... in the country where the product is sold".

DEFINITIONS

27. The delegation of the Federal Republic of Germany proposed to re-define the term "infant" to mean persons up to 6 months, since above that age other foods were given as a supplement to infants. The delegations of Switzerland, United Kingdom and the U.S.A. were opposed to this change. The delegation of Australia was of the opinion that if infant formula was not adequate after the age of 6 months, the label should bear a declaration to this effect. The Committee decided not to make any changes to the definition of "infant".

28. The Committee agreed to the following definition proposed by the delegation of the U.S.A.: "Infant Formula based on milk is a formula prepared using whole milk or skimmed milk as such or with minor modification to supply not less than 90% m/m of the total protein content of the product. Products based on non-milk proteins or proteins separated from milk are not regarded as infant formula based on milk".

ESSENTIAL COMPOSITION AND QUALITY FACTORS

29. The delegation of the United Kingdom proposed that the requirements for available Calories should be re-expressed in terms of joules, to be in conformity with recent international agreements on units. The Committee agreed that both units should be given in the standard.

30. The delegation of the United Kingdom proposed that in Section 4.1.1 constituents should be restricted to those normally used for infant feeding. The delegations of Canada and the U.S.A. were of the opinion that this would be too restrictive and would impede progress in the field of infant nutrition, as only those ingredients could be used which were normally in use at present. The delegation of the Netherlands was of the opinion that the second sentence in this section was redundant. The delegation of Australia proposed that only ingredients, which have been proved to be suitable for infant feeding, should be permitted. The Committee agreed with the following amended text: "Infant Formula is a product based on milk of cows or other animals and/or on other edible constituents of animal, including fish, or plant origin, which have been proved to be suitable for infant feeding".

31. In their written comments, several delegations had expressed the view that provisions for minimum quantities of nutrients were more important for products in which milk was not the principal ingredient than for products based on milk. The Committee agreed that the problem of vitamin and mineral content might not be identical for infant formulae based on milk and for other infant formulae, and, therefore, decided to deal with these two types of products separately in paragraphs 4.1.2.1 to 4.1.2.4., taking into consideration the definition of infant formula based on milk (see para. 28).

A) INFANT FORMULAE NOT BASED ON MILK
(Vitamins per 100 available calories)

32. The delegation of the United Kingdom was of the opinion that, as the nutrient requirements of the standard were related to 100 calories, the calorie value of the product should be related to a given quantity of the liquid product, so as to ensure that the requirements of the infant are provided by the quantity of the formula likely to be consumed according to the age of the infant. The delegation of the U.S.A. was of the opinion that there should be a limit recommended for the dilution of the formula to take this into account. The Committee agreed that this requirement would be covered by the instructions given on the label or the accompanying documents.

33. Reference was made to the Report of the Joint FAO/WHO Expert Group on requirements of vitamin A thiamine, riboflavine and niacin (Rome, 1965), according to which the term Vitamin A covered retinol (Vitamin A alcohol) and its esters, as well as the precursors of retinol. Several delegations were of the opinion that Vitamin A should be expressed in terms of retinol only. Some delegations were in favour of deleting any reference to International Units and to beta-carotene. After discussion, the Committee agreed to delete reference to beta-carotene and to express Vitamin A either as mcg retinol or in International Units. As regards a maximum level for Vitamin A, the Committee agreed to 750 I.U., i.e. 225 mcg retinol.

34. The delegation of the U.S.A. proposed a maximum level of 100 I.U. for Vitamin D. There was a discussion on how high this maximum level could be set internationally, as requirements for Vitamin D varied according to climatic conditions. The delegations of the Federal Republic of Germany and Italy were in favour of reducing this maximum content while the delegation of Finland proposed to increase this level. The Committee adopted the maximum figure of 100 I.U. for Vitamin D and agreed that any additional requirements for this vitamin could be covered by other sources such as pharmaceutical preparations. The delegations of the Federal Republic of Germany and Italy reserved their position on this decision.

35. The Committee discussed whether or not a maximum level should be set for vitamins other than A and D. Several delegations were in favour of such provisions. Other delegations pointed out that these were already covered by para. 2.2 of the standard which required that the product shall be nutritionally adequate. It was also understood that, if provisions were laid down for a maximum vitamin content, there might be a trend in industry towards these maxima and claims in relation to higher vitamin content. The majority of the Committee considered that a minimum content was sufficient and decided not to lay down provisions for maximum quantities of vitamins other than A and D.

36. As regards Vitamin E, the delegation of Denmark expressed the view that, for the sake of analytical simplicity, it would be preferable to provide for a minimum quantity of alpha-tocopherol only and that, in addition, this level should be related to the quantity of poly-unsaturated fatty acids present in the product. Other delegations were in favour of

expressing Vitamin E in terms of International Units, as the various natural tocopherols did not have the same biological activity. The Committee also considered whether the poly-unsaturated fatty acids should be expressed as linoleic acid. After discussion, the Committee agreed to the expression "Vitamin E", in terms of International Units and to a minimum amount of 1 I.U. per gramme linoleic acid. The Committee further agreed that Vitamin E would be permitted to be added only in the form of alpha-tocopherol and its esters and it was recommended by the delegation of the U.S.A that this be only in the form of D-alpha-tocopherol.

37. The Committee agreed to delete the square brackets concerning the minimum amount of folic acid and not to lay down a maximum for this vitamin. The delegation of the Federal Republic of Germany was of the opinion that a maximum level of 12 mcg/100 cal. should be set for folic acid.

38. The Committee agreed to a minimum of 8 microgrammes per 100 Calories for Vitamin K and to permit the addition of only Vitamin K1.

39. On the proposal made by the delegation of the U.S.A., supported by the delegation of Denmark, the Committee agreed to a provision for a minimum amount of 5 mcg biotin (vitamin H) per 100 Calories.

Choline

40. On the proposal made by the delegation of the U.S.A., the Committee examined the question of a minimum requirement for choline. It was considered that this substance, which would not be considered as a vitamin in the strict sense, appeared, nevertheless, to be an essential factor in infant nutrition. The Committee agreed to a minimum amount of 12 mg per 100 Calories for this substance, to be included in the standard under a separate heading.

Minerals

41. On a proposal made by the delegation of the U.S.A., the Committee agreed to provide for a minimum amount of chloride (Cl). As regards the minimum amounts for sodium, potassium and chloride, the Committee agreed that these would be 20, 80 and 60 mg per 100 Calories, respectively. It also agreed that these substances should be limited to the maximum levels of 80, 200 and 150 mg, respectively.

42. The delegation of the Federal Republic of Germany considered that it would be necessary to provide for a maximum amount of iron of 2 mg per 100 Calories. This proposal to establish a maximum level for iron was supported in principle by several delegations, but after discussion the Committee decided that it was not necessary to provide for a maximum level. The delegation of the Federal Republic of Germany reserved its position on this point.

43. As regards other minerals under discussion, the Committee agreed to minimum amounts for copper and zinc of 60 mcg and 0.5 mg, respectively.

44. The Committee discussed the minimum amount of manganese to be provided for in the standard. The delegation of Denmark pointed out that the figure of 0.2 mg, provisionally included, was approximately 200 times higher than levels found in human milk, which contained about 1 mcg manganese per 100 Calories while cows' milk contained approximately 5 mcg. The delegations of the Federal Republic of Germany and France supported the Danish view that a minimum level for manganese of 5 mcg was sufficient and, in any case, permitted the use of higher levels in the product. The delegation of the U.S.A. was in favour of a minimum level of 200 mcg, but agreed that

100 mcg might be sufficient. They pointed out that the provision for manganese should be restricted only to those products which were not based on milk and also indicated that the minimum quantity had been based on a requirement of 0.2 mg manganese per kg body-weight for infants and children. In their opinion, milk-fed infants received this nutrient from other sources such as fruits and vegetables, while infants fed on non-milk infant formulae would receive this preparation as the sole source of food for a longer period. The delegation of Canada supported these views. Several delegations were of the opinion that little information was available on requirements for manganese. The Committee agreed to include a minimum requirement for 100 mcg manganese in the standard. The Committee further agreed to request FAO and WHO to consider the possibility of convening an Expert Group on requirements for trace elements.

45. The Committee had before it a proposal made by the Secretariat to include provisions for maximum and minimum levels of fluorine in Infant Formula (CX/FSDU 71/13). The delegation of the U.S.A. pointed out that the addition of fluorine should be left to the discretion of those countries where this was required by local conditions and suggested that a minimum amount of 40 mcg and a maximum of 80 mcg per 100 Calories could be regarded as a guide. Some other delegations were of the same opinion. After discussion, the Committee decided not to include requirements for fluorine in the standard at this stage.

46. As regards the footnote on Ca:P ratio, the Committee confirmed the values and decided to remove the square brackets in the standard.

47. The delegation of the United Kingdom drew attention to the need to list in the standard the precise substances which should be permitted to be added to the product as necessary in order to provide the nutrient requirements. It was agreed that these substances should be considered by the group of Collaborating Countries on additives in foods for infants (see para. 13).

Protein (per 100 available Calories)

48. The Representative of the Nutrition Div. of FAO informed the Committee on the conclusions of the 18th session of the FAO/WHO/UNICEF Protein Advisory Group (PAG) held in Rome in February 1971 and made reference to the adoption of PAG Guideline No. 8 on "Protein rich mixtures for use as weaning foods". The Committee agreed that this Guideline should, if possible, be appended to this Report (see Appendix VI). He also gave a brief account of the meeting of the FAO/WHO ad hoc Expert Committee on Energy and Protein - requirements and recommended intakes, held in Rome in March 1971, with regard to reference proteins, scoring methods and biological evaluation of proteins.

49. The delegation of the U.S.A. proposed that paragraph 4.1.2.3.1 be amended so as to mention casein as reference protein, because the proposed minimum amount of [1.8 g] had been suggested on this basis- If the egg protein were used as reference, this minimum amount would, therefore, go down to [1.5] since egg protein has a higher biological value than casein.

50. The delegations of Switzerland and Canada expressed the opinion that 1.8 g of protein, equivalent to that of whole egg protein, had to be maintained as a minimum quantity whereas the delegation of the Federal Republic of Germany was of the opinion that 2 g were needed.

51. A consensus was reached so as to establish a minimum 1.8 g of protein equivalent to that of whole egg protein.

52. As regards the quality of the protein, defined in the second sentence of section 4.1.2.3 of the standard, the Committee agreed to maintain the quality of the protein at least 70% of that of whole egg protein.

53. With regard to the total quantity of protein, the delegations of the U.S.A. and Ghana, supported by the delegations of Switzerland, Denmark, Canada and the United Kingdom, proposed that this quantity be raised to 5 g in order to take care of special physiological needs both in industrialized and in developing countries. The delegations of the Federal Republic of Germany and the Netherlands, however, were of the opinion that such a quantity might be harmful to the infant and recommended to set 3.5 g as a maximum. Several delegations felt, however, that this level would be too low for countries with widely different economic conditions, and especially for most developing countries where available protein resources would often be of lower quality than 70% of that of whole egg. An escape clause was, therefore, proposed as follows: "The minimum value set for quality and the maximum for quantity of the protein may be modified by national authorities according to their own regulations and/or local conditions". In the light of this provision, a majority of the delegations agreed that the total protein content should not be more than 4 g per 100 Cal., with a minimum quality requirement of 70% of that of whole egg protein. It was also made clear that the maximum amount was of total protein and was not expressed in terms of reference protein. In this connection, in answer to a question raised by the delegation of Switzerland, the Representative of the FAO Nutrition Division confirmed that the protein rich foods for infants and young children being at present promoted in several developing countries under the auspices of FAO, WHO and UNICEF had a minimum content of 20 g protein of local origin per 100 g, i.e. about 5 g protein of local origin per 100 Calories.

54. The Committee subsequently adopted the following version for paragraph 4.1.2.3.1.:

Protein (per 100 available Calories)

"Shall not be less than 1.8 g protein of nutritional quality equivalent to that of whole egg protein or a greater quantity of other protein in proportion to its biological value. The quality of the protein shall not be less than 70% of that of whole egg protein. The total quantity of protein shall not be more than 4 g. The minimum value set for quality and the maximum for quantity of the protein may be modified by national authorities according to their own regulations and/or local conditions".

55. With reference to paragraph 4.1.2.3.2 concerning the addition of isolated essential amino acids, several delegations were in favour of also authorizing the addition of isolated non-essential amino acids, under strict control to avoid excessive quantities of either type in infant foods.

56. The delegation of Canada agreed with the proposal made by the U.S.A. delegation that the addition of essential isolated amino acids be restricted to the L forms only. The following text was approved:

"4.1.2.3.2

Isolated amino acids may be added to infant formula only to improve its nutritional value for infants. Essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only natural L forms of amino acids may be used".

Fat and Linoleate

57. The Committee agreed to re-word the first sentence to make it clear that "linoleate (in the form of tri-glyceride)" meant tri-glycerides containing linoleate, excluding mono- or di-glycerides as well as substances, other than tri-glycerides, containing at least one molecule of the true linoleic acid. It was understood that the minimum quantity of 300 mg/100 available Calories referred to linoleic acid.

58. The Committee decided that levels for fat should be expressed in grammes per 100 Calories and agreed to a proposal made by the delegation of the U.S.A. for minimum and maximum figures of 2 and 6 g for fat, respectively. The delegations of the Netherlands and the Federal Republic of Germany recommended a minimum of 3 g for fat. It was also agreed that these provisions would apply to both types of Infant Formula.

B) INFANT FORMULA BASED ON MILK

Vitamins

59. The Committee agreed to the same figures for vitamins as in the Infant Formula not based on milk with the exception of Vitamin K1 and biotin (Vitamin H) for which no provisions were included in the standard for products based on milk (see paras 33 - 39).

Choline

60. The Committee agreed that the provision for choline already accepted for Infant Formula not based on milk (see para.40) did not apply to milk based products.

Minerals

61. A proposal was made by the delegation of the U.S.A. to adopt the same provisions as for Infant Formula not based on milk with the exception of manganese, zinc, sodium, potassium and chloride. The delegation of the Federal Republic of Germany proposed also to delete reference to iodine and copper for products based on milk, as sufficient quantities of these elements were usually present in milk. Some delegations were of the opinion that the problem of iodine and copper content of milk should be dealt with on a national basis and that the addition of these minerals to milk was not necessary in all cases. The Committee agreed to the U.S.A. proposal that the decisions taken for Infant Formula not based on milk should apply with the exception of potassium, chloride, sodium, manganese and zinc (see paras 41-47).

Proteins

62. The Committee agreed that the decisions taken for Infant Formula not based on milk would also apply to milk based products (see paras 54-56).

Fat and Linoleate

63. The Committee agreed to apply the decision taken for products not based on milk (see paras 57-58).

C) ALL FORMULAE

Optional Ingredients

64. The delegation of the U.S.A. proposed to delete the square brackets in para. 4.2 and to add a new text which referred to (a) approval by local authorities when an optional ingredient was added, (b) regulating the amount of such an ingredient, (c) prohibition of nutritional claims on the label where such a nutrient was present in the product. This proposal was supported by several delegations. Other delegations were of

the opinion that this Committee was a competent body to judge whether the addition of optional ingredients was needed and whether a positive list of such ingredients should be developed. The delegation of Canada, supported by the delegation of the Federal Republic of Germany and the representative of IOCU, strongly opposed to the provision permitting optional ingredients which had not been shown scientifically to be necessary. The representative of IOCU was of the opinion that any scientific claim should be assessed by national authorities. It was suggested by the delegation of Switzerland to amend the text proposed by the delegation of the U.S.A. by simply requiring that the usefulness of these ingredients be scientifically established for such products. The delegations of the U.S.A. and Denmark were requested to draft a new proposal on the basis of the opinions expressed during the discussions. The Committee subsequently agreed to a new version of para. 4.2, which reads as follows:

"4.2 Optional Ingredients

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

4.2.2 The usefulness of these nutrients shall be scientifically shown.

4.2.3 When any of these nutrients is added, the formula shall contain significant amounts of these nutrients based on levels in human milk."

The delegation of Canada made a general reservation on the whole of section 4.2 concerning optional ingredients.

Clinical Trials

65. The delegation of Canada reiterated its proposal made at the fifth session to include (in para. 2.2 of the standard) a mandatory provision for clinical trials, in order to demonstrate the nutritional adequacy of the product (see ALINORM 71/26 para. 21). Several delegations supported this view. Other delegations recognized that such trials were necessary but that they were difficult to define and to apply uniformly on an international basis and would be better left to the discretion of national authorities. The Committee agreed that clinical trials should not appear in an international standard as a mandatory requirement at this stage, but should be left to the discretion of national authorities.

FOOD ADDITIVES

66. The Committee agreed to the decisions already taken as regards the food additives in foods for infants and children (see paras 12-13 of this Report).

CONTAMINANTS

Pesticide Residues

67. The delegations of Denmark and the U.S.A. were in favour of deleting the last sentence of para. 6.1 in square brackets, which referred to the product being practically free from pesticide residues. In the opinion of these delegations, this sentence was redundant. The delegation of the Federal Republic of Germany referred to the opinion expressed in the 15th Report of the Joint FAO/WHO Expert Committee on Food Additives and was in favour of retaining this sentence and to establish a special list of tolerances to be presented to this Committee at its seventh session. The delegation of Switzerland pointed out that the Codex Committee on Pesticide Residues was the

appropriate body to consider the question of pesticide residue tolerances. It was stated by the Secretariat that the Codex Committee on Pesticide Residues recommended tolerances for raw materials and, except for a few cases, not for the processed products.

68. The Committee agreed to delete the second sentence in square brackets and to retain the first sentence until such time as it was in a position to refer to specific tolerances for pesticide residue tolerances established for this product.

Other Contaminants

69. Some delegations were of the opinion that hormones and antibiotic substances in products for infants and children should be considered in the same way as pesticide residues and recommended that a single text should be written to cover all these contaminants. The Committee agreed that, in any event, the addition of antibiotics to the products would not be permitted. It was informed by the Secretariat that acceptable residue levels for antibiotics in food were being elaborated by the Codex Committee on Food Additives, but that further work had still to be done in this field. The question was also raised of residues of other contaminants referred to in the footnote. The Committee recognized that a provision for all these residues was needed and agreed with the recommendations regarding contaminants that appear in para. 2.3 of the Extract from the 15th Report of the Joint FAO/WHO Expert Committee on Food Additives (CX/FSDU 71/9). It also agreed that, at this stage, it would not be possible to lay down mandatory provisions to control contaminants pending further information on actual levels following good manufacturing practices and toxicological evaluation pertinent to young infants. It was accordingly agreed that the following text be included in the standard:

"Other Contaminants

The product shall be practically free from residues of hormones, antibiotics and other contaminants".

The delegation of France reserved its position regarding this wording and maintained its view that such a product should be made from selected raw materials, free from residues of oestrogens and antibiotics.

HYGIENE

70. On a proposal made by the delegation of Denmark, the Committee agreed that reference also be made to the Code of Hygienic Practice for Processed Meat, which was being elaborated by the Codex Committee on Processed Meat. It also agreed to incorporate the mandatory provision regarding micro-organisms and their toxins previously discussed (see para. 16).

DISTRIBUTION

71. The Chairman informed the Committee that doubts had been expressed as to whether Section 9. Distribution was appropriate to a standard and whether it would not be better placed in a statement on general principles. The Committee was informed that the same text was already included in the Proposed Draft General Principles for Foods for Infants and Children, held at Step 3 of the Procedure (ALINORM 70/26, Appendix V). It was pointed out by the delegation of Denmark that the principle of free distribution was already stated explicitly in the Rules of Acceptance of Codex Commodity Standards. The Committee decided to delete Section 9. Distribution from the standard, but to adopt the principle of free distribution as mentioned in that Section and to proceed further with the General Principles at a later session. The delegation of Italy wished to retain the Section on Distribution in each standard for reasons of national policy.

LABELLING

72. The representative of IOCU referred to their written comments on the labelling of foods for infants and children and was informed that this question of general interest would be discussed at a session of the Codex Committee on Food Labelling.

The Name of the Food

73. The Committee agreed to delete "Complete Infant Food" as the name of the product in para. 10.2.1 and the adjective "complete" in connection with "Infant Formula". It was pointed out that other suitable names to describe the true nature of the product were permitted under para. 10.2.1.

74. The delegation of the U.S.A. proposed to add a provision permitting the use on the label of a sentence such as "This formula meets Codex Alimentarius Standard for Infant Formula". The Committee was informed by the Secretariat that the question of Codex symbols or any mark on the label referring to conformity with Codex standards was a matter of general policy, which was already being dealt with by the Codex Alimentarius Commission. Some delegations were of the opinion that reference to conformity with Codex should be permitted. It was also pointed out that any true statement was permitted by the Recommended International General Standard for the Labelling of Prepackaged Foods. The Committee agreed not to anticipate a decision of the Codex Alimentarius Commission.

75. The delegation of Switzerland raised the point on whether for a product containing a given minimum quantity of milk protein or milk products reference could be made to "milk" according to the standard. The Committee was of the opinion that this provision was already covered by the Recommended International General Standard for the Labelling of Prepackaged Foods and there was no reason why products in conformity with the definition for "Infant formula based on milk" might not be given a name referring to the true nature of this product, provided that it did not contravene the Code of Principles concerning Milk and Milk Products.

76. The delegation of the Netherlands raised the question of advertising Infant Formula. According to the Committee's view, advertising was a matter of general policy which would be dealt with in due time by the Codex Alimentarius Commission and especially by the Codex Committee on Food Labelling.

Declaration of Nutritive Value

77. The question was raised by the delegation of the U.S.A. whether the declaration of nutritive value as provided for in 10.4.2 would not be better expressed per 100 Calories. Several delegations pointed out that this information was intended for the mother and, therefore, should follow the usage of the country where the product was sold. After discussion, the Committee agreed that the declaration per litre, quart or fluid ounce would be permitted as well as per 100 Calories. The Committee further agreed, in the light of its previous decisions, to amend the section to read:

"10.4.2A statement of the number of available Calories (or available kilo/joules) and total quantity of each vitamin, mineral, choline and any optional ingredient, as listed in paragraphs 4.1.2.1, 4.1.2.2, 4.1.2.3 and 4.2 of this standard, per 100 g of food as customarily or usually prepared for consumption, or alternatively per 1 litre or other measure customarily used in the country where the food is sold, shall appear on the label. In

addition, the declaration per 100 Calories (or per 100 kilojoules) is permitted".

STATUS OF THE STANDARD

78. The Committee agreed that the Draft Standard for Infant Formula contained in Appendix III of this Report be submitted to the Commission at Step 8 of the Procedure for the Elaboration of Codex Standards. Concerning food additives for technological purposes, it was envisaged that the Committee would finalize this matter, as outlined in paras 11 - 12 of this Report at its next session proposed to be held prior to the next session of the Commission. The delegation of the United Kingdom considered that the advancement of the standard was premature in view of its incompleteness with regard to food additives and the significant changes which had been made to its provisions after it had last been circulated to governments for comments.

PROPOSED DRAFT STANDARD FOR CANNED BABY FOODS (at Step 4)

79. The Committee discussed the Proposed Draft Standard for Canned Baby Foods contained in Appendix V of ALINORM 71/26 in the light of government comments contained in paper CX/FSDU 71/5. The following amendments and comments were made on the above standard:

TITLE

80. After a discussion of possible changes to the English, French and German titles of the standard, the Committee agreed that the title in English should remain unchanged while the French translation was suggested to read "Aliments homogénéisés (Baby Foods) en conserve".

SCOPE

81. The delegation of the United Kingdom proposed that the Committee should consider whether or not dehydrated baby foods should be included in the standard. The Committee was of the opinion that, in the absence of precise information about how far the requirements of the standard would apply to such a product, it would not be possible to take a decision. The delegation of the United Kingdom was, therefore, requested to prepare a paper for the next session on this subject, at which time the Committee would be in a position to consider dehydrated baby foods.

82. The Committee agreed to delete the description "in liquid or semi-liquid form" since it did not describe accurately the true nature of the consistency of the product. It did not agree with the proposal of the United Kingdom delegation to replace the words "processed by heat" by the words "processed by physical means", as heat treatment, with. or without aseptic filling, was the method generally used.

ESSENTIAL COMPOSITION AND QUALITY FACTORS

83. The delegation of Canada proposed that the word "suitable" be inserted before the words "nutritive material" in para. 3.1. The Committee agreed to this change. The question was raised whether iodized salt was included under the term "added salt". It was agreed that the use of iodized salt was subject to national legislation and that the standard made such a decision by governments possible.

84. Some delegations were of the opinion that the limit of 0.25 g/100 g for added salt should refer to the total salt present in the finished product and that the recommendation of the Joint FAO/WHO Expert Committee on Food Additives required clarification. Other delegations held the view that the recommendation of the Expert Committee clearly

referred to the addition of salt and that this corresponded to the recommendation of the U.S. National Academy of Sciences for 0.25 g/100 g added salt which will result in 1-40 mEq Na per 100 Calories in the product. The delegations of Australia, the Federal Republic of Germany, and the Netherlands were in disagreement with this opinion, as, in their view, the provision should refer to total salt content. It was pointed out by the delegation of Denmark that the provision for added salt would not be enforceable on the finished product. The Committee decided to delete the square brackets and request governments to comment specifically on this provision. It also agreed to request the Joint FAO/WHO Expert Committee on Food Additives to clarify its previous recommendation.

85. The delegation of Denmark proposed to amend paras 3.1 and 3.2 editorially in such a way as to combine these paragraphs since, in its opinion, both 3.1 and 3.2 provided for optional ingredients. The Committee agreed to the following amended text:

- "3.1.1 Canned Baby Food may be prepared from any suitable nutritive material that is used, recognized or commonly sold as an article or ingredient of food, including spices;
- 3.1.2 Food additives may only be added in accordance with Section 4.;
- 3.1.3 Vitamins and minerals may only be added in accordance with the legislation of the country in which the food is sold;
- 3.1.4 Salt may only be added in amounts not exceeding 0.25 g/100 g of the product".

The delegation of Italy was against the deletion of the specific reference to protein concentrates suitable for human consumption.

86. The Committee agreed to include reference to meat and poultry in para. 3.4, requiring that these ingredients shall equally be practically free from pieces of bones.

CONTAMINANTS AND HYGIENE

87. As regards paras 5 and 6, the Committee agreed to the text adopted for Infant Formula concerning contaminants and pathogenic micro-organisms and their toxins (see para 16).

PACKAGING, FILL OF CAN AND DISTRIBUTION

88. On the proposal of the delegation of the U.S.A., the Committee agreed to replace the words "suitable inert gases" by the words "suitable gases which do not react with the product" in para 7, so as clearly not to exclude nitrogen. It was also agreed to substitute the word "container" for "can" in para. 8 of the standard. As regards para. 9 of the standard, the same conclusions were reached as for Infant Formula, i.e. to delete it from the standard (see para. 71).

LABELLING

89. A number of delegations proposed amendments to para. 10.2.1 of the standard so as not to require the declaration of vitamins and minerals added. The delegation of Ghana was of the opinion that the declaration of the nutrient content of baby food would be highly desirable on the label or accompanying literature. The delegation of Denmark expressed the view that declaration of nutritive value should not be mandatory unless special dietary claims were made. Denmark further proposed the following text to paragraph 10.4.1 and 10.4.2 of the standard:

"10.4.1 If a statement implies that the product contains protein, vitamins or minerals the number of available Calories and the amount of protein, fat and carbohydrate supplied by a specified quantity of the food shall appear on the label.

10.4.2 If a statement implies that the product contains vitamins or minerals, the quantity supplied by a specified quantity of the food of each of the stated nutrients shall be declared on the label, and the quantity of each of the nutrients listed shall be not less, per 100 Calories, than the recommended intakes per 100 Calories of the respective nutrient".

In the opinion of Denmark these recommended intakes should be listed in an Appendix of this standard, but these values could for practical purposes be equal to the minimum quantity per 100 Calories laid down in sections 4.1.2.1 and 4.1.2.2 in the Standard for Infant Formula. The delegation of the Federal Republic of Germany was of the opinion that the question of vitamin requirements needed examination in relation to the older infant or child.

90. The delegation of the United Kingdom, supported by other delegations, proposed the deletion of para 10.4.1 concerning the declaration of nutritive value, unless special dietary claims were made. The Representative of the IOCU recommended the declaration of available Calories. The delegation of Canada pointed out that para. 10.4.2 was already covered by para. 3.2 of the standard and could, therefore, be deleted. The delegation of Italy was in favour of retaining para. 10.4.1 and to replace the word "present" by the word "added" in para. 10.4.2 in relation to vitamins and minerals. The delegation of France, supported by the delegation of the Federal Republic of Germany, was of the opinion that the declaration of available Calories, protein, carbohydrate and fat would be adequate. It was agreed that the question of declaration of nutritive value would be considered at the seventh session of this Committee when the general problem of advertising and claims will have been examined by the Codex Committee on Food Labelling.

91. The Committee agreed to keep para. 10.4.1 in square brackets and to include under 10.4.2 a statement that the declaration of vitamins and minerals should be subject to national legislation, as follows:

"A statement on the label of the quantity of each vitamin and mineral added to the food shall be subject to national legislation".

92. The delegation of the Federal Republic of Germany, supported by the Representative of IOCU, proposed that the date of manufacture or expiry should be given in clear. As the question of date marking was to be considered fully by the Codex Committee on Food Labelling, the Committee agreed that this question would not be discussed at this stage.

93. With reference to the decisions reached concerning the question of nitrate content, the delegation of the U.S.A. proposed the addition of the following text to para. 10.8 Information for Utilization of the standard:

"For canned beets (beetroot) and spinach the following statement shall appear on the label: 'Use after the age of 12 weeks. Once opened, do not store for later use'".

The Committee agreed with this amendment.

STATUS OF THE STANDARD

94. The Committee agreed that the Proposed Draft Standard for Canned Baby Foods contained in Appendix IV of this Report be submitted to the Commission at Step 5 of the Procedure for the Elaboration of Codex Standards.

PROPOSED DRAFT STANDARD FOR PROCESSED FOODS FOR INFANTS AND CHILDREN BASED ON CEREALS (at Step 4)

95. The Committee had before it Appendix VI of ALINORM 71/26 containing the above standard and document CX/FSDU 71/4 containing a synopsis of government comments. The following amendments were made to the standard and pointed raised:

TITLE

96. After some discussion on whether or not the title of the standard should be expanded to also include reference to components other than cereals, the Committee decided to retain the present title as a working title.

SCOPE

97. The Committee decided to make the consequential amendments to the Standard concerning the title of Infant Formula. It was suggested that the Scope section should refer to other ingredients, such as legumes (pulses). As these ingredients were already included in the section on composition, the Committee decided to make no such change to the Scope section but agreed to the proposal of the delegation of Denmark to delete reference to the use of this product as a "supplement to human milk or Infant Formula".

DESCRIPTION

98. The Committee agreed to an amendment proposed by the delegation of Norway given below and also decided to include a suitable phrase in Section 2.1 to indicate that pasta was only one example of preparations which required cooking in boiling water: "Dry cereals for infants and children are foods based on cereals and/or legumes (pulses), processed to a low moisture content and so fragmented as to permit reconstitution with water, milk or Infant Formula or, as in the case of preparations such as pasta, used after cooking in boiling water".

99. On the proposal of the delegation of Italy, the Committee agreed to insert a new Section 2.3 defining pasta as follows:

"2.3 Pastas are foods prepared from flours of cereals suitable for the weaning period. They shall contain at least 4% m/m on a dry basis of protein of animal origin."

ESSENTIAL COMPOSITION AND QUALITY FACTORS

100. The delegation of France was of the opinion that provision should be made for the process of dextrination in this Section. The Committee agreed to include the various modified starches which have been found suitable for use in Infant Foods by the Joint FAO/WHO Expert Committee on Food Additives, in order to permit the breakdown of starch to dextrans. The delegation of the Federal Republic of Germany proposed that a provision be made for a minimum of 12% m/m water soluble carbohydrates. Proposals were made for the inclusion of various optional ingredients in the Section 4.2 such as: cocoa (after eight months of age and at a maximum of 3%), amino acids as in the standard for Infant Formula, vegetables, eggs, honey, enzymes, meat, salt (0.25 g/100 g on a reconstituted basis) and potatoes.

101. As regards vitamins and minerals, provided for in para. 4.2.2, the delegation of Norway made the same recommendations as in connection with the standard on Canned Baby Foods.

102. After some discussion it was decided not to provide for a minimum protein content.

103. On the suggestion of the delegation of Norway the Representatives of FAO and WHO agreed to prepare a paper for the next session, on vitamins, minerals and protein contents for products based on cereals.

104. In section 4.6 it was agreed that a slight editorial change be made to bring the wording into conformity with the standard on Infant Formula.

CONTAMINANTS

105. It was decided that this Section should be redrafted in the same way as for the standards on Infant Formula.

DISTRIBUTION

106. It was agreed to delete this Section (see para. 7.1).

WEIGHTS AND MEASURES

107. The delegation of the U.S.A. proposed a minimum fill of 70% for dry cereal in powder and was of the opinion that a method of measuring minimum fill should be developed. The delegation of Norway proposed a figure of 80%. The Committee agreed to delete this Section as it would not be possible to set one figure for the variety of products covered by this standard.

LABELLING

108. The Committee adopted the following amendment to Section 11.1 to permit any suitable name describing the true nature of the product: "... or any appropriate designation indicating the true nature of the food, in accordance with national legislation".

109. The Committee agreed to insert the word "added" before the words "vitamins and minerals" in Section n.2.1. It was also decided to amend Section 11.4.2 as in the Standard for Canned Baby Food. With regard to Section 11.7, the same comments apply as in the case of Canned Baby Food (see para. 92). The Committee agreed to delete reference to moisture in the declaration of nutritive value (Section 11.4.1) in view of the fact that the products covered by this standard were of a very low moisture content.

STATUS OF THE STANDARD

110. The Committee agreed that the Proposed Draft Standard for Processed Foods for Infants and Children Based on Cereals contained in Appendix V of this Report be returned to Step 3 of the Procedure for the Elaboration of Codex Standards. The Secretariat was requested to redraft the standard in the light of the discussions and decisions of the Committee, the written comments received from the governments and the Conference Room document submitted by the delegation of Italy dealing with flours, biscuits and rusks and pasta.

PROPOSED DRAFT STANDARD FOR FOODS FOR USE IN A DIET FOR DIABETICS, FOODS WITH LOW CARBOHYDRATE CONTENT AND GLUTEN-FREE FOODS (at Step 4)

111. The Committee decided not to discuss the above standards until the paper on labelling and claims to be prepared by the delegation of Australia was available; this would also cover the question of claims concerning these categories of foods for special dietary uses. The priority for the consideration of these standards is discussed in para.124 (c). The Secretariat was requested to provide to the delegation of Australia any pertinent information and all previous government comments on these standards.

METHODS OF ANALYSIS IN STANDARDS FOR FOODS FOR INFANTS AND CHILDREN

112. At its fourth session, the Codex Committee on Foods for Special Dietary Uses had agreed that methods of analysis for determining moisture, protein, fat, fiber, ash, minerals, vitamins in infant foods should be considered by the Codex Committee on Methods of Analysis and Sampling on the basis of the "Suggested Guidelines for Sampling Identification and Analytical Procedures for Food" prepared by the U.S. government authorities, together with other methods of analysis already being used in different laboratories for foods for dietary uses. The Committee had also agreed that for certain nutrients such as amino-acids, vitamin B₆ etc., methods of analysis should be developed (ALINORM 70/26, paras 19, 20, 21).

113. Subsequently, comments and proposals had been received from governments and summarized in paper CX/MAS/70/3/6 (plus Addendum 1) which was distributed at the sixth session of the Codex Committee on Methods of Analysis and Sampling. At that session, the Codex Committee on Methods of Analysis and Sampling considered that methods of analysis for foods for special dietary uses (e.g. foods for infants and children) should be given priority at its seventh session (ALINORM 71/23, para. 64).

114. At its sixth session, the Codex Committee on Methods of Analysis and Sampling had also agreed to a proposal made by the delegation of the U.S.A. to circulate a number of methods of analysis for foods for infants and children which had been studied in the U.S.A. As their distribution would have involved the reproduction of a whole book of methods, they were sent to the heads of delegations only (ALINORM 71/23, para. 65).

115. The Committee had before it a paper prepared by the Secretariat (CX/FSDU 71/6) giving the present status of the above methods of analysis and including comments and new proposals made by governments. This paper also contained a list of criteria for which no method had as yet been proposed.

116. The Secretariat informed the Committee that a paper on methods of analysis for the determination of protein quantity and quality had been prepared, but not distributed as it was based on the report of the FAO/WHO Expert Group on Energy and Protein Requirements which was still in draft form. The Committee agreed that both physico-chemical and microbiological methods were needed for the determination of the chemical score of the protein and that biological tests were also necessary. As regards the use of NPU and/or PER, several delegations were of the opinion that both tests should be used as referee methods to verify the quality of the protein. However, the Committee agreed to give preference to PER, as it was easier to perform, and, as mentioned by the U.S. delegation, it gave results for Infant Formulae more closely correlated with clinical trials involving infants. It was understood that PER might be replaced in some years by NPU or other tests at present under consideration. It was agreed to ask the FAO/WHO/ UNICEF Protein Advisory Group's opinion on the methods to be used for biological determination of protein quality.

117. The delegation of France pointed out that those methods should be chosen which would guarantee repeatability, precision, low cost and speed. As methods of analysis for foods for special dietary uses covered a wide variety of foods, often problems occurred owing to the particular composition of the product, which could not necessarily be solved by methods of analysis for foods generally. As regards the determination of folic acid and linoleic acid, the delegation of Canada proposed to provide the Secretariat with new methods which were to be preferred and presented to the Codex Committee on Methods of Analysis and Sampling for endorsement. The Committee agreed with the Canadian proposal. The U.S. delegation drew the Committee's attention to analytical methods, including chemical and microbiological methods, being elaborated by the U.S. Infant Formula Council. Copies of these methods, which would be ready by March 1972, could be made available to this Committee as well as to the Codex Committee on Methods of Analysis and Sampling in due time.

118. The Committee agreed to refer the proposals made in CX/FSDU 71/6 together with comments on them to the Codex Committee on Methods of Analysis and Sampling for examination and decision regarding individual endorsements. It was further agreed that methods of analysis in Standard for Infant Formula should be given first priority at the next session of the Codex Committee on Methods of Analysis and Sampling.

METHODS OF ANALYSIS IN STANDARD FOR SPECIAL DIETARY FOODS WITH LOW SODIUM CONTENT

119. The Committee had before it a document prepared by the Secretariat (CX/FSDU 71/7) which includes the decisions taken by the Codex Committee on Methods of Analysis and Sampling, at its sixth session as well as new proposals regarding methods of analysis for these products. A new method for the determination of sodium content in foods, including low-sodium foods, was proposed by the delegation of the U.S.A. (CX/FSDU 71/17). The Committee agreed to send these new proposals to the Codex Committee on Methods of Analysis and Sampling for examination and endorsement at the seventh session of that Committee.

120. Referring to the proposed method for the determination of choline, based on nitrogen determination, the delegation of the United Kingdom pointed out that some source of error could arise when the product contained flour or other nitrogen-containing diluents, as provided for in the standard.

SAMPLING

121. The Committee had before it a paper prepared by the French delegation regarding sampling plans applicable to foods for special dietary uses (CX/FSDU 71/8). This delegation informed the Committee that its proposal was a first attempt which had to be further elaborated both on the basis of inspection by attributes, in the case of one single determination and by defects per 100 units in the case of several determinations. These proposed sampling plans were elaborated with an AQL of 2.5, but other AQLs could be introduced at a further stage. The delegation of France emphasized the need to elaborate sampling plans which include a constant probability of acceptance as regards AQL, this being an important factor in estimating the cost of production of a food which will be submitted to inspection by attributes.

122. The delegation of Denmark referred to the Sampling Plans for Prepackaged Foods (ALINORM 69/27) adopted by the Codex Alimentarius Commission for a variety of Codex Standards, the main difference of which was in the AQL of 6.5. It pointed out

that within the Codex Programme, statistical sampling plans had so far only been applied to quality factors, such as colour, flavour and texture, and that it had not yet been considered whether other types of requirements were suited for control by statistical sampling plans. Preparatory work along the lines recommended by the Commission at its eighth session (para. 90 of the Report) was therefore needed before any decisions could be taken regarding the suitability of sampling plans in connection with the provisions in Standards for Foods for Special Dietary Uses.

123. The delegation of the United Kingdom supported the Danish proposal and referred to a paper on Sampling (ALINORM 71/17) discussed at the eighth session of the Codex Alimentarius Commission, which pointed out that sampling plans had to be shown to be relevant to particular standards by identifying specific criteria to which they could apply. Defectives had to be defined as products not quite in conformity with the standard but, nevertheless, acceptable to the consumer. For example, would it be acceptable if 6.5% or even 2.5% of foods described as gluten-free, in fact, contained gluten? The delegation of the United Kingdom was of the opinion that these questions should be considered before looking at mathematical aspects. The delegation of the U.S.A. supported this view. The delegation of France also supported the opinion of the United Kingdom and underlined that the AQL of 2.5 had been chosen as a compromise and that, if the AQL were lowered, an increase in the sample size would be necessary. Several delegations expressed the opinion that statistical sampling plans could best be used at the entry of shipments into a country. They could not apply at the retail level.

124. A proposal was made by the Secretariat to prepare a working paper on this subject. The Canadian delegation offered to assist in the drawing up of a questionnaire. The paper, based on replies obtained on the questionnaire, would be sent to governments for comments and examined at a future session of this Committee. It was also proposed to ask the Codex Alimentarius Commission to provide for the help of a consultant who would be requested to make proposals regarding the selection of criteria according to their nutritional or other purposes, medical aspects of defects and the possibility of use of sampling plans for health criteria. The Committee was in general agreement with these proposals.

OTHER BUSINESS

125. The Committee, in discussing its future programme of work, made the following decisions:

- (a) The Collaborating Countries mentioned in para. 13 should meet just prior to the seventh session of the Committee in order to discuss the working paper on technological additives to be prepared by Canada and the U.S.A. and report to the Committee;
- (b) Consideration of the above paper should be given highest priority on the agenda and sufficient time be allowed for full discussion;
- (c) Consideration of the subjects of foods for use in a diet for diabetics, foods with low carbohydrate content and gluten-free foods, should also be given a high priority in the agenda in conjunction with the paper on labelling and claims to be prepared by the delegation of Australia.
- (d) In reply to the delegation of Denmark, the Chairman explained that the Proposed Draft Standard for Consumer Packaged Protein Foods had been omitted from the agenda because of pressure of other work and would be

considered later. The delegation of the United Kingdom expressed its doubts about the need for such a standard.

- (e) With regard to the procedure envisaged for dealing with the technological additives, the seventh session should be held prior to the ninth session of the Codex Alimentarius Commission.

DATE OF THE NEXT SESSION

126 The Committee agreed with the suggestion of the Chairman that it would be convenient for overseas delegates if the next session were held from 9 to 13 October 1972.

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LIST OF DOCUMENTS

<u>Document No.</u>	
CX/FSDU 71/1	Provisional agenda
CX/FSDU 71/2 plus Add. 1	Food Additives (in foods for infants and children)
CX/FSDU 71/3	Bacteriological requirements in standards for foods for Infants and Children
cx/FSDU 71/4	Synopsis of government comments on standard for processed foods for Infants and Children based on Cereals
CX/FSDU 71/5	Synopsis of government comments on standard for Canned Baby Foods
CX/FSDU 71/6	Methods of analysis in standards for Foods for Infants and Children
CX/FSDU 71/7	Methods of analysis in standard for Foods with Low Sodium Content
CX/FSDU 71/8	Explanatory note on Sampling Plans for Foods for Special Dietary Uses
CX/FSDU 71/9	Extract from the 15th Report of Expert Committee on Food Additives
CX/FSDU 71/10	Proposed draft standard for basic preparations for teat-feeding
CX/FSDU 71/11	Synopsis of comments on nitrates in Spinach
CX/FSDU 71/13	Fluorine content of Complete Infant Food
CX/FSDU 71/14 plus Add. 1 & 2	Synopsis of comments on Complete Infant Food
CX/FSDU 71/15	List of documents (Provisional)
CX/FSDU 71/16	Milk Substitutes (by Dr. N. de Heer)
CX/FSDU 71/17	Proposed general flame photometric method for the determination of sodium in foods
CX/FSDU 70/11 plus Add. 1	Nitrates and ascorbic acid in Spinach
CX/FSDU 70/10 plus Add. 1 & 2	Synopsis of comments on foods for use in a diet for diabetics, Foods with low carbohydrate content and Gluten-free foods
ALINORM 70/26	Report of the fourth session of the Codex Committee on Foods for Special Dietary Uses
ALINORM 71/26	Report of the fifth session of the Codex Committee on Foods for Special Dietary Uses
MDS 70/19	Processed infant foods, imitation milks

CX/FSDU 71/18

Protein-rich mixtures for use as weaning food (PAG
Bulletin)

DRAFT STANDARD FOR INFANT FORMULA

(Submitted to the Commission at Stop 3 of the Procedure
for the Elaboration of Worldwide Standards)

1. SCOPE

This standard applies to food in liquid or powdered form intended for use as a substitute for human milk in meeting the normal nutritional requirements of infants. It also applies to those foods intended for infants with special nutritional requirements, except with regard to other provisions concerning these special requirements.

2. DESCRIPTION

2.1 Infant formula, 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 directions for use.

2.3 The product is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.

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" (1 kilojoule is equivalent to 0.239 kilocalories).

3.3 "Infant formula based on milk" is a formula prepared using whole milk or skimmed milk as such or with minor modification to supply not less than 90% m/m of the total protein content of the product. Products based on non-milk proteins or proteins separated from milk are not regarded as "Infant formula based on milk".

4. ESSENTIAL COMPOSITION AND QUALITY FACTORS

4.1 Essential Composition

4.1.1 Infant formula is a product based on milk of cows or other animals and/or on other edible constituents of animal, including fish, or plant origin, which have been proved to be suitable for infant feeding.

4.1.2 Infant formula shall contain, per 100 available Calories (or 100 kilojoules) of intake, the following minimum and maximum levels of vitamins, minerals in an available form, choline, protein, fat and linoleate:

4.1.2.1 Infant formulae not based on milk

a) Vitamins other than vitamin E	<u>Amounts per 100 available Calories</u>		Amounts per 100 available kilojoules	
	<u>Minimum</u>	<u>Maximum</u>	<u>Minimum</u>	<u>Maximum</u>
Vitamin A	250 I.U. or	750 I.U. or	60 I.U. or	180 I.U.

	75 mcg expressed as retinol	225 mcg expressed as retinol	18 mcg expressed as retinol	or 55 mcg expressed as retinol
Vitamin D	40 I.U.	100 I.U.	10 I.U.	24 I.U.
Ascorbic Acid (Vitamin C)	8 mg	(none (specified	1.9	(none (specified
Thiamine (Vitamin B ₁)	25 mcg	"	6 meg	"
Riboflavin (Vitamin B ₂)	60 mcg	"	14 mcg	"
Nicotinamide	250 mcg	"	60 mcg	"
Vitamin B ₆	50 mcg	"	12 mcg	"
Folic Acid	4 mcg	"	1 mcg	"
Pantothenic Acid	300 mcg	"	70 mcg	"
Vitamin B ₁₂	0.15 mcg	"	0.04 meg	"
Vitamin K ₁	8 mcg	"	1.9 meg	"
Biotin (Vitamin H)	5 mcg	"	1.2 mcg	"
b) Vitamin E: minimum of 1 I.U. per g linoleic acid	-	"	-	"
c) Minerals		"		
Sodium (Na)	20 mg	80 mg	5 mg	20 mg
Potassium (K)	80 mg	200 mg	20 mg	50 mg
Chloride (Cl)	60 mg	150 mg	15 mg	35 mg
Calcium (Ca) */	50 mg	none specified	12 mg	none specified
Phosphorus (P) */	25 mg	"	6 mg	"
Magnesium (Mg)*	6 mg	"	1.4 mg	"
Iron (Fe)	1 mg	"	0.25 mg	"
Iodine (I)	5 mcg	"	1.2 mcg	"
Copper (Cu)	60 meg	"	14 mcg	"
Zinc (Zn)	0.5 mg	"	0.12 mg	"
Manganese (Mn)	100 mcg	"	24 mcg	"

*/The Ca:P ratio shall be not less than 1.2 and not more than 2.0.

d) Choline 12 mg 3 mg

e) Protein (per 100 available Calories) ^{1/}

i) Shall not be less than 1.8 g protein of nutritional quality equivalent to that of whole egg protein or a greater quantity of other protein in proportion to its biological value. The quality of the protein shall not be less than 70% of that of whole egg protein. The total quantity of protein

shall not be more than 4 g. The minimum value set for quality and the maximum for quantity of the protein may be modified by national authorities according to their own regulations and/or local conditions.

ii) Isolated amino acids may be added to infant formula only to improve its nutritional value for infants, Essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only natural L forms of amino acids may be used.

f) Fat and Linoleate

The product shall contain linoleate (in the form of tri-glycerides containing linoleic acid) at a level not less than 300 mg expressed as linoleic acid per 100 available Calories (or 70 mg per 100 available kilojoules) and fat at a level not less than 2 g and not more than 6 g per 100 available Calories (or not less than 0.5 g and not more than 1.5 g Per 100 available kilojoules).

4.1.2.2 Infant formulae based on milk

a) Vitamins

The minimum and maximum amounts per 100 available Calories (or 100 available kilojoules) of vitamins listed in sub-section 4.1.2.1 a) and b) shall apply, with the exception of Vitamin K₁ and biotin (Vitamin H).

b) Minerals

The minimum and maximum amounts per 100 available Calories (or 100 available kilojoules) of minerals listed in sub-section 4.1.2.1 c) shall apply, with the exception of sodium, potassium, chloride, manganese and zinc.

c) Proteins

The provision laid down in sub-section 4.1.2.1 e) shall apply.

d) Fat and Linoleate

The provision laid down in sub—section 4.1.2.1 f) shall apply.

4.2 Optional Ingredients

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

4.2.2 The usefulness of these nutrients shall be scientifically shown.

^{1/} Amounts per 100 available kilojoules: multiply all figures given per 100 available Calories by 0.239.

4.2.3 When any of these nutrients is added, the formula shall contain significant amounts of these nutrients, based on levels in human milk.

4.3 Consistency and Particle Size

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

4.4 Purity Requirements

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

4.5 Specific Prohibition

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

5. FOOD ADDITIVES

(List of food additives to be established)

6. CONTAMINANTS

6.1 Pesticide Residues

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

6.2 Other Contaminants

The product shall be practically free from residues of hormones, antibiotics and other contaminants.

7. HYGIENE

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

- a) shall be free from pathogenic micro-organisms, and
- b) shall not contain any substances originating from micro-organisms in amounts which may be toxic.

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

7.3 The ingredients of animal origin shall be obtained from animals in good health, or should be obtained from such animals as have been slaughtered and prepared in conformity with the Code of Hygienic Practice for Fresh Meat (this Code is being elaborated by the Codex Committee on Meat Hygiene) and the Code of Hygienic Practice for Processed Meat Products (this Code is being elaborated by the Codex Committee on Processed Meat Products).

7.4 Fish ingredients shall be the products of edible species of fish, which should be handled and prepared in conformity with the Codes of Hygienic Practice for Fish and Fishery Products (these Codes are being elaborated by the Codex Committee on Food Hygiene).

8. PACKAGING

8.1 The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. When in liquid form the product shall be packed in hermetically sealed containers. Suitable gases which do not react with the product and carbon dioxide may be used as packing media.

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

9. LABELLING

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

9.2 The Name of the Food

9.2.1 The name of the product shall be either "infant formula" or any appropriate designation indicating the true nature of the food, in accordance with national usage.

9.2.2 In addition, a product which contains neither milk nor any milk derivative shall be labelled "free from milk and milk products".

9.3 List of Ingredients

9.3.1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and added minerals, these ingredients need not be listed in such an order.

9.3.2 The specific and not the class name shall be declared for ingredients of animal or plant origin and for food additives.

9.4 Declaration of Nutritive Value

9.4.1 A statement of the levels of moisture, protein, fat, available carbohydrates, mineral matter and crude fibre supplied by a specified quantity of the food as customarily or usually prepared for consumption shall appear on the label. Alternatively, this declaration may be made in percent by weight or as weight per unit volume.

9.4.2 A statement of the number of available Calories (or available kilojoules) and total quantity of each vitamin, mineral, choline and any optional ingredient as listed in paragraphs 4.1.2.1, 4.1.2.2, 4.1.2.3 and 4.2 of this standard, per 100 g of food as customarily or usually prepared for consumption, or alternatively, per 1 litre or other measure customarily used in the country where the food is sold, shall appear on the label. In addition, the declaration per 100 Calories (or per 100 kilojoules) is permitted.

9.5 Net Contents

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

9.6 Name and Address

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

9.7 Country of Origin

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

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

9.8 Lot Identification

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

9.9 Information for Utilization

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

10. 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).

(To be further elaborated along the lines indicated and on the basis of the documents mentioned in paras 110 to 122 of this report. The endorsed methods of analysis will appear in the report of the 7th session of the Codex Committee on Methods of Analysis and Sampling, ALINORM 72/23).

PROPOSED DRAFT STANDARD FOR CANNED BABY FOODS

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

1. SCOPE

1.1 Canned baby food is a food 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.

1.2 Canned baby food is so processed by heat before or after being sealed in the container as to prevent spoilage.

2. DEFINITIONS

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

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

2.3 The term "Calorie" means a kilocalorie or "large calorie" (1 kilojoule is equivalent to 0.239 kilocalories).

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Composition

3.1.1 Canned baby food may be prepared from any suitable nutritive material that is used, recognized or commonly sold as an article or ingredient of food, including spices;

3.1.2 Food additives may only be added in accordance with Section 4;

3.1.3 Vitamins and minerals may only be added in accordance with the legislation of the country in which the food is sold;

3.1.4 Salt may only be added in amounts not exceeding 0.25 g/100 g of the product.

3.2 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.

3.3 Purity Requirements

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

3.4 Specific Prohibition

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

4. FOOD ADDITIVES

(List of food additives to be established)

5. CONTAMINANTS

5.1 Pesticide Residues

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

5.2 Other Contaminants

The product shall be practically free from residues of hormones, antibiotics and other contaminants.

6. HYGIENE

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

- a) shall be free from pathogenic micro-organisms, and
- b) shall not contain any substances originating from micro-organisms in amounts which may be toxic*

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

6.3 The ingredients of animal origin shall be obtained from animals in good health, or should be obtained from such animals as have been slaughtered and prepared in conformity with the Code of Hygienic Practice for Fresh Meat (this Code is being elaborated by the Codex Committee on Meat Hygiene) and the Code of Hygienic Practice for Processed Meat Products (this Code is being elaborated by the Codex Committee on Processed Meat Products).

6.4 Fish ingredients shall be the products of edible species of fish which should be handled and prepared in conformity with the Codes of Hygienic Practice for Fish and Fishery Products (these Codes are being elaborated by the Codex Committee on Food Hygiene).

7. PACKAGING

The product shall be packed in hermetically sealed containers which will safeguard the hygienic and other qualities of the food. Suitable gases which do not react with the product and carbon dioxide may be used as packing media.

8. FILL OF CONTAINER

The fill of container shall be not less than 85% ¹ for products weighing less than 250 g (8 oz.) and not less than 90% ^{1/} for products weighing more than 250 g (8 oz.) of the water capacity of the container. The water capacity of the container is the volume of distilled water at 200 c which the sealed container will hold when completely filled ^{2/}.

9. 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):

9.1 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.

9.2 List of Ingredients

9.2.1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and added minerals, these ingredients need not be listed in such an order.

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

9.3 Declaration of Nutritive Value

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

9.3.2 A statement on the label of the quantity of each vitamin and mineral added to the food shall be subject to national legislation.

9.4 Net Contents

The net contents of Canned baby food shall be declared either by weight or volume according to consistency^{3/}. 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.

^{1/} Note by Secretariat: should be v/v.

^{2/} Note by Secretariat: this wording has been used in Codex standards for fruit juices and for processed fruits and vegetables.

^{3/} Note by Secretariat: editorially amended in the light of the decisions recorded in para 82 of this Report.

9.5 Name and Address

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

9.6 Country of Origin

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

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

9.7 Lot identification

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

9.8 Information for Utilization

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

9.8.2 For canned beets (beetroot) and spinach, the following statement shall appear on the label: "Use after the age of 12 weeks. Once opened, do not store for later use".

10. 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):

(To be developed)

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

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

1. SCOPE

Processed Foods for Infants and Children Based on Cereals are foods intended for use during the weaning period of normal infants or to supplement the diet of children.

2. DESCRIPTION

2.1 Dry cereals for infants and children are foods based on cereals and/or legumes (pulses), processed to a low moisture content and so fragmented as to permit reconstitution with water, milk or Infant Formula or, as in the case of preparations such as pasta, used after cooking in boiling water or other liquids.

2.2 Simple or composite cooked flours of cereals are products which have been cooked in a way that distinguishes them as follows:

2.2.1 Partially cooked flours - which require a second short cooking before use.

2.2.2 Cooked flours as such or for immediate use - which need no further cooking before use.

2.2.3 Dextrinised flours - which are flours in which the starch has been partially transformed into dextrin by heat treatment.

2.3 Enzyme treated flours of cereals are flours prepared with enzymes, the starch of which has been transformed into dextrin, maltodextrin, and maltose.

2.4 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. The biscuits may also be "milk biscuits", based primarily on milk products.

2.5 Pastas are foods prepared from flours of cereals suitable for the weaning period,

3. DEFINITIONS

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

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

3.3 The term "Calorie" means "kilocalorie" or "large calorie" (1 kilojoule is equivalent to 0.239 kilocalories).

4. ESSENTIAL COMPOSITION AND QUALITY FACTORS

4.1 Essential Composition

4.1.1 Dry cereal, rusks and biscuits are prepared primarily from one or more flours of cereals, such as wheat, rice, barley, oat, maize, millet, sorghum and buckwheat and/or legumes (pulses) and also, sesame, arachis and soybean (defatted or low fat).

4.1.2 Milk biscuits consist primarily of whole milk solids, or other solids of milk, with the addition of one or more flours.

4.2 Optional Ingredients

4.2.1 In addition to the raw materials listed under 4.1, the following ingredients may be added:

- protein concentrates and other high protein ingredients suitable for consumption by infants and children; isolated amino acids may be added only to improve the nutritional value of the product. Essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only natural L forms of amino acids may be used;
- milk and milk products;
- eggs;
- meat;
- fats and oils;
- fruits and vegetables;
- nutritive sweeteners;
- malt;
- honey;
- cocoa (only in products to be consumed after 8 months of age, and at the maximum level of 3 percent m/m on a dry basis);
- potatoes;
- starches, including enzyme modified starches and starches treated by physical means;
- ingredients for which Codex standards exist and complying with the provisions of these standards.

4.2.2 Salt, including iodized salt, may also be added in amounts not exceeding 0.25 g/100 of the product.

4.2.3 Vitamins and minerals may only be added in accordance with the legislation of the country in which the food is sold. ¹

4.3 Quality Factors

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

4.3.2 The moisture content of the products shall be reduced to a level at which micro-organisms cannot multiply.

4.3.3 Processed foods for infants and children based on cereals shall contain, on a dry basis, not less than 12 percent m/m of water-soluble carbohydrates.

4.3.4 Rusks, biscuits and pastas shall contain, on a dry basis, not less than 4 percent m/m of protein of animal origin ^{1/}.

4.3.5 The dextrin and maltodextrin content of biscuits intended for consumption by infants less than 6 months of age shall be not less than 50 percent m/m of the starch content, calculated on a dry basis.

4.4 Consistency and Particle Size

When reconstituted according to the label directions for use, dry cereal is of a soft, smooth texture, free of lumps and chewable particles and is suitable for spoon feeding of infants and children. It does not require and does not encourage chewing before being swallowed. Rusks and biscuits may be used in the dry form so as to permit and encourage chewing or they may be used and promoted for use in a liquid form, by mixing with water or Infant Formula, that would be similar in consistency to dry cereals.

4.5 Specific Prohibition

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

5. FOOD ADDITIVES

5.1 Acid-treated starches

5.2 Alkali-treated starches

5.3 Enzyme preparations (see Codex List 'O' CX/FA 72/2)
(List of other food additives to be established).

6. CONTAMINANTS

6.1 Pesticide Residues

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

^{1/} See paras 99, 102 and 103 of this Report.

6.2 Other Contaminants

The product shall be practically free from residues of hormones, antibiotics and other contaminants.

7. HYGIENE

7.1 When tested by appropriate methods of sampling and examination the product

- a) shall be free from pathogenic micro-organisms and
- b) shall not contain any substances originating from micro-organisms in amounts which may be toxic.

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

8. PACKAGING

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

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

9. 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).

9.1 The Name of the Food

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

"Pastas for Infants (and/or Children)", or any appropriate designation indicating the true nature of the food, in accordance with national legislation.

9.2 List of Ingredients

- 9.2.1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and added minerals these ingredients need not be listed in such an order.
- 9.2.2 The specific and not the class name shall be declared for ingredients and food additives.

9.3 Declaration of Nutritive Value

- [9.3.1 A statement of the number of available Calories (or available kilojoules) and the percent weight by weight, or weight per unit volume of protein fat, available carbohydrates, mineral matter and crude fibre contained in the food shall be declared on the label].
- 9.3.2 A statement on the label of the quantity of each vitamin and mineral added to the food shall be subject to national legislation.

9.4 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.

9.5 Name and Address

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

9.6 Country of Origin

- 9.6.1 The country of origin of the food shall be declared if its omission would mislead or deceive the consumer.
- 9.6.2 When the food undergoes processing in a second country which changes its nature, the country in which the processing is performed shall be considered to be the country of origin for the purpose of labelling.

9.7 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.

9.8 Information for- Utilization

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

10. 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). (To be developed).

PROTEIN-RICH MIXTURES FOR USE AS WEANING FOODS

This guideline, Guideline 8, is a recommendation for the composition of weaning foods, including specifications for levels of protein, calories, fats, vitamins and minerals. Physical characteristics, flavour, taste and packaging requirements are also covered. The guideline was adopted by the PAG at its 18th Meeting.

The serious and widespread problem of malnutrition during the weaning period in tropical and sub-tropical countries and the inability of lower income groups to purchase sufficient animal protein foods or high-cost special children's food³ calls for marketing of nutritious low-cost mixtures based mainly on vegetable proteins with admixture of other proteins where appropriate. In addition to low cost, satisfactory tolerance and acceptability on the part of the child and acceptability to the adult(s) responsible for providing the child's food are important factors. Of paramount importance, however, if the primary purpose is to be achieved, is the maintenance of minimal nutritional and sanitary standards, even though this may mean constraints in relation to cost.

Ideally, the protein food mixture should be a supplement which is patterned in accordance with the child's diet in the home and fills the gaps with respect to calories, proteins and other nutrients. In order to be certain that the minimal needs are covered even under unfavourable dietary conditions, the weaning food mixture should provide protein, vitamins and minerals corresponding to recommended allowances when consumed at the recommended level. The recommended daily intake of the supplement is usually of the order of 100 g dry weight with a protein content of no less than 20%. If the recommended daily intake is less than 100 g the content of protein and other nutrients should be correspondingly higher. These products should not be recommended for infants below six months of age unless they are specifically treated to ensure complete digestibility.

1. Level of protein

The provision of adequate protein generally presents the most difficult problem during the weaning period and special attention should be given to the quality and quantity of protein in supplementary weaning foods. The NPU value of the protein should be not less than 60 and preferably near 65 and correspondingly the PER, not less than 2.1 and preferably above 2.3 (casein = 2.5; the value for casein varies with different casein products and the strain of rat used), With protein of this nutritional quality, the level of protein in the supplementary food should be at least 20%. If the quality of the protein is higher the quantity can be reduced accordingly.

2. Calories

The mixture should provide as many calories as possible and this may be achieved by adding fat. Poorly digestible carbohydrate, including fibre, should be held to a practical minimum. The starchy portion of mixtures may be modified through various combinations of heat and mechanical processing or enzyme treatment, so that when prepared with water and ready for feeding, the food has minimal bulk, maximal protein availability and maximum calorie density.

3. Fat

Present knowledge does not permit specifying with certainty a dietary allowance for fat. Even so, it will be of great advantage to incorporate into protein-rich food mixtures as much fat as is technologically feasible without compromising the keeping qualities of the food. The fat will increase the calorie density of the mixture. A level of fat contributing 25% of calories to the mixture would be desirable. The linoleic acid content should be at least 1%. Without any addition of extra fat, the protein food may contain nearly 2 to 3% fat derived from the basic ingredients used in the formula. If the cost, including the need for special packaging to ensure adequate shelf life, is found prohibitive, the addition of food fat or oil when the mixture is prepared for consumption is recommended as a possible approach.

4. Vitamins and minerals

Protein-rich mixtures should be fortified with vitamins and minerals sufficient to satisfy recommended allowances. Special attention should be given to vitamin A, riboflavin, niacin, folate, vitamin B₁₂, ascorbic acid, vitamin D, calcium, iron and iodine. Minimal quantities of various vitamins and minerals as proposed in Section 6 are recommended. However, some adjustment in the light of local nutritional problems may be considered. There may be no need to provide additional vitamins or minerals as medication to the child if the high protein mixture is fed at recommended levels.

5. Physical characteristics, flavour and taste

Acceptability of formulated foods can be enhanced by modern industrial processing such as pre-cooking and roller drying, extrusion cooking and enzyme treatment. The food mixture should be formulated and processed so that by the addition of minimal amounts of freshly boiled water or by boiling after adding water it is easily and quickly prepared as a gruel or porridge of proper consistency for feeding.

Consideration should be given to the processing of starchy components with amylases or by extrusion cooking which will a) reduce the cooking time in the home; and b) reduce the viscosity and water retention capacity, or "bulkiness", of the mixture, thus allowing the feeding of a more concentrated preparation. The addition of sugar to protein-rich food mixtures is permissible provided the cost is not unduly increased, since such an additive enhances acceptability. In general, however, the sweetening of the products should be carried out in the home. There is no evidence that sucrose intolerance is a problem of importance.

There is no need to add ordinary salt to the formulated weaning foods.

6. Guidelines for composition expressed on a dry weight basis

<u>Component</u>	<u>Units per 100 g</u>
Protein	not less than 20 g ^{∗/}
Fat	as much as feasible, up to 10 g
Crude fibre	not more than 5 g ^{**/}
Moisture	preferably 5-10 g
Total ash	not more than 5 g

^{∗/} This protein level assumes an NPU not less than 60 and a PER not less than 2.1. If these values are higher, the level of protein may be reduced accordingly•

^{**/} Crude fibre higher than this may be acceptable although it would require clinical testing.

<u>Component</u>	<u>Units per 100 g</u>
Acid-insoluble ash	not more than 0.05 g
Vitamin A	1300 I.U. (as vitamin A palmitate, equivalent to 400 mcg retinol)
Thiamine	0.3 mg
Riboflavin	0.4 mg
Niacin	5.0 mg
Folate	0.2 mg
Vitamin B ₁₂	2.0 mcg
Ascorbic acid	20 mg
Vitamin D	400 I.U.
Calcium	300 mg (as phosphate or carbonate)
Iron	10 mg (as food-grade compound of adequate iron availability)
Iodine	100 mcg (as iodate or iodide)

Note: Under certain local conditions, the addition of vitamin B₆ (to approximately the level of thiamine) and alpha-tocopherol should be considered.

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

7. Food additives

Use of excessive amounts of flavouring agents, including salt, sugar or other sweeteners, should be avoided. If any food additives are used, they should be those which have been cleared by the Joint FAO/WHO Expert Committee on Food Additives. The amounts used should not exceed the minimum necessary to produce the desired effect. Necessary information must be given on the label about the nature and quantities of food additives used in the product.

8. Standards and purity

8.1 The ingredients in the formula should meet the national and/or international standards with regard to purity. The FAO/WHO/UNICEF Protein Advisory Group has prescribed quality guidelines for the following:

- | | |
|--|-----------------|
| a) Edible groundnut flour | PAG Guideline 2 |
| b) Edible cottonseed protein concentrate | PAG Guideline 4 |
| c) Edible heat-processed soy grits and flour | PAG Guideline 5 |
| d) Fish protein concentrates for human consumption | PAG Guideline 9 |

8.2 Legumes and oilseeds may frequently contain tryptic inhibitors and other undesirable factors which must be reduced by processing before use in high-protein foods. Since all toxic factors may not be eliminated by processing, it is essential that only grain legumes which are nutritionally wholesome and toxicologically safe be used.

8.3 The preparation of a protein concentrate from oilseeds may require solvent extraction. Adequate procedures requiring food-grade solvents are described in a report by the Joint FAO/WHO Expert Committee on Food Additives (FAO Nutrition Meetings Report Series No. 48; WHO Technical Report No. 462). It is necessary that adequate methods of extraction using food-grade solvents be used to eliminate the dangers of toxicity.

8.4 Cereals, oilseeds and other source material to be used in the basic mixture may be contaminated with toxic moulds. The FAO/WHO/UNICEF Protein Advisory Group has reviewed this problem and issued a statement (PAG Statement 2) on the subject.

9. Microbiological and sanitary standards

Separate PAG guidelines for microbiological and sanitary requirements will be issued shortly.

10. Packaging

Packages and the containers in which they are shipped should provide protection from the inroads of insects, micro-organisms, moisture and contaminants. If foods are dispensed from bulk containers, proper sanitary procedures should be observed. Simple but effective information with respect to the correct use of the product should be on the package.

11. Shelf-life

The packaged product should remain acceptable for food use in terms of retention of palatability, nutritional availability and freedom from toxic or other deleterious changes for a period of six months under tropical conditions.

REPORT OF A MEETING OF THE COLLABORATING COUNTRIES ON ADDITIVES IN
FOODS FOR INFANTS

HELD DURING THE 6TH SESSION OF THE
CODEX COMMITTEE ON FOODS FOR SPECIAL DIETARY USES */

Dr. T.K. Murray, who chaired the meeting of the Collaborating Countries set up by the Committee, informed the Committee that discussions at the meeting of the Collaborating Countries were confined to procedural matters - e.g. discussions on what information would be required in order to develop a list of acceptable additives in foods for infants and what precise questions should be asked in order to ensure that the required information be obtained. He informed the Committee that a questionnaire would be developed by the United States and Canada and sent in January to all delegations represented at the session of the Codex Committee on Foods for Special Dietary Uses as well as to the Codex Contact Points, with replies requested by the end of June.

A working document would then be prepared by the United States and Canada and distributed to the Collaborating Countries by the end of August. This paper would be discussed by the Collaborating Countries at an informal meeting to be held immediately before the next session of the main Codex Committee. A report would arise from the meeting of the Collaborating Countries and this would be presented to this Committee as a working paper. Dr. Murray further informed the Committee that the questionnaire would also include requests for information on mineral salts added as nutrients with the view of recommending a suitable list of these substances and that the meeting of the Collaborating Countries had agreed that it would not be possible to consider comments received after the stated deadline and that unsubstantiated proposals would not be considered. Member Countries were requested by the meeting of the Collaborating Countries not to respond to the request for information until the questionnaire had been received.

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See para 13 of this Report.

BACTERIOLOGICAL STANDARDS FOR FOODS FOR BABIES AND INFANTS^{1/}
(Prepared by the Delegation of the Federal Republic of Germany)

The Codex Committee on Foods for Special Dietary Uses, at its 5th session, requested the delegation of the Federal Republic of Germany to amend their paper CX/FSDU 70/7 "Bacteriological Requirements and Microbiological Methods of Analysis for Baby and Infant Foods" in the light of government comments in collaboration with WHO (ALINORM 71/26 -paragraph 54). The present document is the result of this work. Additional remarks from WHO are contained in a footnote. .

BACTERIOLOGICAL STANDARDS FOR BABY AND INFANT FOODS^{**/}

	<u>A</u>	<u>B</u>	<u>C</u>	<u>D</u>
	Ready-to-use or instant products to be consumed after the addition of liquid	Products requiring cooking prior to consumption	Ready-to-use products preserved by thermal treatment in sealed containers, and preparations canned under sterile conditions	Ready-to-use products as far as not covered by C
Total bacterial count Maximum value	50.000/g ^{4/}	200.000/g ^{10/}	After 7 days' incubation at 370 C 13/ no physical, chemical or organoleptic changes must be observed. 1 g of the substance must not contain more than 100 non-pathogenic, non-toxin forming aerobic germs. ^{14/}	10.000/g
Coliform bacteria	neg. in 0.01 g ⁵	neg. in 0.001 g ^{8/ 9/}		neg. in 0.1 g
E. coli	neg. in 1 g ⁶	neg. in 0.1 g ¹¹		neg. in 1 g
Yeasts and hyphomycetes ^{1/}	neg. in [1 g] ^{5/}	neg. in [0.1 g] ^{12/}		neg. in [1 g]
Aerobic spore-forming organisms	neg. in 0.001 g	neg. in 0.001 g	-	neg. in 0.01 g
Anaerobic spore-forming organisms (Clostridia) ²	neg. in 0.1 g	neg. in 0.01 g	neg. in 1 g	neg. in 0.1 g
Salmonellae and shigellae ³	neg. in [30 g] ⁷	neg. in [30 g]	neg. in [30 g]	neg. in [30 g]
Pathogenic staphylococci	neg. in [1 g] ^{2/}	neg. in [0.1 g]	neg. in [1 g]	neg. in [1 g]

neg. = negative (not present)

^{**/} Footnote: 1) According to Dr. Matyas, WHO, tests for Clostridium botulinum should be added if fish protein forms part of the food (See also para 15 of this Report).

2) Furthermore, sampling plans should be elaborated.

^{*/} Governments are requested to send their comments to the Secretariat on this Appendix (See para 17 of this Report),

^{1/} U.S.A. and Canada do not deem it necessary to establish limit values.

^{2/} Canada does not deem it necessary to establish limit values.

^{3/} Hungary would prefer "infectious intestinal bacteria".

^{4/} Poland: for older children; for babies max. 500/g.

^{5/} Poland: 0.1 g

^{6/} Hungary: 0.1 g

^{7/} Hungary: 25 g

^{8/} Hungary: 0.01 g

^{9/} Canada: 0.01 g, on the basis of milk 0.1 g

^{10/} Canada: On the basis of milk 50 000/g;
Poland: On the basis of milk 100 000/g too high

^{11/} Canada: On the basis of milk 1 g

^{12/} Hungary: Hyphomycetes negative in 0.01 g

^{13/} U.S.A., France: 30°C

^{14/} France suggests replacing this sentence by the following provisiON:

"These preparations shall not contain any pathogenic or toxigenic bacteria, toxins, micro-organisms able to modify the durability of the products under normal conditions of storage, nor any active organic enzymes".

CULTURE MEDIA FOR THE BACTERIOLOGICAL CONTROL OF BABY AND INFANT FOODS

Determination of	Culture media and techniques	Literature ^{*/}
Total bacterial count	Tryptone-glucose-yeast extract Agar	Milchw. 16,650 (1961); Die Fleischwirtschaft 47, 1313 (1967)
Coliform bacteria	Brilliant green-lactose-bile bouillon	American standard method for the examination of dairy products, 9th Ed. APHA 1948; Netherlands Standard Specification NEN 955, Neth. Milk Dairy J. 16,302 (1962)
Enterobacteriaceae	Brilliant green-dextrose-bile bouillon according to Mossel, mod. violet red bile-agar according to Mossel	J. Bact. 84, 381 (1962)
E. coli	As under 2, in addition test for gas and indol formation at 44 ⁰ C	Zbl. Bakt. I. Orig. 208

Yeasts and hyphomycetes	Brewers' wort-peptone-agar-Sabouraud-agar	
Aerobic spore forming organisms	Bac. cereus medium according to Mossel et. al.	Appl. Microbiol. <u>15</u> , 650-653 (1967)
Clostridia	Differential-reinforced-clostridial-medium (DRCM) according to Gibbs and Frame	J. appl. Bact. <u>28</u> , 95 (1965)
	Sulfite-azid-thioglycolate-culture medium (SAT) according to Levetzow	Arch. Lebensmittelhyg <u>18</u> , 217 (1962)
Salmonellae and Shigellae	According to usual methods using liquid enrichment culture media	
Staphylococci	Baird-Parker-medium	J. app. Bacteriol. <u>25</u> , 12-19 (1962)

^{2/} The United States recommend the methodology of F.S. Thatcher and D.3. Clark in "Micro—organisms in Food; Their Significance and Methods of Enumeration", Toronto 1968.