

Regulatory Systems of Health Claims in Japan

June, 2011

Consumer Affairs Agency
Food Labelling Division

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.

Organization chart

Division

General Affairs Division

Policy Coordination Division

Policy Planning and International Affairs Division

Consumer Information Division

Local Cooperation Division

Consumer Safety Division

Commercial Business and Price Regulation Division

Representation Division

Food Labelling Division

<I. Planning and Coordination>
Policy planning and coordination function for the resolution of consumer –related troubles.

<II. Enforcement>
Administrative work to enforce CAA's duties/jurisdictions

Prime Minister

Minister of State for Consumer Affairs

Senior Vice-Minister

Parliamentary Secretary of Cabinet Office

CAA

Secretary General

Deputy Secretary General

Director General (2)

Counselor (2)

Relationships among Japanese Agricultural Standards Law (JAS), Food Sanitation Act, and Health Promotion Act

JAS:

Law Concerning Standardization and Proper Labelling of Agricultural and Forestry Products

To help consumers for better food choice

Ingredient lists

Origin of foods

Food Sanitation Act

For safety and security of food

Food allergens

Food additives

Statement of identity

Expiration date

Storage condition

Genetically modified foods

Manufacturer's name and address

Health Promotion Act (Nutrition Labelling and Health Claims System)

For improvement of nutritional status and promotion of health

Health Foods : Category Foods

Pharmaceuticals

Health Foods

So-called "Health Foods"

- Dietary supplements
- Other health related products etc
- Prohibited to indicate Health Claims or Function Claims

Food With Nutrient Function Claims

- Vitamins & Minerals
- Allowed to indicate Claims for Nutrient Function

Food for Specified Health Uses (FOSHU)

- Dietary fibers
- Oligosaccharides
- Isoflavones etc
- Allowed to indicate Claims for Specified Dietary Uses



Food for Special Dietary Uses (FOSDU)

For patients
For pregnant and lactating women
For infants
For dysphagia patients

- Low protein food
- Lactose-free food
- Infant formula etc
- Allowed to indicate Claims for Special Dietary Uses



- Prescribed drugs
- Over-the-Counter drugs

Food With Nutrient Function Claims

12 Vitamins: Niacin, Pantothenic acid, Biotin, Vitamin A, Vitamin B₁, Vitamin B₂, Vitamin B₆, Vitamin B₁₂, Vitamin C, Vitamin D, Vitamin E, and Folic acid

5 Minerals: Zinc, Calcium, Iron, Copper, and Magnesium

Vitamin B₁

Vitamin B₁ is a nutritional element that assists in the production of energy from carbohydrates and in maintaining the health of the skin and mucous membranes.

Vitamin E

Vitamin E is a nutritional element that has antioxidant effects that prevent oxidation of lipids in the body and helps maintain cellular health.

Calcium

Calcium is a nutritional element necessary for bone and tooth formation.

Iron

Iron is a nutritional element necessary for red blood cell formation.

Food for Special Dietary Uses (FOSDU)

FOSDU

➤ approved to label that the food is appropriate for uses to maintain health and/or recover from diseases, particularly in infants, young children, pregnant and lactating women, and patients.

➤ Categories

1. Medical uses for the diseased
2. Formulas for pregnant and lactating women
3. Infant formulas
4. Foods for the elderly with difficulty in masticating or swallowing
5. Foods for Specified Health Uses

➤ Requires approval from CAA in order to sell a food with FOSDU labelling

➤ Reviews

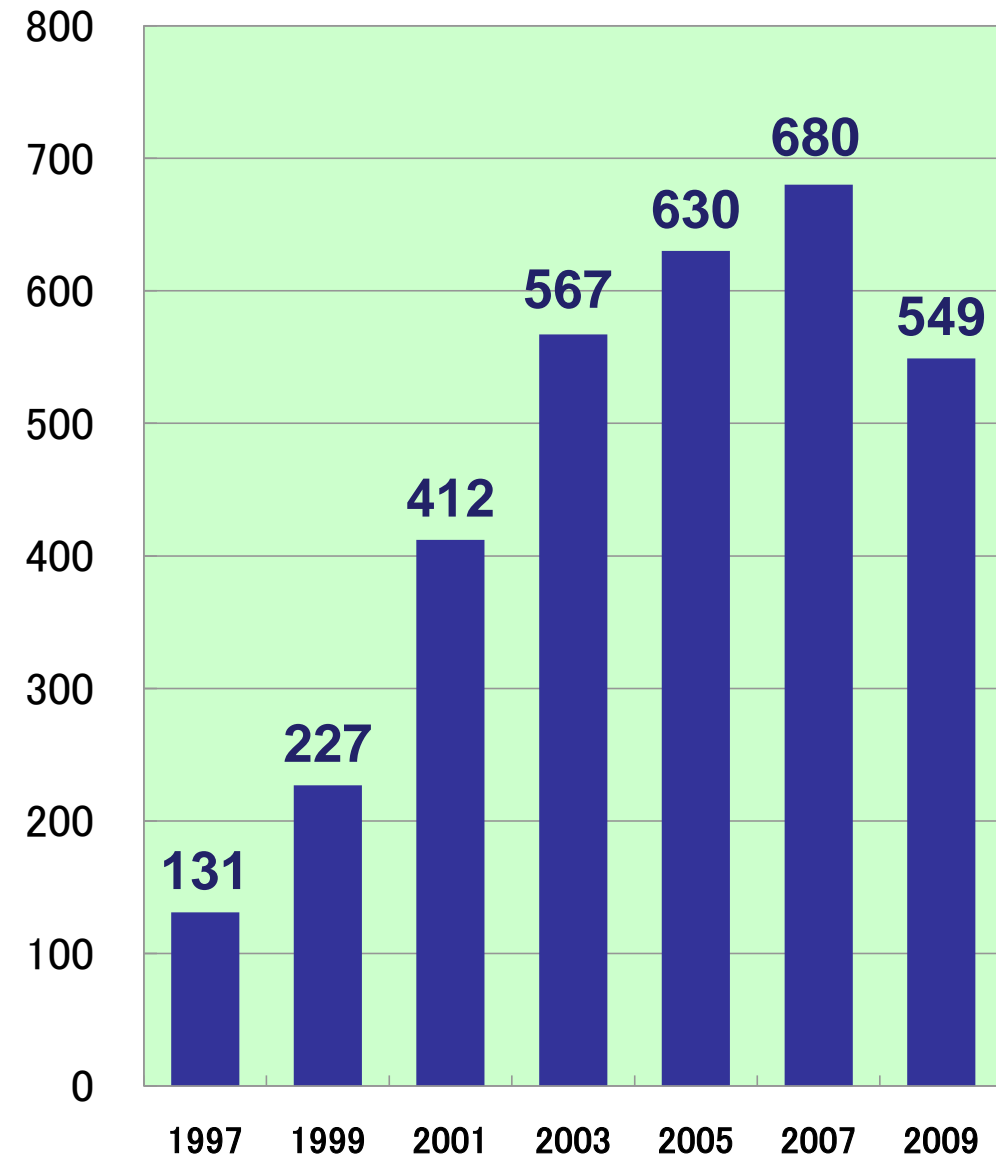
- Standard approval process: checks with the established standards for approval
- Individual approval process: reviews individually in cases of no established standards



Market share of Health Foods

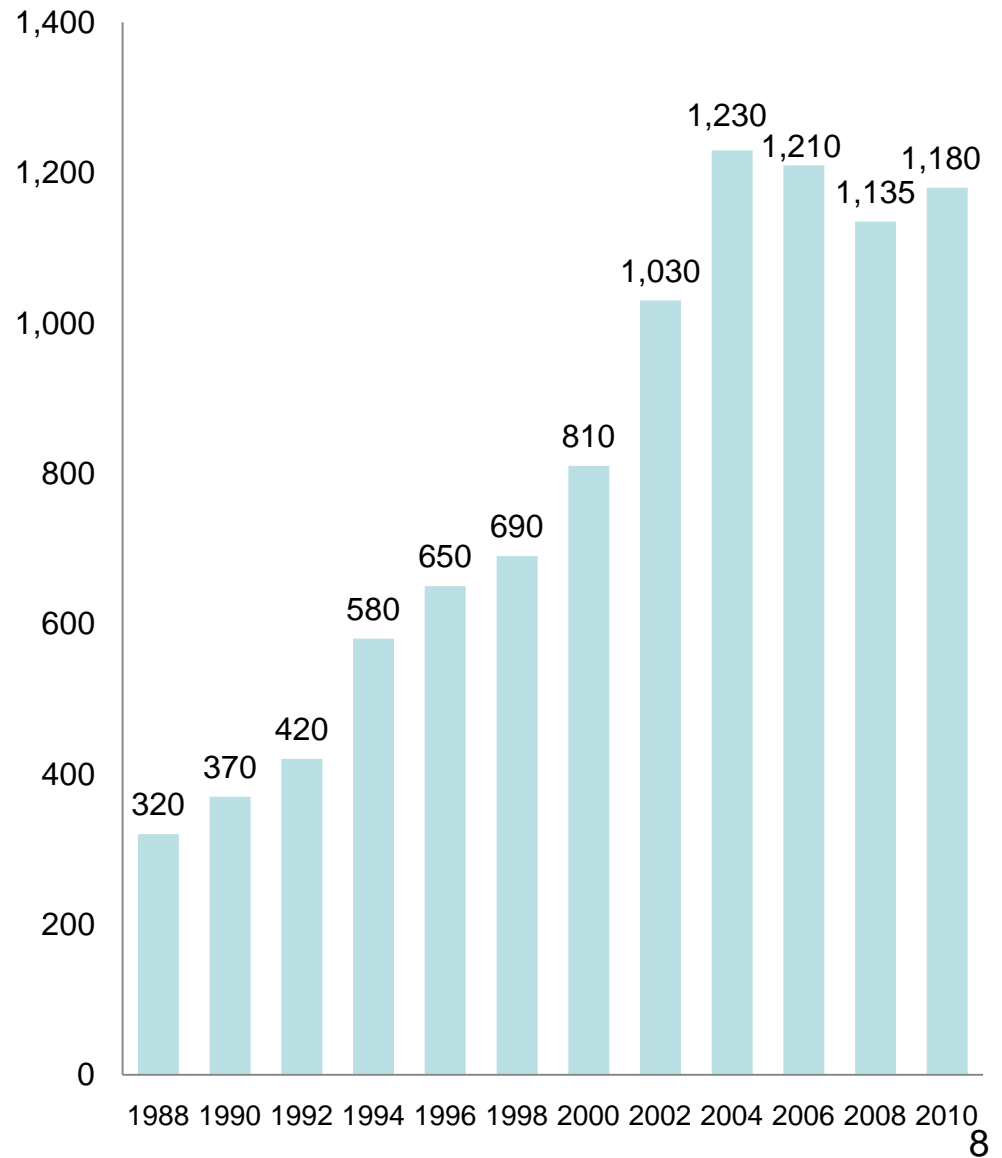
«Market Growth of Food for Specified Health Uses (FOSHU) Products»

(Billion Yen)

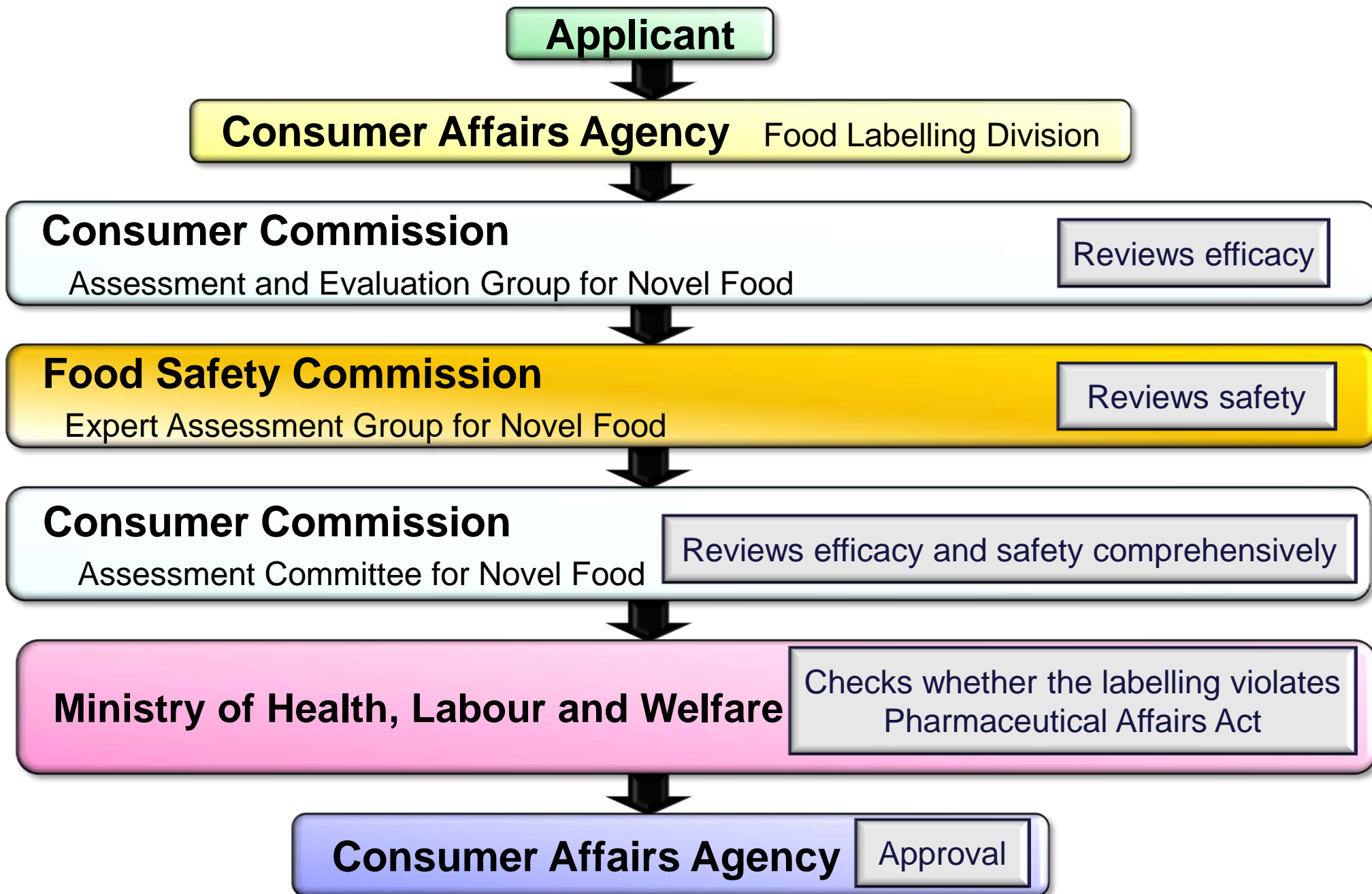


«Market Growth of other Health Foods (excluding FOSHU)»

(Billion Yen)



Procedure Flow for Food for Specified Health Uses (FOSHU)



Categories of Food for Specified Health Uses (FOSHU)

FOSHU

- Requires detailed review process with scientific evidence for each application.



Standardized FOSHU

- No requirement of detailed review process for food products meeting the established standards and specifications.
- Must be accompanied by sufficient accumulation of scientific evidence.
- For efficiency: short cut process for products whose safety of use already approved.



Reduction of disease risk FOSHU

- Requires detailed review process with scientific evidence for each application.
- Permitted for products whose ingredients clinically and nutritionally established to reduce a risk of certain disease (i.e., Calcium for Osteoporosis and Folic acid for neural tube defects).



Qualified FOSHU

- Requires detailed review process with scientific evidence for each application.
- Permitted for products with ingredients showing certain health effects but not reaching the established standards for FOSHU approval.
- Labelled as “Qualified Food for Specified Health Uses.”



Food for Specified Health Uses (FOSHU)

Required conditions for approval

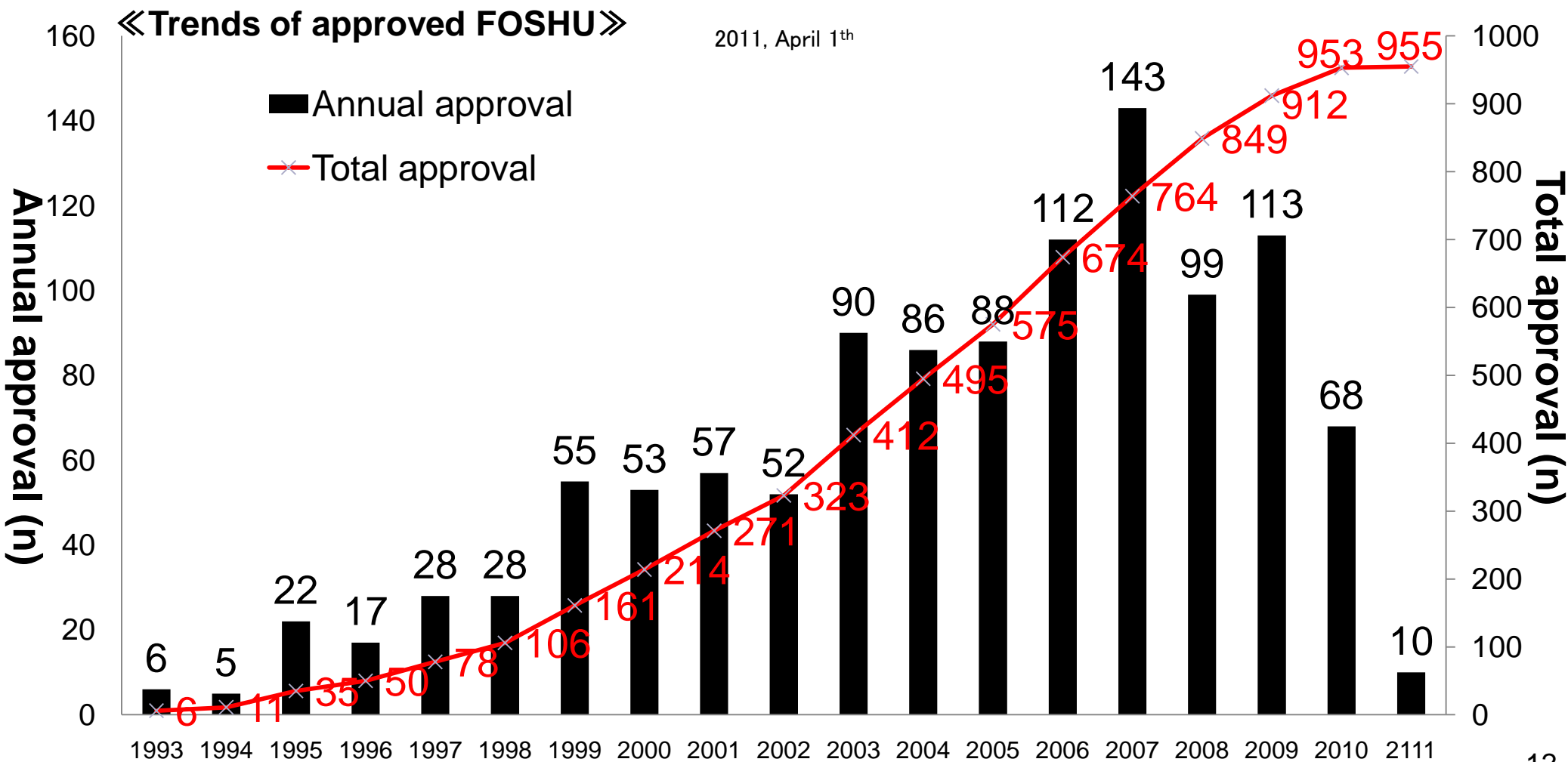
1. Improvement of dietary habits and contribution to health maintenance and enhancement can be expected by consuming the product.
2. Scientific evidence for the claimed health benefit is available.
3. Clinical and nutritional intake level of the product and/or its functional component is established.
4. The product and/or its functional component is safe for human consumption.
5. Following items regarding functional component are defined:
 - a) Physical, chemical, and biological characterization and its methods
 - b) Methods of qualitative and quantitative analytical determination
6. Nutrient constituent of same type of the food is not significantly changed
7. The food is intended to be consumed on a daily basis and not on rare occasions
8. The product or its functional component is not included in the medical drug list

Notification Shokuanhatsu 0201002, 2007 February 1

Food for Specified Health Uses (FOSHU)

- FOSHU refers to any food containing functional component which can provide positive effects on health condition or function^(※) and which is approved to make specific health claim on the food label.
- Currently, 955 foods are approved for FOSHU.

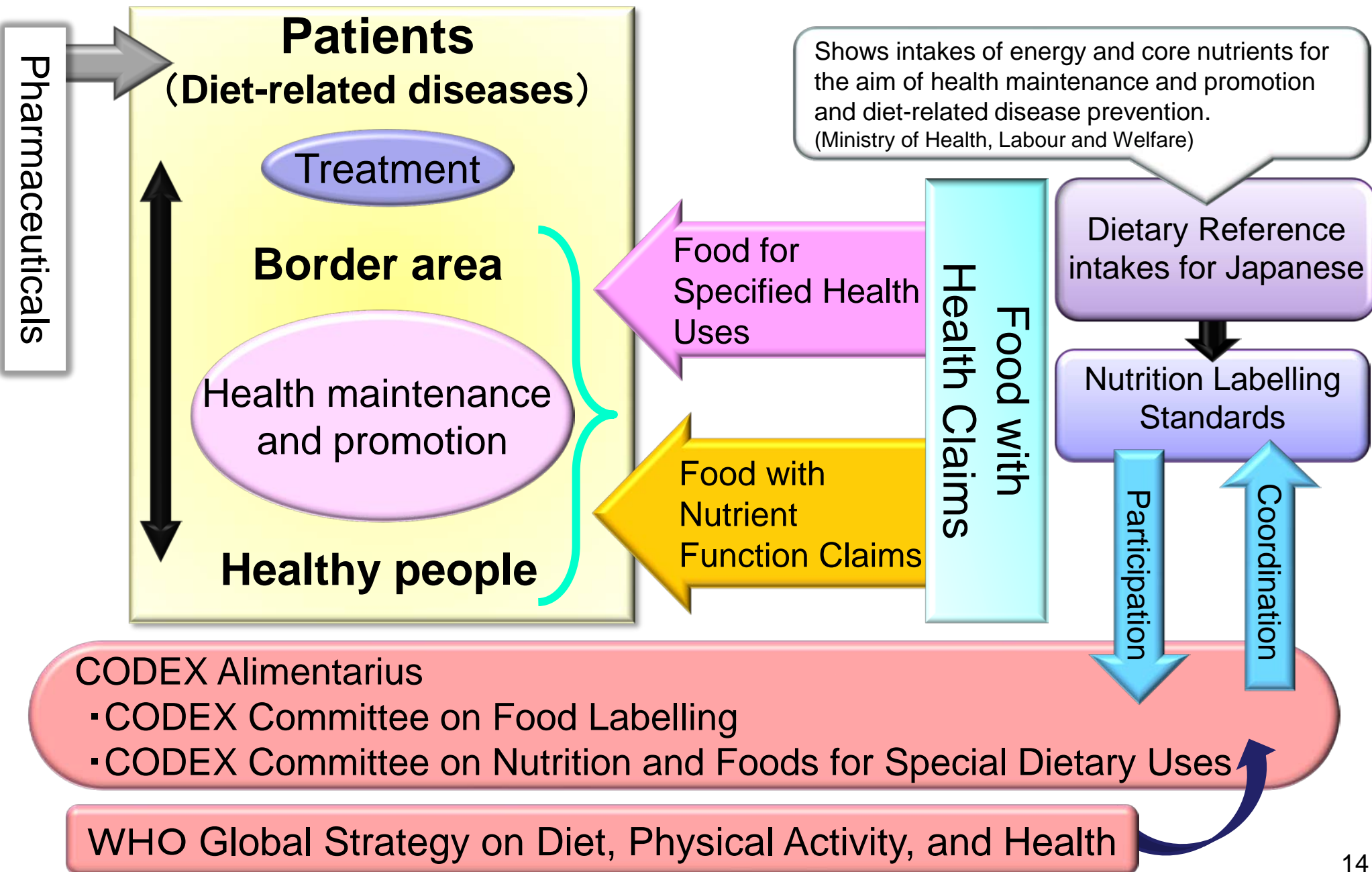
(※) e.g., lowers glucose level /support good bowel movement



Approved Health Claims on FOSHU

Health uses	Food category	Ingredients (Example)	Model Claim, statements	Number approved (As of 2011/04/01)
GI function	Table sugar	Oligosaccharides	<ul style="list-style-type: none"> ● Helps maintain good GI condition. ● Helps improve bowel movement. 	350
Cholesterol level	Powdered soft drink	Chitosan	<ul style="list-style-type: none"> ● Helps lower cholesterol level. 	142
Triacylglycerol Body fat	Refined oil	Medium-chain fatty acids	<ul style="list-style-type: none"> ● Helps resist body fat gain. 	70
	Oolong tea	Polyphenol	<ul style="list-style-type: none"> ● For those concerned about body fat. 	
Blood pressure	Instant powder soup, candy	Peptides	<ul style="list-style-type: none"> ● For those with high blood pressure. 	120
Bone	Soft drink	Soy isoflavone	<ul style="list-style-type: none"> ● Promotes calcium absorption. ● Supports bone health. 	53
Teeth	Chewing gum	Mixture of Xylitol, Calcium Monohydrogen Phosphate and Fukuronori extract	<ul style="list-style-type: none"> ● Helps maintain strong and healthy teeth 	79
Blood glucose level	Soft drink, Instant miso soup	Indigestible dextrin	<ul style="list-style-type: none"> ● For those concerned about blood glucose level. 	141

Consumer's health, dietary habits, and food labelling



Prohibition of False and Misleading Labelling

with respect to Health maintenance and Promotional effects

(Under Health Promotion Act, Articles 32-2 and 32-3)

Effective 2003/08/29

No person shall sell or advertise any prepackaged product containing a label in a manner that

- (1) substantially differs from the declared content or
- (2) likely fall into confusion

with respect to health maintenance or promotional effects



Advisory

Issued when the labelling may cause a significant negative impact on health maintenance and promotion of the public and/or on delivery of accurate information to the public.



Order

issued upon failure to comply with Advisory.



Enforcement action (Penalty, inspection, administrative detention, imprisonment, etc) imposed upon failure to comply with Order.

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 Act
- Enforcement for appropriate labelling of Health Foods



Final report released on August 27th, 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)
 - ✓ Start functional assessment of nutritional components found in foods