

# codex alimentarius commission

FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD HEALTH  
ORGANIZATION

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TO: Codex Contact Points  
Interested International Organizations

FROM: Secretary, Joint FAO/WHO Food Standards Programme  
FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy

SUBJECT: **REQUEST FOR COMMENTS AND INFORMATION ON THE ADVISORY LISTS OF MINERAL SALTS AND VITAMIN COMPOUNDS FOR THE USE IN FOODS FOR INFANTS AND CHILDREN (CAC/GL 10-1979, AMENDED 1983, 1991)**

DEADLINE: **1st February 2000**

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## BACKGROUND

The Advisory Lists of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children were adopted by the Codex Alimentarius Commission at its 13th Session in 1979. The 15th Session in 1983 approved amendments to the special vitamin forms, amendments to the list of mineral salts and the special vitamin forms were adopted by the 19th Session in 1991.

The 21<sup>st</sup> Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (21-25 September 1998) had considered this issue based on CRD 20 provided by the Delegation of New Zealand and recalled that the latest amendments to the Lists had been made in 1991, and that many nutrient sources permitted for use in at the national level were not included in the lists, which could create barriers to trade. In order to take into account the importance of public health and safety, new scientific and technological developments, and the work of JECFA on specifications, and that it was necessary to ensure its consistency with current practice in member countries the Committee agreed to propose the revision of the Lists and the 23<sup>rd</sup> Session of the Commission (ALINORM 99/37, paras 201-211 and Appendix VIII) approved it as new work.

Governments and international organizations are therefore invited to submit their comments or information on the current Advisory Lists Of Mineral Salts And Vitamin Compounds For The Use In Foods For Infants And Children (see Annex) and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission, Tenth Edition, pages 20-21*) preferably by an email to addressees as indicated above **not later than 1st February 2000.**

**ADVISORY LISTS OF MINERAL SALTS AND VITAMIN COMPOUNDS FOR USE IN  
FOODS FOR INFANTS AND CHILDREN  
CAC/GL 10-1979 (AMENDED 1983, 1991)**

**ADVISORY LIST OF MINERAL SALTS FOR USE IN FOODS  
FOR INFANTS AND CHILDREN**

<b>Salts</b>	<b>Purity Requirements</b>	<b>Use in Foods for Infants and Children</b>
<b>1. Source of Calcium (Ca)</b>		
1.1 Calcium carbonate	FCC, FAO/WHO	Milk substitute formulae; Infant cereals
1.2 Calcium chloride	FCC, FAO/WHO	Milk-based and milk substitute formulae
1.3 Calcium citrate	FCC, FAO/WHO	Milk-based, milk substitute, protein hydrolysate and meat-based formulae
1.4 Calcium gluconate	FCC, FAO/WHO	Protein hydrolysate formulae
1.5 Calcium glycerophosphate	FCC	
1.6 Calcium lactate	FCC, FAO/WHO	Electrolyte mixture supplement
1.7 Calcium phosphate, monobasic	FCC, FAO/WHO	Milk substitute and low sodium formulae
1.8 Calcium phosphate, dibasic	FCC	Milk substitute and protein hydrolysate formulae
1.9 Calcium phosphate, tribasic	FCC, FAO/WHO	Milk substitute, protein hydrolysate and premature formulae; infant cereals
1.10 Calcium oxide	FCC, FAO/WHO	Protein supplement formulae
1.11 Calcium sulphate	FCC, FAO/WHO	Infant cereals
<b>2. Source of Phosphorus (P)</b>		
2.1 Calcium phosphate, monobasic	FCC, FAO/WHO	Milk substitute and low sodium formulae
2.2 Calcium phosphate, dibasic	FCC	Milk substitute and protein hydrolysate formulae
2.3 Calcium phosphate, tribasic	FCC, FAO/WHO	Milk substitute, protein hydrolysate and premature formulae; infant cereals
2.4 Magnesium phosphate, dibasic	FCC	Milk substitute and lactose-free formulae
2.5 Magnesium phosphate, tribasic	FCC, FAO/WHO	

<b>Salts</b>	<b>Purity Requirements</b>	<b>Use in Foods for Infants and Children</b>
2.6 Potassium phosphate, monobasic	FCC, FAO/WHO	Protein hydrolysate formulae
2.7 Potassium phosphate, dibasic	FCC, FAO/WHO	Milk-based, milk substitute and protein hydrolysate formulae
2.8 Sodium phosphate, dibasic	FCC, FAO/WHO	Electrolyte mixture supplement
2.9 Phosphoric acid	FCC, FAO/WHO	All infant and follow-up formulae; cereal-based foods for infants and children
<b>3. Source of Chloride (Cl)</b>		
3.1 Calcium chloride	FCC, FAO/WHO	Milk-based, milk substitute and protein supplement formulae; electrolyte mixture supplement
3.2 Choline chloride	FCC, FAO/WHO	Milk-based, milk substitute and protein hydrolysate formulae
3.3 Magnesium chloride	FCC, FAO/WHO	Milk-based, milk substitute and lactose-free formulae
3.4 Manganese chloride	FCC	Milk-based formulae
3.5 Potassium chloride	FCC, FAO/WHO	
3.6 Sodium chloride	FCC, FAO/WHO	Milk-substitute formulae, baby foods and electrolyte mixture supplement
3.7 Sodium chloride, iodized	FCC	Milk substitute formulae
3.8 Hydrochloric acid	FCC, FAO/WHO	All infant and follow-up formulae; cereal-based foods for infants and children
<b>4. Iron (Fe)</b>		
4.1 Ferrous carbonate, stabilized	MI	
4.2 Ferrous citrate	MI	Milk and soy-based liquid infant formulae
4.3 Ferrous fumarate	FCC	Vitamins, iron supplement
4.4 Ferrous gluconate	FCC, FAO/WHO	
4.5 Ferrous lactate	MI	Milk and soy-based liquid infant formulae
4.6 Ferrous succinate	MI	
4.7 Ferrous sulphate	FCC	Milk-based, milk substitute and protein hydrolysate formulae
4.8 Ferric ammonium citrate	FAO/WHO	
4.9 Ferric citrate	MI	Milk and soy-based liquid infant formulae, not allowed in powdered formulae, cereals or canned baby foods

<b>Salts</b>	<b>Purity Requirements</b>	<b>Use in Foods for Infants and Children</b>
4.10 Ferric gluconate	MI	
4.11 Sodium ferric pyrophosphate	MI	
4.12 Hydrogen reduced iron	FCC	Infant cereals; protein supplement formulae
4.13 Electrolytic iron	FCC	Infant cereals
4.14 Carbonyl iron	MI	
4.15 Ferric pyrophosphate	FCC	Milk-based formulae
<b>5. Source of Magnesium (Mg)</b>		
5.1 Magnesium carbonate	FCC, FAO/WHO	Baked products
5.2 Magnesium chloride	FCC, FAO/WHO	Milk-based, milk substitute and lactose-free formulae
5.3 Magnesium oxide	FCC, FAO/WHO	Milk substitute, protein hydrolysate and premature formulae
5.4 Magnesium phosphate, dibasic	FCC	Milk substitute, lactose-free formulae
5.5 Magnesium phosphate, tribasic	FCC, FAO/WHO	
5.6 Magnesium sulphate	FCC	Electrolyte mixture supplement
<b>6. Source of Sodium (Na)</b>		
6.1 Sodium bicarbonate	FCC, FAO/WHO	Milk-based formulae, gazed products
6.2 Sodium carbonate	FCC, FAO/WHO	Protein hydrolysate formulae
6.3 Sodium chloride	FCC, FAO/WHO	Milk substitute formulae, baby foods, electrolyte mixture supplement
6.4 Sodium chloride, iodized	FCC	Milk substitute formulae
6.5 Sodium citrate	FCC, FAO/WHO	Milk-based, milk substitute and protein hydrolysate formulae, electrolyte mixture supplement
6.6 Sodium gluconate	FCC	
6.7 Sodium lactate	FAO/WHO	
6.8 Sodium phosphate, monobasic	FCC, FAO/WHO	Milk substitute formulae
6.9 Sodium phosphate, dibasic	FCC, FAO/WHO	Electrolyte mixture supplement
6.10 Sodium phosphate, tribasic	FCC, FAO/WHO	

<b>Salts</b>	<b>Purity Requirements</b>	<b>Use in Foods for Infants and Children</b>
6.11 Sodium sulphate	FCC	
6.12 Sodium tartrate	FCC, FAO/WHO	
<b>7. Source of Potassium (K)</b>		
7.1 Potassium bicarbonate	FCC, FAO/WHO	
7.2 Potassium carbonate	FCC, FAO/WHO	
7.3 Potassium chloride	FCC, FAO/WHO	
7.4 Potassium citrate	FCC, FAO/WHO	
7.5 Potassium glycerophosphate	FCC	
7.6 Potassium gluconate	MI	
7.7 Potassium phosphate, monobasic	FCC, FAO/WHO	Protein hydrolysate formulae
7.8 Potassium phosphate, dibasic	FCC, FAO/WHO	Milk-based, milk substitute and protein hydrolysate formulae
<b>8. Source of Copper (Cu)</b>		
8.1 Copper gluconate	FCC	
8.2 Cupric carbonate	MI	Baked products, protein supplement formulae
8.3 Cupric citrate	MI	Milk-based, protein hydrolysate and meat-based formulae
8.4 Cupric sulphate	MI	
<b>9. Source of Iodine (I)</b>		
9.1 Potassium iodide	FCC	Milk-based, milk substitute, meat-based formulae
9.2 Sodium iodide	FCC	Milk-based, milk substitute and protein hydrolysate formulae
9.3 Potassium iodate	FCC, FAO/WHO	
<b>10. Source of Zinc (Zn)</b>		
10.1 Zinc acetate	MI	
10.2 Zinc chloride	MI	

<b>Salts</b>	<b>Purity Requirements</b>	<b>Use in Foods for Infants and Children</b>
10.3 Zinc oxide	MI	Protein hydrolysate formulae
10.4 Zinc sulphate	FCC	Milk-based, milk substitute and protein hydrolysate formulae
<b>11. Source of Manganese (Mn)</b>		
11.1 Manganese carbonate	MI	
11.2 Manganese chloride	FCC	Milk-based formulae
11.3 Manganese citrate	MI	
11.4 Manganese sulphate	FCC	Milk-based, milk substitute and protein hydrolysate formulae

**Abbreviations:**

FAO/WHO = General Principles for the Use of Food Additives, Codex Alimentarius Volume 1.

FCC = Food Chemicals Codex

MI = Merck Index

**ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR INFANTS AND CHILDREN**

<b>Vitamin</b>	<b>Vitamin Form</b>	<b>Purity Requirements</b>
1. Vitamin A	Retinyl acetate Retinyl palmitate Retinyl propionate	USP, BP, Ph. Eur., FCC USP, BP, Ph. Eur., FCC USP, BP, Ph. Eur., FCC
2. Provitamin A	Beta-carotene	FAO/WHO, FCC
3. Vitamin D 3.1 Vitamin D <sub>2</sub> 3.2 Vitamin D <sub>3</sub>	Ergocalciferol Cholecalciferol Cholecalciferol-cholesterol	USP, BP, Ph. Eur., FCC USP, FCC DAB
4. Vitamin E	d-alpha-tocopherol dl-alpha-tocopherol d-alpha-tocopheryl acetate dl-alpha-tocopheryl acetate d-alpha-tocopheryl succinate dl-alpha-tocopheryl succinate	NF, FAO/WHO NF, FAO/WHO, FCC NF, FCC NF, FCC FCC NF
5. Thiamin (Vitamin B <sub>1</sub> )	Thiamin chloride hydrochloride Thiamin mononitrate	USP, BP, Ph. Eur., FCC USP, FCC
6. Riboflavin (Vitamin B <sub>2</sub> )	Riboflavin  Riboflavin 5'-phosphate sodium	USP, BP, Ph. Eur., FAO/WHO, FCC BPC, FCC
7. Niacin	Nicotinamide Nicotinic acid	USP, BP, Ph. Eur., FCC NF, BP, Ph. Eur., FCC
8. Vitamin B <sub>6</sub>	Pyridoxine hydrochloride	USP, BP, Ph. Eur., FCC
9. Biotin (Vitamin H)	d-biotin	FCC
10. Folic acid	Folic acid	USP, BP
11. Pantothenic acid	Calcium pantothenate Panthenol	USP, Ph. Eur., FCC FCC
12. Vitamin B <sub>12</sub>	Cyanocobalamin Hydroxocobalamin	USP, BP, Ph. Eur. NF, BP
13. Vitamin K <sub>1</sub>	Phytylmenaquinone	USP, BP
14. Vitamin C	Ascorbic acid  Sodium ascorbate Calcium ascorbate Ascorbyl-6-palmitate	USP, BP, Ph. Eur., FAO/WHO, FCC USP, FAO/WHO, FCC FCC NF, FAO/WHO, FCC
15. Choline	Choline bitartrate Choline chloride	DAB, FCC FAO/WHO, DAB, FCC
16. Inositol		FCC

**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:

	<b>Maximum Level in Ready-to-use Food</b>
(a) Dextrins	100 mg/kg
(b) Modified starches as included in the Supplementary List to Section 5.1, Codex Alimentarius Volume 1	100 mg/kg
(c) Gum arabic (gum acacia)	100 mg/kg
(d) Silicon dioxide	10 mg/kg

**Abbreviations:**

USP = United States Pharmacopoeia

NF = United States National Formulary

BP = British Pharmacopoeia, including addenda

BPC = British Pharmaceutical Codex

Ph. Eur. = European Pharmacopoeia

FAO/WHO = General Principles for the Use of Food Additives, Codex Alimentarius Volume 1

DAB = Deutsches Arzneibuch 7

FCC = Food Chemicals Codex