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The first survey of gap between the actual labelling and efficacy information of functional substances in food under the regulatory processes in Japan

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ABSTRACT

To make well-informed choices, consumers need access to reliable and clear messages regarding the benefits of functional substances in food. This study identified foods with function claims (FFCs) in Japan that had a gap between actual labeling and efficacy information of functional substances not visible on their food package. Between April 1, 2015, to July 20, 2018, 1,310 FFCs were submitted to the regulatory agency and analyzed. The proportion of FFCs with a gap was highest in the health claim category of blood pressure management (79.5%), followed by neutral fat reduction in blood (75%) and suppression of blood sugar spikes (73.4%). These gaps are attributable to differences in food development strategy. Thus, to ensure the quality of benefit communication on FFC to consumers, scientific evidence regarding health claims of functional substances should be managed in an integrated manner.

1. Introduction[1]

Since the late 1980s, Japan has been a pioneer in the field of foods with health claims (FHCs), that adjust an individual's physical condition. To promote self-care against pre-symptomatic conditions, Japan enacted the Foods with Function Claims (FFCs) system on April 1, 2015 based on the dietary supplement system of the United States, which regulates similar FFCs (Tanemura, Hamadate, & Urushihara, 2017b). Japan's FFC system requires food developers to submit results of randomized clinical trials (RCT), systematic review (SR), or both to substantiate efficacy, but a review by regulatory agencies are unnecessary in Japan (Tanemura et al., 2017b), resulting in a substantial increase in the number of FFCs (Tanemura, Hamadate, & Urushihara, 2017a). This system differs from other developed regions such as the European Union, which has a review process by regulatory agencies.

While a regulatory review process is not required, the Consumer Affairs Agency posts FFC application dossiers and summaries on its website (Consumer Affairs Agency, 2015). The public thus has access to FFC efficacy and safety information with scientific evidence, helping consumers make informed food choices. Nevertheless, the highly technical applications may be difficult to read, hampering consumer ability to understand risks and benefits. In addition, the current regulatory system permits food developers to include multiple health claims on the label of a single FFC product. These may cause confusion among consumers regarding the benefits in a food. Consumers should have easier access to benefit information of functional substances in FFCs (Food Safety Commission in Cabinet Office, 2015; Tanemura et al., 2017b).

Currently, the official guidelines of the Consumer Affairs Agency indicate that health claims must be verified using scientific evidence. When consumers unintentionally consume multiple FFC products containing the same ingredient but labelled with separate functions, they may experience unpleasant adverse event due to excessive intake, such as diarrhea with dextrin (National Institutes of Biomedical Innovation, 2020a). We feel that to promote rational and safe use of FFCs, we should begin with understanding the "gap" (discrepancies) between actual labelling of FFCs and the efficacy information of functional substances. However, Japan does not have integrated information management system to organize scientific evidence every functional substance.

In 2020, the Agency publicly released a draft guideline, after-the-fact check of scientific evidence relating to FFCs, intended to strengthen regulation (Consumer Affairs Agency, 2020). This change is expected to emphasize the need to manage and provide timely updates on the efficacy information of functional substances based on the updated latest scientific evidence.

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[1] Abbreviations: foods with health claims (FHCs); Foods with Functional Claims (FFCs); European Union (EU); randomized clinical trial (RCT); systematic review (SR).

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In this study, we aimed to identify FFCs with a gap between actual labeling and efficacy information of functional substances.

2. Materials and methods

2.1. Data sources

This study extracted relevant information from publicly available application dossiers in the online FFC database of Japan's Consumer Affairs Agency (Consumer Affairs Agency, 2015).

Specifically, the data came from Form 1 ("An overview of scientific evidence on FFCs for general consumers") and Form 5 ("Scientific evidence of functionality"). The former included summaries of evidence and administrative information, such as application number, submission date, product name, health claims, and functional substances. The latter included type of evidence (RCTs, SRs, or both) and study summary along with publication/data on file.

The data did not include identifiable subjects because we used official materials available in the public domain. Accordingly, an ethical review was not required under local ethical guidelines.

2.2. Selection of FFCs

FFCs were selected if they used the new application format in the dossiers submitted between April 1, 2015 and July 20, 2018. FFCs with the older format were excluded because their format did not contain the necessary data for conducting this study.

2.3. Definitions

This study defined "actual labeling" as health claim(s) on the food package. "Substance list" is the functional substances written in the application dossier of each FFC product, grouped by associated health claim categories (Table 1). Finally, "potential labeling" is any health claim that could be on the food package based on the substance list, but is absent. The presence of potential labeling indicated that a gap exists between actual labeling and efficacy information of functional substances.

2.4. Data preparation

The FFCs were classified according to their actual labelling into 22 commonly used health claim categories (https://db.plusaid.jp/). This classification was based on study aims of RCTs or SRs described in Form 5 of the application dossiers of selected FFCs (see Supplementary Fig. 1).

The 22 health claim categories were: (a) improvement of cholesterol levels, (b) reduction of body fat, (c) reduction of neutral fat in the blood, (d) suppression in blood sugar spikes, (e) alleviation of stress and tension, (f) management of blood pressure, (g) reduction of fatigue, (h) improvement in sleep quality, (i) improvement of memory ability, (j) skin moisturization, (k) lubrication of joints, (l) acceleration of bone metabolism, (m) improvements in building new muscle, (n) intestinal regulation, (o) maintenance of healthy liver function, (p) alleviation of nose or eye discomfort, (q) improvement of ocular function, (r) maintenance of peripheral temperature, (s) maintenance of walking ability, (t) maintenance of healthy teeth, (u) improvement of basal metabolism, and (v) reduction of leg swelling.

To generate the substance list, each functional substance used in the selected FFCs was grouped by health claim category on the actual labelling (see Supplementary Fig. 1). The FFCs themselves were then analyzed to determine whether they could have placed potential labelling on the food package (see Supplementary Fig. 2).

Table 1
Most-used functional substance every health claim category.

Health claim categories	Functional substance	n
(a)	Procyanidin B1	8
	β-glucan	8
(b)	*Puerariae thomsonii* flower-derived isoflavones	51
(c)	Indigestible dextrin	125
(d)	Indigestible dextrin	127
(e)	Gamma-Amino Butyric Acid (GABA)	61
(f)	Gamma-Amino Butyric Acid (GABA)	83
(g)	Ubiquinone	22
(h)	L-Theanine	36
(i)	*Ginkgo biloba* flavonoid glycosides, *Ginkgo biloba* terpene lactones	66
(j)	Hyaluronic acid sodium salt	63
(k)	Glucosamine hydrochloride	32
(l)	Soy isoflavone	29
(m)	3-Hydroxy-3-methylbutyrate (HMB)	18
(n)	Indigestible dextrin	75
(o)	Curcumin	1
(p)	Curcumin, Bisacron	1
(q)	Methylated catechin	11
(r)	Lutein ester	34
(s)	Monoglucosyl hesperidin	18
(t)	3-Hdroxy-3-methylbutyrate (HMB)	8
(u)	*Reuteri bacteria* (*L. reuteri DSM 17938 strain*)	2
(v)	Capsinoid	1

n, the number of foods with functional claims.
Notes: Health claim categories, (a) improvement of cholesterol levels, (b) reduction of body fat, (c) reduction of neutral fat in the blood, (d) suppression of spikes in blood sugar, (e) alleviation of stress and tension, (f) management of blood pressure, (g) reduction of fatigue, (h) improvement in sleep quality, (i) improvement of memory ability, (j) skin moisturization, (k) joint lubrication, (l) acceleration of bone metabolism, (m) improvement in building new muscle, (n) intestinal regulation, (o) maintenance of healthy liver function, (p) alleviation of nose or eye discomfort, (q) improvement for ocular function, (r) maintenance of peripheral temperature, (s) maintenance of walking ability, (t) maintenance of healthy teeth, (u) improvement of basal metabolism, and (v) reduction of leg swelling.

2.5. Outcome

The outcome in this study was the proportion of FFCs with potential labeling.

2.6. Data analysis

We summed the total number of FFCs and calculated the proportion with potential labeling per health claim category. These analyses were performed using JMP® 13 (SAS Institute Inc., Cary, NC, USA).

3. Results

3.1. Health claim categories of functional substances

Indigestible dextrin was most common functional substance in FFCs. Dextrin was classified into health claim category (d): suppression of blood sugar spikes (n = 127). It was also the primary substance in FFCs that claim to reduce neutral fat in the blood (category c, n = 125) and (n) regulate intestinal health (category n, n = 75; Table 1).

3.2. Study characteristics regarding FFCs

We reviewed 1,408 FFC application dossiers, but excluded 98 due to their use of the old incompatible form. The final analysis examined 1,310 FFCs containing a single or multiple functional substance(s) and labelled with either a single or multiple health claim(s). Of the 22 health claim categories, eight included over 100 FFC submissions, filed

Table 2
Foods with functional claims that have other potential health claims within each category.

Health claim categories	Total	Other potential health claims (Yes)	
	n	n	%
a	30	19	63.3
b	131	42	32.1
c	240	180	75
d	169	124	73.4
e	83	67	80.7
f	122	97	79.5
g	51	33	64.7
h	57	29	50.9
i	114	12	10.5
j	110	8	7.3
k	71	47	66.2
l	38	0	0
m	23	21	91.3
n	171	48	28.1
o	2	0	0
p	15	0	0
q	110	15	13.6
r	24	18	75
s	14	8	57.1
t	3	0	0
u	1	0	0
v	1	0	0

n, the number of foods with functional claims.
Notes: (a) improvement of cholesterol levels, (b) reduction of body fat, (c) reduction of neutral fat in the blood, (d) suppression of spikes in blood sugar, (e) alleviation of stress and tension, (f) management of blood pressure, (g) reduction of fatigue, (h) improvement in sleep quality, (i) improvement of memory ability, (j) skin moisturization, (k) joint lubrication, (l) acceleration of bone metabolism, (m) improvement in building new muscle, (n) intestinal regulation, (o) maintenance of healthy liver function, (p) alleviation of nose or eye discomfort, (q) improvement for ocular function, (r) maintenance of peripheral temperature, (s) maintenance of walking ability, (t) maintenance of healthy teeth, (u) improvement of basal metabolism, and (v) reduction of leg swelling.

in the categories: (b) reduction of body fat (n = 131), (c) reduction of neutral fat in the blood (n = 240), (d) suppression of spikes in blood sugar (n = 169), (f) management of blood pressure (n = 122), (i) improvement of memory ability (n = 114), (j) skin moisturization (n = 110), (n) intestinal regulation (n = 171), and (q) improvement for ocular function (n = 110; Table 2).

3.3. Proportion of FFCs with potential labelling

Management of blood pressure was the health claim category that could have been placed on the highest proportion of FFCs (79.5%), followed by (c) reduction of neutral fat in the blood (75%) and (d) suppression of spikes in blood sugar (73.4%; Table 2). Health claim categories (j) skin moisturization (7.3%), (i) improvement of memory ability (10.5%), and (q) improvement of ocular function (13.6%) had the lowest proportion (Table 2).

4. Discussion

We calculated the proportion of FFCs that could be labeled with scientifically supported health claims absent from their actual labels. This inconsistency likely represents disparate development strategies of food developers that lead to selective exclusion of potential health benefits detected by researchers (van Kleef, van Trijp, & Luning, 2005).

Here, we found that skin moisturization, improvement of memory ability, and improvement of ocular function were the three health claims that were almost always mentioned on labels if the FFC contained substances with these functions. A previous study revealed that consumers prefer short and simple claims (Hodgkins et al., 2019). Therefore, it may be much easier for consumers to understand the association between the health claim and a specific functional substance, allowing labels to be succinct.

In contrast, the top three health claims that could have been placed on labels but were not (potential labeling) included management of blood pressure, reduction of neutral fat in the blood, and suppression of blood sugar spikes. Notably, these categories are related to lifestyle diseases, such as high blood pressure, hyperlipidemia, and diabetes mellitus (Goto & Kawada, 2016). Consumers select FFCs with the expectation of improving their health in their daily lives (Tanemura et al., 2017b). In consideration of public desire for prevention and management of these lifestyle-related diseases, a great interest may be found in FHCs with relevant effects (Ministry of Health Labour and Welfare, 2017). We showed here that numerous consumers with pre-symptomatic conditions of high blood pressure, hyperlipidemia, and diabetes mellitus have the possibility of selecting the FFC with gaps between actual labelling and efficacy information of functional substances in food.

Discrepancies in actual labeling of FFCs may cause unintentional heavy intake of specific functional substances. For example, consider three FFCs with indigestible dextrin as a functional substance, which has health claims A and B. The actual label of FFC #1 might only have health claim A, while FFC #2 might only have health claim B, but FFC #3 might have both health claims A and B. If a consumer selects both FFC #1 and FFC #2 based on their health needs, the recommended daily use of dextrin may exceed. It may cause diarrhea (National Institutes of Biomedical Innovation, 2020a), whereas this would not be found if a consumer took only FFC #3. While this example of dextrin is relatively trivial, the risks may be caused by a gap between actual labelling and efficacy information of functional substances.

Food developers must ensure the benefit information to promote their effective use by consumers (Peters, Hibbard, Slovic, & Dieckmann, 2007). Although food developers are required under Japanese food regulations to make their FFC application dossiers publicly available, we found many FFCs with discrepancies between actual labeling and efficacy information. These gaps are difficult for consumer to detect the best FFCs for their health promotion because consumers must compare FFCs with multiple health claims containing the same functional substance on their own. The presence of functional substance(s) with multiple health claims in a single FFC further exacerbate labeling-efficacy gaps (Todt & Lujan, 2017). Therefore, policy-makers and researchers should devote greater attention to FFCs with those kinds of functional substances for better benefit communication with consumers.

As the primary means of benefits communication in the food system, labeling is also extremely important (Frewer et al., 2016; Lusk, 2019; Tonkin, Webb, Coveney, Meyer, & Wilson, 2016). Consumers rely on food labels to select products that will promote their health (Jacob et al., 2020). Indeed, as early as the 1990s, consumers have expressed a desire to know the contents of a specific supplement and to compare across supplements, while accounting for daily nutritional needs (Dwyer & Coates, 2018). However, it is not effective to put all health claims based on the scientific evidence on food labels showed in the previous survey (Hodgkins et al., 2019), so an integrated database such as a repository of efficacy information with scientific evidence of functional substances may be necessary. In the United States, dietary supplement databases are available that allow for comparisons across FHCs (Dwyer & Coates, 2018). However, although Japan has an efficacy and safety information database on health foods (National Institutes of Biomedical Innovation, 2020b), it has no function to calculate the total exposure to an active ingredient contained in both health foods and other products. With an integrated publicly released repository for both public and industry, scientific evidence on functional substances in FFCs can be shared. Such a system could also facilitate effective communication and in turn, active engagement of consumers, food developers, regulators, and academic researchers (Czarnecki, 2008; Dean,

Lahteenmaki, & Shepherd, 2011).

This study has a limitation. We had no amount of functional substances contained in each FFC in mind. It differs depending on the health claim. However, as a first step, this study is the first work to review gaps between actual labeling on the food package of FFCs and efficacy information of functional substances in Japan.

5. Conclusions

We identified FFCs with a gap between actual labeling and efficacy information of functional substances in the top three health claims such as blood pressure, reduction of neutral fat in the blood, and suppression of blood sugar spikes. Our results lead us to suggest that a publicly available integrated framework, such as a data repository for effective benefit communication. It may allow easier accessibility of relevant efficacy information and enhances the ability of consumers to make informed choices for promoting their health with FHCs.

Author contributions

H.U., N.T., and Y.M. contributed to the design and implementation of the research, the analysis of the results, and the writing of the manuscript. All authors approved the manuscript to be published and agreed to be accountable for all aspects of the work by ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Ethical statements

As this was a retrospective study that used official materials available in the public domain, published on the websites of the Consumer Affairs Agency in Japan, none of the data included identifiable subjects. Accordingly, an ethical review was not required under local ethical guidelines.

Declaration of Competing Interest

The authors declared that there is no conflict of interest.

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Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jff.2020.104047.

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