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Ⅱ.1.1.23 Molybdenum Ⅱ.1.1.24 Potassium

Ⅱ.1.1.25 Chrome

Ⅱ.1.2 Dietary fiber

Ⅱ.1.3 Protein

Ⅱ.1.4 Essential fatty acid

Ⅱ.2 Functional ingredients

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Ⅱ.2.1.1 Ginseng

Ⅱ.2.1.2 Red ginseng

Ⅱ.2.1.3 Plants containing chlorophyll

Ⅱ.2.1.4 Chlorella/Spirulina

Ⅱ.2.2 Phenols

Ⅱ.2.2.1 Green tea extracts

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Ⅱ.2.2.3 Propolis extracts

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Ⅱ.2.2.5 Soybean isoflavone

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Ⅱ.2.3.2 Edible oil containing gamma-linolenic acid

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Ⅱ.2.3.4 Squalene

Ⅱ.2.3.5 Phytosterol / Phytosterolester

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Ⅱ.2.3.8 Japanese apricot extracts

Ⅱ.2.3.9 Conjugated linoleic acid

Ⅱ.2.3.10 Garcinia cambogia extracts

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Ⅱ.2.3.13 Saw palmetto extracts

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Ⅱ.2.4.1 Glucosamine

Ⅱ.2.4.2 N- acetylglucosamine

Ⅱ.2.4.3 Mucopolysaccharide . mucoprotein

Ⅱ.2.4.4 Dietary fiber

Guar gum / Guar gum hydrolysate	Glucomannan (Konjacmannan)
Oat	Indigestible maltodextrin
Soybean fiber	Tree ear (Auricularia auricular)
Wheat fiber	Barley fiber
Arabic gum (acacia gum)	Corn bran
Inulin / Chicory extracts	Psyllium husk
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Ⅱ.2.4.6 Ganoderma lucidum fruit body extracts

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A. [Annexed the Table 1] Table of random sampling numbers and usage method

B. [Annexed the Table 2] Nutrient reference value

C. [Annexed the Table 3] Dietary Reference Intakes for Koreans

D. [Annexed the Table 4] Application Table for Testing Methods

General Provisions

1. Purposes of the Health Functional Food Code

1) This Code establishes the standards and specifications for manufacturing, processing, production, import, distribution, storage, etc., of health functional food for sale.
2) This Code promotes the distribution of standardized health functional food and assures the consumer's safety through providing the standards and specifications for functional ingredients and final product for health functional food.
3) This Code also intends to establish a transparent and scientific regulatory system of health functional food through providing regulatory guidelines to the authorized officers.

2. Scope of the Code

1) The standards and specifications regarding manufacturing, processing, production, import, distribution, storage, etc., of health functional food under the Chapter 14 of the Health Functional Food Act;
2) The ingredients or the compounds of health functional food under the Chapter 15 of the Health Functional Food Act; and
3) Regulation for labeling standards of health functional food under the Chapter 17 of the Health Functional Food Act.

3. Contents of the Code

1) This Code covers general provisions, general standards and specifications, standards and specifications for each functional ingredient, and testing methods.
2) The standards and specifications for each functional ingredient are classified into sections according to the types of health claims, into divisions according to the characteristics of active compound (or marker compound) of functional ingredients, and into groups according to the functional ingredients.
   (1) The sections are classified into nutrients, which have nutrient function and functional ingredients, in order to separately categorize the products being intended to supplement nutrients.

(2) The divisions are classified into terpenes, phenols, fatty acid and lipids, etc according to the characteristics of active compounds (or marker compounds) of functional ingredients.

(3) The groups are classified into vitamins and minerals, edible oil containing gamma-linolenic acid products, glucosamine, etc., which are ingredients provided in the sections or the divisions.

3) The standards and specifications for each functional ingredient cover standards for manufacturing, specifications, specific requirements for the final products and testing methods.

(1) The standards for manufacturing cover raw materials, preparation and/or processing, content of active compound or component (or marker compound), and cautions for preparation or processing. Especially the cautions for preparation or processing include the standards of poisonous or deleterious substances which shall be controlled during manufacturing process.

(2) The term "specifications" refers to the specifications of functional ingredients and/or final products manufactured/processed using functional ingredients therewith.

(3) The prerequisite for the health functional food cover health claims, intake amount, and warning notice for intake, etc.

(4) The testing methods cover testing methods for each specification.

4) The testing methods cover general principles, general testing methods, and testing methods for individual components.

4. Scientific evaluation for safety and claims and setting the standard and specification

The scientific evaluation of safety and claims and setting the standard and specifications for functional ingredients listed in this Code are subject to Regulation on Approval of Functional Ingredients for Health Functional Food.

5. Adding functional ingredients in this Code

The functional ingredients recognized under the Regulation on Approval of Functional Ingredients for Health Functional Food can be added to the Code in case where the functional ingredient falls under any of the following subparagraphs. However, when, after being recognized as a functional ingredient, the business person request the protection of data, the

adding of the functional ingredient can be postponed, till five years from the data of the item manufacturing report or import report, provided the validity of the request.

1) In the case where, after recognized as functional ingredient, two or more years have passed from the date of the item manufacturing report or the import report or where, after recognition, three or more business persons file the item manufacturing report or the import report; or
2) In case where the person who has obtained the recognition under the provision of Article 14 (2) of the Health Functional Food Act requests the adding (Provided three or more persons obtain the recognition, two-third of them shall request the adding together).

6. This Health Functional Food Code shall be principally interpreted and applied by general provisions and general standards and specifications, except otherwise specified.

I. Common Standards and Specifications

I.1 The ingredients used for manufacturing health functional food shall be as follows:

1) Functional ingredients

(1) "The functional ingredient" is a substance providing health benefits and falls under any of the following subparagraphs:

(a) processed raw material originated from animal, plant or microorganism;

(b) extract or purified substance of any ingredient described in subparagraph (a);

(c) synthetic duplicate of purified substance of any ingredient described in subparagraph (b); or

(d) combination of any ingredients described in subparagraph (a), (b), or (c).

(2) The functional ingredients shall be:

(a) specified by the standards and specifications of functional ingredients of this Code; or

(b) recognized under Chapter 15 of the Health Functional Food Act and Regulation on Approval of Functional Ingredient for Health Functional Food. In this case only the business person who obtains the certificate can use it.

2) Nutrients

The term "nutrient" means vitamins and minerals, dietary fiber, protein, essential fatty acid, etc.

3) Other ingredients

(1) The term "other ingredients" means any ingredient or component which can be used for manufacturing health functional food without setting specific standard and specification.

(2) The other ingredients shall:

(a) meet the standards and specifications of food;

(b) meet the standards and specifications of food additives; or

(c) be 1) Functional ingredients or 2) Nutrients. Provided that warning notice for intake shall be provided and less than daily intake value set by the Commissioner of the Food and Drug Administration shall be used. The functional ingredient under 1.1).(2).(b) can only be used by the business person who obtains the certificate.

4) Raw materials

(1) The term "raw material" means source material used for manufacturing ingredients.

(2) The requirements for raw materials shall be as follows:

(a) It has good quality and freshness, and it is not decomposed or deteriorated;

(b) The safety shall be ensured under the 5. General specifications of food of Article 2 of the Common Standards and Specifications for detrimental contaminants such as heavy metal, pathogens, mycotoxins, radioactivity, etc, or residues such as pesticides, veterinary medicines, etc and foreign materials, etc;

(c) For raw material used for manufacturing, any foreign material such as soil, sand, dust, etc shall be sufficiently removed, it shall be washed with drinking water, and any non-edible parts shall be sufficiently removed; and

(d) The water treatment, etc shall be in conformity with the Management of Drinking Water Act, the alcoholic products shall be in conformity with the Liquor Tax Act, salt shall meet the Salt Management Act, and livestock products shall be in conformity with the Livestock processing Act.

I.2 Common standards for manufacturing process

1) The health functional food under this Code shall be manufactured or processed in order to supplement nutrients that may be deficient in daily meal or to provide functional ingredients useful for human body in a form of capsule, tablet, powder, granule, liquid, pill, paste, syrup, gel, bar, etc which is easy to intake per serving. The conventional food or the food which substitutes for meal shall be authorized by the Commissioner of the Food and Drug Administration under the Article 14(2) and 15(2) of the Health Functional Food Act.
2) It is recommended to apply Good Manufacturing Practices as possible.
3) The health functional food shall be manufactured with functional ingredients and the standards for using the functional ingredients shall be as follows:
   (1) The functional ingredients shall be conformed the standards for manufacturing/processing and specifications under II. Standards and Specifications for Each Functional Ingredient of this Code or the Regulation on Approval of Functional Ingredient for Health Functional Food;
   (2) In case where an ingredient of the health functional food which is subject to the permission (or report) is purchased and used, the manufacture business permission for the ingredient in question shall be obtained or the import report shall be filed. The ingredient shall conform to the standards and specifications of the permission (or report). The adulterate ingredients such as product whose sell-by-date has been passed shall not be used;
   (3) The ingredients shall be used according to the daily intake value and cautions for preparation or processing established for each functional ingredient; and
   (4) Two or more functional ingredients can be combined. In this case, it should be verified that the safety and health benefits are maintained.
4) Vitamins and minerals shall be used according to the maximum level under the II. Standards and Specifications for each functional ingredient II.1 Nutrients II.1.1 Vitamins and Minerals.
5) In case where other ingredients are used, the safety and the maintenance of health benefits for functional ingredients should be primarily considered and the following requirements for use should be observed:

(1) It shall meet the relevant standards and specifications of the Food Code, the Food Additive Code, or the Health Functional Food Code; and

(2) It shall be manufactured to contain nutrients which may cause detrimental effects such as fat, cholesterol, sodium, saturated fat and trans fat as low as possible.

6) The solvent for extracting functional ingredients shall be subject to II. Standards and Specifications for Each Functional Ingredient of this Code or the Regulation on Approval of Functional Ingredient for Health Functional Food, and the extraction solvent shall meet the Standards and Specifications of the Food Additive.

7) If a food additive that cannot be used in a certain health functional food is derived from a raw material for which the food additive can be allowed to use, the restriction on the use of food additives may not apply within the range of such deriving from the raw material.

8) Article 2 General Standards and Specifications of Food in General of the Food Code shall apply to the residues such as pesticides, veterinary drug, etc of health functional food. In case where the Food Code provides specific standards for processed products (for example, concentrate, powder, etc), the individual standards in question shall apply in preference to the common standards.

9) In case where radiation is used for health functional food, the source and type of radiation are ^{60}Co gamma ray and the following standards shall be applied:

(1) Absorbed dose of permitted health functional food

Health functional food	Absorbed dose
Aloe vera powder	Not more than 7kGy
Ginseng, Red ginseng	Not more than 7kGy
Chlorella, Spirulina	Not more than 7kGy

(2) Irradiated health functional food shall not be reirradiated and health functional food, which is manufactured/processed from irradiated functional ingredient, shall not be reirradiated.

(3) The irradiated health functional food shall be sold packaged.

10) The Food Code shall apply unless this Code otherwise provides. Other standards for manufacture shall be as follows:

(1) Machine/utensil and other facilities, which are utilized in health functional food manufacturing and processing, shall be hygienically maintained and managed.

(2) The container or the package of health functional food shall be subject to the Food Code under the Food Sanitation Act.

(3) The water used for manufacturing health functional food shall meet the Management of Drinking Water Act.

(4) Thawing of frozen raw material shall be hygienically performed.

(5) The health functional food shall be refrigerated, frozen, or appropriately pasteurized or sterilized depending on the product characteristics.

(6) During manufacturing health functional food, heat treatment, cooling, or freezing process shall appropriately carried out considering the health benefits and the safety of products.

(7) If it is intended to recover the food containers and packaging materials and re-use them, they shall be cleaned to remove any impurities. They shall be used only after it is verified that there are no impurities.

(8) The health functional food shall be promptly and hygienically wrapped as possible to prevent contamination by microbes.

I.3 Common specifications

1) The definitions and the specifications of product types shall be as follows:

(1) The definitions of product types

(a) "Tablet" refers to a product which is compressed into a shape.

(b) "Capsule" refers to a product which is filled in or encapsulated with capsule base. There are two types of capsules, hard capsules and soft capsules.

(c) "Pill" refers to a product which is in spherical shape.

(d) "Granule" refers to a product which is in a granular shape.

(e) "Liquid" refers to a product which is in liquid state with fluidity or a form which is concentrated the liquid state one as it is.

(f) "Powder" refers to a product whose size is smaller than that of granules.

(2) The health functional food in tablet, capsule, pill, and granule shall be passed for disintegration test. The testing method shall be conform III.2.1. Disintegration test of this Code. However, the disintegration test shall not apply to the following cases:

(a) In case where it is taken by chewing or melting; and

(b) In case where it is a granule product whose residue is five percent or less with the No. 35 (500 μm) strainer.

(3) The total aerobic bacteria shall not be over 100 per 1 mL. The testing method shall conform to 8. Microorganism testing method 2) Total aerobic counts of Article 10. General Testing Method of the Food Code. This specification shall apply only to the health functional food in liquid with exemption as follows:

(a) In case where probiotics are used as the functional ingredients; and

(b) In case of the products, on which the sterilization process has been carried out. In this case the total aerobic bacteria shall be negative.

2) For The product, to which vitamins and minerals are added more than the minimum level under the II. Standards and Specifications for Each Functional Ingredient, the contents of nutrient and the ratio (%) for the nutrient reference value shall be labeled under the Standards of Label of Health Functional Food, and the specifications for labeled vitamins and minerals provided in II. Standards and Specifications for Each Functional Ingredient of this Code shall apply.

I.4 Application of the standards and specifications of health functional food

1) As a general rule, I. Common Standards and Specifications and II. Standards and Specifications for Each Functional Ingredient or the standards and specifications which are recognized under the Regulation on Approval of Functional Ingredient for Health Functional Food shall apply together with the specifications of functional ingredients and final products which are manufactured or processed with functional ingredients (See, Table 1).
2) The specifications of each functional compound provided in II. Standards and Specifications for Each Functional Ingredient shall apply differently to the semi-processed products which are not for consumer sale and the final products which are manufactured with the semi-processed products. Provided, that if the semi-processed product is made mixed with fructose, starch, glucose, lactose, maltodextrin, etc. and with a functional ingredient, the content of the functional compound (or marker compound) shall meet the standards for manufacture/process of the functional ingredient in question according to the conversion considering the combination ratio.
3) In case where two or more functional ingredients are combined, all specifications of the functional ingredients in question shall apply and in case of overlapping specifications the stricter specification shall apply.
4) Notwithstanding the standards and specifications of this Code, the standards and specifications which are required by the importers under Chapter 14(3) of the Health Functional Food Act may apply to the health functional food for the export purpose.

[Table 1] Decision tree for setting the standards and specifications of health functional food

<table>
<tr><td></td><td></td><td></td><td><Specifications to be applied></td></tr>
<tr><td rowspan="2">1. Apply the specification by product types in the common specification.</td><td>Capsule, tablet, pill, granule[1)]</td><td>→</td><td>◦Disintegration</td></tr>
<tr><td>Liquid[2)]</td><td>→</td><td>◦Total aerobic bacteria</td></tr>
<tr><td colspan="4">↓</td></tr>
<tr><td colspan="2">2. Apply the specifications of labeled vitamins and minerals contents.
※In case where is added the minimum content level provided in II. Standards and Specifications for each functional ingredient or more.</td><td>→</td><td>◦Nutrient content</td></tr>
<tr><td colspan="4">↓</td></tr>
<tr><td colspan="2" rowspan="5">3. Apply 2) Specification of “Ⅱ. Standards and Specifications for Each Functional Ingredient”.
Apply the specifications approved under the Regulation on Approval of Functional Ingredient for Health Functional Food (For the functional compound (or marker compound), 80 ~ 120% of the labeled value shall be applied. Nevertheless, if the Commissioner of KFDA recognizes the range for the labeled value of a functional compound (or marker compound) in the certificate, it shall be subject to the certificate.)</td><td rowspan="5">→</td><td>◦Appearance</td></tr>
<tr><td>◦Content of functional compound (or marker compound)</td></tr>
<tr><td>◦Heavy metal</td></tr>
<tr><td>◦Solvent residue</td></tr>
<tr><td>◦Coliforms</td></tr>
<tr><td colspan="4">↓</td></tr>
<tr><td colspan="2"></td><td></td><td>◦Others (mycotoxins etc)</td></tr>
</table>

4. Others (preservation methods, etc)	→	◦Bacterial growth (canned or bottled type and retort type)

1) Except for one which is taken by chewing or melting

2) Except when probiotics are used as functional ingredients

I.5 Pass/Fail determination about standards and specifications

1) Health functional food shall be judged in accordance with the standards and specifications recognized by the Commissioner of the Food and Drug Administration (hereinafter referred to as pass/fail determination), and the specifications shall apply to the final health functional products.
2) Pass/Fail determination about hazardous substances (heavy metal, pesticide residue, etc.) shall be in conformity with the regulation in the Food Code and Food additive Code and of which the standards and specifications are not specified in the relevant Code, it may be in conformity with Codex Alimentarius Commission (hereinafter referred to as CAC) regulation. Where there are no standards and specifications in relevant Code and CODEX regulation, the Commissioner of the Food and Drug Administration can apply the standard and specification after a comprehensive review of the relevant data about materials such as foreign countries' standards and specifications, Acceptable Daily Intake (ADI), related intake of health functional food, etc.
3) Pass/Fail determination about the standards and specifications recognized by Commissioner of the Food and Drug Administration is principally performed, however, when a new method is judged to be more precise, this method can be used. Especially, tests of microorganism or toxins, etc. may be performed with a commercial kit and automated analytical equipment. When various results with different outcomes are difficult to judge, the test shall be performed and judged in preference to the specified method.
4) In the event that the standards and specifications are not designated by the Commissioner of the Food and Drug Administration or the testing method is not stated even though standards and specifications are designated, tests can be performed in accordance with the testing methods stated in CODEX regulation, AOAC (Association of Official Analytical Chemists), and PAM (Pesticide Analytical Manual). In cases where the above testing method is not available, authorized testing methods, which are specified in other regulations or internationally recognized, can be applied. Provided that, in this case the testing method and its source shall be submitted.
5) Pass/fail determination with test result through testing methods is judged by the comparison of experimental value (acquired value from test) with standard value (standardized and

specified value, n digit), after the experimental value shall be rounded off to the nearest whole number in one place number more than standard value.

6) The standards and specifications shall apply to the product contents except for the capsule base. Provided microorganism and disintegration test shall be excluded.

7) The detection of food additives (preservatives, etc.) that cannot be used and are derived from raw materials (including capsule base) combined to health functional food shall not be subject to the specifications.

8) “Must not be detected” means not to be detected by tests, which are specified in this Code.

I.6 Preservation and distribution standards

1) All health functional food shall be hygienically dealt with before selling, and the storage area and store shall be located in a clean environment. Rat and insect-proof management shall be thoroughly performed.
2) The health functional food handling place shall be protected from rain, snow, and chemical products, agricultural chemicals and poison, which are harmful to humans, shall not be kept in the same place.
3) One will be cautious that foreign material is not mixed, and health functional food shall be kept separated from other final health functional products which may affect its taste.
4) Final health functional products shall be kept and distributed at a cool place and the health functional food, of which storage cannot be continued for 7 days at normal temperature, shall be kept and distributed at the refrigeration or freezing facility as long as possible.
5) The frozen-products shall be frozen to minimize deterioration. Thawed products shall not be frozen again.
6) Transport of frozen or cold-storage products shall be performed with use of a vehicle able to maintain the specified temperature or in an equivalent or better manner.
7) One shall be cautious that moisture absorption shall not happen to food, which may absorb moisture.
8) One shall be cautious that container/packaging shall not be damaged or severely impacted during transportation or packaging of final health functional product.
9) Any packaged product shall not be sold by subdivision sale, and any product which does not comply the Labeling Standard of Health Functional Food (Food and Drug Administration Notification) or have any label shall not be purchased or sold.
10) Any product which has been decomposed, deteriorated or damaged during the storage shall not be sold.
11) After frozen health functional food is thawed, it shall not be distributed as room temperature or chilled health functional food, and the room temperature or chilled health functional food shall not be distributed as frozen health functional food. Also chilled health functional food shall not be distributed at room temperature.
12) In case the storage and distribution standard is not provided in this Code, The Food Code shall apply unless preservation and distribution standards in this Code states otherwise.

I.7 Sampling and handling

1) Meaning of sampling and handling

Sampling shall be scientifically performed in securing its efficiency in the selection of test target, sampling, handling, transportation/test etc..Authorized officers shall collect sample from the inspection target - in accordance with [Annexed the Table 1] Chapter 20 of Health Functional Food Act and perform tests on both the suitability to standard specification and the safeguards against contaminants. They may take administrative action according to the test results. Because its important purpose, the authorized officers shall perform their duty with full knowledge about sampling and handling methods.

2) Definition

(1) Sample: material collected from test target.

(2) Sample Unit: a quantity of health functional food at a time collected as a composition unit of sample.

(3) Test Target: one target which sample is collected as the same type of health functional food after manufacturing, processing and packaging at the same condition.

3) General Guidance of Sampling

(1) Sampling shall be performed by a person specified in Chapter 20 of Health Functional Food Act and Chapter 22 of the Enforcement Rule of the Health Functional Food.

(2) A minimum quantity of sample shall be collected that will represent overall test target in consideration of the test purpose and test items etc.

(3) A sample is, generally, collected from the test target with the same lot number, manufacture date and expiration date. After understanding several points such as product class, health functional food type, manufacturing company, symbol, export country, export date, arrival date, cargo vessel, transportation vehicle, cargo train, and packaging type and appearance etc. and considering the health functional food characteristics and test purpose, sampling shall be performed.

(4) When a sample is collected, the test target shall be not damaged. In case of collecting sample before packaging or after opening packaged test target, foreign matter shall be not adulterated and the sample shall be not contaminated by microorganisms.

(5) Collected sample shall be sealed so that it shall be able to be opened only by breakdown.

4) Technique in Sampling and Handling

In sampling, the sample's physical chemical biological state such as test purpose, the class and quantity of health functional food, possibility of contamination, homogeneity etc. should be considered.

(1) Sampling Technique

(a) In case of heterogeneous test health functional food;

① It is generally necessary to collect a lot of samples when the sample is heterogeneous. In case of collecting a small quantity of sample because of test efficiency and economical efficiency, the sample can be collected from a suspected target after considering its appearance and storage condition etc.

② A product, which is not homogeneous because of characteristics such as sedimentation floating etc., shall be wholly treated as homogeneous as possible and the sample shall be collected so that it has representative characteristics.

(b) Homogeneity judgment according to test Items

Sample homogeneity is dependent on test items. Because it is regarded that health functional food components such as heavy metal etc, are homogeneous, even though the test health functional food is judged to be heterogeneous, a sample can be collected.

(c) Sampling of packaged health functional food

① A sample of health functional food, which is circulated in a container or packaging such as a can, bottle, box etc., shall be collected in itself, not to be opened as possible.

② For health functional food which is put into large container and packaging, some of the health functional food, which represents the whole test target can be collected as a sample.

(d) Sampling of refrigerated and frozen health functional food

In case of sampling of refrigerated or frozen health functional food, a sample shall be collected as its status is maintained.

(e) Sampling to Require Microorganism test

① When a sample is collected, transported, or stored, an airtight container/package shall be used so that its sampling state can be maintained.

② When a portion of health functional food is collected as a sample, it shall be aseptically performed by using sterilized utensil/container etc.

③ The sample shall be, except in unavoidable situations, collected from normally stored and circulated products.

④ The sample shall be collected from completely packaged products, except in special sampling cases due to relevant information and special collection plan.

(f) Sampling of gas-generation health functional food

① In the event that test result is affected by gas which is generated from the sample at normal temperature, one packaged product shall be collected in itself as sample unit, without opening the package.

② However, when a portion of health functional food is collected as a sample, the collected sample shall be immediately sealed and cooled as soon as possible so that test result shall not be affected.

(g) Paste or Syrup type and so on

① In the event that sampling is difficult because of the high viscosity of the sample, it can be collected in reducing its viscosity by proper method such as heating in a range not to affect the test result.

② In the event that normal method cannot make the sample homogeneous because it is high viscous and heterogeneous, the sample is collected after being treated by using utensil to make it homogeneous by a method not to affect the test result.

(2) Recording of Sampling Statement

The authorized officers shall submit the relevant sample with sampling statement in sampling. However, in the event that it is allowed that the omission of the sampling statement does not affect standard specification test, the observer does not need to submit it.

(3) Sample Transportation Technique

(a) A collected sample shall be transported to the test room in itself so that it is not contaminated, broken, damaged, thawed and deformed.

(b) In case of transporting sample a long distance or by public vehicle, it shall be specially attentively packaged not to be damaged.

(c) Transportation of frozen sample

① Frozen samples shall be transported in itself.

② In case of not utilizing freezer, sample can be transported in maintaining its frozen state by dry ice.

(d) Transportation of refrigerated sample

Cold sample shall be transported in maintaining its temperature. In maintaining its refrigeration temperature by using ice, please be cautious so that the sample should not be contaminated by water melted from ice. In case of using dry ice, please be cautious so that the sample is not frozen.

(e) Transportation of Sample for Microorganism test

① Samples with the possibility of spoilage deterioration

A sample, which requires microbiological test, shall be aseptically collected into sterilized container and transported to the examination agency in maintaining its cold-storage temperature within 36 hours. When refrigeration temperature cannot be maintained or the sample cannot be immediately transported because of an unavoidable situation, it shall be re-collected or its test is requested to the examination agency after recording its collection date and status.

② Samples without the possibility of spoilage deterioration

If there is no possibility of spoilage deterioration during transportation it is not always necessary to transport the sample at refrigeration temperature, even though it requires microbiological test. However, please be cautious to contamination and damage of sample and packaging etc.

③ Caution when using ice etc.

In using ice etc, please be cautious so that sample is not contaminated by water melted from ice.

(f) Transportation of gas-generation sample

When a portion of health functional food is collected as a sample, it shall be transported in properly cold or frozen state.

5) Sampling Utensil and Container

(1) Sampling utensil and container shall be suitable to sampling purpose because of various class, shape, and container/packaging of the sample.

(2) They shall be suitable to Chapter 7. Standard and specification of Utensil, Container and Packaging in the Food Code.

(3) Convenient utensil and containers shall be used in transportation, cleaning, and sterilization. Parts, which are in direct contact with the sample, or with the utensil and container to collect the sample for microbiological test, shall be sterilized.

(4) Utensil and container, which are contacted directly with the sample, shall not affect test result.

(5) Class of Utensil and Containers for Sampling

(a) Sampling Utensil

Pincette, scissors, knife, can opener, wooden hammer, electric saw or saw, grain sampler, dryer, pipette, cutter, pump or tube for liquid sampling, scoop, funnel etc.

(b) Sampling Container/Packaging

Sampling bag (large, medium, small), sampling bottle (jar) etc.

(c) Sterilization Instrument

Alcohol lamp, alcohol, cotton etc.

(d) Others

Tape, icebox, camera, writing materials etc.

Ⅱ. Standards and specifications for each functional ingredient

Ⅱ.1 Nutrients

Ⅱ.1.1 Vitamins and Minerals

1) The health functional food having vitamins and/or minerals as functional ingredients are intended for use in supplementing the daily diet with vitamins and/or minerals. Therefore, these products neither substitute for a meal nor supplement other ingredients. The health functional food having vitamins and/or minerals as functional ingredients shall be manufactured in forms such as capsules, tablets, powders, granules, liquids or pills, etc., that are designed to be taken in measured small-unit quantities but not in a conventional food form.
2) The health functional food having vitamins and/or minerals as functional ingredients may contain all vitamins and minerals that comply with this Code, a single vitamin and/or mineral or an appropriate combination of vitamins and/or minerals.
3) Minimum level of each vitamins and/or minerals in those products per daily portion of consumption shall be 30 % of the Nutrient Reference Value (Annexed the Table 2). When a certain health functional product specifies the intended age group for consumption, the minimum level of each vitamins and/or minerals shall be 30 % of the intake levels for the particular age group recommended by the Korean Dietary Reference Intakes (Annexed the Table 3). When there are more than two recommended intake levels for the age group, the higher level shall be used.
4) A maximum amounts of vitamins and minerals in health functional food per daily portion of consumption are designed to ensure safety from excess intake of vitamin and/or mineral shall be applied to the recommended standards for labeling value of final health functional product.
5) If a certain health functional food contains vitamins and/or minerals at 30 % or more of nutrient reference value, those vitamins and/or minerals shall be presented in nutrition fact.

However, it is not compulsory to describe all health claims of each nutrient (nutrient function claim) in the label.

6) The sources or chemical forms of vitamins and minerals that are allowed in the manufacture or processing of health functional food are listed in this Code. The purity criteria or specifications for each source of vitamins and/or minerals shall be in conformity with the Food Code or the Food Additive Code.

Ⅱ.1.1.1 Vitamin A

1) Standards for manufacturing

(1) Ingredients

(a) Retinyl Palmitate

(b) Retinyl Acetate

※ Use vitamin A in oil or dry forms that are listed in the Korea Food Additives Code

(c) Manufactured/processed food ingredients to supplement vitamin A

(2) Vitamin A and beta-carotene ingredients can be mixed to supplement vitamin A. In this case, the standard for minimum level is in the sum of Vitamin A and beta-carotene, and the maximum level should be considered differently regarding its chemical forms

(3) Conversion factor of beta-carotene into vitamin A is by multiplying 1/2 to the content of beta-carotene. (However, 1.2. 1). (1). (c) for manufactured or processed beta-carotene ingredients that are prepared by pulverizing or simple extraction with water or fermented ethanol, the conversion factor is by multiplying 1/6 to the contents of beta-carotene.)

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Vitamin A: 80 ~ 150 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

(a) Necessary for vision adaptation in dark places

(b) Necessary for the normal structure and function of skin and mucosa

(c) Necessary for the normal growth and development of epithelial cells

(2) Daily intake amount: 210 ~ 1,000 μg RE

4) Testing methods

(1) Vitamin A: Ⅲ.3.1.1 Vitamin A

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.2 Beta-carotene

1) Standards for manufacturing

(1) Ingredients

(a) Processed ingredient in edible and oily form after extraction of beta-carotene from edible algae (dunaliella, chlorella, spirulina), green-leaf plants (seed, fruit), or carrots

(b) Synthetic beta-carotene

(c) Manufactured or processed ingredient by pulverizing or simple extraction with water or fermented ethanol from food ingredients to supplement beta-carotene

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Beta-carotene: 80 ~ 150 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

(a) Necessary for dark adaptation in dark places

(b) Necessary for the normal structure and function of skin and mucosa

(c) Necessary for the normal growth and development of epithelial cells

(2) Daily intake amount

(a) In the case of 1). (1). (a) and (b): 0.42 ~ 7 mg

(b) In the case of 1). (1). (c): 1.26 mg or more

4) Testing methods

(1) Beta-carotene: Ⅲ.3.1.2 Beta-carotene

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.3 Vitamin D

1) Standards for manufacturing

(1) Ingredients

(a) Vitamin D2 (Ergocalciferol)

(b) Vitamin D3 (Cholecalciferol)

(c) It shall be manufactured or processed from food ingredients to supplement vitamin D

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Vitamin D: 80 ~ 180 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

(a) Necessary for the normal absorption and utilization of calcium and phosphorus

(b) Necessary for the normal structure and maintenance of bones

(2) Daily intake amount: 1.5 ~ 10 μg

4) Testing methods

(1) Vitamin D: Ⅲ.3.1.3 Vitamin D

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.4 Vitamin E

1) Standards for manufacturing

(1) Ingredients

(a) D-α -Tocopherol

※ Use D-α-tocopherol concentrate and mixed D-tocopherol concentrate that are listed in Korea Food Additives Code

(b) DL-α -Tocopherol

(c) D-α-Tocopheryl Acid Succinate

(d) D-α-Tocopheryl Acetate

(e) DL-α-Tocopheryl Acetate

(f) It shall be manufactured or processed from food ingredients to supplement vitamin E

(2) Conversion factor

(a) The synthetic tocopherol labeled as "DL-" has half the activity, thus the conversion factor is by multiplying 1/2, in case of item 1). (1). (b) and (e)

(b) Vitamin E in food exists in four different forms of α, β, γ, and δ with different bioactivity, In the case of 1). (1). (f), vitamin E content is estimated from following equation

※ Vitamin E contents (mg α-TE) = 1.0×(α-tocopherol) + 0.5×(mg β-tocopherol) + 0.1×(mg γ-tocopherol) + 0.03×(mg δ -tocopherol)

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Vitamin E: 80 ~ 150 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

(a) Necessary for the protection of cell from free radicals

(2) Daily intake amount: 3 ~ 400 mg α-TE

4) Testing methods

(1) Vitamin E: Ⅲ.3.1.4 Vitamin E

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.5 Vitamin K

1) Standards for manufacturing

(1) Ingredients

(a) Vitamin K1 (Phylloquinone, Phytonadione)

(b) It shall be manufactured or processed from food ingredients the supplement vitamin K

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Vitamin K: 80 ~ 180% of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

(a) Necessary for the normal blood coagulation

(b) Necessary for the normal bone structure

(2) Daily intake amount: 16.5 ~ 1000 μg

4) Testing methods

(1) Vitamin K: Ⅲ.3.1.5 Vitamin K

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.6 Vitamin B1

1) Standards for manufacturing

(1) Ingredients

(a) Dibenzoyl Thiamine

(b) Dibenzoyl Thiamine Hdrochloride

(c) Thiamine Naphthalene-1, 5 -Disulfonate

(d) Thiamine Naphthalene-2,6-Disulfonate

(e) Thiamine Dilaurylsulfate

(f) Thiamine Thiocyanate

(g) Thiamine Hydrochloride

(h) Thiamine Mononitrate

(i) Thiamine Phenolphthalinate

(j) It shall be manufactured or processed from food ingredients to supplement vitamin B1

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Vitamin B1: 80 ~ 180 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

Necessary for the normal carbohydrates and energy metabolism

(2) Daily intake amount: 0.3 ~ 100 mg

4) Testing methods

(1) Vitamin B1: Ⅲ.3.1.6 Vitamin B1

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.7 Vitamin B2

1) Standards for manufacturing

(1) Ingredients

(a) Riboflavin

(b) Riboflavin 5'-Phosphate Sodium

(c) It shall be manufactured or processed from food ingredients to supplement vitamin B2

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Vitamin B2: 80 ~ 180 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

Necessary for the energy production in the body

(2) Daily intake amount: 0.36 ~ 40 mg

4) Testing methods

(1) Vitamin B2: Ⅲ.3.1.7 Vitamin B2

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.8 Niacin

1) Standards for manufacturing

(1) Ingredients

(a) Nicotinic Acid, Niacin

(b) Nicotinamide, Niacinamide

(c) It shall be manufactured or processed from food ingredients to supplement niacin

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Niacin: 80 ~ 150 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

Necessary for the energy production in the body

(2) Daily intake amount

(a) Nicotinic Acid: 3.9 ~ 23 mg

(b) Nicotinamide: 3.9 ~ 670 mg

4) Testing methods

(1) Niacin: Ⅲ.3.1.8 Niacin

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.9 Pantothenic acid

1) Standards for manufacturing

(1) Ingredients

(a) Sodium Pantothenate

(b) Calcium Pantothenate

(c) It shall be manufactured or processed from food ingredients to supplement pantothenic acid

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2)Pantothenic acid: 80~180 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

Necessary for the normal metabolism of lipids, carbohydrates, and proteins and energy production

(2) Daily intake amount: 1.5 ~ 200 mg

4) Testing methods

(1) Pantothenic acid: Ⅲ.3.1.10 Pantothenic acid

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.10 Vitamin B6

1) Standards for manufacturing

(1) Ingredients

(a) Pyridoxine Hydrochloride

(b) It shall be manufactured or processed from food ingredients to supplement vitamin B6

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Vitamin B6: 80 ~ 150 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

(a) Necessary for the utilization of proteins and amino acids

(b) Necessary for the maintenance of normal blood homocysteine levels

(2) Daily intake amount: 0.45 ~ 67 mg

4) Testing methods

(1) Vitamin B6: Ⅲ.3.1.9 Vitamin B6

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.11 Folic acid

1) Standards for manufacturing

(1) Ingredients

(a) Pteroylmonoglutamic Acid, Folic Acid

(b) It shall be manufactured or processed from food ingredients to supplement folic acid

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Folic acid: 80 ~ 150 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

(a) Necessary for the normal structure of cell and blood

(b) Necessary for the normal development of fetal neural tube

(c) Necessary for the maintenance of normal blood homocysteine levels

(2) Daily intake amount: 75 ~ 400 μg

4) Testing methods

(1) Folic acid: Ⅲ.3.1.11 Folic acid

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.12 Vitamin B12

1) Standards for manufacturing

(1) Ingredients

(a) Cyanocobalamin

(b) It shall be manufactured or processed from food ingredients to supplement vitamin B12

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Vitamin B12: 80 ~ 180 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

Necessary for the normal metabolism of folic acid

(2) Daily intake amount: 0.3 ~ 2000 μg

4) Testing methods

(1) Vitamin B12: Ⅲ.3.1.12 Vitamin B12

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.13 Biotin

1) Standards for manufacturing

(1) Ingredients

(a) Biotin

(b) It shall be manufactured or processed from food ingredients to supplement biotin

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Biotin: 80 ~ 180 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

Necessary for the normal metabolism of lipids, carbohydrates, and proteins and energy production

(2) Daily intake amount: 9 ~ 900 μg

4) Testing methods

(1) Biotin: Ⅲ.3.1.13 Biotin

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.14 Vitamin C

1) Standards for manufacturing

(1) Ingredients

(a) L-Ascorbic acid

(b) Sodium L-Ascorbate

(c) L-Ascorbyl Stearate

(d) Calcium Ascorbate

(e) Ascorbyl Palmitate

(f) It shall be manufactured or processed from food ingredients to supplement vitamin C

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Vitamin C: 80 ~ 150 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

(a) Necessary for the normal structure and maintenance of the connective tissue

(b) Necessary for the absorption of iron

(c) Necessary for protection of cell from free radicals

(2) Daily intake amount: 30 ~ 1000 mg

4) Testing methods

(1) Vitamin C: Ⅲ.3.1.14 Vitamin C

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.15 Calcium

1) Standards for manufacturing

(1) Ingredients

(a) Calcium Citrate

(b) Calcium Gluconate

(c) Calcium Glycerophosphate

(d) Calcium Oxide

(e) Calcium Hydroxide

(f) Calcium Chloride

(g) Calcium Lactate

(h) Calcium Phosphate, Tribasic

(i) Calcium Phosphate, Dibasic

(j) Calcium Phosphate, Monobasic

(k) Calcium Carbonate

(l) Calcium Sulfate

(m) It shall be manufactured or processed from food ingredients to supplement calcium

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Calcium: 80 ~ 150 % of labeled amount

(3) Lead (mg/kg): 3.0 or less (In the case of using calcined calcium such as cow bone powder and shell powder)

(4) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

(a) Necessary for the normal structure of bones and teeth

(b) Necessary for the normal function of nerve and muscle

(c) Necessary for normal coagulation of blood

(d) Intake of enough calcium with an appropriate exercise and healthy dietary habits prior to adolescence may reduce the risk of osteoporosis

(2) Daily intake amount: 210 ~ 800 mg

4) Testing methods

(1) Calcium: Ⅲ.3.2.2 Calcium

(2) Lead: Referred to [Annexed the Table 4]

(3) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.16 Magnesium

1) Standards for manufacturing

(1) Ingredients

(a) Magnesium Gluconate

(b) Magnesium Oxide

(c) Magnesium Hydroxide

(d) Magnesium Chloride

(e) Magnesium Carbonate

(f) Magnesium Sulphate

(g) Magnesium Phosphate, Dibasic

(h) Magnesium Phosphate, Tribasic

(i) It shall be manufactured or processed from food ingredients to supplement magnesium

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Magnesium: 80 ~ 150 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

(a) Necessary for the normal energy utilization

(b) Necessary for the normal maintenance of the nerve and muscle

(2) Daily intake amount: 66 ~ 250 mg

4) Testing methods

(1) Magnesium: Ⅲ.3.2.1 Copper, Magnesium, Manganese, Molybdenum, Selenium, Chromium

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.17 Iron

1) Standards for manufacturing

(1) Ingredients

(a) Ferric Citrate

(b) Ferric Ammonium Citrate

(c) Ferrous Gluconate

(d) Ferric Phosphate

(e) Ferrous Lactate

(f) Ferrous Fumarate

(g) Ferric Pyrophosphate

(h) Sodium Ferric Pyrophosphate

(i) Ferrous Sulphate

(j) Heme Iron

(k) Ferric Chloride

(l) Iron Reduced

(m) It shall be manufactured or processed from food ingredients to supplement iron

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Iron: 80 ~ 150 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

(a) Necessary for oxygen transport and blood production in the body

(b) Necessary for energy production

(2) Daily intake amount: 4.5 ~ 15 mg

(3) Warning notice for intake

Excessive consumption should be avoided for kids less than 6 years of age

4) Testing methods

(1) Iron: Ⅲ.3.2.4 Iron

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.18 Zinc

1) Standards for manufacturing

(1) Ingredients

(a) Zinc Gluconate

(b) Zinc Oxide

(c) Zinc Sulphate

(d) It shall be manufactured or processed from food ingredient to supplement zinc

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Zinc: 80 ~ 150 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

(a) Necessary for normal immune function

(b) Necessary for normal cell division

(2) Daily intake amount: 3.6 ~ 12 mg

4) Testing methods

(1) Zinc: Ⅲ.3.2.5 Zinc

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.19 Copper

1) Standards for manufacturing

(1) Ingredients

(a) Cupric Gluconate

(b) Cupric Sulphate

(c) It shall be manufactured or processed from food to ingredients supplement copper

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Copper: 80 ~ 150 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

(a) Necessary for the transport and utilization of iron

(b) Necessary for the protection of cell from free radicals

(2) Daily intake amount: 0.45 ~ 7.0 mg

4) Testing methods

(1) Copper: Ⅲ.3.2.1 Copper, Magnesium, Manganese, Molybdenum, Selenium, Chromium

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.20 Selenium

1) Standards for manufacturing

(1) Ingredients

(a) Sodium Selenite

(b) It shall be manufactured or processed from food ingredients to supplement selenium

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Selenium: 80 ~ 150 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

Necessary for the protection of cell from free radicals

(2) Daily intake amount: 15 ~ 135 μg

4) Testing methods

(1) Selenium: Ⅲ.3.2.1 Copper, Magnesium, Manganese, Molybdenum, Selenium, Chromium

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.21 Iodine

1) Standards for manufacturing

(1) Ingredients

(a) Potassium Iodide

(b) It shall be manufactured or processed from food ingredients to supplement iodine

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Iodine: 80 ~ 150 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

(a) Necessary for the synthesis of thyroid hormone

(b) Necessary for energy production

(c) Necessary for the development of the nerve system

(2) Daily intake amount: 22.5 ~ 150 μg

4) Testing methods

(1) Iodine: Ⅲ.3.2.3 Iodine

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.22 Manganese

1) Standards for manufacturing

(1) Ingredients

(a) Manganese Gluconate

(b) Manganese Chloride

(c) Manganese Sulphate

(d) Manganese Citrate

(e) It shall be manufactured or processed from food ingredients to supplement manganese

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Manganese: 80 ~ 150 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

(a) Necessary for the normal bone structure

(b) Necessary for energy utilization

(c) Necessary for protection of cell from free radicals

(2) Daily intake amount: 0.6 ~ 3.5 mg

4) Testing methods

(1) Manganese: Ⅲ.3.2.1 Copper, Magnesium, Manganese, Molybdenum, Selenium, Chromium

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.23 Molybdenum

1) Standards for manufacturing

(1) Ingredients

(a) Ammonium Molybdate

(b) It shall be manufactured or processed from food ingredients to supplement molybdenum

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Molybdenum: 80 ~ 180 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

Necessary for the activity of oxidase and reductase

(2) Daily intake amount: 7.5 ~ 230 μg

4) Testing methods

(1) Molybdenum: Ⅲ.3.2.1 Copper, Magnesium, Manganese, Molybdenum, Selenium, Chromium

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.24 Potassium

1) Standards for manufacturing

(1) Ingredients

(a) Potassium Citrate

(b) Potassium Gluconate

(c) Potassium Glycerophosphate

(d) Potassium Chloride

(e) Potassium Lactate

(f) Potassium Bicarbonate

(g) Potassium Carbonate

(h) Potassium Phosphate, Monobasic

(i) Potassium Phosphate, Dibasic

(j) It shall be manufactured or processed from food ingredients to supplement potassium

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Potassium: 80 ~ 180 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims

Necessary for balance of water and electrolyte balancing in the body

(2) Daily intake amount: 1.05 ~ 3.7 g

4) Testing methods

(1) Potassium: Ⅲ.3.2.6 Potassium

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.1.25 Chrome

1) Standards for manufacturing

(1) Ingredients

(a) Chromic Chloride

(b) It shall be manufactured or processed from food ingredients to supplement Chrome

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Chrome: 80 ~ 180 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Daily intake amount: 0.015 ~ 9 mg

4) Testing methods

(1) Chrome: Ⅲ.3.2.1 Copper, Magnesium, Manganese, Molybdenum, Selenium, Chromium

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.1.2 Dietary fiber

1) Standards for manufacturing

(1) Raw materials and preparation and/or processing: Food ingredients containing dietary fibers that are indigestible by the human digestive enzymes shall be processed into edible forms

(2) Dietary fiber products are intended to supplement of dietary fiber that may be deficient in daily meal. The ingredients of the dietary fiber products shall be in conformity with the standards and specifications for health functional food, food or food additives

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Dietary fiber: 80 % or more of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Nutrient function

Supplementation of dietary fiber

(2) Daily intake amount

5 g or more as dietary fiber

(3) Warning notice for intake

Should be taken with sufficient water except for liquid type product

4) Testing methods

(1) Dietary fiber: Ⅲ.3.4.4 Dietary fiber

(2) Coliform: Referred to [Annexed the Table4]

Ⅱ.1.3 Proteins

1) Standards for manufacturing

(1) Raw materials: Legumes, oils, eggs, fishes and shellfishes, meats, nuts, cereals

(2) Preparation and/or processing: The raw materials shall be in edible form either by separating and purifying or by decomposed with protease and autodigestive enzyme

(3) Protein products are intended to supplement of proteins that may be deficient in daily meals. The ingredient of the protein products shall be in conformity with the standards and specifications for health functional food, food or food additives

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Crude protein: 80 ~ 120 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Nutrient function

(a) Components of the physical tissues such as muscle and connective tissue

(b) Necessary for the normal formation of enzymes, hormones and antibodies

(c) Necessary for the transport and storage of essential nutrients or active materials in the body

(d) Necessary for the balance maintenance of fluid and acid-base balance

(e) Necessary for the synthesis of energy, glucose, and lipid

(2) Daily intake amount

12.0 g or more as protein

(3) Amino acid score of the final products shall be 85 or more, and individual amino acids may be added to final products to adjust amino acid score

(4) Warning notice for intake

The individual who has an allergy to specific protein must be cautious to intake

4) Testing methods

(1) Crude protein: Ⅲ.3.3.1 Crude protein

(2) Coliform: Referred to [Annexed the Table 4]

【Composition table of standard essential amino acids for amino acid score conversion】

(Unit: mg/g crude protein)

Classification	Histidine	Iso leucine	leucine	Lysine	Methionine + Cysteine	Phenylalanine + Tyrosine	Threonine	Tryptophan	Valine
Composition of amino acid	19	28	66	58	25	63	34	11	35

※ Amino acid score

The content of each essential amino acid in a product is analyzed in terms of mg amino acid per g crude protein. Then, the content of each essential amino acid is divided by the standard content of each essential amino acid shown in the above table, followed by multiplication of 100 to the ratio to convert the ratio into percentage. Among the percentage values of all the essential amino acids, the lowest percentage value is called “amino acid score”. The amino acid score of a product shall be 85 or more.

Ⅱ.1.4 Essential fatty acid

1) Standards for manufacturing

(1) Raw materials and preparation and/or processing: Ingredients containing linoleic and linolenic acid shall be processed into edible forms

(2) Essential fatty acid products are intended to supplement essential fatty acid that may be deficient in daily meal. The ingredients shall be in conformity with the standards and specifications for health functional food, food or food additives

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Linoleic acid, linolenic acid, or the sum of these: 80 ~ 120 % of labeled amount

(3) Residual solvent (mg/kg): 5.0 or less (in case of using hexane)

(4) Coliform: Negative

3) Prerequisite for the health functional food

(1) Nutrient function

Supplementation of essential fatty acid

(2) Daily intake amount

4.0 g or more as linoleic acid or 0.6 g or more as linolenic acid

4) Testing methods

(1) The sum of linoleic acid and linolenic acid: Ⅲ.3.5.1 Fatty acid

(2) Residual solvent: Referred to [Annexed the Table 4]

(3) Coliform: Referred to [Annexed the Table 4]

Ⅱ. 2 Functional ingredients

Ⅱ.2.1 Terpenes

Ⅱ.2.1.1 Ginseng

1) Standards for manufacturing

(1) Raw material: Ginseng (*Panax ginseng* C.A. Meyer)

※ Fresh ginseng; White ginseng, dried fresh ginseng by sunlight, hot air or other methods and Taegeuksam, boiled and dried fresh ginseng

(2) Preparation and/or processing

(a) It shall be in edible form by pulverizing

(b) It shall be in edible form either by extraction the raw materials with water or fermented ethanol (including mixture of water and fermented ethanol), or fermentation after extraction.

(3) Content of functional compound (or marker compound): It shall be contained 0.8 ~ 34 mg/g as the sum of ginsenoside Rg1 and Rb1.

(4) Conditions for manufacturing: Root of Ginseng as raw material shall be in conformity with 'Ginseng Industry Act' and 4 years or more. Dried 1-year-old ginseng, 1-year-old ginseng, the skin of peeled and dried ginseng, and ginseng skin shall not be used. Damaged ginseng can be used after removing the damaged part.

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor.

(2) The sum of ginsenoside Rg1 and Rb1

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 150 % of labeled amount

(3) Total aerobic bacteria: No more than 3,000/1mL (limited to concentrate)

(4) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: support immune function, help to relieve from fatigue

(2) Daily intake amount

3 ~ 80 mg/g as the sum of ginsenoside Rg1 and Rb1

(3) Warning notice for intake

Consult a health care practitioner prior to intake if you are taking medicines related with diabetes and/or blood coagulation

4) Testing methods

(1) Ginsenoside Rg1 and Rb1: Ⅲ.3.7.1 Ginsenoside Rg1 and Rb1

(2) Total aerobic bacteria: Referred to [Annexed the Table 4]

(3) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.1.2 Red Ginseng

1) Standards for manufacturing

(1) Raw material: Ginseng (*Panax ginseng* C.A.Meyer)

※ Red ginseng, steamed by vapor or other methods and dried fresh ginseng

(2) Preparation and/or processing

(a) It shall be in edible form by pulverizing the raw materials.

(b) It shall be in edible form either by extracting the raw materials with water or fermented ethanol (including mixture of water and fermented ethanol) and filtering, or concentrating or fermenting after filtration.

(3) Content of functional compounds (or marker compounds): The sum of ginsenoside Rg1 and Rb1 shall be contained 0.8 ~ 34 mg/g.

(4) Conditions for manufacturing: Root of Ginseng as raw material shall be in conformity with 'Ginseng Industry Act' and 4 years or more. Dried 1-year-old ginseng, 1-year-old ginseng, the skin of peeled and dried ginseng, and ginseng skin shall not be used. Damaged ginseng can be used after removing the damaged part.

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor.

(2) The sum of Ginsenoside Rg1 and Rb1

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 150 % of labeled amount

(3) Total aerobic bacteria: No more than 3,000/1 mL (limited to concentrate)

(4) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claim: Support immune function, help to relieve from fatigue, help to maintain healthy blood flow by inhibiting blood coagulation of platelet

(2) Daily intake amount

(a) Support immune function and help to relieve from fatigue: 3 ~ 80 mg/g as the sum of ginsenoside Rg1 and Rb1

(b) Help to maintain healthy blood flow by inhibiting blood coagulation of platelet: 2.4 ~ 23 mg/g as the sum of Ginsenoside Rg1 and Rb1

(3) Warning notice for intake

Consult a health care practitioner prior to intake if you are taking medicines related with diabetes and/or blood coagulation

4) Testing methods

(1) Ginsenoside Rg1 and Rb1: Ⅲ.3.7.1 Ginsenoside Rg1 and Rb1

(2) Total aerobic bacteria: Referred to [Annexed the Table 4]

(3) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.1.3 Plants containing chlorophyll

1) Standards for manufacturing

(1) Raw material

(a) Barley sprout (sprout of barley, oat or wheat) or young leaf before forming ear in whole or part

(b) Grown leaf, petiole and stem in whole or part of alfalfa

(c) Edible seaweeds containing chlorophyll in whole or part

(d) Single plant in whole or part as edible plants except barley sprout, alfalfa and seaweeds

(2) Preparation and/or processing

(a) The raw materials shall be in edible form either itself, or by pressed and dried

(3) Content of functional compounds (or marker compounds): Total chlorophyll shall be contained 2.4 mg/g or more in barley plumule, 0.6 mg/g or more in alfalfa, and 1.2 mg/g or more in seaweeds and other plant

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Total chlorophyll

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Total pheophorbide (mg/kg): No more than 1,000

(4) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy skin, anti-oxidant activity

(2) Daily intake amount: 8 ~ 150 mg as total chlorophyll

4) Testing methods

(1) Total chlorophyll: Ⅲ.3.7.2 Total chlorophyll

(2) Total pheophorbide: Ⅲ.3.7.3 Total pheophorbide

(3) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.1.4 Chlorella

1) Standards for manufacturing

(1) Raw material: Chlorella genus algae

(2) Preparation and/or processing: Chlorella genus algae shall be in edible form by artificially cultured and dried.

(3) Content of functional compounds (or marker compounds): Total chlorophyll shall be contained 10 mg/g or more.

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor.

(2) Total chlorophyll

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Heavy metal

(a) Lead (mg/kg): No more than 3.0

(b) Cadmium (mg/kg): No more than 1.0

(c) Total mercury (mg/kg): No more than 0.5

(4) Total pheophorbide (mg/kg): No more than 1,000

(5) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy skin, anti-oxidant activity

(2) Daily intake amount

8 ~ 150 mg as total chlorophyll

4) Testing methods

(1) Total chlorophyll: Ⅲ.3.7.2 Total chlorophyll

(2) Lead, cadmium and total mercury: Referred to [Annexed the Table 4]

(3) Total pheophorbide: Ⅲ.3.7.3 Total Pheophorbide

(4) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.1.4 Spirulina

1) Standards for manufacturing

(1) Raw material: Spirulina genus algae

(2) Preparation and/or processing: Spirulina genus algae shall be in edible form by artificially cultured and dried

(3) Content of functional compounds (or marker compounds): Total chlorophyll shall be contained 5 mg/g or more

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Total chlorophyll

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Heavy metal

(a) Lead (mg/kg): No more than 3.0

(b) Cadmium (mg/kg): No more than 1.0

(c) Total mercury (mg/kg): No more than 0.5

(4) Total pheophorbide (mg/kg): No more than 1,000

(5) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy skin, anti-oxidant activity, help to maintain healthy blood cholesterol level

(2) Daily intake amount

(a) Help to skin health and anti-oxidative activity: 8 ~ 150 mg as total chlorophyll

(b) Help to maintain healthy blood cholesterol level: 40 ~ 80 mg as total chlorophyll

4) Testing methods

(1) Total chlorophyll: Ⅲ.3.7.2 Total chlorophyll

(2) Lead, cadmium and total mercury: Referred to [Annexed the Table 4]

(3) Total pheophorbid: Ⅲ.3.7.3 Total pheophorbide

(4) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.2 Phenols

Ⅱ.2.2.1 Green tea extracts

1) Standards for manufacturing

(1) Raw material: Green tea (*Camellia sinensis*, *Thea sinensis*) leaf

(2) Preparation and/or processing: It shall be in edible form by filtering after extracting the raw materials with water, fermented ethanol (including mixture of water and fermented ethanol), or ethyl acetate

(3) Content of functional compounds (or marker compounds): Catechin shall be contained 200 mg/g or more. Catechin shall be the sum of (-)-epigallocatechin (EGC), (-)-epigallocatechin gallate (EGCG), (-)-epicatechin and (-)-epicatechin gallate (ECG) and all four kinds of catechin shall be confirmed. However, in the case of the final product, all four kinds of catechin may not be confirmed

(4) Conditions for manufacturing: Caffeine shall be contained 50,000 mg/kg or less

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Catechin

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Caffeine (mg/kg): No more than 50,000

(4) Solvent residue (mg/kg): No more than 50.0 (in case of using ethyl acetate)

(5) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Anti-oxidant activity

(2) Daily intake amount: 0.3 ~ 1 g as catechin

(3) Warning notice for intake

It may cause side-effect such as anxiousness, insomnia or etc. due to caffeine.

4) Testing methods

(1) Catechin: Ⅲ.3.6.1 Catechin

(2) Caffeine: Ⅲ.2.5.2 Caffeine

(3) Solvent residue: Ⅲ.2.5.5 Ethyl acetate

(4) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.2.2 Aloe whole leaves

1) Standards for manufacturing

(1) Raw material: Aloe (*Aloe vera*, *Aloe arborescence*, *Aloe saponaria*) leaf

(2) Preparation and/or processing

(a) After removing non-edible parts from the raw materials, it shall be in edible form by drying and pulverizing

(b) After removing non-edible parts from the raw materials, it shall be in edible form either by pulverizing, and/or concentrating

(3) Content of functional compounds (or marker compounds): Anthraquinone compounds (as anhydrous barbaloin) shall be contained 2.0 ~ 50.0 mg/g

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor.

(2) Anthraquinone compounds (as anhydrous barbaloin)

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy bowel function

(2) Daily intake amount: 20 ~ 30 mg as anhydrous barbaloin.

4) Testing methods

(1) Anthraquinone compounds (as anhydrous barbaloin): Ⅲ.3.6.2 Anthraquinone compounds (as anhydrous barbaloin)

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.2.3 Propolis extracts

1) Standards for manufacturing

(1) Raw material: Propolis made from resin collected from plant mixed with secretion of honeybee

(2) Preparation and/or processing: After removing wax, it shall be in edible form by extracting the raw materials with water, fermented ethanol (including the mixture of water and fermented ethanol), or carbon dioxide (supercritical fluid extraction)

(3) Content of functional compounds (or marker compounds): Total flavonoids shall be contained 10 mg/g or more, and ρ-coumaric and cinnamic acids shall be confirmed

(4) Conditions for manufacturing: Diethylene glycol shall not be used

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor.

(2) Total Flavonoids

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) ρ -coumaric acid: It shall be confirmed

(4) Cinnamic acid: It shall be confirmed

(5) Lead (mg/kg): No more than 5.0

(6) Diethylene glycol: Not detected

(7) Chlorotetracycline (mg/kg): Not detected

(8) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Anti-oxidant activity and antimicrobial activity in oral cavity

※ Antimicrobial activity in oral cavity shall be limited to the types allowing direct contact with oral cavity (spray, tincture, or chewable soft capsule), and intake amount shall not be applied

(2) Daily intake amount: 16 ~ 17 mg as total flavonoids

(3) Warning notice for intake

The individual who has an allergy to propolis should be cautious to intake

4) Testing methods

(1) Total flavonoids: Ⅲ.3.6.3 Total flavonoid

(2) ρ-Coumaric acid and cinamic acid: Ⅲ.3.6.4. ρ-Coumaric acid and cinamic acid confirmation

(3) Lead: Referred to [Annexed the Table 4]

(4) Diethylene glycol: Ⅲ.2.5.3 Diethylene glycol

(5) Tetracycline, Chlorotetracycline: Referred to [Annexed the Table 4]

(6) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.2.4 Coenzyme Q10

1) Standards for manufacturing

(1) Raw material: *Agrobacterium tumefaciens*, *Paracoccus denitrificans*, *Pseudomonas aeruginosa*, etc.

(2) Preparation and/or processing: It shall be in edible form by purifying and concentrating after extracting culture products with hexane, acetone, isopropyl alcohol or ethyl acetate

(3) Content of functional compounds (or marker compounds): Coenzmye Q10 shall be contained 980 mg/g or more

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Coenzyme Q10

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Solvent residue (In case of using)

(a) Hexane (mg/kg): No more than 5.0

(b) Acetone (mg/kg): No more than 30.0

(c) Isopropyl alcohol (mg/kg): No more than 50.0

(d) Ethyl acetate (mg/kg): No more than 50.0

(4) Heavy metal

(a) Lead (mg/kg): No more than 1.0

(b) Cadmium (mg/kg): No more than 1.0

(c) Total mercury (mg/kg): No more than 1.0

(d) Total Arsenic (mg/kg): No more than 1.0

(5) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to support anti-oxidant activity, help to maintain healthy blood pressure

(2) Daily intake amount: 90 ~ 100 mg as coenzyme Q10

Ⅱ.2.2.5 Soybean isoflavone

1) Standards for manufacturing

(1) Raw material: Soybean (*Glycine max.*)

(2) Preparation and/or processing

(a) It shall be in edible form by filtering or concentrating after extracting the raw materials with water or fermented ethanol (including mixture of water and fermented ethanol)

(b) It shall be in edible form by extracting with water or fermented ethanol (including mixture of water and fermented ethanol), and filtering or concentrating after fermenting the raw materials

(3) Content of functional compounds (or marker compounds): Aglycone soybean isoflavone(the sum of soybean isoflavone glycoside (Daidzin, Genistin, Glycitin) applied the conversion factor and aglycone (Daidzein, Genistein, glycitein)) shall be contained 35 ~ 440 mg/g

(4) Conversion factor

In case of soybean isoflavone glycoside (Daidzin, Genistin, Glycitin), as aglycone soybean isoflavone, the conversion factor is by multiplying 1/1.6 to the contents of soybean isoflavone.

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor.

(2) Soybean isoflavone (as aglycone)

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Heavy metal

(a) Lead (mg/kg): No more than 1.0

(b) Cadmium (mg/kg): No more than 1.0

(c) Total mercury (mg/kg): No more than 1.0

(d) Total Arsenic (mg/kg): No more than 1.0

(4) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain bone health

(2) Daily intake amount: 24 ~ 27 mg as aglycone soybean isoflavone

(3) Warning notice for intake

Infants, children, pregnant and lactating women should be cautious to intake

The individual who has an allergy to soybean should be cautious to intake

The individual who are sensitive to the estrogen should be cautious to intake

Ⅱ.2.3. Fatty acid and lipid

Ⅱ.2.3.1 Edible oil containing omega-3 fatty acid

1) Standards for manufacturing

(1) Raw material: Edible fishes, *Pagophilus groenlandicus*, seaweeds

(2) Preparation and/or processing

The oil shall be in edible form by heating the raw material, pressing and extracting with hexane or carbon dioxide (supercritical fluid extraction) and then filtering

(3) Content of functional compounds (or marker compounds): As the sum of EPA and DHA, it shall be contained 180 mg/g or more from edible fishes, 120 mg/g or more from *Pagophilus groenlandicu* and 300 mg/g or more from seaweeds

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) The sum of EPA and DHA

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Solvent residue (mg/kg): No more than 5.0 (in case of using hexane)

(4) Heavy metal

(a) Lead (mg/kg): No more than 3.0

(b) Cadmium (mg/kg): No more than 1.0

(c) Total mercury (mg/kg): No more than 0.5

(5) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy triglyceride level, help to maintain healthy blood flow

(2) Daily intake amount: 0.5 ~ 2 g as the sum of EPA and DHA

4) Testing methods

(1) EPA and DHA: Ⅲ.3.5.1 Fatty acid

(2) Solvent residue: Referred to [Annexed the Table 4]

(3) Lead, cadmium and total mercury: Referred to [Annexed the Table 4]

(4) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.3.2 Edible oil containing gamma-linolenic acid

1) Standards for manufacturing

(1) Raw material: Evening primrose (*Oenothera biennis*, *Oenothera caespitesa*, *Oenothera hookeri*, *Oenothera odorata*), Borage(*Borago officinalis* L.) or Black currant (*Ribes grossulalis*, *Ribes ussuriense*, *Ribes nigrum*) seed

(2) Preparation and/or processing: The oil shall be in edible form by pressing the raw materials and extracting with hexane or carbon dioxide (supercritical fluid extraction) and then filtering.

(3) Content of functional compounds (or marker compounds): Gamma linolenic acid shall be contained 70 mg/g or more.

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor.

(2) Gamma linolenic acid

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Solvent residue (mg/kg): No more than 5.0 (in case of using hexane)

(4) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy blood cholesterol level, help to maintain healthy blood flow

(2) Daily intake amount

240 ~ 300 mg as gamma linolenic acid.

4) Testing methods

(1) Gamma linolenic acid: Ⅲ.3.5.1 Fatty acid (Gamma linolenic acid shall be used standard compound)

(2) Solvent residue: Referred to [Annexed the Table 4]

(3) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.3.3 Lecithin

1) Standards for manufacturing

(1) Raw material: Soybean, egg yolk

(2) Preparation and/or processing

(a) Soybean lecithin: It shall be in edible form by filtering soybean oil, hydrogenating, separating and extracting oil from lecithin saponificable material.

(b) Egg yolk lecithin: It shall be in edible form by extracting egg yolk with water or fermented ethanol (including mixture of water and fermented ethanol), filtering and then removing solvent.

(3) Content of functional compounds (or marker compounds): Phospholipid (as an acetone insoluble substance) shall be contained 360 mg/g or more. Phosphatidylcholine in phospholipid shall be contained 100 mg/g or more in soybean lecithin, and 600 mg/g or more in egg yolk lecithin.

(4) Conditions for manufacturing: Cholesterol shall be contained 10,000 mg/kg or less in egg yolk lecithin.

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor.

(2) Phospholipid (as an acetone insoluble substance)

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Phosphatidicolin in Phospholipid

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(4) Cholesterol (mg/kg): No more than 10,000 (in case of using egg yolk lecithin)

(5) Solvent residue (mg/kg): No more than 5.0 (in case of using hexane)

(6) Lead (mg/kg): No more than 2.0

(7) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy blood cholesterol level

(2) Daily intake amount

1.2 ~ 18 g as lecithin

(3) Warning notice for intake

The individual who has an allergy to soybean or egg yolk should be cautious to intake.

4) Testing methods

(1) Phospholipid: Ⅲ.3.5.2 Phospholipid (as a acetone insoluble substance)

(2) Phosphatidylcholine in phospholipid: Ⅲ.3.5.3 Phosphatidicolin contents in phospholipid

(3) Cholesterol: Ⅲ.3.5.4 Cholesterol

(4) Solvent residue: Referred to [Annexed the Table 4]

(5) Lead: Referred to [Annexed the Table 4]

(6) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.3.4 Squalene

1) Standards for manufacturing

(1) Raw material: Shark liver

(2) Preparation and/or processing: It shall be in edible form by washing non-saponificable material with water or fermented ethanol (including mixture of water and fermented ethanol), after repeating distillation and saponification of the oil extracted from the raw materials

(3) Content of functional compounds (or marker compounds): Squalene shall be contained 980 mg/g or more

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Squalene

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Anti-oxidant activity

(2) Daily intake amount: 10 g as squalene

(3) The amount of Vitamin A and D in final product shall not be exceed the maximum level of Ⅱ.1.1.1 vitamin A and Ⅱ.1.1.3 vitamin D (The amount of vitamin A and D must be labeled)

4) Testing methods

(1) Squalene: Ⅲ.3.5.6 Squalene

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.3.5 Phytosterol / Phytosterolester

1) Standards for manufacturing

(1) Raw material and preparation and/or processing

(a) The mixture of β-sitosterol, brassicasterol, stigmaserol and campesterol, as distillate which are obtained during deodorization of soybean, corn or canola oil, shall be in edible form by extracting and purifying.

(b) The substance of above (a) shall be in edible form by esterifying to fatty acids originated from edible oil.

(2) Content of functional compounds (or marker compounds): Phytosterol shall be contained 900 mg/g or more. However, in case of using phytosterol ester as ingredients, the sum of total phytosterol and free phytosterol shall be contained 800 mg/g or more and contents of free phytosterol 100 % or less.

(3) Conditions for manufacturing: When analyzing phytosterol, all of β-sitosterol, brassicasterol, stigmasterol and campesterol shall be detected.

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor.

(2) Phytosterol (in case of using phytosterol as ingredients)

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Content of phytosterolester (in case of using phytosterolester as ingredients)

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(4) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy blood cholesterol level

(2) Daily intake amount: 0.8 ~ 3 g as phytosterol

(3) Warning notice for intake

It may inhibit the absorption of β-carotene

4) Testing methods

(1) Phytosterol: Ⅲ.3.5.7 Phytosterol

(2) Phytosterolester:

(a) Content of total phytosterol: Ⅲ.3.5.7 Phytosterol

(b) Free phytosterol: Ⅲ.3.5.8 Free phytosterol

(c) Content of phytosterolester = (total phytosterol - free phytosterol) × 1.6

(3) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.3.6 Shark liver oil containing alkoxyglycerol

1) Standards for manufacturing

(1) Raw material: Shark liver

(2) Preparation and/or processing: It shall be in edible form by washing non-saponificable material with water, deodorizing, heating and filtering after removal of squalene and saponificable material in the oil extracted from the raw materials

(3) Content of functional compounds (or marker compounds): Alkoxyglycerol shall be contained 180 mg/g or more, and batyl alcohol shall be confirmed

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Alkoxyglycerol

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Batyl alcohol: It shall be confirmed

(4) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Support immune function

(2) Daily intake amount

0.6 ~ 2.7 g as alkoxyglycerol

(3) The content of vitamin A and D in the final product shall be not exceed the maximum level of Ⅱ.1.1.1 vitamin A and Ⅱ.1.1.3 vitamin D (The content of vitamin A and D shall be labeled)

4) Testing methods

(1) Alkoxyglycerol: Ⅲ.3.5.9 Alkoxyglycerol

(2) Batyl alcohol: Ⅲ.3.5.10 Batyl alcohol confirmation

(3) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.3.7 Edible oil containing octacosanol

1) Standards for manufacturing

(1) Raw material

(a) Rice bran

(b) Sugarcane

(2) Preparation and/or processing: It shall be in edible form by recrystallizing with fermented ethanol or hexane after saponifying the oil containing octacosanol extracted from the raw materials

(3) Content of functional compounds (or marker compounds): Octacosanol shall be contained 100 mg/g or more in case of manufacturing from rice bran wax, and 540 mg/g or more in case of manufacturing from sugarcane wax

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Octacosanol

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Solvent residue (mg/kg): No more than 5.0 (in case of using hexane)

(4) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to improve endurance capacity

(2) Daily intake amount: 7 ~ 40 mg as octacosanol

4) Testing methods

(1) Octacosanol: Ⅲ.3.5.11 Octacosanol

(2) Solvent residue: Referred to [Annexed the Table 4]

(3) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.3.8 Japanese apricot extracts

1) Standards for manufacturing

(1) Raw material: Japanese apricot (*Prunus mune Sieb.* et Zucc)

(2) Preparation and/or processing: It shall be in edible form by filtering and concentrating after extracting the raw materials with hot water

(3) Content of functional compounds (or marker compounds): Citric acid shall be contained 300 ~ 400 mg/g

(4) Conditions for manufacturing: Cyanide shall be removed

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Citric acid

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Cyanide: Not detected

(4) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to relieve fatigue

(2) Daily intake amount: 1 ~ 1.3 g as citric acid

4) Testing methods

(1) Citric acid: Ⅲ.3.5.5 Citric acid

(2) Cyanide: Ⅲ.2.5.1 Cyanide

(3) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.3.9 Conjugated linoleic acids

1) Standards for manufacturing

(1) Raw material: Safflower seed oil

(2) Preparation and/or processing

(a) After saponifying and conjugated isomerizing the raw materials, the fatty acid shall be in edible form by extracting with fermented ethanol or hexane, or purifying, deodorizing and filtering

(b) Glyceride form: After glycerifying conjugated linoleic acid in fatty acid form with lipase, it shall be in edible form by extracting with fermented ethanol or hexane, or purifying, deodorizing and filtering

(3) Content of functional compounds (or marker compounds): Conjugated linoleic acid (the sum of cis-9 and trans-11 conjugated linoleic acid, trans-10 and cis-12 conjugated linoleic acid, and cis-9 and cis-11 conjugated linoleic acid) shall be contained 660 ~ 850 mg/g

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Content of conjugated linoleic acid (The sum of cis-9/trans-11, trans-10/cis-12, cis-9/cis-11, and trans-9/trans-11 conjugated linoleic acids)

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Contents of cis-9/trans-11 and trans-10/cis-12 conjugated linoleic acids (%): No less than 90% of conjugated linoleic acid content

(4) Contents of trans-9/trans-11 conjugated linoleic acid (%): No more than 3.0 (limited to semi-processed product)

(5) Acid value: No more than 10.0 (limited to semi-processed product of glyceride form)

(6) Lead (mg/kg): No more than 3.0

(7) Cadmium (mg/kg): No more than 1.5

(8) Total arsenic (mg/kg): No more than 5.0

(9) Total mercury (mg/kg): No more than 0.5

(10) Solvent residue (mg/kg): No more than 5.0 (in case of using hexane)

(11) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to reduce body fat in the overweight adult

(2) Daily intake amount

1.4 ~ 4.2 g as conjugated linoleic acid

(3) Warning notice for intake

It may cause gastrointestinal disorder

Infant and pregnant women should be careful for intake

Diet control and exercises together are effective in reducing body fat

4) Testing methods

(1) Content of conjugated linoleic acid: Ⅲ.3.5.1 Fatty acid

(2) Content of cis-9/trans-11 and trans-10/cis-12 conjugated linoleic acids (%): Ⅲ.3.5.1 Fatty acid

(3) Content of trans-9/trans-11 conjugated linoleic acid (%): Ⅲ.3.5.1 Fatty acid

(4) Acid value: Referred to [Annexed the Table 4]

(5) Lead, cadmium, total mercury and total arsenic: Referred to [Annexed the Table 4]

(6) Solvent residue: Referred to [Annexed the Table 4]

(7) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.3.10 Garcinia cambogia extracts

1) Standards for manufacturing

(1) Raw material: *Garcinia Cambogia* fruit peel

(2) Preparation and/or processing: It shall be in edible form by extracting the raw materials with water or fermented ethanol (including mixture of water and fermented ethanol), binding with calcium, potassium or sodium salt single or mixed, and neutralizing sufficiently

(3) Content of functional compounds (or marker compounds): Total (-)-hydroxycitric acid shall be contained 600 mg/g or more.

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor.

(2) Total (-)-hydroxycitric acid

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Heavy metal

(a) Lead (mg/kg): No more than 1.0

(b) Cadmium (mg/kg): No more than 0.5

(c) Total mercury (mg/kg): No more than 0.4

(d) Total arsenic (mg/kg): No more than 1.0

(4) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to reduce body fat by reducing in the overweight adult

(2) Daily intake amount

750 ~ 2,800 g as total (-)-hydroxycitric acid

4) Testing methods

(1) Total (-)-hydroxycitric acid: Ⅲ.3.5.13 Total (-)-hydroxycitric acid

(2) Lead, cadmium, total mercury and total arsenic: Referred to [Annexed the Table 4]

(3) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.3.11 Lutein

1) Standards for manufacturing

(1) Raw material: Marigold (*Tagetes erecta*) flower

(2) Preparation and/or processing: The oil shall be in edible form by crystallizing and pulverizing after extracting the raw materials with hexane or carbon dioxide (supercritical fluid extraction) and saponifying. When crystallizing, ethyl acetate can be used

(3) Content of functional compounds (or marker compounds): Lutein shall be contained 700 mg/g or more

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Lutein

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Solvent residue (limited to using solvent)

(a) Hexane (mg/kg): No more than 50.0

(b) Ethyl acetate (mg/kg): No more than 50.0

(4) Heavy metal

(a) Lead (mg/kg): No more than 1.0

(b) Cadmium (mg/kg): No more than 1.0

(c) Total mercury (mg/kg): No more than 1.0

(d) Total arsenic (mg/kg): No more than 1.0

(5) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: helps the eye health by maintaining the density of macular pigments which can be decreased by aging

(2) Daily intake amount

10 ~ 20 mg as lutein

(3) Warning notice for intake

When taken in excessive amounts, it may turn the skin yellow temporarily

Ⅱ.2.3.12 Haematococcus pluvialis extracts

1) Standards for manufacturing

(1) Raw material: *Haematococcus pluvialis*

(2) Preparation and/or processing: It shall be in edible form by extracting with carbon dioxide (supercritical fluid extraction) or acetone and purifying, after pulverizing dried culture the raw materials

(3) Content of functional compounds (or marker compounds): Astaxanthin shall be contained 60~140 mg/g or more

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Astaxanthin

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Acetone (mg/kg): No more than 30.0 (in case of using)

(4) Heavy metal

(a) Lead (mg/kg): No more than 1.0

(b) Cadmium (mg/kg): No more than 1.0

(c) Total mercury (mg/kg): No more than 1.0

(d) Total arsenic (mg/kg): No more than 1.0

(5) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to improve eye fatigue

(2) Daily intake amount

4 ~ 12 mg as astaxanthin

(3) Warning notice for intake:

When taken in excessive amounts, it may turn the skin yellow temporarily

It may inhibit the absorption of β-carotene

Ⅱ.2.3.13 Saw palmetto fruit extracts

1) Standards for manufacturing

(1) Raw material: Saw palmetto (*Serenoa repens*) fruit

(2) Preparation and/or processing: The oil shall be in edible form by filtering, concentrating after extracting the raw materials with fermented ethanol or carbon dioxide (supercritical fluid extraction)

(3) Content of functional compounds (or marker compounds): Lauric acid shall be contained 220~360 mg/g or more

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Lauric acid

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Heavy metal

(a) Lead (mg/kg): No more than 1.0

(b) Cadmium (mg/kg): No more than 1.0

(c) Total mercury (mg/kg): No more than 1.0

(d) Total arsenic (mg/kg): No more than 1.0

(4) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain prostate health

(2) Daily intake amount

70~115 mg as lauric acid

(3) Warning notice for intake

It may cause digestive system discomfort such as nausea etc., and diarrhea

Ⅱ.2.4. Sugar and carbohydrates

Ⅱ.2.4.1 Glucosamine

1) Standards for manufacturing

(1) Raw material: A shell of crustacea (crab, shrimp, etc.), Mollusk (squid, cuttlefish, etc.) bone, *Aspergillus niger*

(2) Preparation and/or processing

(a) Glucosamine hydrochloride: Chitin (β-1,4 bound polymer of N-acetylglucosamine) or chitosan (diacetylated ingredients of above obtained chitin) obtained by deproteinizing and decalciumating the raw materials, shall be in edible form by crystallizing after hydrolyzing with hydrochloric acid or chitosanase and neutralizing by washing with water or fermented ethanol sufficiently

(b) Glucosamine sulphate: Chitin (β-1,4 bound polymer of N-acetylglucosamine) or chitosan (diacetylated ingredients of above obtained chitin) obtained by deproteinizing and decalciumating the raw materials, shall be in edible form by hydrolyzing with hydrochloric acid, substituting with sulfuric acid, binding with NaCl or KCl single or mixed, crystallizing and neutralizing by washing with water or fermented ethanol sufficiently

(3) Content of functional compounds (or marker compounds): Glucosamine sulphate or hydrochloride shall be contained 980 mg/g or more

(4) Conditions for manufacturing: When neutralizing, it shall be sufficiently washed with water or fermented ethanol

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Glucosamine hydrochloride or sulphate

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Heavy metal

(a) Lead (mg/kg): No more than 5.0

(b) Cadmium (mg/kg): No more than 1.5

(c) Total mercury (mg/kg): No more than 1.0

(4) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy joint and cartilage

(2) Daily intake amount

1.5 ~ 2 g as glucosamine hydrochloride or sulphate

(3) Warning notice for intake:

The individual who has an allergy to crab and/or shrimp should be cautious to intake (limited to using crab and/or shrimp as raw material)

4) Testing methods

(1) Glucosamine: Ⅲ.3.4.1 Glucosamine

(2) Lead, cadmium and total mercury: Referred to [Annexed the Table 4]

(3) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.4.2 N-acetylglucosamine

1) Standards for manufacturing

(1) Raw material: A shell of crustacean (crab, shrimp or etc.) , Mollusk (squid, cuttlefish, etc.) bone

(2) Preparation and/or processing: The acetyl monosaccharide shall be in edible form obtained by swelling, hydrolyzing with chitosanase, desalinizing, concentrating, filtering, and drying from Chitin (β-1,4 bound polymer of N-acetylglucosamine) obtained by deproteinizing and decalciumating the raw materials

(3) Content of functional compounds (or marker compounds): N-acetylglucosamine shall be contained 950 mg/g or more

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) N-acetylglucosamine

(a) Semi-processed product: No less than labeled amount

(b) Final product: 90 ~ 110 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy joint and cartilage, help to maintain healthy skin moisturizing

(2) Daily intake amount

(a) Help to joint and cartilage health: 0.5 ~ 1 g as N-acetyl glucosamine

(b) Help to skin moisturizing: 1 g as N-acetyl glucosamine

(3) Warning notice for intake

The individual who has an allergy to crab and/or shrimp should be cautious to intake (limited to using crab and/or shrimp as raw material)

4) Testing methods

(1) N-acetyl glucosamine: Ⅲ.3.4.2 N-Acetyl glucosamine

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.4.3 Mucopolysaccharide·mucoprotein

1) Standards for manufacturing

(1) Raw material: Cartilage tissues of cattle, swine, sheep, deer, shark, poultry, squid, crab, or fish and shellfish

(2) Preparation and/or processing: After extracting cartilage tissues of cattle, swine, sheep, deer, shark, poultry, squid, crab, fish and shellfish with hot water or hydrolyzing with enzyme, it shall be in edible form by filtering, concentrating and drying.

(3) Content of functional compounds (or marker compounds): Mucopolysaccharide·mucoprotein shall be contained 770 mg/g or more, and the ratio of protein and chondroitin sulfate shall be 1.0 ~ 9.0

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor.

(2) Mucopolysaccharide·protein

(a) Semi- processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Ratio of protein and chondroitin sulfate: 1.0 to below 9.0

(4) Salmonella: Negative

(5) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health clams: Help to maintain healthy joint and cartilage

(2) Daily intake amount

1.2 ~ 1.5 g as mucopolysaccharide·mucoprotein

4) Testing methods

(1) Mucopolysaccharide·mucoprotein

(a) Chondroitin sulfate: Ⅲ.3.4.6 Chondroitin sulfate

(b) Protein: About 10 g of sample are grinded and mixed rapidly before absorbing moisture and 30 mg is weighed accurately, and then Ⅲ.3.3.1 Crude protein

※ Based on gelatin protein (18 % of nitrogen content) in ingredients, nitrogen conversion coefficient of 5.56 shall be applied.

(c) Mucopolysaccharide·mucoprotein content: It shall be calculated by the sum of chondroitin sulfate and protein obtained from (a) and (b).

(2) Ratio of protein and chondroitin sulfate: The ratio of protein and chondroitin sulfate obtained from (1) of Testing Methods

(3) Salmonella: Referred to [Annexed the Table 4]

(4) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.4.4 Dietary fiber

Ⅱ.2.4.4.1 Guar gum / Guar gum hydrolysate

1) Standards for manufacturing

(1) Raw material: Legume family guar (*Cyamopsis tetragonolobus* TAUB.)

(2) Preparation and/or processing:

(a) High molecular weight galactomannan polysaccharide shall be in edible form obtained by pulverizing the seed albumen parts from the raw materials or extracting with warm or hot water.

(b) Galactomannan obtained by method of (a) shall be in edible form by hydrolysis.

(3) Content of functional compounds (or marker compounds): Dietary fiber shall be contained 660 mg/g or more.

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Dietary fiber

(a) Semi-processed product: No less than labeled amount

(b) Final product: No less than 80 % of labeled amount

(3) Lead (mg/kg): No more than 2.0

(4) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy blood cholesterol level, help to maintain healthy postprandial glucose level, help to maintain healthy bowel function, help to maintain healthy gastrointestinal bacteria population

(2) Daily intake amount

(a) Help to maintain healthy blood cholesterol level: 15 ~ 27 g as guar gum or its hydrolysate

(b) Help to maintain healthy postprandial glucose level: 15 ~ 27 g as guar gum or its hydrolysate

(c) Help to maintain healthy bowel function: 5 ~ 12 g as guar gum or its hydrolysate

(d) Help to maintain healthy gastrointestinal bacteria population: 7 ~ 21 g as guar gum or its hydrolysate

(3) Warning notice for intake

Should be taken with sufficient water except for liquid type product

4) Testing methods

(1) Dietary fiber: Ⅲ.3.4.4 Dietary fiber

(2) Lead: Referred to [Annexed the Table 4]

(3) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.4.4.2 Glucomannan (konjacmannan)

1) Standards for manufacturing

(1) Raw material: Arum family konjac (*Amorphophallus konjq*) rhizome

(2) Preparation and/or processing: Polysaccharides shall be in edible form by extracting the raw materials with isopropyl alcohol and purifying

(3) Content of functional compounds (or marker compounds): Dietary fiber shall be contained 690 mg/g or more

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor.

(2) Dietary fiber

(a) Semi-processed product: No less than labeled amount

(b) Final product: No less than 80 % of labeled amount

(3) Solvent residue (mg/kg): No more than 50.0

(4) Lead (mg/kg): No more than 2.0

(5) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy blood cholesterol level, help to maintain healthy bowel function

(2) Daily intake amount

(a) Help to maintain healthy blood cholesterol level: 4 ~ 17g as glucomannan

(b) Help to maintain healthy bowel function: 4 ~ 6g as glucomannan

(3) Warning notice for intake

Should be taken with sufficient water except for liquid type product

4) Testing methods

(1) Dietary fiber: Ⅲ.3.4.4 Dietary fiber

(2) Solvent residue: Referred to [Annexed the Table 4]

(3) Lead: Referred to [Annexed the Table 4]

(4) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.4.4.3 Oat

1) Standards for manufacturing

(1) Raw material: Oat (*Avena sativa*, *Avena sterilisand*, *Avena strigosa*) bran

(2) Preparation and/or processing: It shall be in edible form by washing, drying, pulverizing and extracting

(3) Content of functional compounds (or marker compounds): Dietary fiber shall be contained 200 mg/g or more

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Dietary fiber

(a) Semi-processed product: No less than labeled amount

(b) Final product: No less than 80 % labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy blood cholesterol level, help to maintain healthy postprandial glucose level

(2) Daily intake amount

(a) Help to maintain healthy blood cholesterol level: 3 g or more as oat fiber

(b) Help to maintain healthy postprandial glucose level: 0.8 ~ 8 g as oat fiber

(3) Warning notice for intake

Should be taken with sufficient water except for liquid type product

4) Testing methods

(1) Dietary fiber: Ⅲ.3.4.4 Dietary Fiber

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.4.4.4 Indigestible maltodextrin

1) Standards for manufacturing

(1) Raw material: Corn starch

(2) Preparation and/or processing: The roasted-dextrin shall be obtained by heating the raw materials. The indigestible components shall be in edible form by hydrolyzing the roasted-dextrin with α-amylase (*Bacillus subtilis* or *Bacillus licheniformis* origin) and amyloglucosidase (*Aspergillus niger* origin) and purifying and then separating from dextrin

(3) Content of functional compounds (or marker compounds): Dietary fiber shall be contained 850 mg/g or more (In case of liquid, 580 mg/g or more)

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Dietary fiber

(a) Semi-processed product: No less than labeled amount

(b) Final product: No less than 80 % of labeled amount

(3) Dextrose equivalent (D.E.): 8.0 ~ 18.0 (limited to Semi-processed product)

(4) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy postprandial glucose level, help to maintain healthy bowel function, help to maintain healthy triglyceride level

(2) Daily intake amount

(a) Help to maintain healthy postprandial glucose level: 14~29 g as indigestible maltodextrin (in case of liquid ingredients, 20 ~ 43 g)

(b) Help to maintain healthy bowel function: 3~29 g as indigestible maltodextrin (in case of liquid ingredients, 4~43 g)

(c) Help to maintain healthy triglyceride level: 15~30 g as indigestible maltodextrin (in case of liquid ingredients, 22~44 g)

(3) Warning notice for intake

Should be taken with sufficient water except for liquid type product

4) Testing methods

(1) Dietary fiber: Ⅲ.3.4.4 Dietary fiber (Method 2)

(2) Dextrose equivalent (D.E.): Referred to [Annexed the Table 4]

(3) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.4.4.5 Soybean fiber

1) Standards for manufacturing

(1) Raw material: Soybean (*Glycine max* L.N)

(2) Preparation and/or processing: The dietary fiber shall be in edible form by defatting and deproteinizing the raw materials, and then separating.

(3) Content of functional compounds (or marker compounds): Dietary fiber shall be contained 600 mg/g or more

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Dietary fiber

(a) Semi-processed product: No less than labeled amount

(b) Final product: No less than 80 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy blood cholesterol level, help to maintain healthy postprandial glucose level, help to maintain healthy bowel function

(2) Daily intake amount

(a) Help to maintain healthy blood cholesterol level: 20 ~ 25 g as soybean fiber

(b) Help to maintain healthy postprandial glucose level: 10 ~ 25 g as soybean fiber

(c) Help to maintain healthy bowel function: 20 ~ 60 g as soybean fiber

(3) Warning notice for intake

(a) Should be taken with sufficient water except for liquid type product

(b) The individual who has an allergy to soybean should be cautious to intake

4) Testing methods

(1) Dietary fiber: Ⅲ.3.4.4 Dietary fiber

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.4.4.6 Tree ear (Auricularia auricular)

1) Standards for manufacturing

(1) Raw material: Tree ear (*Auricularia auricula judae*)

(2) Preparation and/or processing: It shall be in edible form by drying and pulverizing the raw materials

(3) Content of functional compounds (or marker compounds): Dietary fiber shall be contained 450 mg/g or more

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Dietary fiber

(a) Semi-processed product: No less than labeled amount

(b) Final product: No less than 80 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy bowel function

(2) Daily intake amount

12 g as Tree ear fiber

(3) Warning notice for intake

Should be taken with sufficient water except for liquid type product

4) Testing methods

(1) Dietary fiber: Ⅲ.3.4.4 Dietary fiber

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.4.4.7 Wheat fiber

1) Standards for manufacturing

(1) Raw material: Wheat (*Triticum turgidum durum*, or *T. spp*)

(2) Preparation and/or processing

(a) The dietary fiber shall be in edible form by separating from by-product during flour manufacturing process

(b) The outer skins or stems of the raw materials shall be in edible form by washing, drying and pulverizing

(3) Content of functional compounds (or marker compounds): Dietary fiber shall be contained 700 mg/g or more

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Dietary fiber

(a) Semi-processed product: No less than labeled amount

(b) Final product: No less than 80 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy postprandial glucose level, help to maintain healthy bowel function

(2) Daily intake amount

(a) Help to maintain healthy postprandial glucose level: 6 ~ 12 g as wheat fiber

(b) Help to maintain healthy bowel function: 36 g as wheat fiber

(3) Warning notice for intake

Should be taken with sufficient water except for liquid type product

4) Testing methods

(1) Dietary fiber: Ⅲ.3.4.4 Dietary fiber

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.4.4.8 Barley fiber

1) Standards for manufacturing

(1) Raw material: Barley (*Hordeum vulgare*)

(2) Preparation and/or processing

(a) The dietary fiber shall be in edible form by defatting and deproteinizing the raw materials

(b) The outer skins or grains of the raw materials shall be in edible form by drying

(3) Content of functional compounds (or marker compounds): Dietary fiber shall be contained 500 mg/g or more.

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Dietary fiber

(a) Semi-processed product: No less than labeled amount

(b) Final product: No less than 80 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy bowel function

(2) Daily intake amount

20 ~ 25 g as barley fiber

(3) Warning notice for intake

Should be taken with sufficient water except for liquid type product

4) Testing methods

(1) Dietary fiber: Ⅲ.3.4.4 Dietary fiber

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.4.4.9 Arabic gum (acacia gum)

1) Standards for manufacturing

(1) Raw material: Legume family acacia senegal (Acacia senegal WILLDENOW) or other same genus plants

(2) Preparation and/or processing

(a) It shall be in edible form by drying and desalinizing the secretion of raw materials

(b) It shall be in edible form by mechanically pressing the secretion of raw materials

(3) Content of functional compounds (or marker compounds): Dietary fiber shall be contained 800 mg/g or more

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Dietary fiber

(a) Semi-processed product: No less than labeled amount

(b) Final product: No less than 80 % of labeled amount

(3) Lead (mg/kg): No more than 2.0

(4) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy bowel function

(2) Daily intake amount

25 g as arabic gum

(3) Warning notice for intake

Should be taken with sufficient water except for liquid type product

4) Testing methods

(1) Dietary fiber: Ⅲ.3.4.4 Dietary fiber

(2) Lead: Referred to [Annexed the Table 4]

(3) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.4.4.10 Corn bran

1) Standards for manufacturing

(1) Raw material: Corn (*Zea mays*) bran

(2) Preparation and/or processing: The raw materials shall be in edible form

(3) Content of functional compounds (or marker compounds): Dietary fiber shall be contained 800 mg/g or more

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Dietary fiber

(a) Semi-processed product: No less than labeled amount

(b) Final product: No less than 80 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy blood cholesterol level, help to maintain healthy postprandial glucose level

(2) Daily intake amount

10 g as corn bran fiber

(3) Warning notice for intake

Should be taken with sufficient water except for liquid type product

4) Testing methods

(1) Dietary fiber: Ⅲ.3.4.4 Dietary fiber

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.4.4.11 Inulin / Chicory extracts

1) Standards for manufacturing

(1) Raw material: Chicory or other Compositae family plants (*Chicorium intybus*)

(2) Preparation and/or processing: It shall be in edible form by extracting the root of raw materials with hot water and then purifying

(3) Content of functional compounds (or marker compounds): Dietary fiber shall be contained 800 mg/g or more

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Dietary fiber

(a) Semi-processed product: No less than labeled amount

(b) Final product: No less than 80 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy blood cholesterol level, help to maintain healthy postprandial glucose level, help to maintain healthy bowel function

(2) Daily intake amount

(a) Help to maintain healthy blood cholesterol level: 9 ~ 10 g as Inulin

(b) Help to maintain healthy postprandial glucose level: 9 ~ 10 g as Inulin

(c) Help to maintain healthy bowel function: 8 ~ 20 g as Inulin

(3) Warning notice for intake

Should be taken with sufficient water except for liquid type product

4) Testing methods

(1) Dietary fiber: Ⅲ.3.4.4 Dietary fiber

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.4.4.12 Psyllium husk

1) Standards for manufacturing

(1) Raw material: Psyllium husk (*Plantago ovata* or *Plantago spp.*)

(2) Preparation and/or processing: It shall be in edible form by pulverizing the raw materials

(3) Content of functional compounds (or marker compounds): Dietary fiber shall be contained 790 mg/g or more

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Dietary fiber

(a) Semi-processed product: No less than labeled amount

(b) Final product: No less than 80 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy blood cholesterol level, help to maintain healthy bowel function

(2) Daily intake amount

(a) Help to maintain healthy blood cholesterol level: 7 g or more as psyllium husk

(b) Help to maintain healthy bowel function: 5 ~ 25 g as psylium husk

(3) Warning notice for intake

Should be taken with sufficient water except for liquid type product

4) Testing methods

(1) Dietary fiber: Ⅲ.3.4.4 Dietary fiber

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.4.4.13 Polydextrose

1) Standards for manufacturing

(1) Raw material and preparation and/or processing: It shall be synthesized from glucose and sorbitol, using organic acid such as citric acid. The degree of polymerization shall be about 12 in average

(2) Content of functional compounds (or marker compounds): Dietary fiber shall be contained 650 mg/g or more

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Dietary fiber

(a) Semi-processed product: No less than labeled amount

(b) Final product: No less than 80 % of labeled amount

(3) Lead (mg/kg): No more than 0.5

(4) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy bowel function

(2) Daily intake amount

7 ~ 12g as Polydextrose

(3) Warning notice for intake

Should be taken with sufficient water except for liquid type product

4) Testing methods

(1) Dietary fiber: Ⅲ.3.4.4 Dietary fiber (Method 2)

(2) Lead: Referred to [Annexed the Table 4]

(3) Coliform: Referred to [Annexed the Table

Ⅱ.2.4.4.14 Fenugreek seed

1) Standards for manufacturing

(1) Raw material: Fenugreek (*Trigonella foenum-graecum*) seed

(2) Preparation and/or processing: It shall be in edible form by pulverizing or defatting the raw materials.

(3) Content of functional compounds (or marker compounds): Dietary fiber shall be contained 450 mg/g or more

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Dietary fiber

(a) Semi-processed product: No less than labeled amount

(b) Final product: No less than 80 % of labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy postprandial glucose level

(2) Daily intake amount

12 ~ 50 g as fenugreek seed

(3) Warning notice for intake

Should be taken with sufficient water except for liquid type product

4) Testing methods

(1) Dietary fiber: Ⅲ.3.4.4 Dietary fiber

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.4.5 Aloe gel

1) Standards for manufacturing

(1) Raw material: Aloe (*Aloe vera*) leaf

(2) Preparation and/or processing

(a) After removing non-edible parts and outer skins, it shall be in edible form by separating, drying and pulverizing the gel compound

(b) After removing non-edible parts and outer skins, it shall be in edible form by separating and i) pulverizing or pressing the gel compound; ii) concentrating thereof, or iii) drying and pulverizing the concentrate

(3) Content of functional compounds (or marker compounds): Total polysaccharide shall be contained 30 mg/g or more in solids

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Total polysaccharide (The polysaccharides originated from other ingredients shall be labeled separately)

(a) Semi-processed product: No less than labeled amount

(b) Final product: No less than 80 % of labeled amount

(3) Anthraquinone compounds (as anhydrous barbaloin) (%): No more than 0.005 (It shall be converted based on the concentration ratio of ingredients and aloe gel converted content as a standard of Aloe vera gel 100%)

(4) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy skin, help to maintain healthy gastrointestinal function, support immune function

(2) Daily intake amount: 100 ~ 420 mg as total polysaccharide content

4) Testing methods

(1) Total polysaccharide: Ⅲ.3.4.5 Total polysaccharide

(2) Anthraquinone compounds (as anhydrous barbaloin): Ⅲ.3.6.2 Anthraquinone compounds (as anhydrous barbaloin)

(3) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.4.6 Ganoderma lucidum fruit body extracts

1) Standards for manufacturing

(1) Raw material: Ganoderma lucidum (*Ganoderma lucidum* or *Ganoderma tsugae*) fruit body

(2) Preparation and/or processing: It shall be in edible form by filtering and concentrating after extracting the raw materials with hot water

(3) Content of functional compounds (or marker compounds): β-glucan shall be contained 10 mg/g or more

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) β-glucan

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of the labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy blood flow

(2) Daily intake amount

24 ~ 42 mg as β-glucan

4) Testing methods

(1) β-glucan: Ⅲ.3.4.3 β-glucan

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.4.7 Chitosan /Chitooligosaccharide

1) Standards for manufacturing

(1) Raw material: A shell of crustacean (crab, shrimp, etc.), Mollusk (squid, cuttlefish, etc.) bone

(2) Preparation and/or processing

(a) Chitosan: It shall be in edible form by diacetylating chitin (β-1,4 bound polymer of N-acetylglucosamine) obtained by deproteinizing and decalcifying the raw materials

(b) Chitooligosaccharide: It shall be in edible form by hydrolyzing chitosan obtained from preparation and/or processing of (a) with enzyme

(3) Content of functional compounds (or marker compounds): The degree of deacetylation (glucosamine remaining ratio in sugar chains) of chitosan shall be contained 80 % or more. Chitosan (as glucosamine) shall be contained 800 mg/g or more and chitooligosaccharide 200 mg/g or more

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Chitosan or Chitooligosaccharide

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Heavy metal

(a) Lead (mg/kg): No more than 3.0

(b) Cadmium (mg/kg): No more than 1.0

(c) Total mercury (mg/kg): No more than 1.0

(4) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy blood cholesterol level

(2) Daily intake amount

1.2 ~ 4.5 g as sum of chitosan and chitooligosaccharide

(3) Warning notice for intake

The individual who has an allergy to crab and/or shrimp should be cautious to intake (limited to using crab and/or shrimp as raw material)

4) Testing methods

(1) Chitosan: Ⅲ.3.4.7 Chitosan(as total glucosamine)

(2) Chitooligosaccharide: Ⅲ.3.4.8 Chitooligosaccharide

(3) Lead, cadmium and total mercury: Referred to [Annexed the Table 4]

(4) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.4.8 Fructooligosaccharide

1) Standards for manufacturing

(1) Raw material and preparation and/or processing

(a) β-1,2 oligosaccharides bound sucrose with 1~3 fructose units shall be manufactured·processed with transferase or microorganisms having transferase after making liquid by melting sugar

(b) It shall be manufactured·processed by hydrolyzing inulin with enzyme

(2) Content of functional compounds (or marker compounds): Fructooligosaccharide shall be contained 410 mg/g or more. The content of fructo-oligosaccharide shall be calculated by sum of 1-kestose (GF2), nystose (GF3) and fructofuranosylnystose (GF4)

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Fructooligosaccharide

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Lead (mg/kg): No more than 1.0

(4) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy gastrointestinal bacteria population, help to maintain healthy bowel function, help to calcium absorption

(2) Daily intake amount

3 ~ 8 g as fructooligosaccharide

4) Testing methods

(1) Fructooligosaccharide: Ⅲ.3.4.9 Fructooligosaccharide

(2) Lead: Referred to [Annexed the Table 4]

(3) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.5 Fermentation microorganisms

Ⅱ.2.5.1 Probiotics

1) Standards for manufacturing

(1) Raw material: The following probiotics itself or mixed

	Kind
Lactobacillus	*L.acidophilus, L.casei, L.gasseri, L.delbrueckii ssp. bulgaricus, L.helveticus, L.fermentum, L.paracasei, L.plantarum, L.reuteri, L.rhamnosus, L.salivarius*
Lactococcus	*Lc. lactis*
Enterococcus	*E.faecium, E.faecalis*
Streptococcus	*S.thermophilus*
Bifidobacterium	*B.bifidum, B.breve, B.longum, B.animalis spp. lactis*

(2) Preparation and/or processing: It shall be in edible form by culturing and pulverizing the above probiotics

(3) Content of functional compounds (or marker compounds): Alive bacteria shall be contained 100,000,000 CFU/g or more

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Probiotics number: No less than labeled amount

(3) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy gastrointestinal bacteria population, help to maintain healthy bowel function

(2) Daily intake amount

100,000,000 ~ 10,000,000,000 CFU

4) Testing methods

(1) Probiotics number

(a) Lacto-bacillus and -coccus: Ⅲ.3.8.1 Lacto-bacillus and -coccus

(b) Bifidobacterium: Ⅲ.3.8.2 Bifidobacterium

(2) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.5.2 Red Yeast Rice

1) Standards for manufacturing

(1) Raw material: Rice and *Monascus anka*, *Monascus purpures*, *Monascus pilosus*, and *Monascus ruber*

(2) Preparation and/or processing: It shall be in edible form by pulverizing after solid-state fermentation by inoculating rice (except for steamed rice) with Monascus anka

(3) Content of functional compounds (or marker compounds): Total monacolin K shall be contained 0.5 mg/g or more, and active form of monacolin K shall be confirmed

(4) Conditions for manufacturing: Citrinin shall be contained 50 μg/kg or less

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and off-flavor

(2) Total monacolin K

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Active form of monacolin K: It shall be confirmed.

(4) Citrinin (μg/kg): No more than 50

(5) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy blood cholesterol level

(2) Daily intake amount

4 ~ 8 mg as total monacolin K

4) Testing methods

(1) Total monacolin K: Ⅲ.3.6.6 Total monacolin K

(2) Active form of monacolin K: It shall be confirmed according to total monacolin K testing Method of above (1)

(3) Citrinin: Ⅲ.2.5.4 Citrinin

(4) Coliform: Referred to [Annexed the Table 4]

Ⅱ.2.6. Amino acid and proteins

Ⅱ.2.6.1 Soybean protein

1) Standards for manufacturing

(1) Raw materials: Soybean (*Glycine max* L.N)

(2) Preparation and/or processing: It shall be in edible form by separating and purifying after removing lipid from the raw materials

(3) Content of functional compounds (or marker compounds): Crude protein shall be contained 600 mg/g or more based on dried materials and daidzein and genistein shall be confirmed

2) Specifications

(1) Appearance: Unique color and flavor, no off-taste and no off-flavor

(2) Crude protein

(a) Semi-processed product: No less than labeled amount

(b) Final product: 80 ~ 120 % of labeled amount

(3) Daidzein: It shall be confirmed

(4) Genistein: It shall be confirmed

(5) Coliform: Negative

3) Prerequisite for the health functional food

(1) Health claims: Help to maintain healthy blood cholesterol level

(2) Daily intake amount

15 g or more as soybean protein

(3) Warning notice for intake

The individual who has an allergy to soybean protein should be cautious to intake

4) Testing methods

(1) Crude protein: Ⅲ.3.3.1 Crude protein

(2) Daidzein, Genistein: Ⅲ.3.6.5 Confirmation of daidzein and genistein

(3) Coliform: Referred to [Annexed the Table 4]

[Annexed the Table 1] Table of random sampling numbers and usage method

	1	2	3	4	5	6	7	8	9	10	
1	95767	26878	94971	75204	64775	52647	35672	97456	89815	16767	1
2	81934	99378	73901	46997	11173	80744	51957	50801	25785	40475	2
3	64959	10235	55441	87439	04966	96170	22582	13512	60227	81391	3
4	88488	81729	60733	84690	94315	10841	99296	47844	87998	01066	4
5	22306	61346	09026	66275	78204	11563	67457	69438	98753	23478	5
6	01436	13553	53487	19706	30740	83272	69602	99251	81599	79264	6
7	35962	90832	21604	29620	01151	81945	61894	91583	41133	83955	7
8	80319	01462	60338	69763	32812	84076	10555	88707	92309	34505	8
9	32141	01977	57874	25052	11567	35505	04797	21900	81703	11848	9
10	99197	78637	67636	35765	36871	22555	94013	15118	81620	76730	10
11	04030	88194	08580	86080	76119	62260	81248	51732	89078	21940	11
12	99835	54210	80413	82015	07459	93910	93694	41184	65698	31977	12
13	26400	63946	83204	36388	30497	24021	93962	25555	00357	93441	13
14	64363	11259	59066	92948	72291	31804	82029	15789	04683	34455	14
15	82878	87304	33618	19490	88779	38883	14481	77089	58544	22761	15
16	19485	82792	88195	31877	74902	13212	02514	47152	17292	62081	16
17	72762	47963	14380	96130	74633	21388	22096	24987	50056	26487	17
18	53747	17433	51614	97763	90426	47833	58245	14890	77303	35338	18
19	84760	29591	96142	02207	79847	89559	66803	15461	39639	23187	19
20	42365	42338	66105	03782	83727	14200	57263	85617	95577	88654	20
21	44336	05322	04540	75989	51385	52279	16661	91446	48811	25346	21
22	52930	61970	05808	22807	85460	22723	61318	23281	63426	69030	22
23	50436	54490	50650	59386	25572	23267	44039	08759	33702	34580	23
24	24980	54548	49428	91704	86913	92940	86923	22428	47877	20510	24
25	94186	95540	75071	10076	10263	27664	98534	81171	61507	74976	25

	1	2	3	4	5	6	7	8	9	10	
26	12359	46569	11050	90529	49289	94545	02258	20678	18898	50931	26
27	57132	49387	74792	50937	62339	43401	82825	03692	37836	68752	27
28	71239	49511	07466	15364	86050	31093	16730	73587	79875	43576	28
29	03935	83975	28893	66615	14015	22410	90938	35961	36373	84810	29
30	72801	73777	79101	26592	45424	00899	78462	74336	60478	13852	30
31	80252	11587	10862	11627	89857	07788	46817	55863	35713	44712	31
32	69388	92356	81282	33832	56676	35132	07119	27613	01304	70032	32
33	40225	60304	13526	47601	12751	19233	02057	28447	46676	29541	33
34	59925	62338	78784	63228	82603	31755	72733	80303	91066	52537	34
35	31172	89780	95384	51947	13841	74371	81016	39798	26690	00978	35
36	45587	42590	08443	20404	15100	74747	50642	34480	68080	23169	36
37	37819	60911	94740	05536	94042	17969	36747	92151	07501	67660	37
38	51402	74213	01105	15098	61470	23047	28521	58559	59305	08761	38
39	93873	99143	82254	53647	11010	68668	25888	36209	65412	00066	39
40	97645	51836	11835	99276	86466	67647	60834	30704	06711	11128	40
41	13123	15323	24885	74046	49145	99982	48231	26711	87670	22062	41
42	72110	70217	23475	48152	83457	01585	90915	69308	89090	77158	42
43	13751	40714	99330	05232	97056	40788	70005	36274	78649	50897	43
44	83809	98109	48292	06947	15924	08787	03919	72577	12906	80694	44
45	46264	57933	37607	58926	60772	62523	66260	95270	46469	45110	45
46	97426	78630	06115	44047	42350	88455	61426	08812	04255	87718	46
47	74715	09140	90315	03927	82118	00800	14314	06984	88951	10983	47
48	92481	55828	20144	77853	18100	13196	12279	20903	01252	00731	48
49	40176	70724	99476	34567	10214	97743	15770	78474	75691	59930	49
50	90176	19360	74015	89080	36337	40242	39621	71369	72350	73430	50

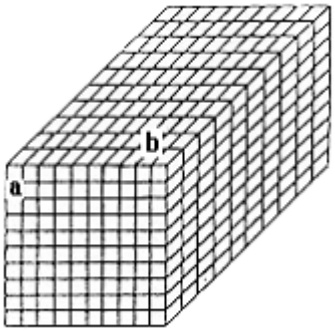
※ Use of random sampling numbers

① Choice a box at random.

Ex: If you choice the second box from top of left side randomly, it applies to "a" in the above figure.

② Choice a point of table of random sampling numbers randomly.

Ex:



① Select a box randomly.

Ex: If you select the second box from the top of the far left side randomly, it is "a" in the above figure.

② Select a point in the Table of Random Numbers.

Ex: You randomly select 75071 located in column 3, row 25 in the random number table, then again randomly select the fourth number 7.

③ Read three numbers upward, downward, leftward, or rightward.

Ex: If you select to read rightward, then 7, 1, 1 are being read from the random number table.

④ A box that will be used for sampling is selected by counting boxes in three sequential directions based in the three selected number.

Ex: If you choose to count boxes rightward, upward, and inward sequence, count 7 rightward from position a, then 1 upward, and finally 1 inward to select the box for sampling, thus box b in the diagram is selected.

[Annexed the Table 2] Nutrient reference value

Nutrient	Reference value	Nutrient	Reference value	Nutrient	Reference value
Carbohydrate (g)	328	Iron (mg)	15	Pantothenic acid (mg)	5
Dietary fiber (g)	25	Vitamin D (μg)	5	Phosphorus (mg)	700
Protein (g)	60	Vitamin E (mgα-TE)	10	Iodine (μg)	75
Lipid (g)	50	Vitamin K (μg)	55	Magnesium (mg)	220
Saturated fatty acid (g)	15	Vitamin B_1 (mg)	1.0	Zinc (mg)	12
Cholesterol (mg)	300	Vitamin B_2 (mg)	1.2	Selene (μg)	50
Sodium (mg)	2,000	Niacin (mg NE)	13	Cupper (mg)	1.5
Potassium (mg)	3,500	Vitamin B_6 (mg)	1.5	Manganese (mg)	2.0
Vitamin A (μg RE)	700	Folic acid (μg)	250	Chromium (μg)	50
Vitamin C (mg)	100	Vitamin B_{12} (μg)	1.0	Molybdenum (μg)	25
Calcium (mg)	700	Biotin (μg)	30		

[Annexed the Table 3] Dietary Reference Intakes for Koreans

Age	Carbohydrate (g)		Lipids (g)		n-6 unsaturated fatty acid (g)		n-3 unsaturated fatty acid (g)		Proteins (g)		Dietary Fiber (g)		Water (ml)		VitaminC (mg)		Thiamin (mg)		Riboflavin (mg)		Niacin (mg NE)		Vitamin B_6 (mg)		Folic acid (μg DFE)		Vitamin B_{12} (mg)		Pantothenic acid (mg)		Biotin (μg)	
	RI	AI	RI	AI	RI	AI	RI	AI	RI	AIAI	RI	AI	RI	AI	RI	AI	RI	AI	RI	AI	RI	AI	RI	AI	RI	AI	RI	AI	RI	AI	RI	AI
Infant 0 ~ 5(Mon)		55		25		2.0		0.3		9.5				700		35		0.2		0.3		2		0.1		65		0.2		1.7		5
6 ~ 11		90		25		4.5		0.8	135					800		40		0.3		0.4		3		0.3		80		0.5		1.8		6
Child 1 ~ 2 (age)									15			12		1,100	40		0.5		0.6		6		0.6		150		0.9		2		8
3 ~ 5									20			17		1,400	40		0.5		0.7		7		0.7		180		1.1		2		10
Male 6 ~ 8(age)									25			19		1,700	60		0.7		0.9		9		0.9		220		1.3		3		15
9 ~ 11									35			23		2,000	70		0.9		1.1		12		1.1		300		1.8		4		20
12 ~ 14									50			29		2,400	100		1.2		1.5		15		1.5		360		2.2		5		25
15 ~ 19									60			32		2,700	110		1.4		1.8		18		1.8		400		2.4		6		25
20 ~ 29									55			31		2,700	100		1.2		1.5		16		1.5		400		2.4		5		30
30 ~ 49									55			29		2,500	100		1.2		1.5		16		1.5		400		2.4		5		30
50 ~ 64									50			26		2,300	100		1.2		1.5		16		1.5		400		2.4		5		30
65 ~ 74									50			26		2,100	100		1.2		1.5		16		1.5		400		2.4		5		30
75 이상									50			26		2,100	100		1.2		1.5		16		1.5		400		2.4		5		30
Female 6 ~ 8(age)									25			18		1,600	60		0.6		0.7		9		0.8		220		1.3		3		15
9 ~ 11									35			20		1,800	70		0.8		0.9		10		1.0		300		1.8		4		20
12 ~ 14									45			24		2,000	90		1.0		1.2		13		1.4		360		2.2		5		25
15 ~ 19									45			24		2,100	100		1.0		1.2		13		1.4		400		2.4		6		25
20 ~ 29									45			25		2,100	100		1.1		1.2		14		1.4		400		2.4		5		30
30 ~ 49									45			23		2,000	100		1.1		1.2		14		1.4		400		2.4		5		30
50 ~ 64									45			22		1,800	100		1.1		1.2		14		1.4		400		2.4		5		30
65 ~ 74									45			22		1,700	100		1.1		1.2		14		1.4		400		2.4		5		30
75 이상									45			22		1,700	100		1.1		1.2		14		1.4		400		2.4		5		30

Pregnancy	+25	+5	+200	+10	+0.5	+0.4	+4	+0.8	+200	+0.2	+1	+0
Lactation	+25	+4	+700	+35	+0.4	+0.5	+4	+0.7	+150	+0.2	+2	+5

[A corporation The Korean Nutrition Society: Korean Dietary Reference Intakes (2005)

* Recommended Intake: As the RI is the daily nutrient intake recommended by age, it should be calculated on the basis of average requirements.

Age	Vitamin A (μg RE)		Vitamin D (μg)		Vitamin E (mg α-TE)		Vitamin K (μg)		Calcium (mg)		Phosphorus (mg)		Sodium (g)		Chlorine (g)		Potassium (g)		Magnesium (mg)		Iron (mg)		Zinc (mg)		Copper (μg)		fluorine (mg)		Manganese (mg)		Iodine (μg)		Selenium (μg)	
	RI	AI	RI	AI	RI	AI	RI	AI	RI	AI	RI	AI	RI	AI	RI	AI	RI	AI	RI	AI	RI	AI	RI	AI	RI	AI	RI	AI	RI	AI	RI	AI
Infant 0 ~ 5(Mon)		350		5		3		4		200		100		0.12		0.18		0.4		30		0.26		1.73		225		0.01		0.008		130		8.5
6 ~ 11		400		5		4		7		300		300		0.37		0.56		0.7		55	7		2.5			290		0.5		0.8		170		11
Child 1 ~ 2 (age)	300			10		5		25	500		500			0.8		1.2		2.5	75		7		3		300		0.6		1.2	80		20	
3 ~ 5	300			10		6		30	600		500			1.0		1.5		3.0	100		7		4		380		0.8		2.0	90		25	
Male 6 ~ 8(age)	400			10		7		45	700		700			1.2		1.9		3.8	140		9		5		440		1.0		2.5	100		30	
9 ~ 11	550			10		9		55	800		1,000			1.5		2.3		4.7	200		12		7		570		2.0		3.0	120		40	
12 ~ 14	700			10		10		70	1,000		1,000			1.5		2.3		4.7	300		12		8		750		2.5		3.3	130		50	
15 ~ 19	850			10		10		80	1,000		1,000			1.5		2.3		4.7	400		16		10		870		3.0		3.5	140		60	
20 ~ 29	750			5		10		75	700		700			1.5		2.3		4.7	340		10		10		800		3.5		3.5	150		50	
30 ~ 49	750			5		10		75	700		700			1.5		2.3		4.7	350		10		9		800		3.5		3.5	150		50	
50 ~ 64	700			10		10		75	700		700			1.3		2.0		4.7	350		10		9		800		3.0		3.5	150		50	
65 ~ 74	700			10		10		75	700		700			1.2		1.8		4.7	350		10		9		800		3.0		3.5	150		50	
75 이상	700			10		10		75	700		700			1.1		1.6		4.7	350		10		8		800		3.0		3.5	150		50	
Female 6 ~ 8(age)	400			10		7		45	700		600			1.2		1.9		3.8	140		9		5		440		1.0		2.3	100		30	
9 ~ 11	500			10		9		55	800		900			1.5		2.3		4.7	200		12		7		570		2.0		2.5	120		40	
12 ~ 14	650			10		10		65	900		900			1.5		2.3		4.7	280		12		7		750		2.5		2.8	130		50	
15 ~ 19	700			10		10		65	900		800			1.5		2.3		4.7	340		16		9		870		2.5		3.0	140		60	
20 ~ 29	650			5		10		65	700		700			1.5		2.3		4.7	280		14		8		800		3.0		3.0	150		50	
30 ~ 49	650			5		10		65	700		700			1.5		2.3		4.7	280		14		8		800		2.5		3.0	150		50	
50 ~ 64	600			10		10		65	800		700			1.3		2.0		4.7	280		9		8		800		2.5		3.0	150		50	
65 ~ 74	600			10		10		65	800		700			1.2		1.8		4.7	280		9		7		800		2.5		3.0	150		50	
75 이상	600			10		10		65	800		700			1.1		1.6		4.7	280		9		7		800		2.5		3.0	150		50	

Pregnancy	+70	+5	+0	+0	+300	+0	+0	+0	+0	+40	+10	+2.5	+130	+0	+0	+90	+4
Lactation	+500	+5	+3	+0	+400	+0	+0	+0.4	+0.4	+0	+0	+5.0	+450	+0	+0	+180	+11

* Adequate Intake: In the absence of recommended intake, AI should be calculated on the basis of dietary reference intakes of healthy individuals from epidemiological study

[Annexed the Table 4] Application Table for Testing Methods

Testing item	Testing methods	Reference
Moisture	10. General testing methods 1. General component methods 1) moisture ※ Ⅱ.2.7.1 For Royal jelly (3) Corresponding for Karl Fischer method	Korea Food Code
Ash	10. General testing methods 1. General component methods 2) ash	
Crude fat	10. General testing methods 1. General component methods 4) Lipid (1) Crude fat	
acid value	10. General testing methods 1. General component methods 4) Lipid (3) Chemical testing methods ① acid value	
Peroxide value	10. General testing methods 1. General component methods 4) Lipid (3) Chemical testing methods ⑤ peroxide value	
Reducing sugar	10. General testing methods 1. General component methods 5) Carbohydrate (1) Sugar ② reducing sugar	
Tar	10. General testing methods 5. Colorant testing methods	
Lead, Cadmium	10. General testing methods 6. Testing Methods of Harmful Metal 1)Preparation of Test solution 2) measurement (1) Automic Absorption Spectrophtometry or (2) ICP	
Total Mercury	10. General testing methods 6. Testing Methods of Harmful Metal 3) Test of each metal (5) mercury	
Total aerobic Counts	10. General testing methods 8. Testing methods of microorganism 2) Total aerobic counts (General aerobic counts)	
Coliforms	10. General testing methods 8. Testing methods of microorganism 5) Coliforms	
Coliforms	10. General testing methods 8. Testing methods of microorganism 6) Coliforms	
Salmonella	10. General testing methods 8. Testing methods of microorganism 13) Salmonella	
Bacterial growth	10. General testing methods 8. Testing methods of microorganism 16) Bacteria (Bacterial growth test)	
Dextrose equivalent (D.E.)	5. Standards and specifications by food type 6. Glucose 6) Testing methods of microorganism (1) Dextrose equivalent (D.E.)	
Methanol	5. Standards and specifications by food type 27-1 Takju 6) Testing methods of microorganism (3) Methanol	
Solvent residues	4. Specification and Standards B. Natural Additives 80. Oleoresin Paprika	Korea Food Additives Code
Solvent residues (Isopropanol)	4. Specification and Standards B. Natural Additives 108. Glucomannan	