

Japanese Legislation on Nutrition and Health Products: The Regulatory Issues and Products on Japanese Market

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National Health Policy in Japan

1 st	Health check in nation-wide Public Health Center in all the districts Station Nutritionists, Public Health Nurse	1978 -
2 nd	Promotion of regular exercises	1988 -
3 rd Health Japan 21	Prevention of diseases Healthcare and Health Promotion Setting of Health Measures Promotion of rational exercises	2000 -
4 th Health Promotion Law etc.	Prevention of life-style related diseases Recognized FOSHU as the important food	2005 -

1952 – 1991 = before FOSHU implemented

1952 -

Health Improvement Law: Nutrients supply, esp. for infants, pregnant women, patients, etc.

1960 -

Pharmaceutical Affairs Law

Medical drugs are defined as such materials that used for diagnosis of diseases of human and animal, and for prevention and/or treatment of diseases of human and animal.

1971 -

Prohibition of non-approved medicals: components, efficacy, uses, etc.

1984 -

Initiation on Special Program on Functional Foods (MEXT):
Labeling of 3 functions of foods

1989 -1990

Study Reports on Functional Foods: Amendments of Health Improvement Law to include foods with functional claims

Foods

- 1) Nutrients = keeping life activity
- 2) Taste = enjoyments, sensory components
- 3) Physiological function = keeping health

biological activity

biodefence (immunological activity)

recovery from disease

prevention of disease

anti-ageing activity

etc.



FOSHU

1991- present = after FOSHU implemented

1991-

Amendment of Health Improvement Law: Start labeling of foods with functional claim

2001 -

Start of system of foods with functional claim: FOSHU was included in the system

2002 -

Health Promotion Law: FOSHU labeling was clearly stated in the law

2003 -

Food Safety Basic Law: established systematic foods safety

2005 -

Amendment of Health Promotion Law: expanded to 4 kinds of FOSHU; Regular FOSHU, Qualified FOSHU, Standardized FOSHU, Reduction of disease risk FOSHU

Peoples can live longer

Male			Female		
Country	Health Age Span	Ave. Life Span	Country	Health Age Span	Ave. Life Span
Japan	71.9	77.6	Japan	77.2	84.3
		(6.7)		(7.1)	
Sweden	71.2	77.1	France	76.9	83.6
Australia	70.8	76.8	Monaco	76.3	83.6
Greece	70.5	75.6	Spain	75.7	83.1
Italy	70.0	76.2	Australia	75.5	83.2
Canada	70.0	76.2	Swiss	75.5	83.0
Spain	69.8	75.3	Italy	75.4	82.1
UK	69.7	74.5	Andra	75.2	82.2
Swiss	69.5	75.6	San Marino	75.0	82.0
France	69.3	74.9	Sweden	74.9	81.9

(2004)

Drugs vs. Foods

The most difficult hurdle to clear to obtain FOSHU approval was **Pharmaceutical Affairs law** and still is.

Basic concept is “medicine first” and “no or little attention to foods and food ingredients”.

The risk reduction of factors for diseases was not allowed fully as yet to label in Japan that has been allowed by FAO/WHO standard and codex.

Concepts of Drugs and Foods

医食同源

I-shoku dogen

The idea, deriving from ancient China, that the same principles underlie a normal diet and medical treatment.

However, it is always considered that “medicine” is much superior to “food”.

Medical doctors are considered as more respectful and superior than food scientists in Japan or else.

Food with Health Claims (FHC)

FHC refer to foods that comply with the specifications and standards established by the Minister of Health, Labor and Welfare and are labeled with certain nutritional or health functions. These foods are categorized into two groups, according to differences in purpose and function:

a) Foods with Nutrient Function Claims (FNFC):
foods that are labeled with the functions of nutritional ingredients (vitamins and minerals)

b) Foods for Specified Health Uses (FOSHU):
foods officially approved to claim their physiological effects on the human body



FNFC refers to all food that is labeled with the nutrient function claims specified by the MHLW. The standards and specifications for indication of nutritional function have been so far established for 17 ingredients (12 vitamins and 5 minerals).

These foods may be freely manufactured and distributed without any permission from or notification to the national government, provided that it meets the established standards and specifications.

Standards and Specifications

- Amount of nutritional ingredient in the recommended daily intake of the product must be within the specified range.
- Not only the nutrient function claims but also the warning indications must be displayed.

Example of description

Nutritional Ingredient

Niacin

Specified Range of nutritional ingredient of the advisable daily intake
3.3 ~ 60 mg

Function Claims

helps to maintain skin and mucosa healthy

Warning Indication

Increased intake of this product will not result in curing diseases nor promoting health. Please comply with the advisable daily intake.

Standard doses of FNFC

	Daily intake
Niacin	3.3 ~ 60 mg
Pantothenic acid	1.65 ~ 30 mg
Biotin	14 ~ 500 µg
Vitamin A	135 ~ 600 µg
Vitamin B ₁	0.30 ~ 25 mg
Vitamin B ₂	0.33 ~ 12 mg
Vitamin B ₆	0.3 ~ 25 mg
Vitamin B ₁₂	0.60 ~ 60 µg
Vitamin C	24 ~ 1000 mg
Vitamin D	1.5 ~ 5.0 µg
Vitamin E	2.4 ~ 150 mg
Folic acid	60 ~ 200 µg
Zinc	2.1 ~ 25 mg
Calcium	210 ~ 600 mg
Iron	2.25 ~ 10 mg
Copper	0.18 ~ 6 mg
Magnesium	75 ~ 300 mg

What are FOSHU ?

Medicines	Foods	
Medicines (include quasi-drug)	Foods with Health Claims	
	FNFC	FOSHU
	Other Foods (may include so-called functional foods)	

FOSHU: Foods for Specified Health Uses

FNFC: Foods with nutrient function claims

Food for Specified Health Uses (FOSHU)

FOSHU refers to foods containing ingredient with functions for health and officially approved to claim its physiological effects on the human body. FOSHU is intended to be consumed for the maintenance / promotion of health or special health uses by people who wish to control health conditions, including blood pressure or blood cholesterol. In order to sell a food as FOSHU, the assessment for the safety of the food and effectiveness of the functions for health is required, and the claim must be approved by the MHLW.



Seal for FOSHU Approval

Requirements for FOSHU Approval

- Effectiveness on the human body is clearly proven
- Absence of any safety issues (animal toxicity tests, confirmation of effects in the cases of excess intake, etc.)
- Use of nutritionally appropriate ingredients (e.g. no excessive use of salt, etc.)
- Guarantee of compatibility with product specifications by the time of consumption
- Established quality control methods, such as specifications of products and ingredients, processes, and methods of analysis

Additional FOSHU to Regular FOSHU

(1) Qualified FOSHU:

Food with health function which is not substantiated on scientific evidence that meets the level of FOSHU, or the food with certain effectiveness but without established mechanism of the effective element for the function will be approved as qualified FOSHU.

(2) Standardized FOSHU:

Standards and specifications are established for foods with sufficient FOSHU approvals and accumulation of scientific evidence. Standardized FOSHU are approved when it meets the standards and specifications.

(3) Reduction of disease risk FOSHU

Reduction of disease risk claim is permitted when reduction of disease risk is clinically and nutritionally established in an ingredient.

Approved FOSHU Products-1

◎Foods to modify gastrointestinal conditions (260)

Oligosaccharides, lactose, bifidobacteria, lactic acid bacteria, dietary fiber (ingestible dextrin, polydextrose, guar gum, psyllium seed coat, etc.)

◎Foods related to blood cholesterol level (65)

Chitosan, soybean protein, degraded sodium alginate

◎Foods related to blood sugar levels (71)

Indigestible dextrin, wheat albumin, guava tea polyphenol, L-arabiose, etc.

◎Foods related to blood pressure (84)

Lactotripeptide, casein dodecanepptide, tochu leaf glycoside (geniposidic acid), sardine peptide, etc.

◎ Foods related to dental hygiene (16)

Paratinose, maltotriose, erythritol, etc.

Approved FOSHU Products-2

◎Cholesterol plus gastrointestinal conditions,
triacylglycerol plus cholesterol (86)

Degraded sodium alginate, dietary fiber from psyllium
seed husk, etc.

◎Foods related to mineral absorption (45)

Calcium citrated malate, casein phosphopeptide, hem
iron, fructo-oligosaccharide, etc.

◎Foods related to osteogenesis (24)

Soybean isoflavone, MBP (Milk basic protein), etc.

◎Foods related to triacylglycerol (17)

Middle chain fatty acid, etc.

Approved FOSHU

Dietary fiber (180)

Lactic Acid Bacteria (91)

Peptides (Protein) (74)

Oligosaccharides (42)

Soybean related-materials (28)

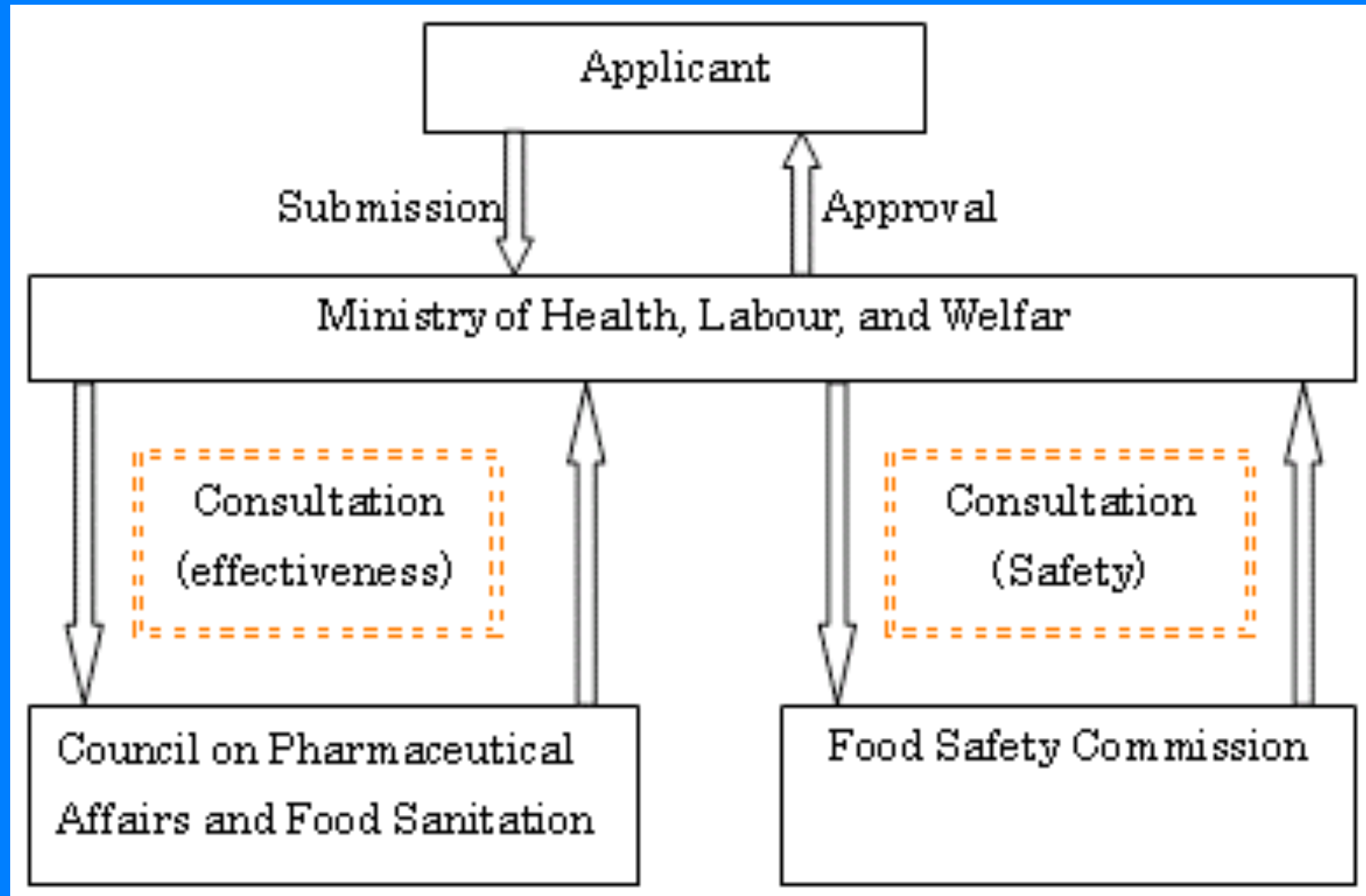
Bacillus subtilis (fermented soybean (3), Propionic acid bacteria (3),

Middle chain fatty acids (7), Sialglycerol (10), Alginates (12), Phytosterol (7), Chatechin (5), Chitosan (17), etc.

Approved Reduction of Disease Risk Claims

- **Calcium and Osteoporosis:** "Intake of proper amount of calcium contained in healthy meals with appropriate exercise may support healthy bones of young women and reduce the risk of osteoporosis when aged."
- **Folic Acid and Neural Tube Defect:** "Intake of proper amount of folic acid contained in healthy meals may support women to bear healthy baby by reducing the risk of neural tube defect, such as spondyloschisis, during fetal development."

Flow Chart of FOSHU Approval



Foods of Special Dietary Uses (FOFDU)

FOSDU refer to foods that are approved/permitted to display that the food is appropriate for specified dietary use. There are five categories of FOSDU:

- (1) Formulas for pregnant or lactating women
- (2) Infant Formulas
- (3) Foods for the elderly with difficulty in masticating or swallowing
- (4) Medical foods for the ill
- (5) Foods for Specified Health Uses (FOSHU)

Labeling System for Nutrient

Nutrition Labeling includes declaration of energy value and nutrients in accordance with the Nutrition Labeling Standards. The labeling is voluntary for all foods except foods with nutrition claims.

Labeling system for Nutrient and an example

Nutrition Labeling includes declaration of energy value and nutrients in accordance with the Nutrition Labeling Standards (hereafter referred to as the Standard). Nutrients covered in the Standards are protein, fat, carbohydrate, sodium, minerals and vitamins .

Minerals and Vitamins Covered in Nutrition Labeling

Minerals: Zinc, Potassium, Calcium, Chromium, Selenium, Iron, Copper, Sodium, Magnesium, Manganese, Iodine, Phosphorus

Vitamins: Niacin, Pantothenic Acid, biotin, Vitamin A, Vitamin B1, Vitamin B2, Vitamin B6, Vitamin B12, Vitamin C, Vitamin D, Vitamin E, Vitamin K, Folic Acid

The mandatory requirements under the Standards:

List of Nutrients:

Biscuit

Nutrition Labeling
Per serving size (75g)
Energy 390 kcal
Protein 5.3 g
Fat 19.1 g
Carbohydrates 49.1 g
Sodium 311 mg
Calcium 20 mg

- Energy value, and the amount of protein, fat, carbohydrate, and sodium are mandatory and must be declared in this order.
- The amount of any other nutrient (e.g. calcium) should be declared after sodium.
- The numerical information should be given in a certain value or in a range of upper and lower limits (XXg~XXg) expressed in per 100g, per 100ml, per package, or per serving,

Nutrient Content Claims

(1) Possible expression for high in XX, etc

- a) High: "high", "many", "rich in", and other similar expressions.
- b) Contain: "source of", "provides", "contains", "in", "used", "added", and other similar expressions.
- c) Enhanced: Used when a nutrient is enhanced compared to other similar food.

In order to display statements above, the amounts of nutrients must be equal or greater than the standard value.

(2) Possible expression for low XX, etc.

- a) Not contained: "none", "zero", "non-", and other similar expressions.
- b) Low: "low", "less", "a little", "light", and other similar expressions.
- c) Reduced: Used when nutrients is reduced compared to other similar food.

In order to display statements above, the amount of nutrients must be equal or lesser than the standard value.

Prohibition of Misleading or Deceptive Labeling Claims

(under Health Promotion Law)

Any claims of efficacy and function made on functional food must be relevant and based on scientific ground.

Advertisements are used in different media, such as internet, to promote food sales. Some are advertised to convey positive effects on health maintenance and promotion not necessarily having scientific evidence on the claim. When these advertisements are not regulated and uncontrolled, consumers who believed the claim might miss an opportunity for an adequate medical constitution, resulting in adverse affect on health. Under Paragraph 2, Article 32 of the Food Promotion Law, exaggerated and misleading claims are prohibited.

Flows of checking labeling

Products sold as food are prohibited to have label related to health maintenance and promotion that is (1)eminently inconsistent with evidence or (2)eminently misleading.



When the claim has a potential to influence public health, recommendation to take appropriate action is made by the Minister of MHLW or the General of Regional Bureau of Health and Welfare.



When appropriate measures are not taken following recommendation, the order to take appropriate action is made by the Minister of MHLW or the General of Regional Bureau of Health and Welfare.



Not conforming to the order results in penalty charges (imprisonment of up to 6 months or a fine not exceeding 1 million yen).

Strategy for FOSHU by Y Company

Intestinal Balance



Difficult to challenge to a new area



Almost Impossible to propose new lactic acid bacteria



An easy-going but steady strategy
Probiotics with complete safety tests for
obtaining an approval for FOSHU

Requirements for FOSHU(1)

- 1, The said foods and components improve the dietary life and sustain & improve human health
- 2, Their nutritional and/or medical claims must have science-based evidences**
- 3, As to the foods and components involved, the amounts to be taken must be set based on nutritional and/or medical science-based evidences
- 4, The Foods and components must be safe proved by attached descriptions
- 5, The components involved must clarify and provide the followings, except having rational reasons for not having them
 - a) Physico-chemical and biological characteristics and the methods for testing them
 - b) Qualitative and Quantitative Analytical methods

Requirements for FOSHU(2)

6, The said foods must not be ones that lost or altered their normal equivalent nutrients

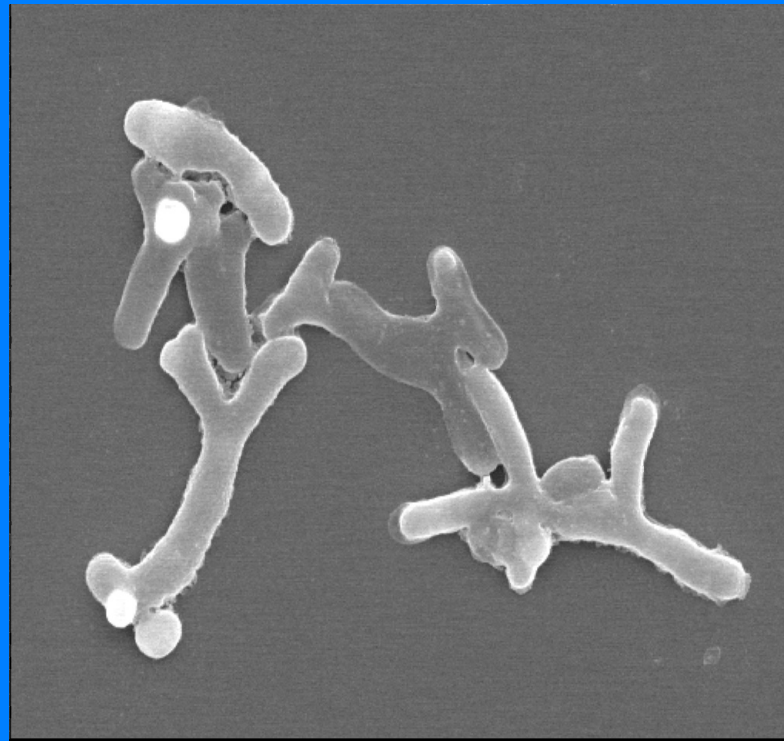
7, The said foods must be the ones that are not taken rarely, but taken regularly

8, The said foods and/or components must not be on the list issued by Ministry of Health and Labor in 1971 (notification (yakuhatu) 476)

Bacteria chosen for Development

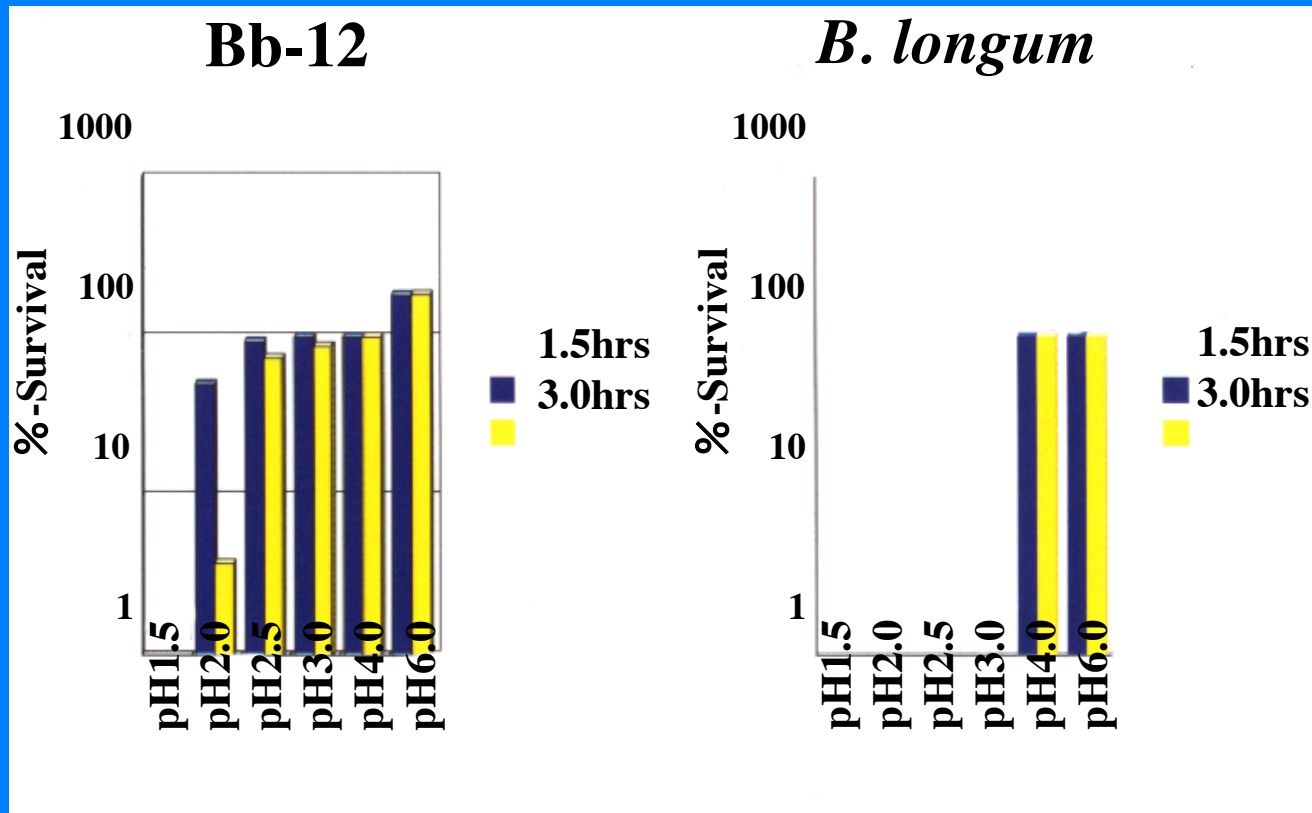
Bifidobacterium animalis subsp. *lactis*
(Bb-12)

From Chr. Hansen Co, but not approved as FOSHU



Physiological Functions-1

① Acid Tolerance, Tolerance to low pH



Chr. HANSEN
RESEARCH NEWS
Vo. 5, No.2, 2000

② Balancing intestinal microbiota

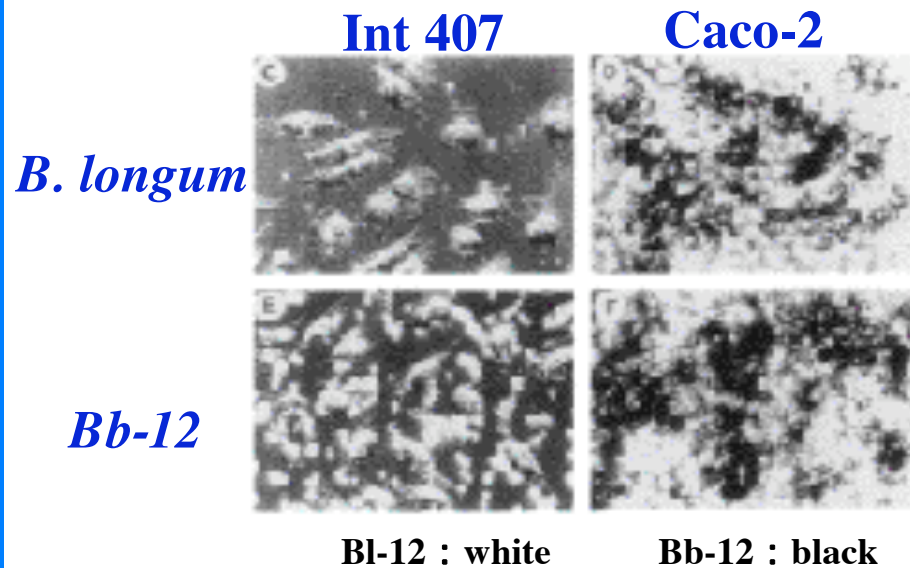
- Suppress diarrhea of infants
- Suppress infection of rota virus in infants

Physiological Functions-2

③ Fixation to intestinal mucosa

- Strong fixation to human intestinal cell-line Int 407 and Caco-2

Fixation of Bb-12 and *B. longum*

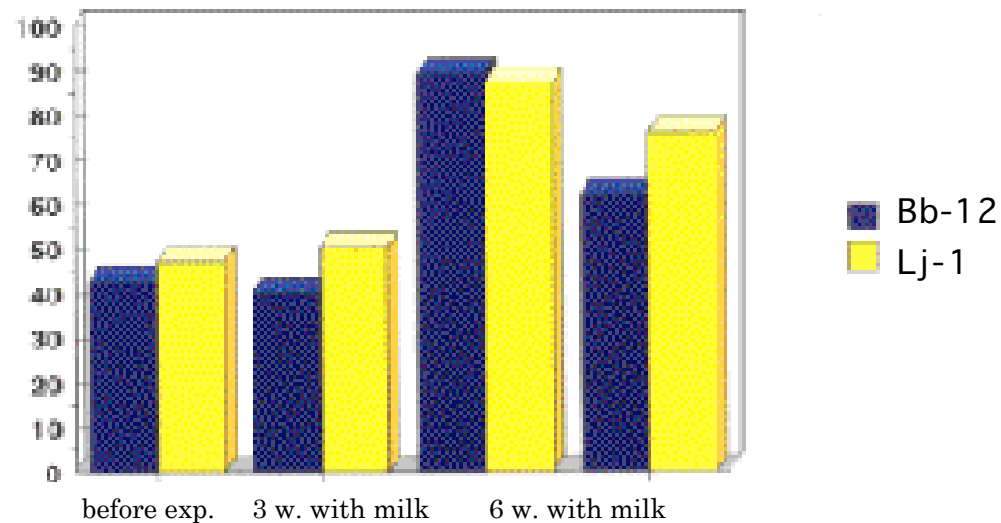


④Immuno- modulation

Physiological Functions-3

- **Enhanced phagocytosis**

Phagocytosis(%)



After 3 weeks giving fermented milk

After Schiffrin et al., 1995

- **Increase in IgA in intestine of infants**
- **Decrease in atopic skin inflammation in infants**

Requirements for FOSHU

~as to foods containing LAB~

1) safety of effective components (uses as diets or not)

- if not or little use as foods, acute toxicity, repeated administration, mutagenicity tests are required

2) effectiveness

- To placebo

significant increase in stool frequency

significant in Bifidobacteria population in stool

3) safety (overdose tests)

- effects when taken 3~5 times dosage of one day dose

4) stability of products

- stability of effective components within recommended period

5) reaching intestine

Human Intervention Trials

Safety test in animals



- 1) Helsinki Declaration
- 2) Ethical Committee
- 3) Under supervision of clinician
- 4) Test subjects are normal to semi-healthy persons
- 5) Double blind tests
- 6) Publication in scientific journals
- 7) Placebo must be taken as a control

Probiotics

“A live microbial feed supplement which beneficially affects the host animal by improving its intestinal microbial balance.”

(Fuller, 1989)、

vs.

“A live microbes beneficial to the host by improving intestinal microbita” (in Japan)

Requirements (by Mitsuoka, 2001)

- 1) safety ness
- 2) (a) members of intestinal microbiota
- 3) resistant to stomach juice and bile acid
- 4) live
- 5) effective to human and adhesion to intestine
- 6) maintain high viable counts in foods
- 7) inexpensive

Time Courses to obtain an approval

2002.11 – 12	Human trials (effectiveness)
2003.6 – 7	Human trials (safety) Scientific papers, stability tests of the products
2004.6	Submitted application
2004.9	Rejected (not significant with stool frequency)
2004.10 – 12	2 nd Human trials (effectiveness)
2004.11 – 12	2 nd Human trials (safety)
2005. 6	Submitted application again再申請
2005.11	Labeling approved (FOSHU)

Requirements fulfill regular FOSHU

Yoghurt containing Bb-12 ($>10^7$ CFU/g) intake

- Bifidobacteria population in stool has significantly increase
- Significant increase in stool frequency was observed compared to placebo intake
- Excess intake did not give mal-effect to digestive system



Approved to label “FOSHU”



FOSHU (in this example)

Product name

「Yoghurt」

Effective component

Bifidobacterium lactis Bb-12

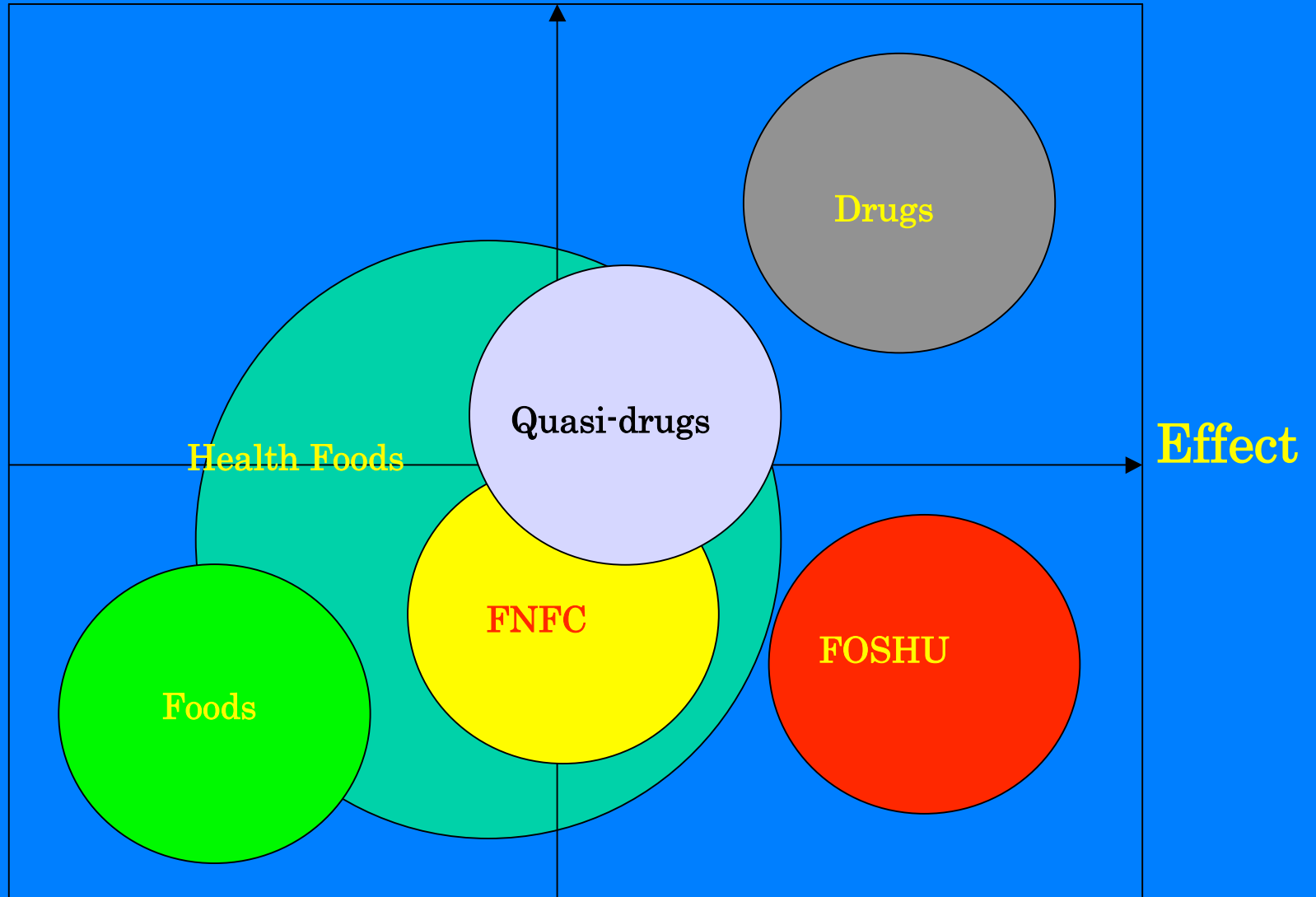
Labeling approved

“A live *Bifidobacterium* Bb-12 reaches intestine and improve intestine environments, and thus achieve balance of intestinal activity.”



Concept map of foods and drugs

Adverse Effect



Regulatory Issues and Products in Japan

Health Promotion
Law

Food for Special Dietary
Uses (FOSDU)

- ⊙ Medical foods for the ill
- ⊙ Formulas for pregnant or lactating women
- ⊙ Infant Formulas
- ⊙ Foods for the elderly with difficulty in masticating or swallowing

Foods for Specified
Health Uses (FOSHU)

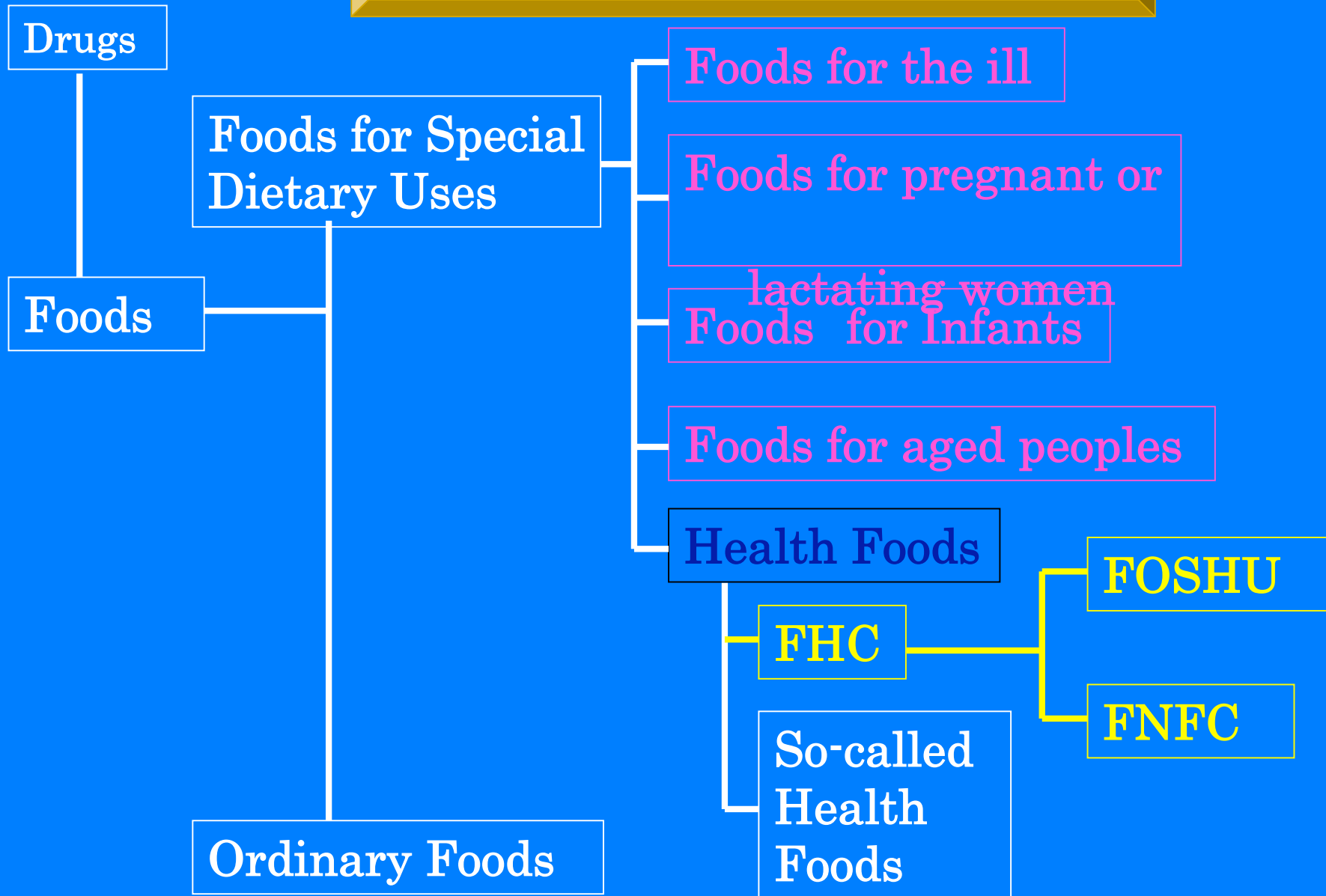
Foods with Nutrient
Function Claims
(FNFC)

Food with Health Claims (FHC)

Food Sanitation Law

Food Safety Basic Law

Drugs and Foods in Japan



Regulations concerning FOSHU

Food Sanitation Law

Food Safety Basic Law

Health Promotion Law

Basic Law on Food, Agriculture and Rural Areas

Law concerning Standardization and Proper Labeling
of Agricultural and
Forestry Products

The Consumer Protection Fundamental Act

Act against Unjustifiable Premiums and Misleading
Representations

Pharmaceutical Affairs Law

Foods vs. Drugs

The most difficult hurdle to clear to obtain FOSHU approval is
Pharmaceutical Affairs law.



Distinction between
medical drugs and Foods

Thank you for your attention !!

Kiitos !