

# codex alimentarius commission

FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD HEALTH  
ORGANIZATION

JOINT OFFICE:

Via delle Terme di Caracalla 00100 ROME: Tel. 5797 Cables Foodagri

ALINORM 76/26A

## CODEX ALIMENTARIUS COMMISSION Eleventh Session - 1976

### Report of the Ninth Session of the CODEX COMMITTEE ON FOODS FOR SPECIAL DIETARY USES Bonn, 22-26 September 1975

#### INTRODUCTION

1. The Codex Committee on Foods for Special Dietary Uses held its ninth session by courtesy of the Government of the Federal Republic of Germany, in Bonn. The session was opened by the Chairman of the Committee, Dr. R. Franck, First Director and Professor of the Federal Health Office, Berlin.

2. The session was attended by 22 government delegations from the following countries:

Australia	Germany, Fed. Rep.	Norway
Belgium	Hungary	Sweden
Brazil	Ireland	Switzerland
Canada	Italy	Thailand
Denmark	Kuwait	United Kingdom
Egypt	Libya	United States of America
Finland	Mexico	
France	The Netherlands	

Observers from 12 International Organizations were present. A list of participants, including the representatives of FAO and WHO, is attached as Appendix I to this Report.

#### ADOPTION OF THE PROVISIONAL AGENDA

3. The Committee adopted the Provisional Agenda with some rearrangements in the order of items to be discussed. The Committee agreed to take into consideration a document made available by the delegation of the United Kingdom containing a draft General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CX/FSDU 75/10) under Item 10(a). The Committee decided to consider the revised Draft Standard for Gluten-free Foods at Step 7 (CX/FSDU 75/8) and the revised version of the Draft Standard for Foods for Use in the Diet of Diabetics (Conference Room Document No. 5) under Items 10(b) and 10(c) respectively.

#### APPOINTMENT OF RAPORTEURS

4. Dr. R.H.C. Fleming (Australia) and Mr. H. Prost (France) were appointed as rapporteurs.

#### AD HOC WORKING GROUP ON METHODS OF ANALYSIS IN STANDARDS FOR FOODS FOR INFANTS AND CHILDREN

5. The Committee decided to establish an ad hoc Working Group to deal with methods of analysis related to the standards for foods for infants and children and to report to the Committee in the course of the session. The Group consisted of members of delegations from the Federal Republic of Germany, France, the United Kingdom and the United States of America, as well as a member of the FAO Secretariat.

MATTERS ARISING FROM SESSIONS OF OTHER CODEX COMMITTEES

6. The Committee agreed that matters arising from the Tenth Session of the Committee on Food Additives, the Tenth Session of the Committee on Food Labelling and the 12th Session of the Committee on Food Hygiene should be dealt with, when the relevant items were discussed.

7. The Committee was informed that the Codex Committee on Food Hygiene had considered a Code of Hygienic Practice for Foods for Infants and Children and had decided to submit the Code at Step 3 to governments for comments (ALINORM 76/13A, paras 57-59). The Committee decided that discussion of the Code should be postponed to a later session.

8. The Committee noted that the Codex Committee on Pesticide Residues had agreed with the opinion of this Committee that it was not possible at the present time to establish an overall limit for pesticide residues in foods for infants and children.

FOOD ADDITIVES IN FOODS FOR INFANTS AND CHILDREN

9. The Committee had before it the report of the ad hoc Working Group on Food Additives in Foods for Infants and Children which had met in The Hague from 29 to 30 May 1975. The Chairman of the Ad Hoc Working Group Dr. T.K. Murray (Canada) explained that the technological justification for the use of food additives in foods for special dietary uses had been thoroughly examined and reported to the Codex Committee on Food Additives.

10. The Committee was informed of those food additive provisions in the standards for Infant Formula, Canned Baby Food and Infant Food based on Cereals, which had been endorsed. The Committee was advised by the representative of WHO that his Organization had no objection to the provisions for the additives proposed in the three standards, provided that:

- (a) the special Infant Formula containing the higher level of carrageenan be restricted to products of special composition in life-saving situations by means of appropriate labelling, in view of the fact that the "maximum daily intake" of carrageenan exceeded its ADI in special formulae (see CX/FSDU 75/6); and
- (b) labelling provisions in the standards for Canned Baby Food and Processed Foods for Infants and Children based on Cereals indicated that these foods were not intended for infants under three months of age.

WHO was also of the view that the "maximum daily intake" per kg infant for ascorbyl palmitate, calculated to be 1.5 mg (see CX/FSDU 75/6), only marginally exceeded the ADI (1.25 mg) and this was not considered to be of toxicological significance.

11. The Committee took no action on (b) above but agreed with the provisos outlined above and noted that concerning (a) the appropriate restriction would be set out in the Food Additive Section of the Standard for Infant Formula. The Food Additive provisions, as endorsed by the Codex Committee on Food Additives, would be incorporated in the texts of the standard accompanying the adopted report of the Committee.

12. The Committee considered the question whether the "Carry-over Principle" referred to Codex Commodity Committees by the Codex Committee on Food Additives should apply in the case of foods for infants and children. In general, the Committee thought that the Principle should not be applied to Infant Formula but decided to invite government comments before coming to any firm conclusion in the case of this product or the other standards for foods for infants and children. The government comments would be considered by the ad hoc Working Group as well as the technical justification for any proposals concerning further food additive provisions. It was agreed that the ad hoc Working Group should continue up to the next session of the Committee and its Chairman Dr. K. Murray (Canada) would arrange for matters to be dealt with either by correspondence or by convening a brief meeting in conjunction with the Codex Committee on Food Additives or on Foods for Special Dietary Uses, as appropriate (see also para 56).

DRAFT STANDARD FOR INFANT FORMULA (Step 7)

13. The Committee had before it the above draft standard (App. III, ALINORM 76/26) and documents containing government comments thereon (CX/FSDU 75/3 and Add. 1 and 2).

SCOPE

14. On the proposal of the delegations of Switzerland and the USA, the Committee decided to amend this section editorially as follows:

"This standard applies to Infant Formula in liquid or powdered form intended for use, where necessary, as a substitute for human milk in meeting the normal nutritional requirements of infants. It also provides a standard for formulae intended for infants with special nutritional requirements, except for certain provisions which must be modified to meet those special requirements".

The changes were thought necessary to make it clear that infant formula was not intended to discourage breast feeding except where such a way of feeding was not adequate and to clarify that the standard applied to products sold under the name "Infant Formula" or an equivalent designation.

ESSENTIAL COMPOSITION

Vitamins other than Vitamin E

15. As regards the provisions for Vitamins A and D, the Committee agreed to reduce the maximum levels to 500 I.U. and 80 I.U. respectively as proposed by Switzerland and in view of the comments submitted by FAO.

Vitamin E

16. The Committee considered comments from governments requested specifically at the last session. After full discussion of the way the requirement for Vitamin E should be expressed and of the minimum level of vitamin E provided for, the Committee agreed to a minimum of 0.7 I.U./g linoleic acid or polyunsaturated fatty acids expressed as linoleic acid, but in no case less than 0.7 I.U. per 100 Cals. The delegation of the Netherlands was of the opinion that the minimum requirement should be 1 I.U./g linoleic acid, whereas the delegation of France was of the opinion that a minimum requirement of 1 mg  $\alpha$ -tocopherol per g linoleic acid was more appropriate. The delegation of Denmark proposed to consider only  $\alpha$ -tocopherol for the sake of analytical simplicity.

Minerals

17. After some discussion as to whether the minimum levels for copper and zinc should be reduced, the Committee decided to leave the provisions unchanged.

Protein

18. The Committee decided to discuss this section from the point of view of (a) the definition of quality of the protein; and (b) the minimum requirement for protein quality with reference to casein. The delegation of the USA proposed to reduce the latter to 70% casein from 85% as provided for in the standard in order to enable countries where animal protein was in short supply to use vegetable protein which, although having a quality lower than that provided for in the standard, was still suitable from a nutritional point of view as recommended by the U.S. Academy of Pediatrics.

19. It was pointed out by some delegations that the standard provided for the addition of amino acids to improve protein quality and that, furthermore, a 30% departure from the reference protein could give rise to errors in the assessment of the quality of the protein in relation to human infants. The Committee decided not to change the minimum requirement for protein quality.

20. On the question of the reference protein, some delegations suggested that casein might not be the best reference material and that other ways, such as the use of the chemical score of human milk, should be explored. The Committee noted that the provision for protein quality had been based on casein as a reference protein and agreed that, for the time being, there was no possibility to make any changes.

21. The Committee then discussed the method of determining protein quality with reference to casein and recalled its previous decision (6th Session) that, as the provisions in the standard were based on the determination of protein efficiency ratio (PER), this method of control should be provided for. The USA recommended that the standard casein test diet contain lactose and fat at levels similar to those in the test formula diet in order to avoid erroneous comparison (see also App. VI to this Report). The Committee agreed and reaffirmed its position on PER but noted that the PER method was not intended to replace the thorough investigation which would be carried out on new formulations or those made with new processing conditions prior to the marketing phase using clinical, biochemical and other methods. Rather, the PER method using casein was intended as a rapid biological method to check compliance. The following footnote was included in the standard:

"Protein quality shall be determined provisionally using the PER method as laid down in Section 11 of this Standard, it being understood that the suitability of the product for infant feeding in conformity with Section 2.2 of this Standard will have been established on the basis of adequate and appropriate tests in the light of current knowledge".

#### Fat and Linoleate

22. The delegation of the United Kingdom maintained their view that the minimum requirement for linoleate should be 100 mg/100 available Calories as investigations so far in that country did not reveal any evidence that this level would give rise to deficiency. The Committee considered that the present value of 300 mg corresponded to current accepted opinion based on levels in human milk as well as on studies of trienoic and tetraenoic fatty acids in serum and agreed that, pending further conclusive evidence, the level should not be lowered. The United Kingdom considered that a maximum level should be prescribed since otherwise the standard could lead to the use of fats with very high linoleic acid content.

#### Other Contaminants

23. Considering a proposal by the delegation of the Federal Republic of Germany and the conclusions of the Codex Committee on Food Additives, the Committee adopted the following amended text:

"The product shall be free from residues of hormones and antibiotics as determined by means of agreed methods of analysis, and practically free from other contaminants, especially pharmacologically active substances".

Noting also the request made by the Codex Committee on Food Additives in para 89 of ALINORM 76/12, the Committee requested governments to send relevant information on the basis of which maximum levels could be established for contaminants such as arsenic, tin, lead and others in foods for infants and children.

#### Hygiene

24. The Committee noted that the Codex Committee on Food Additives had requested that Sections 6.2 and 7.2(c) should be examined for any possible inconsistency. The Committee agreed that both sections were required in the standard and that they were not contradictory as Section 6.2 covered substances resulting from the production of the raw materials or from processing, while Section 7.2(c) referred to toxic substances arising from microbiological contamination.

#### Labelling

25. The Committee noted that the provision concerning the name of the food had been endorsed by the Codex Committee on Food Labelling (Section 10.1.1). Concerning Section 10.1.4, the Committee considered whether to make the declaration of the absence of milk and milk products mandatory. The Committee agreed to leave the provision optional but to change the form of statement to "contains no milk or milk product" or an equivalent phrase. The Committee considered that it would be necessary to add a Section 10.1.5 to require infant formulae intended for infants with special nutritional requirements to so indicate as part of the name of the product as follows:

"A product intended for infants with special nutritional requirements shall be labelled to show clearly the special requirement for which the formula is to be used and the dietary property or properties on which this is based".

26. The Committee agreed that in Section 10.3.1 information on the amount of energy could be expressed in Calories (kcal) and/or kilojoules (kJ), to permit the use of both units, if so desired. It was further agreed to delete Section 10.4 as the declaration of proteins, vitamins and minerals were already covered by Sections 10.3.1 and 10.3.2 and as a declaration of such nutrients in terms of percentage of the recommended daily intake was neither informative nor feasible. The Committee agreed that Section 10.2.2 should be reworded to make the use of class names optional, as follows:

"The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate class names for these ingredients and additives may be included on the label".

27. It was also agreed that the footnote referring to the provision for 1 mg Fe per 100 available Calories in Section 4.1.2(c) should be transferred to the labelling section as follows:

"Products containing not less than 1 mg iron (Fe)/100 available Calories shall be labelled "Infant Formula with Iron" ".

Several delegations agreed with the suggestion of the United Kingdom that the level of 0.15 mg iron (Fe)/100 available Calories for Infant Formula should be expressed as a maximum, but after discussion this was not accepted by the Committee.

#### Date Marking

28. The Committee received the recommendations contained in the Guidelines prepared by the Codex Committee on Food Labelling concerning the various forms of date marking which Codex Commodity Committees should examine in connection with the products for which they were elaborating standards. The Committee considered that the "date of expiry" in Section 10.9.1 should be replaced by the "date of minimum durability" as the preferred statement with the "date of manufacture" as an alternative. The delegation of Belgium was of the opinion that the date of expiry should be retained as an alternative to the date of minimum durability.

#### Information for Utilization

29. In view of the worldwide trend away from breast feeding, the Committee discussed in some detail how best to advise mothers concerning the proper usage of infant formulae as a substitute or supplement to breast feeding. The Committee, whilst considering that the main emphasis should be placed on nutrition education programmes, thought it would nevertheless be of some advantage to the purchasers of infant formula if the product were to bear the following statement or an equivalent phrase, as optional labelling where national authorities considered it appropriate to do so:

"Infant formula is intended to replace or supplement breast feeding where breast feeding is not possible or is insufficient".

This optional provision would be included in the standard as Section 10.11, entitled "Optional Labelling".

30. Concerning the general questions of claims and advertisements for Infant Formula vis-à-vis breast feeding, the Committee requested the Codex Committee on Food Labelling to give advice which would ensure that advertizing and promotional literature did not in any way imply that Infant Formula is better than human milk.

#### Status of the Standard

31. The Committee agreed to advance the standard given as App. II to this Report to Step 8 of the Procedure for the Elaboration of Codex Standards. The delegation of the Netherlands recorded a reservation concerning the protein provision of the standard. The delegation did not agree with the use of casein as the reference protein, nor PER as being adequate for measuring the quality of the protein and further considered that the minimum quantity of protein was too low. The delegation of France shared the opinion of the Netherlands concerning the use of casein as reference protein. The delegation of the United Kingdom wanted to place on record that the Committee would need to consider at a future date the subject of renal osmolar load.

"FOLLOW-UP" OR "WEANING" MILK

32. The Committee considered a proposal submitted by Switzerland that a standard be elaborated for milk products intended to cover the extra nutritional needs of infants and children in respect of protein, calcium and calories from the weaning period onwards. The Committee discussed whether there was a need to elaborate provisions to cover such products. Some delegations agreed in principle that this should be done and the Committee decided to request government comments on the Swiss proposal. The Committee agreed that in the light of government comments a decision could be taken at Step 4 as to whether a separate standard be elaborated or amendments be made to the Standard for Infant Formula. The proposed Draft Standard for comments by governments is contained in App. IX to this Report.

PROPOSED DRAFT STANDARD FOR CANNED BABY FOODS

33. The Committee had before it the above draft standard (App. II, ALINORM 76/26) which was considered in the light of government comments (CX/FSDU 75/4 and Add.1 and 2).

Section 3.1.4

34. The Committee considered the tentative maximum level of 250 mg Na/100 Calories in the light of government comments. During the discussions it became evident that an overall figure for the various types of foods covered by the standard might not be appropriate, but that it was desirable to control the amount of sodium in foods for infants and children. Furthermore, it was noted that it would not be appropriate to express the sodium content on a calorie basis in view of the wide variation of the calorie value of the various foods. For these reasons and taking into account that the use of certain food additives and minerals also contributed to the sodium content of these foods, the Committee adopted the following text:

"The total sodium content of the products shall not exceed 200 mg Na/100 g calculated on a ready-to-eat basis in accordance with directions for use. The addition of salt (NaCl) to fruit products and dessert products based on fruit is not permitted".

Section 3.1.2

35. The Committee agreed to delete this Section as it would be covered by Section 4.

Protein Content

36. The Committee considered a proposal of the French delegation for various minimum limits for protein content according to the predominant source of protein, e.g. meat, fish, liver and mixtures of vegetables or cereals with fish, milk, eggs, etc., as well as a maximum limit in sugar for fruit and dessert products. The Committee agreed that compositional requirements such as those proposed by the French delegation would require further careful studies and might be taken up at a future session of the Committee when more information was available from other countries.

Sections 5.2 and 6

37. The Committee agreed that these sections should be brought into harmony with what had been agreed concerning Infant Formula.

Section 9.3.2

38. The Committee, after a full discussion, and in the light of the fact that it was not yet possible to prescribe detailed compositional requirements for the products, agreed that it would be important to require adequate nutrition information to be declared on the label. The following text was adopted by the Committee and the preamble to Section 9.3 was clarified to make the section clearly mandatory:

"9.3.2 - In addition to any other nutritional information required by national legislation, the total quantity in the final product of each vitamin and mineral added according to Section 3.1.3, shall be declared per 100 g as well as according to the serving size of the food suggested for consumption".

### Section 9.9.2

39. The Committee considered a proposal by the delegation of Norway to replace this section by a text given in para 38 of ALINORM 76/26. Some delegations were of the opinion that the level of 150 mg nitrate/kg proposed by Norway was not realistic as current survey had shown that many types of foods for infants and children contained nitrate in amounts greater than 150 mg/kg. On the other hand, it was pointed out that canned foods for infants and children could be manufactured using vegetables grown under special conditions so as to contain significantly lower than 150 mg nitrate/kg. It was stressed by some delegations that any decision concerning the suitability of nitrate containing foods for the feeding of young infants should be based on considerations of health.

40. The Committee considered that, in the absence of further information, it was not in a position to change the wording of Section 9.9.2, but agreed that the question of the nitrate content of foods intended for infants and children should be reviewed at a future session in the light of analytical, toxicological and other relevant data. Governments were requested to send all information on this problem to the Committee.

41. As regards Sections 9.2.2 and 9.3.1, the Committee reached the same conclusions as given in para 26.

### Status of the Standard

42. The Committee agreed to advance the standard given in App. III to this Report to Step 8 of the Procedure for the Elaboration of Codex Standards.

## PROPOSED DRAFT STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND CHILDREN

### Title of the Standard

43. The Committee agreed that the title of the Standard should be editorially changed in English to bring it into harmony with the French, Spanish and German texts.

### Scope

44. The Committee adopted the following revised text:

"Cereal-based processed foods for infants and children are intended to supplement the diet of infants and children".

### Description

45. The Committee agreed to include glucose in the list of transformed starch products.

### Definitions

46. The Secretariat was requested to harmonize the texts of the Standards for Infant Formula, Canned Baby Food and Cereal-based Foods for Infants and Children.

### Essential Composition

#### Section 4.1.1

47. The Committee agreed to delete the restriction concerning soybeans, namely that the soybean be de-fatted or low fat.

#### Section 4.1.2

48. The Committee, after a full consideration of the government comments, specifically sought on this section and having regard to Section 9.9.2, agreed that a minimum quantity of protein should be required in the cereal products intended for dilution or mixing with water. It was agreed that the minimum limit should be 15% on the dry weight basis for these products. It was further decided to delete from the section the phrase "if the product is recommended as a source of protein". The text of Section 4.1.2 as adopted, was as follows:

"Where the product is intended to be mixed with water before consumption the minimum content of protein shall not be less than 15% on a dry weight basis and the quality of the protein shall not be less than 70% of that of casein".

49. Concerning the absence of other basic nutritive requirements, the delegation of France proposed that limits should be introduced in the standard for sugars, sodium and calcium. A number of delegations thought that calcium should not be singled out among nutrients but agreed that limits should be established for sodium. After a lengthy discussion of the sodium levels likely to be found in the various cereal-based products covered by the standard, the Committee agreed to fix a limit of 100 mg/100 g of the ready-to-eat product for products described in Sections 2.1, 2.2, 2.3 and 2.5 of the Standard. Regarding products described in Section 2.4, the Committee agreed to a limit of 300 mg/100 g of the product as sold. The Committee decided, in view of the maxima for sodium, not to prohibit the addition of salt (sodium chloride) to the products. It was further agreed that if iodized salt were used, it should be in accordance with the national legislation of the country in which the product was sold. As a consequence of these decisions, salt (sodium chloride) would need to be included in the list of optional ingredients in Section 4.2.1 and Sections 4.2.2 and 4.2.3 would be merged. In connection with the proposal to introduce a maximum limit for sugars in the product, the Committee decided not to incorporate such a provision.

#### Quality Factors

##### Section 4.3.3

50. The Committee considered whether a change should be made in Section 4.3.3 concerning moisture content of the finished product. It was agreed that the present text was insufficient to ensure that the moisture content would be at a level which would ensure the maintenance of the nutritional value of the products. The Committee decided to amend the text as follows:

"The moisture content of the products shall be governed by GMP for the individual product categories and shall be at such a level that there is a minimum loss of nutritive value and at which microorganisms cannot multiply".

#### Food Additives

51. The Committee agreed that this Section should only contain those additives which had been proposed by the Committee on Food Additives. The question of the "Carry-Over Principle" referred to in Section 5.2 would be reviewed in the light of the Committee's considerations of government comments at a future session as had been decided in the case of the Standards for Infant Formula and Canned Baby Foods. It was agreed that the ad hoc Working Group should examine the technological need for the use of ammonium bicarbonate for possible inclusion as a chemical leavening agent.

#### Contaminants and Hygiene

52. It was agreed that Sections 6 and 7 should be brought into conformity with the same provisions, as amended, in the Standard for Infant Formula.

#### Information for Utilization

53. The Committee considered in detail the question of how best to provide information on dilution or mixing media for products containing either more or less than 15% protein. The Committee expressed concern that the information on the label should be sufficient to avoid the improper dilution of products which would result in an insufficient amount of protein being fed, whilst at the same time there was a need to deal with situations where there might be an excessive amount of protein being fed. The Committee considered that it was important that both situations should be covered by the Standard and adopted the following texts:

"Section 9.9.2 - When the product contains less than 15% protein and the quality is less than 70% that of casein, directions on the label shall state 'Milk or formula but not water shall be used for dilution or mixing' or an equivalent statement".

"Section 9.9.3 - When the product contains more than 15% protein, the instructions for dilution on the label shall state that water, milk or formula may be used for dilution or mixing, in accordance with medical advice or the legislation of the country in which the food is sold".



### Status of the Standard

54. The Committee agreed to advance the Standard given as App. IV to this Report to Step 8 of the Procedure for the Elaboration of Codex Standards. The United Kingdom delegation expressed reservations on the advancement of the Standard to Step 8. A number of changes had been made and the United Kingdom considered that governments should be given a further opportunity to comment. The delegation of France stated that it would have wished to see more precise requirements provided for in the Standard concerning the nutritional value of the products.

### REPORT OF THE AD HOC WORKING GROUP ON FOOD ADDITIVES FOR INFANTS AND CHILDREN

55. The report of the above Group, held during the session of the Committee, was introduced by the Chairman of the Group Dr. T.K. Murray (Canada). The report is given as App. V to this Report.

56. The Committee adopted the conclusions of the Working Group and agreed that distarch glycerol and acetylated distarch glycerol should be included in the Draft Standard for Canned Baby Food and referred to the Codex Committee on Food Additives for endorsement. Should these two thickening agents be approved by that Committee, the Committee agreed that they should then be included with the other additives already endorsed, when the Recommended Standard is sent by the Commission to governments for acceptance.

### METHODS OF ANALYSIS FOR FOODS FOR INFANTS AND CHILDREN

57. The Report of the above Working Group (see App. VI to this Report) was introduced by the Chairman of the Group, Dr. W. Krönert. During the discussion of the report of the Working Group, the following comments were made or conclusions reached:

#### Carbohydrate Determination

58. The Committee agreed that the term "available carbohydrate" should be changed to "carbohydrate determined by difference" to clarify that the chemical method did not measure biological availability. It served to determine carbohydrate content on the basis of which available calories could be calculated.

#### Available Calories

59. It was also pointed out that the term "available" was not appropriate, as the method of calculation using conversion factors applied to diet rather than a single product. On the other hand, it was noted that the conversion factors and procedure for the calculation of energy content, adopted at a previous session, implied the physiologically available calorie content. The Committee decided not to modify the requirement in the Standard for Infant Formula for "available calories" but agreed that the question of methodology could be reconsidered should further information become available.

#### Linoleic Acid

60. The delegation of Canada pointed out that the GLC method being elaborated by the Codex Committee on Fats and Oils measured total  $C_{18}$  (2 double bond) fatty acids rather than the biologically active linoleic acid and that there was a need to examine enzyme assay methods. The Committee agreed that the Codex Committee on Methods of Analysis and Sampling (CCMAS) should examine this question.

#### Vitamin K<sub>1</sub>

61. The delegation of the USA undertook to make available to the Codex Committee on Methods of Analysis and Sampling a published GLC/TLC method for the determination of Vitamin K<sub>1</sub>.

62. The Committee adopted the conclusions of the Working Group given in App. VI to this Report and referred it, together with the observations and conclusions above to the Codex Committee on Methods of Analysis and Sampling for consideration.

DRAFT GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES

63. The delegation of the United Kingdom introduced its paper on the above subject explaining that it was intended to provide for general provisions to regulate the labelling of and claims made in respect of foods for special dietary uses. The delegation of the United Kingdom was of the opinion that general or horizontal provisions would be required to ensure that foods, which were not the subject of detailed individual standards, were properly controlled. Sections 1 to 4 of the General Standard were designed to achieve this. Section 5 introduced by way of examples some vertical or specific provisions for certain categories of special dietary foods. The Committee expressed its appreciation of the UK paper and the earlier work which had been done by the delegation of Australia. The Committee was in general agreement that provisions such as those contained in Sections 1 to 4 should be further developed, and at a later stage, if necessary, certain specific aspects of foods not covered by individual standards might be included in a Section 5.

64. The Committee considered that it might also be necessary to review the "Guidelines for the Elaboration of Codex Standards for Foods for Special Dietary Uses", although it was recognized that these were in fact guidelines for the Committee itself. The Committee considered that, in order of priority, it should continue to elaborate individual standards for foods for special dietary uses defined on the basis of medically recognized needs. A General Standard such as that proposed by the United Kingdom would prevent any lacuna arising among the individual standards and in the field of foods for special dietary uses as intended to be covered by the Codex Alimentarius.

65. The Committee agreed to request government comments on Sections 1 to 4 of the General Standard (see App. VII to this Report) and to consider the General Standard in the light of these at its next session, at Step 4.

DRAFT STANDARD FOR "GLUTEN-FREE" FOODS

66. The Committee considered a revised text of the above mentioned standard, which had been prepared at the request of the Committee in the light of government comments by the delegation of Finland. The delegation of the Netherlands informed the Committee that further testing was still proceeding on what initially appeared to be a good sensitive method for the measurement of gluten.

67. A number of delegations considered that the question of the declaration of nutrients removed with the gluten should be examined by the Committee with a view to deciding whether their replacement would be provided for in the Standard. In this connection it was emphasized that, as gluten-free foods were used for long periods of life, their nutritional value was of importance. It was also considered often important in the case of persons requiring gluten-free food that the source and type of carbohydrates and type or source of protein be declared on the label. In view of the number of matters still requiring detailed consideration by the Committee, it was decided to return the Standard to Step 6 and to request the delegations of Finland and the Netherlands to revise the Standard (see App. VIII to this Report) in the light of further government comments to be sought by the Secretariat. It was agreed that the revised Draft Standard and government comments should be placed high up on the agenda of the next session.

LISTS OF MINERAL SALTS AND VITAMIN COMPOUNDS

68. The Committee had before it the above lists contained in App. V and App. VI to ALINORM 76/26 and papers containing government comments on those lists as well as replies to a questionnaire issued by the Secretariat (CX/FSDU 75/7 and Add. 1). The Committee discussed the basic questions of (a) whether the lists should be open or exclusive; (b) whether specifications of identity and purity should be elaborated for the compounds on the list; and (c) how they should be further elaborated.

69. Concerning question (a) above, the Committee noted that exclusive lists should be understood to mean that no other substances may be added to food than those which appeared on the lists. This did not mean that the lists could not be amended by the deletion or addition of compounds on the basis of certain agreed criteria. A number of delegations expressed themselves in favour of exclusive lists.

70. As regards the need for specifications, the Committee considered that it would not be feasible to embark at this time on the elaboration of Codex specifications for the numerous compounds on the lists and agreed that referencing to existing national or international specifications would be sufficient.

71. The Committee discussed details of the lists in the light of government comments. Regarding the proposal to delete nicotinic acid from the list on pharmacological grounds, the Committee noted that the Standard for Infant Formula provided only for nicotinamide and decided to reconsider this matter at the next session. It also agreed to postpone decision on thiamine mononitrate and vitamin D<sub>2</sub>-cholesterol complex pending further information. It was also agreed that questions of nomenclature such as the use of the term pteroyl monoglutamic acid as a synonym of folic acid should be resolved.

72. The Committee decided that the lists of mineral salts and vitamin compounds should be redrafted by the delegations of the USA and Switzerland respectively, using all the comments and information received so far and submit them to governments for comments and proposals regarding further additions or deletions. The Secretariat indicated that some substances or moieties of substances might have to be considered by the Codex Committee on Food Additives and that appropriate steps would be taken in this direction. It was agreed that the working papers prepared by the USA and Switzerland would be examined at the next session at which time the question of the status of the lists and the procedure would be discussed.

#### FUTURE WORK

73. The Committee took account of work arising from the present and previous meetings and also considered other special dietary foods which could possibly be covered by Codex Standards. It was agreed that the Chairman of the Committee, in consultation with the Secretariat, would determine what items should be discussed at the next session of the Committee. However, it was agreed that the Draft Provisional Standard for Gluten-Free Foods and the Draft General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses should be discussed at the next session early on the agenda.

#### (a) Status of Standards

Recommended International Standard for Low-Sodium Foods including Salt Substitutes (CAC/RS 53-1971)	At Step 9
Draft Standard for Infant Formula (App. II, ALINORM 76/26A)	Advanced to Step 8
Draft Standard for Canned Baby Foods (App. III, ALINORM 76/26A)	Advanced to Step 8
Draft Standard for Cereal-Based Processed Foods for Infants and Children (App. IV, ALINORM 76/26A)	Advanced to Step 8
Draft Standard for Gluten-Free Foods (App. VIII, ALINORM 76/26A)	Returned to Step 6
Proposed Draft Standard for Foods for Use in a Diet for Diabetics <sup>1/</sup> (App. VII, ALINORM 70/26)	At Step 4
Proposed Draft Standard for Follow-Up Milk for Infants and Children (App. IX, ALINORM 76/26A)	Advanced to Step 3
Proposed Draft Standard for Low-Carbohydrate Foods <sup>1/</sup> (App. IX, ALINORM 70/26)	At Step 4

X  
1/ Will be redistributed as a working document.

Proposed Draft General Standard for the  
Labelling of and Claims for Prepackaged  
Foods for Special Dietary Uses  
(App. VII, ALINORM 76/26A)

Advanced to Step 3

Proposed Draft Standard for Consumer-  
Packaged Protein Food  
(App. VII, ALINORM 71/26)

At Step 4

(b) Proposals for Future Standards

Standard for Low-calorie Foods

Standard for Low-protein foods

Standard for Cholesterol-reduced foods

Suggested by Canada

(c) Other Texts Under Consideration

List of Mineral Salts 1/

Sent to governments for  
comments

List of Vitamin Compounds 1/

Sent to governments for  
comments

Sampling Plans for Foods for Infants  
and Children 1/

To be elaborated by the  
Working Group on Sampling

Code of Hygienic Practice for Foods for  
Infants and Children  
(App. V, ALINORM 76/13A)

Advanced to Step 3  
(by the Codex Committee on  
Food Hygiene)

OTHER BUSINESS

74. The Chairman indicated that the next session of the Committee would be held between the 11th and 12th sessions of the Codex Alimentarius Commission, probably early 1977.

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1/ Will be redistributed as a working document.

LIST OF PARTICIPANTS  
LISTE DES PARTICIPANTS  
LISTA DE PARTICIPANTES

Chairman Dr. R. Franck  
Président First Director and Professor  
Presidenta Federal Health Office - Berlin  
D-1 Berlin 33, Postfach

AUSTRALIA  
AUSTRALIE

Dr. R.H.C. Fleming  
Director  
Food Administration Section  
Department of Health  
P.O. Box 100  
Woden, A.C.T. 2606

BELGIUM  
BELGIQUE  
BELGICA

R.J.L. van Havere  
Inspecteur des Denrées Alimentaires  
Ministère de la Santé Publique et  
de la Famille  
Cité Administrative  
Quartier Vésale 4  
1010 Bruxelles  
Raphael Pollet  
Observateur de l'industrie  
Nestlé S.A.  
221 rue de Birmingham  
1070 Bruxelles

BRAZIL  
BRESIL  
BRASIL

Germinio Nazario  
Ministry of Health  
Comissão Nacional Normas e Padrões  
de Alimentos  
Ministerio da Saude  
Av. Brasil  
4036 Rio de Janeiro

CANADA

Dr. T.K. Murray  
Director  
Bureau of Nutritional Sciences  
Health Protection Branch  
Dept. of Health and Welfare  
Ottawa

DENMARK  
DANEMARK  
DINAMARCA

J.P. Funch  
Head of Section  
The National Food Institute  
Mørkhøj Bygade 19  
DK-2860 Søborg

EGYPT  
EGYPTE  
EGIPTO

Dr. Shawky Y. Mohamed Elzifzaf  
Assistant Professor  
College of Agriculture  
University of Zagazig

FINLAND  
FINLANDE  
FINLANDIA

Dr. J. Idanpaan-Heikkila  
Docent  
National Board of Health  
Siltasaarenkatu 18A  
SF-00530 Helsinki 53  
Dr. T.E. Doty  
The Finnish Sugar Co., Ltd.  
Mannerheimintie 15  
SF-00250 Helsinki 25  
Aimo Kastinen  
Chief Officer  
National Board of Health  
Siltasaarenkatu 18A  
SF-00530 Helsinki 53  
Dr. P. Kuitunen  
Assistant Chief  
Children's Hospital  
Stenbackstreet 11  
Helsinki 29  
Tarja Luukkanen, M.Sci.  
Valio Finnish Cooperative  
Dairies Association  
Sähkötie 3  
00370 Helsinki 37  
Prof. J.K. Visakorpi  
University of Tampere  
Loutunkatu 2  
SF-33560 Tampere 56

FRANCE  
FRANCIA

Dr. H. Prost  
Ministère de l'Agriculture  
Inspecteur Divisionnaire de la  
Répression des Fraudes et du  
Contrôle de la Qualité  
42 bis rue de Bourgogne  
F-75007 Paris

FRANCE (Cont.)

Dr. M. Astier-Dumas  
Conseil Supérieur d'hygiène  
Publique de France  
3, rue du Dôme  
F-75116 Paris

J. Cognard  
Directeur Services techniques  
Union Biscuiterie et Produits  
Diététiques  
194 rue de Rivoli  
F-75001 Paris

Rey  
Professeur Pédiatrie  
Université Paris V  
Hôpital des Enfants Malades  
149 rue de Sèvres  
F-75015 Paris

M. Vansteenberghé  
Direction recherche et développement  
Société DIEPAL  
Les Gêmeaux  
F-69400 Gleize

Guelard  
Ingenieur Chimiste  
Service Recherche et Développement  
Société des Produits du Mais  
Zone Industrielle  
F-54710 Ludres

GERMANY, Fed. Rep. of  
ALLEMAGNE, Rép. Féd.  
ALEMANIA, Rep. Fed.

Dr. Günter Pahlke  
Direktor u. Professor  
Bundesgesundheitsamt  
1 Berlin 33, Postfach

Dr. E. Hufnagel  
Regierungsdirektorin  
Bundesministerium für Jugend,  
Familie und Gesundheit  
Deutschherrenstrasse 87  
D-53 Bonn - Bad Godesberg 1

Carl-Heinz Kriege  
Ministerialrat  
Bundesministerium für Ernährung,  
Landwirtschaft und Forsten  
D-53 Bonn  
Am Münster 2

D. Gnauck  
Ministerialrat  
Bundesministerium für Jugend,  
Familie und Gesundheit  
Deutschherrenstrasse 87  
D-53 Bonn - Bad Godesberg 1

Prof. Dr. med. Schmidt  
Deutsche Gesellschaft für  
Kinderheilkunde  
Moorenstrasse 5  
D-4 Düsseldorf

GERMANY, Fed. Rep. of (Cont.)

Dr. W. Pölert  
Wissenschaftlicher Leiter  
Bund für Lebensmittelrecht und  
Lebensmittelkunde  
D-534 Bad Honnef  
Im Gier 42

Bettina Muermann  
Wissenschaftliche Mitarbeiterin  
Bund für Lebensmittelrecht und  
Lebensmittelkunde  
D-534 Bad Honnef  
Im Gier 42

Friedrich Frede  
Stellv. Geschäftsführer  
Bundesverband der diätetischen  
Lebensmittelindustrie  
D-638 Bad Homburg  
Kelkheimer Str. 10

Erhard Wigand  
2. Vorsitzender  
Bundesverband der diätetischen  
Lebensmittelindustrie  
D-657 Kirn (Nahe)  
Bürgermeister Tschepke Str. 13

Dr. Behringer  
AGV  
Arbeitsgemeinschaft der  
Verbraucher e.V.  
D-5042 Eeftstadt  
Rotdornweg 6

Walter Schmelz  
Produktionsleiter  
Nestlé-Allgäuer Alpenmilch AG  
D-8 München  
Prinzregentenstr. 155

Dr. Ursula Wachtel  
Leiterin der Pharm.-Wissenschaftl.  
Abteilung  
Maizena Gesellschaft mbH  
Spaldingstr. 218  
D-2 Hamburg 1

Dr. Manfred Schmid  
Fa. Milupa AG  
Anspacherstr. 39  
D-638 Bad Homburg v.d.H.

Dr. W. Krönert  
Direktor und Professor  
Bundesgesundheitsamt  
1 Berlin 33, Postfach

Dr. Klaus Trenkle  
Oberregierungsrat  
Bundesministerium für Ernährung,  
Landwirtschaft und Forsten  
D-53 Bonn, Am Münster 2

Dr. Horst Dilthey  
Managing Director  
Lorenz & Lihn GmbH  
D-405 Mönchengladbach 2  
Maria Kasper Str. 62

HUNGARY  
HONGRIE  
HUNGRIA

Prof. Dr. Karoly Lindner  
Academy of Commerce and Gastronomy  
Alkotmany-n. 9/11  
H-1054 Budapest V

Dr. E. Dworschak  
Head of Dept. of Protein  
and Vitamin Research  
Institute of Nutrition  
H-1097 Gyali út 3/a  
Budapest

IRELAND  
IRLANDE  
IRLANDA

J. Sexton  
Assistant Principal Officer  
Department of Health  
Custom House  
Dublin 1

Dr. Th. Fitzgerald  
Medical Officer  
Department of Health  
Custom House  
Dublin 1

ITALY  
ITALIE  
ITALIA

Prof. Anna Ferro-Luzzi  
Medical Nutritionist  
National Institute of Nutrition  
Via Lancisi 29  
Roma

KUWAIT  
KOWEIT

Nizar Al-Nusif  
Head of Chemical Food Lab.  
Ministry of Public Health  
Amiri Hospital, Blood Bank Building  
P.O. Box 4077  
Kuwait

Dr. Nellie P. Fernando  
Consultant Paediatrician  
Ministry of Health  
P.O. Box 4078  
Al Sabah Hospital  
Kuwait

LIBYAN Arab Republic  
Rép. Arabe LYBIENNE  
Rep. Arabe de LIBIA

Derbali Mohamed Muftah  
Engineer (Food Sciences)  
Council of Food Affairs and  
Marine Health  
Tripoli

MEXICO  
MEXIQUE

M. Ibarra  
Counsellor  
Gerber Products, S.A. de C.V.  
La Fontaine 57  
Mexico 5, D.F.

NETHERLANDS  
PAYS-BAS  
PAISES BAJOS

G. Loggers  
Ministry of Public Health and  
Environmental Hygiene  
Dokter Reijersstraat 10  
NL-Leidschendam

H. Prins  
Director of Quality Control  
N.V. Nutricia  
P.B. 1  
NL-2280 Zoetermeer

J. Velde  
Ministerie van Landbouw en Visserij  
Bezuidenhoutseweg 73  
Den Haag

O.C. Knottnerus  
Hoofd. Produktschap voor  
Akkerbouwprodukten  
Stadhouderplantsoen 12  
Den Haag

NORWAY  
NORVEGE  
NORUEGA

O. Aasmundrud  
Department Manager  
Collett/Marwell Hauge A/S  
Drammensveien 852  
N-1370 Asker

Ottar Christiansen M.D.  
Deputy Director  
Division of Hygiene and  
Epidemiology  
The Health Services of Norway  
Akersgt. 42,  
Oslo Dep. Oslo 1

Prof. Dr. F.C. Gran  
Institute for Nutrition Research  
University of Oslo  
P.B. 1046  
Blindern

SWEDEN  
SUEDE  
SUECIA

Dr. Wolf Jenning  
Head of Food Standards Division  
The National Food Administration  
Box 622  
S-751 26 Uppsala

O. Ågren  
Deputy Head of Food Standards Div.  
National Food Administration  
Box 622  
S-751 26 Uppsala

L. Hellving  
Director  
Semper AB  
Fack  
S-104 35 Stockholm

Bertil Lindquist  
Professor of Pediatrics  
University of Lund  
Department of Pediatrics  
University Hospital  
S-221 85 Lund

Dr. Med. Lars Söderhjelm  
Sundsvall Hospital  
S-851 86 Sundsvall

SWITZERLAND  
SUISSE  
SUIZA

J. Ruffy  
Expert  
Service féd- de l'hygiène publique  
Codex Alimentarius  
Haslerstrasse 16  
CH-3008 Berne

Dr. W. Hausheer  
Schweiz. Codx Komitee  
Grenzacherstrasse 124  
CH-4002 Basel

Ing. F. Jeanrichard  
Sté. Ass. Technique pour Produits  
Nestlé S.A.  
Case Postale 88  
CH-1814 La Tour de Peilz

THAILAND  
THAILANDE  
TAILANDIA

Theera Satasuk  
Chief Food Control Div.  
Food and Drug Administration  
Ministry of Public Health  
Bangkok

UNITED KINGDOM  
ROYAUME-UNI  
REINO-UNIDO

F.S. Anderson  
Principal  
Food Standards Division  
Ministry of Agriculture,  
Fisheries and Food  
Great Westminster House  
Horseferry Road  
London SW 1 P 2 AE

I.M.V. Adams  
Principal Scientific Officer  
Ministry of Agriculture,  
Fisheries and Food  
Great Westminster House  
Horseferry Road  
London SW 1 P 2 AE

Dr. W.F.J. Cuthbertson  
Research Director  
Glaxo Research Ltd.  
Sefton Park  
Stoke Poges  
Buckinghamshire

Dr. S.J. Darke  
Senior Medical Officer  
Department of Health and Social  
Security DHSS  
Alexander Fleming House  
Elephant and Castle  
London SE 6BY

R.A. Hendey  
Chief Chemist  
Head of Research and Nutrition  
Cow and Gate Baby Foods  
40/42 Stoke Road  
Guildford, Surrey

Robert F. Shadbolt  
Senior Executive Officer  
Food Standards Division  
Ministry of Agriculture,  
Fisheries and Food  
Great Westminster House  
Horseferry Road  
London SW 1 P 2 AE

Victor Staniforth  
Manager  
H.J. Heinz Co., Ltd.  
Hayes Park  
Hayes, Middlesex

UNITED STATES OF AMERICA  
ETATS-UNIS D'AMERIQUE  
ESTADOS UNIDOS DE AMERICA

Dr. Robert W. Weik  
Assistant to Director  
Bureau of Foods (HFF-40)  
Food and Drug Administration  
Washington, D.C. 20204



UNITED STATES OF AMERICA (Cont.)

L.M. Beacham  
National Cannery Association  
1133 20th St., N.W.  
Washington, D.C. 20036

Dr. George A. Purvis  
Research Manager  
Gerber Products Co.  
445 State St.  
Fremont, Mich., 49412

Dr. H.P. Sarett  
Vice President  
Nutritional Science Resources  
Mead Johnson Research Center  
Evansville, Indiana 47721

Dr. R.M. Tomarelli  
Advisor  
Wyeth Labs.  
Representative Infant Formula Council  
Radnor PA 19087

O.B. Wurzburg  
Advisor  
National Starch and Chemical Inc.  
RDI Box 45  
White House Station  
08889 New Jersey

INTERNATIONAL ORGANIZATIONS  
ORGANISATIONS INTERNATIONALES  
ORGANIZACIONES INTERNACIONALES

ASSOCIATION OF OFFICIAL ANALYTICAL  
CHEMISTS (AOAC)

Dr. Robert W. Weik  
Assistant to Director  
Bureau of Foods (HFF-40)  
Food and Drug Administration  
Washington, D.C. 20204 (U.S.A.)

EUROPEAN ECONOMIC COMMUNITY (EEC)

E. Gaerner  
Hauptverwaltungsrat  
Kommission der Europäischen  
Gemeinschaften  
200 rue de la Loi  
B-1049 Bruxelles (Belgium)

M. Graf  
Administrateur  
Secrétariat Général du  
Conseil des Communautés Européennes  
170, rue de la Loi  
B-1048 Bruxelles (Belgium)

INTERNATIONAL ASSOCIATION FOR  
CEREAL CHEMISTRY (ICC)

Dr. A. Menger  
Wiss. Angest.  
Bundesforschungsanstalt für  
Getreideverarbeitung  
D-493 Detmold  
Schützenberg 12 (Fed. Rep. of Germany)

INTERNATIONAL ORGANIZATIONS (Cont.)

IDACE

Jean Colanéri  
Secrétaire Général  
IDACE-Association des Industries  
des Aliments diététiques de la CEE  
194 rue de Rivoli  
F-75001 Paris (France)

INTERNATIONAL FEDERATION OF GLUCOSE  
INDUSTRIES (IFG)

E.G. Rapp  
4, Ave. Ernest Claes  
B-1980 Tervueren  
Bruxelles (Belgium)

INTERNATIONAL SECRETARIAT FOR THE  
INDUSTRIES OF DIETETIC FOOD PRODUCTS  
(ISDI)

Dr. W. Schultheiss  
Geschäftsführer  
Bundesverband der Diätetischen  
Lebensmittelindustrie  
Kelkheimer Strasse 10  
D-638 Bad Homburg v.d.H.  
Postfach (Fed. Rep. of Germany)

INTERNATIONAL UNION OF NUTRITIONAL  
SCIENCES (IUNS)

Dr. M. Astier-Dumas  
3, rue du Dôme  
F-75116 Paris (France)

INSTITUT EUROPEEN DES INDUSTRIES DE  
LA GOMME DE CAROUBE (INEC)

Peter Rønnau  
Manager  
IFAG Interfrimulsion GmbH  
24 Lübeck  
P.O.Box 1384 (Fed. Rep. of Germany)

INSTITUT EUROPEEN DES INDUSTRIES DE  
LA PECTINE (IEIP)

R. Petit  
Unipectine S.A.  
26, Avenue de l'Opéra  
75001 Paris (France)

CENTRE DE LIAISON DES INDUSTRIES DE  
TRAITEMENT DES ALGUES MARINES DE LA CEE

P. Deville  
Directeur général CLITAM  
11, rue Morane Savinier  
F-78140 Velizy Villacoublay (France)

WORLD HEALTH ORGANIZATION (WHO)

Dr. W. Keller  
Medical Officer  
Nutrition Unit  
WHO, Avenue Appia  
CH-1211 Geneva 27 (Switzerland)

Peter S. Rönisch, M.D.  
Regional Officer for Mother and Child  
World Health Organization  
Regional Office for Europe  
8, Scherfigsvej  
DK-2100 Copenhagen (Denmark)

FAO SECRETARIAT

G.O. Kermode  
Chief  
FAO/WHO Food Standards Programme  
FAO, Rome (Italy)

B. Dix  
Food Standards Officer  
FAO/WHO Food Standards Programme  
FAO, Rome (Italy)

Dr. L.G. Lodomery  
Food Standards Officer  
FAO/WHO Food Standards Programme  
FAO, Rome (Italy)

GERMAN SECRETARIAT

Dr. W. Hölzel  
Angestellter  
Bundesministerium für Jugend,  
Familie und Gesundheit  
Deutschherrenstrasse 87  
D-53 Bonn - Bad Godesberg

H. Hauser  
Oberamtsrat  
Bundesministerium für Jugend,  
Familie und Gesundheit  
Deutschherrenstrasse 87  
D-53 Bonn - Bad Godesberg

DRAFT STANDARD FOR INFANT FORMULA  
(Advanced to Step 8)

1. SCOPE

This Standard applies to Infant Formula in liquid or powdered form intended for use, where necessary, as a substitute for human milk in meeting the normal nutritional requirements of infants. It also provides a standard for formulae intended for infants with special nutritional requirements, except for certain provisions which must be modified to meet those 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).

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:

(a) <u>Vitamins other than Vitamin E</u>	<u>Amounts per 100 available Calories</u>		<u>Amounts per 100 available kilojoules</u>	
	<u>Minimum</u>	<u>Maximum</u>	<u>Minimum</u>	<u>Maximum</u>
Vitamin A	250 I.U. or 75 µg expressed as retinol	500 I.U. or 150 µg expressed as retinol	60 I.U. or 18 µg expressed as retinol	120 I.U. or 37 µg expressed as retinol
Vitamin D	40 I.U.	80 I.U.	10 I.U.	19 I.U.
Ascorbic acid (Vitamin C)	8 mg	none specified	1.9 mg	none specified
Thiamine (Vitamin B <sub>1</sub> )	40 µg	" "	10 µg	" "
Riboflavin (Vitamin B <sub>2</sub> )	60 µg	" "	14 µg	" "
Nicotinamide	250 µg	" "	60 µg	" "
Vitamin B <sub>6</sub> 1/	35 µg	" "	9 µg	" "
Folic acid	4 µg	" "	1 µg	" "
Pantothenic acid	300 µg	" "	70 µg	" "

1/ Formulae with a higher protein content than 1.8 g protein/100 Calories should contain a minimum of 15 µg Vitamin B<sub>6</sub> per gramme of protein.

(a) <u>Vitamins other than Vitamin E</u> (Cont.)	<u>Amounts per 100 available Calories</u>		<u>Amounts per 100 available kilojoules</u>	
	<u>Minimum</u>	<u>Maximum</u>	<u>Minimum</u>	<u>Maximum</u>
Vitamin B <sub>12</sub>	0.15 µg	none specified	0.04 µg	none specified
Vitamin K <sub>1</sub>	4 µg	" "	1 µg	" "
Biotin (Vitamin H)	1.5 µg	" "	0.4 µg	" "
(b) Vitamin E (α-tocopherol compounds)	0.7 I.U./g linoleic acid <sup>3/</sup> , but in no case less than 0.7 I.U./100 available calories	" "	0.7 I.U./g linoleic acid <sup>3/</sup> , but in no case less than 0.15 I.U./100 available kilojoules	" "
(c) <u>Minerals</u>				
Sodium (Na)	20 mg	60 mg	5 mg	15 mg
Potassium (K)	80 mg	200 mg	20 mg	50 mg
Chloride (Cl)	55 mg	150 mg	14 mg	35 mg
Calcium (Ca) <sup>1/</sup>	50 mg	none specified	12 mg	none specified
Phosphorus (P) <sup>1/</sup>	25 mg	" "	6 mg	" "
Magnesium (Mg)	6 mg	" "	1.4 mg	" "
Iron (Fe) <sup>2/</sup>	1 mg	" "	0.25 mg	" "
Iron (Fe)	0.15 mg	" "	0.04 mg	" "
Iodine (I)	5 µg	" "	1.2 µg	" "
Copper (Cu)	60 µg	" "	14 µg	" "
Zinc (Zn)	0.5 mg	" "	0.12 mg	" "
Manganese (Mn)	5 µg	" "	1.2 µg	" "
(d) <u>Choline</u>	7 mg	" "	1.7 mg	" "
(e) <u>Protein</u>	<p>(i) Shall not be less than 1.8 g per 100 available calories (or 0.43 g per 100 available kilojoules) of protein of nutritional quality equivalent to that of casein or a greater quantity of other protein in proportion to its biological value. The quality <sup>4/</sup> of the protein shall not be less than 85% of that of casein. The total quantity of protein shall not be more than 4 g per 100 available calories (or 0.96 g per 100 available kilojoules). 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.</p> <p>(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 shall be used.</p>			
(f) <u>Fat and Linoleate</u>	<p>The product shall contain linoleic acid (in the form of glycerides) at a level not less than 300 mg per 100 available Calories (or 70 mg per 100 available kilojoules) and fat at a level not less than 3.3 g and not more than 6 g per 100 available Calories (or not less than 0.8 g and not more than 1.5 g per 100 available kilojoules).</p>			

<sup>1/</sup> The Ca:P ratio shall be not less than 1.2 and not more than 2.0.

<sup>2/</sup> See Section 10.1.6.

<sup>3/</sup> Or per g polyunsaturated fatty acids, expressed as linoleic acid.

<sup>4/</sup> Protein quality shall be determined provisionally using the PER method as laid down in Section 11 of this Standard, it being understood that the suitability of the product for infant feeding in conformity with Section 2.2 of this Standard will have been established on the basis of adequate and appropriate tests in the light of current knowledge.

4.2 Optional Ingredients

4.2.1 In addition to the vitamins and minerals listed under 4.1.2(a), (b) and (c), 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.

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 odour.

4.5 Specific Prohibition

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

5. FOOD ADDITIVES

The following additives are permitted in the preparation of Infant Formula, as described in Section 1 of this Standard, and within the restrictions stated below:

5.1 Thickening Agents

Maximum level in 100 ml of the ready-to-drink product

Guar gum	0.1 g in all types of Infant Formula
Locust bean gum <sup>1/</sup>	0.1 g in all types of Infant Formula
Distarch phosphate, singly or in combination	} 0.5 g in soy-based Infant Formulae only, in hydrolyzed protein and/or amino acid-based Infant Formulae only
Acetylated distarch phosphate, singly or in combination	
Phosphated distarch phosphate, singly or in combination	
Hydroxypropyl starch, singly or in combination	} 2.5 g in soy-based Infant Formulae only, in hydrolyzed protein and/or amino acid-based Infant Formulae only
Carrageenan	
	} 0.03 g in regular, milk- and soy-based liquid Infant Formulae only
	} 0.1 g in hydrolyzed protein and/or amino acid-based liquid Infant Formulae only

5.2 Emulsifiers

Lecithin	0.5 g in all types of Infant Formula
Mono- and diglycerides	0.4 g in all types of Infant Formula

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<sup>1/</sup> Temporarily endorsed.

5.3 pH-Adjusting Agents

Maximum level in 100 ml of the ready-to-drink product

Sodium hydrogen carbonate	} Limited by GMP (within the limits for Na and K in Section 4.1.2(c)) in all types of Infant Formulae
Sodium carbonate	
Potassium hydrogen carbonate	
Potassium, carbonate	
Sodium citrate	
Potassium citrate	
L(+)Lactic acid	Limited by GMP in all types of Infant Formulae
L(+)Lactic acid producing cultures	Limited by GMP in all types of Infant Formulae
Citric acid	Limited by GMP in all types of Infant Formulae

5.4 Antioxidants

Mixed tocopherols concentrate	1 mg in all types of Infant Formulae
L-Ascorbyl palmitate	1 mg in all types of Infant Formulae

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 free from residues of hormones and antibiotics, as determined by means of agreed methods of analysis, and practically free from other contaminants, especially pharmacologically active substances.

7. HYGIENE

7.1 To the extent possible in good manufacturing practice, the product shall be free from objectionable matter.

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

- (a) shall be free from pathogenic microorganisms;
- (b) shall not contain any substances originating from microorganisms in amounts which may represent a hazard to health; and
- (c) shall not contain any other poisonous or deleterious substances in amounts which may represent a hazard to health.

7.3 The product 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 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; nitrogen 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. FILL OF CONTAINER

In the case of products in ready-to-eat form, the fill of container shall be:

- (i) not less than 80% v/v for products weighing less than 150 g (5 oz.);
- (ii) not less than 85% v/v for products in the weight range 150-250 g (5-8 oz.);  
and
- (iii) not less than 90% v/v 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 20°C which the sealed container will hold when completely filled.

10. LABELLING

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

10.1 The Name of the Food

10.1.1 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.

10.1.2 The sources of protein in the product shall be clearly shown on the label.

10.1.3 If 90% or more of the protein is derived from whole or skim milk, as such or with minor modification, the product may be labelled "Infant Formula based on Milk".

10.1.4 A product which contains neither milk nor any milk derivative may be labelled "contains no milk or milk products" or an equivalent phrase.

10.1.5 A product intended for infants with special nutritional requirements shall be labelled to show clearly the special requirement for which the formula is to be used and the dietary property or properties on which this is based.

10.1.6 Products containing not less than 1 mg Iron (Fe)/100 available calories shall be labelled "Infant Formula with Iron".

10.2 List of Ingredients

10.2.1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and added minerals, these ingredients shall be arranged as separate groups for vitamins and minerals, respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.

10.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate class names for these ingredients and additives may be included on the label.

10.3 Declaration of Nutritive Value

The declaration of nutrition information shall contain the following information in the following order:

10.3.1 The amount of energy, expressed in calories (kcal) and/or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grammes of the food as sold as well as per specified quantity of the food as suggested for consumption.

10.3.2 The total quantity of each vitamin, mineral, choline and any optional ingredient as listed in paragraphs 4.1.2 and 4.2 of this Standard per 100 grammes of the food as sold as well as per specified quantity of the food as suggested for consumption. In addition, the declaration per 100 calories (or per 100 kilojoules) is permitted.

10.4 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.

10.5 Name and Address

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

10.6 Country of Origin

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

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

10.7 Lot Identification

Each container shall be embossed or otherwise permanently marked, in code or in clear, to identify the producing factory and the lot.

10.8 Date Marking and Storage Instructions

10.8.1 The date of manufacture or, preferably, the date of minimum durability shall be declared in clear and whichever is used shall be indicated.

10.8.2 Storage instructions shall appear on the label or on the accompanying leaflet.

10.9 Information for Utilization

10.9.1 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.

10.9.2 Information that infants over six months of age should receive supplemental foods in addition to formula shall appear on the label.

10.10 Optional Labelling

An indication that Infant Formula is intended to replace or supplement breast feeding, where breast feeding is not possible or is insufficient, may be given on the label.

11. METHODS OF ANALYSIS AND SAMPLING

The methods of analysis and sampling described hereunder are international referee methods (will be inserted at Step 8).

APPENDIX III

DRAFT STANDARD FOR CANNED BABY FOODS  
(Advanced to Step 8)

1. SCOPE

1.1 Baby Foods are foods intended primarily for use during the normal infant's weaning period and also for the progressive adaptation of infants and children to ordinary food. They may be either in ready-to-eat form or in dry form requiring reconstitution with water only. They do not include products covered by the Codex Standards for Infant Formula or for Processed Cereal-Based Foods for Infants and Children.

1.2 Baby Foods in ready-to-eat form are processed by heat before or after being sealed in their containers, and Baby Foods in dry form are processed by physical means, in each case so 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 persons 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 Baby Foods 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 Vitamins and minerals may only be added in accordance with the legislation of the country in which the food is sold.

3.1.3 The total sodium content of the products shall not exceed 250 mg Na/100 g calculated on the ready-to-eat basis in accordance with directions for use. The addition of salt (NaCl) to fruit products and dessert products based on fruit is not permitted.

3.2 Consistency and Particle Size

3.2.1 Ready-to-eat baby foods are 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.

3.2.2 Dry baby foods, after reconstitution with water or other suitable liquid, approximate to the consistency and particle size of strained or junior foods under 3.2.1.

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

The following additives are permitted in the preparation of Canned Baby Food, within the restrictions stated below:

4.1 Thickening Agents

	<u>Maximum level in 100 g of the ready-to-eat product (unless otherwise indicated)</u>
Locust bean gum <u>1/</u>	0.2 g
Distarch phosphate	} 6 g, singly or in combination
Acetylated distarch phosphate	
Phosphated distarch phosphate	
Hydroxypropyl starch	
Acetylated distarch adipate	
Distarch glycerol <u>2/</u>	
Acetylated distarch glycerol <u>2/</u>	
Non-amidated pectin	1 g in canned fruit-based Baby Foods only.

1/ Temporarily endorsed.

2/ Pending endorsement by the Codex Committee on Food Additives (see paras 55-56, ALINORM 76/26A).

4.2 Emulsifiers

Maximum level in 100 g of the ready-to-eat product (unless otherwise indicated)

Lecithin 0.5 g  
Mono- and diglycerides 1 g/100 g fat

4.3 pH Adjusting Agents

Sodium hydrogen carbonate ) Limited by GMP (within the limit for Na in  
Sodium carbonate ) Section 3.1.3)

Potassium hydrogen carbonate )  
Calcium carbonate ) Limited by GMP

Citric acid and Na salt 0.5 g (also within the limit for Na in  
Section 3.1.3)

L(+)Lactic acid 0.2 g

Acetic acid 0.5 g

4.4 Antioxidants

Mixed tocopherols concentrate ) 300 mg/kg fat, singly or in combination

α-Tocopherol )

L-Ascorbyl palmitate 200 mg/kg fat

L-Ascorbic acid and its Na and K salts 0.5 g/kg, expressed as ascorbic acid and  
within the limit for Na in Section 3.1.3

4.5 Flavours

Vanilla extract Limited by GMP

Ethyl vanillin 7 mg

Vanillin 7 mg

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 free from residues of hormones and antibiotics as determined by means of agreed methods of analysis and practically free from other contaminants, especially pharmacologically active substances.

6. HYGIENE

6.1 To the extent possible in good manufacturing practice the product shall be free from objectionable matter.

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

- (a) shall be free from pathogenic microorganisms;
- (b) shall not contain any substances originating from microorganisms in amounts which may represent a hazard to health; and
- (c) shall not contain any other poisonous or deleterious substances in amounts which may represent a hazard to health.

6.3 The product 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 Committee on Food Hygiene).

7. PACKAGING

The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. If in ready-to-eat form, it shall be packed in hermetically sealed containers; nitrogen and carbon dioxide may be used as packing media.

8. FILL OF CONTAINER

In the case of products in ready-to-eat form, the fill of container shall be:

- (i) not less than 80% v/v for products weighing less than 150 g (5½ oz.);
- (ii) not less than 85% v/v for products in the weight range 150-250 g (9 oz.); and
- (iii) not less than 90% v/v for products weighing more than 250 g (9 oz.) of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20°C which the sealed container will hold when completely filled.

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 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 shall be arranged as separate groups for vitamins and minerals, respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.

9.2.2 The specific name shall be declared for ingredients and food additives. In addition, appropriate class names for these ingredients and additives may be included on the label.

9.3 Declaration of Nutritive Value

The declaration of nutrition information shall contain the following information in the following order:

9.3.1 The amount of energy, expressed in calories (Cal) and/or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grammes of the food as sold as well as per specified quantity of the food as suggested for consumption.

9.3.2 In addition to any other nutritional information required by national legislation, the total quantity in the final product of each vitamin and mineral added according to Section 3.3, shall be declared per 100 g as well as according to the serving size of the food suggested for consumption.

9.4 Net Contents

The net contents of Baby Food shall be declared either by weight or volume according to consistency. 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.

9.5 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 code or in clear, to identify the producing factory and the lot.

## 9.8 Date Marking and Storage Instructions

9.8.1 The date of manufacture or the date of expiry shall be declared in clear and whichever is used shall be indicated.

9.8.2 Storage instructions shall appear on the label or on the accompanying leaflet.

## 9.9 Information for Utilization

9.9.1 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.

9.9.2 For canned beets (beetroot) and spinach, the following statement shall appear on the label "Use after the age of 12 weeks".

## 10. METHODS OF ANALYSIS AND SAMPLING

The methods of analysis and sampling described hereunder are international referee methods (will be inserted at Step 8).

### APPENDIX IV

#### PROPOSED DRAFT STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND CHILDREN (Advanced to Step 8)

##### 1. SCOPE

Processed Cereal-Based Foods for Infants and Children are intended to supplement the diet of infants and 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 dilution with water, milk or other suitable liquid 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 Dextrinized 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, maltose and glucose.

2.4 Pasta are foods prepared from milled cereal products suitable for the weaning period.

2.5 Rusks and biscuits are cereal 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 other suitable liquids. "Milk biscuits" consist primarily of cereals and contain milk solids.

### 3. DEFINITIONS

- 3.1 The term "Infant" means a person not more than 12 months of age.
- 3.2 The term "Children" means persons from the age of more than 12 months up to the age of three years.
- 3.3 The term "Calorie" means a "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, rusk, biscuits and pasta are prepared primarily from one or more milled cereal products, such as wheat, rice, barley, oats, rye, maize, millet, sorghum and buckwheat and/or legumes (pulses) and also, sesame, arachis and soybean.
- 4.1.2 Where the product is intended to be mixed with water before consumption, the minimum content of protein shall not be less than 15% on a dry weight basis and the quality of the protein shall not be less than 70% of that of casein.
- 4.1.3 Milk biscuits are prepared from one or more milled cereal products with the addition of not less than 10% m/m milk proteins.
- 4.1.4 The sodium content of the products described in Sections 2.1 to 2.4 of this Standard shall not exceed 100 mg/100 g of the ready-to-eat product.
- 4.1.5 The sodium content of the products described in Section 2.5 of this Standard shall not exceed 300 mg/100 g of the product as sold.

#### 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. Essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only natural L forms of amino acids shall be used;
- salt (sodium chloride)
- milk and milk products;
- eggs;
- meat;
- fats and oils;
- fruits and vegetables;
- sugars (nutritive carbohydrate sweeteners);
- malt;
- honey;
- cocoa (only in products to be consumed after 9 months of age, and at the maximum level of 5% m/m on a dry basis);
- potatoes;
- starches, including enzyme modified starches and starches treated by physical means.

4.2.2 The addition of vitamins, minerals and iodized salt shall be in conformity with the legislation of the country in which the product is sold.

#### 4.3 Quality Factors

- 4.3.1 All ingredients, including optional ingredients, shall be clean, safe, suitable and of good quality.
- 4.3.2 All processing and drying should be carried out in a manner that minimizes loss of nutritive value, particularly protein quality.
- 4.3.3 The moisture content of the products shall be governed by good manufacturing practice for the individual product categories and shall be at such a level that there is a minimum loss of nutritive value and at which microorganisms cannot multiply.

#### 4.4 Consistency and Particle Size

4.4.1 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.

4.4.2 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 other suitable liquid, 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

The following additives are permitted in the preparation of Processed Cereal-based Foods for Infants and Children, as described in Sections 2.1 to 2.5 of this Standard:

5.1 Emulsifiers

In 100 g of product, on a dry weight basis  
(unless otherwise indicated)

Lecithin	1.5 g
Mono- and diglycerides	1.5 g

5.2 pH Adjusting Agents

Sodium hydrogen carbonate	Limited by GMP (within the limits for Na in Sections 4.1.4 and 4.1.5)
Potassium hydrogen carbonate	Limited by GMP
Calcium carbonate	Limited by GMP
L(+)-Lactic acid	1.5 g
Citric acid	2.5 g

5.3 Antioxidants

Mixed tocopherols concentrate	300 mg/kg fat, singly or in combination
$\alpha$ -Tocopherol	300 mg/kg fat, singly or in combination
L-Ascorbyl palmitate	200 mg/kg fat
L-Ascorbic acid and its Na and K salts	50 mg, expressed as ascorbic acid and within the limits for Na in Sections 4.1.4 and 4.1.5

5.4 Flavours

Vanilla extract	Limited by GMP
Ethyl vanillin	7 mg
Vanillin	7 mg

5.5 Enzymes

Malt carbohydrasés	Limited by GMP
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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 free from residues of hormones, antibiotics as determined by means of agreed methods of analysis and practically free from other contaminants, especially pharmacologically active substances.

7. HYGIENE

7.1 To the extent possible in good manufacturing practice the product shall be free from objectionable matter.

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

- (a) shall be free from pathogenic microorganisms;
- (b) shall not contain any substances originating from microorganisms in amounts which may represent a hazard to health; and
- (c) shall not contain any other poisonous or deleterious substances in amounts which may represent a hazard to health.

7.3 The product 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 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 (or "Milk Biscuits") for Infants (and/or Children)" or "Pasta 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 shall be arranged as separate groups for vitamins and minerals, respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.

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

9.3 Declaration of Nutritive Value

The declaration of nutrition information shall contain the following information in the following order:

9.3.1 The amount of energy, expressed in Calories (Cal) or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grammes of the food as sold as well as per specified quantity of the food as suggested for consumption.

9.3.2 If special dietary claims are made that the food contains proteins, vitamins or minerals, the label shall also contain the following information: The amount per 100 grammes of the food as sold as well as per specified quantity of the food as suggested for consumption of protein and each of the stated vitamins and minerals, expressed in percentage of the recommended daily intake of the respective nutrient.

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 purposes of labelling.

9.7 Lot Identification

Each container shall be embossed or otherwise permanently marked in code or in clear to identify the producing factory and the lot.

9.8 Date Marking and Storage Instructions

9.8.1 The date of manufacture or the date of expiry shall be declared in clear and whichever is used shall be indicated.

9.8.2 Storage instructions shall appear on the label or on the accompanying leaflet.

9.9 Information for Utilization

9.9.1 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.

9.9.2 When the product contains less than 15% protein and the quality is less than 70% that of casein, directions on the label shall state "Milk or formula but no water shall be used for dilution or mixing" or an equivalent statement.

9.9.3 When the product contains more than 15% protein, the instructions for dilution on the label shall state that water, milk or formula may be used for dilution or mixing, in accordance with medical advice or the legislation of the country in which the food is sold.

10. METHODS OF ANALYSIS AND SAMPLING

The methods of analysis and sampling described hereunder are international referee methods (will be inserted at Step 8).

APPENDIX V

SECOND REPORT OF THE AD HOC WORKING GROUP ON FOOD ADDITIVES IN FOODS FOR INFANTS AND CHILDREN

1. The Working Group on Food Additives in Foods for Infants and Children met during the session of the Committee under the Chairmanship of Dr. T.K. Murray (Canada) to consider the technological justification for distarch glycerol and acetylated distarch glycerol. These substances were inadvertently omitted in the earlier meeting of the Working Group (see ALINORM 76/26, para 93).
2. Distarch glycerol and acetylated distarch glycerol are effective in suspending solids and imparting a palatable texture. They are resistant to severe processing conditions and have a low sensitivity to salts. Acetylated distarch glycerol has excellent freeze-thaw and low temperature stability, particularly in acid foods.
3. The Group agreed that these starches were technologically justified additions to the list of modified starches already approved as thickening agents for Canned Baby Food. The level of use and ADI is the same as for other modified starches (see CX/FSDU 75/6).
4. The Working Group also considered briefly the proposal from Mexico for the use of BHA and BHT in processed foods based on cereals. Agreement was not reached and it was decided to defer a recommendation until next year. It is requested that countries, particularly those with hot climates, who require these antioxidants, submit justification to the Chairman of the Working Group.



5. The Working Group requested that all submissions and comments on the applicability of the Carry-over principle to foods for infants and children reach them by no later than April 1976 to permit the Group to request such additional information as may be required in making recommendations to the Committee.

#### APPENDIX VI

### REPORT OF THE AD HOC WORKING GROUP ON METHODS OF ANALYSIS IN STANDARDS FOR FOODS FOR INFANTS AND CHILDREN

1. The above Ad Hoc Working Group, set up at the beginning of the session (see para 5 of the main report), discussed Conference Room Document No. 6 under the Chairmanship of Dr. W. Krönert, Director and Professor of the Federal Health Office, Berlin. The conclusions of the Group are as follows:

#### Determination of Fat

2. The Group noted that a method was being collaboratively tested for the determination of fat in various types of foods for infants and children and recommended that this method, if endorsed by the Codex Committee on Methods of Analysis and Sampling, should be inserted into the three standards being elaborated.

#### Determination of Crude Fibre

3. The Group noted that the determination of crude fibre was intended primarily to assess available carbohydrates by difference. As methods using acid hydrolysis (e.g. AOAC/ISO method being elaborated) would have an error of around 0.5 to 1% in the product, it was considered that the determination of crude fibre in products containing crude fibre of a similar order of magnitude was not of any great consequence. The Group was of the opinion that the Codex Committee on Methods of Analysis and Sampling should give this matter its consideration in relation to the three standards in Appendices II, III and IV to this Report. It was noted that an enzymatic method was currently under investigation and the Group agreed that such a method, when developed, should be compared collaboratively with the AOAC/ISO method.

#### Determination of Carbohydrates

4. The Group agreed that this should be determined by difference, calculated from results of the determination of crude fibre, fat, ash, protein and water for which the establishment of methods was necessary.

#### Determination of Crude Protein

5. The Group considered that basically in the determination of crude protein it was a question of the use of appropriate and agreed conversion factors. The Group agreed that the Codex Committee on Methods of Analysis and Sampling should be requested to examine the factors previously suggested by the Committee in view of the fact that the foods in question contained various types of protein and mixtures of proteins.

#### Determination of Linoleic Acid

6. The Group considered that the method which was being elaborated by the Codex Committee on Fats and Oils, would be suitable for the quantitative determination of linoleic acid and agreed that the Codex Committee on Methods of Analysis and Sampling should be requested to examine the problem of the extraction of linoleic acid from Infant Formula.

#### Protein Efficiency Ratio (PER)

7. The Group proposed that the AOAC method (1970, 39.166-39.170) should be submitted to the Codex Committee on Methods of Analysis and Sampling for endorsement, but noted that the presence of lactose interfered with the determination unless the test group and reference group of test animals both received the same amount of this sugar in their daily diet. The Group agreed that the Codex Committee on Methods of Analysis and Sampling should be requested to give this matter further consideration and amend the AOAC method, if necessary.

Vitamin A, Ascorbic Acid, Pantothenic Acid

8. The Group noted that two methods had been endorsed for the determination of each of these substances. It was thought that, given the range of foods to be covered, this might indeed be necessary. The Group agreed that the Codex Committee on Methods of Analysis and Sampling should be requested to reexamine this question.

Carotenes

9. The determination of these substances was thought to be necessary where they had been added as a source of Vitamin A.

General Considerations

10. The Group agreed that the methods to determine vitamins and minerals should apply to Infant Formula and the other infant foods where a quantitative declaration of the presence of vitamins and minerals was made on the label. It was also agreed that methods endorsed for foods for infants and children should be tested collaboratively to establish their reliability. The Group was of the opinion that the Secretariat should be authorized to finalize the Sections on Methods of Analysis and Sampling on the basis of the decisions of the Codex Committee on Methods of Analysis and Sampling.

APPENDIX VII

PROPOSED DRAFT GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES (at Step 3)

1. SCOPE

The provisions of this Standard govern the labelling of prepackaged foods for special dietary uses and claims made for such foods. The provisions in the Recommended International Standard for the Labelling of Prepackaged Foods (CAC/RS 1-1969) will also apply but in the event of conflict, the provisions of this standard will take precedence.

2. DEFINITION OF TERMS

For the purposes of this Standard:

2.1 Foods for special dietary uses (or special dietary foods) means those processed foods on general sale which (a) are specially prepared (and claimed to be such) to meet the dietary need of persons whose normal process of assimilation or metabolism are disturbed or for whom a particular effect is to be obtained by a controlled intake of certain substances in food; or (b) without modification are comparable to such foods. They are only those foods for which there is a specified dietary class. Dietary class means the special dietary characteristics of the food and shall not contain any reference to the physiological or pathological condition in which it is intended to alleviate except as provided for in individual Codex standards for special dietary foods covering dietary classes. Dietary classes shall be those provided for in individual standards and subsequent additions thereto (see Section 5).

2.2 Claim means an assertion on a label or in a visual or oral advertisement or an implication or inference which might reasonably be considered to arise out of the use of any words, pictures or devices on a label or in such an advertisement, that the food has special properties, qualities or ingredients which render it suitable for a special dietary use. The inclusion of substances mentioned only in a list of ingredients shall not constitute a claim. Advertisement includes any statement in promotional literature but not in literature provided solely for persons qualified to prescribe special diets for patients with specific digestive or metabolic disorders.

3. MANDATORY LABELLING OF PREPACKAGED FOODS FOR SPECIAL DIETARY USES

3.1 The Name of the Special Dietary Food

(a) The name of the food shall have associated with it the name prescribed for the dietary class to which it belongs, except as provided in individual Codex standards for special dietary foods covering dietary classes;

- (b) if the name of the dietary class is associated with a "coined" or fanciful name, it shall also be associated with an appropriately descriptive term;
- (c) disorders or diseases for which certain special dietary foods are intended shall not be associated with the name of such food except as provided for in individual Codex standards for special dietary foods covering dietary classes;
- (d) the term "health" shall not be used in association with the name of a special dietary food and the name of the food shall not imply health giving properties.

### 3.2 List of Ingredients

A complete list of ingredients shall be declared on the label in descending order of proportion by weight except that in the case of dehydrated foods which are intended to be reconstituted by the addition of water or milk, the ingredients may be listed in order of proportion in the reconstituted produce provided that the list of ingredients is headed by a statement such as "ingredients when reconstituted".

### 3.3 Lot Identification

Each container shall be embossed or otherwise permanently marked, in code or in clear, to identify the producing factory and the lot.

### 3.4 Date Marking

To be elaborated in the light of discussions in the Codex Committee on Labelling.

### 3.5 Information for Utilization

#### (a) Storage for Unopened Food

Storage instructions for unopened special dietary food packages shall be included on the label if such information is necessary to ensure that the product will conform with the Standard at the time it is opened for use;

#### (b) Storage of Opened Food

Storage instructions for opened packages of special dietary food shall be included on the label if necessary to ensure that the opened product maintains wholesomeness and nutritive value. A warning should be included on the label if the food is not capable of being stored after opening, or is not capable of being stored in the container after opening;

#### (c) Directions for Use

Directions for use shall be included on the label if necessary to ensure correct utilization. In particular, directions for reconstitution should be included on the label, if applicable.

## 4. CLAIMS

4.1 Where a claim is made that a food is in a dietary class, that food shall comply with all the provisions of this standard.

4.2 A food which is without special modification is comparable to a particular class of dietary food, shall not be claimed to be a special dietary food and notwithstanding 3.1(a), shall not include the dietary class in its name. Such a food may, however, bear a statement in the label that "this food is naturally 'x' ('x' indicating the distinguishing characteristic such as low in sodium)" provided that such a statement is true and not likely to mislead the purchaser and that the food conforms to the conditions of this standard and, where appropriate, to those of the individual standard.

4.3 Claims shall not be made for preventive or curative properties or guarantee results for foods in a dietary class nor shall there be any implication that the advice of a physician is not necessary.

4.4 Claims shall not be made for foods in a dietary class regarding their suitability for any disease or disorder except as provided for in individual Codex standards for special dietary foods covering dietary classes.

4.5 No claim shall be made that a food in a dietary class is a "slimming" food or has intrinsic weight-reducing properties but notwithstanding the provisions of Article 4.3, it shall not be prohibited to make a claim asserting usefulness for slimming or weight reduction provided that the label contains a statement to the effect that the food cannot aid slimming or weight reduction except as part of a diet in which the total intake of calories is controlled.

4.6 No claim should state or imply that a food in a dietary class has medical or other professional support.

4.7 No claim shall be made that a food in a dietary class is "sugar-free".

## 5. DIETARY CLASSES

The following are examples of dietary classes of foods for special dietary uses (see Section 2.1) for which Codex standards have been or are being elaborated or which are envisaged:

- Foods with low sodium content (including salt substitutes)
- Gluten-free foods
- Foods for use in a diet for diabetics
- Low-carbohydrate foods
- Low-calorie foods
- Low-protein foods
- Cholesterol-reduced foods

## APPENDIX VIII

### PROPOSED DRAFT STANDARD FOR "GLUTEN-FREE" FOODS (Returned to Step 6)

#### 1. SCOPE

1.1 This Standard applies to foods which are represented directly or indirectly or by implication as intended for special dietary uses by reason of being "free" from gluten.

1.2 The standard refers only to the specific provisions related to the special dietary purpose for which these foods are intended.

#### 2. DESCRIPTION

##### 2.1 Definition

"Gluten-free food" is a food so described, normally containing wheat, rye, barley, or oat flour, in which the gluten of this flour has been extracted, or in which ingredients not containing gluten have been substituted for the wheat, rye, barley, or oat flour normally used in foods of that kind.

##### 2.2 Subsidiary Definitions

2.2.1 For the purpose of this Standard, "gluten" includes only those protein fractions of such grains as wheat, rye, barley and oats which are capable in certain predisposed subjects of causing gluten-induced enteropathies.

2.2.2 For the purpose of this Standard, "gluten-free" means that the gluten content, if any, does not cause unequivocal clinical signs of intolerance nor intestinal mucosal damage in persons sensitive to gluten under clinical or experimental testing conditions.

#### 3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

A "gluten-free" food shall be based on or shall contain:

- (a) wheat, rye, barley or oat flour from which all gluten has, so far as is practicable, been extracted, or;
- (b) ingredients which do not contain gluten in substitution for wheat, rye, barley or oat flour normally used in a food of that kind; or
- (c) any mixture of two or more such ingredients.

4. LABELLING

The following provisions in respect of the labelling of this product are subject to endorsement by the Codex Committee on Food Labelling:

4.1 In addition to any labelling provisions applying to the particular food concerned, the following specific provisions for the labelling of "gluten-free foods" shall apply.

4.2 The description "gluten-free" shall be given in immediate proximity to the name of the product.

4.3 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 shall be arranged as separate groups of vitamins and minerals, respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.

4.4 The declaration of nutrition information shall contain the following: the amount of energy, expressed in Calories (Cal) or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grammes of the food as sold or, where appropriate, of a unit (e.g. one biscuit) of the product.

4.5 The true nature of the carbohydrate (or carbohydrates) and the protein (or proteins) as well as the specific plant or animal source of each carbohydrate and protein present in the product shall be declared on the label.

5. PACKAGING

"Gluten-free" foods shall only be sold in containers.

6. METHODS OF ANALYSIS AND SAMPLING

The methods of analysis and sampling described hereunder are subject to endorsement by the Codex Committee on Methods of Analysis and Sampling.

6.1 Determination of Moisture Content

According to the AOAC (1970) method 1/ (Official Methods of Analysis of the AOAC, 1970, 7.003: Moisture - Official Final Action. I. Drying in Vacuo at 95-100° (2)). Results are expressed as g moisture/100 g.

6.2 Determination of Ash Content

According to the AOAC (1970) method (Official Methods of Analysis of the AOAC, 1970, 7.010: Ash (7) - Official Final Action). Results are expressed as g ash/100 g to the first decimal place.

6.3 Determination of Fat Content

(Methods to be endorsed) 2/

6.4 Determination of Crude Fibre Content

(Method to be endorsed) 3/

6.5 Determination of Protein Content

(Method to be endorsed) 3/

6.6 Determination of Available Carbohydrates Content

(Methods to be endorsed) 4/

6.7 Calculation of Available Calories (Available Kilojoules)

(Method to be endorsed) 5/

6.8 Determination of Gluten Content

(Method to be elaborated)

1/ Temporarily endorsed (ALINORM 72/23, para 26) for other products.

2/ See ALINORM 72/23, para 28 and ALINORM 74/26, paras 6-7.

3/ See ALINORM 72/23, paras 29, 30 and 31, and ALINORM 74/26, para 9 and App. IIB.

4/ See ALINORM 72/23, para 32 and ALINORM 74/26, para 10.

5/ See ALINORM 72/23, para 31 and ALINORM 74/26, para 8 and App. IIA.

PROPOSED DRAFT STANDARD FOR FOLLOW-UP MILK FOR INFANTS AND CHILDREN 1/  
(At Step 3)

1. SCOPE

This Standard applies to foods in liquid or powdered form intended for use during the normal infants' weaning period and during the progressive adaptation of infants and children to ordinary food. These foods are intended to constitute the milky part of the infants' and children's diet besides processed foods based on cereals and baby foods at the age when diversification in the feeding of infants and children is recommended. However, this Standard does not include products covered by the Codex standards for Infant Formula, for Processed Cereal-based Foods for Infants and Children or for Canned Baby Foods.

2. DESCRIPTION

2.1 Follow-up milk, 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. DEFINITION

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

3.2 The term "children" means persons from the age of more than 12 months 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 Follow-up milk is a product based on milk of cows or other animals and edible constituents of plant and animal origin, which have been proved to be suitable for infants and children starting from the weaning period. Ninety percent of the total protein content shall be of lactic origin.

4.1.2 Follow-up milk shall contain, per 100 available calories (100 kilojoules) of intake, the following minimum and maximum levels of vitamins, minerals in an available form, choline, protein, fat and linoleate 2/:

(a) <u>Vitamins other than Vitamin E</u>	<u>Amounts per 100 available calories</u>		<u>Amounts per 100 available kilojoules</u>	
	<u>Minimum</u>	<u>Maximum</u>	<u>Minimum</u>	<u>Maximum</u>
Vitamin A	250 I.U. or 75 µg expressed as retinol	500 I.U. or 150 µg expressed as retinol	60 I.U. or 18 µg expressed as retinol	120 I.U. or 37 µg expressed as retinol
Vitamin D	40 I.U.	80 I.U.	10 I.U.	19 I.U.
Ascorbic acid (Vitamin C)	8 mg	None specified	1.9 mg	None specified

1/ Another name could be "Weaning Milk".

2/ Provisions in this Section which differ from those in the Standard for Infant Formula (App. II) are marked with an asterisk. The provisions for Vitamins A and D have been brought into line with the Standard for Infant Formula by the Secretariat.

(a) <u>Vitamins other than Vitamin E (Cont.)</u>	<u>Amounts per 100 available calories</u>		<u>Amounts per 100 available kilojoules</u>	
	<u>Minimum</u>	<u>Maximum</u>	<u>Minimum</u>	<u>Maximum</u>
Thiamine (Vitamin B <sub>1</sub> )	40 µg	None specified	10 µg	None specified
Riboflavin (Vitamin B <sub>2</sub> )	60 µg	None specified	14 µg	None specified
Nicotinamide	250 µg	None specified	60 µg	None specified
* Vitamin B <sub>6</sub> <u>1/</u>	38 µg	None specified	9 µg	None specified
Folic acid	4 µg	None specified	1 µg	None specified
Pantothenic acid	300 µg	None specified	70 µg	None specified
Vitamin B <sub>12</sub>	0.15 µg	None specified	0.04 µg	None specified
Vitamin K <sub>1</sub>	4 µg	None specified	1 µg	None specified
Biotin (Vitamin H)	1.5 µg	None specified	0.4 µg	None specified
(b) Vitamin E (α-tocopherol - compounds calculated as dl-α-tocopherol-acetate) minimum of 0.7 I.U. per g polyunsaturated fatty acids calculated as linoleic acid. <u>2/</u>		None specified	-	None specified
(c) <u>Minerals</u>				
* Sodium (Na)	20 mg	100 mg	5 mg	24 mg
* Potassium (K)	80 mg	250 mg	20 mg	60 mg
* Chloride (Cl)	55 mg	200 mg	14 mg	48 mg
* Calcium (Ca) <u>3/</u>	60 mg	None specified	14 mg	None specified
* Phosphorus (P) <u>3/</u>	35 mg	None specified	8 mg	None specified
Magnesium (Mg)	6 mg	None specified	1.4 mg	None specified
Iron (Fe)	1 mg <u>4/</u>	None specified	0.25 mg <u>4/</u>	None specified
Iron (Fe)	0.15 mg	None specified	0.04 mg	None specified
Iodine (I)	5 µg	None specified	1.2 µg	None specified
* Copper (Cu)	6 µg	None specified	1.4 µg	None specified
Zinc (Zn)	0.5 mg	None specified	0.12 mg	None specified
Manganese (Mn)	5 µg	None specified	1.2 µg	None specified
(d) <u>Choline</u>	7 mg	None specified	1.7 mg	None specified

1/ Formulae with a higher protein content than 2.5 g protein/100 calories should contain a minimum of 15 µg vitamin B<sub>6</sub> per gramme of protein.

2/ See Section 4.1.2(b) of the Standard for Infant Formula in App. II to this Report.

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

4/ See Section 10.1.6 of this Standard.

(e) Protein \*

- (i) Shall not be less than 2.5 g per 100 available Calories (or 0.60 g per 100 available kilojoules) of protein of nutritional quality equivalent to that of casein or a greater quantity of other protein in proportion to its biological value. The quality of the protein shall not be less than 85% of that of casein. The minimum value set for quality may be modified by national authorities according to their own regulations and/or local conditions.
- (ii) Isolated amino acids may be added to follow-up milk only to improve its nutritional value for infants and children. Essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only natural L forms of amino acids shall be used.

(f) Fat and linoleate \*

The product shall contain linoleic acid (in the form of glycerides) at a level not less than 300 mg 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).

4.2 Optional Ingredients

\* 4.2.1 In addition to the vitamins and minerals listed under 4.1.2(a), (b) and (c), other nutrients may be added, provided they are suitable for the feeding during the weaning period.

4.2.2 The usefulness of these nutrients shall be scientifically shown.

4.2.3 Restrictions to the ingredients quoted under 4.1.1:

- Cocoa: Only in products to be consumed after 9 months of age and at the maximum level of 5% m/m on a dry basis.

4.3 Consistency and Particle Size

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

4.4 Purity Requirements

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

4.5 Specific Prohibition

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

5. FOOD ADDITIVES <sup>1/</sup>

The following additives are permitted in the preparation of Follow-up Milk for Infants and Children, as described in Sections 2.1 to 2.3 of this Standard:

5.1 Emulsifiers

	<u>In 100 g of product, on a dry weight basis (unless otherwise indicated)</u>
Lecithin	1.5 g
Mono- and diglycerides	1.5 g

<sup>1/</sup> The original proposal by Switzerland was to include in Section 5 the additives listed in Section 5, App. IV of ALINORM 76/26. The Secretariat has included the additives provided for in the revised standard for Processed Cereal-based Foods for Infants and Children (see App. IV of this Report), except that Na and K salts have also been made subject to Section 4.1.2(c) of this Standard.



5.2 pH Adjusting Agents

In 100 g of product, on a dry weight basis (unless otherwise indicated)

Sodium hydrogen carbonate	( Limited by GMP (within the limits for Na and K in Section 4.1.2(c))
Potassium hydrogen carbonate	
Calcium carbonate	Limited by GMP
L(+)-Lactic acid	1.5 g
Citric acid	2.5 g

5.3 Antioxidants

Mixed tocopherols concentrate	300 mg/kg fat, singly or in combination
$\alpha$ -Tocopherol	300 mg/kg fat, singly or in combination
L-Ascorbyl palmitate	200 mg/kg fat
L-Ascorbic acid and its Na and K salts	50 mg, expressed as ascorbic acid (within the limits for Na and K in Section 4.1.2(c))

5.4 Flavours

Vanilla extract	Limited by GMP
Ethyl vanillin	7 mg
Vanillin	7 mg

5.5 Enzymes

Malt carbohydrases	Limited by GMP
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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 free from residues of hormones and antibiotics as determined by means of agreed methods of analysis and practically free from other contaminants, especially pharmacologically active substances.

7. HYGIENE

7.1 To the extent possible in good manufacturing practice, the product shall be free from objectionable matter.

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

- (a) shall be free from pathogenic microorganisms;
- (b) shall not contain any substances originating from microorganisms in amounts which may represent a hazard to health; and
- (c) shall not contain any other poisonous or deleterious substances in amounts which may represent a hazard to health.

7.3 The product 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 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; nitrogen 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. FILL OF CONTAINER

In the case of products in ready-to-eat form, the fill of container shall be:

- (i) not less than 80% v/v for products weighing less than 150 g (5 oz.);
- (ii) not less than 85% v/v for products in the weight range 150-250 g (8 oz.); and
- (iii) not less than 90% v/v 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 20°C which the sealed container will hold when completely filled.

10. LABELLING

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

10.1 The Name of the Food

10.1.1 The name of the product shall be "Follow-up Milk" or any appropriate designation indicating the true nature of the food, in accordance with national usage.

10.1.2 The sources of protein in the product shall be clearly shown on the label.

10.1.3 If 90% or more of the protein is derived from whole or skim milk, as such or with minor modification, the product may be labelled "Follow-up Milk based on Milk".

10.1.4 A product which contains neither milk nor any milk derivative may be labelled "contains no milk or milk products" or an equivalent phrase.

10.1.5 A product intended for infants or children with special nutritional requirements shall be labelled to show clearly the special requirement for which the food is to be used and the dietary property or properties on which this is based.

10.1.6 A product containing more than 1 mg Iron (Fe)/100 Cal shall be labelled as "Follow-up Milk with Iron".

10.2 List of Ingredients

10.2.1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and added minerals, these ingredients shall be arranged as separate groups for vitamins and minerals, respectively, and within these groups the vitamins and minerals need not to be listed in descending order of proportion.

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

10.3 Declaration of Nutritive Value

The declaration of nutrition information shall contain the following information in the following order:

10.3.1 The amount of energy, expressed in Calories (kcal) and/or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grammes of the food as sold as well as per specified quantity of the food as suggested for consumption.

10.3.2 The total quantity of each vitamin, mineral, choline and any optional ingredient as listed in paragraphs 4.1.2 and 4.2 of this Standard per 100 grammes of the food as sold as well as per specified quantity of the food as suggested for consumption. In addition, the declaration per 100 Calories (or per 100 kilojoules) is permitted.

#### 10.4 Net Contents

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

#### 10.5 Name and Address

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

#### 10.6 Country of Origin

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

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

#### 10.7 Lot Identification

Each container shall be embossed or otherwise permanently marked, in code or in clear, to identify the producing factory and the lot.

#### 10.8 Date Marking and Storage Instructions

10.8.1 The date of manufacture or, preferably, the date of minimum durability shall be declared in clear and whichever is used shall be indicated.

10.8.2 Storage instructions shall appear on the label or on the accompanying leaflet.

#### 10.9 Information for Utilization

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

### 11. METHODS OF ANALYSIS AND SAMPLING

✓The same methods of analysis will be listed here as in the Draft Standard for Infant Formula, in App. II of this Report.