Health Claims in Japan

What scientific evidence are we looking for?

AGENDA

1. Overall Regulatory Framework on Food Labelling in Japan

2. Health Claims in Japan
   - What scientific evidence are we looking for?

The Consumer Affairs Agency (CAA) was established in 2009 to protect consumers and enhance their benefits.

The Food Labelling Act 2013 and Food Labelling Standards 2015 were newly introduced by integrating/unifying labelling provisions from the Food Sanitation Act (managed by MHLW), Japan Agricultural Standard Act (MAFF) and Health Promotion Act (MHLW).

In cooperation with the local Governments, the CAA is primarily responsible for all food labelling issues, specifically on Foods with Nutrient Function Claims (FNFC), Foods for Specified Health Uses (FOSHU), Foods with Function Claims (FFC) and Foods for Special Dietary Uses (FSDU) as well as general food nutrition labelling and claims.
Food/Dietary Supplements, which are generally considered in tablet, capsule or powder forms and may be called as health foods or health supplements, are not specifically defined in Japan and those are treated and regulated in the same manner as for foods.

They are also applicable to the labelling provisions and systems for nutrition labelling including nutrient declaration and nutrition claims, and also for health claims, such as Foods with Nutrient Function Claims (FNFC), Foods for Specified Health Uses (FOSHU) and Foods with Function Claims (FFC).

AGENDA

1. Overall Regulatory Framework on Food Labelling in Japan
   - What scientific evidence are we looking for?

FOODs and PHARMACEUTICALs in Japan

FOODs
- Foods in General
  - Nutrient Declaration
  - Nutrient Content Claims
  - Nutrient Comparative Claims
  - Non-addition Claims
- Foods with Health Claims
  - Health Claims
- Foods for Special Dietary Uses
  - Special Dietetic Claims
- Foods with Nutrient Function Claims
  - Nutrient Function Claims
- Foods for Specified Health Uses
  - Other Function Claims & Reduction of Disease Risk Claims
- Foods with Function Claims
  - Other Function Claims

PHARMACEUTICALs
- Pharmaceuticals, including OTC and Quasi-pharmaceutical products
  - Medical/Therapeutic Claims
- Health Claims in Japan

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PHARMACEUTICALs
- Pharmaceuticals, including OTC and Quasi-pharmaceutical products
  - Medical/Therapeutic Claims

Health Claims in Japan
**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 (2001).

- **Legal framework:**
  - Food Sanitation Act (1947),
  - Health Promotion Act (2002),
  - Food Labelling Act (2013),
  - Food Labelling Standards (2015)
- **Pre-authorized Nutrient Function Claims (by the CAA)**
- **Min. & max. daily dose levels specified for each nutrient**
- **No pre-marketing permission nor notification required**

### Authorized Nutrient Function Claims (1)

<table>
<thead>
<tr>
<th>NUTRIENTS</th>
<th>NUTRIENT FUNCTION CLAIMS</th>
<th>Min. / Max. per Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A (2001.04.01)</td>
<td>A nutrient that helps maintain vision at night, helps maintain healthy skin and mucosa</td>
<td>231 / 600 (μg)</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>A nutrient that promotes absorption of calcium and aids in the development of bone</td>
<td>1.60 / 5.0 (μg)</td>
</tr>
<tr>
<td>Vitamin E</td>
<td>A nutrient that helps protect fat in the body from being oxidized and helps maintain healthy cells</td>
<td>1.89 / 150 (mg)</td>
</tr>
<tr>
<td>Vitamin B1</td>
<td>A nutrient that helps produce energy from carbohydrate and helps maintain healthy skin and mucosa</td>
<td>0.36 / 25 (mg)</td>
</tr>
<tr>
<td>Vitamin B2</td>
<td>A nutrient that helps produce energy from carbohydrate and helps maintain healthy skin and mucosa</td>
<td>0.42 / 12 (mg)</td>
</tr>
<tr>
<td>Niacin</td>
<td>A nutrient that helps produce energy from carbohydrate and helps maintain healthy skin and mucosa</td>
<td>3.9 / 60 (μg)</td>
</tr>
<tr>
<td>Biotin</td>
<td>A nutrient that helps produce energy from carbohydrate and helps maintain healthy skin and mucosa</td>
<td>15 / 500 (μg)</td>
</tr>
<tr>
<td>Pantothenic acid</td>
<td>A nutrient that helps produce energy from carbohydrate and helps maintain healthy skin and mucosa</td>
<td>1.44 / 30 (mg)</td>
</tr>
<tr>
<td>Vitamin B6</td>
<td>A nutrient that helps produce energy from protein and helps maintain healthy skin and mucosa</td>
<td>0.39 / 10 (mg)</td>
</tr>
<tr>
<td>Folic acid</td>
<td>A nutrient that aids in red blood cell formation, contributes to the normal growth of a fetus</td>
<td>72 / 200 (μg)</td>
</tr>
<tr>
<td>Vitamin B12</td>
<td>A nutrient that aids in red blood cell formation, and has anti-oxidizing effect</td>
<td>0.72 / 60 (μg)</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>A nutrient that helps to maintain healthy skin and mucosa, and has anti-oxidizing effect</td>
<td>30 / 1,000 (mg)</td>
</tr>
<tr>
<td>Iron</td>
<td>A nutrient that is necessary for red blood cell formation</td>
<td>2.04 / 10 (mg)</td>
</tr>
</tbody>
</table>

### Authorized Nutrient Function Claims (2)

<table>
<thead>
<tr>
<th>NUTRIENTS</th>
<th>NUTRIENT FUNCTION CLAIMS</th>
<th>Min. / Max. per Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium</td>
<td>A nutrient that is necessary in the development of bone and teeth</td>
<td>204 / 600 (mg)</td>
</tr>
<tr>
<td>Zinc (2004.04.01)</td>
<td>A nutrient that is necessary to maintain the normal function of the sense of taste</td>
<td>2.64 / 15 (mg)</td>
</tr>
<tr>
<td>Copper</td>
<td>A nutrient that helps red blood cell formation, helps normal function of various enzymes in the body and development of bone</td>
<td>0.27 / 6.0 (mg)</td>
</tr>
<tr>
<td>Magnesium</td>
<td>A nutrient which is necessary in the development of bone and teeth</td>
<td>96 / 300 (mg)</td>
</tr>
<tr>
<td>Vitamin K (2015.04.01)</td>
<td>A nutrient that helps maintain normal coagulation of blood</td>
<td>45 / 150 (μg)</td>
</tr>
<tr>
<td>Potassium</td>
<td>A nutrient that is necessary to maintain normal blood pressure</td>
<td>840 / 2,800 (mg)</td>
</tr>
<tr>
<td>n-3 Fatty acids</td>
<td>Nutrients that help maintain healthy skin</td>
<td>0.6 / 2.0 (g)</td>
</tr>
</tbody>
</table>

### Health Claims in Japan

- **FOODs**
  - Foods in General
  - Foods with Health Claims
  - Foods with Special Dietary Uses
  - Foods for Specified Health Uses
  - Foods with Function Claims
- **PHARMACEUTICALS**
  - Pharmaceuticals, including OTC and Quasi-pharmaceutical products
  - Medical/Therapeutic Claims
Health Claims 1-2: 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 (1991).

Legal framework:
- Food Sanitation Act (1947),
- Nutrition Improvement Act (1952),
- Health Promotion Act (2002),
- Food Labelling Act (2013),
- Food Labelling Standards (2015)

Product-specific Claims
- Pre-marketing permission/approval by the CAA required for Claims based on Scientific Substantiation
- Applicable Food Forms: Ordinary Prepackaged Foods and Tablet/Capsule Forms

Documentation Required for Substantiation of the Safety

5. Documentation demonstrating the safety of the food and its constituents concerned
   1) *In vitro* and *in vivo* animal studies confirming basic information on the limits of safe intake
   2) Clinical studies confirming the safety in the case of excessive consumption

   3 to 5 times higher level of recommended daily intake of the food or its constituents concerned should be applied.

Documentation Required for Substantiation of FOSHU Claims

4. Clinical and nutritional documentation demonstrating the specified health use and showing determination of the recommended daily intake for the food and its constituents concerned. Results should be statistically significant ($p<0.05$), ($0.05<p<0.1$) applicable for Qualified FOSHU.

   1) *In vitro* and *in vivo* animal studies explaining the effects, mechanisms of action and metabolism & pharmacokinetics (absorption, distribution, metabolism and excretion) on the constituents concerned, results of which should be statistically significant
   2) Clinical studies (generally for 12 weeks) using the food applied and confirming the specified health effects and the recommended daily intake, results of which should be statistically significant

   Randomized double blind controlled clinical study (RCT) using local subjects is required. Non-RCT could be applicable for Qualified FOSHU.


Number of FOSHU Approvals by Year Cumulative Number of Approvals, expired/withdrawals excluded
## Examples for FOSHU Claims

<table>
<thead>
<tr>
<th>Health Claims (Examples)</th>
<th>Functional Ingredients</th>
<th>No. of FOSHU (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Helps maintain good gastrointestinal condition”</td>
<td>Oligosaccharides, Dietary Fiber, Lactobacillus, Bifidobacterium</td>
<td>339 (31.4)</td>
</tr>
<tr>
<td>“Good for those who have high serum cholesterol / are concerned about their serum triglycerides”</td>
<td>Soy Protein, Peptides, MCTs, Dietary Fiber, Plant Sterol / Stanol (Esters), Coffee Polyphenols</td>
<td>304 (28.2)</td>
</tr>
<tr>
<td>“Good for those who have high blood glucose levels”</td>
<td>Dietary Fiber, Albumin, Polyphenols, L-Arabinose</td>
<td>187 (17.3)</td>
</tr>
<tr>
<td>“Good for those who have high blood pressure”</td>
<td>Peptides, Glucosides, Amino Acids</td>
<td>110 (10.2)</td>
</tr>
<tr>
<td>“Helps maintain good dental health”</td>
<td>Xylitol, Polyols, Tea Polyphenols, CPP-ACP</td>
<td>87 (8.1)</td>
</tr>
<tr>
<td>“Helps improve absorption of calcium minerals”</td>
<td>CPP, CCM, Oligosaccharides, Heme Iron, MBP, Vitamin K2, Soy Isoflavonoids</td>
<td>49 (4.5)</td>
</tr>
<tr>
<td>“Good for those whose skin condition tends to drying”</td>
<td>Glucosylceramides</td>
<td>2 (0.2)</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td><strong>1,078 (100)</strong></td>
</tr>
</tbody>
</table>

### Health Claims in Japan

**FOODs**

- Foods in General
  - Nutrient Declaration
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  - Non-addition Claims

- Foods with Nutrient Function Claims
  - Nutrient Function Claims

- Foods for Specified Health Uses
  - Other Function Claims & Reduction of Disease Risk Claims

- Foods for Special Dietary Uses
  - Special Dietetic Claims

**FUNCTIONS**

- Other Function Claims

**PHARMACEUTICALS**

- Pharmaceuticals, including OTC and Quasi-pharmaceutical products
  - Medical/Therapeutic Claims

### How is the Safety of FFC evaluated?

The safety is evaluated by one of the following methods.

- A history of safe consumption/use of a finished product or a functional substance by humans
- or, Research of existing information/studies on safety of the product or a functional substance
- or, Safety testing/evaluation on the product or a functional substance using animal tests and/or human studies

Any interactions with drugs, etc. is also requested to evaluate.

**Health Claims 1-3 : Foods with Function Claims (FFC)**

- Food Business Operators (FBOs), on their own responsibility, are required to evaluate the safety and effectiveness in accordance with rules prescribed by the Guidelines. ([Guidelines on Notification of Food with Function Claims, 2018.03.28 rev.](https://www.fld.caa.go.jp/caaks/cssc01/))
- FBOs must then submit the information required to the Consumer Affairs Agency (CAA) 60 days prior to marketing their products. ([Notification number provided from CAA](https://www.fld.caa.go.jp/caaks/cssc01/))
- Submitted documents are disclosed on the CAA website. ([CAA website above](https://www.fld.caa.go.jp/caaks/cssc01/))
- Consumers can check the product information on how the safety and effectiveness of the products were ensured before the products on the market. ([CAA website above](https://www.fld.caa.go.jp/caaks/cssc01/))
- Applicable Food Forms: Ordinary Prepackaged Foods, Tablet/Capsule Forms and Fresh Produce
The effectiveness of the product is evaluated by one of the following methods.

- Human Clinical Trial(s) using the Finished Product, in compliance with FOSHU guidelines
  - Applicable Claim: the product has a function to/of …..
- or, Literature Review on Studies with Finished Products or Functional Substances therein, through Systematic Review(s) or Meta-analysis
  - Applicable Claim: the product/functional substance has been reported to have a function to/of …..

How is the Effectiveness of FFC evaluated?

Food Business Operator: Submission

- Submission Process for Submission and Marketing of FFC
- CAA: Issue of Notification Number
- Marketing the Product with Function Claims with a Notification Number
  - CAA reviews the submitted documents.
  - Related information are disclosed on the CAA website.
  - In cases where deficiencies are identified, a notification and related documents are returned.

Process for Submission and Marketing of FFC

- 60 days prior to the targeted launch date, a completed notification and related documents must be submitted to CAA
- Following documents must be submitted to CAA:
  1. Details of the product labelling
  2. Basic information, such as name of the Food Business Operator
  3. Scientific Substantiation based on Clinical Studies or Systematic Reviews for Effectiveness and Safety
  4. Information for Production and Quality control system
  5. Systems for collection of adverse health events
  6. Other required information

- Putting the product on the market is not the end of the process. Information about adverse health events must be collected continuously after introduction of the product on the market.

Summary of FFC Notified by Food Category

<table>
<thead>
<tr>
<th>Food Category</th>
<th>2015 (A)</th>
<th>2016 (B)</th>
<th>2017 (C)</th>
<th>2018 (D)</th>
<th>TOTAL (2015/04/01-2018/06/08)</th>
<th>Literature Reviews on Finished Products or Functional Substances therein (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ordinary Prepackaged Foods</td>
<td>136</td>
<td>332</td>
<td>215</td>
<td>16</td>
<td>699 (52)</td>
<td>17</td>
</tr>
<tr>
<td>Dietary Supplements (Capsules, Tablets and/or Powder forms)</td>
<td>130</td>
<td>249</td>
<td>228</td>
<td>16</td>
<td>623 (47)</td>
<td>59</td>
</tr>
<tr>
<td>Fresh Produce (Agricultural, Fishery Products)</td>
<td>3</td>
<td>5</td>
<td>6</td>
<td>1</td>
<td>15 (1)</td>
<td>0</td>
</tr>
<tr>
<td><strong>SUB TOTAL</strong></td>
<td>269</td>
<td>586</td>
<td>449</td>
<td>33</td>
<td>1,337 (100)</td>
<td>76</td>
</tr>
<tr>
<td><strong>Withdrawn</strong></td>
<td>38</td>
<td>34</td>
<td>3</td>
<td>0</td>
<td>75 (5)</td>
<td>0</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>307</td>
<td>620</td>
<td>452</td>
<td>33</td>
<td>1,412 (100)</td>
<td>76</td>
</tr>
</tbody>
</table>

Summary of Functional Substances and Food Forms (1)

<table>
<thead>
<tr>
<th>Functional Substances</th>
<th>Functional Claims Submitted</th>
<th>Food Forms</th>
<th>Total (%)</th>
<th>Substantiation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indigestible Dextrin, Barley β-Glucan</td>
<td>Helps regulate gastro-intestinal conditions Slows down the absorption of glucose Attenuates the absorption of dietary fats</td>
<td>196 5</td>
<td>201 (15)</td>
<td>4 197</td>
</tr>
<tr>
<td>GABA, Lactotripeptides</td>
<td>Helps maintain normal blood pressure</td>
<td>115 (2)</td>
<td>154 (12)</td>
<td>0 154</td>
</tr>
<tr>
<td>Lutein, Anthocyanin, Astaxanthin</td>
<td>Helps improve visual performance / functions</td>
<td>8</td>
<td>112</td>
<td>120 (9)</td>
</tr>
<tr>
<td>DHA-EPA</td>
<td>Helps attenuate increase of post prandial serum triglycerides</td>
<td>74 (1)</td>
<td>44</td>
<td>119 (9)</td>
</tr>
<tr>
<td>Bifidobacterium, Lactobacillus, L. Gasseri</td>
<td>Helps regulate gastro-intestinal / bowel conditions Helps attenuate body fat mass</td>
<td>66</td>
<td>43</td>
<td>109 (8)</td>
</tr>
<tr>
<td>Ginkgo biloba flavonoids</td>
<td>Helps improve cognitive functions</td>
<td>3</td>
<td>65</td>
<td>68 (5)</td>
</tr>
<tr>
<td>Hyaluronates</td>
<td>Helps maintain skin moisture and alleviate drying</td>
<td>41</td>
<td>24</td>
<td>65 (5)</td>
</tr>
</tbody>
</table>
## Functional Substances and Food Forms (2)
(Notification numbers issued, 2015/04/01–2018/06/08)

<table>
<thead>
<tr>
<th>Functional Substances</th>
<th>Functional Claims Submitted</th>
<th>Food Forms</th>
<th>Total (%)</th>
<th>Substantiation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Ordinary Foods (Fresh Produce)</td>
<td>Supplement</td>
<td>(%</td>
</tr>
<tr>
<td>Glucosamine Collagen</td>
<td>Helps improve knee functionality / pain</td>
<td>8</td>
<td>50</td>
<td>58</td>
</tr>
<tr>
<td>Arrowroot Isoflavones</td>
<td>Helps attenuate body fat mass</td>
<td>26</td>
<td>26</td>
<td>52</td>
</tr>
<tr>
<td>L-Theanine</td>
<td>Helps improve quality of sleep</td>
<td>10</td>
<td>36</td>
<td>46</td>
</tr>
<tr>
<td>Soybean Isoflavones</td>
<td>Helps regulate bone metabolism and to be helpful for bone heath</td>
<td>13</td>
<td>16</td>
<td>34</td>
</tr>
<tr>
<td>Acetic acids, Citric acids</td>
<td>Helps attenuate body fat mass</td>
<td>31</td>
<td>0</td>
<td>31</td>
</tr>
<tr>
<td>Coenzyme Q10</td>
<td>Helps energy production of cells and reduce daily physical fatigue</td>
<td>0</td>
<td>17</td>
<td>17</td>
</tr>
<tr>
<td>β-Cryptoxanthins</td>
<td>Helps regulate bone metabolism and to be helpful for bone heath</td>
<td>4</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td>699</td>
<td>623</td>
<td>1,337</td>
</tr>
</tbody>
</table>

### Thank You & Questions Welcome!