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ALINORM 76/26

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX ALIMENTARIUS COMMISSION
Eleventh Session - 1976

REPORT OF THE EIGHTH SESSION OF THE CODEX COMMITTEE ON FOODS FOR SPECIAL DIETARY USES
Bonn-Bad Godesberg, 9-14 September 1974

INTRODUCTION

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

2. Dr. D. Eckert, Ministerialdirigent, welcomed the delegations on behalf of the Federal Minister for Youth, Family and Health. In his opening remarks, he stressed the growing importance of the Codex Alimentarius Commission in the context of international organizations, in particular with regard to developing countries. Dr. Eckert elaborated on the special tasks of the Codex Committee on Foods for Special Dietary Uses. In this connection, he pointed out the necessity of reconsidering in detail the questions related to the use of additives following the discussions of the Third Joint FAO/WHO Conference on Food Additives and Contaminants and the Tenth Session of the Codex Alimentarius Commission:

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

Australia	Hungary	Poland
Belgium	Ireland	Sweden
Canada	Italy	Switzerland
Czechoslovakia	Madagascar	Sudan
Denmark	Mexico	Thailand
France	Netherlands	United Kingdom
Finland	Norway	United States of America
Federal Republic of Germany		

Observers from 10 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

4. 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 being made available by the Delegation of the U.S.A. in the discussions of the Proposed Draft Standard for Infant Formula. This paper contained recommendations elaborated by the Committee on Nutrition, American Academy of Pediatrics, for updating Formula Standards in the U.S.A.

APPOINTMENT OF RAPPORTEURS

5. Mr. L.M. Beacham (U.S.A.) and Mr. H. Prost (France) were appointed as rapporteurs.

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

Tenth Session of the Codex Alimentarius Commission (July 1974 - ALINORM 74/44)

6. The Committee noted that the Commission had decided to advance the Draft Standards for Processed Foods for Infants and Children Based on Cereals and for Gluten-Free Food to Step 6 of the Procedure.

7. The Secretariat informed the Committee of the deliberations concerning the relationship and balance of responsibilities between Codex Commodity Committees and the Codex Committee on Food Additives on the justification of additives for use in foods (ALINORM 74/44, paras 224-229).

8. The Committee noted that it had the primary responsibility for determining the technological need for an additive. It further noted the instruction of the Commission that the Report of the meeting should "include sufficient information on the basis of which the Codex Committee on Food Additives would consider whether or not the need for a food additive had been technologically justified".

9. There was some discussion on how the request to supply "sufficient information" should be interpreted. The Committee noted that in the Report of the Codex Alimentarius Commission it was stated that "a brief synopsis of technological justification" would suffice. It was pointed out that presenting the full documentation to both Committees might lead to duplication of work and it would moreover require governments to delegate experts in this particular area to the sessions of both Committees.

10. The Delegation of the U.S.A. had some reservations with regard to the statement by the Commission that "the maximum levels for food additives proposed should represent the smallest amount of the additives needed". It was pointed out that there would be no problem for existing foods but problems might arise with modifications of these foods or new foods. Additives in new foods should not a priori be limited to the maximum levels for food additives accepted for existing foods.

SAMPLING OF FOODS FOR INFANTS AND CHILDREN

11. At its eighth session, the Codex Committee on Methods of Analysis and Sampling had authorized the Secretariat to obtain the views of the Codex Committee on Foods for Special Dietary Uses on the need to draw up a sampling procedure for Infant Formula and to indicate the details that would be necessary to draw up an appropriate sampling plan. The Delegation of the Federal Republic of Germany had prepared a working paper "Sampling Plans for Infant Formula (CX/FSDU 74/13)" in which a differentiation was made between health risks and economic risks. The Delegation of the U.S.A. pointed out that in addition to the above paper document CX/MAS 73/4 "Tentative Draft Code of Sampling for Infant Formula" should be taken into consideration.

12. The Committee discussed both the general aspects and special problems related to the matter and agreed that the working document CX/FSDU 74/13 should be revised to include sampling requirements for different foods and should be split into two sections - a technological section and a statistical section. The Committee agreed to set up a working group. The delegations of France, the Federal Republic of Germany (coordinator), the United Kingdom and the U.S.A. agreed to prepare a revised document for the next meeting of the Committee.

DRAFT STANDARD FOR CANNED BABY FOODS

13. The Committee had before it the above standard (ALINORM 72/26, App. IV) at Step 7 of the Procedure. It further considered a working paper prepared by the delegation of the United Kingdom containing a revision of the standard (CX/FSDU 72/9 and government comments on the standard (CX/FSDU 74/4 and Add. I).

Title

14. The delegation of Australia stated that in its opinion the title of the standard should be brought into line with the product actually covered by the standard. In its view, the reference to "baby" was misleading as the products to be covered by the standard were not intended for babies in the generally accepted sense of the word.

15. The delegation of Australia and several other delegations made a number of proposals for a new title. In this connection it was also suggested that the present standard be merged with the Draft Standard for Processed Foods for Infants and Children Based on Cereals. The Committee agreed to return to the matter when dealing with the latter standard (see para 119 of this Report).

16. At the suggestion of several French-speaking delegations, the French translation of the title (if it were to remain unchanged) was amended to read "Aliments diversifiés de l'enfance ("Babyfoods")".

Scope

17. The delegation of the United Kingdom reiterated its proposal to extend the scope of the standard to cover certain dehydrated baby foods. Several other delegations also stated that these products were marketed in their countries and supported the proposal. It was thought that by providing for the dehydrated products the need for a further standard to cover these foods would be avoided.

18. A number of other delegations held the view, however, that the inclusion of dried products would unduly complicate the standard. Doubts were raised on the feasibility of covering such a broad range of products in the hygiene provisions, and a proposal was made to include the dried products in the Standard for Processed Foods for Infants and Children Based on Cereals, rather than in the present standard. It was further pointed out that the scope, which was intended to cover a specific class of supplementary foods, could be misconstrued to include foods normally eaten by adults.

19. The Committee agreed after ample discussion to broaden the scope of the standard to include dried products which required only water for reconstitution, and to clarify the question on the type of food to be covered. The revised text would read: "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-for-use form or in dry form requiring reconstitution with water only. They do not include products covered by the Codex Standards for Infant Formula or Processed Foods for Infants and Children Based on Cereals".

20. It was further agreed that in sub-section 1.2 dealing with the prevention of spoilage of the foods, provision should be made for the dry products to be processed by physical means. Other amendments consequential upon the inclusion of dehydrated foods were made throughout the standard.

Definitions

21. The Committee considered briefly a proposal to increase the upper age limit for "children" from three years to four years, but decided not to make such a change.

Salt

22. The Committee agreed that the salt level (sub-section 3.1.4) should relate to the total salt, taking into consideration any naturally occurring quantity in the various components of the particular product, and that this be expressed as an upper limit for the sodium ion.

23. One proposal was made to relate such limits to the classes of food, such as fruits, meats, etc, using percentage by weight. Another proposal was made to express them in relation to the energy value of the product. Two delegations suggested that no salt should be added at all.

24. A number of delegations made specific proposals with regard to the maximum sodium level. At the request of the Chairman, these were submitted to the delegation of the Federal Republic of Germany, who suggested 250 mg Na/100 Cal as a possible compromise. The Committee agreed to accept this as a temporary limit and to request governments to comment specifically on the suggested level.

Specific prohibition of ionizing radiation

25. The proposal was made to make the provision more specific by stating that the prohibition against treatment by ionizing radiation did not include UV-radiation, as it was said that under certain circumstances exposure to the latter might result in quite low levels of ionization. It was pointed out that the whole question of ionizing radiation was still in an investigational phase and that therefore more specific wording than the present did not seem advisable. It was further pointed out that it would be increasingly difficult to state with certainty that the various raw materials (e.g. cereals, potatoes) used in the manufacture of a product had not been exposed to ionizing radiation from artificial sources. It was agreed, however, to leave the provision unchanged but to accept that it should be interpreted as excluding UV-radiation. The delegations of the Federal Republic of Germany and the Netherlands held the view that intentional exposure to UV-radiation of baby foods should not be allowed.

Pesticide Residues

26. The Committee noted that the Codex Committee on Pesticide Residues at its seventh session had re-endorsed this provision (ALINORM 74/24, para 18). The delegation of the Federal Republic of Germany proposed to set an upper limit of 0.01 ppm for all pesticide residues. The Committee, however, held the view that this was not feasible.

Other Contaminants

27. With regard to residues of hormones and antibiotics, the Committee was of the opinion that these should not be present in the product and amended the provision accordingly. As it was not considered practicable to set limits for other contaminants, the Committee retained the requirement that the product should be practically free from other contaminants. It was suggested by some delegations that specific reference might be made to nitrates, nitrites and nitrosamines; this was further discussed under "Information for Utilization" (see para 37).

Hygiene

28. The Committee noted that the Codex Committee on Food Hygiene had revised this section (ALINORM 74/13, para 32). In view of the change in the scope of the standard, whereby the products could be liquid or dry, it was agreed to make some amendments in the text proposed by the Food Hygiene Committee.

Packaging

29. It was agreed that the statement that for ready-for-use products "suitable gases which do not react with the product" could be used as packing media was too broad. The Committee agreed to limit the gases to be used as packing media to nitrogen and carbondioxide.

Fill of Container

30. The delegation of the Federal Republic of Germany proposed and the Committee agreed that the minimum fill of containers should be differentiated into three categories instead of two; for products weighing 150 g (5 ⅓ oz.) or less the minimum fill should be at least 80 per cent. The two categories already contained in the provision remained unchanged.

Labelling

31. The Committee noted that this section had been considered by the Codex Committee on Food Labelling and had not been endorsed (ALINORM 74/22, paras 46-48).

The Name of the Food

32. It was pointed out that in this provision a distinction was made between components and ingredients and that it was not required that both terms be contained in the name of the product, as "components" might be understood to be protein, carbon-hydrate, etc. The Committee agreed to the deletion of this word.

List of Ingredients

33. In line with a recommendation of the Codex Committee on Food Labelling (ALINORM 74/22A, para 22) the provision on the listing of ingredients was revised to clarify the way in which vitamins and mineral salts were to be declared.

Declaration of Nutritive Value

34. Various delegations proposed redrafts of this sub-section. After ample discussion, the Committee agreed to accept a text prepared by the delegation of Denmark which is contained in the revised draft standard (Appendix II). It was pointed out that the amended text required that quantitative declarations with regard to proteins, vitamins or minerals would have to be related to 100 g of the food as sold as well as to quantities of the prepared food suggested for consumption. This double declaration requirement was thought by some delegations to be unnecessary and in countries with labels in more than one language might present space problems. It was further pointed out that the requirement that amounts of vitamins and minerals present be expressed as a percentage of the recommended daily intake of the respective nutrients was equivalent to introducing requirements based on certain current national legislation since there were no internationally accepted recommended daily allowances. The Committee nevertheless agreed to make no further amendments.

Country of Origin

35. The delegation of Poland proposed to delete the second part of the provision allowing for the possibility not to declare the country of origin in case the omission did not mislead or deceive the consumer. It was pointed out that the text of the provision had been quoted from the Recommended International General Standard for the Labelling of Prepackaged Foods (sub-section 3.5) and the Committee agreed to leave the wording unchanged.

Lot Identification

36. In line with a recommendation of the Codex Committee on Food Labelling (ALINORM 74/22, paras 43 and 47), the Committee agreed to make a distinction between lot identification and date marking and to introduce in the standard the wording proposed by the Food Labelling Committee.

Information for Utilization

37. A number of delegates pointed out that there was no scientific evidence for the requirement of a statement on the labels of carrots, canned beets and spinach that the container, once opened, should not be stored for later use. The particular restriction had been included, bearing in mind the possible development of nitrites and nitrosamines during storage. It was pointed out that subsequent to opening a container contamination from various sources might lead to deterioration of the product.

38. The delegation of Norway proposed that all products containing nitrate should be covered by the provision and presented the following text for consideration by the next session of the Committee:

> "9.8.2 For products containing more than [....] ppm nitrate (NO_3^-) the following statement shall appear on the label: "Do not give to infants under the age of 12 weeks. Once opened, do not store for later use."

39. The Committee noted that the requirement not to store an opened container for later use might well lead to substantial losses of good food. The feasibility of giving a time limit on the label beyond which the product in an opened container should not be kept was discussed. It was agreed, however, that this might lead to undesirable results. Similarly, the possibility of indicating the temperature at which the products should be stored was considered. In view of various climatic conditions and the absence of refrigeration facilities in large parts of the world such a statement was not considered practicable.

40. The Committee decided to limit the information for utilization of canned carrots, beets and spinach only to a minimum age of the infant, after which the product could be fed. The delegation of France proposed that this minimum age limit be raised to 16 weeks. The Committee was of the opinion, however, that the present limit of 12 weeks provided sufficient safeguards.

41. The delegation of Australia stated that a number of cases of over-feeding infants with canned baby foods had been reported and suggested that a provision for warning to this effect be included. The Committee was of the opinion, however, that although this problem could well be a real one in developed countries, the issue as such was a matter of controlling advertising in relation to the product and therefore should not be contained in the standard. The representative of the IOCU supported the views presented by the delegation of Australia.

Status of the Standard

42. The Committee agreed that the Draft Standard for Canned Baby Foods should be returned to Step 6 of the Procedure in view of the substantial amendments made in the course of its deliberations. The revised standard is contained in Appendix II to this Report.

DRAFT STANDARD FOR INFANT FORMULA

43. The Committee had before it the above standard (ALINORM 72/26, App.III) at Step 7 of the Procedure, government comments on the above standard (CX/FSDU 74/4 and Add. 1) and the comments of an ad hoc Working Party of the Protein Advisory Group (CX/FSDU 74/3) on the same standard. It further considered a working paper prepared by the delegation of the United Kingdom (CX/FSDU 74/4-Add) and a paper prepared by Dr. H.P. Sarett of the delegation of the U.S.A. on recommendations

developed to update formula standards by the Committee on Nutrition of the American Academy of Pediatrics (see also para 4). The two latter documents were distributed during the session. (The United Kingdom document had been submitted to the Secretariat in the Federal Republic of Germany but had not been distributed prior to the meeting.) The delegation of Ireland stated its reservation concerning discussing the U.S. document without prior consultation with his government.

44. Considerable discussion took place on the proposal of the United Kingdom delegation to return the standard to Step 6. The Committee agreed to decide on the status of the standard after full discussion of the standard.

45. While introducing his paper, Dr. Sarett drew attention to the fact that the availability of milk in different parts of the world might not be adequate and other sources of proteins would have to be used in increasing proportions in the preparation of infant formulae. To facilitate the transition, no distinction should be made in basic nutrition requirements between infant formulae based on milk and infant formulae not based on milk. Dr. Sarett further proposed that the reference standard for protein quality used in the standard should be changed from whole egg to casein since, in the light of present knowledge, the latter appeared to be more appropriate for use in the testing of infant foods.

46. In presenting its paper (CX/FSDU 74/4-Add), the delegation of the United Kingdom expressed its doubts about the Draft Standard for Infant Formula for the following reasons. The standard was in conflict with the basic concept of the Codex Alimentarius which sets out to provide acceptable minimum standards; new knowledge in the sphere of nutrition justified a more flexible approach; comments in the report of the Protein Advisory Group (CX/FSDU 74/3) should be considered, and the problem of misleading promotion and advertising required examination. The United Kingdom delegation proposed that the standard be referred back to Step 6.

47. The Committee agreed to the proposal of the delegation of the U.S.A. not to make any distinction between infant formulae based on milk and infant formulae not based on milk.

48. The definition "infant formulae based on milk" (3.3) was deleted. The Committee decided, however, to introduce in the labelling section a provision dealing with the declaration on the label of the protein source in the product.

Minerals

49. Several delegations pointed out that only those minimal nutrients were to be added which were necessary to achieve an adjustment of the mineral levels of the formula to the relevant ones in human milk. Furthermore, the Committee was of the opinion that only those minerals should be added for which enough data and exact methods of analysis were readily available, even for the very small quantities required. It was stated by the delegation of the United Kingdom that caution should be exercised in prescribing standards for trace elements since these nutrients in ionic form might not have the same physiological effects as the trace nutrients in breast milk.

Iron

50. The Committee discussed the need to produce infant formulae with different amounts of iron depending on specific requirements and agreed to change the minimum amount of iron per 100 available calories (Cal) from 1 mg to 0.15 mg on the basis of results of recent research. It also agreed to provide for a second product with a minimum of 1.0 mg iron per 100 Cal which would be labelled as infant formula with iron. The delegation of the Netherlands, supported by the delegations of Denmark and France, stated that in its opinion the product with 0.15 mg iron was deficient in iron and that this should be borne out by appropriate labelling. The delegation of the United Kingdom stated that, in the light of recent research, the addition of any iron could increase the risk of gastroenteritis, especially in developing countries.

Copper

51. The minimum amount of copper of 60 mcg/100 available calories (Cal) was discussed and mention was made of the need to maintain the zinc and copper ratio and of the possibility of copper deficiency in infants under stress. The Committee confirmed the present figure of 60 mcg minimum amount of copper in the standard. The delegation of the United Kingdom was supported by the delegation of Australia in stating its reservation on this decision and expressed the opinion that there was no need for addition of copper to the diet of infants under six months of age, since young infants have very adequate stores of copper in the liver and there was no evidence of copper deficiency in normal infants or before the age of 7-9 months.

Manganese

52. The Committee took note of the deliberations on manganese of the WHO Expert Committee on Trace Elements in Human Nutrition (WHO Techn. Rep. Series No. 532 - 1973). In the light of new results of research on manganese requirements in infant food, the Committee agreed to lower the minimum amount of manganese per 100 available calories (Cal) from 100 mcg to 5 mcg.

Chloride

53. The Committee discussed whether to delete the minimum/maximum levels for chloride from the list of minerals, since the quantity in the product was determined by the chemical formulae of the components. It was decided nevertheless to retain the principle of a minimum/maximum level, but to reduce the minimum limit to 55 mg per 100 available Calories (Cal), because this figure would equal the chloride level of human milk.

Sodium

54. The Committee was of the opinion that the upper limit of sodium appeared to be very high and agreed to reduce the maximum level of sodium to 60 mg per 100 available Calories (Cal).

Calcium/Phosphate Ratio

55. Several delegations pointed out that the prescribed range for the ratio Ca:P of not less than 1.2 and not more than 2.0 was in some instances difficult to obtain, depending on geographical location, seasonal variations, and especially when using buffalo milk. A number of proposals were made and the Committee decided finally to retain the Ca:P ratio of not less than 1.2 and not more than 2.0, taking into account that, if needed, calcium may be added to the product.

Vitamin B_6

56. The Committee agreed to reduce the minimum limit for vitamin B_6 from 50 to 35 mcg/100 Cal which the Protein Advisory Group and other sources considered adequate for formulae containing 1.8 g protein/100 Cal. It was further agreed that formulae with a higher protein content should contain a minimum of 15 mcg vitamin B_6/gram of protein.

Vitamin K_1

57. For infant formulae based on milk no minimum requirements had been set at previous meetings for vitamin K_1 in view of the natural presence of vitamin K_1 in milk at a level where no evidence of deficiency had been noted: 4 mcg/100 Cal.

58. The Committee agreed that for the various formulae, including non-milk based products, the requirement could be set at a uniform minimum level of 4 mcg/100 Cal. The delegation of Canada was not certain that the new lower limit would suffice for the non-milk based products.

Biotin

59. The Committee agreed to reduce the requirement for the minimum amount of Biotin to 1.5 mcg/100 Cal.

Vitamin E

60. The delegation of the U.S.A. proposed that the minimum for vitamin E in infant formulae be 0.314/100 Cal and linoleic acid 0.7 IU/g.

61. In discussing this suggestion and the level of vitamin E to be established, the Committee also considered a proposal to relate the quantity of polyunsaturated acids rather than linoleic acid; the matter of how best to express the quantity in IU or mg; and whether to measure vitamin E as α-tocopherol or α-tocopherol acetate. As no definite agreement could be reached on any of these questions it was decided to leave the provision unchanged, except that "α-tocopherol compounds" was to appear in parenthesis after vitamin E. It was further decided to note the comments of the delegations of the U.S.A., Canada, Denmark and the Netherlands in arriving at a final value and a method of stating this.

Choline

62. The delegation of the U.S.A. proposed reducing the level of choline from 12 to 7 mg/100 available Calories. Over a large number of years commercial products with a lower level had been marketed and no evidence of deficiency had been noted. The delegation of the Netherlands pointed out that choline could be synthesized in the human body

and preferred no mandatory requirement for the substance in the standard. The Committee decided to adopt a minimum level which was set at 7 mg/100 Cal.

Thiamine

63. It was pointed out that present knowledge indicated that the optimum level of thiamine was 40 mcg/100 Cal in particular when a substantial portion of the calories originated from carbohydrates. The Committee agreed to this proposed level.

Protein

64. At the Sixth Session of the Committee, the minimum level of protein per 100 available Calories had been discussed in detail by the Committee and agreement had been reached on the minimum quantity related to egg protein as well as the minimum requirements for the quality.

65. The delegation of the U.S.A. stated that in 1967 the Committee on Nutrition of the American Academy of Pediatrics had recommended that the minimum level of protein in infant formula be 1.8 g/100 Cal with a protein quality equal to or greater than that of casein as measured by PER (protein efficiency ratio studies in rats).

66. This recommendation had been based on balance and growth studies in infants fed with formulae made with different levels and qualities of protein as well as infants fed with human milk. This was the basis on which a proposal was made to the Committee at its sixth session for a minimum level of 1.8 g protein/100 Cal in the Standard for Infant Formula. The Committee had accepted the figure but had changed the reference protein from casein to whole egg. The scientific reason for this amendment is not recorded in the Report.

67. The delegation of the U.S.A. explained at this session that when proteins are evaluated in the rat the relative value of egg is greatly exaggerated because the protein and amino acid requirements of the rat are much higher than and somewhat different from those of the human being. A reference is made to this in the FAO/WHO Report on "Protein and Energy Requirements", FAO Nutrition Meetings Report Series No. 52, 1973 (WHO Techn. Rep. Series No. 522, 1973) in which protein requirements are discussed, based on a provisional amino acid scoring pattern for infants. Using this pattern, it is shown that for infants casein and cows' milk protein are virtually equivalent to egg protein. Moreover the amino acids in 1.8 g casein/100 Cal adequately supply all of the amino acids required by an infant.

68. The delegation of the U.S.A. further stated that as amino acids scores did not show that amino acids in a protein were fully available, protein quality should also be assayed in animal studies using an appropriate protein reference standard. As casein reference standards are available and egg reference standards are not available, and since the amino acids in 1.8 g casein/100 Cal supply all that the infants need, and furthermore, since results of infant feeding studies have been correlated with PER studies using casein as a standard, it recommended that casein be used as the reference standard and that the minimum amount of protein of this quality be 1.8 g/100 Cal as endorsed by the Committee on Nutrition, American Academy of Pediatrics.

69. Some delegations held the view that a transition of the protein quality from whole egg to casein was acceptable, but that the most important factor was that any claims could be easily verified even though this might have to be based on an approximation. Other delegations did not wish the protein standard to be changed from whole egg to casein.

70. It was also stated that the change from whole egg protein to casein as a reference implied that the minimum quality ratio would have to be increased and a figure of 85% was suggested. Furthermore, the upper limit for the quantity might have to be readjusted and 4.5 g instead of 4.0 g were mentioned. It was pointed out that an upper limit of 4.5 g would go beyond the limit set by the Protein Advisory Group. On the other hand, to require a ratio of 85% would not allow the use of certain protein resources such as wheat, oats, etc., which would thus remain untapped.

71. The delegation of the Netherlands stated that the Protein Advisory Group (CX/FSDU 74/3, para 1.3.2) had agreed that a minimum quantity of 1.8 g of protein/100 Cal (protein quality equivalent to that of whole egg protein) was adequate for the infants' daily needs. Other investigations in this field came to the same conclusion. It found the proposal of the U.S.A. to change this reference protein quality of whole egg protein equivalent to that of a standard casein unacceptable because in this way the minimum quantity of useful protein for the infant would in the Netherlands' view be lowered to about two-thirds of the originally accepted value.

72. Before going any further into the problem of adjusting protein levels, the Netherlands' delegation was of the opinion that the method for comparing the value of different proteins had first to be agreed upon and that government comments should be solicited specifically on this matter.

73. The delegation of Norway agreed that the question of a suitable reference protein was dependent on the method selected for the evaluation of the protein quality and suggested that this be specified in terms of NPU values, which it considered to be preferable to PER values. It considered the presently available chemical methods of analysis not to be satisfactory for determining protein quality.

74. The Committee agreed to retain the minimum protein requirement at 1.8 g but to change the nutritional quality equivalent to that of casein instead of whole egg protein. The requirement for the quality of the protein was changed from 70% of whole egg protein to 85% of casein. The upper limit for the quantity of protein was kept at 4 g.

Fat and Linoleate

75. The Committee agreed to refer to linoleic acid (in the form of glycerides) rather than linoleate. Several proposals were made to change the existing minimum limits for linoleic acid (300 mg/100 Cal), ranging from 100 mg (United Kingdom) to 500 mg (Canada) per 100 Cal. The former figure was thought sufficient to reduce the danger of rancidity. It was stated that clinical observations with regard to deficiency of essential fatty acids were of paramount importance in the interpretation of biochemical investigation in order to assure sound conclusions. In support of the latter figure, the delegation of Canada stated that 500 mg/100 Cal represented the best present estimate of the infant requirement. This level approximated the amount of essential fatty acid (including arachidonic acid) found in human milk. The Committee decided to retain the limit of 300 mg/100 Cal.

76. The Committee decided to increase the minimum fat level from 2 to 3.3 g/100 Cal, but to retain the upper limit at 6 g/100 Cal.

Infant Formulae based on Milk

77. In line with the decision to make no distinction between milk based and non-milk based formulae, this provision was deleted (4.1.2.2).

Pesticide Residues

78. The Committee noted that this provision had been re-endorsed by the Codex Committee on Pesticide Residues (ALINORM 74/24, para 18).

Other Contaminants

79. In line with the decision taken with regard to a similar provision in the Standard for Baby Food, it was required that hormones and antibiotics should be absent and that the products should be practically free from other contaminants.

Hygiene

80. The Committee noted the revision of this section by the Codex Committee on Food Hygiene and followed the proposal of that Committee (ALINORM 74/13, para 32).

Packaging

81. As for canned baby foods, the gases used as packing media were limited to nitrogen and carbon dioxide.

Fill of Container

82. It was noted that no provision was made in the standard for "Fill of Container", and it was decided that the revised text agreed to for baby foods would be included in the standard.

The Name of the Food

83. The Committee agreed to revise the second paragraph of this provision to take into account its earlier decision not to distinguish between products of formulae based on milk and those not based on milk. It was considered necessary to require that sources of protein in the product should be clearly shown on the label. The delegation of Switzerland proposed, and the Committee agreed, to provide for a statement on the label "Infant Formulae based on Milk", provided that 90% or more of the protein was derived from whole or skim milk, as such or with minimum modification; it further agreed to allow the statement "Free from Milk and Milk Products" for a product containing neither milk nor milk derivatives.

List of Ingredients

84. Wording similar to that introduced in the relevant provision of the Draft Standard for Baby Foods was approved.

Declaration of Nutritive Value

85. In line with the changes made in the relevant provision in the Draft Standard for Baby Foods, the provision requiring a statement of the levels of the various nutrients in the product was revised. The declaration of such nutrients per 100 Cal remained optional.

86. The proposal was made to introduce a provision allowing for a statement to appear on the label that the product met with the requirements of the Codex Standard for Infant Formula. Those delegations opposed to this proposal pointed out that an analogy existed between such a statement and the use of a Codex mark or symbol, discussed at the Tenth Session of the Commission. Bearing in mind the decision of the Commission with regard to such a mark or symbol such an identified option seemed undesirable. It was further stated that this was a matter which was not restricted to the various products under consideration but that it seemed to apply accross the board for all commodity standards being elaborated by the Codex Alimentarius Commission. The majority of the delegations appeared not to be in favour of such a provision.

Lot Identification

87. It was agreed to revise the provision in line with the relevant proposal of the Codex Committee on Food Labelling (ALINORM 74/22, para 43).

Information for Utilization

88. In addition to the provision on preparation, etc., it was thought desirable that a requirement that information to the effect that infants over six months of age should receive supplemental foods in addition to the formulae should appear on the label. This would be very much in line with the relevant proposal made by the Protein Adivsory Group (document CX/FSDU 74/3, page 2). The provision was included in the standard.

Status of the Standard

89. The Committee discussed at some length whether the standard should be retained at Step 7 and comments should be invited on specific issues, or whether it would be preferable to return the standard to Step 6 in order to allow for observations to be made on the standard as a whole. In view of the importance and urgency of the standard, the delegation of the Federal Republic of Germany and a number of other delegations considered it more appropriate that the standard be retained at Step 7 of the Procedure. A slight majority of the delegations, however, expressed themselves in favour of returning the standard to Step 6 of the Procedure, in view of the large number of changes, in particular with regard to the protein question. The standard was therefore returned to Step 6 of the Procedure.

FOOD ADDITIVES IN

(a) Draft Standard for Infant Formula
(b) Draft Standard for Canned Baby Foods
(c) Draft Standard for Processed Foods for Infants and Children Based on Cereals

90. The Committee had before it the Lists of Food Additives for Technological Purposes in Foods for Infants and Children (ALINORM 74/26, Appendices IV and V) and government comments on the above lists (documents CX/FSDU 74/12 and 74/5 and their addenda).

91. It was noted that the Codex Committee on Food Additives at its ninth session had not endorsed the above lists. These were referred back to this Committee for reconsideration, taking into account the views expressed at the FAO/WHO Meeting on Additives in Baby Foods (Rome, 1971 - WHO Techn. Rep. Series No. 488) and the observations made by the Codex Committee on Food Additives (ALINORM 74/12, paras 62-68).

92. Furthermore, the Committee took note of the decision made at the Tenth Session of the Codex Alimentarius Commission that Commodity Committees should explain and substantiate the technological justification for the proposed use of food additives in the standard to the Codex Committee on Food Additives.

93. Because the additional data that were requested from governments were not yet available to the meeting, it was agreed that no detailed consideration should be given to the food additive lists. The Committee was of the opinion that a working group should be established to prepare a paper for the next session of this Committee on the basis of government comments received (for details, see paras 127-128). It expressed the view that only those food additives should be considered which were already included in the

present lists, with the exception of distarch glycerol, acetylated distarch glycerol (proposed by the delegation of the U.S.A.) and of disodium phosphate (proposed by the delegation of France), because these substances had already been presented to the meeting.

94. Some general problems were discussed, including the one related to the carry-over principle in the Standard for Canned Baby Foods. The delegation of the Federal Republic of Germany stressed that the carry-over principle should not be applied to these products. It was also proposed to delete those paragraphs from the standards which left the choice of individual substances from the different groups of food additives to the discretion of national legislation. Some delegations held the view that no additives should be added to the products under consideration if they were intended to be fed to infants under 12 weeks of age.

95. The delegation of the Sudan stressed the need to consider very carefully the level of amino acids used for fortification of vegetable protein which might be necessary in certain parts of the world, and proposed that methionine be placed in square brackets. Other delegations held the view that a properly supervised use of methionine for fortification purposes had resulted in beneficial effects. Decisions on the above issues had to be postponed until the next meeting of the Committee.

MINERAL SALTS FOR USE IN FOODS FOR INFANTS AND CHILDREN

96. At its last session, the Committee had agreed to request governments to send any relevant information on mineral salts suitable for use as nutrients in foods for infants and children to the delegation of the U.S.A. (ALINORM 74/26, para 47).

97. The U.S. delegation had, on the basis of the information received and in collaboration (by correspondence) with the delegations of the Federal Republic of Germany, Switzerland and the United Kingdom, prepared a list of the compounds supplying essential mineral elements for which minimum levels had been set in the Draft Standard for Infant Formula. The list, moreover, contained columns for minimum levels per 100 Cal; salts considered to be reasonable sources of each mineral; and some comments (CX/FSDU 74/6).

98. During the general discussion of the document, the question was raised whether it would not be possible to include upper limits for the various substances. It was pointed out that these limits might be misconstrued as goals for better nutrition, and that therefore maximum limits had not been listed. The delegation of the U.S.A. stated that in respect of a number of the compounds on the list it had corresponded with various members of the Working Group and suggested that for the benefit of the other members of the Committee this correspondence might be circulated generally.

99. The Committee agreed to append the list of mineral salts to the Report of this meeting, and, for general reference purposes, also to include the correspondence mentioned above (Appendix V).

VITAMIN SUPPLEMENTATION OF FOODS FOR INFANTS AND CHILDREN

100. At the request of the Committee at its seventh session, the delegation of Switzerland, in collaboration with the delegations of the Federal Republic of Germany, the United Kingdom and the U.S.A., had prepared a list of vitamin compounds to be used in foods for infants and children (CX/FSDU 74/7). During the discussions, which were restricted to general aspects of the matter, some amendments were made to the document before the Committee. The Committee agreed to append the document to the Report of the session (Appendix VI).

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

101. The Committee had before it the above standard (ALINORM 74/26, Appendix IV) at Step 7 of the Procedure, and a synopsis of government comments (CX/FSDU 74/5 and Addenda). Furthermore, the Committee considered the comments of the Protein Advisory Group on the standard (CX/FSDU 74/3).

Scope

102. The Committee agreed to retain the text of the scope section.

Description

103. Discussion took place as to whether the description of the products should be made more detailed, but it was decided not to make any change in the present text.

Essential Composition

104. Several delegations made suggestions on how the comments of the Protein Advisory Group, with special emphasis on the protein content of the product, could be incorporated into the present format of the standard.

105. It was agreed to insert a new paragraph 4.1.2, reading as follows:

["If the product is to be mixed with water before consumption, or if the product is recommended as a source of protein, the quality of the protein shall be not less than 70% of that of casein."]

and to make the corresponding change in the numbering of the subsequent paragraph.

106. The delegation of the Netherlands pointed out that for technological it would like to substitute the present figure of 25% m/m milk solids with the equivalent figure of 10% m/m milk proteins having the same quality as whole milk. The Committee agreed to this proposal.

Optional Ingredients

107. After some discussion, it was decided to change the term "nutritional sweeteners" to "sugars (nutritive carbohydrate sweeteners)". In the provision for cocoa, the brackets were omitted and the age limit was reduced from 12 months to 9 months.

108. It was agreed to amend para 4.2.2 to read: "The addition of iodized salt shall be in conformity with the national legislation of the country where the product is sold."

Quality Factors

109. Some delegations pointed out that the quality of the product depended very much on the technological procedures used for its preparation. The Committee agreed to include in this section a provision to avoid quality losses:

"All processing and drying should be carried out in a manner that minimizes loss of nutritive value, particularly protein quality."

Specific Prohibition

110. The wording agreed to for a similar provision in the Standard for Canned Baby Foods was also used for this standard (see para 25 of this Report).

Food Additives

111. This section was discussed in conjunction with the relevant sections of the other standards (see paras 90-100 of this Report).

Hygiene

112. The Committee noted the provision of this section proposed by the Codex Committee on Food Hygiene (ALINORM 74/13, para 30). The question was raised why, in contrast to the hygiene provisions of the Standards for Infant Formula and for Canned Baby Foods, the product did not have to comply with the Code of Hygienic Practice for Foods for Infants and Children. It was further questioned why a mandatory requirement had been introduced that all ingredients used in the preparation of the product should conform with all the hygienic provisions of all applicable codes of practice. A number of delegations stated that they did not consider this latter provision to be practicable. The delegation of Federal Republic of Germany held the view that para 7.2 of Appendix IV to ALINORM 74/26 should be retained as drafted since processed foods for infants and children should conform to the same bacteriological requirements as infant formula and canned baby foods. It was agreed by the Committee to substitute "should" for "shall" and to refer this and the question of consistency among the hygiene provisions for the three standards to the Codex Committee on Food Hygiene.

List of Ingredients

113. In order to harmonize the wording in the various standards, a revised provision of the list of ingredients which had been adopted for canned baby food was inserted.

Declaration of Nutritive Value

114. The Committee agreed to amend this provision and introduce the same wording as had been agreed to for Baby Foods. A consequential amendment was made in the provision for utilization of the product.

Lot Identification

115. The text proposed by the Codex Committee on Food Labelling for Infant Formula and Canned Baby Foods, whereby a distinction is made between the requirements used for lot identification and those needed in date marking and storing instructions, was introduced in the standard.

116. The Committee held a brief discussion on the matter of date marking but did not discuss it any further in view of the fact that this particular subject was under consideration by the Codex Committee on Food Labelling.

Information for Utilization

117. With reference to a recommendation of the Protein Advisory Group that the standard should include two categories of cereal based foods, the Committee agreed that for products containing less than 15% protein on a dry weight basis, a recommendation on the label should appear, stating that the product should be used together with milk or infant formula.

Methods of Analysis and Sampling

118. The representative of the International Association for Cereal Chemistry (ICC) stated that a number of methods of analysis developed by the ICC had been adopted by ISO. Some of these might also be appropriate for inclusion in this particular section of the standard and had been attached to the comments paper CX/FSDU 74/4. The Committee agreed to take these methods of analysis into consideration.

Status of the Standard

119. The Committee agreed to return the Draft Standard for Processed Foods for Infants and Children Based on Cereals to Step 6 of the Procedure for a further round of government comments, and decided to consider at its next session the question of the desirability of merging this standard with the revised standard which was previously designated as canned baby foods. The revised Standard for Processed Foods for Infants and Children Based on Cereals is contained in Appendix IV of this Report.

GENERAL PRINCIPLES CONCERNING FOODS FOR SPECIAL DIETARY USES

120. The Committee agreed to a general discussion on the above document (CX/FSDU 74/9 - revised) in conjunction with the Draft Standard for the Labelling of Foods for Special Dietary Uses (CX/FSDU 74/10 - amalgamated), the "Guidelines for the Elaboration of Codex Standards for Foods for Special Dietary Uses" (CX/FSUD 74/11 and 15) and a paper on Labelling and Claims concerning foods for people with other disturbances of digestion or metabolism (CX/FSDU 74/8).

121. The delegation of Finland proposed some amendments to the definition for carbohydrate reduced food (see CX/FSDU 74/9, para 4.1.4.1); the general chapter dealing with foods for diabetics (CX/FSDU 74/8, paras 7-10); and the provision (9.) "certain foods for diabetics".

122. The Committee noted that on a number of occasions during the discussions of the three standards which it had considered during the present session, the need for horizontal presentation of the requirements applicable to the various standards had become obvious. It therefore welcomed the offer of the delegations of Australia and the United Kingdom to review the Proposed Draft Standard for the Labelling of Foods for Special Dietary Uses and requested governments to send any comments they might wish to make to the heads of these two delegations. It was also agreed that the Proposed Draft Standard would be dealt with at Step 2.

123. It was agreed that at the next session of the Committee due priority would be given on the agenda to the Draft General Standard for the Labelling of Foods for Special Dietary Uses (CX/FSDU 74/10).

124. The delegation of the Federal Republic of Germany proposed that it should revise the Proposed Draft Standard for Foods for Use in a Diet for Diabetics (at Step 3), (ALINORM 70/26, App. VII). It was pointed out that at the Seventh Session of this Committee in 1972 (ALINORM 74/26, para 90), the Committee had agreed that this Proposed Draft Standard should be maintained at Step 3, pending the elaboration of a Standard for the Labelling of Foods for Special Dietary Uses. The Committee noted this and agreed that the revision by the delegation of the Federal Republic of Germany should be considered with the proposed revision of the Draft General Standard for the Labelling of Foods for Special Dietary Uses by Australia and the United Kingdom.

FUTURE WORK

DRAFT STANDARD FOR GLUTEN-FREE FOODS

125. The Committee noted that at its next session it would have before it the above draft standard at Step 7 of the Procedure. Several delegations stated their particular interest in gluten-free foods. As a basis for the discussion of the document, the delegations of Finland and the Netherlands agreed to prepare together a working document, taking into account government comments (these have been requested through CL 1974/32).

DATE AND PLACE OF NEXT SESSION

126. As indicated in the schedule of meetings of Codex Committees, contained as an Appendix to the Report of the Tenth Session of the Codex Alimentarius Commission (ALINORM 74/44), the next session of this Committee would in all probability take place in September 1975 and would be held in the Federal Republic of Germany.

MEETING OF WORKING GROUP ON FOOD ADDITIVES IN FOODS FOR SPECIAL DIETARY USES

127. During the present session of the Committee, several delegations (Belgium, Canada (coordinator), Sweden, Federal Republic of Germany, Italy, the Netherlands, Switzerland, the United Kingdom and the U.S.A.) had agreed to participate in a Working Group which would prepare a working paper for the next session of the Committee, presenting the technological justifications for the use of certain food additives in foods for special dietary uses. It was tentatively agreed that this Group would meet in conjunction with the meeting of the Codex Committee on Food Additives, towards the end of May 1975. The delegation of the Netherlands undertook to investigate the possibility of hosting the session of the Working Group in its country.

128. The coordinator of the Group agreed to prepare a questionnaire to be distributed towards the end of September 1974, requesting specific technological data from governments, and which would have to be returned before the end of this year. The assembled information was to form the basis of the discussions of the Working Group when it met.

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SUMMARY STATUS OF WORK

Standard/Code	Step	To be dealt with by	Document
- Canned Baby Foods	6 returned	9th FSDU	ALINORM 76/26, II
- Infant Formula	6 returned	9th FSDU	ALINORM 76/26, III
- Processed Foods for Infants and Children Based on Cereals	6 returned	9th FSDU	ALINORM 76/26, IV
- Gluten-free Foods	6 advanced	9th FSDU	ALINORM 74/26, VII
- Code of Practice - General Principles for Foods for Special Dietary Uses	2	9th FSDU	CX/FSDU 75/...
- Labelling of Foods for Special Dietary Uses	2	9th FSDU	CX/FSDU 75/...
- Foods for Use in a Diet for Diabetics	3 in abeyance	9th FSDU	ALINORM 70/26, VII
- Mineral Salts for Use in Foods for Infants and Children	-	9th FSDU	ALINORM 76/26, V
- Vitamins Supplementation of Foods for Infants and Children	-	9th FSDU	ALINORM 76/26, VI
- Sampling of Foods for Infants and Children	-	9th FSDU	CX/FSDU 75/...
- Code of Hygienic Practice for Foods for Infants and Children	2	12th Food Hygiene	CX/FH 75/8

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DRAFT STANDARD FOR CANNED BABY FOODS

(Returned to Step 6)

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-for-use 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 Foods for Infants and Children Based on Cereals.

1.2 Baby Foods in ready-for-use 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 children from the age of more than 12 months up to the age of three years.

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

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Composition

3.1.1 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 Food additives may only be added in accordance with Section 4.

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

3.1.4 The sodium content of the product calculated on the ready-to-use basis shall not exceed [250] mg Ma/100 g.

3.2 Consistency and Particle Size

3.2.1 Ready-for-use 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

(List of food additives to be established).

5. CONTAMINANTS

5.1 Pesticide Residues (Endorsed ALINORM 74/24, para. 18)

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 and practically free from other contaminants.

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 micro-organisms;

(b) shall not contain any substances originating from micro-organisms 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-for-use 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-for-use form, the fill of container shall be:

(i) not less than 80%v/v for products weighing less than 150 g (5½oz.);

(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 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 grams of protein, carbohydrate and fat per 100 grams 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 grams 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 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 Marketing 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 (which are to be endorsed by the Codex Committee on Methods of Analysis and Sampling):

(To be developed).

ALINORM 76/26
APPENDIX III

DRAFT STANDARD FOR INFANT FORMULA

(Returned to Step 6)

1. SCOPE

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

2. DESCRIPTION

2.1 Infant formula, when in liquid form, may be used either directly or diluted with water before feeding as appropriate. In powdered form it requires water for preparation.

2.2 The product shall be nutritionally adequate to promote normal growth and development when used in accordance with its directions for use.

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

3. DEFINITIONS

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

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

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) Vitamins other than vitamin E	Amounts per 100 available Calories		Amounts per 100 available kilojoules	
	Minimum	Maximum	Minimum	Maximum
Vitamin A	250 I.U. or 75 mcg expressed as retinol	750 I.U. or 225 mcg expressed as retinol	60 I.U. or 18 mcg expressed as retinol	180 I.U. or 55 mcg expressed as retinol
Vitamin D	40 I.U.	100 I.U.	10 I.U.	24 I.U.
Ascorbic Acid (Vitamin C)	8 mg	none specified	1.9	none specified
Thiamine (Vitamin B_1)	40 mcg	"	10 mcg	"
Riboflavin (Vitamin B_2)	60 mcg	"	14 mcg	"
Nicotinamide	250 mcg	"	60 mcg	"
Vitamin B_6 1/	35 mcg	"	9 mcg	"
Folic Acid	4 mcg	"	1 mcg	"
Pantothenic Acid	300 mcg	"	70 mcg	"

1/ Formulae with a higher protein content than 1.8 g protein/100 Calories should contain a minimum of 15 mcg vitamin B_6 per gram of protein.

(a) Vitamins other than vitamin E (Cont.)	Amounts per 100 available Calories		Amounts per 100 available kilojoules	
	Minimum	Maximum	Minimum	Maximum
Vitamin B_{12}	0.15 mcg	none specified	0.04 mcg	none specified
Vitamin K_1	4 mcg	"	1 mcg	"
Biotin (Vitamin H)	1.5 mcg	"	0.4 mcg	"
(b) Vitamin E (α tocopherol compounds) minimum of 1 I.U. per g linoleic acid	-	"	-	"
(c) Minerals				
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) */	50 mg	none specified	12 mg	none specified
Phosphorus (P) */	25 mg	"	6 mg	"
Magnesium (Mg)	6 mg	"	1.4 mg	"
Iron (Fe)	1 mg **/	"	0.25 mg **/	"
Iron (Fe)	0.15 mg	"	0.04 mg	"
Iodine (I)	5 mcg	"	1.2 mcg	"
Copper (Cu)	60 mcg	"	14 mcg	"
Zinc (Zn)	0.5 mg	"	0.12 mg	"
Manganese (Mn)	5 mcg	"	1.2 mcg	"
(d) Choline	7 mg		1.7 mg	

(e) Protein (per 100 available Calories) 1/

(i) Shall not be less than 1.8 g protein of nutritional quality equivalent to that of 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 total quantity of protein shall not be more than 4 g. The minimum value set for quality and the maximum for quantity of the protein may be modified by national authorities according to their own regulations and/or local conditions.

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

(f) Fat and Linoleate

The product shall contain 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).

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

**/ This product is to be labelled Infant Formula with Iron.

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

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

(List of food additives to be established).

6. CONTAMINANTS

6.1 Pesticide Residues (endorsed ALINORM 74/24, para 18)

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 and practically free from other contaminants.

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 micro-organisms;

(b) shall not contain any substances originating from micro-organisms 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-for-use 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 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 "free from milk and milk products".

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) or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 grams 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 grams 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 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 grams 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.

10.5 Net Contents

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

10.6 Name and Address

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

10.7 Country of Origin

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

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

10.8 Lot Identification

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

10.9 Date Making and Storage Instructions

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

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

10.10 Information for Utilization

10.10.1 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.

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

11. METHODS OF ANALYSIS AND SAMPLING

The Methods of Analysis and Sampling described hereunder are international referee methods (which are to be endorsed by the Codex Committee on Methods of Analysis and Sampling See paras 24-42 of ALINORM 74/23 and paras 23-58 of ALINORM 72/23).

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

(Returned to Step 5)

1. SCOPE

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

2. DESCRIPTION

2.1 Dry cereals for infants and children are foods based on cereals and/or legumes (pulses), processed to a low moisture content and so fragmented as to permit 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 Dextrinised flours - which are flours in which the starch has been partially transformed into dextrin by heat treatment.

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

2.4 Rusks and biscuits are cereal 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.

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

3. DEFINITIONS

3.1 The term "infants" applies to children less than 12 months of age.

3.2 The term "children" applies to young children between 1 and 3 years of age.

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

4. ESSENTIAL COMPOSITION AND QUALITY FACTORS

4.1 Essential Composition

4.1.1 Dry cereal, 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 (defatted or low fat).

4.1.2 [If the product is to be mixed with water before consumption, or if the product is recommended as a source of protein, the quality of the protein shall be not 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.

4.2 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 may be used;

- 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 iodized salt shall be in conformity with the national legislation of the country in which the product is sold.

4.2.3 Vitamins and minerals may only be added in accordance with the legislation of the country in which the food 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 reduced to a level at which micro-organisms 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 provisions in respect of food additives and their specifications as contained in section ..... of the Codex Alimentarius are subject to endorsement by the Codex Committee on Food Additives.

5.1 The food additives listed below are subject to selection according to national legislation, no more than two additives being used from each group in a product.

Name of Substance	Quantity in percent m/m in ready-to-eat product
5.1.1 Thickening Agents	
Guar gum 1/	1
Locust bean gum 1/ (Caroub gum)	1
Pectin	1.5
Alginic acid and its sodium, potassium and calcium salts	1
Agar-agar	1

1/ Subject to toxicological evaluation.

	Name of Substance	Quantity in percent m/m in ready-to-eat product
5.1.2	Emulsifiers	
	Lecithin	1.3
	Mono and di-glycerides of long-chain fatty acids which occur naturally in food	3
5.1.3	Inorganic Stabilizers	
	Calcium chloride	GMP
5.1.4	pH Adjusting Agents	
	Sodium bicarbonate Potassium bicarbonate Calcium carbonate Sodium hydroxide Citric acid L-lactic acid	GMP
5.1.5	Antioxidants	
	Tocopherols 1-Ascorbyl-6-palmitate 1-ascor acid and its sodium and potassium salts	GMP
5.1.6	Flavours	
	Harmless natural flavouring materials and their identical synthetic counterparts Ethyl vanillin	GMP
5.1.7	Enzymes	
	Amylase	GMP

5.2 Carry-over

The carry-over principle applies as defined by the Codex Committee on Food Additives, unless otherwise stated.

6. CONTAMINANTS

The following provisions in respect of contaminants are subject to endorsement by the Codex Committee on Food Additives.

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 and practically free from other contaminants.

7. HYGIENE (see ALINORM 76/13, para 30)

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 micro-organisms;
(b) shall not contain any substances originating from micro-organisms 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 All ingredients used in the preparation of the product should conform with all the hygiene provisions of all applicable codes of practice.

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 grams of protein, carbohydrate and fat per 100 grams 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 grams 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 the accompanying leaflet.

9.9.2 Milk or formula, but not water, should be recommended for reconstituting products having less than 15% protein on a dry weight basis.

10. METHODS OF ANALYSIS AND SAMPLING

The methods of analysis and sampling described hereunder are international referee methods (which have been endorsed by the Codex Committee on Methods of Analysis and Sampling unless otherwise stated).

10.1 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.

10.2 Determination of Ash Content

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

10.3 Determination of Fat Content

(Methods to be endorsed) 2/ .

10.4 Determination of Crude Fibre Content

(Method to be endorsed) 3/ .

10.5 Determination of Protein Content

(Method to be endorsed) 3/ .

1/ Temporarily endorsed (ALINORM 72/23, para 26).
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 Appendix IIB.

10.6 Determination of Available Carbohydrates Content

(Methods to be endorsed) 1/ .

10.7 Calculation of Available Calories (Available Kilojoules)

(Method to be endorsed) 2/ .

10.8 Determination of Sodium Content

According to the U.S. flame photometry method, using dry-ashing at 525-550° (CX/FSDU 71/17) 3/ .

10.9 Determination of Chloride Content

(Method to be proposed by governments).

10.10 Determination of Milk Solids Content

(Method to be proposed by governments).

10.11 Determination of Cocoa Solids Content

(Method to be proposed by governments).

1/ See ALINORM 72/23, para 32 and ALINORM 74/26, para 10.
2/ See ALINORM 72/23, para 31 and ALINORM 74/26, para 8 and Appendix IIA.
3/ Temporarily endorsed (ALINORM 72/23, paras 38 and 60).

MINERAL SALTS SUITABLE FOR ADDITION TO FORMULAE AND FOODS FOR INFANTS AND CHILDREN 1/

Mineral	Minimum Level per 100 Kcal in Codex Draft Standard for Infant Formulae	Allowable Salts	Comments
Calcium (Ca)	50 mg/100 Kcal	Calcium carbonate Calcium chloride Calcium citrate Calcium gluconate Calcium glucuronate Calcium glycerophosphate Calcium lactate Calcium malate Calcium phosphate, monobasic Calcium phosphate, bibasic Calcium phosphate, tribasic Calcium tartrate	Ratio of calcium to phosphorous must be unequivocally expressed as not more than 2.0 : 1.0* and not less than 1.2 : 1.0
Phosphorous (P)	25 mg/100 Kcal	Calcium phosphate, monobasic Calcium phosphate, bibasic Calcium phosphate, tribasic Magnesium phosphate, dibasic Magnesium phosphate, tribasic Potassium phosphate, monobasic Potassium phosphate, dibasic Sodium phosphate, dibasic Sodium ferric, pyrophosphate	idem
Magnesium (Mg)	6 mg/100 Kcal	Magnesium acetate Magnesium carbonate Magnesium chloride Magnesium oxide Magnesium phosphate, dibasic Magnesium phosphate, tribasic Magnesium sulphate Magnesium trisilicate	
Iron (Fe)	1 mg/100 Kcal	Ferrous carbonate, stabilized Ferrous citrate Ferrous fumarate Ferrous gluconate Ferrous glucuronate Ferrous glycerophosphate Ferrous lactate Ferrous saccharate ** Ferrous succinate Ferrous sulphate Reduced iron (Ferrum reductum) Electrolytic iron Ferric ammonium citrate Ferric oxide saccharate Ferric phosphate Ferric pyrophosphate Ferric tartrate Sodium ferric pyrophosphate	Iron is readily available from some ferric salts in liquid formulae, but not in other foods Particle size of reduced iron affects availability. Specifications are needed

* Proposal United Kingdom and Federal Republic of Germany.

** Suggested by two countries; U.S.A. is not acquainted with its use.

1/ This table and the U.S. letter of 24 September 1973 reproduced hereunder were presented to the 8th Session of the Codex Committee on Foods for Special Dietary Uses as document CX/FSDU 74/6 - See also paras 96-99 of the Report of the Meeting.

Mineral	Minimum Level per 100 Kcal in Codex Draft Standard for Infant Formulae	Allowable Salts	Comments
Copper (Cu)	60 mcg/100 Kcal	Cupric acetate Cupric citrate Cupric gluconate Cupric sulphate	
Iodine (I)	5 mcg/100 Kcal	Calcium iodostearate * Potassium iodide * Sodium iodide * Sodium chloride, iodized*	
Zinc (Zn)	0.5 mg/100 Kcal	Zinc acetate Zinc chloride Zinc lactate Zinc sulphate	
Manganese (Mn)	100 mcg/100 Kcal	Manganese carbonate Manganese chloride Manganese citrate Manganese lactate Manganese sulphate	
Sodium (Na)	20 mg/100 Kcal	Sodium bicarbonate Sodium chloride Sodium chloride, iodized* Sodium citrate Sodium ferric pyrophosphate Sodium gluconate Sodium glucuronate Sodium glycerophosphate Sodium iodide * Sodium lactate Sodium malate Sodium phosphate, monobasic Sodium phosphate, dibasic Sodium sulphate Sodium tartrate Sodium phosphate, tribasic	
Potassium (K)	80 mg/100 Kcal	Potassium bicarbonate Potassium carbonate Potassium chloride Potassium citrate Potassium gluconate Potassium glycerophosphate Potassium glucuronate Potassium iodide * Potassium lactate Potassium malate Potassium phosphate, monobasic Potassium phosphate, dibasic Potassium phosphate, tribasic Potassium tartrate	

* United Kingdom and Federal Republic of Germany: to delete.
Switzerland: Possibly tolerance.

Mineral	Minimum Level per 100 Kcal in Codex Draft Standard for Infant Formulae	Allowable Salts	Comments
Chloride (Cl)	60 mg/100 Kcal	Calcium chloride Choline chloride Manganese chloride Magnesium chloride Potassium chloride Sodium chloride Sodium chloride, iodized * Zinc chloride **	

* United Kingdom and Federal Republic of Germany: to delete.
** Reservation: United Kingdom and Federal Republic of Germany.

General Remark

Reservations are being made partly by Switzerland, United Kingdom and Federal Republic of Germany concerning the following substances:

magnesium oxide
magnesium trisilicate
reduced iron
electrolytic iron
ferrous saccharate
ferric oxide saccharate
ferric phosphate
ferric pyrophosphate
sodium ferric pyrophosphate
calcium iodostearate
ferrous fumarate
tribasic sodium phosphate
tribasic calcium phosphate

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1. Letter sent by Mr. L.M. Beacham (U.S.A.) on 24 September 1973 to the members of the Working Group: Federal Republic of Germany, Switzerland and United Kingdom.

" As recorded in ALINORM 74/26 paragraph 47, you will recall that governments were invited to send any relevant information on a list of mineral salts suitable for use in foods for infants and children to me, who would serve as a coordinator. With this information, a small group of countries consisting of the Federal Republic of Germany, Switzerland, the United Kingdom and the United States would collaborate by correspondence in developing a proposed list which would be forwarded to the Secretariat for distribution before the next meeting of the Codex Committee on Foods for Special Dietary Uses. With that background, I am now submitting a tentative list. This list summarizes the information on mineral salts that we have received in reply to the request given in paragraph 47, as well as the mineral salts which we suggested to the Canadian delegate prior to the last meeting, and those listed in ALINORM 74/26 pages 28-29.

The enclosed table lists the essential mineral elements for which minimum levels were set in the Codex Draft Standard for Infant Formula (ALINORM 72/26, Appendix III). The minimum levels per 100 kilo calories are also shown in response to the request of the Hungarian delegate for information on approximate daily requirements. Total requirements per day depend on age and body weight of the infants and the children.

" The next column shows those salts that are considered to be reasonable sources of each mineral; these should be allowed when it is desired to add any of these minerals to infant formulae and foods. In many cases, certain mineral salts may be referred to by more than one name, i.e., potassium bicarbonate is also called potassium hydrogen-carbonate. When this is the case, we have tried to list the name which most clearly identifies the salt in use.

The last column contains additional comments on the use of some of these minerals.

Since there are many suitable salts of most minerals, we propose that the limits of those allowed not be restricted only to salts now in use, but that any salt of the mineral element may be used if there is conclusive scientific evidence showing that the mineral is available from the salt and that the anion is safe and suitable in the diet. Along the same line we have not included acids and bases in the list, but would propose that acids such as hydrochloride, phosphoric, etc., that are used in adjusting pH for neutralizing formulae and foods could be used to provide anions in such salts as chloride, phosphate, etc. Similarly, bases such as sodium hydroxide, potassium hydroxide, calcium hydroxide, etc., could be used to provide sodium, potassium, calcium, etc.

We recommend that the labels of all infant formulae and infant foods contain a list of ingredients, including the names of the mineral salts which have been added. In addition, the individual level of each mineral added or claimed in the product should be listed as the total weight of that mineral element in the product and not of the mineral salt.

I am sending an identical copy of this letter, together with the list, to the other participating members of the Coordinating Group, as well as to the Secretariat. If you concur in the tentative list or have comment or suggestions, I suggest you communicate with me with copies to the Secretariat and other members of the group. "

2. Letter sent by Dr. E. Matthey (Switzerland) on 10 December 1973 to U.S.A. (copied to other members of the Working Group).

" Thank you for your letter of 24 September 1973 with which you sent us a tentative list of mineral salts suitable for addition to formulae and foods for infants and children. We have examined this draft with our experts and can approve it to a great extent. We make some reservations only as regards the following few points:

1. Calcium salts

The "edible bone phosphate (bone meal)" which you mention at the end of your list, was, if our memory is correct, already discussed at the last meeting in Cologne and it was refused because of the possibility of contaminants sticking to it. We are still of the opinion that this product should not be used in baby foods as it can be replaced easily by other purer calcium phosphates.

2. Magnesium salts

Here it is the question, whether "magnesium trisilicate" can be resorbed and can therefore supply magnesium at all.

3. Iron salts

"Fumaric acid" is until now not added to foods in Switzerland and many other countries and we therefore wonder whether the use of "ferrous fumarate" is really necessary. Furthermore we would like to drop - with the reservation of further study - "reduced iron" and "electrolytic iron" as we do not consider this form of iron supply suitable for infants and children. We would prefer to omit all "ferric salts" since, as far as we know, the iron is not resorbed as good as from the "ferrous salts". This would also have the advantage to reduce the long list of iron salts.

4. Sodium and potassium salts

We doubt whether the sodium and potassium phosphate, tribasic, which is quite strongly alkaline, should be taken into consideration. We would propose to delete them.

" These are our comments on your list of mineral salts. Moreover we cannot fully agree with your opinion that apart from the salts listed, any salt of the mineral element may be used, if there is conclusive scientific evidence showing that the anion is safe. In this case it would not be necessary to have a list at all.

We think that the established list has the character of a positive list, which can be completed any time it is considered to be necessary, but only by decision of the Codex Committee on Foods for Special Dietary Uses.

We hope that our observations will be a useful contribution to the establishment of a list of mineral salts. "

3. Letter sent by Mr. L.M. Beacham (U.S.A) on 25 January 1974 to Switzerland (copied to other members of the Working Group).

" I am responding to your letter of December 10, 1973 .....

1. Calcium Salts

Unfortunately, I did not recall the discussion in Cologne on "Edible Bone Phosphate (bone meal)" which was recommended as a source of calcium by the United Kingdom. In our view, bone meal was an excellent source of calcium for infant cereals for many years and, when proper specifications for purity were used, there was no concern about contaminants. Precaution had only to be taken that the level of fluoride was not too high in relation to its level of use in the product. For many years, before the benefits of fluoride were realized, bone meal fortuitously supplied fluoride to infants and children, and helped their dental development. Purified calcium phosphate may of course be used in place of bone meal, but the trace nutrients in bone meal are not harmful, and indeed may be useful. However, if other countries in our working group wish to delete "edible bone phosphate (bone meal)" from the list, the U.S. will not object.

2. Magnesium salts

We include magnesium trisilicate on the basis of studies on rats showing that absorption and retention of magnesium provided as silicate was similar to that fed as oxide, phosphate and sulfate- and only slightly lower than that of carbonate or chloride. (Cook, D.A.: Availability of Magnesium: Balance Studies in Rats with Various Inorganic Magnesium Salts, J. Nutr., 103:1365-1370, 1973). I am enclosing a reprint of this paper.

3. Iron Salts

Reduced iron and ferrous fumarate have been shown to be very good sources of iron and are widely used in the U.S., and, we understand, in Finland and other countries. Correct specifications on particle size for "reduced" or "electrolytic" iron are important to assure good utilization. Reduced iron powders serve as an extremely important source of iron in infant cereals, but are not used in infant formulae. Some ferric salts are needed for certain foods, and are fairly well used where the corresponding ferrous salts do not function satisfactorily. For the reasons discussed below, we would like to see these salts remain in the list.

Recently, the Food and Drug Administration contracted with the Life Sciences Research Office, Federation of American Societies of Experimental Biology (FASEB), to review the available data on the use of iron as a food supplement. I am enclosing a copy of their report which is entitled "The Bioavailability of Iron Sources and their Utilization in Food Enrichment, August 1973". Two of the main points in this report are that (1) reduced iron is the most important iron source in the enrichment of foods in the U.S. (effects of particle size and methods of manufacture on the biological properties of these iron powders are discussed), and (2) although ferrous sulfate is one of the best available sources of iron, ferrous salts have been found to be incompatible with stability during storage and with functional properties of certain food products; therefore, it is often necessary to use other iron compounds even though availability of the iron may be somewhat diminished.

" Ferrous fumarate has been shown to be as well utilized as ferrous sulfate, biologically. (Fritz, J.C., Pla, G.W., Roberts, T., Boehne, J.W., and Hove, E.L.: Biological Availability in Animals of Iron from Common Dietary Sources, J. Agr. Food Chem., 18:647, 1970). (See also p.28 of the FASEB report referred to above). Ferrous fumarate is relatively insoluble as compared with ferrous sulfate and therefore shows less incompatibility in contact with other nutrients in foods. The fumarate anion (fumaric acid) occurs naturally, e.g., in grape juice, and is formed from succinic acid in the citric acid cycle of all animals and man; fumaric acid is then hydrated to l-malic acid. Toxicity studies in various species show that ferrous fumarate is approximately three times as safe as ferrous sulfate (P.F. D'Arcy, B. Pharm, and E.M. Howard: Iron Therapy. The Pharmaceutical Jnl., p. 223, September 8, 1962).

We understand your concern about the use of ferric salts since the iron in some of these is poorly available; however, other ferric salts are fairly good sources of iron (see Fritz et al., referenced above). In certain foods, ferrous salts are entirely incompatible, causing rancidity, loss of other nutrients, discoloration, etc., and it is sometimes necessary to use a ferric salt (or reduced iron) in which the iron is admittedly somewhat less available, as the only way of making the food.

In foods such as infant formula products made with liquid soy isolate, the utilization of ferric pyrophosphate and sodium iron (ferric) pyrophosphate is markedly enhanced by the processing of the formula. Some of the ferric iron is probably converted to ferrous iron (R.C. Theuer, K.S. Kemmerer, W.H. Martin, B.L. Zoumas, and H.P. Sarett: Effect of Processing on Availability of Iron Salts in Liquid Infant Formulae Products. Experimental Soy Isolate Formulae. Agr. & Food Chem., 19:555-558, 1971). For example, although processing had little effect on the availability of ferrous sulfate, it increased the relative availability of iron of ferric pyrophosphate from 39 to 93% of the availability of ferrous sulfate. The iron in a commercial soy isolate infant formula containing sodium iron pyrophosphate as the added iron salt was 77% available as compared to ferrous sulfate. In a milk-based formula, the iron of ferric pyrophosphate was as available as that in ferrous sulfate after processing the formula (R.C. Theuer, W.H. Martin, J.F. Wallander, and H.P. Sarett: Effect of Processing on Availability of Iron Salts in Liquid Infant Formula Products. Experimental Milk-based Formulae. Agr. & Food Chem., 21:482-485, 1973). Data on other ferric salts are also shown in the paper.

Perhaps sodium ferric pyrophosphate should not be on the list for infant cereals, but it is well utilized from heat sterilized liquid infant formulae. Ferric salts should be used only when there is an important technological reason for not using a ferrous salt, but we would recommend that none of the iron salts on this list be deleted at this time.

4. Sodium and Potassium Salts

We realize that sodium and potassium phosphate, tribasic, are quite strongly alkaline, and we would probably not recommend them in a household recipe, but we do not believe this to be a reason for excluding them from a list of substances to be used in commercial and manufactured food products. They would, of course, be neutralized in the manufacture of food, or are used to neutralize acid components of foods. As a matter of fact, their strong alkalinity provides an important reason for the use of these salts, namely, to neutralize acidic components with as little phosphate as possible, whereas a much greater quantity of the dibasic salts would be needed to neutralize a given degree of acidity. Phosphate levels in our foods are quite high now (particularly as related to the calcium level in the diet), and should not be further increased. Tribasic salts provide the same cations and anions as dibasic or monobasic salts and we feel that their alkalinity is no reason, per se, why they should not be allowed in food.

The concept in our letter of September 24, 1973, "that any salt of a mineral element may be used if there is conclusive scientific evidence that the mineral is available from the salt and that the anion is safe and suitable in the diet" is important, we feel, particularly in view of the length of time it would take to get a new list of mineral salts modified and adopted through the Codex procedures. This concept does not really open the list indiscriminately, since the list now shows those anions that the Committee judges to be safe and useful in providing various mineral salts in the diet and these anions can serve

"as a guide for new salts. For example, gluconate salts are listed for calcium, iron, copper, sodium and potassium, showing that gluconate is a safe and useful anion. Gluconate salts are not presently listed for magnesium, zinc and manganese, only because these salts are not produced commercially. However, if magnesium gluconate were to become an article of commerce and were found to have some technological advantages in new or existing products, it would appear reasonable to allow the use of this salt in foods, if studies were conducted to show the magnesium was properly available from the salt. There would be no reason to delay the acceptance of this salt until the Codex Committee went through all the steps necessary to formally revise the list, which would take considerable time even with the present somewhat abbreviated procedure for amending existing standards. Perhaps you would find our concept more acceptable if we should reword it to read: "any new salt of an approved mineral element may be used if the anion is already approved in salts of other minerals in the list, and there is conclusive scientific evidence that the mineral element is biologically available from the new salt." "

4. Letter sent by Dr. D. Eckert (Fed. Rep. of Germany) on 17 May 1974 to U.S.A. (copied to other members of the Working Group).

" The preparation of the documents on Mineral Salts and on Vitamins has, unfortunately, been considerably delayed owing to a number of circumstances.

Re Working Paper on Mineral Salts (See Table I of Appendix V and the letter of the U.S.A. of 24 September 1973 to the members of the Working Group)

The Delegation of the Federal Republic of Germany follows the observations of the Swiss Delegation of 10 December 1973 and proposes that paragraph 5 (of the letter of the U.S.A. of 24 September 1973 to the members of the Working Group: "Since there are....." - Secretariat), as well as the compounds specified by the Swiss Delegation, be deleted. Of the elements of sodium, potassium and chlorine, there should be deleted the iodine compounds and/or iodized compounds, as an addition of such compounds should only be made in cases where an increase of the iodine content is absolutely required.

Moreover, it is deemed necessary that a tolerance be provided also for the proportion of calcium phosphate, a tolerance of 2 g being proposed therefore by us.

Paragraph 6 (of the U.S.A. letter of 24 September 1973-Secretariat) would, furthermore, appear to give rise to misunderstandings. The wording should express more clearly that, in the case of an addition as well as in the case of a reference being made to a content without addition of mineral salts, the total quantity (natural content and added quantity) contained in the food should be indicated.

Re Working Paper on Vitamins (See Table I of Appendix VI)

The Delegation of the Federal Republic of Germany proposes that, for Vitamin D, there be included as a further compound Vitamin D 3-cholesterine with the purity requirements of the German Pharmacopoeia, 7th Edition. The molecular combination with cholesterine is of a higher stability.

Objections are being raised against the inclusion of thiamine mono-nitrate, since nitrates should, on principle, never be added to infant foods (WHO Techn. Rep. Ser. No. 488, p.35). There should, furthermore, not be included in the List d - and/or dl-alpha-tocopherol succinate, because of the lack of data on such compounds, e.g. on the enzymatic decomposition.

The addition of silicon-dioxide should be kept restricted to the technologically necessary purposes of use and quantities. The following formulation is being proposed for the Working Paper:

"Silicon dioxide (as anti-caking agent for water-soluble B-vitamins; maximum content 10 g per Kg)." "

5. Letter sent by Mr. L.M. Beacham (U.S.A.) on 11 June 1974 to Fed. Rep. of Germany (copied to other members of the Working Group).

" This is in reply to your letter of May 17, 1974 in the matter of mineral salts and vitamins in foods for infants and children. Although you refer to the letter of Dr. Matthey of December 10, 1973 addressed to me, and endorsed the observations therein, it does not appear that you are aware of the response that we made to those observations in my letter of January 25, 1974 to Dr. Matthey. A copy of that letter was also sent to Mr. Mollenhauer, but it seems likely that it has not come to your attention. It will perhaps be helpful to you to know the response that we made to the points raised by the Swiss delegation, since this continues to represent our views at the present time. Therefore, I am enclosing a copy of the January 25, 1974 letter.

Regarding the iodine or iodide compounds, we agree that an addition of such compounds should only be made in cases where an increase of the iodine content is required, but if they are not included in a list of permitted food additives it would not be permissible to use them even in such instances. In this regard we do not envisage that all of the permitted additives will be generally used, but we seek to provide for their use in those circumstances and in those products where they are needed.

We do not quite understand the significance of your suggestion that a tolerance of 2 g be established for calcium phosphate. In what quantity of the food would 2 g be permitted?

In paragraph 6, to which you referred, we apparently did not make our meaning clear. It was our intention to express the idea that when reference to a mineral element is made on the label, the total quantity (whether added, or natural, or both) should be listed in terms of the total weight of the element itself, e.g., C_a or F_e rather than as the weight of the mineral salts, e.g., $C_a\ SO_4$ or $F_e\ SO_4$.

In reference to the Vitamin D_3 compound, we have no objection to its addition to the list, although we are not familiar with the use of "cholesterine" as a namefor a compound. Is this perhaps a combination of Vitamin D_3 with cholesterol? We would suggest that perhaps a more chemically descriptive name might be used.

We would not favor the deletion of thiamine mononitrate. The quantity of nitrate added by the use of thiamine mononitrate is negligible at the levels used, amounting, we estimate, to not more than 0.075 mg of nitrate in the infant's daily intake. Objections to nitrate in meat and meat products have been concerned with 0.05 percent of nitrate. Assuming a daily consumption of 50 g of meat, this would amount to 25 mg of nitrate. The quantities, as you see, are of completely different orders of magnitude. Furthermore, it has been demonstrated that thiamine mononitrate is a more stable compound than other thiamine compounds in dry products. We would not wish to prohibit the use of a more effective compound "on principle" when in practical application its use presents no problem.

Data on the biological availability of d-alpha-tocopheryl succinate were published by P.L. Harris and M.I. Ludwig, J. Biol. Chem. 180:611, 1949; M. Joffe and P.L. Harris, J.Amer. Chem. Soc. 65:925, 1943; and L. Friedman, W. Weiss, F. Wherry and O.L. Kline, J. Nutr. 65:143, 1958 (copies enclosed). In these studies, the biological activity of d-alpha-tocopheryl succinate was similar to that found for d-alpha-tocopheryl acetate. D-alpha-tocopheryl succinate is an accepted form of vitamin E, listed in the Food Chemical Codex, p. 829 (copy enclosed). We recommend that d-alpha-tocopheryl succinate be retained in the list of vitamins (the dl-succinate ester apparently isn't used, and this can be omitted from the list).

We would have no objection to the restriction on the use of silicon dioxide that you suggest. "

6. Letter sent by Miss D.M. Radford on 17 June 1974 to Fed. Rep. of Germany

" Thank you for your letter of 17 May enclosing draft working papers CX/FSDU 74/6 and 74/7 on mineral salts and vitamins. For the sake of convenience I propose to comment on the papers separately, but before doing so I must apologise for our having failed to make a positive contribution to the preparatory work of Switzerland and the USA. This has been due largely to a substantial reorganization of food standards work and personnel since the last meeting of the Committee in October 1972.

CX/FSDU 74/6 Mineral salts

Like the Swiss and the Federal Republic we have a number of reservations on the paper drawn up by the USA. However having seen Mr. Beacham's letter of 25 January to Dr. Matthey I think that it is unlikely that we would be able to reach complete agreement on a paper for this September's meeting. My preference, therefore, would be to present paper CX/FSDU 74/6 as drafted by the USA and to include a note of the counter suggestions made by Germany, Switzerland and the UK. This approach rather than one of agreement could lead to a more purposeful discussion at the Eighth Session.

On behalf of the UK delegation I would like to record the following observations:

a. we have doubts about assimilability of certain of the mineral salts listed, in particular:

magnesium oxide
magnesium trisilicate
reduced iron
electrolytic iron
ferrous saccharate
ferric oxide saccharate
ferric phosphate
ferric pyrophosphate
sodium ferric pyrophosphate
calcium iodostearate

b. restrictions may be required on the addition of certain mineral salts, for example zinc chloride;

c. we agree with the FRG that the iodine compounds should be deleted as their use should be restricted to instances of real need;

d. the ratio of calcium to phosphorous must be unequivocally expressed as not more than 2.0 : 1.0 and not less than 1.2 : 1.0;

e. we agree that all ingredients should be listed on the label and that any statement of the mineral content should be related to the total content present and not confined to that added.

CX/FSDU 74/7 Vitamins

A similar approach to that on mineral salts could be adopted, i.e. table the Swiss paper as it stands and record any observations made by Germany, UK and USA.

Like the Federal Republic we would question provision being made for thiamine mononitrate. In addition we suggest that:

a. consideration might be given to providing for "pteroylmonoglutamic acid" under folic acid and the K_2 series under vitamin K;

b. terminology be brought into line with that suggested by the International Union of Nutritional Sciences Committee on Nomenclature. "

VITAMINS AND THEIR SPECIAL FORMS FOR THE ENRICHMENT OF FOODS FOR INFANTS AND CHILDREN 1/

Vitamin	Vitamin form	Purity Requirements
Vitamin A	Vitamin A Acetate	USP, BP
	Vitamin A Palmitate	USP, BP
	Beta-Carotene (Provitamin A)	FAO/WHO
Vitamin D	Vitamin D_2 (Ergocalciferol)	USP, BP, Ph. Eur
	Vitamin D_3 (Cholecalciferol)	USP
	Vitamin D_3 - Cholesterol	
Vitamin B_1	Thiamine Hydrochloride	USP, BP, Ph. Eur
	Thiamine Mononitrate	USP
Vitamin B_2	Riboflavin	FAO/WHO, USP, BP, Ph. Eur
	Riboflavin-5'-Phosphate sodium	BPC
Vitamin PP	Nicotinamide (Niacinamide)	USP, BP, Ph. Eur
	Nicotinic Acid (Niacin)	BP, NF
Vitamin B_6	Pyridoxine Hydrochloride	USP, BP, Ph. Eur
	Pyridoxal-5'-Phosphate	-
Folic Acid	Folic Acid	USP, BP
Pantothenic Acid	Calcium D-Pantothenate	USP
	Sodium D-Pantothenate	-
	D-Panthenol	-
Vitamin B_{12}	Cyanocobalamin	USP, BP, Ph. Eur
	Hydroxocobalamin	-
Vitamin K	Vitamin K_1 (Phytomenadione)	USP, BP
Vitamin H	d-Biotin	-
Vitamin C	L-Ascorbic Acid	FAO/WHO, USP, BP, Ph. Eur
	Sodium L-Ascorbate	FAO/WHO, USP
	Calcium L-Ascorbate	-
	L-Ascorbyl-6-Palmitate	FAO/WHO, NF
Vitamin E	d-alpha-Tocopherol	FAO/WHO, NF
	dl-alpha-Tocopherol	FAO/WHO, NF
	d-alpha-Tocopheryl Acetate	NF
	dl-alpha-Tocopheryl Acetate	NF
	d-alpha-Tocopheryl Succinate	-

Special Vitamin Forms

For reasons of stability and easier handling, some vitamins have to be converted into suitable preparations, e.g. stabilized oily solutions, gelatine coated products, fat embedded preparations. For this purpose, the edible materials and the additives included in the respective Codex Standard may be used. In addition the following substances are permitted:

Gelatine ; Gum arabic (Gum acacia) ; Silicon dioxide (as anti-caking agent): maximum content 10 g per kg.

Proposal of the United Kingdom Delegation

a. Consideration might be given to providing for "pteroylmonoglutamic acid" under folic acid.

b. Terminology should be brought into line with that suggested by the International Union of Nutritional Sciences Committee on Nomenclature.

Abbreviations

USP: United States Pharmacopoeia XVIII
NF: United States National Formulary XIII
BP: British Pharmacopoeia 1968, including addenda
BPC: British Pharmaceutical Codex 1968, including the supplement
Ph. Eur: European Pharmacopoeia Vol. I-1969 and II-1971
FAO/WHO: Joint FAO/WHO Food Standards Programme

1/ This list was prepared by the Swiss Delegation in collaboration with the delegations of the Fed. Rep. of Germany, United Kingdom and the United States. See also para 100 of the Report of the meeting.

Note: See also letters No. 4 (FRG), 5 (USA) and 6 (UK) attached to Appendix V.