07 Food Functionality and Health Claims in Japan

Situation
The American Chamber of Commerce in Japan (ACCJ) and European Business Council in Japan (EBC) applaud the Japanese government's amending of the existing "Foods for Specific Health Uses" (FOSHU) regulations and the implementation of revisions on functional claims pertaining to health foods and dietary supplements effective April 1, 2015. Obtaining the necessary approval for product claims under previous FOSHU regulations was deemed costly and time consuming by the Abe Administration. In 2013, in an effort to resolve some of the regulatory issues, officials recognized the need to establish a new category of claims that recognizes the health benefits of functional foods. The increased commerce facilitated by recognition of functional claims has been identified as a potential area of economic growth under "Abenomics." The revised regulations do not, however, fully reflect the direction proposed by the Prime Minister, nor do they incorporate global best practices. The following is a summary of primary concerns with the newly mandated regulations:

1. Ingredient-Use Limitations: Supported by extensive scientific evidence, food components such as vitamins, minerals and other ingredients are globally recognized as providing benefits for consumers in the form of improved health. As such, excluding such ingredients from the government's "Food with Functional Claims" category would be unreasonable. Under new regulations, which are based on drug regulations, linkage in this classification to health benefits is limited to a single chemical entity. In reality, the evaluation of an isolated compound by itself without consideration of the various compounds within the same food cannot adequately represent all possible health benefits that the various compounds that make up the food provide when taken all together, since in composite these components work in a way that is more powerful than their effects when used separately. Since nutrients can work together to create greater health effects than they can when used separately, the health benefits from either the food or the food constituents that can be backed by significant scientific evidence, should be allowed as the basis for making functional claims.

2. Usage Limitations Based on Scientific Evidence: Current regulations prohibit the use of patient data in scientific research studies for the substantiation of claims. This methodology is not in accordance with globally recognized procedures and would prevent a substantial amount of evidence from being considered—ultimately providing a disservice to consumers.

3. Target Audience/Category Limitations: Products specifically targeting minors, pregnant, nursing or prenatal women are currently banned under the amended regulations. If deemed safe and effective for the aforementioned persons, their uses should be allowed. Furthermore, under the revised regulations, vitamins and minerals are limited to one claim per category. A given single ingredient, such as a particular vitamin or mineral, can provide various health benefits, so in some cases, multiple claims should be allowed for a single ingredient.

4. Quality Control Systems Not Mandated: When addressing the exportation of goods to foreign markets, the regulation of quality control in manufacturing should be based on international best practices. Manufacturing guidelines such as current Good Manufacturing Practice (cGMP), which is used in major modern markets for dietary supplements, and the Hazard Analysis and Critical Control Points (HACCP) approach to food safety have been established to conform to regulations set by the U.S. Federal Drug Administration (FDA), World Health Organization (WHO) and other pertinent agencies.

In Japan, the quality of health food products is regulated through the Food Sanitation Act.

This Japan-specific guideline does not take into account as much as it could international manufacturing guidelines and standards. Thereby it puts the domestic health food and the dietary supplement industry at a significant disadvantage when it comes to exportation.

Recommendations

1. Ingredients such as vitamins and minerals are already pre-approved for sale in Japan. Under the new regulations, nutritional ingredients such as vitamins and minerals should not only be deemed eligible as nutrients, but they should be allowed to make multiple functional claims as well. As consumers expect food to be functional, the elimination of ingredients proven to deliver added health benefits from the functional claims category, such as vitamins and minerals, renders consumers unable to make informed decisions. In order for consumers to make informed choices, scientific information about the links between diet and health is necessary. We urge the Japanese government to promptly initiate discussions on the greater use of scientifically backed health-related evidence in the food and dietary supplement industry by forming an expert panel with qualified, decision-making members whose expertise matches the specific needs of the project.

2. In the United States, the FDA currently sets guidelines, often referencing literature produced by industry. This cooperation between regulators and industry is beneficial for both parties. We urge the Japanese government to consider adopting a similar method of working with industry to set standards and publish guidelines for improved quality control systems. We recommend that internationally standardized cGMP guidelines be established and mandated, as they would not only further the promotion of international trade but would aid in assuring consumers that products of low quality are not imported into the Japanese market. In 2013, the Ministry of Health, Labour, and Welfare (MHLW) took steps to address these issues by conducting a nationwide survey of cGMP compliance. We respectfully request disclosure of the results.

3. Under the newly implemented guidelines, sources of scientific evidence are limited to healthy people; thus, patient data use is not permissible. Dietary supplements can be used in conjunction with prescribed medications for added health benefits. Additionally, health claims based on published authoritative statements from agencies operating within the health sector, from both within Japan and abroad, should be recognized as sufficient evidence for claim substantiation.

4. Generally, health foods and dietary supplements are useful for all generations including minors, and pregnant, nursing, or prenatal women, depending upon the scientific evidence. However, those categories of individuals have all been excluded as potential consumers of health foods and dietary supplements in the newly implemented regulations. Further clarification of product usage is needed (underlined below):

   "Disclaimer: Although this product has not been formulated for minors, those suffering from disease, and pregnant, nursing, or prenatal women, consumption by the aforementioned does not pose limitation of usage."

5. As the global dietary supplement market continues to grow and more supply chains form, there is an increasing need for national cGMP standards to be harmonized with global standards. A compliance deadline for

Japan must be set. Furthermore, adherence to global cGMP standards should suffice as quality control – thus deeming the analysis of specific ingredients unnecessary.

Possible Outcomes

1. Reductions in Health Care Costs

Scientific research published in the United States in 2013[1] concludes that targeted daily supplement regimes can provide substantial health benefits; thus greatly reducing healthcare expenditures. Although further research is needed to address health issues relating to Japanese people, if consumers take advantage of dietary supplementation as a part of a well-balanced diet, benefits in the form of improved health can be felt not only by consumers, but by healthcare practitioners and insurance systems as well.

2. Industry Development

Allowing dietary supplements to carry statements on their labels that describe the role of a nutrient or dietary ingredient could contribute to the health of the general population. With consumers living longer, many are interested in preventing chronic disease; thus the demand for information on food and dietary supplements will likely grow as well. Not only would potential sales produce benefits in the form of improved health and medical cost reductions, but market growth through international trade would be realized by creating employment opportunities and providing a larger base for tax revenues. This favorable outcome was included in Prime Minister Abe's economic recovery plan. Insight can be taken from the dietary supplement industry in the United States, which has quadrupled in size over the last 20 years.

References

1. Council for Responsible Nutrition Foundation: *Health care cost savings resulting from the targeted use of dietary supplements* http://www.crnusa.org/CRNfoundation/HCCS/chapters/CRNFrostSullivan-fullreport0913.pdf

7. Major Differences in Supplement Systems between Japan and the US

	Japan (New CAA Regulation)	US
Definition of Dietary Supplement	No Labeling rule is set under new rule	Yes
Legal status	Only control labeling by food labeling law	DS-specific laws
Compliance with manufacturing and quality control standard (cGMP)	Voluntarily	Mandatory with audit
Guideline for manufacturing and quality control	Only outline in 5 pages	Detailed guidelines
100% identification test of raw materials when manufactured	Optional	Mandatory
Targeted food and ingredients	Not cover all foods, Identification of actives necessary, No standard specification, Vitamins and minerals are excluded	Reasonable standards for food, Standard specifications, Vitamins and minerals are included
Structure/Function Claims including organs and body parts	Partially yes	Possible
Submission of product label claims	Pre-submission at least 60 days before product launch	Post-submission after 30 days of product launch
Required documents for submission	Much more than US	Only a letter in 1-2 pages
Severe adverse event report	Mandatory	Mandatory
Market size (as of 2012)	$8 billion	$32. 5 billion

7. Gap between Prime Minister/Cabinet Decision and Newly Implemented Regulations made by Consumer Affairs Agency