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ORIGINAL RESEARCH

Usability Evaluation of Foods with Function Claims Labelling as Health Information in Japan: A User-Testing Study

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Purpose: The saturation of health foods in the market is coupled with inadequate information on their safe usage. Recently, health issues caused by Foods with Function Claims (FFCs) have resulted in 81 suspected deaths in Japan, where labelling precautions proved ineffective. We previously developed a Communication Index to assess usability and comprehension of FFC labelling from the perspective of healthcare professionals (HCPs). It is important to explore ways to evaluate and improve labelling usability from the consumers' perspective to ensure safe usage.

Patients and Methods: We conducted user testing from the consumers' perspective on labels of five different FFCs, utilizing semi-structured interviews with 50 participants of diverse ages and sexes. Two levels of passing criteria were established for accessibility to correct answers: ≥90% of all questions within 1 min and 2 min. After the user testing, we qualitatively analyzed the participants' feedback. Furthermore, we created a revised version of labels, which participants then evaluated against the current version using a 5-point scale.

Results: Only one FFC label met the acceptance criteria within 2 min, while none did so within 1 min. The response rate for questions critical to safe use was particularly low, averaging around 70%. Participants' feedback revealed lack of familiarity with FFCs, suggesting that the terms and text on the labels were often confusing and overly technical.

Conclusion: We demonstrated that FFC label assessments from users' perspective did not meet the passing criteria. User testing offered valuable insights into how FFC labelling can be improved to ensure safer and more appropriate use by aligning with users' understanding and perceptions. For the first time, we developed a framework that integrates evaluations from both users and HCPs, highlighting the challenges and potential improvements with the FFC label as a source of health information.

Keywords: health literacy, food with health claims, safety use, semi-structured interview, risk communication

Introduction

Health Information Provision and Consumer Understanding in Japan

Numerous health foods saturate the Japanese market. These are not defined by law in Japan but refer to the whole of a food widely sold or used as food contributing to health conservation and enhancement.[1] However, the prevalence of inaccurate and unreliable health information sources can mislead consumers, potentially leading to inappropriate use of the product and associated health risks.[1] Health information materials serve as crucial tools for effective risk communication.

An online survey in 2016 revealed that only 16% of consumers clearly understood the characteristics of Foods with Function Claims (FFCs).[2] Another survey in 2017 reported that 17% of consumers using health food products

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experienced poor physical conditions.[3,4] In March 2024, tragically, 81 people were fatally poisoned by FFCs containing beni kōji fermented rice in Japan.[5] While the incident was likely caused by a contaminant, it underscored the challenge consumers face in checking the safety of FFCs, which are readily available. Consequently, the provision of easy-to-understand information is crucial to ensuring safe product usage and empowering consumers to make informed choices. A comparative analysis of Japanese and European consumer health literacy surveys[6,7] indicated that 41.8% of respondents in Japan, 36.2% in Europe, and 30.1% in the Netherlands had difficulty understanding information on food packages.[6,7]

Given the health literacy gap between professionals and consumers, establishing a communication system that ensures the quality of information aligns with consumer needs is imperative.

Previous studies investigated consumers' comprehension of the nutrition facts label, health claims, and food labels using online surveys, including questionnaires.[8–10] A qualitative study was conducted to investigate how claims can affect consumers' perceptions and behavior.[11] While these studies investigated food labelling, they were not specific to FFC labelling. Although surveys have been conducted in Japan on consumers' awareness and attitudes towards FFC,[12] no surveys have been conducted to assess HCPs' and consumers' perspectives on labelling.

Currently, there is no system available in Japan for evaluating the usability of health information materials. To enhance the utility of these materials, it is vital to evaluate information from the perspective of HCPs and further verify it from the users' perspective. Previously, we developed a usefulness evaluation index for FFC labelling from the HCPs' or providers' perspective.[13] In this study, we developed and evaluated a user testing to gauge the accessibility and comprehensibility of the same FFC materials from consumers' perspectives. In addition to user testing, we conducted interviews with a qualitative analysis of the comments obtained from the consumers. The development of these integrated methods considering the HCPs' and consumers' perspectives represents the first study on the comprehension of health information using FFC labelling.

Labelling of Foods with Health Claims in Japan

Based on the Health Promotion Law, the "Foods with Health Claims" system was established in April 2015 to facilitate the appropriate use of such foods for self-care.[14,15] This system comprises Foods for Specified Health Uses (FOSHU), Foods with Nutrient Function Claims, and FFCs (Figure 1). FOSHU undergoes "Individual Evaluations" for efficacy and safety and is approved by the Secretary General of the Consumer Affairs Agency (CAA).[16] In contrast, FFCs can display function claims based on scientific evidence, with the responsibility lying on the food business operator. Prior to marketing, information supporting the safety and efficacy of the product is submitted to the Secretary-General of the CAA.[17]

As of 18 August 2024, there were 8683 notified FFCs,[18] while 1042 FOSHU products received approval.[19] An FFC must feature 16 specified items (Cabinet Office Ordinance No. 10, 2015; Table 1 and Figure 2). In addition, FFC labels should bear the following: the product's name, storage method, best before date or expiration date, ingredients, additives, nutritional ingredients, total weight, calorific value of nutritional ingredients, and the name and address of the food business operator.[20] In the actual labels of the product containers and packaging, the order, font size, and position of these items differ from the examples given by the CAA (Figure 2).

Evaluation of FFC Labelling

Evaluation from the Perspective of HCPs

Foods with Health Claims should present clear information on their labels so that the information is easily understandable to consumers with diverse levels of health literacy. In recent years, public organizations in Europe and the United States have introduced standards to facilitate the creation and provision of health information that is easily understandable for consumers and patients. In the United States, various tools such as "Clear & Simple"[21] and "Toolkit for Making Clear and Effective Information"[22] are available. Notably, the Centers for Disease Control and Prevention (CDC) released the "Clear Communication Index (CCI)" in 2014 as a research-based tool for developing and accessing health communication materials.[23] The CCI comprises 20 items, including the main message and action recommendations, with the CDC recommending a score of 90% (18 items) or higher. In this context, a group comprising six university employees, all of

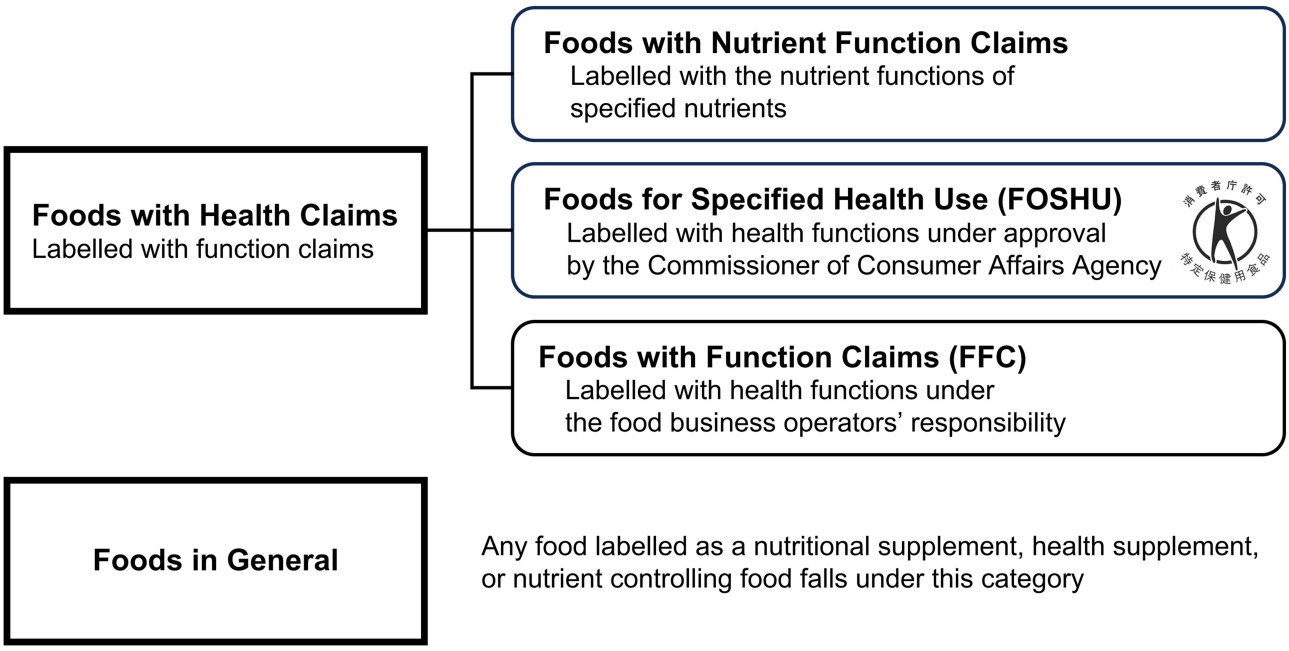

Figure 1 Classification of Food with Health Claims.
Note: The copyright of the FOSHU approval seal belongs to the Consumer Affairs Agency, but prior permission is not required for its use. Available from the following website. https://www.caa.go.jp/policies/policy/food_labeling/foods_for_specified_health_uses.

whom were qualified as pharmacists and public health professionals, has developed our own CCI for evaluating the FFC labelling (F-CCI) (Table 2).

Using the F-CCI index, we assessed five FFC products from the perspective of healthcare professionals (HCPs), achieving an approximate level of 70% (12–14 items), details of which have been previously published.[13] None of the five products met the acceptance criteria for the following questions: "Does the material consistently use language familiar to the primary audience? (F-CCI Q7)", "Is the most important information that the primary audience needs summarized in the first paragraph or section? (Q10)", and "Does the material consistently explain the meaning of the numbers and units used? (Q16)". With regard to Q10, usage precautions, such as advising immediate discontinuation of product usage and recommending consultation with a doctor if any physical changes are noticed, were described at the

Table 1 Labelling Items on Containers and Packaging of Foods with Functional Claims

1)	A statement indicating that the product is a food with function claims
2)	The active ingredient with validated functionality along with the functionality of the ingredient or the food containing it
3)	Quantity and calorific value of the nutritional ingredient
4)	Quantity of the active ingredient within each recommended daily allowance
5)	Approximate daily allowance
6)	Notification number
7)	Contact details of the food business operator
8)	A statement indicating that the product has not undergone evaluation for functionality and safety by the regulatory agency
9)	Instructions for the mode of intake
10)	Cautionary information for intake
11)	Language promoting a well-balanced diet
12)	A statement outlining special precautions, if any, required for the cooking or preservation method
13)	A statement indicating that the product is not intended for the diagnosis, treatment, or prevention of diseases
14)	Information aimed at individuals with diseases, minors, pregnant or nursing women (including those planning to conceive), and lactating women
15)	A statement recommending individuals with diseases to consult a physician, and those taking medications to consult either a physician or a pharmacist before using the product
16)	A directive to discontinue product intake immediately and consult a physician in case of any physical discomfort

Notes: The 16 items indicated in the Food Labelling Standards. (Cabinet Office Ordinance No.10, 2015) [20].

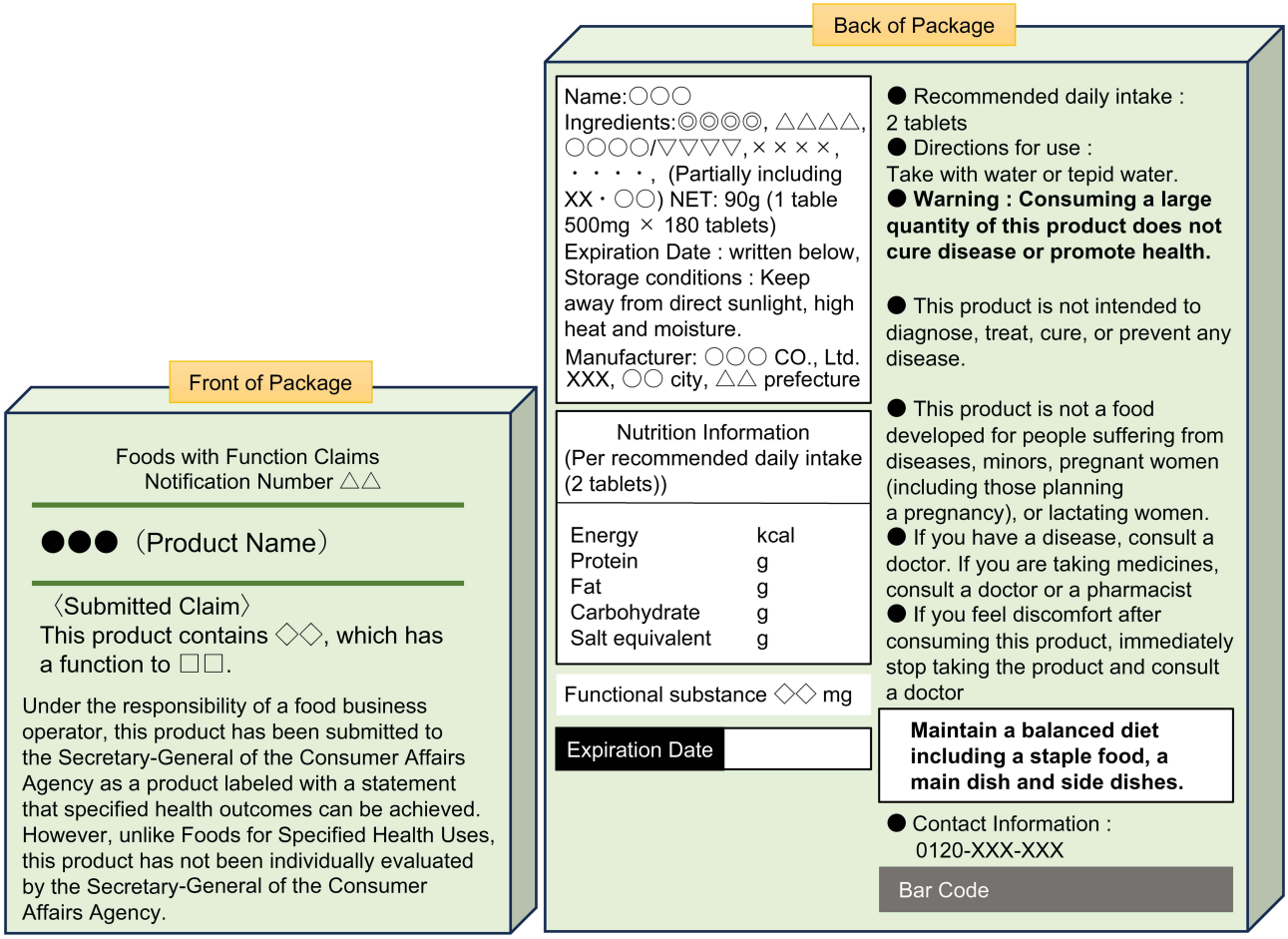

Figure 2 Model of the label for foods with function claims by the Consumer Affairs Agency.
Note: The labelling is displayed on box-type packages, but it is recommended to use the same wording for bottles and other packaging formats by the Consumer Affairs Agency.

bottom of the label without any particular emphasis. For Q7, certain sentences indicated by the CAA included technical jargon that was not commonly used by the public. The results indicated that the readability and location of the main message, in particular, should be improved.

Evaluation of FFC Labelling Through User Testing

In addition to evaluation from the perspective of HCPs, it is imperative to assess FFC labelling from the users' standpoint. Therefore, a comprehensive evaluation from both perspectives is crucial.

Table 2 Clear Communication Index for Evaluation of FFC Labelling (F-CCI)

Part A (Core)	F-1	Does the material contain one main message statement? (Does not necessarily have to match the Submitted Claim)
	F-2	Is the main message at the top or beginning, or on the front of the material?
	F-3	Is the main message emphasized with visual cues?
	F-4	Does the material contain at least one visual that conveys or supports the main message?
	F-5	Does the material include one or more calls to action for the primary audience?
	F-6	Do both the main message and the call to action use the active voice?
	F-7	Does the material always use words the primary audience uses?
	F-8	Does the material use bulleted or numbered lists?
	F-9	Is the material organized in chunks with headings?
	F-10	Is the most important information that the primary audience needs summarized in the first paragraph or section?

(*Continued*)

Table 2 (Continued).

Part B (Behavioral Recommendation)	F-11	Does the material include one or more behavioral recommendations on functionality for the primary audience?
	F-12	Does the material include one or more behavioral recommendations on safety for the primary audience?
	F-13	Does the material explain why the behavioral recommendation(s) on safety is necessary for the primary audience?
	F-14	Does the behavioral recommendation(s) include specific directions about how to perform the behavior?
Part C (Numbers)	F-15	Does the material always present numbers that the primary audience uses?
	F-16	Does the material always explain what the numbers and units mean?
	F-17	Does the audience have to conduct mathematical calculations?
Part D (Risk)	F-18	Does the material explain the nature (eg, about specific harms) of the risk?

Abbreviations: FFC, Foods with Function Claims; CCI, Clear Communication Index.

User testing is used to assess whether users can easily access and understand FFC.[24–26,] It is widely used for assessing the efficacy of health information, ranging from booklets and leaflets to online resources. User testing aims to enhance the understanding of the information provided to consumers and patients.[25–29] The interviewer asked participants to answer questions about the content of the information materials. When conducting user testing, it is recommended to employ a cohort of 10 participants at a time. This approach is well-established and supported by European Union (EU) and Australian guidelines, and meeting user-testing criteria is one of the conditions for the approval of new medicines in the EU.[27–29] This methodology has been widely used, as demonstrated by Raynor et al.[30–32]

Our initial user testing in Japan targeted the Drug Guides for Patients, which are the label information of prescription drugs for patients.[33] Subsequently, we have continued user testing and gained experience in this field.[34] In the test, the passing criterion is as follows: 90% of the participants should successfully locate and understand the information.

In this study, we evaluated five FFC labels using the F-CCI and user testing on five FFCs (Figure 3). Interviews with 50 participants (five cohorts of 10 participants) in the user testing were conducted to gain insights into users' attitudes and enhance the overall quality of the FFC labelling.

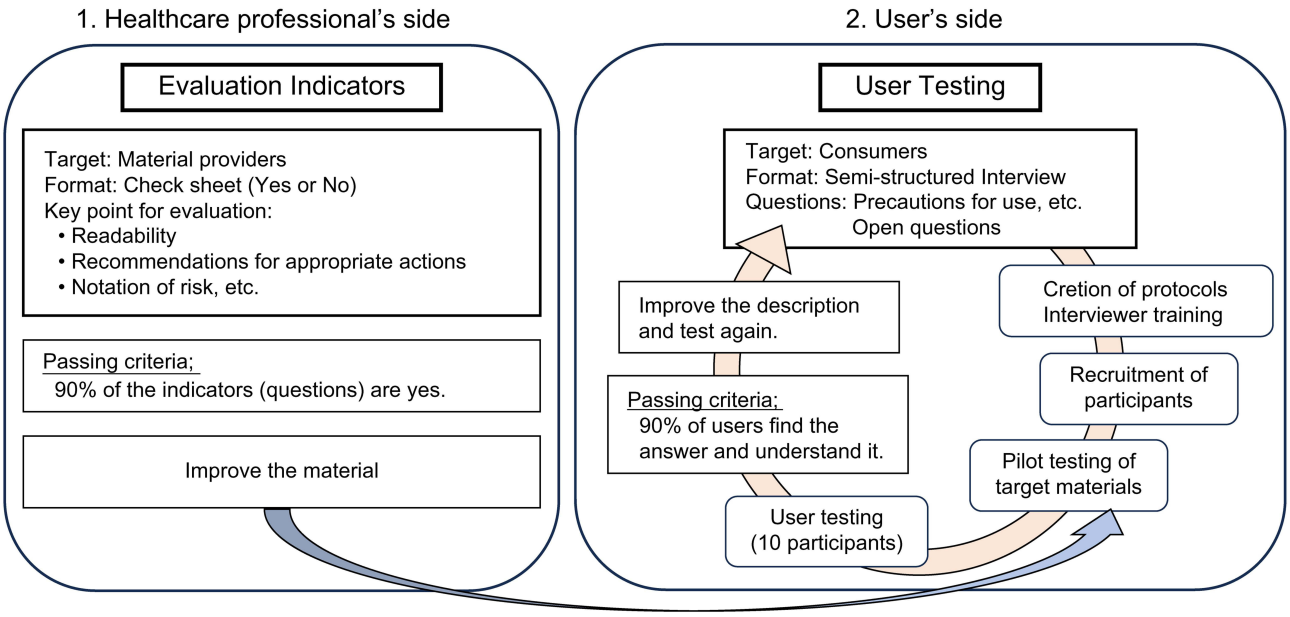

Figure 3 Integrated evaluation framework of usability of health information materials.
Note: This system evaluates health information material through healthcare professionals (experts) and consumers (laypersons). Experts conduct the initial evaluation, followed by user testing with consumers.

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Materials and Methods

Materials

On the FFC search site provided by the CAA,[18] we searched for FFC relevant to keywords "triglyceride", "presbyopia", "absorption of sugar and fat", "hypertension", and "cholesterol". These topics are of particular interest to middle-aged and older adults. After reviewing approximately 100 labelling of FFCs in a preliminary study, we selected five products, each with distinct claims of functionality that were considered commonplace. Table 3 provides an overview of these five products. Subsequently, we purchased each product and evaluated its labelling content. The labelling and labelling sample (Form VI of the submitted claim) can be found on the CAA website (accessed on 5 January 2020).

Participants

For generalizability of the outcomes of user testing, it is imperative to carefully recruit a participant sample that accurately reflects the characteristics of users of the specific product under consideration.[27–29] The distribution of variables such as age, sex, literacy level (eg, education), and others within the participant sample should closely mirror the distribution observed among the actual users of the product in question. It is noteworthy, however, that the utilization

Table 3 Characteristics of Foods with Function Claims Subjected to User Testing

	Functional substance	Sales copy	Submitted claim	Containers or packaging	Product format
Product A	Eicosapentaenoic acid, Docosahexaenoic acid: substance A	Reduces triglyceride in individuals with elevated triglyceride levels.	This product contains substance A, known for its triglyceride-reducing properties and reported health benefits for individuals with elevated triglycerides.	Cardboard box	Soft capsules
Product B	Lutein astaxanthin (as free form), Cyanidin-3-glucoside, Docosahexaenoic acid: substance B	Promotes improved focus on near objects to enhance eye health in middle-aged and older individuals. Designed for alleviating difficulties reading small print up close, eliminating the need for reliance on glasses.	This product contains substance B, known to assist with near focus and relieve neck and shoulder pain associated with eye strain.	Plastic pouch	Tablets
Product C	Non-digestible dextrin (dietary fiber): substance C	Reduces the absorption of dietary sugar and fat.	This product contains substance C, reported to suppress the absorption of dietary fat and sugar.	PET bottle	Liquid
Product D	Lactotripeptide (Valyl-Prolyl-Proline, Isoleucyl-Prolyl-Proline): substance D	Designed for individuals with high blood pressure.	This product contains substance D, reported to lower blood pressure in individuals with elevated levels. It is recommended specifically for those with high blood pressure.	PET bottle	Liquid
Product E	Pine bark-derived procyanidins (as procyanidin B1): substance E	Lowers bad cholesterol. Controls cholesterol (LDL).	This product contains substance E, reported to lower bad cholesterol (LDL) levels. Consequently, this beverage is recommended for individuals concerned about bad cholesterol (LDL).	PET bottle	Liquid

Abbreviations: PET, polyethylene terephthalate; LDL, low-density lipoprotein.

of random sampling may not be necessary in all cases.[29] We conducted the recruitment between April and September 2022 using recruitment flyer distribution, social networking services, and a market research company.

Criteria for Participant Suitability

The designated number of participants per product is set at 10, given the execution of five cohorts, resulting in the recruitment of a total of 50 participants. To guarantee a comprehensive representation within the target group, the following criteria are established for the inclusion of participants.

(1) Age: Individuals aged between 30 and to 70 years, aligning with the age range during which FFC products are most commonly utilized.

(2) Sex: Each sex category must be represented by a minimum of four individuals.

(3) Literacy Level: High school and vocational school graduates or equivalents are to be included, ensuring diverse educational backgrounds within the target group.

(4) Occupation: Includes two or more people who do not regularly use written information as part of their occupation.

Exclusion Criteria for Participants

The following four points were set as criteria for the exclusion of participants.

(1) Individuals who are currently using or have used FFC products under investigation within the past 6 months.

(2) Individuals whose family members are using FFC.

(3) Individuals involved in health professions, pharmaceutical professions, occupations associated with health products, or those with prior work experience in these domains.

(4) Individuals who have been participants of a user testing within 6 months.

We considered a balanced distribution in terms of sex, age, and literacy level (education background), as described in Table 4.[27,28] We provided potential participants with written explanations outlining the purpose and methods of the test and obtained their written informed consent. No people refused to participate or dropped out of the user testing.

Table 4 Characteristics of Participants in the User Testing of Foods with Function Claims

Variable	Product A cohort[a]	Product B cohort[a]	Product C cohort[a]	Product D cohort[a]	Product E cohort[a]
Sex					
Male	5	5	5	5	5
Female	5	5	5	5	5
Age					
30s	2	2	2	2	2
40s	2	2	2	2	2
50s	2	2	2	2	2
60s	2	2	2	2	2
70s	2	2	2	2	2
Educational level					
High school	0	1	1	1	2
Technical school or Two-year college	1	2	3	2	2
Undergraduate degree	9	7	6	7	6
Regular use of written information as part of occupation					
Yes	8	7	8	7	7
No	2	3	2	3	3

Note: [a]n = 10.

User-Testing Procedure

The user testing was conducted as follows:

(1) Preliminary preparation

i) Development of protocols

The user-testing procedures and methods were consolidated into a protocol. Specific questions were developed for products.

ii) Interviewers

The two interviewers underwent training to standardize their levels of observational and listening skills before engaging in user testing. They are pharmacists and university employees with Ph.D. They are qualified interviewers accredited by the Japanese Interviewer Association.

iii) Conducting a pilot test

The pilot user testing was conducted from October 1st, 2020, to January 31st, 2021, with three participants to assess the appropriateness of the testing procedure, the manner and wording of the questions, and response time settings. The protocol was then adjusted based on these findings.

(2) User testing

The user testing took place between April 1st, 2021, and December 30th, 2022. Written informed consent was obtained from all participants involved in the study.

i) Place and timing of the interview

A quiet room with adequate privacy was prepared for the participants to relax and be interviewed at our workplace. Each interview was scheduled to last approximately 1 h, including the time needed to explain the user testing procedure and obtain consent. The interviews were recorded with the participants' consent.

ii) User-testing questions

We developed a dozen questions on labelling according to the characteristics of each of the five FFC labels. Among them, 10 common questions were selected that were considered important. Their order was arranged randomly rather than following that on the label. These questions were short and open-ended, as outlined in Table 5. Standardized questions were prepared addressing the appropriate and safe use of the five products. Finally, participants were asked to provide feedback on the comprehensibility, issues, design, and layout of the labels (Table 6).

Table 5 Questionnaire on the Content of Foods with Function Claims Labelling

Q1	What should you pay attention to in your diet?
Q2	What should you do if you are taking medicines?
Q3	What is the recommended daily intake?
Q4	Who is not subject to the development of this product?
Q5	If you are ill, what should you do?
Q6	If you have allergies, where on the label can you find the relevant information?
Q7	What should you do if you experience an unpleasant reaction or develop a concerning symptom?
Q8	What precautions should be observed when storing this product?
Q9	What considerations should be kept in mind when handling this product?
Q10	Where can you find the contact details of the food business operator?

Note: Common questions on the five products' labelling for safe and appropriate use.

Table 6 Questionnaire on Labelling Foods with Function Claims for Participants' Comments

Q1	Do you know what FFC are?
Q2	Besides FFC, there are FOSHU; do you know the difference between FFC and FOSHU?
Q3	If there are any words or sentences in the label contents that you find unclear, please specify.
Q4	Did you face any other challenges in comprehending the information provided in the labelled information?

Note: These questions aimed to ascertain the participants' level of understanding of FFC and FFC labelling and to record their perceptions and views on the subject.

Abbreviations: FFC, Foods with Function Claims; FOSHU, Foods for Specified Health Uses.

Outcome Measurement

The participants were asked to locate the relevant information, and the response time was recorded for each question across the five FFC products. In addition to providing answers, participants were asked to rephrase the information in their own words to assess their understanding of the materials. Two cut-off points, at 1 min and 2 min of response time, were used to evaluate participants' understanding. The 1-min cut-off was established based on our previous user testing on drug information, which indicated that, on average, people need 1 min to understand 1000 characters of information correctly.[32,33] Given that FFC labelling contains ≤ 1000 characters, in theory, 1 min should suffice. The 2-min cut-off was also used based on the results from the pilot test, indicating that participants needed approximately 2 min to answer each FFC-related question. The product was considered to pass the test if 90% or more of the participants could find and correctly understand the information for all 10 questions before the specified cut-off time. If a participant could not find the answer within 2 min, their response time was recorded as 2 min. Descriptive statistics were summarized using the median and interquartile range (IQR). The relationship between respondents' age and response time to each question was examined using Spearman's rank correlation coefficient, and $p<0.05$ was judged to be statistically significant. This analysis was performed using SPSS Statistics Version 29.0.1.0 (IBM, Armonk, NY, USA).

Qualitative Analysis of Participants' Comments

Using semi-structured interviews, participants were asked to respond to the questions following each user testing (Table 6). In our analysis, we incorporated elements of the KJ Method, a qualitative research strategy developed by Kawakita.[35,36] Qualitative analysis was conducted for each question to gain insights from participants' responses.

Comparison Between the Current Version and the Revised Version of the Standardized Wording

Our analysis using the F-CCI indicated potential areas for improvement in the standardized wording included in the FFC label, originally developed by CAA. Some of the wordings were considered difficult to understand. Furthermore, the user testing conducted in this study showed that the current wording was difficult to understand and time-consuming. Therefore, we developed a revised version of the standardized wording to be used on the FFC label and compared it against the current version developed by CAA (Figure 4). To enhance the comprehensibility of container and packaging labels, a QR code can be added to the label. This code can direct the user to a page with clear and concise explanations. The terms "Submitted Claim" and "Individual Evaluations", as well as the distinction between FFC and FOSHU, were explained.

Twenty participants who underwent user testing of products C and D assessed the current and revised versions on a 5-point scale (5 = very easy to understand, 4 = easy to understand, 3 = neither, 2 = difficult to understand, and 1 = very difficult to understand) across four questions (Q1: Size, legibility, and length; Q2: terms and sentences; Q3: Usefulness of the information; Q4: Overall evaluation). The Wilcoxon signed-rank test was performed to compare participant evaluations of the current and revised versions. This test was chosen because the data consisted of paired ordinal measurements collected on a 5-point Likert scale. Results are reported as medians with interquartile ranges (IQR), and statistical significance was set at $p<0.05$. This analysis was performed using SPSS Statistics Version 29.0.1.0 (IBM, Armonk, NY, USA).

Results

Accessibility and Understandability of the FFC Labelling in the User Testing

The median response times for each question for FFC labelling are shown in Table 7. When the 2-min cut-off was used, only one product (product B) among the five user-tested products met the threshold of 90% for all 10 questions (Table 8). However, the overall results were relatively positive. Products A and E achieved 90% or more correct responses for all questions but one (Q6). Product C missed the passing score for Q4 and Q5. Product D, which had the smallest font size on its labelling, showed the poorest performance among the five products, with two questions (Q1, Q2) not meeting the criterion. When participants successfully found an answer to a question, we confirmed their understanding of its content.

Current version
(the standardized wording in FCCs labelling)

■Under the responsibility of a food business operator, this product has been submitted to the Secretary-General of the Consumer Affairs Agency as a product labelled with a statement that specified health outcomes can be achieved. However, unlike Foods for Specified Health Uses, this product has not undergone individual evaluation by the Secretary-General of the Consumer Affairs Agency.■This product is not intended for the diagnosis, treatment, or prevention of disease. It is not a food developed for people suffering from diseases, minors, pregnant women (including those planning a pregnancy), or lactating women.■Consult a physician if you are suffering from a disease, or a doctor or pharmacist if you are taking any medications.■If you experience any changes in your health condition, discontinue use immediately and consult with a physician.

Description specified in the Food Labelling Standards Article 3

Proposed version
(Improvement proposal)

Food with Functional Claims

■This product has been notified to the Consumer Affairs Agency (CAA) by the business operator in the hope of a specific health purpose. But it has not undergone individual evaluation by the CAA, unlike Food for Specified Health Uses.
■It is not intended to diagnose, treat, or prevent disease. Note that this food is not developed for people who are ill, minors, pregnant women (including those who may become pregnant) or nursing mothers. Consult a doctor pharmacist before use.
■Consult a doctor if you are ill, or a doctor or pharmacist if you are use drugs.
■**If you feel unwell, stop taking it right away and consult a doctor.**

Click here for detailed instructions.

To the following explanation by QR code

Food with Functional Claims: Based on the rules set by the government, this is a food product that can be labelled with its functionality if the classifier notifies the Commissioner of the Consumer Affairs Agency of the necessary matters, including scientific evidence regarding the safety and functionality of the food, prior to its sale. Unlike Food for Specified Health Use, the government does not conduct an examination, thus business operators are responsible for proper labelling based on chemical evidence.

Foods for Specified Health Uses: Food for Specified Health Use is a food that contains health-functional ingredients that affect the physiological functions of the body and can be labelled to indicate that a specific health purpose can be expected from its intake (indication of health use).

Individual evaluation: In order to sell a food as a Food for Specified Health Uses, each food must undergo a government review of its functionality and safety and be approved by the government. This is called an individual examination.

Submitted Claim: The content for which the business operator has notified the Commissioner of the Consumer Affairs Agency of the functionality based on scientific evidence is labelled. The contents that can be expected to have a specific health purpose (help maintain and promote health) are labelled.

Item	Foods for Specified Health Uses (FOSHU) System	Foods with Functional Claims (FFC) System
Individual Evaluation	Yes (by the Consumer Affairs Agency)	No
Notification to the Consumer Affairs Agency	Yes	Yes
Mark of approval by the Consumer Affairs Agency	Yes	No
Disclosure of information on safety, functionality and quality	No obligation	Yes (the Consumer Affairs Agency Website [under a food business operators' responsibility])
How to demonstrate functionality and safety	Need to show scientific evidence by conducting human trials.	Need to show scientific evidence by human trial or by literature review.
Enforcement year of the system	1991	2015

Figure 4 Current standardized version by the CAA and its proposed revision in the label.
Note: The copyright of the FOSHU approval seal belongs to the Consumer Affairs Agency, but prior permission is not required for its use. Available from the following website. https://www.caa.go.jp/policies/policy/food_labeling/foods_for_specified_health_uses.

When evaluated at 1 min, the overall performance was considerably poorer than that at 2 min, with no product meeting the 90% criterion for all questions (Table 9). Products A and B performed well, only missing the passing score for two questions (Q1, Q6). Product E failed to meet the passing score on four questions (Q2, Q6, Q7, Q8). Product D remained the worst-performing product, not reaching the 90% threshold for more than half of the questions.

Questions about diet, concomitant medications, illnesses, allergies, side effects, storage, and handling, which are essential for the safe use of FFC, were answered in the 70th percentile at 1 min.

Table 7 Accessibility of the 10 Questions for the Five FFC Products in the User-Testing

	Product A		Product B		Product C		Product D		Product E	
	Median (IQR)	**Min–Max**	**Median (IQR)**	**Min–Max**	**Median (IQR)**	**Min–Max**	**Median (IQR)**	**Min–Max**	**Median (IQR)**	**Min–Max**
Q1	42.0 (16.5–57.5)	5–84	13.5 (5.0–64.0)	1–83	39.5 (5.3–56.5)	3–120	57.0 (22.0–112.5)	2–120	10.0 (1.0–57.8)	1–120
Q2	28.0 (6.0–39.8)	5–45	28.0 (1.8–37.8)	1–100	43.0 (23.8–76.3)	8–119	68.0 (36.8–120.0)	12–120	32.5 (6.3–64.3)	1–116
Q3	5.5 (2.0–8.0)	2–36	6.0 (1.8–24.2)	1–36	7.5 (5.0–16.3)	2–65	8.5 (4.0–13.0)	4–51	8.0 (1.0–15.0)	1–20
Q4	6.5 (3.0–26.8)	2–50	1.5 (1.0–2.3)	1–22	39.0 (22.8–75.8)	10–120	21.0 (5.3–28.5)	3–55	13.0 (5.3–25.3)	1–60
Q5	12.0 (6.8–29.5)	4–84	6.0 (1.8–32.0)	1–50	32.5 (9.8–112.5)	1–120	88.5 (38.0–120.0)	12–120	1.5 (1.0–13.3)	1–120
Q6	66.5 (18.8–116.3)	12–120	3.5 (1.0–68.8)	1–120	14.0 (6.5–46.5)	5–103	10.0 (6.3–33.3)	1–120	16.5 (5.0–120.0)	1–120
Q7	4.0 (3.0–5.8)	2–11	1.0 (1.0–4.0)	1–11	9.0 (6.0–49.3)	2–100	10.0 (3.8–31.3)	3–47	1.5 (1.0–22.8)	1–75
Q8	8.0 (2.8–19.3)	1–30	1.0 (1.0–8.5)	1–120	80.0 (29.0–106.3)	3–119	17.5 (5.8–53.3)	2–100	35.5 (9.8–61.3)	3–120
Q9	7.5 (5.3–10.3)	3–17	25.5 (1.8–40.8)	1–96	56.0 (27.5–87.5)	21–120	95.0 (8.8–116.3)	4–120	4.0 (1.0–29.5)	1–51
Q10	5.0 (1.0–10.5)	1–26	6.5 (2.8–27.5)	1–72	19.5 (8.8–38.3)	2–85	31.5 (15.0–46.5)	9–109	4.5 (1.0–7.5)	1–24

Notes: Values are presented as median (IQR) for n = 10.
Abbreviations: FFC, Foods with Function Claims; IQR, interquartile range.

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Table 8 Proportion of Participants Who Correctly Identified the Answers for Each Question Within 2 min

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Passed Criterion[a]
Product A	100%	100%	100%	100%	100%	80%	100%	100%	100%	100%	No
Product B	100%	100%	100%	100%	100%	90%	100%	100%	90%	100%	Yes
Product C	90%	100%	100%	80%	80%	100%	100%	100%	90%	100%	No
Product D	80%	70%	100%	100%	100%	90%	100%	100%	90%	100%	No
Product E	90%	90%	100%	100%	90%	70%	100%	90%	100%	100%	No
Average per question[b]	92%	92%	100%	96%	94%	86%	100%	98%	94%	100%	

Notes: [a]The pass criterion is "at least 90% of participants can find and correctly understand all 10 questions within 2 minutes". [b] The value represents the average pass rate for each product for the same question.

Table 9 Proportion of Participants Who Correctly Identified the Answers for Each Question Within 1 min

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Passed Criterion[a]
Product A	80%	100%	100%	100%	90%	50%	100%	100%	100%	100%	No
Product B	80%	90%	100%	100%	100%	80%	100%	90%	90%	90%	No
Product C	90%	70%	90%	70%	60%	90%	80%	30%	50%	90%	No
Product D	50%	50%	100%	100%	50%	80%	100%	80%	30%	90%	No
Product E	90%	70%	100%	100%	90%	70%	80%	80%	100%	100%	No
Average per question[b]	78%	76%	98%	94%	78%	74%	92%	76%	74%	94%	

Notes: [a]The pass criterion is "at least 90% of participants can find and correctly understand all 10 questions within 1 minute". [b] The value represents the average pass rate for each product for the same question.

A Spearman's rank correlation coefficient was calculated to assess the relationship between participants' age and the time taken to respond to each question. The analysis revealed a significant correlation between age and response time ($r=0.177$, $p<0.001$).

Qualitative Analysis of Participants' Comments

For each question, comments were collected during the interviews, and similar comments were grouped (Table 10). Many participants had insufficient knowledge of FFC and perceived it as potentially beneficial for their health based on its image. Additionally, a significant number were unaware of the distinction between FFC and FOSHU, with 30% (15/50) of participants incorrectly believing that FFC was superior in effectiveness to FOSHU. The labelling included numerous technical terms such as "Submitted Claim" and 'Individual Evaluations.' Some sentences posed challenges in comprehension and interpretation. For instance, it was difficult to discern the intended meaning of the statement, 'This product is not a food developed for people suffering from diseases, minors, pregnant women (including those planning a pregnancy), or lactating women.' As a result, the participants were unclear as to whether the relevant people were allowed to take it or not.

While the sales copy was easily understood because of its large font size and good design, the labelling itself presented difficulties in reading due to the small font size and the shape of its container or packaging.

Comparison Between the Current Version and the Revised Version of the Standardized Wording

In this user testing of FFC, the participants' comments showed that the standardized wording developed by CAA (current version) is difficult to understand and is consistent with our previous findings. Therefore, we developed a revised version to enhance the original model created by CAA and conducted additional user testing for comparison (Figure 4). Due to limited space on the packaging, a QR code is provided to access more detailed information, including terminology, which can be obtained by scanning the QR code. Twenty participants were asked to compare them on a five-point scale for the revised labelling. The results of the evaluation are shown in Table 11. The revised version received higher ratings than the current version across all four elements (size, legibility, and length; terms and sentences; usefulness of the information; and overall evaluation). The differences were all statistically significant.

Table 10 Classification of Participants' Perceptions and Comments on the Labelling of FFC

Questions	Grouping of comments	Examples of comments
What do you think FFCs are?	I do not know what it's like. (21)	I do not understand it.
		I do not know the difference between drugs and food products.
	A little healthier image (26)	It may be foods with specialized functions.
		It may be somewhat effective.
		It is not for therapeutic purposes. It provides support for the disease.
		There is an image that many middle-aged and older people use it.
		It would be safe and effective.
	Others (3)	The government sets the national standards, and they are safe to use.
		It is safe, but not good to take a lot.
		I am doubtful about the effectiveness and think that sales copy is exaggerated
In addition to FFCs there are FOSHU, and what is the difference between them?	I do not know the difference. (22)	I cannot distinguish between the two.
		Does not care.
		Not interested.
	FFCs are more effective than FOSHU. (15)	FFCs would be more effective than FOSHU.
		FFCs have a hygienic image.
		FFCs are well advertised and known, so they seem to be effective.
	FOSHU are more effective than FFCs. (13)	FOSHU would work better.
		FOSHU have more corporate responsibility than Foods with Function Claims.
		FOSHU would have more proven functionality.

(*Continued*)

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Table 10 (Continued).

Questions	Grouping of comments	Examples of comments
If there are words or sentences in the content of the label that you do not understand, please indicate them specifically.	Words that are incomprehensible (or difficult to understand). (47)	Technical jargon
		"Submitted Claim", "Individual Evaluations", and "Afflicted with Disease". "Normal temperature, high temperature and humidity" (not sure how much)"
		Ingredient name (eg, procyanidin, lactopeptide)
		Wording regarding sales copies (eg, multi-purpose support design, particular design)
	Text that is incomprehensible (or difficult to understand). (50)	"This product is not a food developed for people suffering from diseases, minors, pregnant women (including those planning a pregnancy), or lactating women".
		·This text does not mention whether or not the relevant people can take it, which makes it difficult to understand.
		·There were two interpretations: that it may be taken and that it should not be taken.
		"Under the responsibility of a food business operator, this product has been submitted to the Secretary General of the CAA as a product labelled with a statement that specified health outcomes can be achieved. However, unlike FOSHU, this product has not been individually evaluated by the Secretary-General of the CAA".
		·This text explains FFCs and FOSHU, but is difficult to understand and interpret them.
What is difficult to understand or question in the contents of the label?	Storage and keeping precautions (21)	For the user, the preservation and storage precautions are similar, but the two are listed at different locations, making them difficult to understand them.
	Nutrition Facts, Functional Ingredients, Ingredients. (26)	Each item is difficult to understand because they seem similar.
	The distinction between what is important and what is not is not clear. (14)	The sales copy is easy to read with a large font and clear coloring, but the section on precautions (safety) is difficult to understand.
		I think the Submitted Claim is different from the sales copy.
	Font size (42)	The text sections are small and difficult to read.
		The labelling section is small compared to the sales copy.
	Design and coloring. (31)	The sales copy is well-designed and easy to understand.
		Illustrations make it easier to understand.
		If the color of the text sections in the labelling is the same color as the background, it is not clear in the labelling

Abbreviations: FFC, Foods with Function Claims; FOSHU, Foods for Specified Health Uses; CAA, Consumer Affairs Agency.

Table 11 Comparison Between the Current Standardized Version by the CAA and Its Proposed Revision in the Label

	Questions	Current version Median (IQR)	Revised version Median (IQR)	P-value
Q1	Size, legibility, and length	3.00 (2.00–4.00)	4.00 (4.00–5.00)	0.016*
Q2	Terms and sentences	3.00 (2.00–3.00)	4.50 (3.75–5.00)	0.011*
Q3	Usefulness of the information	3.00 (2.75–3.00)	4.00 (4.00–5.00)	0.006**
Q4	Overall evaluation	2.50 (2.00–3.00)	5.00 (4.00–5.00)	0.004**

Note: n = 20, Current version: the standardized wording shown by the CAA on the labeling, revised version: Improvement Proposal based on the current version. Values are presented as median (IQR). *p<0.05, **p<0.01.
Abbreviations: CAA, Consumer Affairs Agency; IQR, interquartile range.

Discussion

To date, there has been a lack of studies investigating health food labelling from both HCPs and user perspectives, even in international contexts. In this study, we conducted user testing for five FFCs, which we had previously evaluated using the F-CCI. The results of this user testing showed that, in many cases, FFC labels provide inadequate explanations and are difficult to understand. In particular, the correct response rate was notably low for bottle labels, partly due to the small text and the round shape, which made the labels difficult to read. Additionally, the correlation between age and correct response rate was very weak, suggesting that the readability issue affected participants regardless of age.

In consumer research on food labelling, qualitative research should be conducted from the consumer's point of view, using a range of approaches, including observation and semi-directive interviews in addition to questionnaire surveys.[37] This study marks the first user testing of FFC labelling, complemented by qualitative research, providing novel insights into the evaluation of FFC labelling. When assessing the labelling of FFC, it is crucial to approach the evaluation from the perspectives of both the HCPs and the end-users.

We previously evaluated FFC labelling from the HCPs' perspective.[13] None of the five products met the acceptance criteria for the F-CCI questions. Certain sentences indicated by the CAA included technical jargon that was not commonly used by the public.

Important information was often not immediately accessible because it was not summarized in the first section or was scattered throughout the label. Based on our previous user testing on drug-related information and considering the word count of the FFC label, we initially expected that 1 min would suffice for consumers to capture and comprehend the information accurately. However, the testing revealed consumers needed 2 min, twice as long as for drug-related information. One factor contributing to the longer time required for response is that the order of entry, position of entry, and font size in the FFC label are not specified, unlike those in drug labels. This underscores a clear need for improvements in FFC labelling to enhance information accessibility and consumer understanding. In light of the recent incident in Japan, it is particularly important to more clearly note the precautions for safe use. Furthermore, it should be emphasized that physical health care is crucial in self-care.

However, during the interviews, it became evident that the participants not only lacked sufficient knowledge about FFC but also held misconceptions. This could pose a fundamental challenge to the proper use of FFC. Taking into account consumers' health literacy levels, information providers should offer easy-to-understand materials.

The evaluations of the two surveys yielded largely consistent outcomes, highlighting the need for improved labelling to enhance consumer safety and product usage. Overall, there is often a focus on product promotion through design and sales copy rather than facilitating consumer access to important information and comprehension of messages. In particular, precautions for safe use must be presented in a manner that is more easily understandable for consumers.

This study has certain limitations. First, we only evaluated five FFCs. In selecting the five products, we considered more than 100 FFC labelling cases and found a similar trend in labelling content, with the wording portion recommended by the CAA accounting for about half of the labelling cases. Nevertheless, future research should explore a broader spectrum of FFCs. Second, the representativeness of the sample should also be mentioned. The age and sex distributions of the participants closely aligned to those of the general population in Japan according to the national census of 2020.[38] However, educational attainment was skewed, with 100% of respondents having completed high school, compared to

85.9% of the total population. Furthermore, given the voluntary nature of participation, it is possible that individuals with a higher interest in functional foods or health-related topics would be more likely to participate, which may have introduced self-selection bias. Despite these limitations, valuable insights into consumer perceptions were garnered through live feedback from 50 interviewees.

We believe that the standardized language used in food labelling requires improvement as it currently contains numerous technical terms that pose difficulties for consumers to comprehend. In the development of health information materials, such as FFC, the newly established system facilitates the creation of optimal materials. This is achieved by enabling HCPs to assess and enhance the materials using a communication index as a specified indicator, followed by a validation process to ascertain their effectiveness and assess consumer comprehension. In the future, we intend to promote a website that we have developed to evaluate the usefulness of health-related information materials.[34]

Conclusion

In this study, we undertook the first user testing of FFC labelling in Japan to ascertain users' perceptions and comprehension. The results suggested that consumers encountered challenges in locating and understanding information within the current FFC labelling. The evaluation of the user testing underscores the need to improve the presentation of key information to ensure the safe and appropriate use of FFC, given that most consumers are not familiar with FFC.

A combined evaluation of HCPs' and users' perspectives identified common challenges in the safe use of FFCs. A critical evaluation is imperative from both viewpoints in the development and application of FFC labelling for effective risk-benefit communication. Establishing an integrated method for assessing usefulness becomes paramount in this context.

This initiative is significant as it has the potential to significantly contribute to consumer decision-making and the secure utilization of health food products, including FFC.

Data Sharing Statement

Data are available from the corresponding author upon request.

Ethics Approval and Informed Consent

The research protocol was submitted to the Ethics Committee of the Graduate School of Life Sciences, Kumamoto University on June 16, 2020. The research plan is based on a decision made by the Ethics Committee of the Department of Epidemiology and General Research, Graduate School of Life Sciences, Kumamoto University, on June 16, 2020 (Ethics No. 2039). Written informed consent was obtained from all participants involved in the study. This study complies with the Declaration of Helsinki.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors report no conflicts of interest in this work.

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