

# Overview

## Report by the Committee for Ensuring the Safety of Health Foods

With the increase of public interest in health, various kinds of foods are being distributed as health foods, including those that have never been served for eating or drinking and those that are served in a particular form. Under such circumstances, to supply safer products to consumers, a wide range of measures should be taken throughout the whole process from manufacturing to marketing stage.

Collecting and appropriate handling information on health problems is also required.

### Specific measures at the manufacturing stage

- (1) Ensuring the safety of ingredients (*Conduct documentary research. When a history of consumption as food is insufficient, conduct toxicity studies.*)
- (2) Ensuring the safety of health foods through the manufacturing process management (*Control manufacturing and quality based on GMP throughout the whole manufacturing process.*)
- (3) Ensuring abovementioned effectiveness (*Introduce a third-party certification system.*)

### Enhancement of the system to collect and handle information on health problems

Collect information more proactively, even in cases where the causal relationship between the health foods and the health problems is not clear.

Provide information, such as on the current use situation of health foods and cases of health problems in the past, to the doctors and other public health experts.

### Information dissemination and awareness-raising to consumers

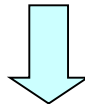
- (1) Label information on the adequate intake and warnings should be provided by manufacturers.
- (2) The quality of training programs for advisers and of their activities should be kept at a certain level.

## Ensuring the Safety of Ingredients

Manufacturers of food products, including health foods, should endeavor to take measures required to ensure the safety of ingredients of foods that they produce (Article 3 of the Food Sanitation Act).

For tablet/capsule form foods, it is very important to ensure the safety of their ingredients from the viewpoint of possibility of health problems attributable to excessive consumption.

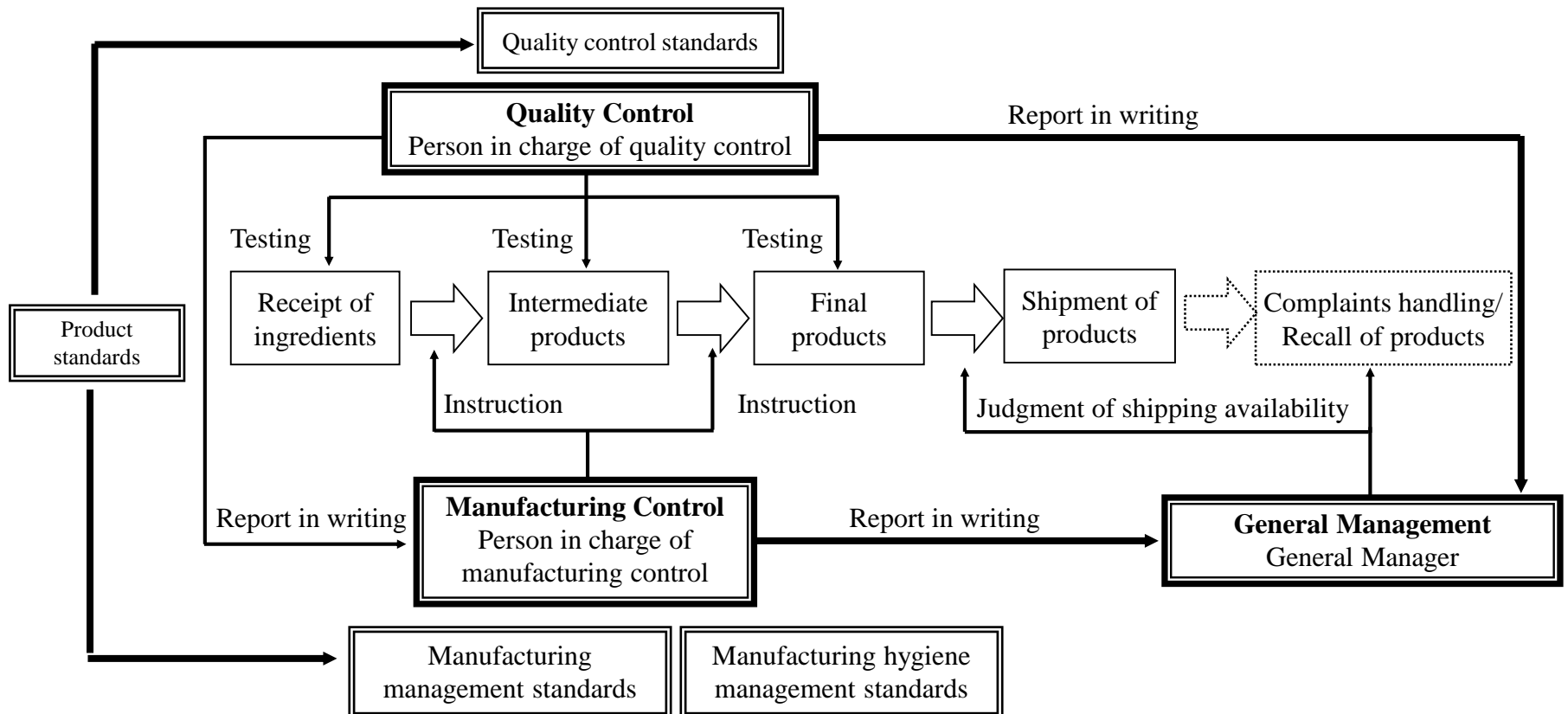
On the original ingredients used for manufacturing health foods, collect safety/toxicity information through documentary research.



When the safety of health foods cannot be assured based on a history of consumption as food, conduct toxicity studies using their ingredients.

# Ensuring the Safety through Manufacturing Process Management Based on GMP

For tablet/capsule form health foods treated with some processes like concentration of ingredients, to homogenize the products and improve the safety and reliability of them, it is critical to develop a system for manufacturing and quality control based on GMP (Good Manufacturing Practice) throughout the whole manufacturing process, from the receipt of ingredients to the packaging and shipment of final products.



# Third-Party Certification System for Ensuring Safety of Health Foods

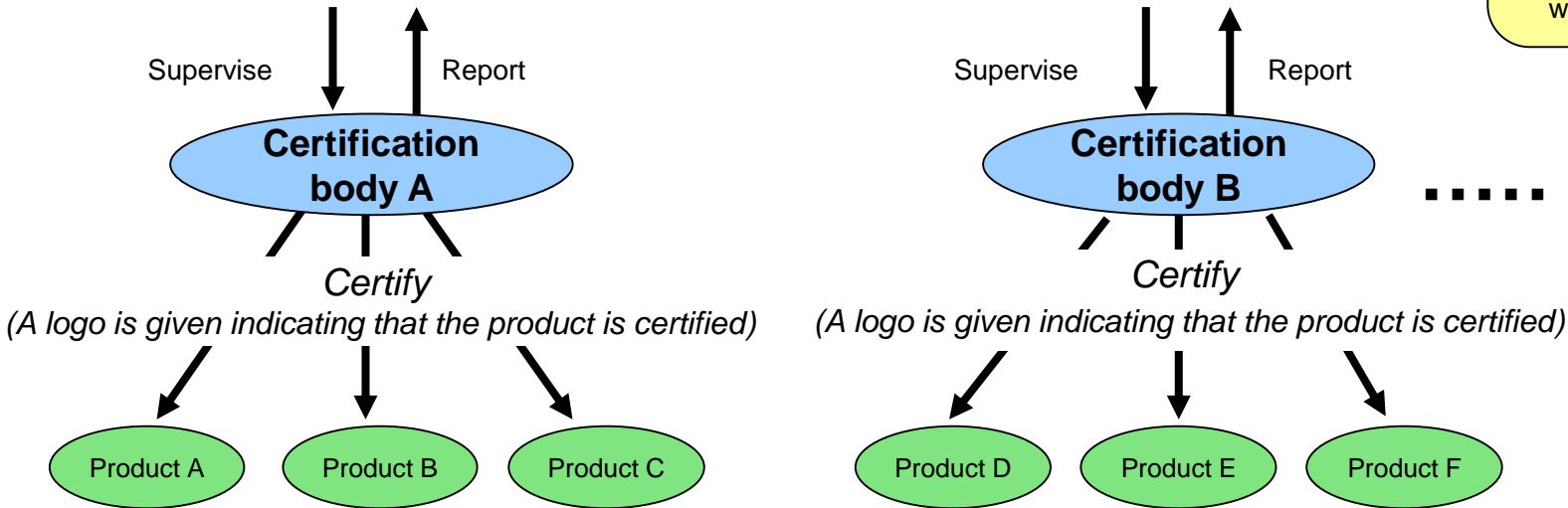
In ensuring ingredient safety and food safety through GMP based on manufacturing process management, it is imperative to confirm whether such safety is reached at a certain level with the help of third-parties other than business operators from an objective viewpoint.  
It is desirable to use certification standards and labeling information that are as unified as possible.

## Certification Council

- \* Composed mainly of academic experts, consumers, and manufacturers.
- \* Establishes standards for designating certification bodies and specifications/standards for certification work conducted by the certification bodies.
- \* Supervises the certification bodies and provides guidance to them so that health food products can be certified in accordance with the MHLW's guidelines.

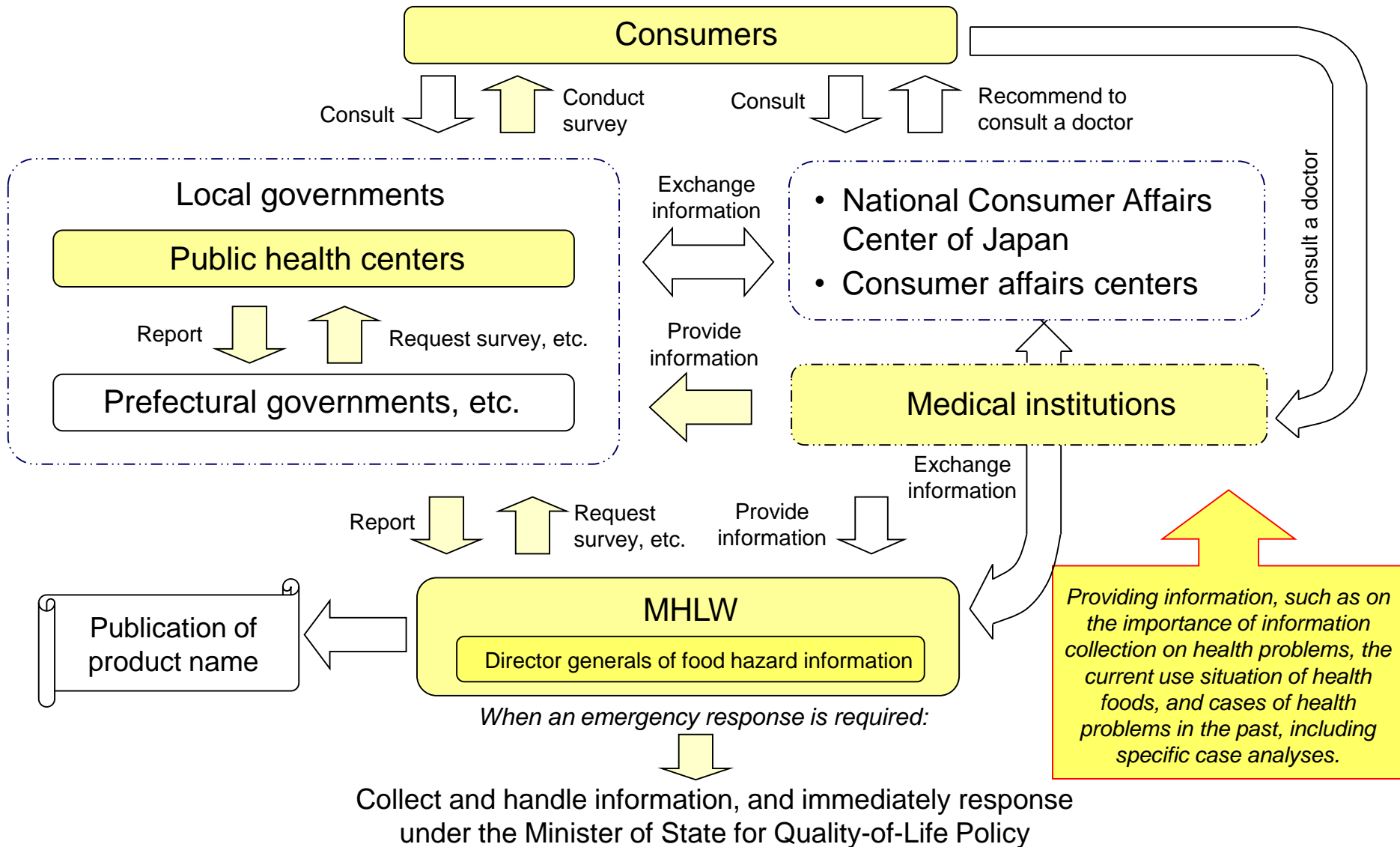
## Ministry of Health, Labour and Welfare (MHLW)

Supports activities of the Certification Council through information dissemination to and information exchange with relevant parties.



# Enhancement of the System to Collect and Handle Information on Problems Associated with Health Foods

Information collection concerning health problems is effective to prevent further occurrences and recurrence of health problems. Relevant national and local organs should endeavor to proactively collect related information.



## Information Dissemination and Awareness-Raising to Consumers

To deal with misinformation on and excessive expectations for health foods, it is very important to raise public awareness and disseminate correct information on the safety of health foods and basic knowledge on them.

### *Provision of safety information by manufacturers*

- Provide information on the safety of product ingredients and the appropriateness of manufacturing process management.
- Optimize labeling of ingredients, adequate intake, and warnings.

### *Dissemination of basic knowledge on health foods and public awareness-raising*

- Make efforts to ensure the quality of training programs for and activities of advisers at a certain level so that they can provide correct information on the characteristics of ingredients contained in health foods, the necessity and use purposes of the ingredients, and how to consume them.

# Health Foods

There is no legal definition for “health food.” It is thought that “health food” refers to all foods sold and used as food products that contribute to the maintenance and promotion of people’s health in general. The committee report targets the above-mentioned food products, excluding foods for specified health uses, which are individually reviewed by the national government for their efficacy and safety.

