

## Brief Communication



# Definition on “Foods With Function Claims (FFC)” and How to Resolve the Issues Caused by the FFC

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## ABSTRACT

General foods cannot be labeled or advertised for their functionality. Although the Food with Function Claims (FFC) belongs to general foods, it is permitted to claim functionality only in a limited scope when it fulfills certain requirements. The implementation of the function claim system generates two issues. First, it is difficult for consumers to discern the FFC from health functional foods (HFF). Second, the system does not conform to laws and regulatory systems because the implementation is bound by subordinate legislation not by law. It has been controversial over how to solve the issues. To address the problems, InSoon Nam, a member of the National Assembly, is currently pushing to amend the “Entire Revision (Bill) of the Health Functional Food Act” to HEALTH FUNCTIONAL FOODS ACT. The attempt for revision is considered helpful to regulate functional foods comprehensively and systematically in especially managing raw materials or ingredients of functional foods.

**Keywords:** Health Functional Foods (HFF); Functional Labeling System on General Foods; Functional Labeling; ACT ON LABELING AND ADVERTISING OF FOODS; Unfair Labeling or Advertising

## OVERVIEW OF THE FOOD WITH FUNCTION CLAIMS

The Food with Function Claims (FFC) means “nutrient ingredients or raw materials contained in food product which may help improve body structure and functions.” It refers to the foods labeling and advertising the notification made by the Minister of Food and Drug Safety. It is prescribed as a subject to be reviewed in advance by a voluntary review board in accordance with Paragraph 4 of Article 10 of the ENFORCEMENT DECREE OF THE ACT ON LABELING AND ADVERTISING OF FOODS (hereinafter referred to as “ACT ON LABELING AND ADVERTISING OF FOODS”). The “Articles on functional labeling or advertisement on foods, etc. which are not considered unfair labeling or advertisement” (Ministry of Food and Drug Safety [MFDS], Notification No. 2020-129) define the scope of its functionality and requirements.<sup>1,2</sup>

If the FFC satisfies certain requirements on general foods in which the functional labeling and advertisement are prohibited, the functional labeling and advertisement of the FCC may be viewed capable of creating a new market for the FCC, by allowing the FCC to be used in marketing general foods via functional labeling and advertisement.

The FCC is currently classified as general foods, so it has a limit in conducting the functional labeling or advertisement. However, considering that FCC incorporates functional raw materials or ingredients and its functional labeling and advertisement are partially admitted, it is valid to interpret that the FCC has a characteristic conforming to the HFF. In other words, raw materials or ingredients used in the FCC are asked to fulfill the standards and specifications of the HFF and to be manufactured and processed in business premises adopting Good Manufacturing Practice (GMP). Besides different quantities in functional raw materials or ingredients, it is challenging for consumers to discover significant difference from the HFF. It also appears that there is a limit in the functional labeling and advertisement details of the FCC. In light of the abovementioned circumstances, it seems that the FCC effectively has much more similarity with the HFF rather than with general foods.

## DRAWBACKS IN LAW AND REGULATORY SYSTEM

Currently, it is implied that foods are classified into 2 groups of general foods and the HFF. Thus, the standard and specification of general foods are specified based on the “standards and specifications of foods” of the FOOD SANITATION ACT and those of the HFF are defined based on the “standards and specifications of foods” of the HEALTH FUNCTIONAL FOODS ACT, respectively. Unlike general goods and the HFF, the FCC is prescribed according to the standards and specifications of neither the FOOD SANITATION ACT nor HEALTH FUNCTIONAL FOODS ACT. The requirement satisfying the FCC is determined in accordance with the notification (Articles on Functional Labeling or Advertisement of Foods Not Considered Unfair Labeling or Advertisement) based on the ACT ON LABELING AND ADVERTISING OF FOODS.

As described above, the FCC has a purpose to permit the functional labeling and advertisement on general foods, but the requirement of the FCC is not prescribed by the standards and specifications of foods based on the FOOD SANITATION ACT but by the notification of the Minister of Food and Drug Safety. This has caused confusion among consumers in understanding of the food classification. Furthermore, the FCC seems to have a third form of food in addition to general foods and the HFF.

The food classification clearly has 2 groups of general foods and the HFF. In principle, the functional labeling or advertisement on general foods are prohibited. On one hand, if the FCC fulfills its requirement while belonging to general foods, the functional labeling and advertisement of the FCC may be considered possible. On the other hand, the ACT ON LABELING AND ADVERTISING OF FOODS does not permit the functional labeling or advertisement on general foods. Thus, it seems that an evidence shall be guaranteed in a different law to exceptionally allow the functional labeling and advertisement possible on general foods. It appears that the permission on the labeling and advertisement on the FCC is prescribed to receive a prior review based on the Article 10 of the ENFORCEMENT DECREE OF THE ACT ON LABELING AND ADVERTISING OF FOODS and the acknowledgement is achieved via the notification “The regulation on the functional labeling or advertisement on foods, etc. not considered unfair labeling or advertisement” of the MFDS.

Conclusionally, the ENFORCEMENT DECREE OF THE ACT ON LABELING AND ADVERTISING OF FOODS and the notification of the MFDS accept the functional labeling and advertisement on general foods forbidden by the ACT ON LABELING AND ADVERTISING OF

FOODS, so it can be said that a lower statute violates a higher statute. Accordingly, it appears that the approval on the labeling and advertisement on the FCC does not conform to the regulatory system of the labeling and advertisement on food. Furthermore, if an aspect where the Minister of Food and Drug Safety has enabled a business entity selling general foods, etc. to conduct the functional labeling and advertisement through the notification is strictly examined, it can be considered that there is a possibility of interpreting such permission even in a way that authority not given or permitted by law was exercised.

The Article 10 of the ENFORCEMENT DECREE OF THE ACT ON LABELING AND ADVERTISING OF FOODS prescribes that the FCC shall receive a prior review on the FCC. It can be said that the aspect that the principle of conducting post review on general foods is already confirmed with several cases of the Constitutional Court of Korea, which are related to the labeling and advertisement. As it appears necessary to make much more rigorous decision on whether any unconstitutional factor exists in the current articles of the ACT ON LABELING AND ADVERTISING OF FOODS, it seems required to more scrupulously review whether it is appropriate to expand the scope of prior review or not.

In view of the purpose of the verification system introduced in the ACT ON LABELING AND ADVERTISING OF FOODS, it looks valid to interpret that in terms of the labeling and advertisement of food, a post review is the principle, but with the self-regulation and verification system to be conducted by a food business entity, the system attempts to make food business entities responsible for their own labeling and advertisement. Considering the FCC only, it may be evaluated in a way that the prior review on the FCC may make the verification system under the ACT ON LABELING AND ADVERTISING OF FOODS useless.

The Subparagraph 3 of Paragraph 1 of Article 8 of the ACT ON LABELING AND ADVERTISING OF FOODS prohibits “the labeling or advertisement with concerns that it may make non HFF recognized as the HFF.” In light of the current food classification where foods are classified into general foods and the HFF, it is regarded as a highly predictable scenario where there is an increasing possibility of making consumers mistake general foods as the HFF by permitting the functional labeling and advertisement on general foods.

## OPINION ON THE DIRECTION FOR IMPROVEMENT

The FCC also contains functional raw materials and ingredients, so the applicable functionality may be exerted. Thus, in this respect, it is difficult to interpret that categorizing the FCCs as general foods and partially allowing the labeling and advertisement on the FCC are proper. If the “Entire Revision (Bill) of the Health Functional Food Act” lately proposed by National Assembly member InSoon Nam on Apr 5, 2022 is entirely amended to HEALTH FUNCTIONAL FOODS ACT, it is considered that it is necessary to control functional raw materials or ingredients and comprehensively and uniformly regulate the HFF.<sup>3</sup> Accordingly, it appears an appropriate a method, which is differentiating the FCC from HFF while adding the FCC into the HFF not to general foods.

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