



# **Regulations/Guidelines Relating to Functional Foods in Japan**

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# Chronology of Regulations/Guidelines on Nutrition and Health Claims in Japan

**1991 : Foods for Specified Health Uses (FOSHU)**

**1995 : Nutrition Labeling Standards**

**1997-2001 : Deregulation on Vitamins, Minerals,  
Herbs and Amino acids for Food  
(Supplement) Use**

**2001 : Foods with Nutrient Function Claims (FNFC)**

**2003 : Food Safety Commission**

**2005 : Amendment of FOSHU (Standardized, QHC  
& Disease Risk Reduction Claims)**

**2009-10 : Consumer Affairs Agency, Roundtable on  
Health Claims on Health Foods incl.**

**FOSHU**



## Foods for Special Dietary Uses

(Regulated under the Health Promotion Act)

- **Standardized Formula**
- **Product-specific Approvals**

**Foods for patients (medical purposes)**

**Foods for pregnant and lactating women**




**Foods for infants**

**Foods for dysphagia patients**

**Foods for Specified Health Uses (FOSHU) (1991)**

# Foods with Health Claims

(2001: Rev. in 2005)

<p>Drugs (including quasi-drugs)</p>	<p><b>Foods for Special Dietary Uses</b></p> 	<p><b>Foods with Nutrient Function Claims (FNFC, 2001)</b></p> <p><b>Standardized formula/labeling system</b></p> <p><b>12 vitamins</b> <b>5 minerals</b></p> <p>Nutrition facts Nutrient function claims Warning Statements</p>	<p><b>Foods for Specified Health Uses (FOSHU, 1991)</b></p> <p><b>Product-specific approval system</b></p> <ol style="list-style-type: none"> <li><b>FOSHU</b></li> <li><b>Qualified FOSHU</b></li> <li><b>Standardized FOSHU</b></li> <li><b>Reduction of Disease Risk FOSHU</b></li> </ol>  <p>Nutrition facts Health claims Warning statements</p>	<p><b>[Unregulated]</b></p> <p>All other types of food (including the majority of so-called health foods)</p>  <p>Nutrition facts only</p>
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# Introduction of Nutrient Function Claims

## Foods with Health Claims (FHC)

Foods for Specified Health Uses (FOSHU) (1991)

**Foods with Nutrient Function Claims (FNFC) (2001)**

**Definition:** Foods that are intended to provide or supplement necessary nutrients and to describe the physiological role of the nutrients in normal growth and development or preserving health of the body.

- **MHLW Pre-authorized Nutrient Function Claims**
- **Min. & max. daily dose levels for each nutrient specified**
- **No pre-marketing permission/notification required**

# Authorized Nutrient Function Claims (1)

NUTRIENTS	Min./Max. per Day	NUTRIENT FUNCTION CLAIMS
Vitamin A ( $\mu\text{g}$ )	135 600	<p>A nutrient which helps maintain vision at night</p> <p>A nutrient which helps maintain healthy skin and mucosa</p>
Vitamin D ( $\mu\text{g}$ )	1.50 5	<p>A nutrient which promotes absorption of calcium and aids in the development of bone</p>
Vitamin E (mg)	2.40 150	<p>A nutrient which helps protect fat in the body from being oxidized and helps maintain healthy cells</p>
Vitamin B1 (mg)	0.30 25	<p>A nutrient which helps produce energy from carbohydrate and helps maintain healthy skin and mucosa</p>
Vitamin B2 (mg)	0.33 12	
Niacin ( $\mu\text{g}$ )	3.3 60	

# Authorized Nutrient Function Claims (3)

NUTRIENTS	Min./Max. per Day	NUTRIENT FUNCTION CLAIMS
<b>Calcium</b> (mg)	<b>210</b> <b>600</b>	<b>A nutrient which is necessary in the development of bone and teeth</b>
<b>Iron</b> (mg)	<b>2.25</b> <b>10</b>	<b>A nutrient which is necessary for red blood cell formation</b>
<b>Zinc</b> (mg)	<b>2.10</b> <b>15</b>	<b>A nutrient which is necessary to maintain the normal function of the sense of taste</b> <b>A nutrient which helps maintain healthy skin and mucosa</b> <b>A nutrient which is involved in the metabolism of protein and nucleic acid, and helps maintain good health</b>
<b>Copper</b> (mg)	<b>0.18</b> <b>6</b>	<b>A nutrient which helps red blood cell formation</b> <b>A nutrient which helps normal function of various enzymes in the body and development of bone</b>
<b>Magnesium</b> (mg)	<b>75</b> <b>300</b>	<b>A nutrient which is necessary in the development of bone and teeth</b> <b>A nutrient which helps normal function of various enzymes, helps generate energy, and is necessary to maintain normal blood circulation</b>

# Definition of FOSHU (2001)

## Foods with Health Claims (FHC)

### Foods with Nutrient Function Claims (FNFC)

- ◆ MHLW Pre-authorized Nutrient Function Claims
- ◆ No pre-marketing permission/notification required

## Foods for Specified Health Uses (FOSHU)

**Definition:** Foods that contain constituents that have science based specific health benefits on physiological functions or biological activities of the body, and to contribute to preserving or improving health or to other specified health uses.

- **Product-specific Claims**
- **Pre-marketing permission required for Claims based on Scientific Substantiation**



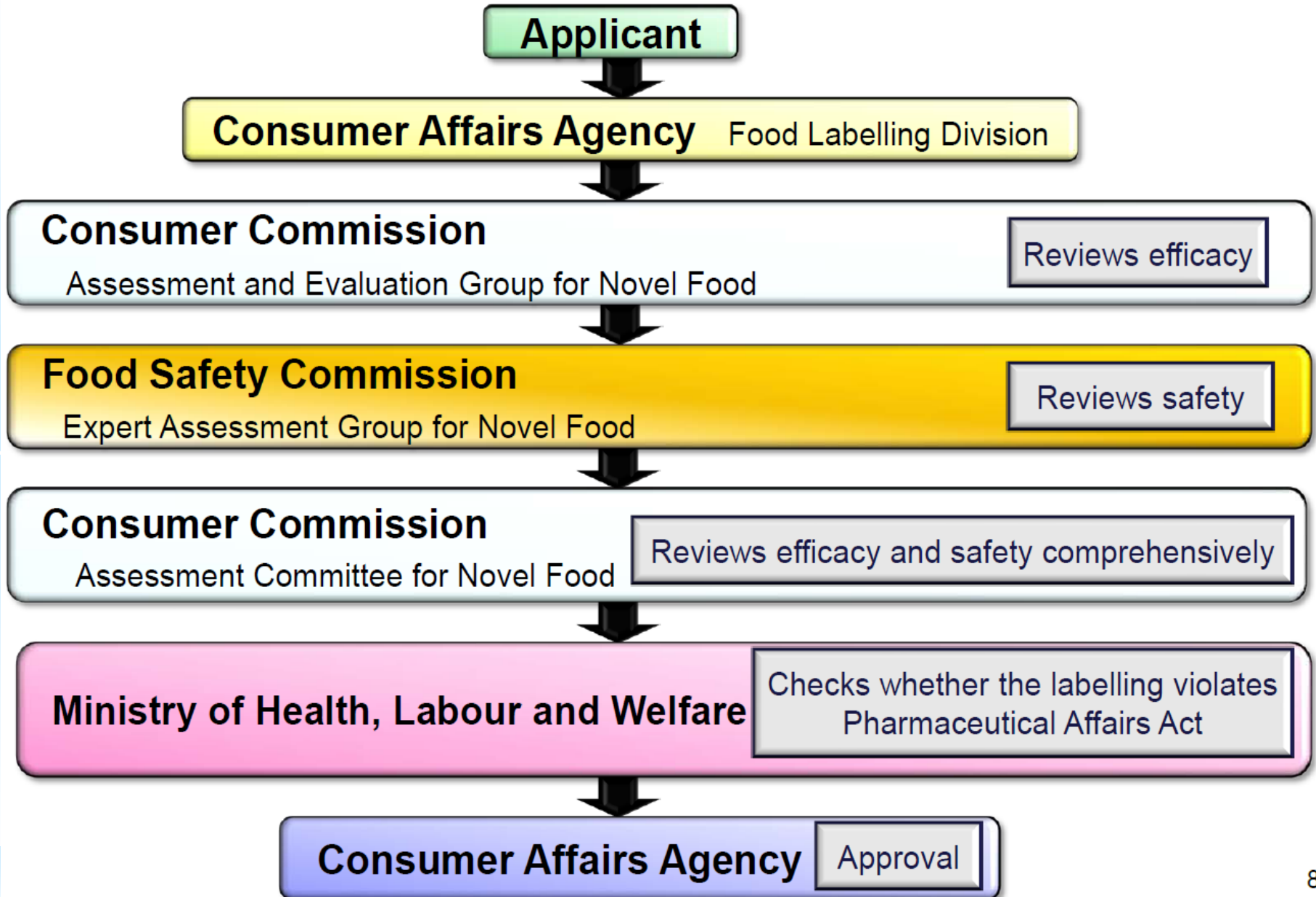
# Applicable Claims for FOSHU

- 1. Maintenance and improvement of clinical indices of physical conditions that can be easily measured**  
e.g. “Helps maintain normal blood glucose levels”  
“Helps promote decomposition of body fat”
- 2. Maintenance or improvement of good physical conditions and/or biological functions**  
e.g. “Helps regulate bowel movements”  
“Helps improve absorption of calcium”
- 3. Improvement of subjective and temporary, but not persistent or chronic, changes in physical conditions**  
e.g. “Helpful for those who feel physically fatigued”
- 4. Reduction of Disease Risk (later added in 2005)**  
e.g. “May reduce the high risk of osteoporosis”

# Evidence that must be included in the application material

1. Effectiveness :
  - The mechanism of the function itself or of the functions based on *in – vitro* and/or human clinical studies
  - Amount of intake
  - Scientific evidence for claiming of the specified health use
2. Safety :
  - Judged from history of safe use
  - Toxicity, long-term/excessive intake
3. Quality :
  - Physico-chemical properties of the functional component and analytical methods
  - Stability tests

# Procedure Flow for Foods for Specified Health Uses (FOSHU)



## Examples of Actual Claims Permitted (1)

<p><b>Dietary Fiber</b></p>	<p><b>This product contains dietary fiber to supplement fiber intake which tends to be insufficient in the daily diet. It helps maintain a comfortable gastro-intestinal condition and is suitable for those who are concerned about their gastro-intestinal condition.</b></p>
<p><b>Yogurt</b> <i>(Lactobacillus casei Shirota)</i></p>	<p><b>(company name)'s <i>lactobacillus casei Shirota</i> is alive when it arrives in the intestines. The <i>Shirota</i> strain helps increase good bacillus and decrease bad ones. This improves the gastro-intestinal environment and keeps the intestines healthy.</b></p>

## Examples of Actual Claims Permitted (2)

<p><b>Cooking Oil (Diacylglycerol)</b></p>	<p><b>The main component of this product is diacylglycerol. This is why, compared with other types of cooking oil, it restrains increase of postprandial serum triglycerol and body fat. (This product is recommended for maintaining one's good health and for those who tend to be overweight with higher level of cholesterol and body fat.)</b></p>
<p><b>Sterilized Lactic Acid Drink (Lacto-tripeptide)</b></p>	<p><b>This product is suitable for those who are concerned about their higher blood pressure.</b></p>
<p><b>Soft Drink (Milk base protein)</b></p>	<p><b>This product is suitable for those who are concerned about their bone health, as it contains MBP which helps increase bone mineral density.</b></p>

# FOSHU Amended in 2005

## 1. **Standardized FOSHU:**

Standardized Claims for 3 Dietary Fibers and 6 Oligosaccharides. No clinical efficacy study, but safety study on excessive consumption still required on a product basis

## 2. **Qualified Health Claims for FOSHU:**

Evidence (supporting data) is suggestive, but not conclusive

## 3. **Reduction of Disease Risk Claims for FOSHU:**

Calcium and osteoporosis, Folic acid and neural tube defects; No clinical efficacy study, but safety study on excessive consumption still required on a product basis

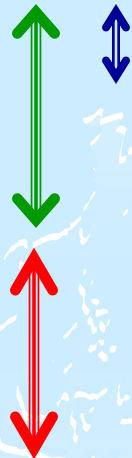
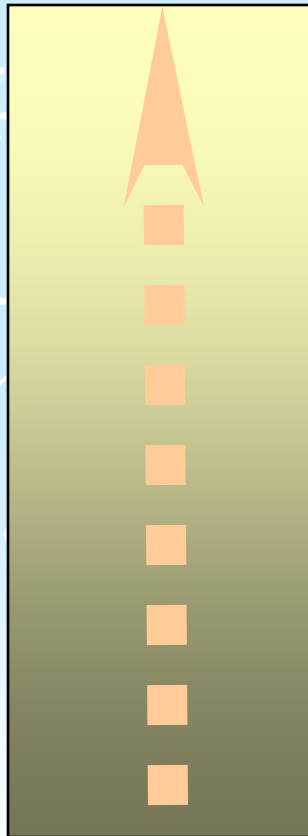
# Standardized FOSHU

Functional Ingredients		Recommended Daily Dose	Standardized Claims
<b>Dietary Fibre</b>	<b>Indigestible Dextrin</b>	3~8 g	As it contains (name of the functional ingredient), it helps regulate gastro-intestinal condition.
	<b>Polydextrose</b>	7~8 g	
	<b>Partially Hydrolyzed Guar Gum</b>	5~12 g	
<b>Oligo-saccharides</b>	<b>Soybean Oligosaccharides</b>	2~6 g	As it contains (name of the functional ingredient) and increases <i>bifidobacteria</i> , and thus helps maintain a good intestinal environment, it helps regulate gastro-intestinal condition.
	<b>Fructo-oligosaccharides</b>	3~8 g	
	<b>Lacto-sucrose</b>	2~8 g	
	<b>Galacto-oligosaccharides</b>	2~5 g	
	<b>Xylo-oligosaccharides</b>	1~3 g	
	<b>Isomalt-oligosaccharides</b>	10 g	

# Qualified Health Claims for FOSHU

## Continuum of Scientific Evidence

Strength of Scientific Evidence



**Scientific Consensus**

- **Significant Scientific Agreement**

- **Qualified Health Claims**

- **suggestive, but not conclusive**

- **limited and not conclusive**

- **very limited and preliminary**

- **highly unlikely/uncertain**

**Emerging Evidence**



## **Reduction of Disease Risk Claims**

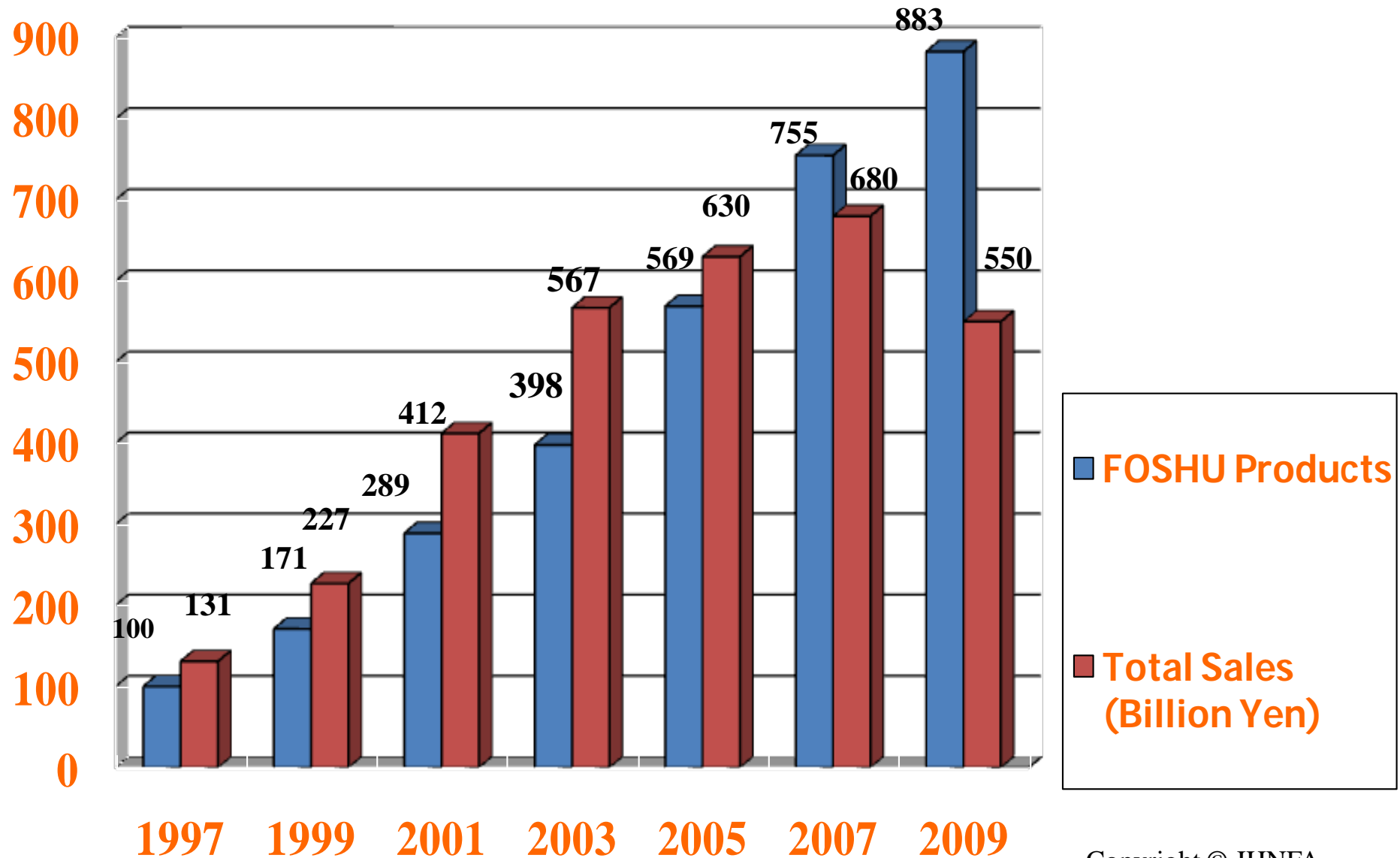
### **Calcium (300 to 700 mg per day) :**

**“This product is rich in Calcium. Regular exercise and a healthy diet with enough calcium helps young women maintain good bone health and may reduce their risk of osteoporosis later in life.”**

### **Folic acid (400 to 1,000 mcg per day) :**

**“This product is rich in Folic acid. Healthful diets with adequate Folic acid may reduce a woman’s risk of having a child with neural tube defects such as spinal cord defects.”**

# Foods for Specified Health Uses (FOSHU) Market



# Foods for Specified Health Uses (FOSHU)

## 955 Food Products Approved as of April 1, 2011

Health Claims	Functional Ingredients (Examples)	FOSHU products	Share
“Helps maintain good gastro-intestinal condition”	Oligosaccharides, Lactobacillus, Bifidobacterium, Dietary Fiber	<b>351</b>	<b>37%</b>
“Good for those who have high serum cholesterol / are concerned about serum triglycerides ”	Soy Protein, Peptides, Dietary Fiber, Plant Sterol / Stanol (Esters), Diacylglycerol, MLCT	<b>214</b>	<b>22%</b>
“Good for those who have high blood glucose levels”	Dietary Fiber, Albumin, Polyphenols, L-Arabinose	<b>141</b>	<b>15%</b>
“Good for those who have high blood pressure”	Peptides, Glucosides, Amino Acids	<b>120</b>	<b>13%</b>
“Helps maintain dental health ”	Xylitol, Polyols, Tea Polyphenols, CPP-ACP	<b>78</b>	<b>7%</b>
“Helps improve absorption of calcium minerals”	CPP, CCM, Oligosaccharides, Heme Iron, MBP, vitamin k <sub>2</sub>	<b>51</b>	<b>5%</b>
“Good for those who have bones health”	Soy Isoflavonoids		

# Mission of the Consumer Affairs Agency (CAA)

- ◆ Article 2 of the Consumer Basic Act sets out the state's role to protect consumer's right and support consumer's independence in the society where the consumer takes a lead for life with safety and security. The mission of the CAA is:
  - to protect and promote consumer's interest and benefit
  - to ensure the voluntary and rational choice of goods and services
  - to ensure fair labelling of the goods which is closely related with life of consumers.

# Roundtable on Health Claims

**Time period:** From November 2009 to July 2010

## Areas of Discussion

- Review current systems of Health Foods and identify areas in need of improvement
- Labelling systems of Food for Specified Health Uses (FOSHU) and other foods under Health Promotion Law
- Enforcement for appropriate labelling of Health Foods



## Final report released on August 27<sup>th</sup>, 2010

- **FOSHU Approval**
  - ✓ Improve approval process (e.g., speed, clarity, and transparency)
  - ✓ Improve labelling presentation of information (e.g., clear, accurate, and understandable)
- **Regulation of so-called “Health Foods”**
  - ✓ Develop Guidelines for tightening regulatory control on False and misleading labelling
  - ✓ Collect scientific evidence on targeted nutritional components for further discussion about authorization
- **Further issues**
  - ✓ Transfer some responsibilities of Consumer Affairs Agency to Consumer Commission (e.g., Discussion on standards of suspension and expansion of regulation)





厚生労働省許可

# 特定保健用食品《トクホ》

Foods for Specified Health Uses (FOSHU)



*Thank you for your attention!!*