

The system of "Foods with Function Claims" provides "opportunities for consumers to make voluntary and reasonable product choices." With a proper understanding of the new system, food business operators need to take responsibility for providing consumers with accurate information and not misleading consumers.

This pamphlet has been developed to explain the system of "Foods with Function Claims." Before submitting a premarket notification, please refer to the website of the Consumer Affairs Agency for the "Guidelines on Notification of Foods with Function Claims," the Food Labelling Standards and the notices regarding the Standards.
<http://www.caa.go.jp/foods/index18.html>

Guidance for Industry

The system of "Foods with Function Claims" has been launched!

Before considering
development and sale of products



1 Background on the Introduction of the "Foods with Function Claims" System

- Before this system was in place, making function claims on food labels had only been allowed for government-approved Foods for Specified Health Uses (FOSHU) and for Foods with Nutrient Function Claims (FNFC) that comply with the specifications and standards designated by the government. These systems remain in place.
- In addition to these categories, this new type of Foods with Health Claims, called Foods with Function Claims, was introduced in April 2015 in order to make more products available clearly labeled with certain nutritional or health functions and to enable consumers to make more informed choices.

2 Characteristics of the New System

- Food business operators* can make function claims on food labels when they submit to the Secretary-General of the Consumer Affairs Agency necessary information including scientific evidence on food safety and effectiveness in accordance with the rules prescribed by the law before marketing the product.

*Food business operator refers to food importers, food manufacturers, food producers and food retailers.

- All food products* including fresh produce are subject to this system.

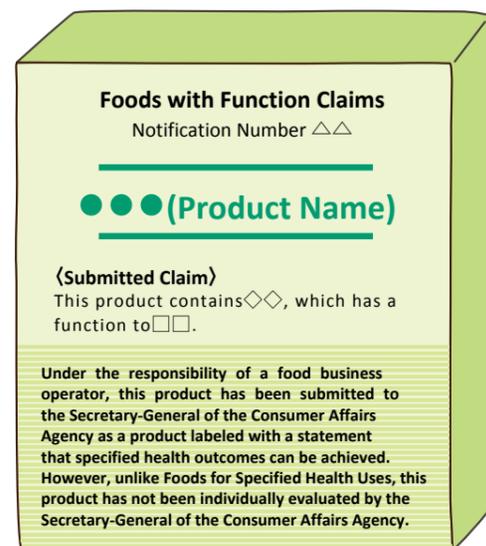
*Excluding Foods for Special Dietary Uses (including FOSHU), FNFC, alcohol-containing beverages, and food products that may lead to the excessive consumption of fat, cholesterol, sugar (limited to mono- and disaccharides, excluding sugar alcohols), or sodium.

- Unlike FOSHU, the government does not evaluate the safety and effectiveness of Foods with Function Claims. Food business operators make appropriate function claims based on scientific evidence for which they are responsible. The scientific evidence for function claims must be obtained from clinical trial(s)* or systematic literature review(s).

* Intervention study that involves human subjects and evaluates the effects of consumption of a certain substance or food on health outcomes

Expertise in performing clinical trials and/or systematic literature reviews is required. If such knowledge is insufficient, please consult a professional.

- To make function claims under the new system, it is required to submit a premarket notification and to label the package in accordance with the Food Labelling Standards pursuant to the Food Labelling Act as well as the "Guidelines on Notification of Foods with Function Claims."



Labelling requirements such as the amount of functional substance per unit of recommended daily intake, directions for use, warnings, and contact information of the food business operator are regulated in the Food Labelling Act and Standards.

*All required information must be labeled in Japanese.

3 Foods Labeled with Certain Nutritional or Health Functions

These food products are allowed to label the function of food which is that the specified health effects can be achieved (i.e., helpful for maintaining and promoting health) such as "Helps maintain good GI condition" or "Slows fat absorption."

Foods for Specified Health Uses

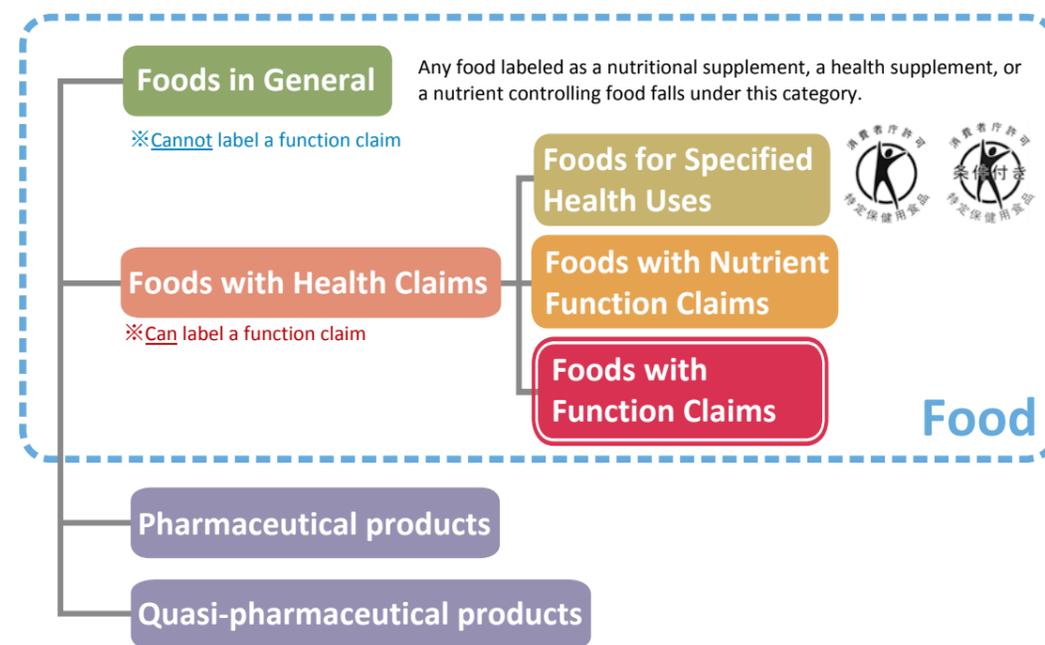
Foods for Specified Health Uses (FOSHU) are scientifically recognized as helpful for maintaining and promoting health and are permitted to bear claims such as "Slows cholesterol absorption." The government evaluates the claimed effects and safety, and the Secretary-General of the Consumer Affairs Agency gives approval for the labelling of each food product that satisfies the requirements.

Foods with Nutrient Function Claims

Foods with Nutrient Function Claims (FNFC) can be used to supplement or complement the daily requirement of nutrients (vitamins, minerals, etc.) which tend to be insufficient in everyday diet. Given that the food product contains certain amounts of nutrient whose function has already been substantiated by scientific evidence, it can bear a nutrient function claim prescribed by the Standards without submitting a notification to the government.

Foods with Function Claims

Under the food business operator's own responsibility, Foods with Function Claims can be labeled with function claims based on scientific evidence. Information on the evidence supporting the safety and effectiveness of the product are submitted to the Secretary-General of the Consumer Affairs Agency before the product is marketed. However, unlike FOSHU, the product is not individually pre-approved by the Secretary-General of the Consumer Affairs Agency.



4 Procedures Required for Marketing Foods with Function Claims

Please check the following procedures. To submit a notification, it is required to fulfill all of 1 to 6 procedures.

1. Determining whether your product is subject to Foods with Function Claims

If your product corresponds to any of the following items, your product cannot be subject to Foods with Function Claims.

- A food product developed for people suffering from diseases, minors, pregnant women (including those planning a pregnancy) or lactating women
- A food product whose functional substance(s) has not been identified
- A food product whose functional substance(s) is any of nutrients for which Dietary Reference Intakes for Japanese has been set by the Ministry of Health, Labour and Welfare
- Foods for Specified Dietary Uses (including FOSHU), FNFC, alcohol-containing beverages
- A food product that may lead to the excessive consumption of fat, saturated fatty acid, cholesterol, sugar (limited to mono- and disaccharides, excluding sugar alcohols), or sodium.

2. Substantiating the product safety

- (1) Product safety must be evaluated and explained by one of the following methods.
- Evaluating the history of consumption by humans based on actual intake data
 - Collecting secondary information through databases
 - Conducting safety test on a finished product or functional substance(s)
- (2) The interaction of the functional substance(s) must be evaluated. If the interaction is detected, the appropriateness for selling such a product must be explained.
- Identify any interactions of functional substance(s) with drugs. If an interaction is confirmed, the appropriateness for selling such a product must be scientifically explained.
 - If the product contains multiple functional substances, identify any interactions among substances. If an interaction is confirmed, the appropriateness for selling such a product must be scientifically explained.

3. Establishing a system of production, manufacturing, and quality control

- A system for ensuring safety in terms of sanitation and quality control during the production and manufacturing processes must be established and described.
- Structures to control facility and employee sanitation in food processing/Sanitation control procedures for producing and harvesting fresh food, fishing, etc.
 - Systems designed to prevent distribution of out-of-specification products
 - An analytical method for quantitative determination of functional substance(s) and substance(s) that require safety assurance, etc.
- ※ It is desirable to voluntarily and proactively implement HACCP, GMP, etc.

4. Establishing a system to collect adverse health events

- For prevention of the occurrence and spread of adverse health outcomes, a system to collect and report information must be established.
- Establishing a system to receive information from consumers, health professionals, etc.

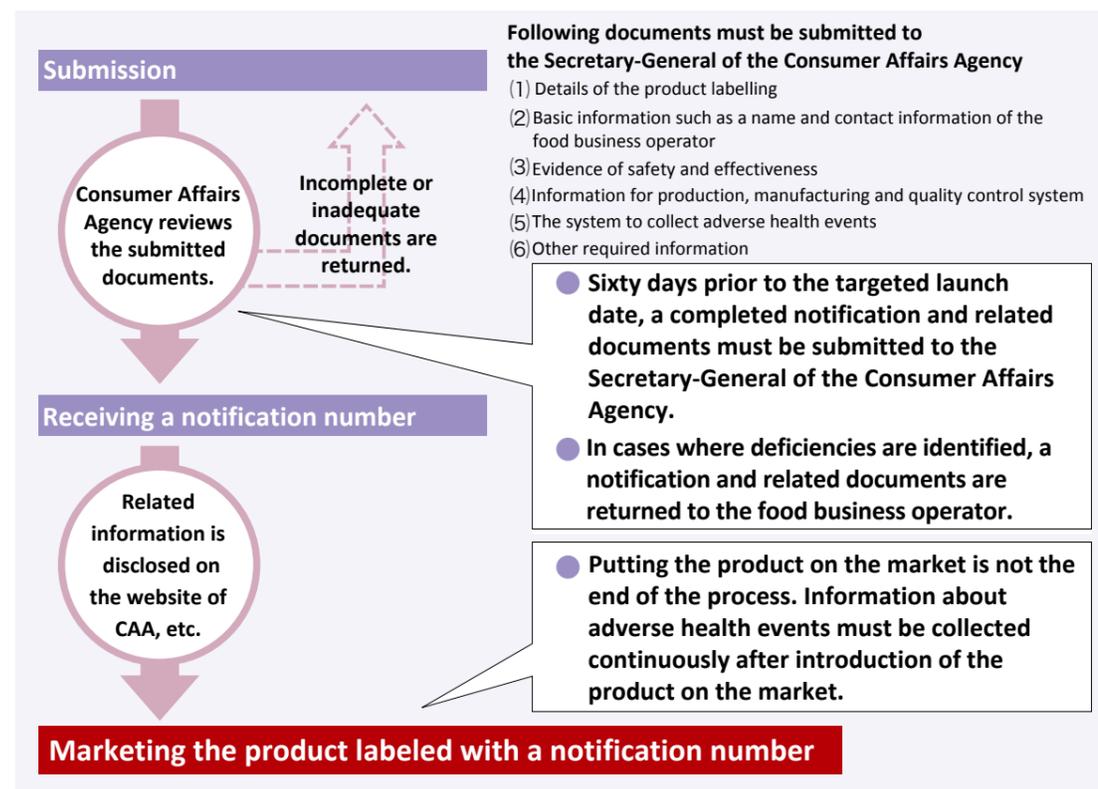
5. Substantiating the product effectiveness

- The scientific evidence for the proposed function claims must be explained by one of the following methods.
- Clinical trial(s) with a finished product (equivalent level of study required for Foods for Specified Health Uses)
 - Systematic literature review(s) on a finished product or functional substance(s)

6. Labeling the product properly

- Packages must be properly labeled.
- Product labelling must be in accordance with the Food Labelling Standards, notices and Q&A regarding such Standards, and the "Guidelines on Notification of Foods with Function Claims."

The procedure shown on this page is an outline of the system of "Foods with Function Claims." When actually submitting a premarket notification, please refer to the "Guidelines on Notification of Foods with Function Claims" as well as the Food Labelling Standards. <http://www.caa.go.jp/foods/index23.html>



In making a function claim, the following should be noted.

Possible function claims are confined to a statement to the effect that a food product is helpful or suitable for maintaining and promoting the health of people not suffering from any disease.

- The use of medical terms such as "diagnose", "prevent", "cure", or "treat" is prohibited.
- A claim that implies the effectiveness of treatment or prevention is prohibited. A claim that targets people suffering from a specific disease, such as "for people suffering from diabetes", is also prohibited.
- Function claims cannot be appealed to minors, pregnant women (including those planning a pregnancy), or lactating women.
- Claims that state intentional enhancement of health such as body building, hair-growth treatment, skin-whitening, etc. are prohibited.
- A function claim which is not sufficiently substantiated by scientific evidence cannot be made on food labels.

False or misleading labelling shall be subject to legal penalties...

- If labelling does not comply with the Food Labelling Standards, in violation of the Food Labelling Act, it may be subject to an instruction, order or penalty under the Food Labelling Act.
- A product labeled beyond the scope of the scientific evidence may fall into the misleading representation provision under the Act against Unjustifiable Premiums and Misleading Representations or the false or exaggerated advertising provision under the Health Promotion Act.



5 The Responsibilities of Food Business Operators who Sell Foods with Function Claims

The system of "Foods with Function Claims" allows food business operators, under their own responsibility, to make claims to the effect that a food product is helpful for maintaining and promoting health on food labels. Food business operators who submit a notification have the following responsibilities:

Responsibility for making sure that the wording of a proposed claim reflects the scientific evidence

Food business operators need to take responsibility that the wording of the proposed claim is not misleading or inconsistent with the safety and effectiveness which is substantiated by the scientific evidence.

Responsibility for the content and interpretation of the scientific evidence for safety and effectiveness

Food business operators may contract with a third-party organization to verify the scientific evidence; however, the responsibility for the content and interpretation of such scientific evidence still lies with the food business operator who submits a notification.

Responsibility for the development of a system to collect and report information in order to prevent occurrence or spread of adverse health outcomes.

When information on adverse health outcomes is reported, a food business operator has the responsibility to inform the Consumer Affairs Agency, etc.

Responsibility for matters regarding intellectual property rights

Food business operators need to take responsibility to confirm that the interpretation of scientific evidence, etc. are not in violation of intellectual property rights when submitting a notification.

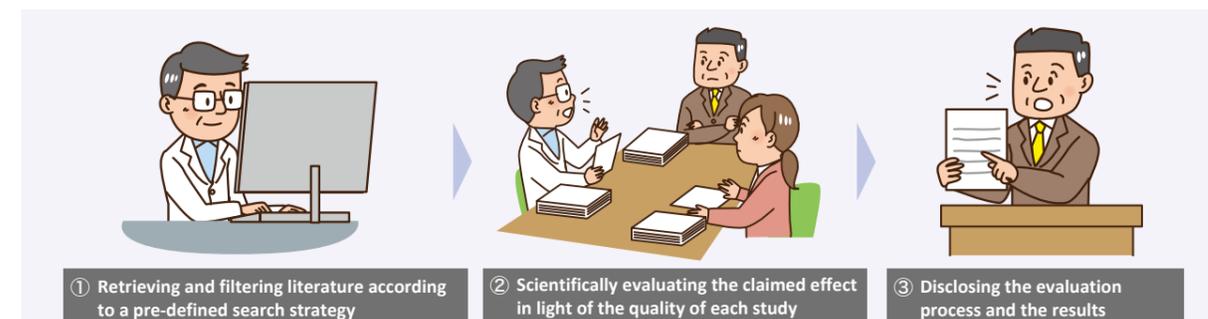
6 Evaluation of the Claimed Effect

There are two ways to provide scientific evidence when evaluating a claimed effect.

- One way is to conduct clinical trial(s) with a finished product. A clinical trial is an intervention study that involves human subjects and evaluates the effects of consumption of a certain substance or food on health outcomes.
- The other way is systematic literature review(s) (performing a literature search by following certain rules and evaluating the data comprehensively).

A systematic literature review may be conducted through such steps as follows. The basic concept of the procedure for performing a systematic literature review is presented in the Guidelines.

- 1 The authors of a systematic literature review retrieve research papers by searching databases that contain articles on such as clinical trials and observational studies* related to the claimed effect of the finished product or the functional substance(s) in the finished product according to a pre-defined methodological approach prepared by the authors. **It is not acceptable to intentionally retrieve only studies reporting favorable results in relation to the claimed effect.**
* Studies that involve human subjects and evaluate the effects of consumption of a certain substance or food on health outcomes.
- 2 All retrieved studies are filtered by assessing against inclusion/exclusion criteria such as characteristics of finished product, target population, a proposed claim, etc. Those studies that meet the pre-determined criteria are then grouped according to whether or not their results support the effectiveness of the finished product or the functional substance(s).
- 3 The totality of evidence on the claimed effect of finished product or functional substance(s) should be considered by taking all favorable, unfavorable, and equivocal results together.
- 4 **To permit reproducibility of the systematic literature review**, all of the processes of the systematic literature review, such as used databases, set of keywords, the inclusion/exclusion criteria, and the title of excluded studies, **need to be thoroughly documented and submitted.**



Main considerations for performing a systematic literature review

- 1 **Included literature must be scientifically reviewed and support the claimed effect.**
(The following data sources are not suitable: information presented at an academic conference; lectures, comments from experts; articles published in newspapers, magazines; theory, origin, history, etc.)
- 2 **The claimed effect is supported by studies on humans using experimental or observational designs.**
(Animal and in vitro research are not considered. Observational studies for foods in supplement form are not considered.)
- 3 **A systematic literature review may not include only studies on the population whose demographics such as age, sex and ethnicity are substantially different from the target population of the product.**
- 4 **When performing a systematic literature review of a functional substance, an equivalence between the substance in the review and the substance in the finished product must be considered.**
- 5 **A systematic literature review must be performed by multiple independent specialists in order to ensure its reliability.**
- 6 **A systematic literature review must not violate the Copyright Law.**