

**A Functional Remedy for A Dysfunctional Regulatory Policy of Functional Foods: An
Analysis of The Current Regulations of Functional Foods**

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I. Introduction

Walk into a grocery store today and you will find a variety of items that claim some type of benefit to your overall well-being. Such items range from a box of cereal that claims to “help maintain a normal functioning digestive system” to a pill that claims to “energize the mind.” What was once a place to buy food, the grocery store now resembles the shop of a 17th century apothecary filled with remedies and elixirs to improve the well-being of the body.

Foods that make such claims have been termed “Functional Foods.” The increasing prevalence of functional foods in the markets is a response by manufactures to the increased vigilance of consumers regarding their own health. Advances in medical research have allowed the consumer to become more educated in the prevention of diseases that have proved to be troublesome amongst prior generations. Thus, in an effort to reduce their dependence on drugs to treat future diseases and disorders, the consumer has turned to functional foods. However, even though the functional food industry will reach 49 billion dollars by 2010¹, the FDA still does not recognize functional foods as a category of food. Instead, the FDA can regulate a functional food ranging from a conventional food to a drug.² Because of the different levels of scrutiny between the different categories of food, a functional food might need pre-approval before being marketed or could enter the market with no such pre-approval. Thus, there is no uniformity in regulating functional foods.

Since functional foods are so prevalent in today’s market, the FDA must establish a uniform and concise regulatory provision for functional foods in order to protect the average consumer from deceptive claims and reliance solely on functional foods to prevent ailments that

¹ Doyle, Michael. *FDA Hearing Will Review Rules For Functional Foods*. McClatchy News Papers. October 26, 2006. <http://www.commondreams.org/headlines06/1026-03.htm>

² Bruce A. Silverglade and Ilene Ringel Heller. *Are Functional Foods the Solution to Dysifunctional Diets? A Review of U.S. Regulatory Requirements and Lessons From Abraod*. Food and Drug Law Journal Vol. 52 1997 at 314.

affect the body. Thus, the goal of this paper is to provide a brief background on what constitutes a functional food, examine the current regulations of functional foods and then use this understanding of a functional food to formulate a regulatory policy. In formulating such a regulatory policy, the paper investigates the Food Drug and Cosmetic Act (FDCA), the Dietary Supplemental Health and Education Act (DSHEA), Nutrition and Labeling Education Act (NLEA) and the Japanese Functional Food regulation called, FOSHU, in order to create a permanent way to regulate Functional Foods.

II. What Are Functional Foods?

A. Definition of Functional Food

While the FDA has not defined what a functional food is, there are various definitions that are associated with functional foods. One definition states that a functional food is a conventional food with health related benefits that include novel ingredients.³ Another definition states they are foods that by virtue provide a health benefit beyond basic nutrition.⁴ Thus, from these definitions a functional food is a food that is supplemented by ingredients in addition to the food's normal nutritional value. In a way a functional food is combination of a food and dietary supplement.

B. Examples of Functional Foods

Look around your local grocery store and you will find many foods with an added ingredient. In an effort to organize the types of functional foods, the literature groups them by the bioactive ingredient which is added to the food.⁵ Many manufactures are supplementing food

³ W. Patrick Noonan and Chris Noonan. *Legal Requirements for "functional food" claims*. Toxicology Letters. 150 (2004) 19-24. At p. 19.

⁴ Clare M. Hasler. *The Changing Face of Functional Foods*. Journal of American Nutrition 19(5) (2000) 499S-506S. At p. 500S

⁵ I.S. Arvanitoyannis and M. Van Houlwelingen-Horkaliarglou. *Functional Foods: A Survey of Health Claims, Pros, and Cons, and Current Legislation*. Critical Reviews in Food Science and Nutrition, 45(5) (2005) 385-404, at p. 386..

with vitamins and minerals in order to allow people to get their daily recommended dose. For example, a popular item is orange juice fortified with calcium. Calcium is a popular additive because it helps promote strong bones. Another increasing trend is to add portions of vitamins that one would normally consume in a tablet form of a multi vitamin into water. Drinks like *Smart Water* add a percentage of the daily recommended dose of vitamins into a bottle of water. This allows the consumer to obtain his or her recommended dose while having a simple glass of water.

A second category of ingredients added to foods are fatty acids. The most widely added fatty acid is the Omega-3 fatty acid. Such an example is eggs enriched with Omega-3 fatty acids. Omega-3 fatty acids are commonly found naturally in fish and are known for their beneficial affects in fighting cardiovascular disease.⁶

While herbs and root extracts have predominantly existed in the realm of dietary supplements, these herbal remedies are fast finding themselves within the realm of food. An example of such a herb is ginseng. Ginseng which is said to have come from China has been shown to increase the mental performance of individuals.⁷ The popularity of ginseng has lead Pepsi Co. to add the herb in their new drink called, *Pepsi Max*. Ginseng is also seen with another mental stimulant, Ginkoba Biloba.⁸ The combination of these two herbs is seen in *Arizona Tea Company's Diet Green Tea*.

Probiotics is another popular area of functional foods. Probiotics are “live microbial food supplements which benefit the host by improving the intestinal microbial form.”⁹ Basically these

⁶ Peter J. Jones. *Clinical Nutrition: 7. Functional foods-more than just nutrition*. Canadian Medical Association Journal 2002. 166(12)1555-63.

⁷ http://www.mayoclinic.com/health/ginseng/NS_patient-ginseng. This is the website of the Mayo Clinic which gives the uses and properties of natural herbs.

⁸ Id.

⁹ Charles H. Halsted. *Dietary supplements and Functional foods: 2 sides of a coin?* American Journal of Clinical Nutrition 77(supl) (2003) 1001S-7, at p. 1005s

are bacteria that are normally found in the digestive system, but have become under represented. The most prominent probiotics added to foods are *Lactobacillus* and *Bifidiobacterium*.¹⁰ The addition of such bacteria is said to aid in the prevention of pathogens from entering into the gut (stomach).¹¹ Yogurt such as *Dannon Actvia* adds Bifidiobacterium in the form of Bifidius Regularis and *Youplait Yogurt* adds Lactobacillus in the form of Acidophilus.

Dietary Fiber as seen in products such as *Quaker Oats Oatmeal*, is another prevalent category because dietary fiber is found in many fruits, vegetables and whole grain products. The term dietary fiber refers to any non-starch polysaccharide or protein not degraded by the digestive process of a mammal.¹² Dietary Fiber is said to help lower cholesterol/triglyceride levels and decrease constipation.¹³

Phytochemicals are also abundantly found in many foods. The term phytochemical refers to chemical compounds of a plant. Some examples of phytochemicals are phenolic compounds, sterols, stanols, and phytoestrogens just to name a few.¹⁴ These compounds are said to reduce the risk of cancer along with lowering cholesterol levels by blocking cholesterol absorption.¹⁵ One such example that contains plant stanol ester is *Benacol*. *Benacol* is a margarine that contains this compound as a way in lowering cholesterol.

The above mentioned functional foods are just some from a laundry list of functional foods. Such a list is only likely to grow in the future.

¹⁰ Id.

¹¹ Peter J. Jones, *supra*, at p 1560

¹² Arvanitoyannis, *Supra*, at p 387.

¹³ Id.

¹⁴ Id.

¹⁵ Winston J. Craig. *Phytochemicals Guardians of our Health*. Journal of the American Dietetic Association. 95(10)(1)(October 1997) S199-S204, at p. S200-S2001

C. Why do Functional Foods Need to Be Controlled?

After reading the uses of functional foods above, one might wonder why there is a need to regulate this category of foods. The reason is that even though there are beneficial uses to functional foods, there is also a downside to these foods. Because functional foods can provide benefits for consumers, consumers tend not to also look at the negative effects and over estimate the efficacy of these foods; especially when these foods make structure function claims on the label. When people see these claims on foods, they assume that these claims are substantiated with evidence and that they have been properly tested.

However, these claims on foods may or may not need pre-approval. Such strong reliance on these claims by consumers can be detrimental to the consumer because a person seeing a claim on oatmeal stating, “helps with cardiovascular health” might stop taking his or her heart medicine in reliance on this claim. An important fact to remember is that the average person does not have the scientific knowledge to make the distinction between the efficacy of a functional food and their medicine. In an era of rising drug costs, people are looking to become less dependent on drugs. Thus, such claims may be misleading to consumers and cause them to reduce or discontinue their current medication.

Functional foods taken in high doses can also have a negative effect on the consumer’s health. For example, foods fortified with Vitamin C could cause negative effects on the consumer. People like to take Vitamin C because it is purported to promote better health. However, exceeding 1000 mg of Vitamin C daily can cause nausea, diarrhea, and kidney stones.¹⁶ The average person already receives doses of Vitamin C from fruits and vegetables.¹⁷

¹⁶ Mi Young Hwang, *How Much Vitamin C Do You Need?* Journal of the American Medical Association. 281(15)(April 21, 1999) at p. 1460

¹⁷ Id.

A person in thinking that Vitamin C is good for the body might buy multiple items enriched with Vitamin C without realizing that he or she is exceeding the daily recommend dose.

Another negative effect can occur when the added ingredient of a functional food interacts with a prescribed drug the consumer is taking. Often times a consumer will be less likely to check an interaction between a food supplement and a drug than he would if he took the supplement in pill form. This is because the ingredient being in pill form gives a drug like resemblance. Thus, it has been shown that Ginkgo biloboa can raise the blood pressure of an individual when taken with a thiazide diuretic for hypertension (high blood pressure).¹⁸ In another case, a patient who was suffering from coronary heart disease was taking Aspirin and Gkikgo biloboa at the recommended dose when he spontaneously started bleeding.¹⁹ This is due to the fact that Ginkgo biloboa has anti-platelet properties.²⁰ Such anti platelet properties promotes less clotting of the blood.

Thus, while functional foods do have beneficial uses, they also have properties that can make them antagonistic to consumers. Therefore, under the current regulatory scheme of functional foods, the consumer is not afforded the protection they deserve.

III. Current Regulation of Functional Foods

As mentioned before, since the FDA does not recognize functional foods as a category of food, it is necessary to determine how these foods are regulated within the current scheme of regulations. Thus, because of this uncertainty, a functional food could be regulated as a food, food for special dietary use, a medical food or as a dietary supplement.²¹ Depending on how a functional food is categorized will dictate the scrutiny with which it will be examined. For the

¹⁸ Angelo A. Izzo and Edzard Ernst. *Interactions Between Herbal Medicines and Prescribed Drugs*. *Drugs*. 61(15) (2001) 2163-2173. Pg. 2165.

¹⁹ *Id.*

²⁰ *Id.*

²¹ Noonan, *supra*, at p. 19

purposes of this analysis a fictional product will be used in order to evaluate the regulatory schemes. The fictional product is called *Intelegencia*. This is a cookie made with a Chinese herb called *Foshi* (fictional herb) which is known to stimulate the mental processes of an individual. While *Foshi* has been around for 1000 years, its uses and effects have not been well documented. The product claims to help in bettering cognitive function.

A. Regulation Under The Food and Drug Cosmetic Act (FDCA)

First, in order for the *Intelegencia* to be qualified as a food it must come under the definition of “food” under the FDCA. According to the FDCA, a “food” means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.²² Thus, in the case, a cookie would definitely be qualified as a food.

The next step is to determine if the *Foshi*, which is contained inside the cookie, would be considered a food additive or generally recognized as safe (GRAS). Thus, any ingredient must be (GRAS) or be approved through a food additive regulation by the FDA.²³ However, there is a difference between GRAS and food additives. GRAS substances are those that have been in use for a long time and have a proven record of being safe.²⁴ Any substance that is recognized as GRAS is not required to obtain FDA approval. However, the FDA is not the only entity that can affirm a substance as GRAS. Companies seeking an ingredient as GRAS can self affirm the ingredient as GRAS by filing a petition and proving the validity of their petition.²⁵ The FDA then has the option in rejecting or approving the petition. Companies are more prone to filling a

²² Food Drug and Cosmetic Act § 201(f)

²³ Noonan, *supra*, p. 20

²⁴ Carol Rados. *GRAS: Time-Tested, and Trusted, Food Ingredients*. FDA Consumer Magazine. 38(2) March-April 2004, http://www.fda.gov/fdac/features/2004/204_gras.html

²⁵ Donna Gorsky. *ABC's For Ingredient Approval*. Dairy Foods. (March 1996). http://findarticles.com/p/articles/mi_m3301/is_n3_v97/ai_18305036

GRAS petition rather than a food additive petition because the GRAS petition takes less time to get approved.²⁶

A food additive on the other hand is a substance that has not been in use for a long period of time and no documented evidence of its safety.²⁷ Thus, FDA approval is required. The process requires a petition to the FDA which offers evidence that the additive is safe and can be used as intended.²⁸ Elements that should be included in the petition are as follows: Identity, Probable exposure, evaluation of safety and Limitations of conditions of use (may be necessary to ensure safe use).²⁹ Once the FDA has evaluated the substance, a regulation approving the food additive will be issued.

Thus, in this case, *fushi* because it is relatively unknown and cannot be considered GRAS, the company would have to file a food additive petition. Thus, *fushi* would go through some type of scrutiny in order to determine its safety and provide substantial evidence that its intended use is safe.

Under the FDCA, a functional food could also be classified as a special dietary food or a medicinal food. Special dietary food is distinguished from general food in that it is used for particular dietary needs which exist by reason of a physical, physiological, pathological or other condition.³⁰ However, the claims for special dietary use may require additional information.³¹ A medical food is intended for the dietary management of a disease or condition that creates the need for the specific medical food.³² The medical food must be administered by a doctor.³³ No

²⁶ Id.

²⁷ Id.

²⁸ <http://www.cfsan.fda.gov/~dms/petqagui.html>. This is the FDA website that explains the petition process for getting a food claim approved.

²⁹ Id.

³⁰ 21 CFR § 105.3

³¹ Noonan, *supra*, at p. 21.

³² 21 CFR § 101.9(J)(8)

³³ Id.

prior approval is needed to make a medical food claim as long as the claim is based on recognized scientific principles that are established by medical evaluation.³⁴³⁵

B. Regulation Under The Dietary Supplement Health Education Act (DSHEA)

Contrastingly, a dietary supplement is not subject to the same scrutiny as a food. According to the statutory definition, a dietary supplement is a product that is intended to supplement the diet with the following substances considered to be a supplement: “(A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).”³⁶ The dietary supplement must be ingested in capsule, tablet, liquid, soft gel form.³⁷ The dietary supplement cannot be represented as a conventional food or as the only item for a meal or diet.³⁸

However, a dietary supplement is still considered a food under the FDCA, but is afforded certain exemptions.³⁹ Thus, a dietary supplement is not subject to the food additive requirement of a regular food.⁴⁰ As a result, the dietary supplement just needs to show that it is not “poisonous and deleterious” and it does not present a significant or unreasonable risk of injury or illness.⁴¹ A company has to offer this safety information to the FDA 75 days before the product enters the marketplace for all new dietary supplements.⁴² Any dietary supplement in existence prior to 1994 is grandfathered in and is not required to submit safety findings to the FDA.

³⁴ Id.

³⁵ Noonan, *supra*, at p. 21

³⁶ 28 U.S.C. § 321(ff)(1)

³⁷ Neal D. Fortin, *Food Regulation: Law, Science, Policy and Practice Chapter 8: Dietary Supplements I* (2004).

³⁸ 28 U.S.C. § 321(ff)(2)(B)

³⁹ Id. at § 321(ff)

⁴⁰ Id. at § 321(s)(6)

⁴¹ Id. at § 342(f)(1)(A), § 342(a)(1)

⁴² Id. at § 350b(2)

Thus, as a result of not having to file a petition for food additive approval, dietary supplements are able to be marketed more easily than a regular food. Even though the dietary supplement still needs to show safety, the burden is on the FDA to show that the dietary supplement is unsafe for consumption.⁴³ A company then only needs to show that it is reasonably safe, unlike a food, where there has to be a long track record that the additive is safe. Not to mention the fact that any dietary supplement in use before 1994 does not even have to have proof that it is even “reasonably safe.”

Thus, a company who is trying to market a new ingredient is more likely to try to market the ingredient as a dietary supplement. This is where the vulnerabilities of the current mode of regulations are exposed. For, example, the hypothetical product *Intelegencia*, could be manipulated in order to fit the definition of a dietary supplement. In its current form as a cookie, the *Intelegencia* would be considered a food because no dietary supplement can be represented as a food. However, to side step the food additive approval process, the manufactures could take the *fushi* out of the cookie and market the *fushi* as a liquid that comes with the cookies, but has to be sprinkled on the cookies. The manufactures of *Intelegencia* would argue that since the *fushi* is not being represented as a conventional food, but rather as a supplement to the cookie, it should accordingly be treated as a dietary supplement. Without recognizing functional foods as its own category, this grey area of food law will persist for years to come.

This example demonstrates how the current pre-market approval system is inconsistent because the same functional food can be regulated as both a food and dietary supplement. This incongruence in regulation further allows companies to manipulate the current regulatory scheme in ways that require less scrutiny.

⁴³ Id. at § 342(f)(1)

C. Labeling Functional Foods

The regulatory process does not only determine where the substance will be categorized, but is also used to dictate what type of claims can be made on the label of a food or dietary supplement. .

The first category known as health claims “characterize the relationship of a food to a disease or health related condition.”⁴⁴ Such a claim can be seen on oatmeal boxes that purport to lower cholesterol levels. The NLEA states that such claims cannot be made without the approval of the FDA. A health claim petition must be submitted to the FDA and then is evaluated based on extensive scientific literature that examines the relationship between the food/dietary supplement and the health condition.⁴⁵

The FDA, under the Food and Drug Modernization Act, allows health claims without FDA pre-approval as long as the claims are based on authoritative statements from a scientific body of the U.S. Government or the National Academy of Sciences.⁴⁶ However, dietary supplements are not permitted to make these authoritative claims.⁴⁷

One exception to health claims is known as the jelly bean rule.⁴⁸ This rule states a food with a minimal amount of nutritional value will not be able to display a health claim.⁴⁹ Such a regulation would ban a doughnut with omega-3-fatty acids that claims to lower cholesterol.

Another type of claim is known as a structure/function claim. These are claims that state the given substance affects the structure and function of the body. An example of such a claim would be “Aids in maintaining a healthy nervous system.” Under the DSHEA, dietary

⁴⁴ §201(g)(1)(D) FDCA

⁴⁵ *Claims That Can Be Made for Conventional Foods and Dietary Supplements* FDA/CFSAN, <http://www.cfsan.fda.gov/~dms/hclclaims.html>

⁴⁶ Id.

⁴⁷ Id.

⁴⁸ J. Craig Rowlands and James E. Hoadley. *FDA perspectives on health claims for food labels*. Toxicology 221(1) (April 2006) 35-43, at p. 39.

⁴⁹ Id.

supplements can make structure and function claims, but the claims must be evaluated by the FDA.⁵⁰ The FDA requires that such structure and function claims should be substantiated with evidence that the structure/function claims are not misleading.⁵¹ The dietary supplement must also place a disclaimer on the label stating that the product has not been approved by the FDA.⁵² The manufacturer has up until 30 days after the marketing of the product to notify the FDA of such a claim.⁵³ The DSHEA also commands that the label identify and quantify the dietary supplement being used.⁵⁴

An example of how the FDA has regulated such dietary supplements using this scheme can be seen in a warning letter the FDA sent to Window Rock Enterprises, Inc., the maker of Cortislim in 2004.⁵⁵ In the letter, the FDA stated that Window Rock was in violation of the DSHEA and subsequently the FDCA because the structure/function claims were not substantiated by reliable scientific evidence. The Cortislim product made structure/function claims such as: “enhance weight loss through thermogenics” and “controls cortisol levels within in a healthy range.” The FDA concluded that because these claims were unsubstantiated, the claims were false and misleading and thus misbranded.⁵⁶

⁵⁰ 21 USC § 343 (r)(6)

⁵¹ Id. § 343 (r)(6)(B)

⁵² Id. § 343 (r)(6)

⁵³ Id § 343 (r)(6)

⁵⁴ Id. § 343 (s)

⁵⁵ <http://www.infomercialwatch.org/fda/cortislim.shtml>. This website published the letter sent to Window Rock Enterprises.

⁵⁶ Id.

However, structure/function claims for foods are not subject to pre-approval by the FDA as long as they do not go into the realm of Drug and unapproved health claims.⁵⁷ The only such requirement is that the structure function claim should not be false or misleading.⁵⁸

Thus, unlike food additives where it is easier to get a dietary supplement passed, structure and function claims undergo much more scrutiny in making such claims on dietary supplement products than regular foods do. Such a discrepancy once again leaves the functional food category in limbo because a functional food's structure/function claim could be regulated in two different ways depending on how the functional food is classified. In looking at the hypothetical explained above, if *Intellegencia* is marketed in its cookie form with the *fushi* already included inside the cookie, then the label can bare a structure function claim without FDA approval. However, if *Intellegencia* is marketed as a dietary supplement with the *fushi* in liquid form that can be sprinkled on to the cookie, it will then be subject to FDA evaluation within 30 days after marketing and have to be substantiated by evidence. Thus, once again the same product will be subject to regulation in two different ways.

D. Regulation of Functional Foods In Japan

While it is blatantly obvious that the United States does not have a standard regulation for functional foods, Japan is one of the few countries that does formally recognize and regulate functional foods. While Japan does not use the term “functional food,” they have come up with a system called “Foods For Specified Health Uses”(FOSHU). This system has been in effect since 1991.⁵⁹ FOSHU is now part of the bigger regulatory provision called the “Food With Health

⁵⁷ Silvergrade, *supra*, at P 313

⁵⁸ 21 U.S.C § 343(a)

⁵⁹ Toshio Shimizu. *Health Claims on Functional foods: the Japanese regulations and an International comparison*. Nutrition Research Reviews (2003) 16, 241-252, at 242.

Claims” (FHC).⁶⁰ The other sub category of the FHC is Foods with nutrient function claims (FNFC).⁶¹

The FNFC regulates minerals and vitamins that are used in conjunction with health claims.⁶² A nutrient function claim describes the “physiological role of the nutrient in growth, development and normal functions of the body.”⁶³ Such claims have been well documented by scientific experts from around the world. Thus, regulation for these vitamins and minerals is done in a generalized manner. Once a vitamin or mineral is listed with a claimed function, the vitamin or mineral does not need to obtain approval again.

The basic scheme of FOSHU is to regulate foods that claim health benefits. In regulating functional foods, FOSHU’s main purpose is to authorize claims made on the label for specific products are in fact capable of producing such results.⁶⁴ However, one caveat to FOSHU is that it remains a voluntary process.⁶⁵ A company can still make a health claim for a food as long as the claim does not expressly state that it is health related.⁶⁶ Thus, a company could still make an implied health claim.

In order to gain approval under FOSHU, it is necessary to file an application with the Ministry of Health and Welfare for the whole product. Such an application should include: how the product will help consumers; what purpose is being served by creating the product; evidence proved scientifically of safety, quality, and effectiveness by clinical studies and other laboratory

⁶⁰ Toshia Shimizu . *Newly established regulation in Japan: foods with health claims* Asia Pacific Journal of Clinical Nutrition Volume 11 Issue 2 Page S94-S96, June 2002

⁶¹ Id. at S95

⁶² Id. The following are the vitamins and minerals that have been approved under the FNFC: Vitamin A, C, D, E, B_{1,2,6}, Niacin, Biotin, Pantothenic acid, folic acid, Vitamin B12, Calcium and Iron.

⁶³ Id.

⁶⁴ *CSPI Reports: International Functional Foods. Public Health Boon or 21st Century Quackery*. The International Consumer Association of Consumer Food Organizations.

⁶⁵ Id.

⁶⁶ Id.

research.^{67 68} The application should also set forth the process of making the product along with the list and proportion of the ingredients.⁶⁹ Such ingredients should be nutritionally appropriate.⁷⁰

The scientific evidence required for testing safety, quality, and effectiveness must be based on human studies along with biochemical studies.⁷¹ However, merely conducting the studies is not enough under FOSHU. Studies should be well planned by paying attention to details such as sample size and functional subjects.⁷² It is also a requirement under FOSHU to continue monitoring the product for safety and efficacy and accumulate reports and complaints even after the product is on the market.⁷³

While FOSHU has kept these stringent policies intact, there have been some measures of FOSHU that have been relaxed. The first key change has been that the manufacturers can publish their scientific research instead of having an outside expert examine the research.⁷⁴ An additional change is that the manufacturer can test the product in its own facilities and then submit these results instead of having the product tested by the National Health and Nutrition Laboratory.⁷⁵ However, the Ministry of Health and Welfare may still inspect manufacturing plants in order to evaluate the post-market efficacy of the product.⁷⁶

Keeping with the trend to facilitate more voluntary FOSHU applications, two new types of FOSHU approval have been created. The first one known as “Qualified FOSHU,” is food

⁶⁷ Shimizu, *supra*, at 242

⁶⁸ Hirobumi Ohama, Hideko Ikeda, Hiroyoshi Moriyam. *Health foods and foods with health claims in Japan*. Toxicology 221 (2006) 95-111, at p 102.

⁶⁹ The information was taken from the website of Japan’s Ministry of Health, Labor and Welfare. <http://www.mhlw.go.jp/english/topics/foodsafety/fhc/02.html>

⁷⁰ *Id.*

⁷¹ Shimizu, *supra*, at 242

⁷² *Id.* at 243

⁷³ Kaori Nakajima. *Regulation Nation*. Functional Foods and Nutraceuticals. 2004 (online edition) <http://www.functionalingredientsmag.com/fimag/articleDisplay.asp?strArticleId=347&strSite=FFNSITE&Screen=CURRENTISSUE>

⁷⁴ *CSPI Reports: International Functional Foods. Public Health Boon or 21st Century Quackery*. The International Consumer Association of Consumer Food Organizations

⁷⁵ *Id.*

⁷⁶ Shimizu at 243

which claims a health function, but is not substantiated on scientific evidence that meets the level of FOSHU.⁷⁷ Such food is effective, but no established mechanism meets the requirements of FOSHU.⁷⁸ The second type of approval is known as “Standard FOSHU.” This type of approval occurs when a food has a sufficient amount of FOSHU approvals in that specific standards and specifications are established for the food.⁷⁹ Thus, such a food will be granted the “Standard Foshu” designation when these specific standards and specifications are met.⁸⁰

Under FOSHU, the product makes an enhanced function claim in which “specific beneficial effects of the consumption of foods and their constituents on physiological functions or biological activities.”⁸¹ These claims can claim affects on the early stages of diseases, but cannot specifically state that the product can cure the disease itself.⁸²

Thus, the Japanese system of regulating functional foods has both its pros and cons. One of the cons is the fact that it is a voluntary system. A voluntary system still allows manufactures to circumvent the approval process. The second con is that their approval system requires too stringent a requirement in scientific evidence. While clinical trials are a great method of obtaining proof, this may still may place too much of a burden on the manufacturers. Such a burden might lead to increased prices of the product because manufactures are not able to get their product on the market soon enough to recoup development costs. However, at the same time, the requirement of demonstrating safety and efficacy of the product provides the consumer with added protection. While the system in Japan is not perfect, it nonetheless provides a basic framework for the FDA to formulate its own functional food regulatory policy.

⁷⁷ Id. at <http://www.mhlw.go.jp/english/topics/foodsafety/fhc/02.html>

⁷⁸ Id.

⁷⁹ Id.

⁸⁰ Id.

⁸¹ Shimizu, *supra*, at S95.

⁸² Id.

IV. The Future Regulatory Policy of Functional Foods

A. Reaction To The Current Regulatory Policy of the United States

While the popularity of functional foods continues to increase at a rapid pace, so has the debate over the current regulatory scheme. While non-profit groups such as the Center for Science in the Public Interest (CSPI) push the FDA to come up with a formalized policy for regulating functional foods, there is also pressure from the food industry to leave the system as it is.

As a response to this tension between CSPI and the food industry, the FDA held a public hearing in December of 2006 to hear recommendations for suggestions on how to regulate functional foods. Recommendations for a change in the regulatory system were given by organizations such as, The Institute of Food Technologists (IFT).⁸³ The IFT recommended that health claims for functional foods should be based on “nutritive value or through the provision of a physical or physiological effect” that have been substantiated scientifically or is supported by a large amount of evidence.⁸⁴ The Food Products Association/Grocery Manufacturers Association held the opposite opinion in that the nature of all foods are functional in nature and thus having a separate category would serve no purpose.⁸⁵

The FDA heard these suggestions, but still has not presented any type of proposed regulatory scheme. Such an apparent controversy makes it apparent that a regulatory scheme regarding functional foods must be created in the near future.

⁸³ This article is from Nutraingredients.com. The article was a report on the public meeting on functional foods held by the FDA. www.nutraingredients-usa.com/news/printNewsBis.asp?id=72592

⁸⁴ Id.

⁸⁵ Id.

B. Proposed Regulatory Scheme

While the FDA has not proposed such a regulatory scheme, the following is a suggestion of how functional foods should be regulated. The following scheme uses aspects of FOSHU and the current regulatory scheme, while also implementing new and novel considerations.

In order to create a separate category of functional foods, it is imperative to define what a functional food is so companies can be put on notice and abide by the regulations set forth. As seen earlier, a major problem with functional foods is that they can fit into many of the prescribed categories of food, and thus can be regulated in many different ways. Thus, the goal of this definition is to eliminate this problem and have functional foods fall under one category. A functional food should be defined as: (A.) A product represented as a conventional food or beverage that has an added ingredient or ingredient associated with the product that purports to better an individual's health and/or structure/ function of the body's processes. (B). A conventional food and beverage will still be viewed as a functional food even if the manufacturer does not specify that an added ingredient is responsible for the subsequent structure/function claim. Therefore, the main goal of this definition is to protect the consumer from added ingredients in everyday food that make such claims.

An example, of how this definition eliminates the ambiguities is the hypothetical situation of *Intelegencia* that has been described in this paper. Under the proposed definition, either form of *Intelegencia* would be regulated as a functional food. This is because even when the functional ingredient "fushi" is added separately to the cookie, it is still "associated" with the product and thus comes under the category of functional foods. This definition will ensure that manufacturers cannot manipulate how they use the functional ingredient in order to get more lenient regulations. The provision of the definition that incorporates even those foods and beverages that make a

structure and function claim without attributing it to a specific ingredient prevents manufacturers from escaping the functional food regulation by removing any attribution to a specific ingredient. Thus, the such a definition will more adequately close the regulatory loopholes that currently lurk under the current regulations.

Thus, products that qualify as functional foods should therefore be required to submit an approval application for the product 8 months before it becomes available on the market. It is important to note that like FOSHU, each product must gain approval, not just the functional ingredient. This distinction is important because it makes sure the ingredient is compatible with the product in which it is being added. Unlike FOSHU, which is voluntary, the application should be mandatory. The first part of the application should deal with the safety of the ingredient as used in the food. For manufactures whose claims are not based on a specific added ingredient, they must specify what ingredients in the product give rise to their purported claims. Thus, this requirement forces the manufacturer to divulge the functional ingredients so these ingredients don't go unnoticed.

In order to prove the safety of the ingredient a manufacturer must provide evidence that is scientifically viable. The manufacturer can furnish this scientifically viable evidence in the form of their own scientific studies or in the form of well documented proof through scientific journals. This level of scientific evidence is not as stringent as FOSHU in that clinical trials are not required, but is more stringent than GRAS which only requires safety over a long period of time. .

There will be those who contend that the FDA does not have the time and resources to evaluate all the safety claims of functional foods. However, such a functional food regulation should have a system similar to GRAS. Once a particular product is approved for safety under the

Act, any future product that uses the functional ingredient in the product in a similar manner with similar claims should not be subject to the safety requirement. Such a list should be called Functional Ingredients Deemed Safe (FIDS). Thus, the goal of promoting safety will be advanced while also lessening the burden of the FDA.

A second requirement of the application should be to demonstrate the efficacy of the functional claims. This requirement will protect the consumer from bogus and misleading claims. Regulation of Health Claims should still be regulated according to the parameters of the NLEA. However, the major difference would be that the structure and function claims would now have to be pre-approved by the FDA. Unlike dietary supplements that must provide scientific evidence for structure/function claims within 30 days after marketing, such scientific evidence would be due at the time of application for the product. This would prevent products with false claims from entering the stream of commerce. Evidence must be presented to show that the functional ingredients play a substantial role with the results being claimed in the claim. Such evidence may be presented in the form of laboratory research or clinical research conducted by the manufacturer. The manufacturer may also offer evidence in the form of scientific research conducted by third parties. Such third party research that should be accepted would be published research from scientific journals and reports. However, there should be substantial support for the claim amongst the literature.

One caveat to the efficacy requirement is that even if the product is deemed effective, it may not make a structure/function claim if the nutritive value of the product is low. This requirement would be similar to both FOSHU and the NLEA regulation on health claims. As was the case for the safety requirement, any functional ingredient that is used in a similar manner in another product and purports the same structure function claims would be able to make such a

claim without FDA pre-approval. This would be known as Accurate Functional Food Claim (AAFC). A manufacturer would have to file an AAFC petition when filing a Functional Food Application to be exempt from providing scientific evidence.

However, even after a functional food application is approved, this should not foreclose any further measures in regulating the safety and efficacy of the functional food product. Much like FOSHU requires, the manufacturer should continue to monitor the product for safety and efficacy even after the product is on the market. Such monitoring should be done by documenting consumer complaints or any instances where the integrity of the product is questioned. Such a provision will protect the consumer from any changes in the safety or efficacy of the product even after being marketed for a period of time.

Again there will be opponents of this requirement because they will contend this requirement puts too much burden on the manufacturer and the FDA. One possible argument could be that approval process for functional foods is becoming more like a drug approval process due the increased requirement of scientific data. However, this provision does not put excess burden on the manufacturer because the scientific evidence required is not requiring a three stage, double blind trial that is required for drug approval. All the functional food regulation requires is that the claim be substantiated by scientific evidence that is credible and determinative. Furthermore, the FDA is not being over burdened because it is not actually conducting any of the clinical or research trials. Instead, all the FDA is doing is evaluating the research. Not to mention that the AAFC petition further lightens the load on the FDA. Without such an efficacy requirement, the public would be left vulnerable to claims that could be misleading and even dangerous.

The labeling of the functional food is also very important because this is what alerts the consumer as to what he or she is buying. Along with the standard labeling requirements under the NLEA, there should be some additional requirements. First like the DSHEA requires of dietary supplements, there should be some type of disclaimer on the label of a functional food. A functional food should bear a label that states, “This product is not intended to treat or cure any physiological or physical disease.” Such a disclaimer would be helpful because it would alert the consumer that the functional food should not to take the place of a drug. A further disclaimer should warn the consumer of possible side effects when taken with medications and advise the consumer to discontinue consumption of the product if these side effects persist.⁸⁶

Another requirement should be that the functional ingredient being linked to the claim should be placed separately from the other ingredients and be in larger print. This will alert the consumer as to what the functional ingredient is and put them on notice as to what they are consuming. Like the DSHEA requires of dietary supplements, the amount of the functional ingredient should be listed in conjunction with the recommended daily dose of the ingredient.⁸⁷ Having such information will prevent consumers from consuming too much of a certain ingredient.

Members of the food industry will certainly not be receptive to the disclaimers placed on their foods because they will claim that the disclaimers are detracting from the commercial nature of the product. That such disclaimers will make consumers second guess using the product. However, the main purpose of coming up with functional food regulations is to protect the consumer. Placing these disclaimers is important because it will communicate with the consumer that while these products are beneficial, they should not be solely relied upon. Are these

⁸⁶ Arvanitoyannis, *supra*, at 399.

⁸⁷ *Id.*

disclaimers promoting hyper-vigilance? No. Are they promoting vigilance? Yes. Such vigilance is a must when the consumer may be at risk.

V. Conclusion

As we continue to become more informed and aware of the human body, the use and production of functional foods will only continue to grow. An increase in the use of functional foods also means an increase in the number of claims that will be communicated to the public. Thus, the time has come for the FDA to formulate a formal regulatory policy for functional foods. The current regulatory system through the FDCA, NLEA, FDMA, and DSHEA is inadequate, ambiguous and incongruent. Such a regulatory scheme allows manufacturers to manipulate their product in ways most beneficial to them. However, the regulations should be beneficial to the consumer. If the FDA was to adopt the regulatory scheme described in this paper, the consumer would surely benefit. Such a policy unifies the regulations for all functional foods and eliminates the ambiguities and incongruence of the prior regulatory scheme while fulfilling its purpose of protecting the consumer from unsafe and ineffective functional products. Therefore, formulating a functional food regulation is not an option that the FDA has, but rather an obligation it owes to the average consumer.