Regulatory Systems of Health Claims in Japan

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Regional Symposium in Hong Kong on October 29-30, 2012
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2. Regulatory systems of health claims in Japan
3. Issues
Contents

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
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
Contents

2. Regulatory systems of health claims in Japan
In principle, functional claims are prohibited.
Regulation

• Health Claims are prohibited for foods except for two categories:
  – Foods with Nutrient Function Claims (FNFC)
  – Foods for Specified Health Uses (FOSHU)
<table>
<thead>
<tr>
<th>JAPAN</th>
<th>CODEX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foods with Nutrient Function Claims (FNFC)</td>
<td>Nutrient function claims</td>
</tr>
<tr>
<td>Foods for Specified Health Uses (FOSHU)</td>
<td>Other function claims</td>
</tr>
<tr>
<td></td>
<td>Reduction of disease risk claims</td>
</tr>
</tbody>
</table>
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 Fiscal Year
FOSHU

• Requires detailed review process with scientific evidence for each application.
<table>
<thead>
<tr>
<th>Health uses</th>
<th>Component</th>
<th>Model claim, statements</th>
</tr>
</thead>
</table>
| GI function         | Oligosaccharides   | - Helps maintain good GI condition  
<p>|                     |                    | - Helps improve bowel movement                               |
| Cholesterol level   | Chitosan           | - Helps lower cholesterol level                               |
| Triacylglycerol/     | Medium-chain       | - Helps resist body fat gain                                 |
| Body fat            | fatty acids        |                                                              |
|                     | Polyphenol         | - For those concerned about body fat                         |</p>
<table>
<thead>
<tr>
<th>Health uses</th>
<th>Component</th>
<th>Model claim, statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood pressure</td>
<td>Peptides</td>
<td>- For those with high blood pressure</td>
</tr>
<tr>
<td>Bone</td>
<td>Soy isoflavone</td>
<td>- Promotes calcium absorption</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Supports bone health</td>
</tr>
<tr>
<td>Teeth</td>
<td>Mixture of Xylitol, Calcium Monohydrogen Phosphate</td>
<td>- Helps maintain strong and healthy teeth</td>
</tr>
<tr>
<td></td>
<td>and Fukuronoriextract</td>
<td></td>
</tr>
<tr>
<td>Blood glucose level</td>
<td>Indigestible dextrin</td>
<td>- For those concerned about blood glucose level</td>
</tr>
</tbody>
</table>
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 woman’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

1. **Applicant**
2. **Consumer Affairs Agency**
   - Food Labelling Division
   - Consumer Commission
     - Assessment and Evaluation Group for Novel Food
       - Reviews efficacy
3. **Food Safety Commission**
   - Expert Assessment Group for Novel Food
     - Reviews safety
4. **Consumer Commission**
   - Assessment Committee for Novel Food
     - Reviews efficacy and safety comprehensively
5. **Ministry of Health, Labour and Welfare**
   - Checks whether the labelling violates Pharmaceutical Affairs Act
6. **National Institute of Health and Nutrition**
   - or other Designated Examining Bodies
     - Quantitative Analysis of relevant component
7. **Consumer Affairs Agency**
   - Approval
## Efficacy data required for approval

<table>
<thead>
<tr>
<th></th>
<th>Product</th>
<th>Functional component</th>
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<tbody>
<tr>
<td><strong>FOSHU</strong></td>
<td>√</td>
<td>√</td>
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<tr>
<td>Standardized FOSHU</td>
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<td>_</td>
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<tr>
<td>Reduction of disease risk FOSHU</td>
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<td>√ a</td>
</tr>
<tr>
<td>Qualified FOSHU</td>
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<td>√</td>
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</table>

* Unnecessary for Calcium and Folic acid
### Required levels of scientific evidence

<table>
<thead>
<tr>
<th>Mechanism</th>
<th>Clear</th>
<th>FOSHU</th>
<th>Qualified FOSHU</th>
<th>Qualified FOSHU</th>
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<th>—</th>
</tr>
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<tbody>
<tr>
<td>RCT</td>
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<tr>
<td>non-RCT</td>
<td>p≤0.1</td>
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<td>non-controlled trial</td>
<td>p≤0.05</td>
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<tr>
<td>Unclear</td>
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<tr>
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<tr>
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<td>Product</td>
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<tr>
<td>FOSHU</td>
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<tr>
<td>Reduction of disease risk FOSHU</td>
<td>√ b</td>
<td>√ c</td>
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<tr>
<td>Qualified FOSHU</td>
<td>√</td>
<td>√</td>
<td></td>
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</tr>
</tbody>
</table>

- a Overdose test only (Long-term test is unnecessary)
- b Overdose test only (for Calcium and Folic acid)
- c Unnecessary for Calcium and Folic acid
Contents

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

Expert Team of System Research
To research the system of functional assessment of foods in the world.

Report

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

- Patients (Diet-related diseases)
  - Treatment
- Border area
  - Health maintenance and promotion
- Healthy people

Pharmaceuticals

Food with Health Claims: FOSHU, FNFC