Report by the Committee for Ensuring the Safety of Health Foods

July 4, 2008

1. Introduction

With the increase of public interest in health, various kinds of health foods* are being distributed and consumed. For these health foods, administrative authorities concerned have been making various efforts, including the establishment of specifications and standards for general matters and labeling standards, so that the people can select health foods appropriately according to their eating habits.

* There is no legal definition for health foods. It is considered that they refer to the foods sold and consumed as foods that can contribute to maintain and promote people's health in general. In this report, the term health foods means above-mentioned foods excluding foods for specified health uses, whose efficacy and safety have been separately reviewed by the national government.

In recent years, various new types of foods have been distributed as health foods. They include foods whose ingredients have not been served thus far for eating/drinking and those that are served in a specific form, such as tablets or capsules.

In such situation that ingredients without a history of consumption as food has been increasing, the important issue tackled is how to ensure the safety of the ingredients at each stage up to the manufacturing stage of health foods. Also, to ensure the quality of products, appropriate management of the manufacturing process is required more than before.

At the stage of the sales of health foods, there is no labeling information provided to serve as a criterion for consumers to choose products. It includes information that shows to what extent the manufacturers have taken measures to ensure the safety of the products. In addition, there is no sufficient system developed for consumers to receive proper information and receive support for consultation on health foods.

Even when a health problem suspected to be caused by a health food occurs, it is often difficult to grasp the causal relationship between the health problem and the health food in question. In such case, the information may not have been collected and analyzed; therefore, these cases may not have been utilized enough for the prevention of similar incidents in the future.

In the situation as described above, the Committee for Ensuring the Safety of Health Foods has held its meetings nine times in total since July 2007. The committee has

heard from all relevant organizations (11 organizations) that had wished to provide information. Also, from July 11 to July 31, 2007, the committee solicited public comment mainly through the website of the Ministry of Health, Labour and Welfare (MHLW), and have discussed how the ensuring of the safety of health foods should be in the future. The committee reports the results of the discussions as below.

2. Specific measures to ensure the safety of health foods at the manufacturing stage

(1) Basic concept

The Food Safety Basic Act (Act No. 48 of 2003), in Article 8, Paragraph (1), stipulates that the food-related business operators shall be responsible for appropriately taking the necessary measures to ensure food safety at each stage of the food supply processes. This shall be done based on the recognition that they bear the primary responsibility for ensuring food safety when conducting their business activities. The Food Sanitation Act (Act No. 233 of 1947), in Article 3, Paragraph (1), also stipulates that the food manufacturers shall work to take necessary measures to ensure the safety of foods on their own responsibility, such as ensuring the safety of ingredients that they manufacture.

As shown above, manufacturers of foods including health foods shall be primarily responsible for ensuring the safety of the ingredients of foods they produce. For foods in tablet or capsule form, however, considering the possibility that even small amounts of substances naturally occurring in their ingredients are concentrated in such foods, the MHLW prepared and published the guidelines for manufacturers' self-inspection for the safety of ingredients of such foods and the guidelines for appropriate manufacturing process management (Notice of the Director of the Department of Food Safety, Pharmaceutical and Food Safety Bureau, MHLW, *食安発* No.201003, February 1, 2005).

In the current situation, however, persons other than business operators, such as consumers who purchase products, are not able to know easily whether the manufacturers are sufficiently working on such activities. The committee therefore shows specific measures to ensure the safety at the manufacturing stage of health foods.

One of the measures is introduction of a system in which an external organization independent from food business operators verifies the safety of health foods.

(2) Ensuring the safety of ingredients of health foods

Unlike pharmaceutical products that require an approval for manufacturing and sale for each item based on the Pharmaceutical Affairs Act (Act No.145 of 1960), foods can be manufactured without approvals as a general rule. Such a handling of foods is based on the basic thought that, in general, a history of consumption as food verifies the safety of foods and their ingredients.

Some products manufactured as health foods, however, contain ingredients that do not have sufficient history of consumption as food (including a case when the food concerned was produced through methods different from conventional ones).

Health foods manufacturers thus should collect safety and toxicity information through documentary research on the original ingredients used for manufacturing health foods. If they judge that the safety of health foods is not able to be assured based on a history of food consumption, they should conduct toxicity studies on the ingredients and other relevant substances if necessary, to obtain additional information.

Basically, the safety of ingredients should be evaluated based on the data on a history of consumption as ingredients. In some cases, however, it can be evaluated based on the determination as to whether the newly developed food is equivalent to an existing similar food, for example, whether they are similar in form or amount ingested as foods. Safety evaluation should focus on the ingredients but final products should also be the target to be examined.

Whether such evaluations are appropriately conducted depends greatly on the documentary research skills on the safety of health foods. Therefore, business operators should acquire a certain level of the research skills and the operators and relevant parties throughout the industry should work together to enhance their skill.

It is considered that, if a third-party can objectively confirm that the safety evaluations conducted by health food manufacturers have reached a certain level, the safety of

health foods will be further ensured and thereby reliability for such products will increase.

(3) Ensuring safety through manufacturing process management

For health foods in tablet or capsule form 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 processes, from the receipt of ingredients to the packaging and shipment of final products.

Note: As standards for manufacturing process and quality control system development, in addition to GMP, standards such as ISO (International Organization for Standardization) are available. Since this report is a proposal for the system development related to ensuring safety of health foods, the committee has decided to center on the concept based on the GMP that was developed as consistent with the characteristics of the manufacturing process of health foods in reference to the system based on GMP introduced for the manufacturing and quality control of pharmaceutical products.

The GMP requires first, the setting of standards for the structure and facilities to ensure a proper manufacturing environment, which is sanitary, reasonable, and easy-to-work in, as well as the preparation of an appropriate procedure manual from the receipt of ingredients to packaging and shipping of products. Then, the GMP requires management according to the standards and manual. Specific management systems, however, should be established according to the nature of individual product and the actual manufacturing process. The manufacturing process of the ingredients should also be managed in a similar way.

Without the proper implementation of the GMP, there is a possibility that the product's homogeneity and the safety are not ensured, and it is also difficult to exactly know the ingredients contained in the product and each amount of them. If a health problem caused by a health food occurs, such situation without the proper implementation of the GMP may bring negative effects to causal identification.

Objective confirmation by a third-party about whether the GMP system has reached a certain level is the key to further ensuring the safety of products. Consequently, it is expected that objective third-party confirmation will contribute to enhance the reliability of such products.

(4) Specific measures for ensuring the effectiveness of the safety of health foods

Introducing third-party certification—in which a third-party verifies whether GMP is properly implemented and whether the safety of health food ingredients is ensured—will lead to the distribution of higher-quality products and an increase in consumer choice.

In developing specific systems for third-party certification, the following circumstances should be thoroughly considered besides the basic concept described in section (1): (a) at this point, it is difficult to establish individual safety standards for each health food since the ingredients and processing methods are diverse; and (b) it is desirable to use certification standards and labeling information that are as unified as possible to gain a broad understanding of consumers.

Under the operation of the third-party certification system, it is not planned that a certification council designate certification bodies based on laws or regulations. To ensure that appropriate certification procedures are carried out by certification bodies, following operations are considered to be reasonable.
- A certification council consisting of academic experts, consumers, and manufacturers is organized.
- The council establishes requirements, and sets certification standards and designates certification bodies according to the requirements.
- The council also guides and supervises the certification bodies.

The roles that the certification council should play have a public aspect. When the council is organized, therefore, administrative authorities should cooperate in the public relations to the relevant parties, and support its smooth establishment. In the operation of the council, organizations concerned, including administrative authorities, should cooperate with each other and thoroughly exchange information to resolve issues they face.

It is recommended that the products certified by a third-party be labeled with a logo indicating that fact—for those certified for the safety evaluation of ingredients and for those certified for the GMP, a logo showing the safety and a logo showing proper implementation of the GMP, respectively—and that such information enable consumers to choose health foods based on food safety.

That a health food is allowed to be labeled with such a logo simply means that a third-party has confirmed, based on their knowledge, that the product has passed a process necessary to ensure food safety; for example, the safety of the ingredients of the product have been evaluated, or the product is manufactured based on GMP. It should be noted that having the logo does not guarantee the absolute safety nor the usefulness of the product.

Thus, if the meaning of the logo is not made well known, labeling products with such a logo may just give rise to misunderstanding and excessive expectations to the public on the safety and usefulness of such products.

Also, to promote the efforts for ensuring the safety of health foods in general, more products should be manufactured based on GMP and through safety evaluation of the ingredients. In addition, a highly transparent third-party certification system is required. It is necessary to develop a framework so that consumers fully understand the significance of these measures, and that third-party bodies can give appraisal to the products that have gone through such procedures, distinguishing such products from other products.

It is appropriate that third-party certification bodies enhance the information dissemination on safety evaluation of the ingredients and on GMP compliance while allowing certified products to be labeled with the logo.

3. Enhance the system to collect and handle information on health problems

Cases of food-caused health problems shall be, like the food poisoning cases, reported to public health centers from doctors of the medical institutions that the patients consulted, and then reported to the MHLW through local governments that have jurisdiction over the public health centers.

The Guidelines for Preventive Measures for Health Problems Caused by Health Foods and Unapproved/Unlicensed Pharmaceutical Products (Notice of the Director-General of the Pharmaceutical and Medical Safety Bureau, MHLW, *医薬発* No. 1004001, October 4, 2002) provide procedures for developing systems for the prevention of the occurrence of health problems caused by health foods, etc., and executing measures to prevent further occurrences of health problems when they occur. The Guidelines have been playing a specific role in preventing the occurrence and further occurrences of health problems, mainly through the publication of overviews of the severe cases caused by health foods.

In the event of an emergency in which urgent response is required for a health problem caused by a health food, Director Generals of Food Hazard Information will be called by the Minister of State for Quality-of-Life Policy. They will collect and analyze the information possessed by relevant ministries and agencies, and provide urgent measures.

Continuing broad information gathering on food-associated health problems will contribute to obtaining certain knowledge on the relationship between the components of a health food and symptoms of a health problem, even for a case that the causal relationship between a health food and a health problem is not clear or that the degree of a problem is not severe. This will, it is expected, lead to the prevention of the occurrence of another health problem.

Therefore, administrative organizations should previously provide adequate information to doctors who may provide medical care to the patients at occurrence of health problems suspected to be caused by health foods, and pharmacists who may attend to customers purchasing health foods, in order to ensure that administrative agencies concerned including health centers are informed by the doctors and pharmacists of sufficient information on health food-associated health problems. The information to be provided to the doctors and pharmacists includes specific case analysis on health problems in the past, the importance of collecting information on health problems, and the current situation of health foods.

In addition, the food safety administrative department should enhance the cooperation with these relevant organizations on a daily basis, in order to collect and analyze

accurately the information on health problems suspected to be caused by health foods, etc. that the National Consumer Affairs Center of Japan and the consumer affairs centers have.

Health foods include various ingredients. People who have developed symptoms might have ingested various health foods at the same time, or the interaction of the health foods might have caused health problems. Thus, it is not easy to define the causality in general. However, when new information or knowledge is obtained as a result of analyzing collected information on health problems, they should be widely published to consumers, medical institutions, and health food manufacturers.

For some products, post-marketing research has been conducted on a trial basis by the manufacturers. Such efforts should be expanded to grasp the actual consumption status of consumers. Also, improving the response to after-sales complaints and the function of consultation counters will be expected to enhance safety assurance at manufacturing.

4. Information dissemination and awareness-raising to consumers

These days, some products sold as health foods contain pharmaceutical ingredients, or others emphasize their usefulness without scientific evidence. Not a few consumers expect that such foods will contribute to the healing of an illness or recovery of physical functions.

The key to healthy life is well-balanced meals. Consumption of the abovementioned products, such as those containing pharmaceutical ingredients and those with exaggerated health claims, may not demonstrate expected effects. On the contrary, it may cause health problems, due to excess consumption and other reasons.

It is essential to deepen consumers' understanding through disseminating information on the safety of health foods and knowledge of health foods in general, and raising their awareness.

Thus far, consumers have been showing less interest in whether the safety of health foods is ensured. Many consumers' interest is in the usefulness of them. As a result, both food manufacturers and distributors have not been proactively providing consumers with information on their efforts on ensuring the safety of health foods.

In addition to the importance of the information on whether the safety of product ingredients is ensured or whether manufacturing process is adequately managed as pointed out in Section 2, to avoid excessive consumption of health foods, the manufacturers and distributors are required to take adequate measures to have consumers understand the importance of labeling information on warnings and recommended intake of each product, which is specified based on scientific evidence, on the premises of accurate ingredient labeling. They need to take such measures on their responsibility.

To disseminate information and raise awareness on health foods in general, advisers who are close to consumers; understand the functions, necessity, purpose of use, and usage methods of ingredients contained in health foods; and can provide accurate information to consumers are required. From this perspective, it has been expected that advisers, such as registered dietitians and pharmacists, play such an active role. The development of such human resources has been progressing to some extent; however, the knowledge level varies depending on the person, and the existence of the advisers is not well known by consumers.

To gain more credibility for the advisers from consumers, it is necessary to advance the efforts to ensure a certain knowledge level of them while cooperating with relevant parties regarding the training programs for them and the details of their activities. Also, it is expected that a system will be developed to, through the utilization of such competent advisers, provide information on the safety of health foods, interactions with other foods, and the usefulness of health foods, based on the latest knowledge.