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# Regulatory Systems of Health Claims in Japan

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## 1. About Consumer Affairs Agency



# Consumer Affairs Agency (CAA)

- An external organ of the Cabinet Office
- Established on September 1, 2009

# Our mission

- 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 closely related with consumers' life

Prime Minister

Minister of State  
for Consumer Affairs

Senior Vice-Minister

Parliamentary Secretary  
of Cabinet Office

**CAA**

Secretary General

Deputy Secretary General

Director General (3)

Counselor

**<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

**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**

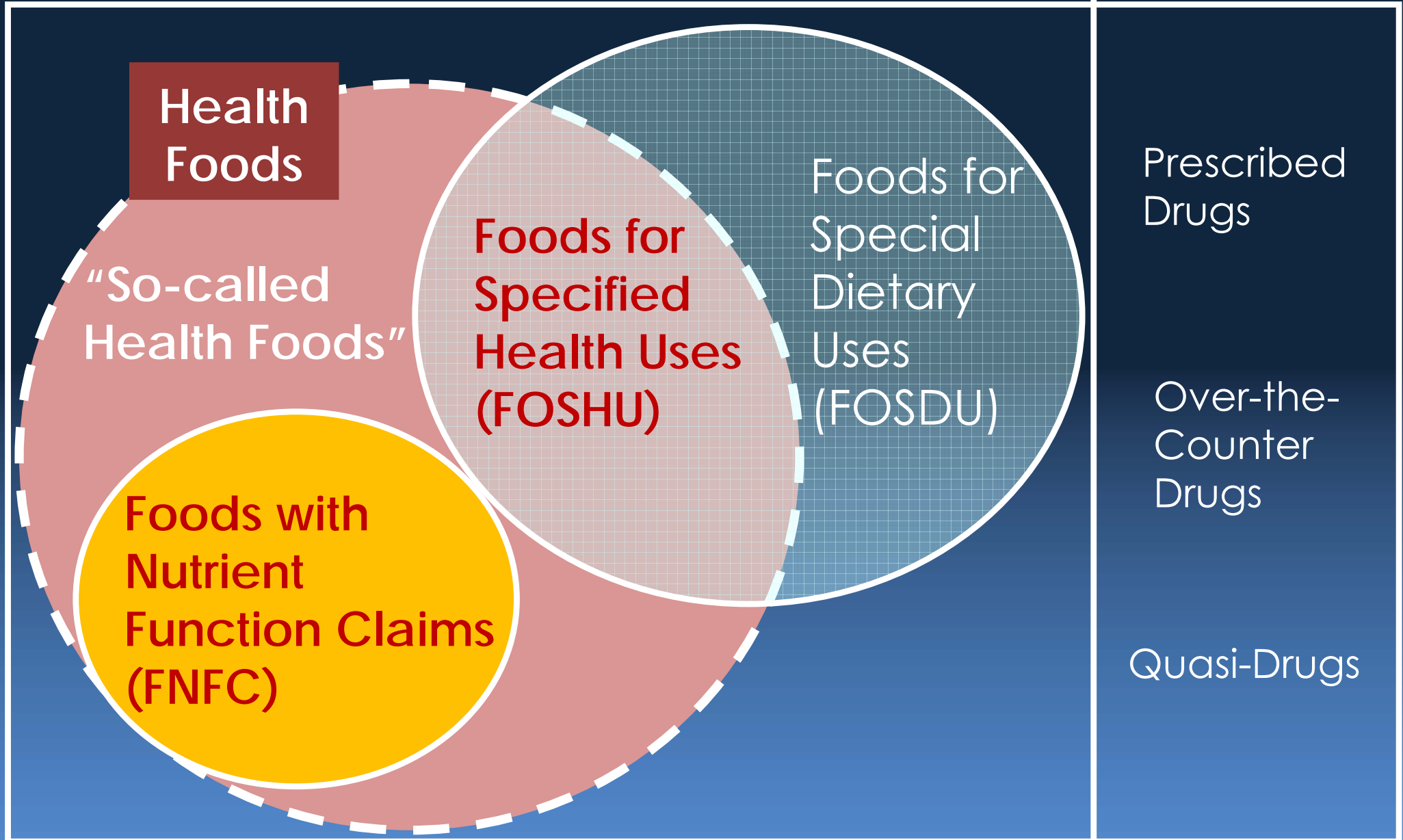
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## 2. Regulatory systems of health claims in Japan

## Foods

In principle, functional claims are prohibited

## Pharmaceuticals





# Regulation

- Health Claims are prohibited for foods except for two categories:
  - Foods with Nutrient Function Claims (FNFC)
  - Foods for Specified Health Uses (FOSHU)

JAPAN	CODEX
Foods with Nutrient Function Claims (FNFC)	Nutrient function claims
Foods for Specified Health Uses (FOSHU)	Other function claims
	Reduction of disease risk claims

# Foods with Nutrient Function Claims (FNFC)

# Foods with Nutrient Function Claims (FNFC)

- Standardized formula/labelling system with no requirement for notification
- 12 vitamins and 5 minerals
  - Vitamin A, D, E, C, B1, B2, B6, B12, Niacin, Folic acid, Biotin, and Pantothenic acid
  - Calcium, Magnesium, Iron, Zinc, and Copper

# Examples of nutrient function claims

- *“Vitamin E is a nutritional element that has antioxidant effects that prevent oxidation of lipids in the body and helps maintain cellular health.”*
- *“Calcium is a nutritional element necessary for bone and tooth formation.”*

# Requirements for FNFC

- A daily amount of relevant vitamins or minerals must be:
  - within predetermined ranges
  - expressed in metric units and as Japan's NRV%

# Major requirements of labelling of FNFC 1/2

- Attention and warning statement
  - *“Excess intake of this product neither cures disease nor promotes health”*
  - *“Ingest no more than the optimum amount”*
- Disclaimer statement
  - *“Unlike FOSHU, this product has not received an individual examination from Secretary-General of the CAA. ”*

# Major requirements of labelling of FNFC 2/2

- Enlightenment statement on FOP
  - *“Eating habits: the dietary balance based on staple food, the main dish, and the side dish”*

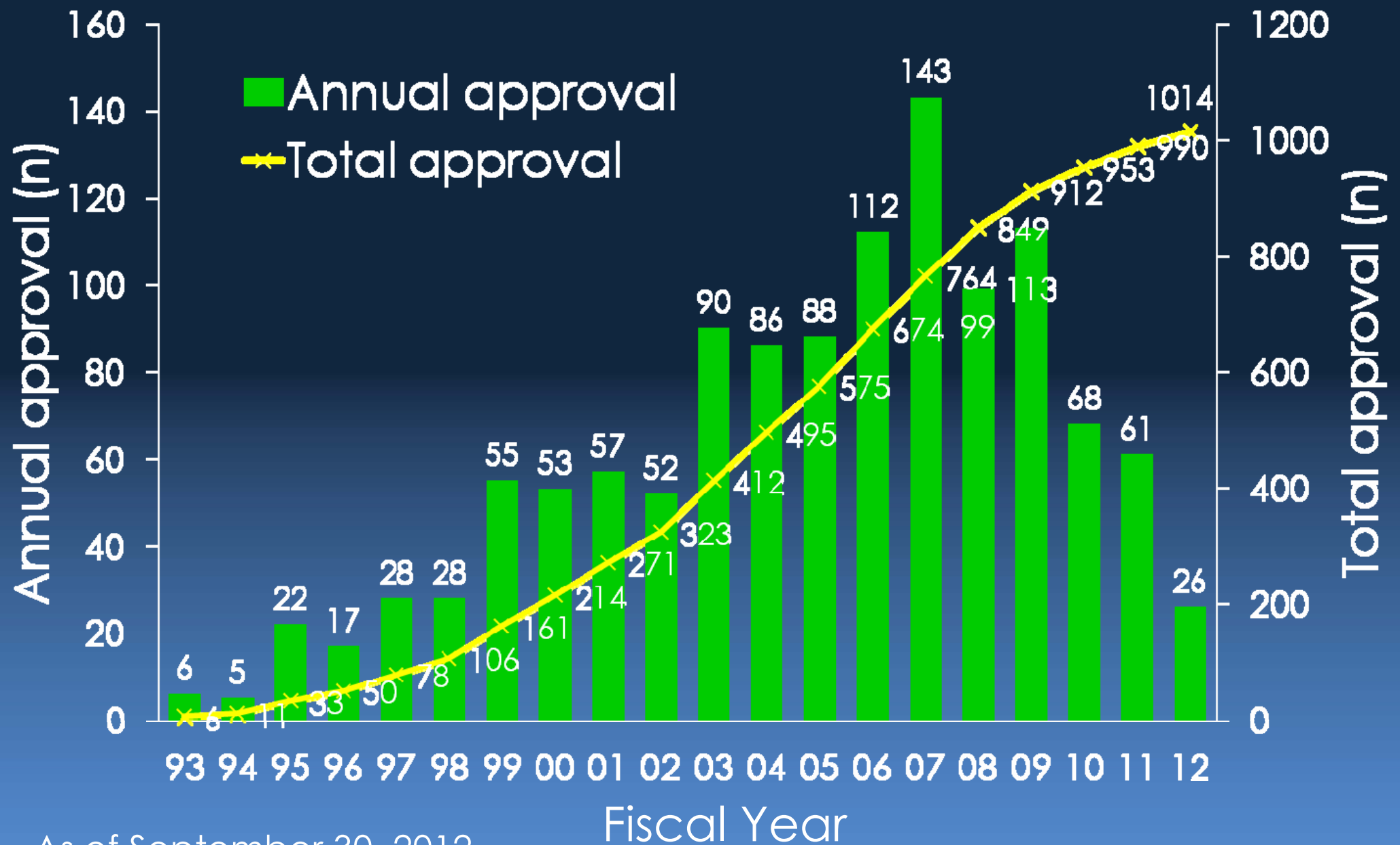


# Foods for Specified Health Uses (FOSHU)

# Foods for Specified Health Uses (FOSHU)

- Individual approval /  
Standard regulation system
- Four categories
  - FOSHU
  - Standardized FOSHU
  - Reduction of disease risk FOSHU
  - Qualified FOSHU

# Trends of approved FOSHU



As of September 30, 2012

# FOSHU

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



# Examples of approved claims 1/2

Health uses	Component	Model claim, statements
GI function	Oligosaccharides	<ul style="list-style-type: none"><li>- Helps maintain good GI condition</li><li>- Helps improve bowel movement</li></ul>
Cholesterol level	Chitosan	<ul style="list-style-type: none"><li>- Helps lower cholesterol level</li></ul>
Triacylglycerol/ Body fat	Medium-chain fatty acids	<ul style="list-style-type: none"><li>- Helps resist body fat gain</li></ul>
	Polyphenol	<ul style="list-style-type: none"><li>- For those concerned about body fat</li></ul>

# Examples of approved claims 2/2

Health uses	Component	Model claim, statements
Blood pressure	Peptides	- For those with high blood pressure
Bone	Soy isoflavone	- Promotes calcium absorption - Supports bone health
Teeth	Mixture of Xylitol, Calcium Monohydrogen Phosphate and Fukuronoriextract	- Helps maintain strong and healthy teeth
Blood glucose level	Indigestible dextrin	- For those concerned about blood glucose level

# 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 be clinically and nutritionally established to reduce a risk of certain disease

## Approved function

- Calcium for Osteoporosis
- Folic acid for neural tube defects





# Reduction of disease risk claims (Calcium)

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

# Reduction of disease risk claims (Folic acid)

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

*“Qualified”*



# Disclaimer statement of Qualified FOSHU

- *“This product contains XXX, but the scientific evidence of the efficacy is not established. However, this product is suggested to be appropriate for YYY health condition.”*
- One product only  
(as of September 30, 2012)

# Procedure Flow of FOSHU

**Applicant**

**Consumer Affairs Agency** Food Labelling Division

**Consumer Commission**

Assessment and Evaluation Group for Novel Food

**Reviews efficacy**

**Food Safety Commission**

Expert Assessment Group for Novel Food

**Reviews safety**

**Consumer Commission**

Assessment Committee for Novel Food

**Reviews efficacy and safety comprehensively**

**Ministry of Health, Labour and Welfare**

**Checks whether the labelling violates  
Pharmaceutical Affairs Act**

**National Institute of Health and Nutrition  
or other Designated Examining Bodies**

**Quantitative Analysis  
of relevant component**

**Consumer Affairs Agency**

**Approval**

# Efficacy data required for approval

	Product	Functional component
FOSHU	√	√
Standardized FOSHU	—	—
Reduction of disease risk FOSHU	√ <sup>a</sup>	√ <sup>a</sup>
Qualified FOSHU	√	√

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<sup>a</sup> Unnecessary for Calcium and Folic acid

# Required levels of scientific evidence

		RCT		non-RCT	non-controlled trial
		$p \leq 0.05$	$p \leq 0.1$	$p \leq 0.05$	$p \leq 0.05$
Mechanism	Clear	FOSHU	Qualified FOSHU	Qualified FOSHU	—
	Unclear	Qualified FOSHU	Qualified FOSHU	—	—

# Safety data required for approval

	Product	Functional component
FOSHU	√	√
Standardized FOSHU	√ <sup>a</sup>	—
Reduction of disease risk FOSHU	√ <sup>b</sup>	√ <sup>c</sup>
Qualified FOSHU	√	√

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<sup>a</sup> Overdose test only (Long-term test is unnecessary)

<sup>b</sup> Overdose test only (for Calcium and Folic acid)

<sup>c</sup> Unnecessary for Calcium and Folic acid



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## 3. Issues

# Roundtable on Health Claims

- Held from November 2009 to July 2010
- Several issues regarding FOSHU and “so-called Health Foods” were suggested in the final report

# Issues on FOSHU

- CAA was asked to improve/consider followings:
  - Approval process  
e.g., speed, clarity, and transparency
  - Collection of new scientific findings even after approval
  - Labelling presentation of information  
e.g., clear, accurate, and understandable

# Issues on regulation of “so-called Health Foods”

- CAA was asked to address followings:
  - Develop Guidelines for tightening regulatory control on False and misleading labelling
  - Collect scientific evidence on targeted nutritional or functional components for further discussion about authorization

# The Pilot Project of Functional Assessment of Foods

- Conducted from July 2011 to March 2012
- Made a pilot standard of evidence-based assessment for functional components, and assessed 30 functions of 11 components with it on trial
- Extracted issues on evidence-based assessment

## Assessment Panel



**Make standard of assessment on trial**

**Assess each component on trial**

Report

Report



Expert Team of  
System Research

To research the system of functional assessment of foods in the world.



Expert Team of  
Functional  
Assessment

To collect evidence related to each component.

# 11 components assessed

- Selenium
- n-3 fatty acids
- Lutein
- Coenzyme Q-10
- Hyaluronic acid
- Blueberry Extract
- Glucosamine
- BCAA
- Ginkgo Biloba Leaf Extract
- Saw Palmetto
- Lactoferrin

# Issues on evidence-based assessment 1/3

- Lack of information regarding conflict of interest
- Potential publication bias



*“Future human studies should be reported based on internationally agreed guidelines”*



# Issues on evidence-based assessment 2/3

- Elaboration of how to assess functions based on subjective outcomes only
- Whether or not the followings should be included for assessment:
  - Results from patients (relevant/irrelevant disease)
  - Results from studies which used functional components as a complement of drugs

# Issues on evidence-based assessment 3/3

- Elaboration of criteria to judge consistency of results among studies
- Further discussion about methodologies to assess functions of:
  - components in the light of totality of evidence
  - extracts containing different components

# Main limitations

- The followings remain to be addressed:
  - Assessment considering not only statistical significance but also effect size
  - Review of optimal and excessive intake, and management system for safety information

# Target of Food with Health Claims

