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Japan's New Health Claims Labeling System Creates Opportunities

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Report Highlights:
In April 2015, Japan's Consumer Affairs Agency (CAA), the governmental organization charged with oversight of food labeling and health claims, introduced a third category of health claim labeling for food and expanded the reach of another category, opening the door to new marketing strategies for U.S. health foods. This new category of voluntary labeling is known as Food with Functional Claims (FFC) and allows companies to display a product's specific health benefit (aka "functionality") and an associated area of the human body on retail food packaging.[1] This new FFC registration process is more affordable and faster than the registration process for Food for Specialized Health Uses (FOSHU). CAA also revised its regulations for Food with Nutrient Functional Claims (FNFC) to increase product eligibility, expand the list of eligible nutrients, and to include fresh foods. These changes by the CAA should create new opportunities for U.S. exporters to the world's third largest health food market.

[1] FFC claims cannot be made on the packages already bearing the FOSHU or FNFC labels. Further, alcoholic beverages and products that lead to excessive intake of fat, cholesterol, sugar and sodium are further excluded from FFC eligibility.

Keywords: Food with Functional Claims, FFC, Consumer Affairs Agency, CAA, health claims, JA5025

General Information:
In order to increase the number of foods with functional claims and to promote a healthier, longer-lived society, the Government of Japan (GOJ) decided to establish the Food with Functional Claims (FFC) category of health claims labeling on June 14, 2013. This move was in line with the Abe Administration's Regulatory Reform Plan (aka the Third Arrow of 'Abenomics'[2]) and the Japan Revitalization Strategy, and it was well received by Japanese food manufacturers as the lengthy and expensive FOSHU registration process had previously limited the food industry's ability to market the health benefits of specific products, a particularly effective marketing strategy in Japan.

The GOJ established a fourteen-member committee representing academia, national food and drug laboratories, consumer groups, and health food companies among others to develop the FFC guidelines in December 2013. In July 2014, the committee released a report on how the FFC system would function in terms of securing food safety, citing scientific evidence for functional claims, avoiding false labeling, and the role of government. The CAA established the FFC category based largely on that report and included the FFC in the comprehensive Food Labeling Standard that went into effect on April 1, 2015 (see GAIN JA4043 for more information on the Food Labeling Standard). The official FFC guidelines for the preparation of an FFC-compliant food label also became effective on April 1, 2015.

Overview of the Previous Health Claims System
Prior to FFC, there had been two categories of health claims in Japan: Food for Specialized Health Uses (FOSHU) and Food with Nutrient Functional Claims (FNFC). FOSHU was introduced in 1991, and the number of FOSHU products registered as of July 22, 2015 was 1,173. But utilization of FOSHU has remained limited due to the rigorous requirements for eligibility. Clinical trials of a product are required to acquire FOSHU, which has proven too great a burden for small- and medium-sized companies in terms of cost and time; some companies have paid more than 100 million yen (about $ 810 thousand) and had to wait more than three years for approval.

The FNFC system was introduced in 2001. Unlike FOSHU, there is no registration procedure for FNFC. Products containing vitamins and minerals that meet the standards determined by CAA are eligible to be labeled without application, registration or prior notification. Under FNFC, products may use approved standard statements of functionality for a limited number of nutritional ingredients (vitamins, minerals and fatty acids) on product labels. Subsequent revisions of FNFC are addressed later in this report.

In August 2014, the Agricultural Trade Office in Tokyo issued a report on "Japan's Health Food Market" (GAIN Report JA4509), explaining the FOSHU and FNFC labeling categories as well as providing an overview of the health food market in Japan. Please note the report was written before the

[2] 'Abenomics' is a term coined by the second administration of Prime Minsiter Shinzo Abe to encompass his three-part strategy to revitalize the Japanese economy and break the cycle of persistent deflation.

creation of the FFC and the revision of FNFC.

FFC Overview

Under the FFC category, food manufacturers may label a package with the specific health claims associated with functional components in a product in order to maintain and promote the health of one who is not suffering from disease.[3] FFC claims can be made for all foods, including fresh foods, except for foods with FOSHU or FNFC claims or those that lead to an excessive intake of fat, cholesterol, sugar, and/or sodium. Following the FFC guidelines, food manufacturers must provide CAA with scientific information on the safety and functionality of their products. Among other pieces of information, manufacturers are required to provide: the FFC health claims labeling contents; information about the manufacturer, including company name and address; information on production and quality management; and a system to gather information on possible adverse health outcomes from the use of the product. Please refer to the Japanese language version of the Guidelines for additional required information and other necessary information. Food manufacturers must provide all required information to the CAA no less than 60 days prior to the release of FFC-labelled products. Following a 'desk audit,' the CAA will issue an acceptance number and add the products and associated FFC health claim information to the CAA website. The CAA may request additional information from a manufacturer before issuing an FFC acceptance number if the FFC information package is incomplete.

Unlike FOSHU, FFC labeling claims do not receive individual approval from the CAA, since the CAA does not review the safety and functionality of the product. The FFC system places responsibility for the scientific accuracy of health claims on the manufacturers themselves, requiring that they refer to either a clinical trial or a systematic review of scientific evidence. Manufacturers must follow the guidelines for FFC labeling contents, including the amount of a functional component in the product, a warning label about intake method, and the manufacturers' contact information. The labeling content requirements, the guidelines, and related Q&As are included in the Appendix.

As of July 15, 2015, no FFC health claims have been accepted for a fresh food. Industry sources have noted that the FFC process may pose significant challenges for fresh foods, which may not be able to demonstrate a minimum content of a functional component as the quantities of such compounds vary across seasons and growing areas. Further, it is not clear how fresh food producers will be able to prepare labels for individual items at retail stores, establish measures to avoid comingling with similar non-FFC notified products, and whether producers will be able to recover the investment in establishing such systems through increased prices/sales based on increased consumer valuation of the product as a result of the FFC health claim.

FNFC Revisions

FNFC health claims maybe used on food package labels if the functional nutrients in the product conform to CAA-established standards. Manufacturers need not prepare an application or notification to the CAA in order to use FNFC claims on their labels, and they may produce and sell products with FNFC claims, at their own risk. In April 2015, the CAA revised the lower limit of the specified range for approved nutrients based on the nutrient labeling standard values. This move expanded eligibility for FNFC claims to products that previously did not have enough of the specific functional nutrient to qualify for FNFC claims. In addition, the CAA added three new functional nutrients to the approved list

[3] The definition of "one who is not suffering from disease," excludes minors, pregnant women (including women planning to become pregnant) and nursing women.

(n-3 fatty acid, vitamin K and potassium) and expanded the range or products eligible for FNFC claims to include fresh foods. The 20 approved functional nutrients (13 vitamins, 6 minerals and one fatty acid) eligible for FNFC health claims labeling are shown in the table below:

Nutritional Ingredients of FNFC

Nutritional Ingredient	**Specified Range of nutritional ingredient of the advisable daily intake**	**Function Claims**	**Warning Indication**
n-3 fatty acid	0.6 g – 2.0 g	Helps to maintain skin	Increased intake of this product will not result in curing diseases or promoting health. Please comply with the advisable daily intake.
Zinc	2.64 mg - 15 mg	Necessary nutrient to maintain normal taste and helps to maintain healthy skin and mucous membranes. It is involved in the metabolism of proteins and nucleic acids and is helpful in maintaining health.	Increased intake of this product will not result in curing diseases nor promoting health. Too much intake of zinc might inhibit absorption of copper. Please comply with the advisable daily intake. Infants and young children should avoid use of this product.
Potassium	840 mg– 2,800 mg	Helps to maintain proper blood pressure.	Increased intake of this product will not result in curing diseases nor promoting health. Please comply with the advisable daily intake. One with loss of hepatic function should avoid use of this product.
Calcium	204 mg - 600 mg	Necessary in the development of bone and teeth.	Increased intake of this product will not result in curing diseases nor promoting health. Please comply with the advisable daily intake.
Iron	2.04 mg - 10 mg	Necessary in the red blood cell formation.	
Copper	0.27 mg – 6.0 mg	Helps to form red blood cells and helps the proper function of many body enzymes and bone formation.	Increased intake of this product will not result in curing diseases nor promoting health. Please comply with the advisable daily intake. Infants and young children should avoid use of this product.
Magnesium	96 mg - 300 mg	Necessary in the development of bone and teeth, maintain proper blood circulation, and helps proper function of	Increased intake of this product will not result in curing diseases nor promoting health. Increased intake may cause diarrhea. Please comply with the advisable daily intake. Infants and young children should avoid use of this product.

		many body enzymes and energy generation.	
Niacin	3.9 mg - 60 mg	Helps to maintain skin and mucosa health.	Increased intake of this product will not result in curing diseases nor promoting health. Please comply with the advisable daily intake.
Pantothenic acid	1.44 mg - 30 mg		
Biotin	15 µg - 500 µg		
Vitamin A	231 µg - 600 µg	Helps to maintain vision in the dark, and helps to maintain skin and mucosa healthy.	Increased intake of this product will not result in curing diseases nor promoting health. Please comply with the advisable daily intake. Women within the third month of pregnancy or women considering becoming pregnant should be careful of over consumption.
Vitamin B1	0.36 mg - 25 mg	Helps to produce the energy from carbohydrate and to maintain skin and mucosa health.	Increased intake of this product will not result in curing diseases nor promoting health. Please comply with the advisable daily intake.
Vitamin B2	0.42 mg - 12 mg	Helps to maintain skin and mucosa health.	
Vitamin B6	0.39 mg - 10 mg	Helps to produce energy from protein and to maintain skin and mucosa health.	
Vitamin B12	0.72 µg - 60 µg	Aids in red blood cell formation.	
Vitamin C	30 mg - 1,000 mg	Helps to maintain skin and mucosa health and has anti-oxidizing effect.	
Vitamin D	1.65 µg - 5.0 µg	Promotes absorption of calcium in gut intestine and aids in the growth of bone.	
Vitamin E	1.98 mg - 150 mg	Helps to protect fat in the body from being oxidized and to maintain the cell health.	
Vitamin K	45 µg - 150 µg	Helps to maintain proper blood	Increased intake of this product will not result in curing diseases nor promoting

		coagulability.	health. Please comply with the advisable daily intake. One who takes an anticoagulant should avoid use of this product.
Folic acid	72 - µg 200 µg	Aids in the red blood cell formation, and contributes the normal growth of the fetus.	Increased intake of this product will not result in curing diseases nor promoting health. Please comply with the advisable daily intake. This product helps normal development of fetus, but increased intake of this product will not result in better development of fetus.

Conclusion

The recent revisions to the Japanese health claims labeling system should present a variety of new opportunities for U.S. food manufacturers to tap into the lucrative Japanese health food market. The creation of the FFC category eliminates the need for lengthy and costly approvals before adding a specific functional claim to a product label. It remains difficult to predict if and how producers will be able to capitalize on the expansion of this new functional labeling to fresh foods. While FNFC may be the more feasible of the two health claims labeling categories for fresh food producers, seasonal and geographical variations that affect the quantity of functional nutrients in fresh food products (and the costs associated with verifying those quantities) could limit the value of expanding functional labeling systems to include fresh foods.

Perhaps even more promising, FFC health claims labels will offer food manufacturers the opportunity to evaluate market demand for certain functional ingredients and health claims before investing in the costly FOSHU process. As explained in GAIN report JA4509, "Japan's Health Food Market," developing functional ingredients for processed foods without FOSHU certification is more cost effective and less risky than bringing a FOSHU product to market in Japan. For example, a form of indigestible dextrin developed as a functional ingredient, is currently used in several FOSHU products. As of July 15, 2015, food manufacturers have already notified eight previously uncertified products using indigestible dextrin for FFC health claim labels by using the scientific data compiled for FOSHU applications.

Appendix

Labeling Contents Required under FFC

FFC labeling must include cross-category quality labeling items[4] and the following 16 specific items:

1. Indication of FFC.
2. Functional components based on scientific basis and the functionality of the said components or

[4] For processed foods: name, ingredients, net contents, use-by date, storage instructions, and name/trade-name and address of manufacturer. For fresh foods: name and place of origin.

foods containing the said components.
3. Adequate daily intake.
4. Amount of nutritional components and calories in an adequate daily intake.
5. Contained amount of a functional component in an adequate daily intake.
6. Acceptance number.
7. Phone number as contact information of the manufacturer.
8. Notice: functionality and safety are not evaluated by CAA.
9. Method of intake.
10. Instruction on intake.
11. Notice: To promote popularity of the idea of a balanced diet.
12. Precaution statement for products which require special attention when cooking or storing.
13. Notice: The product does not intend to diagnose, treat, or prevent disease.
14. Notice: Not to target one suffering from disease, minors, pregnant women (including women planning to become pregnant) and nursing women.
15. Notice: Recommend that one suffering from disease consult with a physician, and that one taking drugs consult a physician or pharmacist.
16. Notice: In case of unusual physical change, recommend stopping eating a product immediately and consult a physician.

Useful Links (all of the following resources are currently only available in Japanese):
Food Labeling Standards (749 pages)
http://www.caa.go.jp/foods/pdf/150320_kijyun.pdf

Notice on Food Labeling Standards (Detailed explanation of Food Labeling Standards, 404 pages)
http://www.caa.go.jp/foods/pdf/150601_tuchi-togo.pdf

Q&A for Food Labeling Standards (553 pages)
http://www.caa.go.jp/foods/pdf/150331_qa-togo.pdf

Guidelines to Apply for FFC (112 pages)
http://www.caa.go.jp/foods/pdf/150330_guideline.pdf

Information of products notified for FFC (Detail of notifications received)
#1-#25
http://www.caa.go.jp/foods/todoke_1-25.html
http://www.caa.go.jp/foods/todoke_26-50.html#51-#75
http://www.caa.go.jp/foods/todoke_51-75.html