

**DECISION No. 6289/2003/QĐ-BYT OF  
DECEMBER 9, 2003, PROMULGATING  
THE REGULATION ON ADDITION OF  
MICRONUTRIENTS TO FOOD****THE MINISTER OF HEALTH**

*Pursuant to the Government's Decree No. 49/  
2003/ND CP of May 15, 2003, defining the  
functions, tasks, powers and organizational  
structure of the Ministry of Health;*

*Pursuant to the Government's Decree No. 86/  
CP of December 8, 1995, on the assignment of  
state management responsibilities for goods  
quality;*

*At the proposal of the director of the Food  
Safety and Hygiene Department, the director of  
the Legal Department and the director of the  
Science and Training Department under the  
Ministry of Health,*

**DECIDES:**

**Article 1.-** To promulgate together with this  
Decision the Regulation on addition of  
micronutrients to food.

**Article 2.-** This Decision takes effect 15 days  
after its publication in "CONG BAO."

**Article 3.-** The director of the Office, the chief  
inspector, and the directors of the Science and  
Training Department and the Legal Department  
of the Ministry of Health; the director of the Food  
Safety and Hygiene Department, directors of  
provincial/municipal Health Services, and heads

of units attached to the Ministry of Health shall  
implement this Decision.

*For the Minister of Health*  
*Vice Minister*  
**TRAN CHI LIEM**

**REGULATION ON ADDITION OF  
MICRONUTRIENTS TO FOOD**

*(Promulgated together with the Health Minister's  
Decision No. 6289/2003/QĐ-BYT of December  
9, 2003)*

**Chapter I****GENERAL PROVISIONS**

**Article 1.-** This Regulation governs the  
addition of micronutrients to food.

**Article 2.-** This Regulation applies to Vietnam-  
based producers, processors and traders of food  
added with micronutrients.

**Article 3.-** In this Regulation, the terms below  
are construed as follows:

1. Micronutrients include vitamins and  
minerals of a very small quantity (weighed in  
microgram or milligram) which are essential for  
the growth, development and maintenance of life  
of human bodies.

2. Addition of micronutrients to food means the intentional insertion of a certain quantity of one or many micronutrients into food.

### *Chapter II*

#### **REQUIREMENTS ON MICRONUTRIENTS AND SOME KINDS OF FOOD TO BE ADDED WITH MICRONUTRIENTS**

**Article 4.-** Micronutrients to be added to food are subject to state inspection of their quality, hygiene and safety.

**Article 5.-** Micronutrients to be added to food must satisfy the following conditions:

1. Not affecting the nature of food (color, smell, taste, structure or processing characteristics);
2. Not reducing products' use duration.

**Article 6.-**

1. The addition of micronutrients to food must comply with regulations applicable to each kind of food:

a/ Baby food must comply with the regulations in Appendix 1.

b/ Fish sauce must comply with the regulations in Appendix 2.

c/ Wheat flour must comply with the regulations in Appendix 3.

d/ Cooking oil must comply with the regulations in Appendix 4.

e/ Edible sugar must comply with the regulations in Appendix 5.

2. The addition of vitamins and minerals to

baby food and wheat flour must comply with the regulations in Appendix 6.

### *Chapter III*

#### **REQUIREMENTS ON PRODUCERS, PROCESSORS AND TRADERS OF FOOD ADDED WITH MICRONUTRIENTS**

**Article 7.-** Before putting products into circulation on the market, producers, processors and traders of food added with micronutrients shall carry out procedures for food quality, hygiene and safety standard announcement with the Ministry of Health (the Food Safety and Hygiene Department).

**Article 8.-** Producers and processors of food added with micronutrients shall satisfy food hygiene and safety conditions specified by law.

Establishments producing and processing food added with micronutrients are encouraged to apply Hazard Analysis and Critical Control Points (HACCP) or Good Manufacture Practices (GMP).

**Article 9.-** Producers and processors of food added with micronutrients are responsible for the quality, hygiene and safety of their food products and shall conduct periodical inspections according to regulations to ensure the quality and quantity of micronutrients as announced.

### *Chapter IV*

#### **REQUIREMENTS ON LABELING, PACKING, PRESERVATION AND TRANSPORTATION OF FOOD ADDED WITH MICRONUTRIENTS**

**Article 10.-** The labeling of products must comply with the Prime Minister's Decision No. 178/1999/QĐ-TTg of August 30, 1999, promulgating the Regulation on labeling of domestically circulated, imported and exported goods, and guiding legal documents. In addition, a product label must bear the phrase "*Thức phẩm bổ sung vi chất dinh dưỡng*" (Food added with micronutrients).

**Article 11.-** Containers of food added with micronutrients must ensure food hygiene and safety so as not to denature the food, and suit preservation and transportation conditions.

**Article 12.-** The preservation and transportation of food added with micronutrients must satisfy food hygiene and safety conditions prescribed by law and must not reduce the quantity of micronutrients in food.

#### **Chapter V**

#### **EXAMINATION, INSPECTION, AND HANDLING OF VIOLATIONS**

##### **Article 13.-**

1. The Food Safety and Hygiene Department shall assume the prime responsibility for, and coordinate with the Inspectorate and functional Departments and Bureaus under the Ministry of Health and concerned agencies in, examining and inspecting the implementation of this Regulation nationwide.

2. Provincial/municipal Health Services shall

coordinate with concerned agencies in examining and inspecting the implementation of this Regulation in their localities.

**Article 14.-** Organizations or individuals that violate this Regulation shall, depending on the nature and severity of their violations, be administratively handled or examined for penal liability and, if causing damage, pay compensation therefor in accordance with law.

#### **Chapter VI**

#### **IMPLEMENTATION PROVISIONS**

##### **Article 15.-**

1. Producers, processors and traders of food added with micronutrients shall implement this Regulation.

2. The Food Safety and Hygiene Department shall assume the prime responsibility for, and coordinate with functional Departments and Bureaus under the Ministry of Health, the National Institute of Nutrition and concerned agencies in, guiding and directing the implementation of this Regulation.

3. Provincial/municipal Health Services shall organize the implementation of this Regulation in their localities.

**For the Minister of Health  
Vice Minister  
TRAN CHI LIEM**

### Appendix 1

#### Regulations on addition of micronutrients to baby food

Baby food means additional food for infants aged 6 months or older, which are produced from such main cereals as rice, wheat, soybeans, green peas and powdered milk, added with vitamins and minerals in a quantity estimated to satisfy around 30-50% of daily needs of infants.

Added substances	Content/100 Kcal	
	Minimum	Maximum
1. Vitamin A (RE)	250 IU	500 IU
2. Vitamin D	40 IU	80 IU
3. Vitamin C	8 mg	40 mg
4. Vitamin B1	40 µg	200 µg
5. Vitamin B2	60 µg	300 µg
6. Folic acid	4 µg	20 µg
7. Vitamin B12	0.15 µg	1.5 µg
8. Vitamin K	4 µg	40 µg
9. Calcium (Ca)	50 mg	250 mg
10. Iron (Fe)	0.5 mg	2.5 mg
11. Zinc (Zn)	0.3 mg	2 mg

### Appendix 2

#### Regulations on addition of iron to fish sauce

Usable form of iron: NaFeEDTA

Added dose:

- Minimum: 30 mg of element iron/100 ml of fish sauce
- Maximum: 50 mg of element iron/100 ml of fish sauce

Allowable NaFeEDTA standard:

Scientific name: Sodium Iron (III) Ethylene Diamine Tetra Acetate, trihydrate

Chemical formula:  $C_{10}H_{12}FeN_2NaO_8 \cdot 3H_2O$

Molecular weight: 421.09 (trihydrate)

Purity: according to JECFA standard.

Characteristics	Allowable content
Iron component	12.5 - 13.5%
EDTA component	65.5 - 70.5%
pH of 1%-solution	3.5 - 5.5
Water-insoluble rate	Maximum 0.1%
Nitritoltriacetic acid	< 0.1%
Arsenic (As)	Maximum 1 mg/kg
Lead (Pb)	Maximum 1 mg/kg

### Appendix 3

#### Regulations on addition of micronutrients to wheat flour

Added substances	Added quantity
1. Iron (Fe)	60 mg/kg
2. Zinc (Zn)	30 mg/kg
3. Thiamine (vitamin B1)	2.5 mg/kg
4. Riboflavin (vitamin B2)	4 mg/kg
5. Folic acid	2 mg/kg

### Appendix 4

#### Regulations on addition of vitamin A to cooking oil

Usable form of vitamin A: vitamin A palmitate

Added dose:

- Minimum: 50 IU/gram of oil
- Maximum: 100 IU/gram of oil

Preservation conditions:

- Cooking oil added with vitamin A must be preserved in colored cans to avoid direct sunlight.
- 50% of the quantity of vitamin A can be preserved within 6-9 months.

### Appendix 5

#### Regulations on addition of vitamin A to edible sugar

Usable form of vitamin A: vitamin A palmitate

Added dose:

- Minimum: 15  $\mu$ g/gram of sugar

- Maximum: 30  $\mu$ g/gram of sugar

Preservation conditions:

- Sugar added with vitamin A must be preserved in airtight boxes to avoid direct sunlight.

- 50% of the quantity of vitamin A can be preserved within 6 months.

### Appendix 6

#### Regulations on addition of vitamins and minerals to baby food and flour

Vitamin	Form of vitamin	Purity
1. Vitamin A	Retinyl acetate Retinyl palmitate Retinyl propionate Beta-carotene	USP, BP, Ph.Eur, FCC USP, BP, Ph.Eur, FCC USP, BP, Ph.Eur, FCC FAO/WHO, FCC
2. Vitamin D	Ergocalciferol (vitamin D2) Cholecalciferol (vitamin D3)	USP, BP, Ph.Eur, FCC USP, FCC
3. Vitamin C	Ascorbic acid Sodium ascorbate Calcium ascorbate	USP, BP, Ph.Eur FAO/WHO, FCC USP, FAO/WHO, FCC
4. Vitamin B1	Thiamine chloride hydrochloride Thiamine mononitrate	USP, BP, Ph.Eur, FCC USP, FCC
5. Vitamin B2	Riboflavin Riboflavin 5'-sodium phosphate	USP, BP, Ph.Eur, FAO/WHO, FCC
6. Folic	Folic acid	USP, BP
7. Vitamin B12	Xyanocobalamin Hydroxocobalamin	USP, BP, Ph.Eur NF, BP

8. Vitamin K	Phytolmenaquinone	USP, BP
9. Calcium (Ca) sources	Calcium carbonate	FCC, FAO/WHO
	Calcium citrate	FCC, FAO/WHO
	Calcium lactate	FCC, FAO/WHO
	Calcium phosphate, tribasic	FCC, FAO/WHO
10. Iron (Fe)	Ferrous fumarate	FCC
	Ferrous gluconate	FCC, FAO/WHO
	Ferrous lactate	MI
	Ferrous sulfate	FCC
11. Zinc (ZN) sources	Zinc acetate	MI
	Zinc oxide	MI
	Zinc sulfate	FCC

*Notes:*

- USP: United States Pharmacopoeia
- NF: United States National Formulary
- BP: British Pharmacopoeia
- BPC: British Pharmaceutical Codex
- Ph.Eur: European Pharmacopoeia

- MI: Merck Index

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

- DAB: Deutsches Arzneibuch 7

- FCC: Food Chemicals Codex.-