Regulation of the Food Labelling Systems for Health and Nutrition in Japan and Associated Role of the National Institute of Health and Nutrition

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ABSTRACT

Objective: This article aimed to review the Japanese regulation of the food labelling systems for health and nutrition, and associated role of the National Institute of Health and Nutrition (NIHN).

Methods: We investigated the development of standards and challenges associated with the Japanese regulation of food labelling system for health and nutrition. We also examined the contribution of the National Institute of Health and Nutrition to the development of the systems.

Results: In 1991, the Ministry of Health and Welfare established the concept of Foods for Specified Health Uses (FOSHU), under the Nutrition Improvement Act. In 2001, the labelling system for vitamins and minerals was established under the Foods with Nutrient Function Claims regulations, and the Foods with Health Claims (FHC) system was set up with FOSHU. In 2015, the Foods with Function Claims classification was established under the Food Labelling Act by the Consumer Affairs Agency. Despite the regulated food labelling system in Japan, some “health foods” may have inappropriate use and labelling. The NIHN functions to (1) measure the amount of nutrients and ingredients in foods, ensuring accurate information on the labels for approval by the foods labelling system; (2) assess safety and efficacy of health foods including FHC providing scientific evidences on their nutritional and physiological effects; and (3) provide reliable online information regarding health foods, the FHC and their labelling.

Conclusions: The NIHN has an important role within the regulation systems of health foods including FHC system in Japan.

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Key words: Foods with Health Claims, Foods for Specified Health Uses, Foods with Nutrient Function Claims, Foods with Function Claims, Foods for Special Dietary Uses

I. Introduction

In recent years, health foods have gained popularity due to aging of the population and a rise in health consciousness. In line with this, research into functional foods has expanded in Japan. “Health food” is a name given to various foods that are believed to have positive effects on health, although the name itself has no standardized definition or legal basis.

Large-scale research into food function, including systematic analysis and the development of food function, analysis of the bioregulatory function of food, and analysis and molecular design of functional foods, under Grants-in-aid for Scientific Research on Priority Areas from the Ministry of Education (currently, Ministry of Education, Culture, Sports, Science and Technology), was started in Japan in the 1980s-1990s. This served to promote basic and applied research on the role of nutrition in the regulation of bodily functions (Table 1). Subsequently, the increase in the number of older adults worldwide, next to the increase in prevalence of lifestyle-related diseases, among others, have caused broad interest in functional foods. Despite these circumstances, the quality of information available to the public regarding these foods is...
questionable. In 1991, the Ministry of Health and Welfare [MHW] (currently, the Ministry of Health, Labour, and Welfare [MHLW]) established the Foods for Specified Health Uses (FOSHU) category under the Nutrition Improvement Act (currently, the Health Promotion Act) to improve consumer knowledge for appropriate food selection. In 2001, the Foods with Nutrient Function Claims (FNFC) system, a labelling system used to communicate the nutritional value of vitamins and minerals, was launched, and the Foods with Health Claims (FHC) category was established, which encompasses the FNFC and FOSHU4. Furthermore, in 2015 the Foods with Function Claims (FFC) system was established under the Food Labelling Act.

Despite a regulated food labelling system in Japan, there remain so-called “health foods” that do not fit into...
any of the available frameworks. Concurrently, the term “supplement” has been introduced to the general public as another word for “health food.” Nevertheless, the term “supplement” is derived from the term “dietary supplement,” which is defined in Dietary Supplement Health and Education Act in the United States. In contrast, in Japan, the term “supplement” has no legal definition; in fact, it is generally accepted that terms “health food” and supplement are equivalent.

Labelling of functional foods is important for both consumers and manufacturers. Accurate labels allow consumers to interpret the features, contents, and likely effects of the foods they consume, and assist with dietary choices. Recently, health concerns have become a leading factor in driving consumer purchases. Concurrently, clear and accurate labels can help manufacturers to emphasize the benefits of their products and promote sales. Therefore, food labelling should be clear, accurate, and supported by scientific evidence. In Japan, the FHC and Foods for Special Dietary Uses (FOSDU) systems have been established under the Health Promotion Act and Food Labelling Act (Figure 1). The aim of these systems is to provide consumers with information to support their food choices.

This review article examines the FHC and FOSDU systems in Japan (Figure 1)\(^5\), associated challenges, and the role of the National Institute of Health and Nutrition (NIHN) in the development of these systems.

II. Methods

We investigated the development of the FHC standards, describing the changes and challenges from conception until the present. We also present the contributions of the NIHN to the FHC and FOSDU systems.

III. Results

Figure 1 shows the food labelling systems in Japan\(^5\). The FOSDU applies to foods for special use, and is categorized into five types: Foods for Medical Uses, Infant Formulas, Powdered Formulas for Pregnant or Lactating Women, Foods for People with Dysphagia, and FOSHU. The FHC system applies to foods with health function claims, and is categorized into three types: FOSHU, FNFC, and FFC. FOSHU belongs to both FHC and FOSDU under the Health Promotion Act. The remaining foods, including the so-called “health foods,” are ordinary foods; their effects and functions cannot be labelled.

NIHN had been contributing to the food labelling systems for health and nutrition with MHW or MHLW. From September 1, 2009, operations related to the food labelling systems, previously conducted by the MHLW, have been transferred to the Consumer Affairs Agency (CAA). Since the CAA launch in 2009, NIHN has been contributing to the FHC and FOSDU systems in cooperation with the CAA as well as MHLW (Table 2). Moreover, in cooperation with the MHLW, NIHN have also contributed to the safety of the health foods based under the Food Sanitation Law. We show parts of projects and studies in this article.

1. Foods for Special Dietary Uses (FOSDU)

Foods for Special Dietary Uses are considered suitable to support people with disease or illness (special use indication)\(^6\), infant growth, and to maintain or restore the health of women who are pregnant or lactating, and people with dysphagia. In order for foods to fall under the FOSDU category, their labelling must be approved by a Secretary-General from the CAA, as required by the Health Promotion Act.

Approval of labelling is required, as well as an analysis for compliance with standards or requirements. Infant formulas are included in both a powder and liquid form; the liquid form was added into the FOSDU in 2018\(^7\). The NIHN has conducted several projects related to the FOSDU (Table 2): Laboratory validation of the analytical method for Foods for People with Dysphagia under FOSDU from 2015~2016; validation of the inductively coupled plasma mass spectrometry (ICP-MS) method, involving selenium content analysis of infant formulas in liquid form under FOSDU in 2018; and laboratory validation of the test method for the viscosity of a thickener used for thickness adjustment of foods in 2018.

2. Foods with Nutrient Function Claims (FNFC)

Products under the FNFC category can be used to supplement or complement the daily diet to ensure that nutritional requirements are met. A total of 13 vitamins, 6 minerals, including calcium, magnesium, iron, zinc, copper, potassium, and n-3 fatty acids fall into this category (Table 3). As these products tend to contain nutrients with well-known functions, they can be given a nutrient function claim prescribed by the Standards, without submit-
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Table 2  Government-commissioned projects related to the Foods with Health Claims system of Japan

| Year    | Policy research projects                                                                 | Government branch |
|---------|----------------------------------------------------------------------------------------|-------------------|
| 2001~   | Work on oversight, including data scrutiny, of products that fall under the category of Foods for Specified Health Uses, and assessment of newly-developed foods | COCC*1            |
| 2004~   | Collect and provide information on health foods through websites (Information system on safety and effectiveness for health foods) | MHLW*2            |
| 2006    | Standardization of the analytical method for soy isoflavone for the category of Foods for Specified Health Uses | MHLW              |
| 2008–2010 | Research on securing the reliability of the Registered Inspection Body, including external quality control testing of the registered test organizations, based on the Health Promotion Act | MHLW              |
| 2009–   | Business Cooperation agreement signed with the Consumer Affairs Agency Food Labeling Division | CAA*3             |
| 2012    | Examination of the standardization and quality control methods for nutritional components, based on the Health Promotion Act Standardization of analysis methods for vitamin K and molybdenum that was established alongside the analytical precision management methods for general nutritional components | CAA               |
| 2013    | Standardization of the analysis methods for vitamin K and molybdenum alongside removal tests for nutrient compositions. This project involved validation of the molybdenum analysis methods established during the previous year; the inductively coupled plasma optical emission spectrometry (ICP-ONES) analytical methods for Foods for Special Dietary Uses, and Foods for Medical Uses were verified. A survey on nutritional component analysis within registered laboratories was conducted | CAA               |
| 2015    | Modification of the standard analysis methods for Foods for Special Dietary Uses and Foods for People with Dysphagia, involving the approval of methods capable of measuring food molecules smaller than previously proposed | CAA               |
| 2016~   | Verification of the scientific evidence for the validity of labelling and advertising of the health foods and supplements (Second opinion work) | CAA               |
| 2016    | Laboratory validation of the analytical method established during the previous year, for Foods for People with Dysphagia and Foods for Special Dietary Uses | CAA               |
| 2018    | Validation of the inductively coupled plasma mass spectrometry (ICP-MS) method, involving selenium content analysis of infant formulas in liquid form under the Foods for Special Dietary Uses | CAA               |
| 2018    | Laboratory validation of the test method for viscosity of a thickener used for the thickness adjustment of foods | CAA               |

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ting a notification to the government.

The target foods are processed foods and fresh foods aimed for general use. The FNFC was established in 2001, and all fresh foods have been eligible for labels with nutritional function claims since 2015. However, labelling of nutrient function should be based on internationally recognized findings, for example, as presented in the Codex Alimentarius (CAC/GL23-1997)9. Moreover, labelling should be easy for consumers to understand. Food labels with health claims should include the recommended daily intake, and cautions regarding the intake of each nutrient.

3. Foods for Specified Health Uses (FOSHU)

FOSHU refers to foods containing ingredients with verified claims of physiological effects on the human body. FOSHU products are available for health maintenance and promotion, or for consumption by those who wish to control a health condition. To sell a product under FOSHU, it has to be first evaluated by the government for its effects and safety. The Secretary General of the CAA approves the labelling of each food product that satisfies the applicable requirements. The applicant is then permitted to use the approved health claim on the label, alongside the FOSHU logo (Figure 1), which captures the concept of “jumping for health.”

Until January 2020, 1,806 items have been approved as FOSHU products10. The health claims that fall under FOSHU are classified into ten categories, including gastrointestinal conditions, body fat, blood pressure, blood cholesterol levels, blood sugar levels, absorption of minerals, blood triglyceride levels, dental health, bone health, and skin moisture (Table 4)10. Under FOSHU, the claims cannot include words associated with medical treatments,
such as "prevent," "cure," "treat," and "diagnose."

In addition to the "regular" FOSHU, the following FOSHU subtypes were distinguished in 2005.

1) Standardized FOSHU: Standards and specifications are established for foods with FOSHU approval and sufficient scientific evidence. Standardized FOSHU applies to foods that meet standards and specifications, including digestion-resistant dextrin and oligosaccharides, among others.

2) Reduction of disease risk FOSHU: Claims about risk reduction of disease are permitted when reduction of disease risk has been clinically established and a link to the nutritional ingredients has been reported. Both calcium and folic acid have been granted an FOSHU approval under this category. The approved calcium health claim is aimed at young women to

Table 3 Overview and classification of Foods with Nutrient Function Claims (FNFC)

| Nutrient | Nutrient function claims | Cautions |
|----------|--------------------------|----------|
| Vitamins |                          |          |
| Vitamin A | Maintains vision in the dark. Helping maintain skin and mucous membrane health | Consuming a large quantity of this product does not cure disease or promote health. Please use no more than the recommended daily intake. Women in first trimester pregnancy or planning to be pregnant or expecting should be careful of excess intake. In the case of β-carotene, the caution above may be omitted. |
| Vitamin B₁ | Helping maintain skin and mucosal membrane health, and extract energy from carbohydrates |          |
| Vitamin B₂ | Helping maintain skin and mucosal membrane health |          |
| Vitamin B₃ | Supporting energy production from protein, and maintaining skin and mucosal membrane health |          |
| Vitamin B₉ | Supporting red blood cell formation |          |
| Vitamin C | Helping maintain skin and mucosal membrane health; has an antioxidative effect | Consuming a large quantity of this product does not cure disease or promote health. Please use no more than the recommended daily intake. |
| Vitamin D | Promoting intestinal calcium absorption, and maintaining bone formation |          |
| Vitamin E | Preventing lipid oxidizing through an antioxidative effect within the body; helping maintain cell health |          |
| Vitamin K | Maintains blood coagulation properties | Consuming a large quantity of this product does not cure disease or promote health. Please use no more than the recommended daily intake. If you are taking anticoagulants, avoid taking this product. |
| Folic acid | Helps red blood cell formation and contributes to fetal development | Consuming a large quantity of this product does not cure disease or promote health. Please use no more than the recommended daily intake. Folic acid is a nutrient that contributes to the normal development of the fetus; high intake does not improve fetal growth. |
| Niacin | Helping maintain skin and mucosal membrane health |          |
| Pantothenic acid | Helping maintain skin and mucosal membrane health |          |
| Biotin | Helping maintain skin and mucosal membrane health |          |
| Minerals |                          |          |
| Zinc | Necessary for maintaining normal taste, helpful to maintain skin and mucosal membrane health; mediating protein and nucleic acids metabolism to maintain health | Consuming a large quantity of this product does not cure disease or promote health. As consuming a large quality of this product may inhibit copper absorption, excessive intake should be avoided. Please use no more than the recommended daily intake. Infants and children should avoid. |
| Potassium | Necessary to maintain blood pressure | Consuming a large quantity of this product does not cure disease or promote health. Please use no more than the recommended daily intake. If you have reduced renal function, please avoid consuming this product. |
| Calcium | Necessary for bone and tooth formation | Consuming a large quantity of this product does not cure disease or promote health. Please use no more than the recommended daily intake. |
| Iron | Necessary for red blood cell formation |          |
| Copper | Supporting red blood cell formation, proper function of many body enzymes and bone formation | Consuming a large quantity of this product does not cure disease or promote health. Please use no more than the recommended daily intake. Infants and children should avoid. |
| Magnesium | Necessary for bone and tooth formation as well as blood circulation, supporting proper function of many body enzymes and energy production | Consuming a large quantity of this product may cause diarrhea. Please use no more than the recommended daily intake. Infants and children should avoid. |
| Fatty acid |                          |          |
| N-3 fatty acid | Maintaining skin health | Consuming a large quantity of this product does not cure disease or promote health. Please use no more than the recommended daily intake. |
reduce the risk of osteoporosis, and the folic acid health claim is aimed at pregnant women to support fetal development by reducing the risk of neural tube defects, such as spina bifida.

3) Qualified FOSHU: Food that has a health function not substantiated by scientific evidence meeting the FOSHU criteria, or that has a certain effect, but lacks an established mechanism of function required to qualify as FOSHU.

The NIHN conducts many studies and projects related to FOSHU (Table 2). This includes work on oversight, including data scrutiny, of products that fall under the category of FOSHU, and the assessment of newly-developed foods since 2001. The standardization of analytical methods for soy isoflavone for FOSHU in 2006. Since 2004, the NIHN has also been responsible for collecting and providing information on health foods, including FOSHU, through their website (information system on safety and effectiveness for health foods). Furthermore, the NIHN has verified scientific evidence for the validity of labelling and advertising of the health foods and supplements (the second opinion work) since 2016.

4. Foods with Function Claims (FFC)

The FFC category was launched in 2015. Under the food industry’s own responsibility, FFC is a label that applies to foods with structure and function claims based on scientific evidence\(^\text{[11]}\). The claim and supporting evidence on the efficacy and safety of the product are submitted to the Secretary-General of the CAA before the product is marketed, and the product’s supporting information is published on the CAA website. However, unlike with FOSHU designation, the products eligible for FFC are not individually pre-approved by the Secretary General of the CAA.

As of February 2020, 2,715 items have been submitted for FFC labelling\(^\text{[12]}\). Foods, including fresh foods, tablets, and capsules, can also be labeled with functional claims. Foods under the FFC category do not carry an approval logo, and have functional health claims similar to those under the FOSHU, except that under the FFC category, functional substances with new health functions can be considered. Foods under the FFC category have the same functional health claims as foods under the FOSHU category; however, the FFC group includes new functional substances with health functions, which are not eligible for approval under the FOSHU category. Table 5 shows the new function claims and functional substances considered under the FFC category, including reduction of fatigue, eye care, stress relief, memory improvement, sleep improvement and support, knee joint health, relief from eye and nose discomfort, and maintenance of peripheral body temperature.

| Table 4 | Health claims and principal ingredients on Foods for Specified Health Uses (FOSHU) category |
|---------|-----------------------------------------------------------------------------------------|
| Specified health use | Principal ingredients (ingredients exhibiting health functions) |
| Gastrointestinal condition | Oligosaccharides, polydextrose, digestion resistant dextrin, guar gum, psyllium, bifidobacterial, and others. |
| Body fat | Green tea catechin, medium chain fatty acids, oolong tea polymerized polyphenols, digestion resistant dextrin, psyllium, and others. |
| Blood pressure | Lactotripeptide, eucommia leaf glycoside, sardine peptides, γ-aminobutyric acid (GABA), chlorogenic acid glycoside, and others. |
| Blood cholesterol levels | Soy proteins, chitosan, plant sterols, tea catechins, tea polyphenols, and others. |
| Blood sugar levels | Digestion resistant dextrin, guava leaf polyphenols, wheat albumin, L-arabinose, and others. |
| Mineral absorption | Calcium citrate malate, casein phosphopeptide, fructo-oligosaccharide, and others. |
| Blood triacylglycerol levels | Docosahexaenoic acid, eicosapentaenoic acid, globin protein degradation products, oolong tea polymerized polyphenols, beta-conglycinin, and others. |
| Dental health | Xylitol, palatinose, maltitol, erythritol, tea polyphenols, and others. |
| Bone health | Soy isoflavones, vitamin K2, milk basic protein (BMP), polyglutamic acid, and calcium* |
| Skin moisture | Glucosylceramide. |
* Risk reduction of osteoporosis
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1) Government-commissioned projects

The NIHN is an impartial and independent organization (Figure 2). First, the NIHN measures the nutrients and ingredients in the product and verifies the details reported by the manufacturer, ensuring accurate information on the labels. Additionally, the NIHN is currently developing, improving, and standardizing the analytical methods for the evaluation of nutritional components and other components involved in FOSHU classification. Second, the NIHN assesses the safety and efficacy of health foods, and conducts research on their nutritional and physiological effects; this provides academic support to the government food labelling systems. Third, the NIHN continually collects information on the safety and efficacy of health foods, including FHC, and ingredients based on scientific evidence; this information is then shared in the “Information system on safety and effectiveness for health foods,” which is available on the website. This publication is widely used by the general public and professionals in Japan. Table 2 shows the contributions of the NIHN to the FHC and FOSDU systems. On this article, we show the studies on the assessment of safety and efficacy of health food ingredients as follows for example.

2) Studies on the assessment of the safety and efficacy of health food ingredients

The NIHN has evaluated the safety and efficacy of numerous health food ingredients and published substantial evidence in this regard. In this example, we discuss studies on soy isoflavones, many of which are marketed as FOSHU, FFC, and health foods.

Soy isoflavones have weak estrogenic effects, and their beneficial effects on bone health have been reported in both animals and humans. However, there have been concerns regarding the safety of their estrogenic activity.
In 2001, soy isoflavones were approved as a principle ingredient in FOSHU, based on their reported benefits for bone health. The safety of soy isoflavones was assessed by the Food Safety Commission (FSC) in the Cabinet. In 2006, the FSC reported that the upper limit of safe supplementary intake of soy isoflavone aglycone as a FOSHU was 30 mg, and the upper limit of safe daily intake of aglycone as soybean products was 75 mg\(^{17}\). Our studies on the efficacy and safety of soy isoflavones were cited as scientific evidence on the report\(^{18, 19}\). In the report, supplementary intake of isoflavones was not recommended for infants, and pregnant and lactating women. Moreover, it was reported that the available data on equol, a metabolite of the soy isoflavone daidzein, were limited, and thus, further investigation was required. It was subsequently found that equol inhibited the decrease in bone mineral density without an increase in uterine weight in OVX mice\(^{20, 21}\). Moreover, it was shown that equol transferred from lactating dams, fed daidzein in the diet, to nursing infants via the milk\(^{22}\). Furthermore, we performed a 1-year double-blind, randomized, placebo-controlled trial with natural S-equol supplements for non-equol-producing menopausal Japanese women\(^{23}\).

IV. Discussion

The diversification of health claims may contribute to the health of the population, and lead to progress in food science and technology, and the development of food industries. However, new challenges have also emerged since the establishment of the FFC system. Unlike for the FOSHU certification, governmental inspection and verification are not required by the FFC system; and due to the simplified registration system, the number of products under the FFC label, claiming new health-promoting functions, has rapidly increased. It is difficult for consumers to understand the differences between the FOSHU and FFC categories, or the differences between the so-called “health foods” and FFC. Unlike FOSHU, FFC does not require approval from governmental committees; thus, its standard for scientific basis and credibility is lower than that of FOSHU. Moreover, there are many so-called “health foods” on the Japanese market that do not fall under the FOSHU, FNFC, or FFC categories, and which have not undergone a proper efficacy or safety evaluation.

In particular, products containing herbal ingredients may be subject to inappropriate use, and require labelling. Therefore, a safety, efficacy, and quality assessment of health foods, alongside an effective public communication strategy, is urgently needed.

Hepatic dysfunction is often reported as a serious health consequence of health food consumption\(^{24, 25}\). Thus, we have assessed the safety and efficacy of certain ingredients, such as Siberian ginseng\(^{26}\), licorice root\(^{27}\), isoflavones from *Pueraria* (Kudzu) flower extract\(^{28}\), and proanthocyanidin derived from pine bark extract in cooperation with the Research Center for Medicinal Plant Resources, National Institutes of Biomedical Innovation, Health and Nutrition.

Recently, the use of health foods for beauty purposes, including *Pueraria mirifica*, has caused many health problems in Japan. In 2017, the MHLW, the CAA, and the National Consumer Affairs Center of Japan released information and alerts on the use of health foods, including *Pueraria mirifica*\(^{29, 30}\). It has been reported that one of the main reasons for the health problems associated with *Pueraria mirifica* was the amount of a component with inadequate physiological activity for women, particularly the young generation, that was present in their products\(^{29, 30}\). Indeed, the amount of incorrect information available on the health foods and food ingredients prevents popularization of the FHC system. This also creates challenges for the promotion of appropriate lifestyles, and may increase the prevalence of health hazards. Indeed, the accuracy of the amount of functional ingredients reported on health food labels remains problematic. Thus, safety, efficacy, and quality assessment of health foods are urgently required alongside improved strategies for communicating these foods' health effects to the public. The NIHN (1) measures the amounts of nutrients and ingredients of foods ensuring accurate information on the labels for the approval on the foods labelling system, (2) assesses safety and efficacy of health foods, and provides scientific evidences on their nutritional and physiological effects, and (3) provides reliable online information regarding health foods, FHC and their labelling.

V. Conclusion

The NIHN is an important institution that conducts
scientific evaluation within the national health food system in Japan. It provides summaries of food analysis, conducts basic in vitro and in vivo research as well as human trials, and publishes online information on health foods and its labelling, playing an important role within the FHC system in Japan. The NIHN continues to contribute to ensuring consumer and food safety, and maintaining and improving population health.

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Conflict of Interest

There are no conflicts of interest to declare.

References

1) The Consumer Commission: The survey on consumers’ use of “the Healthy Foods” (Questionnaire Survey) (2012) (in Japanese), https://www.ca.go.jp/consumer/doc/20120605_chousa_houkoku.pdf (Accessed June, 20, 2020)
2) Ministry of Health, Labour and Welfare: Summary of Comprehensive Survey of Living Conditions (2016) (in Japanese), https://www.mhlw.go.jp/toukei/saikin/hw/k-tyosa/k-tyosa16/dl/16.pdf (Accessed June, 20, 2020)
3) Arai, S.: Studies on functional foods in Japan-state of the art, Biosci. Biotechnol. Biochem., 60, 9–15 (1996)
4) Director General, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare: Creation for the food with health claims system, Iyakuhatsu Notification No. 244 (2001) (in Japanese)
5) Consumer Affairs Agency: Website on Outline of Food Labelling Systems for Health and Nutrition, https://www.caa.go.jp/en/policy/food_labeling/pdf/food_labeling_191001_0001.pdf (Accessed June, 20, 2020)
6) Consumer Affairs Agency: Website on “What is Food for Special Dietary Uses?” (in Japanese), https://www.caa.go.jp/policies/policy/food_labeling/health_promotion/pdf/food_labeling_cms206_190909_01.pdf (Accessed June, 20, 2020)
7) Consumer Affairs Agency: Criteria for Labeling Permission for “Foods for Special Dietary Uses” (hereinafter referred to as “FOSDU”), Syousyokuhouyou Notification No. 403 (2018) (in Japanese)
8) Codex Alimentarius: The Food and Agriculture Organization of United Nations and World Health Organization: Nutrition and Health Claims (CAC/GL 23-1997), http://www.fao.org/ag/humannutrition/32444-09f5545b8abe9a0c3ba01a1502ac36e4.pdf (Accessed June, 20, 2020)
9) Consumer Affairs Agency: Website on “the list of approved Specified Health Uses (Approval type)” (in Japanese), https://www.caa.go.jp/policies/policy/food_labeling/health_promotion/#n02 (Accessed June, 20, 2020)
10) Consumer Affairs Agency: Guidelines for handling and guidance on foods for specified health use, Syousyokuhouyou Notification No. 141 (2015) (in Japanese), https://www.caa.go.jp/policies/policy/food_labeling/health_promotion/pdf/food_labeling_cms206_200401_01-2.pdf (Accessed June, 20, 2020)
11) Consumer Affairs Agency: Website on “What is Food with Function Claims (FFC)?”, https://www.caa.go.jp/policies/policy/food_labeling/information/pamphlets/pdf/151224_1.pdf (Accessed June, 20, 2020)
12) Consumer Affairs Agency: Website on “The database of Food with Function Claims” (in Japanese), https://www.fld.caa.go.jp/caaks/cssc/Article05.html (Accessed June, 20, 2020).
13) National Institute of Health and Nutrition, National Institutes of Biomedical Innovation, Health and Nutrition: Website on “Department of Food Function and Labeling”, https://www.nibiohn.go.jp/ eiken/english/research/program_function.html (Accessed June, 20, 2020)
14) National Institute of Health and Nutrition, National Institutes of Biomedical Innovation, Health and Nutrition: Information system on safety and effectiveness for health foods (in Japanese), https://hfnet.nibiohn.go.jp/ (Accessed June, 20, 2020)
15) Ishimi, Y.: Dietary equol and bone metabolism in post-menopausal Japanese women and osteoporotic mice, J. Nutr., 140, 1373S-1376S (2010)
16) Munro, I.C., Harwood, M., Hlywka, J.J., et al.: Soy isoflavones: a safety review, Nutr. Rev., 61, 1–33 (2003)
17) The Food Safety Commission: Basic concept of safety evaluation of the Foods for Specified Health Uses including soy isoflavones (2006) (in Japanese), https://www.fsc.go.jp/hyouka/kyu_singi-isoflavone_kihon.pdf (Accessed June, 20, 2020)
18) Ishimi, Y., Miyaura, C., Ohmura, M., et al.: Selective effects of genistein, a soybean isoflavone, on B-lymphopoiiesis and bone loss caused by estrogen deficiency, Endocrinology, 140, 1893–1900 (1999)
19) Ishimi, Y., Arai, N., Wang, X., et al.: Difference in effective dosage of genistein on bone and uterus in ovariectomized mice, Biochem, Biophys, Res. Commun., 11, 697–701 (2000)
20) Fujikawa, M., Nakamura, M., Wu, J., et al.: Equol, a metabolite of daidzein, inhibits bone loss in ovariectomized mice, J. Nutr., 134, 2623–2627 (2004)
21) Tousen, Y., Ishihata, H., Ishimi, Y., et al.: Equol, a metabolite of daidzein, is more efficient than daidzein for bone formation in growing female rats, Phytother. Res., 29, 1349–1354 (2015)
22) Tousen, Y., Umeki, M., Ishimi, Y., et al.: Different effects of the soy isoflavones, genistein and daidzein, on
pregnant and lactating rats and their offspring, *Jpn. J. Nutr. Diet.*, 64, 161–172 (2006)

23) Tousen, Y., Ezaki, J., Fujii, Y., et al.: Natural S-equol decreases bone resorption in postmenopausal, non-equol-producing Japanese women: a pilot randomized, placebo-controlled trial, *Menopause*, 18, 563–574 (2011)

24) Navarro, V.J., Khan, I., Björnsson, E., et al.: Liver injury from herbal and dietary supplements, *Hepatology*, 65, 363–373 (2017)

25) Avigan, M.I., Mozersky, R.P., Seeff, L.B.: Scientific and Regulatory Perspectives in Herbal and Dietary Supplement Associated Hepatotoxicity in the United States, *Int. J. Mol. Sci.*, 3(17), 331, doi: 10.3390/ijms17030331 (2016)

26) Tousen, Y., Matsumoto, Y., Nishide, Y., et al.: Effects of Siberian ginseng on hepatic drug metabolizing enzymes and bone mineral density in ovariectomized mice, *Jpn. J. Nutr. Diet.*, 75(6), 151–163 (2017)

27) Ishimi, Y., Takebayashi, J., Tousen, Y., et al.: Quality evaluation of health foods containing licorice in the Japanese Market, *Toxicol Rep.*, 21(6), 904–913, doi: 10.1016/j.toxrep.2019.08.013 (2019)

28) Tousen, Y., Takebayashi, J., Kondo, T., et al.: Safety and Efficacy Assessment of Isoflavones from Pueraria (Kudzu) Flower Extract in Ovariectomised Mice: A Comparison with Soy Isoflavones, *Int. J. Mol. Sci.*, 12(20), 2867, doi: 10.3390/ijms122867 (2019)

29) Director of Food Standards Review Division, Pharmaceuticals and Health Care Bureau, Ministry of Health, Labour and Welfare, Food and Safety Division, Pharmaceuticals and Health Care Bureau, Ministry of Health, Labour and Welfare, and Deputy Director-General, Consumer Affairs Agency: Handling of “healthy foods” containing *Pueraria mirifica* as a raw material., Yakuseisyokukanhatu Notification No. 0922-1, Yakuseisyokukanhatu Notification No. 0922-1, and Syousyokuhyou Notification No. 457 (2017) (in Japanese)

30) National Consumer Affairs Center of Japan: Health foods containing “Pueraria mirifica” for beauty purposes, Harmful to young women! Please avoid easy intake-. Corporate number 4021005002918 (2017) (in Japanese), http://www.kokusen.go.jp/pdf/n-20170713_1.pdf (Accessed June, 20 2020)

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日本の健康と栄養に関する食品表示制度における規制ならびに関連する国立健康・栄養研究所の役割

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【目的】日本の健康と栄養に関する食品表示制度における規制ならびに関連する国立健康・栄養研究所の役割をレビューした。

【方法】健康と栄養に関する日本の食品表示制度の発展および課題、ならびに本制度の発展における国立健康・栄養研究所の寄与について調査した。

【結果】1991年、当時の厚生省は栄養改善法に基づき、特定保健用食品制度を創設した。2001年には、ビタミンとミネラルを対象とした栄養機能食品制度が創設され、特定保健用食品とあわせて保健機能食品と位置づけられた。2015年には、食品表示法に基づいて消費者庁により機能性表示食品制度が創設された。日本における食品の表示制度は規制されているにも拘わらず、「健康食品」の使用方法と表示は不適切である可能性がある。そこで国立健康・栄養研究所は、(1)食品表示制度における許可を受けた表示に関する正確な情報を保証するため、食品中の栄養素や成分量を測定し、(2)保健機能食品を含む健康食品の安全性と有効性を評価し、それらの栄養生理学的効果における科学的根拠を提供し、(3)健康食品、保健機能食品およびそれらの表示に関して、オンラインにより信頼できる情報を提供している。

【結論】国立健康・栄養研究所は、日本の保健機能食品制度を含む健康食品の規制制度において、重要な役割を果たしている。

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