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National Food Safety Standard for the Use of Nutritional Fortification Substances in Foods

食品安全国家标准 食品营养强化剂使用标准

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National Food Safety Standard for the Use of Nutritional Fortification Substances in Foods

1 Scope

This Standard specifies the fundamental purposes of nutritional fortification in foods, the requirements of using nutritional fortification substances, the selection requirements for fortifiable food categories and application requirements for nutritional fortification substances.

This Standard is applicable to the application of nutritional fortification substances in foods, unless otherwise stated in national laws and regulations and/or standards.

2 Terms and Definitions

2.1 Nutritional fortification substances

The natural or artificially-synthesized nutrients and other nutritional ingredients added to foods in order to increase the nutritional ingredient (value) in foods.

2.2 Nutrient

The substances which have specific physiological effects in foods and are required and able to maintain the growth, development, activity, reproduction, and normal metabolism, including protein, fat, carbohydrate, mineral substances and vitamin, etc.

2.3 Other nutritional ingredients

Other food compositions which have nutrition and/or physiological functions except nutrients

2.4 Foods for special diets

Food made by special process or formula in order to meet special physical/psychological conditions and/or meet special diet demands under the conditions of diseases or disorder. The contents of nutrients and/or other nutritional ingredients in these foods are obviously different from comparable ordinary foods.

3 Fundamental Purposes of Nutritional Fortification

3.1 Make up the nutrient loss caused during normal process and storage of foods.

3.2 In a given territorial scope, where the intake of some nutrients for a large scale of crowd is low or lacked, the caused poor health effects may be improved by fortification.

3.3 The nutrient intake level for some crowd is low or lacked because of the dietary habit and/or other causes, the caused poor health effects may be improved by fortification.

3.4 Replenish and adjust the contents of nutrients and/or other nutritional ingredients in foods for special diets.

4 Requirements of Using Nutritional Fortification Substances

4.1 Utilization of nutritional fortification substances shall not result in intake excess or imbalance of nutrients or other nutritional ingredients, neither the metabolism abnormality of any nutrient and other nutritional ingredients.

4.2 Utilization of nutritional fortification substances shall not encourage and lead the food consumption pattern against the national nutrition policies.

4.3 The quality of nutritional fortification substances added to foods shall be able to be kept stable under specific conditions of storage, transportation and eating.

4.4 The nutritional fortification substances added to foods shall not result in obvious bad changes of general characteristics of foods, such as color, luster, flavor, smell and cooking characteristics.

4.5 The content or effect of a certain nutritional ingredient shall not be exaggerated by the application of nutritional fortification substances to mislead and cheat consumers.

5 Selection Requirements of Fortification Food Categories

5.1 Foods consumed universally by target population and obtained easily shall be selected for fortification.

5.2 The consumption of foods as the fortification carriers shall be relatively stable.

5.3 The foods which are advocated to reduce the eating amount in the diet guideline of China should not be used as the fortification carriers.

6 Application Rules of Nutritional Fortification Substances

6.1 Application scope and application amount of nutritional fortification substances in foods shall meet the requirements of Appendix A; the origin of the allowable utilization compound

Appendix A

Application Rules of Nutritional Fortification Substances in Foods

Application rules of nutritional fortification substances in foods are detailed in Table A.1.

Table A.1 -- Allowable Application Species, Application Scope [a] and Application Amount of Nutritional Fortification Substances

Nutritional fortification substance	Food Cat. No.	Food category (name)	Application amount
Vitamin			
Vitamin A	01.01.03	Modulation milk	600μg/kg~1000μg/kg
	01.03.02	Modulation milk powder (excluding milk powder for children, pregnant and lying-in women)	3000μg/kg~9000μg/kg
		Modulation milk powder (only for children)	1200μg/kg~7000μg/kg
		Modulation milk powder (only for pregnant and lying-in women)	2000μg/kg~10000μg/kg
	02.01.01.01	Vegetable oil	4000μg/kg~8000μg/kg
	02.02.01.02	Margarine and its similar products	4000μg/kg~8000μg/kg
	03.01	Ice cream and popsicles	600μg/kg~1200μg/kg
	04.04.01.07	Bean flour and soybean milk powder	3000μg/kg~7000μg/kg
	04.04.01.08	Soybean milk	600μg/kg~1400μg/kg
	06.02.01	Rice	600μg/kg~1200μg/kg
	06.03.01	Wheaten flour	600μg/kg~1200μg/kg
	06.06	Instant cereals, including rolled oats	2000μg/kg~6000μg/kg
	07.02.02	Western cookies	2330μg/kg~4000μg/kg
	07.03	Biscuit	2330μg/kg~4000μg/kg
	14.03.01	Milky drinks	300μg/kg~1000μg/kg
	14.06	Solid drinks	4000μg/kg~17000μg/kg
	16.01	Jelly	600μg/kg~1000μg/kg
	16.06	Puffed food	600μg/kg~1500μg/kg
β-carotene	14.06	Solid drinks	3mg/kg~6mg/kg
Vitamin D	01.01.03	Modulation milk	10μg/kg~40μg/kg
	01.03.02	Modulation milk powder (excluding milk powder for children, pregnant and lying-in women)	63μg/kg~125μg/kg
		Modulation milk powder (only for children)	20μg/kg~112μg/kg
		Modulation milk powder (only for pregnant and lying-in women)	23μg/kg~112μg/kg

Folic acid	01.01.03	Modulation milk powder (only for pregnant and lying-in women)	400μg/kg~1200μg/kg
	01.03.02	Modulation milk powder excluding milk powder for children, pregnant and lying-in women)	2000μg/kg~5000μg/kg
		Modulation milk powder (only for children)	420μg/kg~3000μg/kg
		Modulation milk powder (only for pregnant and lying-in women)	2000μg/kg~8200μg/kg
	06.02.01	Rice (only for free-elutriation rice)	1000μg/kg~3000μg/kg
	06.03.01	Wheaten flour	1000μg/kg~3000μg/kg
	06.06	Instant cereals, including rolled oats	1000μg/kg~2500μg/kg
	07.03	Biscuit	390μg/kg~780μg/kg
	07.05	Other bakery products	2000μg/kg~7000μg/kg
	14.02.03	Fruit and vegetable juices (pulp) (including fermentation type products, etc.)	157μg/kg~313μg/kg
	14.06	Solid drinks	600μg/kg~6000μg/kg
	16.01	Jelly	50μg/kg~100μg/kg
Pantothenic acid	01.03.02	Modulation milk powder (only for children)	6mg/kg~60mg/kg
		Modulation milk powder (only for pregnant and lying-in women)	20mg/kg~80mg/kg
	06.06	Instant cereals, including rolled oats	30mg/kg~50mg/kg
	14.04.01	Carbonated drinks	1.1mg/kg~2.2mg/kg
	14.04.02.02	Flavored drinks	1.1mg/kg~2.2mg/kg
	14.05.01	Tea drinks	1.1mg/kg~2.2mg/kg
	14.06	Solid drinks	22mg/kg~80mg/kg
	16.01	Jelly	2mg/kg~5mg/kg
Biotin	01.03.02	Modulation milk powder (only for children)	38μg/kg~76μg/kg
Choline	01.03.02	Modulation milk powder (only for children)	800mg/kg~1500mg/kg
		Modulation milk powder (only for pregnant and lying-in women)	1600mg/kg~3400mg/kg
	16.01	Jelly	50mg/kg~100mg/kg
Inositol	01.03.02	Modulation milk powder (only for children)	210mg/kg~250mg/kg
	14.02.03	Fruit and vegetable juices (pulp) (including fermentation type products, etc.)	60mg/kg~120mg/kg
	14.04.02.02	Flavored drinks	60mg/kg~120mg/kg
Mineral substances			
Iron	01.01.03	Modulation milk	10mg/kg~20mg/kg
	01.03.02	Modulation milk powder (excluding milk powder for children, pregnant and lying-in women)	60mg/kg~200mg/kg
		Modulation milk powder (only for children)	25mg/kg~135mg/kg

	14.0	Drinks (except the species involved in 14.01 and 14.02 and 14.06)	160mg/kg~1350mg/kg
	14.02.03	Fruit and vegetable juices (pulp) (including fermentation type products, etc.)	1000mg/kg~1800mg/kg
	14.06	Solid drinks	2500mg/kg~10000mg/kg
	16.01	Jelly	390mg/kg~800mg/kg
Zinc	01.01.03	Modulation milk	5mg/kg~10mg/kg
	01.03.02	Modulation milk powder (excluding milk powder for children, pregnant and lying-in women)	30mg/kg~60mg/kg
		Modulation milk powder (only for children)	50mg/kg~175mg/kg
		Modulation milk powder (only for pregnant and lying-in women)	30mg/kg~140mg/kg
	04.04.01.07	Bean flour and soybean milk powder	29mg/kg~55.5mg/kg
	06.02	Rice and its products	10mg/kg~40mg/kg
	06.03	Wheaten flour and its products	10mg/kg~40mg/kg
	06.04	Grain powder and its products	10mg/kg~40mg/kg
	06.06	Instant cereals, including rolled oats	37.5mg/kg~112.5mg/kg
	07.01	Bread	10mg/kg~40mg/kg
	07.02.02	Western cookies	45mg/kg~80mg/kg
	07.03	Biscuit	45mg/kg~80mg/kg
	14.0	Drinks (except the species involved in 14.01 and 14.06)	3mg/kg~20mg/kg
	14.06	Solid drinks	60mg/kg~180mg/kg
	16.01	Jelly	10mg/kg~20mg/kg
Selenium	01.03.02	Modulation milk powder (excluding milk powder for children)	140μg/kg~280μg/kg
		Modulation milk powder (only for children)	60μg/kg~130μg/kg
	06.02	Rice and its products	140μg/kg~280μg/kg
	06.03	Wheaten flour and its products	140μg/kg~280μg/kg
	06.04	Grain powder and its products	140μg/kg~280μg/kg
	07.01	Bread	140μg/kg~280μg/kg
	07.03	Biscuit	30μg/kg~110μg/kg
	14.03.01	Milky drinks	50μg/kg~200μg/kg
Magnesium	01.03.02	Modulation milk powder (excluding milk powder for children, pregnant and lying-in women)	300mg/kg~1100mg/kg
	01.03.02	Modulation milk powder (only for children)	300mg/kg~2800mg/kg
		Modulation milk powder (only for pregnant and lying-in women)	300mg/kg~2300mg/kg
	14.0	Drinks (except the species involved in 14.01 and 14.06)	30mg/kg~60mg/kg

Lutein	01.03.02	Modulation milk powder (only for children; the liquid is converted according to dilution times)	1620μg/kg~2700μg/kg
Fructo-oligosaccharide	01.03.02	Modulation milk powder (only for children, pregnant and lying-in women)	≤64.5g/kg
1,3-oleic acid2-triglycercide palmitic acid	01.03.02	Modulation milk powder (only for children; the liquid is converted according to dilution times)	24g/kg~96g/kg
Arachidonic acid (AA or ARA)	01.03.02	Modulation milk powder (only for children)	≤1% (percentage of total fatty acids)
Docosahexaenoic acid (DHA)	01.03.02	Modulation milk powder (only for children)	≤0.5% (percentage of total fatty acids)
		Modulation milk powder (only for pregnant and lying-in women)	300mg/kg~1000mg/kg
Lactoferrin	01.01.03	Modulation milk	≤1.0g/kg
	01.02.02	Flavored fermented milk	≤1.0g/kg
	14.03.01	Milky drinks	≤1.0g/kg
Casein calcium peptide	06.0	Grain and grain products, including rice, flour, coarse grain and starch, etc. (except the species involved in 06.01 and 07.0)	≤1.6g/kg
	14.0	Drinks (except the species involved in 14.01)	≤1.6g/kg (Application amount is increased according to reconstitution multiple for solid drinks)
Casein phosphor peptides	01.01.03	Modulation milk	≤1.6g/kg
	01.02.02	Flavored fermented milk	≤1.6g/kg
	06.0	Grain and grain products, including rice, flour, coarse grain and starch, etc. (except the species involved in 06.01 and 07.0)	≤1.6g/kg
	14.0	Drinks (except the species involved in 14.01)	≤1.6g/kg (Application amount is increased according to reconstitution multiple for solid drinks)
[a] Application scope is expressed by Food Cat. No. and food category (name) in Table A.1.			

Appendix B

List of Origins of Allowable Nutritional Fortification Substance Compounds

List of origins of allowable nutritional fortification substance compound for application is detailed in Table B.1.

Table B.1 -- List of Origins of Allowable Nutritional Fortification Substance Compounds for Application

Nutritional fortification substances	Compound origin
Vitamin A	Retinyl acetate (Vitamin A acetate) Retinyl palmitate (Vitamin A palmitate) All-trans retinol β-carotene
β-carotene	β-carotene
Vitamin D	Ergocalciferol (Vitamin D_2) Cholecalciferol (Vitamin D_3)
Vitamin E	d-α-Tocopherol dl-α-Tocopherol d-α-Tocopheryl Acetate dl-α-Tocopheryl Acetate Mixed tocopherol concentrate Vitamin E calcium succinate d-α-Tocopherol succinic acid dl-α-Tocopherol succinic acid
Vitamin K	Phytonadione
Vitamin B_1	Thiamine hydrochloride Thiamine nitric acid
Vitamin B_2	Riboflavin Riboflavin-5'-sodium phosphate
Vitamin B_6	Pyridoxine hydrochloride Pyridoxal 5'-phosphate
Vitamin B_{12}	Cyanocobalamin Cobalamin hydrochloric acid Hydroxycobalamin
Vitamin C	L-ascorbic acid L-calcium ascorbate Magnesium ascorbyl phosphate L-sodium ascorbate L-potassium ascorbate

Appendix C

Origin of Nutritional Fortification Substances and Compounds Allowable for Foods for Special Diets

C.1 Table C.1 specifies nutritional fortification substances and compound origin allowable for foods for special diets.

C.2 Table C.2 specifies other nutritional ingredients that are only allowed to be used in partial foods for special dietary uses, as well as their dosage.

Table C.1 -- Nutritional Fortification Substances and Compound Origin Allowable for Foods for Special Diets

Nutritional fortification substances	Compound origin
Vitamin A	Retinyl acetate (Vitamin A acetate) Retinyl palmitate (Vitamin A palmitate) β-carotene All-trans retinol
Vitamin D	Ergocalciferol (Vitamin D_2) Cholecalciferol (Vitamin D_3)
Vitamin E	d-α-Tocopherol dl-α-Tocopherol d-α-Tocopheryl Acetate dl-α-Tocopheryl Acetate Mixed tocopherol concentrate d-α-Tocopherol succinic acid dl-α-Tocopherol succinic acid
Vitamin K	Phytonadione
Vitamin B_1	Thiamine hydrochloride Thiamine nitric acid
Vitamin B_2	Riboflavin Riboflavin-5'-sodium phosphate
Vitamin B_6	Pyridoxine hydrochloride Pyridoxal 5'-phosphate
Vitamin B_{12}	Cyanocobalamin Cobalamin hydrochloric acid Hydroxycobalamin

Zinc	Zinc sulfate Zinc gluconate Zinc oxide Zinc lactate Zinc citrate Zinc chloride Zinc acetate
Manganese	Manganese sulfate Manganese chloride Manganese carbonate Manganese citrate Manganese gluconate
Calcium	Calcium carbonate Calcium gluconate Calcium citrate L-Calcium lactate Calcium hydrogen phosphate Calcium chloride Tricalcium phosphate (calcium phosphate) Calcium glycerophosphate Calcium oxide Calcium sulfate
Phosphorus	Tricalcium phosphate (calcium phosphate) Calcium hydrogen phosphate
Iodine	Potassium iodate Potassium iodide Sodium iodide
Selenium	Sodium selenate Sodium selenite
Chromium	Chromium sulfate Chromic chloride
Molybdenum	Sodium molybdate Ammonium molybdate
Taurine	Taurine (amino-ethanesulfonic acid)
L-methionine	Non-animal origin
L-tyrosine	Non-animal origin
L-tryptophan	Non-animal origin
L-carnitine	L-carnitine L-Carnitine-L-Tartrate

Appendix D

Food Category (Name) Explanation

Food category (name) explanation is detailed in Table D.1.

Table D.1 -- Food Category (Name) Explanation

Food Cat. No.	Food category (name)
01.0	Milk and dairy products (except the species involved in 13.0 foods for special diets)
01.01	Pasteurized milk, sterile milk and modulation milk
01.01.01	Pasteurized milk
01.01.02	Sterile milk
01.01.03	Modulation milk
01.02	Fermented milk and flavored fermented milk
01.02.01	Fermented milk
01.02.02	Flavored fermented milk
01.03	Milk powder and its modulation products
01.03.01	Milk powder
01.03.02	Modulation milk powder
01.04	Condensed milk and its modulation products
01.04.01	Unsweetened condensed milk
01.04.02	Modulation condensed milk
01.05	Single cream (unsalted butter) and its similar products
01.06	Cheese and reproduced cheese
01.07	Instant dessert mainly made by milk and its precast product (excluding ice cream and flavored yoghurt)
01.08	Other dairy products (such as whey powder and casein flour)
02.0	Fat, grease and fat emulsions
02.01	Basically-anhydrous fat and grease
02.01.01	Vegetable grease
02.01.01.01	Vegetable oil
02.01.01.02	Hydrogenate vegetable oil
02.01.02	Animal grease (including lard oil, beef tallow, fish oil and other animal fats, etc.)
02.01.03	Anhydrous butter and anhydrous milk fat
02.02	Water-oil fat emulsification products
02.02.01	Emulsification products with fat content above 80%
02.02.01.01	Butter and condensed butter
02.02.01.02	Margarine and its similar products (such as butter and margarine mixed products)
02.02.02	Emulsification products with fat content below 80%
02.03	Emulsification product except that in 02.02, including mixed and/or flavored emulsification products

10.03.01	Dehydrated egg products (such as albumen powder, dried egg yolk and albumen flakes)
10.03.02	Thermo-setting egg products (such as yolk cheese, preserved egg sausage)
10.03.03	Frozen egg products (such as ice eggs)
10.03.04	Liquid eggs
10.04	Other egg products
11.0	Sweetening agent including honey
11.01	Sugar
11.01.01	White sugar and white sugar products (such as white granulated sugar, soft plantation white sugar, rock candy and cube sugar etc.)
11.01.02	Other sugars and syrups (such as brown sugar, brown granulated sugar and maple syrup)
11.02	Starch sugar (fruit sugar, glucose, maltose and partial invert sugar, etc.)
11.03	Honey and pollen
11.04	Table sweeteners
11.05	Flavored syrup
11.06	Other sweetening agents
12.0	Flavoring material
12.01	Salt and salt substitutes
12.02	Delicate flavor agent and flavor enhancer
12.03	Vinegar
12.04	Soy
12.05	Sauce and sauce products
12.06	-
12.07	Cooking wine and products
12.08	-
12.09	Spices
12.10	Compound flavoring
12.10.01	Solid compound flavoring
12.10.02	Semisolid compound flavoring
12.10.03	Liquid bouillon cube (except the species involved in 12.03 and 12.04)
12.11	Other flavoring
13.0	Foods for special diets
13.01	infants and young children formula foods
13.01.01	Infant formula foods
13.01.02	Formula foods for relatively big infants and young children
13.01.03	Infant formula foods for special medical purposes
13.02	Complementary foods for infants and young children
13.02.01	Cereal-based complementary foods for infants and young children
13.02.02	Canned complementary foods for infants and young children
13.03	Formula foods for special medical purposes (except the species involved in 13.01)
13.04	Formula foods with low energy

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