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## Critical Factors for the Use of Foods with Function Claims!

✓ **First, reconsider your dietary habits.**

— It is important to have a balanced diet consisting of meals including a staple food, a main dish and side dishes.

✓ **Consuming more Foods with Function Claims does not necessarily result in better outcomes. Excessive intake may cause adverse health effects.**

— Carefully check warning statements printed on the package when consuming Foods with Function Claims.

— Carefully read the recommended daily intake, directions for use, and warnings printed on the package.

✓ **If you feel discomfort after consuming Foods with Function Claims, immediately stop consuming the product.**

— Whenever you do not feel well after consuming Foods with Function Claims, immediately stop consuming the product and consult a doctor.

— The contact phone number of the food business operator is printed on the package. When any adverse health event associated with the use of the product occurs, contact that number.



### For more details

● Consumer Affairs Agency <http://www.caa.go.jp/foods/index23.html>

## For Consumers

## What are "Foods with Function Claims"?

The new system of Foods with Function Claims has been launched. This is different from Foods for Specified Health Uses and Foods with Nutrient Function Claims.



● **"Foods with Function Claims"** are foods submitted to the Secretary-General of the Consumer Affairs Agency as products whose labels bear function claims based on scientific evidence, under the responsibility of food business operators.

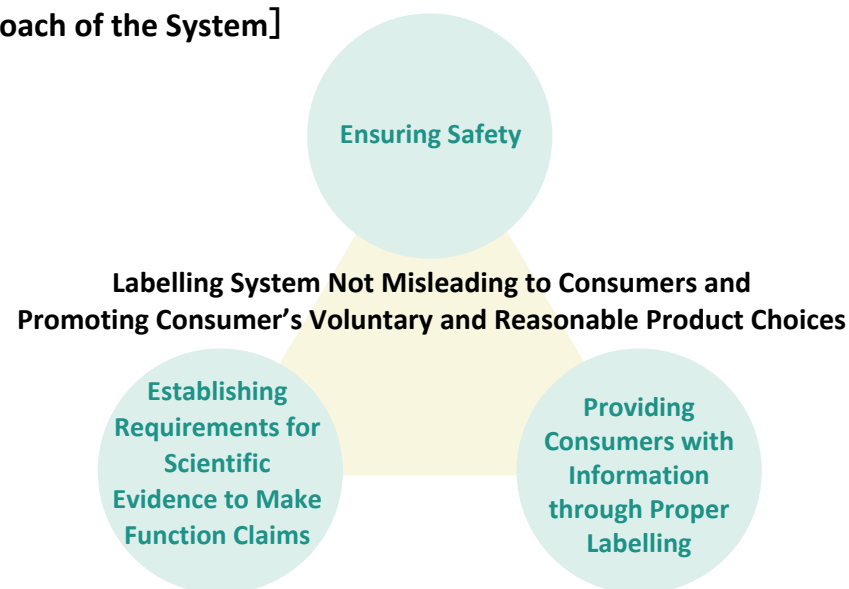
● Before purchasing and consuming Foods with Function Claims, carefully check the warnings on the product label and the information disclosed on the website of the Consumer Affairs Agency.

# 1 What are Foods with Function Claims?

- 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.

- 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."
- Under the condition that the safety of the food product is ensured, the food product is labeled with a function claim which is based on **scientific evidence** and also **under the food business operator's own responsibility**\*.
- \*Food business operator refers to food importers, food manufacturers, food producers and food retailers.
- In order to enable consumers to make a product choice without misunderstanding the information, **the information must be provided** through proper labeling, etc.

## [Basic Approach of the System]



## Characteristics of the System

1. Foods with Function Claims are for people not suffering from any disease (excluding minors, pregnant women (and those planning a pregnancy), or lactating women).
2. All food products including fresh produce are subject to this system.
3. Prior to market entry, food business operators are required to submit information, such as on food safety and effectiveness and the system in place to collect information on adverse health effects, to the Secretary-General of Consumer Affairs Agency.
4. Unlike Foods for Specified Health Uses, the government does not evaluate the safety and effectiveness of the submitted product.
5. The submitted information is disclosed on the website of the Consumer Affairs Agency.

## Foods Labeled with Certain Nutritional or Health Functions

### Foods for Specified Health Uses

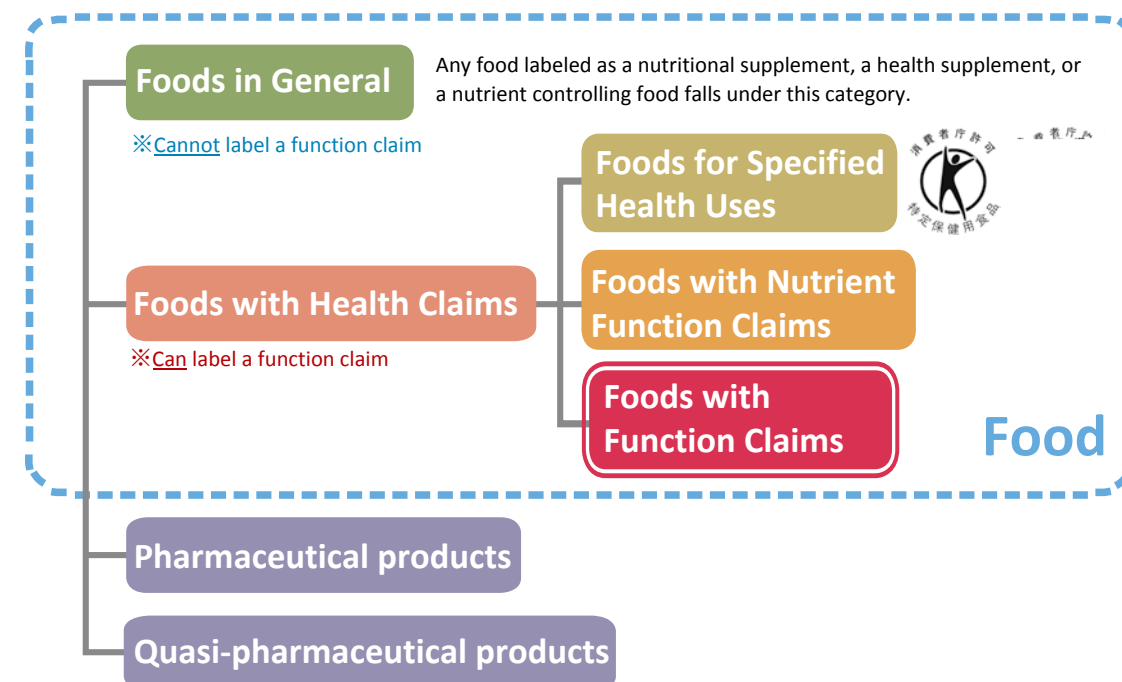
Foods for Specified Health Uses (FOSHU) are scientifically recognized as helpful for maintaining and promoting health and are permitted to bear claims such as "Slows cholesterol absorption." The government evaluates the claimed effects and safety, and the Secretary-General of the Consumer Affairs Agency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



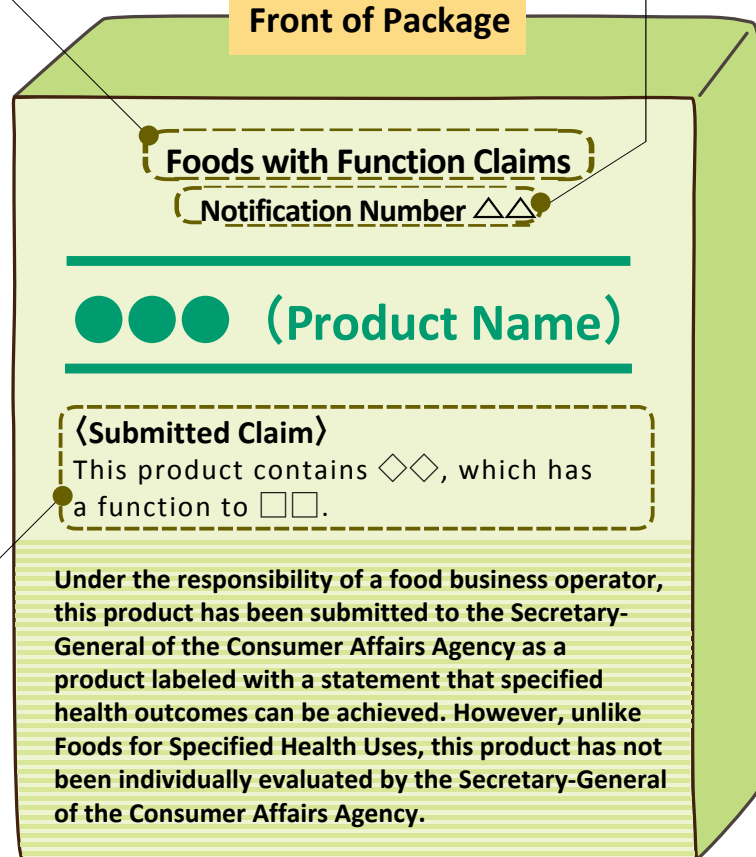
## 2 What is written on the label of Foods with Function Claims?

The product is labeled as "Foods with Function Claims" on the principal display panel.

A notification number is on the label.

A notification number can be used to check information regarding the evidence on safety and effectiveness of the product on the website of the Consumer Affairs Agency.

Front of Package



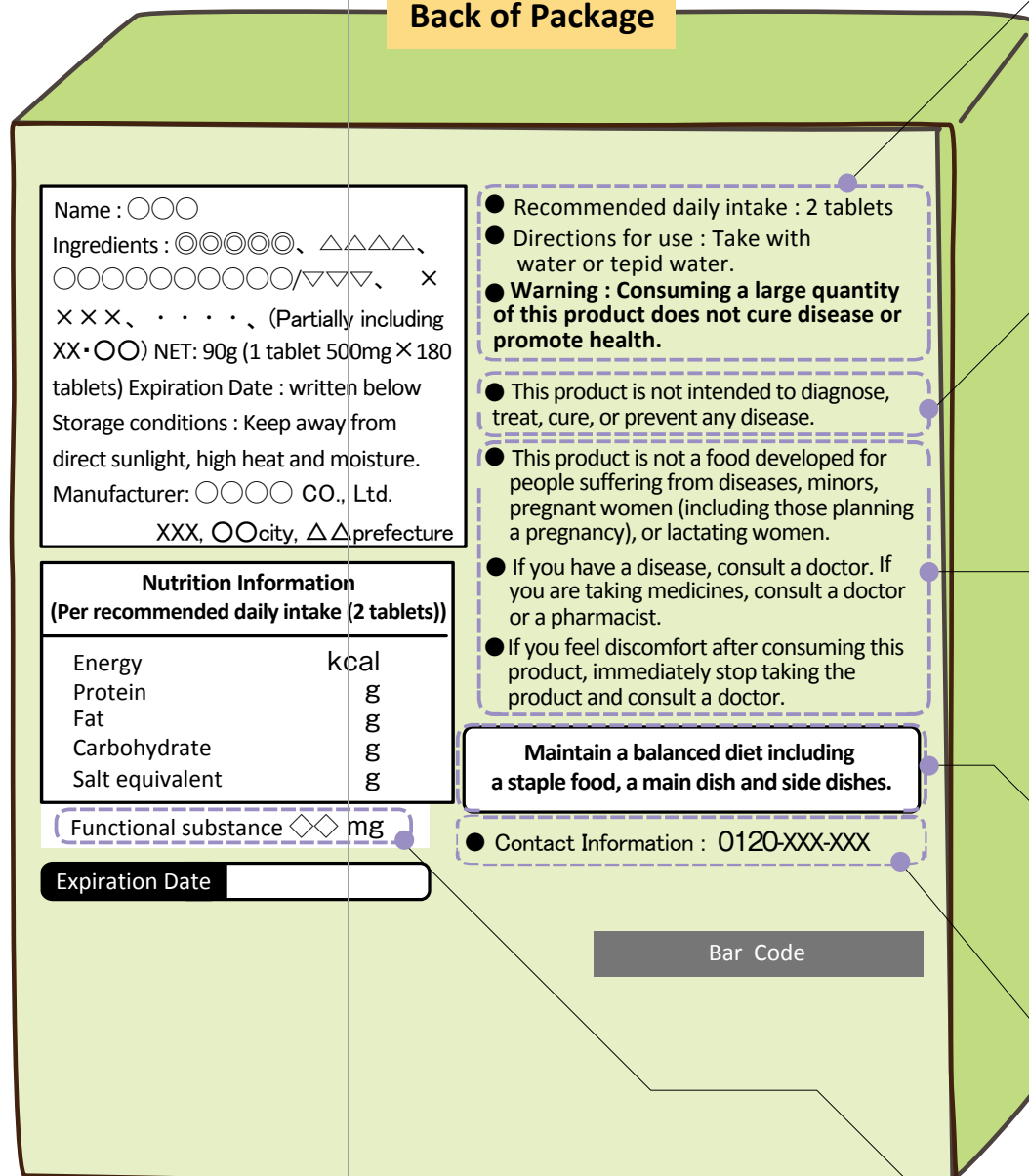
The label bears the claim submitted to the Secretary-General of the Consumer Affairs Agency. The submitted claim states the effectiveness of the product or the functional substance(s), which is based on the scientific evidence.

The function claim states that the specified health effect can be achieved (i.e., it is helpful for maintaining and promoting health.).



More detailed information such as evidence on safety and effectiveness of the product submitted by food business operators is disclosed on the website of the Consumer Affairs Agency.  
<http://www.caa.go.jp/foods/index23.html>

Back of Package



Follow the recommended daily intake and directions for use, and check warnings on the label.

**"Foods with Function Claims" are not pharmaceutical products.** They are not intended for use in the diagnosis, cure, or prevention of disease. People who have a disease or are taking medicines should consult a doctor or a pharmacist.

It is not a food developed for people suffering from diseases, minors, pregnant women (including those planning a pregnancy), or lactating women.  
※ Although this statement is not on the label of fresh produce, the same approach also applies to fresh produce.

If your meal includes a staple food, a main dish and side dishes, you are more likely to have a nutritionally balanced meal.

Consumers can call a phone number on the label to make an inquiry or contact the food business operator.

This indicates the quantity of functional substance per unit of recommended daily intake.



# 3 How is the safety and effectiveness of Foods with Function Claims ensured?

- Food business operators are required to evaluate the safety and effectiveness in accordance with certain rules prescribed by the government and to establish systems of production, manufacturing, quality control, and collecting information on adverse health events. They must then submit the information to the Secretary-General of the Consumer Affairs Agency 60 days prior to marketing the product.
  - Submitted documents are disclosed on the website of the Consumer Affairs Agency.
  - Consumers can check the product information on how the safety and effectiveness of the product is ensured before the product is placed on market.
- ◆ The Consumer Affairs Agency will lead the post-market surveillance.

### 1. How is the safety evaluated?

The safety is evaluated by one of the following methods.

- A history of consumption by humans
- Research of existing information on safety
- Safety testing on animals or humans

Any interactions with drugs, etc. are also evaluated.

### 2. How is the effectiveness evaluated ?

The effectiveness is evaluated by one of the following methods.

- Clinical trial(s) with a finished product
- Systematic literature review(s)\* on a finished product or functional substance(s)

This reveals: types of scientific evidence substantiating the claimed effects, the target population, the frequency and amount of consumption, and the effectiveness of product.

- When the scientific evidence is provided by clinical trial(s) with a finished product, the product package bears a claim that the product has a function to ○○○○.
- When the scientific evidence is provided by systematic literature review(s), the product package bears a claim that the product/functional substance(s) has been reported to have a function to ○○○○.

### 3. How are systems of production, manufacturing and quality control managed?

Food business operators are required to establish following systems.

- For processed food, structures of sanitary control for facilities and employees
- For fresh produce, sanitation control procedure for producing, harvesting, or fishing
- Systems designed to prevent distribution of out-of-specification products
- An analytical method for the functional substance(s) Etc.

### 4. How are adverse health events collected?

Food business operators should establish a system to receive information from consumers, health professionals, etc. The contact information of the food business operator (a telephone number) is always printed on the product label.



Please check the website of the Consumer Affairs Agency where the information (1~4) submitted by the food business operator is disclosed. You can get information about the evidence on food safety and effectiveness, which is arranged by notification number.

### ※What is a systematic literature review?

A systematic literature review is one of the considered methods for providing scientific evidence on the claimed effect. It determines the totality of evidence on the claimed effect based on not only favorable results but also unfavorable results.

The authors of a systematic literature review retrieve research papers by searching databases that contain study literature. The authors develop a search strategy such as keywords that will be used to retrieve literature beforehand. All retrieved literature is filtered, and then the literature that meets the pre-determined criteria is grouped according to whether or not their results support the effectiveness of the finished product or functional substance(s). A food business operator is not allowed to intentionally retrieve only studies reporting favorable results in relation to the claimed effect.

- ① Retrieving and filtering literature according to a pre-defined search strategy
- ② Scientifically evaluating the claimed effect in light of the quality of each study
- ③ Disclosing the evaluation process and the results