

## BASIC PROVISIONS ON FUNCTIONAL FOOD SUPERVISION

(Regulation of the Head of the Food and Drug Supervisory Board No. HK 00.05.52.0685 dated January 27, 2005)

### THE HEAD OF THE FOOD AND DRUG SUPERVISORY BOARD,

Considering:

- a. that various kinds of food products claimed beneficial in caring and enhancing health, commonly called functional food grow rapidly;
- b. that the public must be protected from the distribution and use of functional food failing to meet the requirements for security, quality, nutrition as well as label and advertisement;
- c. that in connection with the matters as meant in points a and b, it is necessary to stipulate a decision of the Head of the Food and Drug Supervisory Board;

In view of:

1. Law No. 7/1996 on food (Statute Book of 1996 No. 99, Supplement to Statute Book No. 3656);
2. Law No. 8/1999 (BN No. 6321 pages 1A - 7A and so on) on consumer protection (Statute Book of 1999 No. 42, Supplement to Statute Book No. 3821);
3. Government Regulation No. 17/2001 (BN No. 6706 pages 24A - 28A) on tariffs of non-tax state revenues effective within the Food and Drug Supervisory Board (Statute Book of 2001 No. 35, Supplement to Statute Book No. 4087);
4. Government Regulation No. 28/2004 on security, quality and nutrition of food (Statute Book of 2004 No. 107, Supplement to Statute Book No. 4424);
5. Presidential Decree No. 103/2001 on the status, tasks, functions, authority and organizational structures of non-ministerial government institutions, as already amended by Presidential Decree No. 46/2002;
6. Presidential Decree No. 110/2001 on first-echelon organizational units and tasks of non-ministerial government institutions, as already amended by Presidential Decree No. 48/2002;
7. Decision of the Head of the Food and Drug Supervisory Board No. 02001/SK/KBPOM dated February 26, 2001 on the organization and working arrangement of the Food and Drug Supervisory Board as al-

- ready amended by Decision of the Head of the Food and Drug Supervisory Board No. 00.05.21.4231/2004;
8. Decision of the Head of the Food and Drug Supervisory Board No. HK. 00.05.1.2569 dated May 31, 2004 on criteria and procedures for evaluation of food products;

### D E C I D E S :

To stipulate:

THE REGULATION OF THE HEAD OF THE FOOD AND DRUG SUPERVISORY BOARD ON BASIC PROVISIONS ON FUNCTIONAL FOOD SUPERVISION

### CHAPTER I GENERAL PROVISION

#### Article 1

Referred to in this regulation as:

1. Food shall be everything coming from biological resources and water, whether processed or not, designated as food or drink for human consumption, including food supplement, food raw material and other materials used in the process of preparation, processing and/or production of food or beverage.
2. Processed food shall be food or beverage resulting from a process by certain means or method, with or without additive.
3. Functional food shall be proceeded-food containing one functional component or more, which based on scientific analysis has certain physiological functions, is proven not dangerous and beneficial to health.
4. Food label shall be every kind of information about food, in the form of picture, writing, combination of writing and picture, or other form attached to the food, inserted into, affixed at or being part of food package.
5. Food advertisement shall every kind of information or statement on food in the form of picture, writing or other form, realized in various methods to market and/or trade food.

## Other Requirement:

Claim must be accompanied with a statement "People with kidney problems and who are under diuretic medicament must consult a doctor".

## 2.3. Calcium

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (according to AKG of target group per day) more than similar food	"Calcium plays a role in the formation of bones and in maintaining solidity of bones and teeth"	'Routine physical activity and healthy diet accompanied with sufficient calcium help adolescents and adult women maintain their health properly and may help reduce osteoporosis in the future'.  Requirement: Food is a high source of calcium (at least contains calcium of 20% of the recommended depending on age per serving)
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (according to AKG of target group per day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (according to AKG of target group per day) per serving		

## Other requirements:

- 1) Claim must be accompanied with the requirement "accompanied with high physical activity and consumption of food with balanced nutrition. It is better to have a sufficient consumption of calcium starting from young age to maintain bone health and to prevent osteoporosis in old age".
- 2) Products with calcium content of more than 400 mg must be accompanied with a statement that consumption of more than 2,000 mg per day will not produce additional benefits in maintaining bone health.
- 3) Phosphor content in functional food shall not exceed calcium content.
- 4) Must contain AKG percentage of calcium.
- 5) Must contain quantity of active calcium.

## 2.4. Iron

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (according to AKG of target group per day) more than similar food	"Iron may help prevent and overcome anemia as a result of iron deficiency"	Label and advertisements shall not contain statement on health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (according to AKG of target group per day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (according to AKG of target group per day) per serving		

components by submitting scientific evidence and claim for evaluation by the Peer Reviewer Team.

- (4)Based on the evaluation by the Peer Reviewer Team as meant in paragraph (2), the Head of the Board in this case the Deputy in Charge of Supervision Over Food Security and Dangerous Materials shall give approval as functional food and the claim permitted for the components.

#### CHAPTER V PRODUCTION

##### Article 6

- (1)Industries producing functional food of the certain processed food category shall meet the proper production method of food and system of Hazard Analysis and Critical Control Points (HACCP).
- (2)The functional food as meant in paragraph (2) shall be stipulated by the Head of the Board.

#### CHAPTER VI L A B E L

##### Article 7

- (1) Labels of functional food shall meet the provisions in Decision of the Board of the Food and Drug Supervisory Board No. HK.00.05.52.4321 on general guidelines on the labeling of food products.
- (2)The labels of functional food shall mention warning and other information in accordance with recommendations of the Peer Reviewer Team.
- (3)The labels of functional food shall mention claim about *content of nutrition, function of nutrition and/or benefit to the health as contained in the attachment to this regulation.*
- (4)The functional food can mention claims other than those mentioned in paragraph (3) after securing approval from the Head of the Board on the basis of recommendations of the Peer Reviewer Team.

##### Article 8

- (1)If functional food labels emphasize one functional component or more having nutrition sufficiency figure not yet stipulated or *description of food certifies*

the advantage of the material, the percent of content (b/b) of the material shall be mentioned.

- (2)If food labeling emphasizes on one material or more having low content, the percentage of content of the material shall be disclosed.

##### Article 9

Functional food only can be advertised after securing approval of registration.

##### Article 10

- (1)Substances of functional food advertisements shall secure approval from the Head of the Board, before the distribution.
- (2)Procedures for securing the approval of functional food advertisement shall be regulated further in a special regulation.

#### CHAPTER VIII SANCTION

##### Article 11

Any violation of the provisions in this regulation shall be liable to administrative sanction and criminal sanction in accordance with the provisions of the law in force.

#### CHAPTER IX CONCLUSION

##### Article 12

The Head of the Board shall stipulate further matters not yet regulated sufficiently in this regulation.

##### Article 13

The regulation shall come into force as from the date of stipulation.

Stipulated in Jakarta

On January 27,2005

THE HEAD OF THE FOOD AND DRUG SUPERVISORY  
BOARD

sgd

H. SAMPURNO

ATTACHMENT . . . . ( TO BE CONTINUED )

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# BASIC PROVISIONS ON FUNCTIONAL FOOD SUPERVISION

(Regulation of the Head of the Food and Drug Supervisory Board No. HK 00.05.52.0685  
dated January 27, 2005)

[ Continued from Business News No. 7196 - 7197 pages 29A - 31A ]

## ATTACHMENT:

### I. VITAMINS

#### 1.1. Vitamin A

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (according to AKG of target group per day) more than similar food	Vitamin A may help maintain wholeness of mucosa.	Label and advertisements shall not contain health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (according to AKG of target group per day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (according to AKG of target group per day) per serving		

Other Requirements:

Claim must contain:

- \* For pregnant mothers, recommended consumption shall not exceed 1800 mcg or 6000 IU because it may result in teratogenic effect on embryo.
- \* Type and quantity of vitamin A content.
- \* AKG percentage fulfilled.

#### 1.2. Carotenoid

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (according to AKG of target group per day) more than similar food	"Carotenoid may function as anti oxidant in the body"	Label and advertisements shall not contain health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 10%-19% of the recommended (according to AKG of target group per day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (according to AKG of target group per day) per serving		

## 1.3. Vitamin B1

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (according to AKG of target group per day) more than similar food	"Vitamin B1 plays a role as co-enzyme for changing carbohydrate to energy"	Label and advertisements shall not contain health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (according to AKG of target group per day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (according to AKG of target group per day) per serving		

Other Requirements:

Claim must contain:

- \* Quantity and source of vitamin B1.
- \* AKG requirement percentage fulfilled.

## 1.4. Vitamin B2

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (according to AKG of target group per day) more than similar food	<ul style="list-style-type: none"> <li>* "Vitamin B2 plays a role as co-enzyme in health reaction forming energy".</li> <li>* "Vitamin B2 may help prevent migraine on 400 mg dosage/day".</li> <li>* "Vitamin B2 plays a role as anti oxidant on 400 mg dosage/day".</li> </ul>	Label and advertisements shall not contain health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (according to AKG of target group per day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (according to AKG of target group per day) per serving		

Other Requirements:

Claim must contain:

- \* Type and quantity of riboflavin content.
- \* AKG requirement percentage fulfilled.
- \* Giving of vitamin B2 at high dosage must be according to doctor's recommendation.

## 1.5. Vitamin B3

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (according to AKG of target group per day) more than similar food	"Vitamin B3 may help prevent pellagra, dermatitis, digestion problem, queasiness, unhealthy feeling, anemia, irritation, confusion, dementia".	Label and advertisements shall not contain health claims

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (according to AKG of target group per day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (according to AKG of target group per day) per serving		

Other Requirements:

Claim must contain:

\* Type and quantity of B4 vitamin content.

\* AKG requirement percentage fulfilled.

#### 1.6. Vitamin B5

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (according to recommended consumption by target group per day) more than similar food	Label and advertisements shall not contain nutrient function claims	Label and advertisements shall not contain health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (according to recommended consumption by target group per day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (according to recommended consumption by target group per day) per serving		

Other Requirements:

Claim must contain:

\* Type and quantity of pantothenic acid content.

\* AKG requirement percentage fulfilled.

#### 1.7. VITAMIN B5 . . . . . ( TO BE CONTINUED )

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# BASIC PROVISIONS ON FUNCTIONAL FOOD SUPERVISION

(Regulation of the Head of the Food and Drug Supervisory Board No. HK 00.05.52.0685  
dated January 27, 2005)

[ Continued from Business News No. 7201 - 7202 pages 30A - 32A ]

## 1.7. Vitamin B5

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (according to AKG of target group per day) more than similar food	* "Giving of Vitamin B6 at high dosage may help eliminate abnormality of peripheral nerve". * "Giving of vitamin B6 continually will help repair inborn error." * Vitamin B6 plays a role in the regulating of steroid hormone (overcoming depression in premenstrual tension)". * "Vitamin B6 may affect immune system (in old age)." * Vitamin B6 may eliminate queasiness during pregnancy and post-radiation as cancer medication (50-200 mg/day)".	Label and advertisements shall not contain health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (according to AKG of target group per day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (according to AKG of target group per day) per serving		

Claim must contain:

- \* Type and quantity of vitamin B6 content.
- \* AKG requirement percentage fulfilled.

## 1.8. Vitamin B12

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (according to AKG of target group per day) more than similar food	* Vitamin B12 plays a role as co-enzyme in protein metabolism/formation of nucleic acid of DNA and RNA". * Vitamin B12 may help prevent or heal deficiency anemia and motorical, social, and intellectual underdevelopment (on high dosage)".	Label and advertisements shall not contain health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (according to AKG of target group per day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (according to AKG of target group per day) per serving		

## Other Requirements:

Claim must contain:

- \* Type and quantity of kobatamin content.
- \* AKG requirement percentage fulfilled.

## 1.9. Folic Acid

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (according to AKG of target group per day) more than similar food	Label and advertisements shall not contain nutrient function claims	<p>"Diet of balanced nutrition with sufficient folic consumption may reduce risk of congenital abnormality on embryo, for example, problems in neural tube development in the form of abnormality of brain or spinal cord (anencephall, spina bifida)".</p> <p>Requirements:</p> <ul style="list-style-type: none"> <li>* Food is a good folic source (with folic content at least 40 mcg per serving).</li> <li>* The foregoing claim may not be contained if functional food product contains more than 100% of AKB for vitamin A in the form of retinoid or pro vitamin A or vitamin D.</li> <li>* It is necessary to contain that the cause of abnormality in neural tube development is multi factorial.</li> </ul>
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (according to AKG of target group per day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (according to AKG of target group per day) per serving		



## 1.10. Vitamin C

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (according to AKG of target group per day) more than similar food	* "Vitamin C plays a role as anti oxidant working together with other anti oxidants, especially vitamin E" * "Vitamin C plays a role in the formation of collagenic tissue"	Label and advertisements shall not contain health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 19% of the recommended (according to AKG of target group per day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (according to AKG of target group per day) per serving		

Other Requirements:

- \* Shall not contain claims relating to increase of stamina or prevention of cancer.
- \* Must contain vitamin C.
- \* Must contain AKG percentage of vitamin C.

## 1.11. Vitamin D

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (according to AKG of target group per day) more than similar food	Label and advertisements shall not contain nutrient function claims	Label and advertisements shall not contain health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 19% of the recommended (according to AKG of target group per day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (according to AKG of target group per day) per serving		

## 1.12. Vitamin E

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (400 mg) more than similar food	As anti oxidant, vitamin E may help reduce possible risk of coronary heart disease if it is accompanied by low saturated fat and physical activities	Label and advertisements shall not contain health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (400 mg) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (400 mg) per serving		

Other Requirement:

Must clearly contain the form of vitamin E because of its different activities, especially as anti oxidant.

## 1.13. Para Amino Benzoic Acid

Nutrient Content Claim	Nutrient Function Claim	Health Claim
Label and advertisements shall not contain nutrient content claims	Label and advertisements shall not contain nutrient function claims	Label and advertisements shall not contain health claims

## 2. MINERAL

## 2.1. Sodium

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Sodium, free'	Less than 5 mg of sodium per serving	Label and advertisements shall not contain nutrient function claims	'Low-sodium food may help reduce possible risk of hypertension, a kind of disease related to many factors'.  Requirement: Having fulfilled low sodium requirement.
'Very low sodium'	35 mg of sodium or less per serving		
'Low sodium'	140 mg of sodium or less per serving		
'Reduced or less sodium'	At least contain 25% less than the usual sodium content in food products		
'Light in sodium'	Contain 50% less than the usual sodium content in food products; limited to food products containing more than 40 Kcal per serving or containing fat of more than 3 g per serving		
'Salt free'	Less than 5 mg of sodium per serving		
'Low sodium meal'	Containing 140 mg of sodium or less per 100 g		
'Unsalted or no added, sodium free'	During processing, unsalted, but not sodium free, because it contains sodium, which is naturally contained in foodstuff		

Other Requirement:

Claim must be accompanied with a statement "People with hypertension must consult a doctor".

## 2.2. Kalium

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (according to the recommended consumption of target group per day) more than similar food	Label and advertisements shall not contain nutrient function claims	'Food, which is a good source of kalium, is accompanied with low sodium, which may help reduce risk of hypertension and stroke'  Requirements: * Good source of kalium * Low in sodium * Low in total fat * Low in saturated fat * Low in cholesterol
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (according to the recommended consumption of target group per day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (according to the recommended consumption of target group per day) per serving		

## Other Requirement:

Claim must be accompanied with a statement "People with kidney problems and who are under diuretic medicament must consult a doctor".

## 2.3. Calcium

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (according to AKG of target group per day) more than similar food	"Calcium plays a role in the formation of bones and in maintaining solidity of bones and teeth"	'Routine physical activity and healthy diet accompanied with sufficient calcium help adolescents and adult women maintain their health properly and may help reduce osteoporosis in the future'.  Requirement: Food is a high source of calcium (at least contains calcium of 20% of the recommended depending on age per serving)
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (according to AKG of target group per day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (according to AKG of target group per day) per serving		

## Other requirements:

- 1) Claim must be accompanied with the requirement "accompanied with high physical activity and consumption of food with balanced nutrition. It is better to have a sufficient consumption of calcium starting from young age to maintain bone health and to prevent osteoporosis in old age".
- 2) Products with calcium content of more than 400 mg must be accompanied with a statement that consumption of more than 2,000 mg per day will not produce additional benefits in maintaining bone health.
- 3) Phosphor content in functional food shall not exceed calcium content.
- 4) Must contain AKG percentage of calcium.
- 5) Must contain quantity of active calcium.

## 2.4. Iron

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (according to AKG of target group per day) more than similar food	"Iron may help prevent and overcome anemia as a result of iron deficiency"	Label and advertisements shall not contain statement on health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (according to AKG of target group per day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (according to AKG of target group per day) per serving		

## 2.5. Zinc

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (according to AKG of target group per day) more than similar food	Label and advertisements shall not contain statement on nutrient function claims	Label and advertisements shall not contain statement on health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (according to AKG of target group per day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (according to AKG of target group per day) per serving		

## 2.6. Copper

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (2,000 mcg/day) more than similar food	Label and advertisements shall not contain statement on nutrient function claims	Label and advertisements shall not contain statement on health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (2,000 mcg/day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (2,000 mcg/day) per serving		

## 2.7. Iodine

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (2,000 mcg/day) more than similar food	"Iodine helps prevent GAKI (disturbance as a result of lack of iodine), which is manifested in, amongst others, aneurysm and cretinism Label and advertisements shall not contain statement on health claims	Label and advertisements shall not contain health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (2,000 mcg/day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (2,000 mcg/day) per serving		

## 2.8. Magnesium

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (according to AKG of target group per day) more than similar food	Label and advertisements shall not contain statement on nutrient function claims	Label and advertisements shall not contain statement on health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (according to AKG of target group per day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (according to AKG of target group per day) per serving		

Other requirement:

Claim must be accompanied with a statement "Not recommended for persons with kidney problems and coronary heart disease, except with doctor's recommendation".

## 2.9. Manganese

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (11 mg/day) more than similar food	Label and advertisements shall not contain statement on nutrient function claims	Label and advertisements shall not contain statement on health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (11 mg/day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (11 mg/day) per serving		

## 2.10. SELENIUM . . . . . ( TO BE CONTINUED )

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### BASIC PROVISIONS ON FUNCTIONAL FOOD SUPERVISION

(Regulation of the Head of the Food and Drug Supervisory Board No. HK 00.05.52.0685  
dated January 27, 2005)

*[ Continued from Business News No. 7203 pages 26A - 32A ]*

#### 2.10. Selenium

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (55 mcg/day) more than similar food	Label and advertisements shall not contain statement on nutrient function claims	Label and advertisements shall not contain statement on health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (55 mcg/day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (55 mcg/day) per serving		

#### 2.11. Chromium

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (200 mcg/day) more than similar food	"Chromium may help regulate sugar (glucose) content in blood in diabetes sufferers if accompanied with low consumption of sugar (glucose)"	Label and advertisements shall not contain statement on health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (200 mcg/day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (200 mcg/day) per serving		

## Other requirements:

1. It must be mentioned that the use of calcium carbonate and antacids as supplements may hamper the absorption of chromium; and the use of corticosteroid will increase requirement for chromium.
2. Diabetes sufferers who are under medicament with insulin or other medicines must obtain doctor's approval before consuming an additional amount of chromium.

## 2.12. Boron

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (3 mg/day) more than similar food	Label and advertisements shall not contain statement on nutrient function claims	Label and advertisements shall not contain health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (3 mg/day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (3 mg/day) per serving		

## 2.13. Vanadium

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (1.8 mg/day) more than similar food	Label and advertisements shall not contain statement on nutrient function claims	Label and advertisements shall not contain health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (1.8 mg/day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (1.8 mg/day) per serving		

## 3. ALCOHOLIC SUGAR

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (20 g/day) more than similar food	Label and advertisements shall not contain statement on nutrient function claims	"Too frequent consumption of sugar-rich food may damage the teeth. Alcoholic sugar in (name of food) does not add to teeth damage".  Requirement: sugar free
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (20 g/day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (20 g/day) per serving		

## Other requirements:

1. If the fermentable carbohydrate is contained in food containing alcoholic sugar, the food shall not reduce pH of plaque on teeth to be lower than 5.7 as a result of fermentation caused by bacteria during consumption or 30 minutes after consumption.
2. For each recommended consumption or per serving; food containing sugar (sucrose, glucose, or fructose) must be lower than 0.5 g.
3. Package with size of its surface less than 38 cm<sup>2</sup> may use shortened claim: "This food does not damage teeth" or "This food may reduce teeth damage".
4. In the information on nutrient content, name of alcoholic sugar or name of compound must be written.
5. Claim shall not mention the degree of reduction of risk of tooth decay as a result of consumption of food containing alcoholic sugar.
6. Claim shall not mention that consumption of food containing alcoholic sugar is the only method to reduce risk of tooth decay.

## 4. UNSATURATED FAT

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (according to the recommended consumption of target group per day) more than similar food	1) "Omega 3 fatty acid may hamper increasing inflammation reaction, for example, rheumatoid arthritis" 2) "In pregnancy, DHA is needed for normal development of placenta and embryo" 3) "The giving of DHA and ARA during pregnancy, babyhood and childhood (up to 2 years old) will optimize brain development and learning competence"	Requirements: * Low saturated fat, * Low cholesterol, and * Low fat
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (according to the recommended consumption of target group per day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (according to the recommended consumption of target group per day) per serving		

## Other requirements:

1. Claim must be accompanied by the mentioning of fatty acid, type and quantity of each fatty acid, total calories per serving, and percentage of the recommended amount.
2. Health claim that helps reduce risk of coronary heart disease must mention n-6 and n-3 ratios accompanied by diet of low total fat, low saturated fat, and low cholesterol.
3. Label must contain limit of serving per day so that it does not exceed the recommended amount of consumption of fat (total fat consumed is 25% of total calories per day, fatty acid, saturated fatty acid: = 10%, single unsaturated fatty acid: 10%, multiple unsaturated fatty acid: 10%).
4. Only cod liver oil, which is given additional EPA and DHA, may indicate containing EPA and DHA and write down the suitable claim, because cod liver oil is the source of vitamin A.



## 5. PEPTIDE AND CERTAIN PROTEINS

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Whey Protein Content Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (10 g of whey protein per day) more than similar food	Label and advertisements shall not contain nutrient function claims	<p>"25 grams of whey protein per day as part of diet of low saturated fat and cholesterol may help reduce risk of heart disease.</p> <p>Each serving of (name of food) provides ... grams of whey protein."</p> <p>Or:</p> <p>"Diet of low saturated fat and cholesterol containing 25 grams of whey protein per day may reduce risk of heart disease. Each serving of (name of food) provides ..... grams of whey protein".</p>
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (10 g of whey protein per day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (10 g of whey protein per day) per serving		
Nutrient Content Claim		Nutrient Function Claim	Health Claim
Laktoferin Content Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (250 mg of laktoferin per day) more than similar food		<p>Requirements:</p> <ul style="list-style-type: none"> <li>- At least contain 6.25 g of whey protein per serving.</li> <li>- Low in saturated fat.</li> <li>- Low in cholesterol, and</li> <li>- Low fat (except if food is entirely made of soy beans not containing fat).</li> <li>- Claim must mention amount of whey protein per serving.</li> </ul>
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (250 mg of laktoferin per day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (250 mg of laktoferin per day) per serving		
Whey Protein Content Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (25 g of whey protein per day) more than similar food		
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (25 g of whey protein per day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (25 g of whey protein per day) per serving		

## 6. AMINO ACID

## 6.1. Arginine

Nutrient Content Claim	Nutrient Function Claim	Health Claim
Label and advertisements shall not contain nutrient content claims	Label and advertisements shall not contain nutrient function claims	Label and advertisements shall not contain health claims

## 6.2. Lysin

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (according to the recommended consumption for target group) more than similar food	Label and advertisements shall not contain nutrient function claims	Label and advertisements shall not contain health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (according to the recommended consumption for target group) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (according to the recommended consumption for target group) per serving		

## 6.3. Tryptophan

Nutrient Content Claim	Nutrient Function Claim	Health Claim
Label and advertisements shall not contain nutrient content claims	Label and advertisements shall not contain nutrient function claims	Label and advertisements shall not contain health claims

## 6.4. Glutamine

Nutrient Content Claim	Nutrient Function Claim	Health Claim
Label and advertisements shall not contain nutrient content claims	Label and advertisements shall not contain nutrient function claims	Label and advertisements shall not contain health claims

## 6.5. Taurine

Nutrient Content Claim	Nutrient Function Claim	Health Claim
Label and advertisements shall not contain nutrient content claims	Label and advertisements shall not contain nutrient function claims	Label and advertisements shall not contain health claims

## 7. FOOD FIBRE

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (25g/day) more than similar food	a. "Food fibre (psillium, oats, and inulin) may help reduce cholesterol content in blood"	<p>'Food, which is low, rich in food fibre contained in seeds, fruits, and vegetables may help reduce possible risk of cancer, a disease related to many factors'.</p> <p>Requirements:</p> <p>Meeting low fat requirement and is a good source of food fibre (without fortification).</p> <p>"Food, which is low in saturated fat, rich in fruits, vegetables, and seeds containing several kinds of soluble food fibre may help reduce risk of heart disease, a disease related to many factors".</p> <p>Requirements:</p> <p>Containing fruits, vegetables, and seeds, and must meet low fat requirement, low cholesterol, and containing soluble food fibre of at least 0.6 g per serving (without fortification).</p> <p>"Food, which is low in fat, rich of fruits, and vegetables (low fat food, vitamin A, or vitamin C) may help reduce risk of several kinds of cancer, a disease related to many factors".</p> <p>Requirement:</p> <p>Meeting low fat requirement, is a good source for one of the components, namely food fibre, vitamin A or vitamin C (without fortification).</p> <p>"Food, which is low in saturated fat and cholesterol containing soluble food fibre, from wheat, may help reduce the risk of heart disease, a disease related to many factors".</p> <p>Requirement:</p> <p>Meeting low fat requirement, low saturated fat, and low cholesterol, and at least containing 0.75 g of soluble food fibre per serving.</p>
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (25g/day) per serving	b. "Food fibre (psillium, oats, and inulin) may help strengthen digestion system"	
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (25g/day) per serving	c. "Food fibre (psillium, oats, and inulin) may help control sugar content in blood in type II diabetes mellitus patients";	
<p><b>Note:</b></p> <p>For every food fibre content claim, if the food is not low in its total fat content, the fat content must also be contained.</p>		d. "Unsoluble Food fibre may help enable laxative defecation".	

## Other Requirements:

1. Must contain type of food fibre (soluble or insoluble), forming components, and the sources.
2. Shall not contain a statement relating to colon cancer.
3. Claim must be completed with a statement "completed with consumption of low fat food, low saturated fat and/or low cholesterol".

## 8. PRE-BIOTIC

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (10 g/day) more than similar food	Label and advertisements shall not contain nutrient function claims	Label and advertisements shall not contain health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (10 g/day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (10 g/day) per serving		

## Other Requirements:

Claim must be completed with information on pre-biotic sources.

## 9. PREO-BIOTIC

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added', 'More in Fermented and Non-Fermented Products'.	Must contain one of types of the micro-organisms above at minimum *) dosage of pro-biotic of 106 CFU per day. Method of production of pro-biotic powder milk product must be able to maintain stability from living bacteria after production time and final time of shelf life.	"Pro-biotic (Lactobacillus and Bifidobacterium, except L. bulgaricus) may help maintain functioning of the digestion system".	Label and advertisements shall not contain health claims
'Contain', 'Provide', 'Is a Good Source' of Fermented and Non-Fermented Products"	Must contain one of the types of micro-organisms as mentioned above at the minimum dosage of pro-biotic of 107 CFU per day.		
'High', 'Rich of', 'Is a Very Good Source' in Fermented and Non-Fermented Products	Must contain one of the types of micro-organisms as mentioned above at the minimum dosage of pro-biotic of 108 CFU per day		
*) There has not been an international consensus regarding probiotic dosage, but the recommended minimum dosage is 106-109 CFU/day and it depends very much on the type of micro-organism.			

## Other Requirements:

1. Label and advertisements containing pro-biotic must contain information as the following:
  - \* Genus, species, and strains (in case the selection process has reached strain level, specifications of the strains should be informed, because physiological effect is very much related to type of the specific strains).

- \* Minimum amount of pro-biotic living at the end of shelf-life time.
- \* The recommended household size to describe accurate dosage of pro-biotic related to health claims.
- \* Information on accurate amount of antibiotic against its physiological effect;
- \* Accurate condition of storage place.
- \* Detailed information on name of the company that can be contacted for consumer information.

2. Results of evaluation is based on tests on Indonesian, at least 20 persons.

## 10. CHOLIN, LECITHIN, AND INOSITOL

### 10.1 Cholin

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (182 mg/day) more than similar food	1. "Cholin plays a role as a material that forms phosphatidicholin, an important part of cell membrane". 2. "Cholin may handle reduction of cognitive competence in old age, which is the possible start of dementia".	Label and advertisements shall not contain health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (182 mg/day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (182 mg/day) per serving		

### 10.2. Lecithin

Nutrient Content Claim	Nutrient Function Claim	Health Claim
Label and advertisements shall not contain nutrient content claims	Label and advertisements shall not contain nutrient function claims	Label and advertisements shall not contain health claims

### 10.3. Inositol

Nutrient Content Claim	Nutrient Function Claim	Health Claim
Label and advertisements shall not contain nutrient content claims	Label and advertisements shall not contain nutrient function claims	Label and advertisements shall not contain health claims

## 11. CARNITINE AND SQUALENE

### 11.1. Carnitine

Nutrient Content Claim	Nutrient Function Claim	Health Claim
Label and advertisements shall not contain nutrient content claims	Label and advertisements shall not contain nutrient function claims	Label and advertisements shall not contain health claims

### 11.2. Squalene

Nutrient Content Claim	Nutrient Function Claim	Health Claim
Nutrient content claims shall be indicated by containing squalene content based on dry weight percentage (% b/b, dry basis)	"Squalene may function as "Quencher" of oxygen cover to maintain skin from lipid peroxidase as a result of ultra violet radiation of the sun".	Label and advertisements shall not contain health claims

Other requirements:

1. Must contain source (plant/animal) of squalene.
2. Shall not contain statement "may prevent cancer or coronary heart disease".

## 12. ISOFLAVONE

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (50 mg/day) more than similar food	"Isoflavon of soy beans (daldzein, daldzin, genistein, genistin) may help reduce cholesterol content in blood so that it may reduce the risk of atherosclerosis and coronary heart disease.	Label and advertisements shall not contain health claims
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (50 mg/day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (50 mg/day) per serving		

Other requirements:

1. Food must contain protein or soy peptide (as non-isoflavone component and is not pure isoflavone, because research shows that the giving of isoflavone (pure) tablet on post-menopause women does not create a good effect on LDL or HDL cholesterol.
2. Nutrient function claim must be completed with a statement "accompanied with consumption of food, which is low in fat, low in saturated fat, and/or low in cholesterol".

## 13. PHYTOSTEROL AND PHYTOSTANOL

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (1.3 g of ester sterol per day or 3.4 g of ester stanol per day) more than similar food	Label and advertisements shall not contain nutrient function claims.	Food containing at least 0.65 grams of phytosterol per serving shall be consumed twice a day so that the total amount of daily consumption is at least 1.3 grams, as part of diet of low saturated fat and cholesterol, may help reduce the risk of heart disease. One serving of (name of food) provides ... grams of phytosterol. Or: Diet of low saturated fat and cholesterol consists of two servings of food so that it provides daily amount of consumption of 3.4 grams of phytostanol
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (1.3 g of ester sterol per day or 3.4 g of ester stanol per day) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (1.3 g of ester sterol per day or 3.4 g of ester stanol per day) per serving		

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
			<p>in two times consumption may help reduce the risk of heart disease. One serving of (name of food) provides ... grams of phytosterol.</p> <p>Requirements:</p> <ul style="list-style-type: none"> <li>- Containing at least 0.65 grams of phytosterol per serving for spread and salad dressing or</li> <li>- Containing at least 1.7 grams of phytosterol per serving for spread, salad dressing, snack bars, and food supplements,</li> <li>- Low in saturated fat,</li> <li>- Low in cholesterol.</li> </ul>

Other requirements for Health Claims:

- 1) Food must be low in saturated fat and low in cholesterol and shall not contain total fat of more than 1.3 g per serving or per 50 g of food.
- 2) For spread and salad oil, fat content may exceed 13 g per 50 g of functional food by adding statement "see nutrient information for fat content", but shall still contain 0.65 g of plant ester sterol or 1.7 of plant ester stanol per 50 grams of food.
- 3) Change of words "phytosterol" and "phytosterol" to become ester sterol and ester stanol of vegetable oil is permitted providing that vegetable oil is the only source of ester sterol/stanol in food.

#### 14. POLYPHENOL

Nutrient Content Claim		Nutrient Function Claim	Health Claim
Claim	Requirement		
'Enriched', 'Fortification', 'Extra', 'Plus', 'More', 'Added'	At least contain 10% of the recommended (extract of green tea, which has been standardized to 375 mg/day containing around 300 mg of total polyphenol) more than similar food	"Polyphenol of tea (catekin or teaflavine) may help reduce the risk of atherosclerosis through prevention of oxidation from LDL (low density lipoprotein)	<p>"Food containing extract of green tea, which has been standardized as part of diet of low saturated fat and cholesterol may help reduce the risk of heart disease, a disease related to many factors".</p> <p>Requirement:</p> <p>Meeting the requirement of low fat, low saturated fat and cholesterol, and at least containing 60-90 mg of extract of green tea, which has been standardized per serving (containing around 48-72 mg of total polyphenol).</p>
'Contain', 'Provide', 'Is a Good Source'	At least contain 10-19% of the recommended (extract of green tea, which has been standardized to 375 mg/day containing around 300 mg of total polyphenol) per serving		
'High', 'Rich of', 'Is a Very Good Source'	At least contain 20% of the recommended (extract of green tea, which has been standardized to 375 mg/day containing around 300 mg of total polyphenol) per serving		

Other requirement:

Claim must be completed with statement "Additional milk may reduce anti-oxidant activities of polyphenol of tea".

Stipulated in Jakarta

On January 27, 2005

HEAD OF FOOD AND DRUG SUPERVISORY AGENCY OF THE REPUBLIC OF INDONESIA

Sgd

H. SAMPURNO

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