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Amended Food Labeling Standards revising the Foods with Functional Claims System

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1. Introduction

The recent "beni koji" red yeast rice health hazard case (hereinafter referred to as "the Case") called elements of the Foods with Functional Claims ("FFCs")[1] system into question. In response, the Japanese government announced on 31 May 2024 that it would be revising the FFC system based on the final report of a study group established by the Consumer Affairs Agency. Since then, a proposed amendment to the Food Labeling Standards revising the FFC system has been discussed by the Consumer Commission of the Cabinet Office and subjected to public comment. The amended Food Labeling Standards were officially published on 23 August 2024. In this alert, we provide an overview of the changes to the FFC system.

2. Overview of the changes

The government has stated that it will promptly implement measures (1) through (3) below to prevent a recurrence of the Case. The key new requirements are (1) mandatory provision of information on health hazards and (2) compliance with Good Manufacturing Practices ("GMPs") when manufacturing or selling nutritional supplements (e.g., tablets, powders, capsules or liquids) under the FFC system.

(1) Mandatory provision of information on health hazards

Under the Guidelines for Notification of Foods with Functional Claims, the manufacturer or seller of an FFC must investigate and promptly report any adverse incident — including a causal relationship with any health hazard — to the Consumer Affairs Agency. In the Case, it reportedly took a long time before the government received a report because the manufacturer of the product engaged in a lengthy investigation and internal deliberations before providing it.

Starting this month (September 2024), business operators who manufacturer or sell FFCs (“FFC Business Operators”) are now required under the Food Labeling Standards to promptly provide information on suspected health hazards[2] associated with their FFCs to the Commissioner of the Consumer Affairs Agency or the leader of the relevant local authority, even if the causal relationship between an FFC and a suspected health hazard is unclear. This will make it possible for regulators to take administrative measures to instruct

[1] The FFC system allows FFC Business Operators to label food products as functional if they notify the Commissioner of the Consumer Affairs Agency of certain necessary matters established by government rules (e.g., scientific evidence regarding the safety and functionality of the food product) prior to marketing it. Unlike Food for Specified Health Uses (FOSHU), the government does not conduct an examination, and FFC Business Operators bear the risk of ensuring that their labeling is based on scientific evidence.
[2] Limited to health hazards diagnosed by a medical doctor.

or order FFC Business Operators not to make functional claims if they fail to comply with the Food Labeling Act's requirements.

On a related note, the revised Regulations for Enforcement of the Food Sanitation Act which came into effect on 1 September 2024 require FFC Business Operators to provide information they obtain on suspected hazards[3] associated with their FFCs. By making the provision of information obligatory, the government will be able to promptly detect health hazards associated with FFCs. If an FFC Business Operator fails to meet its obligation to provide information, administrative measures — including prohibition of the FFC or a suspension of an FFC Business Operator's business — will be taken based on the Food Sanitation Act.

(2) Compliance with GMPs with respect to nutritional supplement FFCs

In order to thoroughly ensure product quality throughout the manufacture of nutritional supplement FFCs, the Food Labeling Standards will require FFC Business Operators to ensure that their manufacturing processes are based on GMPs. The new GMP compliance requirement will take effect on 1 April 2025, followed by a grace period lasting until 31 August 2026. FFC Business Operators will be required to self-inspect to ensure GMP compliance and the Consumer Affairs Agency will conduct on-site inspections based on the Food Labeling Act after establishing the necessary systems.

(3) Other measures to ensure credibility

The revisions to the Food Labeling Standards also contain other measures, including the following, intended to enhance the credibility of the FFC system.

- If an FFC Business Operator fails to conduct an annual self-evaluation of its compliance with the post-notification compliance requirements and report the results of the same to the Commissioner of the Consumer Affairs Agency, the Agency may take administrative action under the Food Labeling Act instructing or ordering the FFC Business Operator not to make functional claims.

- The Food Labeling Standards have been clarified to provide that functional claims cannot be made if the Commissioner of the Consumer Affairs Agency finds that such claims are inappropriate given updated scientific knowledge obtained post-notification.

3. Next steps

FFC Business Operators are already required (as of 1 September 2024) to provide information on health hazards associated with their products and are therefore obligated to promptly provide information on any such hazards to the relevant authorities.

Despite the two-year grace period before full enforcement of the GMP requirements associated with nutritional supplement FFCs, FFC Business Operators are advised to begin preparing now due to the considerable amount of time that reviewing manufacturing and quality management processes can be expected to take. In this regard, the Consumer Affairs Agency promulgated draft standards for manufacturing and quality management based on GMPs on 30 August 2024. These draft standards require, for example, that manufacturers, etc. collect and evaluate safety information on substances contained in raw materials that may pose a health

[3] Limited to health hazards diagnosed by a medical doctor.

hazard (Article 17). FFC Business Operators that manufacture and sell nutritional supplement FFCs are encouraged to promptly review their manufacturing and quality management processes based on these draft standards and on the final standards when they are published.