Ensuring the Reliability of Food Nutrition Labeling in Japan: Regulation and Laboratory Analysis

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ABSTRACT

Objective: To review the regulatory system for nutrition labeling, especially for nutrient declaration, in Japan, and to highlight the contributions made by the National Institute of Health and Nutrition (NIHN) with regard to the reliability of nutrition labeling of food in recent years.

Methods: We investigated the laws and official documents related to nutrition labeling of food in Japan, as well as relevant academic papers published by the NIHN from 1996 to 2020.

Results: In Japan, under the Food Labeling Act, nutrient declaration of the five nutritional components, namely energy, protein, fat, carbohydrates, and salt equivalent, has been mandatory for all prepackaged processed foods since 2015. Declared nutritional values should be consistent with the values obtained by laboratory analysis in principle, but “the value obtained by reasonable estimate” is permitted under certain conditions. Laboratory analysis is indispensable for verifying the accuracy of label values of foods with nutrient content or health claims. The NIHN has contributed to the regulatory system of nutrition labeling from the following three standpoints: 1) legal inspection body for the Foods for Special Dietary Uses, including the Foods for Special Health Uses, (approval testing) and other prepackaged foods bearing nutrient declaration (compliance testing); 2) proficiency testing provision for organizations performing food nutrition analysis; and 3) research institute to develop and improve analytical methods for nutritional and functional components in foods.

Conclusions: The NIHN has played pivotal roles in ensuring the reliability of nutrition labeling for more than half a century and will continue to do so in the future.

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Key words: regulatory system for nutrition labeling in Japan, legal inspection for nutrient declaration, proficiency testing provider, development and improvement of analytical methods

I. Introduction

Adequate nutrient intake is essential for the maintenance of health and prevention of disease. However, it is often difficult to judge the nutrient content of processed foods from appearance alone. Therefore, consumers require nutrition labels to select foods that meet their nutritional requirements. The Codex Alimentarius Commission published a guideline on nutrition labeling (CAC/GL 2-1985)3. This guideline provides a means for transmitting information on the nutrient content of a food on the label and emphasizes that nutrient declaration should not describe false, misleading, deceptive, or insignificant information. Nowadays, nutrient declaration of key nutrients on the package of prepackaged foods is mandatory in many countries5. In Japan, from May 1996 to March 2015, nutrient declaration for foods without nutrition or health claims was voluntary under the Nutrition Labeling Standards, based on the Health Promotion Act. However, from April 2015, new regulations under the Food Labeling Standards5, based on the Food Labeling Act5, require mandatory nutrient declaration for all prepackaged foods.
in principle.

The National Institute of Health and Nutrition (NIHN) has contributed to the regulatory frameworks on nutrition labeling in Japan since 1952, when the regulatory system to approve foods with nutrition or health claims was launched under the Nutrition Improvement Act. Thereafter, several systems for nutrition labeling have been established, such as nutrient declaration of the foods mentioned above, Foods for Specified Health Uses (FOSHU, in 1991)\textsuperscript{5}, and Foods with Function Claims (FFC, in 2015)\textsuperscript{6}. The NIHN has engaged in legal inspection of these food products by measuring the nutritional and functional components, such as active ingredients of FOSHU, by laboratory testing\textsuperscript{5, 7}.

This article aims to review the regulatory system for nutrition labeling, especially for nutrient declaration, in Japan, and to highlight the contributions made by the NIHN to ensure the reliability of nutrition labeling of foods in the last 25 years.

II. Method

We investigated the acts\textsuperscript{4}, orders\textsuperscript{3}, notices\textsuperscript{8}, and official documents\textsuperscript{9} related to food nutrition labeling in Japan. Furthermore, we conducted a literature search to clarify the contributions made by the NIHN, using the annual reports of the NIHN (from 1996 to 2014) and the publication database (monthly reports) on the NIHN website (https://www.nibiohn.go.jp/eiken/) from 2015 to present.

III. Results

1. Review of the regulatory system for nutrition labeling of food in Japan

1) Regulatory system for nutrient declaration

In Japan, under the Food Labeling Standards\textsuperscript{3}, based on the Food Labeling Act\textsuperscript{4}, nutrient declaration has been principally mandatory for all prepackaged processed foods and food additives since 2015. The exceptions to this rule are as follows:

- Food packages are too small (less than around 30 cm\textsuperscript{2} surface area for labeling).
- Alcoholic beverages
- Products of low nutritional contribution
- Products of which the ingredients change very quickly
- Products manufactured by very small companies

In addition, nutrient declaration of fresh foods is voluntary. The Food Labeling Standards were fully enforced on April 1, 2020.

The amounts of the five key nutritional components, namely energy, protein, fat, carbohydrate, and salt equivalent, are mandatory to provide in the format shown in Figure 1A. Figure 1B indicates the format used to declare mandatory and voluntary nutrients, such as dietary fiber, minerals, and vitamins. The first column of Table 1 shows the mandatory and voluntary nutrients under regulation in Japan. The second column of Table 1 indicates the units of nutrients to be expressed. The other features related to nutrient declaration formats are annotated in the legend of Figure 1.

![Figure 1 Nutrient declaration format in Japan](https://www.nibiohn.go.jp/eiken/)

**Figure 1** Nutrient declaration format in Japan

Created based on Appended Forms 2 and 3 of the Food Labeling Standard\textsuperscript{5}. The left panel (A) is the declaration format for mandatory nutrients only. The right panel (B) is the declaration format for voluntary nutrients as well as mandatory nutrients.

\textsuperscript{a)} Reference amount, such as per 100 g, 100 ml, serving (indicate the amount for one serving), package, or other standard sizes, is shown as food units.

\textsuperscript{b)} Sodium content should be declared in salt equivalent (sodium (mg) \times 2.54/1,000).

\textsuperscript{c)} A nutrient declaration based on a reasonable estimate is acceptable in certain situations.

\textsuperscript{d)} Specific types of fat and carbohydrates can be broken down and displayed.

\textsuperscript{e)} Saturated fat and dietary fiber are voluntary but recommended declarations.

\textsuperscript{f)} Available carbohydrates and dietary fiber should be shown together.

\textsuperscript{g)} Voluntary nutrients that are not declared are omitted from this format.
| Nutrient            | Unit | Official methods                                      | Tolerance limit                                      | Zero declaration |
|---------------------|------|------------------------------------------------------|------------------------------------------------------|------------------|
| Protein             | g    | Nitrogen determination and conversion method         | ± 20% (± 0.5 g in the case of < 2.5 g/100 g)          | 0.5 g            |
| Fat                 | g    | Ether extraction method, chloroform/methanol extraction method, Gerber method, acid hydrolysis method, Roese-Gottlieb method | ± 20% (± 0.5 g in the case of < 2.5 g/100 g)          | 0.5 g            |
| Saturated fatty acid| g    | GC                                                   | ± 20% (± 0.1 g in the case of < 0.5 g/100 g)          | 0.1 g            |
| n-3 Fatty acid      | g    | GC                                                   | ± 20%                                                | –                |
| n-6 Fatty acid      | mg   | GC                                                   | ± 20%                                                | –                |
| Cholesterol         | mg   | GC                                                   | ± 20% (± 5 mg in the case of < 25 mg/100 g)           | 5 mg             |
| Carbohydrate        | g    | By-difference method (subtract total weight of protein, fat, ash§, and water|| from food weight) | ± 20% (± 0.5 g in the case of < 2.5 g/100 g)          | 0.5 g            |
| Available carbohydrate | g   | By-difference method (subtract total weight of protein, fat, dietary fiber, ash§, and water|| from food weight) | ± 20% (± 0.5 g in the case of < 2.5 g/100 g)          | 0.5 g            |
| Sugars              | g    | GC, HPLC                                             | ± 20% (± 0.5 g in the case of < 2.5 g/100 g)          | 0.5 g            |
| Dietary fiber       | g    | Prosky method, HPLC                                  | ± 20%                                                | –                |
| Zinc                | mg   | AAS, ICP-OES                                         | + 50% and – 20%                                      | –                |
| Potassium           | mg   | AAS, ICP-OES                                         | + 50% and – 20%                                      | –                |
| Calcium             | mg   | Potassium permanganate method, AAS, ICP-OES          | + 50% and – 20%                                      | –                |
| Chromium            | µg   | AAS, ICP-OES                                         | + 50% and – 20%                                      | –                |
| Selenium            | µg   | Fluorometric determination method, AAS               | + 50% and – 20%                                      | –                |
| Iron                | mg   | AAS, ICP-OES                                         | + 50% and – 20%                                      | –                |
| Copper              | mg   | AAS, ICP-OES                                         | + 50% and – 20%                                      | –                |
| Sodium§             | mg¹¹ | AAS, ICP-OES                                         | ± 20% (± 5 mg in the case of < 25 mg/100 g)           | 5 mg             |
| Magnesium           | mg   | AAS, ICP-OES                                         | + 50% and – 20%                                      | –                |
| Manganese           | mg   | AAS, ICP-OES                                         | + 50% and – 20%                                      | –                |
| Molybdenum          | µg   | ICP-MS, ICP-OES                                      | + 50% and – 20%                                      | –                |
| Iodine              | µg   | Titration method, GC                                 | + 50% and – 20%                                      | –                |
| Phosphorus          | mg   | Vanadomolybdate absorption photometry, spectrophotometric molybdenum blue method, ICP-OES | + 50% and – 20%                                      | –                |
| Niacin              | mg   | HPLC, microbiological assay                          | + 80% and – 20%                                      | –                |
| Pantothenic acid    | mg   | Microbiological assay                                | + 80% and – 20%                                      | –                |
| Biotin              | µg   | Microbiological assay                                | + 80% and – 20%                                      | –                |
| Vitamin A           | µg   | HPLC, absorption spectrum method                     | + 50% and – 20%                                      | –                |
| Vitamin B₁          | mg   | HPLC, biochrome method                               | + 80% and – 20%                                      | –                |
| Vitamin B₂          | mg   | HPLC, lumiflavin method                              | + 80% and – 20%                                      | –                |
| Vitamin B₆          | mg   | Microbiological assay                                | + 80% and – 20%                                      | –                |
| Vitamin B₁₂         | µg   | Microbiological assay                                | + 80% and – 20%                                      | –                |
| Vitamin C           | mg   | 2, 4-Dinitrophenylhydrazine method, indophenol-xylene extraction method, HPLC, redox titration method | + 80% and – 20%                                      | –                |
| Vitamin D           | µg   | HPLC                                                 | + 50% and – 20%                                      | –                |
| Vitamin E           | mg   | HPLC                                                 | + 50% and – 20%                                      | –                |
| Vitamin K           | µg   | HPLC                                                 | + 50% and – 20%                                      | –                |
| Folate              | µg   | Microbiological assay                                | + 80% and – 20%                                      | –                |
| Energy              | kcal | Modified Atwater method                              | ± 20% (± 5 kcal in the case of < 25 kcal/100 g)       | 5 kcal           |

Created based on Appended Table 9 of the Food Labeling Standard. AAS: Atomic absorption spectroscopy, GC: Gas chromatography, HPLC: High-performance liquid chromatography, ICP-MS: Inductively coupled plasma-mass spectrometry, ICP-OES: Inductively coupled plasma-optical emission spectrometry.

† Detailed protocols of the official methods are shown in the notice entitled “Notification regarding food labeling standards.”

‡ Amounts less than the indicated value per 100 g (ml) may be expressed as zero.

§ Ash is determined by the magnesium acetate addition ashing method, direct ashing method, or sulfate addition method.

|| Water is determined by the Karl-Fischer method, drying aid method, vacuum drying method, air drying method, or plastic film method.

¶ The amount of sodium can be declared in addition to the amount of salt equivalent when no sodium salt is added.

†† If the amount of sodium is > 1,000 mg, the unit can be changed from “mg” to “g.”
Numerical declarations of nutrient contents can be provided in two ways: a “single value” or “ranged values (lower value-upper value).” The compliance of food declaration with the Food Labeling Standards is assessed by comparing the analytical value with the presented value. The third column of Table 1 shows the official methods authorized by the Food Labeling Standards to obtain analytical values. In the case that a single value is presented, the analytical value as a percentage of the presented value should be within the tolerance limit designated to each nutrient. Generally, the tolerance limits are ± 20% for energy, macronutrients, and sodium; −20% to +50% for other minerals and fat-soluble vitamins; and −20% to +80% for water-soluble vitamins. However, the tolerance limits for several nutrients may be extended to lower concentrations (see the fourth column of Table 1 for more details). Furthermore, very low concentrations may be expressed as zero (see the fifth column of Table 1 for more details). However, in the case that ranged values are presented, the analytical value should be between the lower and upper values.

When nutrient contents are not under sufficient control, “the value obtained by reasonable estimate” (estimated value) is permitted in cases where all of the following conditions are satisfied:

- The fact that the value may be outside the tolerance limit is explicitly declared using fixed terms, namely “Estimated value” or “This nutrient declaration is a rough indication.”
- Data on which the presented value is based are properly preserved.
- The product has no nutrition claim, including nutrition content and health claims.

2) Regulatory system for nutrient content claims

The nutrition content claim explains the levels of nutrients (e.g., “high in calcium” or “low in fat”). In the case of the nutrients that are recommended to be increased (i.e., protein, dietary fiber, 6 minerals [zinc, potassium, calcium, iron, copper, and magnesium], and 13 vitamins [niacin, pantothenic acid, biotin, vitamin A, vitamin B1, vitamin B2, vitamin B6, vitamin B12, vitamin C, vitamin D, vitamin E, vitamin K, and folate]), the conditions applied are as follows:

- Nutrient content claims are made in comparison with nutrient reference values (NRVs) for food labeling10.
- “Source of (name of the nutrient)” can be labeled when the product contains ≥10% of the NRV per 100 g (protein), ≥15% of the NRV per 100 g (vitamins and minerals), or ≥3 g per 100 g.
- “High in (naming the nutrient)” can be labeled when the product contains two or more times the nutrients for “source.”
- “Increased in (naming the nutrient)” can be labeled when the increase is ≥15% of the NRV per 100 g and the rate of increase is ≥25% between the compared foods (protein and dietary fiber), or when the increase is ≥10% of the NRV per 100 g between the compared foods (vitamins and minerals). Full details of the comparison, such as the food being compared and the amount of difference, should be given along with the nutrition content claim.

In the case of nutrients recommended to be reduced (i.e., energy, fat, saturated fatty acid, cholesterol, sugars, and sodium), the conditions applied are as follows:

- “Low in (naming the nutrient)” can be labeled when the product contains ≤40 kcal per 100 g (energy), ≤3 g per 100 g (fat), ≤1.5 g per 100 g (saturated fatty acid), ≤20 mg per 100 g (cholesterol), ≤5 g per 100 g (sugars), or ≤120 mg per 100 g (sodium).
- “Free of (naming the nutrient)” can be labeled when the product contains ≤5 kcal per 100 g (energy), ≤0.5 g per 100 g (fat), ≤0.1 g per 100 g (saturated fatty acid), ≤5 mg per 100 g (cholesterol), ≤0.5 g per 100 g (sugars), or ≤5 mg per 100 g (sodium).
- “Reduced in (naming the nutrient)” can be labeled when the reduction is not less than the figure defined as “low” and the rate of reduction is ≥25% between the compared foods. Full details of the comparison, such as the food being compared and the amount of difference, should be given along with the nutrition content claim.

3) Regulatory system for health claims

Health claims refer to statements on food labels concerning the relationship between nutritional/functional components and health. In Japan, as in many countries around the world, health claims are not permitted on regular food. The exceptions are as follows:

- “Foods for Special Health Uses (FOSHU)” can be labeled a functional claim for an active ingredient such as “This product contains indigestible dextrin,
which suppresses the elevation of postprandial blood glucose levels." The government reviews the claimed effects and safety, and the Consumer Affairs Agency (CAA) approves the labeling of each product. The content of an active ingredient in a FOSHU product should be confirmed by laboratory analysis by third-party organizations before and after the sale.

• “Foods with nutrient function claim (FNFC)” can be labeled as a functional claim for a specific nutrient such as “Vitamin C is a nutrient that helps keep your skin and mucous membranes healthy and has an antioxidizing effect.” These claims should be provided by using fixed sentences for individual nutrients determined by the CAA. The unsaturated n-3 fatty acids, 6 minerals (zinc, potassium, calcium, iron, copper, and magnesium), and 13 vitamins (niacin, pantothenic acid, biotin, vitamins A, B₁, B₂, B₉, B₁₂, C, D, E, K, and folic acid) are permitted FNFC. Unlike FOSHU, FNFC does not require individual permission from the CAA. The amount of nutrients claimed in the FNFC should be between the maximum and minimum daily intakes designated for individual nutrients.

• “Foods with Function Claim (FFC)” can be labeled as a functional claim for an active ingredient, similar to FOSHU. The evidence for safety and efficacy is submitted to the CAA before the sale. However, unlike FOSHU, FFC is not individually approved by the CAA. The content of an active ingredient in an FFC product should be confirmed by laboratory analysis by third-party organizations after the sale.

2. Contributions made by the NIHN to ensure the reliability of food nutrition labeling

1) Approval testing for FOSDU, including FOSHU, and compliance testing for foods with nutrition labeling

As described in the Introduction, the NIHN has played a public role in confirming the values on food nutrition labels. FOSDU, including FOSHU products, need to undergo pre-marketing legal inspection (approval testing) to determine whether they contain nutritional or functional components in accordance with the information provided by the food labels. Other prepackaged foods bear nutrient declaration, as well as nutritional content claims and/or health claims, under the responsibility of food companies. National and local governments perform compliance testing to verify their compliance with the regulations. Originally, laboratory analyses for approval testing and compliance testing in Japan were solely assigned to the NIHN, but they later expanded to other third-party organizations, namely “registered test and inspection bodies” under the Health Promotion Act with respect to approval testing, and “registered conformity assessment bodies” under the Food Sanitation Act with respect to compliance testing. In response to these changing situations, the NIHN has shifted its main role from an inspection organization to a supervising organization.

2) Proficiency testing schemes for organizations that perform food nutrition analysis

Laboratory analysis is essential to obtain correct values for the nutrients contained in foods; however, considerable errors remain a possibility. Thus, the NIHN developed a protocol for proficiency testing schemes for analytical organizations that perform food nutrition analysis. The NIHN has provided a proficiency testing scheme based on this protocol once per year in cooperation with the Food and Drug Safety Center since 2017. There were 65 and 73 participating organizations in 2017 and 2018, respectively, and more than 70% of them were registered conformity assessment bodies. Energy, protein, fat, carbohydrate, salt equivalent, calcium (2018 only), and iron (2018 only) in pork and chicken sausages were target analytes in these years (Table 2). Approximately 10% of the organizations reported inadequate values for one or more nutrients subject to mandatory declaration. In particular, the reported values for carbohydrate or salt equivalent tended to be inappropriate. Therefore, the
Table 2  Summary of the suitable or unsuitable values reported from proficiency testing schemes for food nutrition analysis in Japan

| Subjects               | 2017, n = 65 (54) | 2018, n = 73 (54) |
|------------------------|-------------------|-------------------|
|                        | Suitable          | Unsuitable        | Suitable          | Unsuitable        |
| Energy                 | 61 (53)           | 3 (1)             | 69 (52)           | 3 (2)             |
| Protein                | 65 (54)           | 0 (0)             | 69 (52)           | 4 (2)             |
| Fat                    | 62 (53)           | 3 (1)             | 71 (53)           | 2 (1)             |
| Carbohydrate           | 61 (53)           | 3 (1)             | 66 (50)           | 6 (4)             |
| Salt equivalent        | 60 (51)           | 4 (3)             | 67 (51)           | 4 (3)             |
| Above-listed nutrients | 58 (49)           | 7 (5)             | 62 (47)           | 11 (7)            |
| Calcium                | Not applicable    |                   | 44 (33)           | 6 (6)             |
| Iron                   | 47 (36)           | 3 (3)             |                   |                   |

Created based on reference[13]. Numbers in parentheses indicate the number of public organizations, such as registered conformity assessment bodies, and prefectural and municipal public health institutes.

Table 3  Overview of the scientific contributions made by the NIHN to the reliability of food nutrition labeling in the last 25 years (1996-2020)

| Nutrients                | Approach                  | Description                                                                 | Reference(s) |
|--------------------------|---------------------------|-----------------------------------------------------------------------------|---------------|
| Macronutrients           |                           |                                                                             |               |
| Dietary fiber            | HPLC                      | A simple solid-phase extraction method of desalting test solutions to determine the level of soluble dietary fiber in food by HPLC was developed and validated in inter-laboratory validations. | 14            |
| Minerals                 |                           |                                                                             |               |
| Selenium                 | HG-AAS                    | The conditions to measure selenium in food samples by HG-AAS were optimized. | 15            |
| Selenium                 | ICP-MS                    | A simple method to determine the level of selenium in liquid infant formula by ICP-MS was developed and validated in single- and cross-laboratory validations. This method can be used for an approval inspection of infant formulas for the inclusion in Foods for Special Dietary Uses (FOSDU). | 16            |
| Molybdenum               | ICP-MS, ICP-OES           | Quantitative determination methods of molybdenum in foods by ICP-MS and ICP-OES after dry ashing were studied and validated in a single laboratory validation. These methods can be used for an approval inspection of comprehensive nutrition food products for inclusion in FOSDU. | 17, 18        |
| Vitamins                 |                           |                                                                             |               |
| Biotin, niacin, pantothenic acid, vitamin B6 | Microbiological assay | The efficacy of microbiological assays for biotin, niacin, pantothenic acid, vitamin B6, and inositol was improved by using lyophilized cells. | 19, 20        |
| Vitamin B12              | Microbiological assay     | Various models for calibration curve construction were compared to determine the levels of vitamin B12 and niacin in infant formula using microbiological assays. | 21            |
| Vitamin B12              | Microbiological assay     | The factors affecting the interlaboratory analytical accuracy of vitamin B12 contents in fortified food measured by microbiological assay were clarified. | 22            |
| Vitamin B12              | HPLC                      | An HPLC method to determine cyanocobalamin (vitamin B12) in multivitamin tablets was developed and validated in a single laboratory validation. | 23            |
| Vitamin C                | HPLC                      | The determination of vitamin C in plasma and food samples using HPLC with an electrochemical detector was studied. | 24, 25        |
| Vitamin C                | Method comparison         | The vitamin C contents in selected vegetables obtained by the three analytical methods used to establish present and past versions of the Standard Tables of Food Composition in Japan were compared. | 26            |
| Vitamin D                | HPLC                      | Two-step HPLC methods for the determining vitamin D content in foods were improved and validated in single- or inter-laboratory validations. | 27, 28        |
| Folate                   | Microbiological assay     | Tea catechins have no practical impact on the results of a microbiological assay for folate in green tea. | 29            |
| Active ingredients for Foods for Specified Health Uses (FOSHU) and/or Foods with Function Claims (FFC) |                           |                                                                             |               |
| Isoflavone, soy protein  | Survey                    | Contents of isoflavone and/or soy protein in soy foods and/or health foods, including FOSHU, marketed in Japan were evaluated. | 30-32         |
| Isoflavone               | HPLC                      | The analytical methods for isoflavones based on the Official Method of AOAC International (OMA) 2001.10 and OMA 2008.03 were improved and validated in single- and inter-laboratory validations. | 33            |
| Catechin                 | HPLC                      | Methods for the determination of the levels of tea catechins in plasma and foods by HPLC with an electrochemical detector were developed. | 34, 35        |
| 1,4-Dihydroxy-2-naphthoic acid | HPLC | Analytical precision of 1,4-dihydroxy-2-naphthoic acid, one of the active components of FOSHU, was improved by adding dithiothreitol to the mobile phase of HPLC. | 36            |
| Quercetin                | HPLC                      | Applicability of OMA 2008.07 for quercetin in ginkgo dietary supplements to onion samples was verified in single- and inter-laboratory validations. | 37            |
| Glabridin                | Survey                    | Contents of glabridin, one of the functional ingredients of FFC, in health foods containing licorice were evaluated. | 38            |
| Others                   |                           |                                                                             |               |
| Hardness, Adhesiveness   | Food texture analysis     | A measurement method using a small-scale dish was developed to determine food texture profiles (hardness, adhesiveness, and cohesiveness) of FOSDU for people with difficulty swallowing. | 39            |

HG-AAS: Hydride generation - atomic absorption spectrometry, HPLC: High-performance liquid chromatography, ICP-MS: Inductively coupled plasma-mass spectrometry, ICP-OES: Inductively coupled plasma-optical emission spectrometry.
NIHN continues to provide proficiency testing for the purposes of quality assurance and continuous improvement of organizations performing food nutrition analysis.

3) Scientific contributions made by the NIHN to ensure the reliability of food nutrition labeling

Through the works related to inspection and supervision, the NIHN has provided 26 relevant publications in the last 25 years (Table 3). The breakdown by nutrients shows that one of the publications dealt with macronutrients, four dealt with minerals, eleven dealt with vitamins, nine dealt with active ingredients, and one dealt with others. These studies have contributed not only to the verification of food nutrition labels, but also to scientific improvement in nutritional and functional components analysis.

IV. Discussion

In Japan, the regulatory system for nutrition labeling has dramatically changed since the Food Labeling Act was enforced in 2015. Essential information on nutrient contents in almost all prepackaged foods is available to everyone by the nutrient declaration. Food nutrition labeling has the potential to be a strong tool to promote public health. Therefore, one of the specific goals of “Health Japan 21”, the Japanese health promotion plan from 2000 to 2012, was to “increase the proportion of persons who read nutrition labels when dining out or purchasing food”. This goal was premised on a tacit agreement that nutrient labeling was accurate and reliable. There seem to be three essential factors for ensuring the reliability of food nutrition labels, as follows:

- The enforcement of appropriate regulations. Currently, the regulatory system for nutrition labeling in Japan is more complicated than before. A science-based system for verifying compliance with standards by laboratory analysis is increasingly important.
- Good performance of individual laboratories for food component analysis. For reliable food nutrition labeling, whole laboratory analysis processes should be properly managed in all laboratories engaged in food nutrition labeling.
- A proper analytical method. The methods for the analysis of nutritional components should be updated with advances in science. Continued efforts to develop and improve analytical methods are required to provide more reliable nutrition labeling.

The NIHN has played pivotal roles in these areas for more than half a century, and will continue to contribute to ensure the reliability of nutrition labeling of foods; the ultimate goal of which is to help extend the healthy life expectancy in Japan.

Conflict of Interest

There are no conflicts of interest to declare.

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日本における食品栄養表示の信頼性確保：規制および試験室分析

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【目的】日本における食品の栄養表示（特に栄養成分表示）に関する規制の枠組みについて概説し、栄養表示の信頼性を確保するために国立健康・栄養研究所（健栄研）が近年果たしてきた役割を明らかにした。

【方法】日本における食品の栄養表示に関連した法令や公文書、1996年から2020年の間に健栄研から発表された学術論文を調査した。

【結果】2015年以降、日本では食品表示法に基づき、全ての加工食品について熱量、たんぱく質、脂質、炭水化物および食塩相当量の5成分の栄養成分表示が義務付けられている。栄養成分表示値は、原則的に試験室分析の結果と一致する必要があるが、「合理的な推定により得られた値」を表示することが許されている場合もある。しかし、栄養強調表示や健康強調表示がなされた食品については、必ず試験室分析で表示値を検証する必要がある。健栄研は、1）特別用途食品（特定保健用食品を含む）の許可試験および栄養成分表示がなされた全食品の養試験の実施、2）栄養成分解析を行っている機関への技能試験の提供、3）栄養成分や機能性成分に関する適切な分析方法の開発および改良を行うことにより、栄養表示の規制の枠組みに寄与している。

【結論】健栄研は、50年以上の長きにわたり、栄養表示の信頼性確保において中心的な役割を担っており、今後も引き続きその役割を果たすことが望まれる。

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