



Comments

Roll Sushi, Roll: Defining “Sushi Grade” for the Consumer and the Sushi Bar

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I. INTRODUCTION

Behind the glass partition of the sushi counter, a young sushi chef meticulously slices a fresh piece of Bluefin tuna, carefully molds it around a ball of vinegared rice, and artfully arranges it for service. The young chef exercises ancient precision, but such a display is neither for the swanky hipster at the table across the room nor for the self-indulgent businessman seated at the bar. Instead, the young chef exhibits such craftsmanship with honor because his ancestors have taught him to; he is the modern-day samurai.¹

The honor ends at the sushi counter however; globalization and capitalism have diluted the ancient art in exchange for mass production and profit margin. This departure from tradition does more than diminish sushi’s cultural significance: it creates new risks when ancient

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1. SASHA ISSENBERG, *THE SUSHI ECONOMY: GLOBALIZATION AND THE MAKING OF A MODERN DELICACY* x (2007) (“Japanese history killed off the samurai at the same point in the mid-nineteenth century that it birthed the sushi chef, and a significant inheritance—to be a lone, knife-wielding guardian of honor and order—was bequeathed at that time.”).

techniques are honored no longer and requires regulation where capitalists abused sushi demand.

A 28-year-old male from New York recently told his story about the violent illness he suffered a day after consuming an upscale sushi meal.² The investment banker believed the cause of his illness was the raw fish, but, nevertheless, he declared his intention to return to the restaurant because “[i]t was so good.”³ Health risks have been shown on a larger scale as well. In 2008, the New York Times published an article wherein the writers tested sushi from 20 Manhattan stores.⁴ The tests’ findings were astounding: “A regular diet of six pieces of sushi a week would exceed the levels [of mercury] considered acceptable by the Environmental Protection Agency.”⁵ The tests included an even more alarming aspect: the owners of the sushi stores did not know that the fish posed a risk to consumers.⁶ One owner said: “I’m startled by this. Anything that might endanger any customer of ours, we’d be inclined to take off the menu immediately and get to the bottom of it.”⁷

Targeting areas of urbanization and economic growth, sushi restaurateurs have established locations in cities across the United States over the past twenty years.⁸ The Midwest, in particular, has seen an explosion in the opening of sushi restaurants.⁹ “By mid-2006 there were [25 restaurants] in St. Louis, [23] in the Twin Cities of Minneapolis and St. Paul, [22] in Indianapolis, [22] in Cincinnati, [20] in Cleveland, [16] in Columbus, [13] in Kansas City, [11] in Oklahoma City, [11] in Milwaukee, [10] in Wichita, and [6] in Omaha, Nebraska.”¹⁰ As another means of expansion, sushi is being sold at the counters of large grocery-store chains, including Wal-Mart.¹¹ Innovative locations and services have also helped to increase sushi’s popularity.¹² For example: “Fans of

2. Joseph Mayton, *The Truth About Your Sushi*, BIKYAMASR (Aug. 17, 2010), <http://bikyamasr.com/wordpress/?p=15830>.

3. *Id.*

4. Marian Burros, *High Mercury Levels Are Found in Tuna Sushi*, N.Y. TIMES, Jan. 23, 2008, available at http://www.nytimes.com/2008/01/23/dining/23sushi.html?pagewanted=1&_r=1 (last visited Sep. 10, 2010).

5. *Id.*

6. *Id.*

7. *Id.*

8. Jessica Chen, *Biting Into Sushi*, ENTREPRENEUR, Dec. 12, 2007, available at <http://www.entrepreneur.com/startingabusiness/businessideas/restaurantcenter/article188012.html>.

9. TREVOR CORSON, THE ZEN OF FISH: THE STORY OF SUSHI, FROM SAMURAI TO SUPERMARKET 132 (2007) (noting Chicago and its suburbs, alone, have 150 restaurants serving sushi).

10. *Id.* at 132-33.

11. *Id.* at 133 (noting that Advanced Fresh Concepts (AFC) has plans to franchise 200 sushi counters in Wal-Mart stores around the country).

12. *Id.*

the Chicago Bears can buy sushi while watching football at Soldier Field Stadium. Wealthy residents of Chicago can pay \$500 to eat sushi off naked women.”¹³ Advances in technology, transportation, and emerging changes in tastes have supplied the fuel necessary for sushi to “take off” in global popularity.¹⁴

As sushi spreads, however, so do the health risks posed by the consumption of raw fish. One such risk is the ingestion of high levels of mercury, found in fish and seafood.¹⁵ Additional health concerns include other toxins, viral and bacterial contaminants, and parasites.¹⁶ Consumers often find comfort in a “sushi grade” label that is used by many retailers; however, the Food and Drug Administration (FDA) does not currently regulate or define “sushi grade” seafood.¹⁷ Compounding this scary fact, the FDA and Environmental Protection Agency (EPA) have failed to provide consistent and useful information regarding mercury consumption.¹⁸ Because of the lack of regulation, the “sushi grade” label, common to raw fish products, has no true meaning.¹⁹ Instead, retailers are free to define the term as they see fit, creating a two-fold problem: consumers believe they are purchasing fish that conforms to what is in reality a false standard, and subsequently, they believe that consuming such fish is safe.

This Comment addresses the need for a uniform, governmentally enforced definition of “sushi grade” to reduce consumers’ misunderstanding of the faux grading and curb health risks associated with the consumption of raw fish. Ultimately, this Comment will propose a working definition of “sushi grade” through a synthesis of federal regulations and optional code provisions.

Part II of this Comment will discuss the history of sushi by providing a general definition of the term “sushi,” explaining its cultural significance, and finally recounting the cuisine’s spread to the United States. This section also discusses the major health risks associated with the consumption of raw fish.

13. *Id.*

14. ISSENBERG, *supra* note 1, at 1.

15. Lara Endreszel, *Mercury Rising: Physician Hopes to Help Raise Eyebrows for Fish Regulations*, NUTRITION & DIET, Oct. 25, 2008, available at <http://www.healthnews.com/nutrition-diet/mercury-rising-physician-hopes-help-raise-eyebrows-fish-regulations-1995.html>.

16. Warren Ransom, *Sushi Health Risks*, THE SUSHI FAQ, <http://www.sushifaq.com/sushi-health-risks.htm> (last visited Oct. 5, 2010).

17. See Warren Ransom, *What is Sushi Grade Fish?*, THE SUSHI FAQ, <http://www.sushifaq.com/sushi-grade-fish.htm> (last visited Oct. 5, 2010).

18. Endreszel, *supra* note 15.

19. See *What is Sushi Grade Fish?*, *supra* note 17.

Part III.A of this Comment will discuss current regulations and guidelines, including Federal Regulations and the FDA's Food Code, that govern the safety of sushi. The general framework of the regulations and guidelines also will be discussed. Part III.B will discuss how the health concerns surrounding sushi consumption parallel the concerns of the meat industry prior to the adoption of the Meat Inspection Act. This section also will discuss why the use of "sushi grade" is "misbranding" under the Food, Drug, and Cosmetic Act. Part III.C will examine the government regulations and provisions that should be compiled in defining "sushi grade." Positive and negative aspects of each portion of the definition also are examined. Finally, Part III.D will propose a sound definition of "sushi grade," built from components discussed in Part III.C. This section also will explore how the definition, if implemented, will increase food safety and regulate marketing in the raw fish arena by addressing the problems with current sushi regulation.

Part IV of this Comment will revisit the increasing presence of sushi in the United States and abroad. This Comment will conclude by explaining that eating sushi can be a low-risk and healthy option given proper governmental safeguards.

II. BACKGROUND

A. *Sushi: History and Cultural Significance*

Many people may be surprised to know that the origins of sushi lie outside of Japan. The practice of making sushi began in South-East Asia, moved to China in the second century A.D., and finally migrated to Japan in the seventh century A.D.²⁰ Japan, however, is responsible for the greatest developments in sushi, which were perpetuated by three cultural necessities: a deep respect for nature, the spread of Buddhism, and food preservation.²¹

The first necessity that influenced sushi's origination was the Japanese culture's deep respect for nature.²² Sushi found its way to the culinary world through a number of traits that exemplify the essence of the Japanese style of eating and preparing food.²³ Sushi chefs

20. STEVEN PALLETT, *SIMPLY SUSHI* 4-6 (Jasmine Chan ed., Hinkler Books 2006) (2004).

21. *See id.*; OLE G. MOURITSEN, *SUSHI: FOOD FOR THE EYE, THE BODY & THE SOUL* 15 (Mariela Johansen ed., Springer 2009).

22. PALLETT, *supra* note 20, at 4.

23. *Id.* The emphasis on fresh food is part of the deep respect for nature that is important in Japanese culture. *Id.* It is believed that the products of the earth and sea should be prepared in ways that preserve their natural forms and flavors as much as possible as to show off their own special character. *Id.*

demonstrate their deep respect for nature through their use of the freshest ingredients available, natural flavors, and minimal animal fats.²⁴ A famous Japanese chef, Tsuji, said, “food should be prepared so as to do honor to the essence of the ingredients chosen.”²⁵

The rise of a new religion in Japan, Buddhism, also perpetuated sushi’s development. Buddhism was well-established in China by the second century A.D., and by the sixth century, the religion’s influence had spread through Korea to Japan, where it coexisted with earlier Japanese religions.²⁶ People in Japan traditionally ate meat and drank milk, both being products from “the land.”²⁷ These products could be consumed immediately and did not need to be transported.²⁸ As Buddhism grew in the sixth century, the consumption of meat was prohibited.²⁹ Therefore, people turned to the consumption of fish; the origination of sushi in Japan actually resulted as a means of preserving fish.³⁰

Before refrigerators or freezers existed to transport fish from the coast to the mountainous inlands, the Japanese needed a way to preserve their catch during travel.³¹ The preferred preservation method involved a curing and fermenting process, accomplished by packing the fish with cooked rice.³² This packing method produced lactic acid that essentially pickled the fish.³³ The Japanese soon discovered that the combination of fermented fish and cooked rice resulted in an interesting taste and pleasing texture.³⁴ At that moment, sushi was created!

Defining “sushi” is relatively simple: it consists of vinegared rice with fish or vegetables on top or inside.³⁵ There are five main types of sushi: nigiri-zushi (squeezed sushi), maki-zushi (rolled sushi), chirashi-zushi (scattered sushi), oshi-zushi (pressed sushi), and maze-zushi (mixed sushi).³⁶ Nigiri-zushi are small fingers of rice with a topping of mostly raw seafood, served in pairs at the sushi bar.³⁷ Maki-zushi are composed of layers of seasoned rice and strips of seafood placed upon a

24. *See id.*

25. *Id.*

26. Dr. C. George Boeree, *History of Buddhism*, SHIPPENSBURG UNIV., <http://webpace.ship.edu/cgboer/buddhahist.html> (last visited Oct. 5, 2010).

27. MOURITSEN, *supra* note 21, at 15.

28. *See id.*

29. *See* MOURITSEN, *supra* note 21, at 14; *see also* Boeree, *supra* note 25.

30. *See* PALLETT, *supra* note 20, at 6.

31. *See* MOURITSEN, *supra* note 21, at 14.

32. PALLETT, *supra* note 20, at 6.

33. *Id.*

34. MOURITSEN, *supra* note 21, at 14.

35. *Id.* at 19.

36. PALLETT, *supra* note 20, at 7.

37. *Id.*

sheet of toasted nori seaweed.³⁸ The combination is then rolled and cut into rounds.³⁹ Chirashi-zushi are seafood and vegetables in or on rice, typically served in a bowl.⁴⁰ Oshi-zushi are molded pieces of sushi that often have cooked or marinated seafood at the bottom of the mold.⁴¹ Maze-zushi encompass all sushi not included in the above categories.⁴² Thus, while sushi variations are endless, its components are constant: rice, fish, and vegetables.

B. Sushi: Health Risks

The average consumer is usually under the impression that sushi is a nutritious, healthy food.⁴³ While this perception is relatively sound, raw fish consumption is not without health risks: namely toxins, parasites, bacterial contaminants, and viral contaminants.⁴⁴ Due to underreporting and difficulties in illness diagnoses, actual quantification of all health risks associated with seafood consumption is difficult.⁴⁵ Furthermore, non-health concerns associated with sushi consumption include overfishing and endangering certain sea life.⁴⁶

38. *Id.*

39. *Id.*

40. *Id.*

41. PALLETT, *supra* note 20, at 7.

42. *Id.*

43. *See Sushi Health Risks, supra* note 16.

44. *Id.*

45. HAROLD F. UPTON, CONGRESSIONAL RESEARCH SERVICE, RS22797, SEAFOOD SAFETY: BACKGROUND AND ISSUES 1 (2010), available at <http://www.nationalaglawcenter.org/assets/crs/RS22797.pdf>. “In 2007, the U.S. Centers for Disease Control and Prevention (CDC) reported 1,097 outbreaks, [which are incidents involving at least two persons, resulting] in 21,244 cases of illness. Among the 235 outbreaks that could be attributed to a single commodity, seafood (finfish or shellfish) was reported as the cause for 57 outbreaks (24.2% of the total) and 318 illnesses. In comparison, red meats were reported in 54 outbreaks (23%), and poultry in about 40 outbreaks (17%).” *Id.* “To put these data in context, annual U.S. per capita consumption of seafood was about 16 pounds in 2008, compared with 108 pounds for red meats and 73 pounds for poultry.” *Id.* (citing U.S. Department of Agriculture (USDA), Economic Research Service (ERS), *Food Availability (Per Capita) Data System*, available at <http://www.ers.usda.gov/Data/FoodConsumption/>).

46. *See* B. Freitas, et al., *Too Few Fish: A Regional Assessment of the World’s Fisheries*, OCEANA (May 2008), available at <http://na.oceana.org/en/our-work/promote-responsible-fishing/fishing-subsidies/news-reports> (discussing how overfishing affects the structure, functioning, and resilience of the ocean ecosystem as well as the need to address fisheries management and sustainability). *See also* Seafood Watch: Sustainable Seafood Guide, MONTEREY BAY AQUARIUM (July 2010) available at <http://www.edf.org/page.cfm?tagID=19174> (discussing the best choices for, good alternatives to, and specific species of fish to avoid to support ocean sustainability when dining at sushi restaurants).

1. Toxins

Toxins found in seafood may occur naturally or may result from environmental pollutants. Ciguatera is the most commonly reported type of seafood poisoning.⁴⁷ Ciguatera results from the consumption of tropical and subtropical fish that have ingested naturally-occurring algae that contain the toxin.⁴⁸ A second common seafood toxin, mercury, usually enters the environment through pollution of water sources.⁴⁹ Fish in these water sources absorb the toxin, beginning a chain reaction that results in higher mercury levels in fish higher up the food chain.⁵⁰ In the sushi context, the top of the food chain is the Bluefin tuna.⁵¹ Humans may be exposed to the toxin, and its numerous health risks,⁵² through their consumption of fish that have been contaminated by methylmercury.⁵³

Scombroid poisoning is another type of intoxication that may result from the consumption of seafood. Scombroid poisoning results from eating certain species of fish⁵⁴ that have not been stored properly and have spoiled.⁵⁵ The spoilage of the fish releases toxins that cannot be eliminated by freezing, cooking, smoking, *et cetera*.

47. SEAFOOD NETWORK INFORMATION CENTER, SEAFOOD SAFETY (2007), <http://seafood.ucdavis.edu/Pubs/safety1.htm> (last visited Oct. 4, 2011).

48. U.S. FOOD AND DRUG ADMIN., BAD BUG BOOK (2009), <http://www.fda.gov/Food/FoodSafety/FoodborneIllness/FoodbornePathogensNaturalToxins/BadBugBook/ucm070772.htm> (last visited Oct. 4, 2011).

49. AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, CAS # 7439-97-6, TOXFAQS: MERCURY (1999), *available at* <http://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=113&tid=24> (discussing the most frequently asked health questions about mercury).

50. U.S. FOOD AND DRUG ADMIN., DRAFT RISK AND BENEFIT REPORT: SECTION II, EXPOSURE TO METHYLMERCURY IN THE U.S. (Jan. 15, 2009), <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FoodbornePathogensContaminants/Methylmercury/ucm173271.htm>.

51. *Id.*

52. Exposure to high levels of organic mercury can permanently damage the brain, kidneys, or a developing fetus. Effects on brain functioning may result in irritability, shyness, tremors, changes in vision or hearing, and memory problems. AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, *supra* note 49.

53. *Id.*

54. The FDA regulations provide that:

Scombroid toxin-forming species encompass tuna, bluefish, mahi mahi, and other species, whether or not in the family Scombridae, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that permit the growth of mesophilic bacteria.

21 C.F.R. 123.3(m)(2010).

55. U.S. FOOD AND DRUG ADMINISTRATION, ADVISORY NOTE: SCOMBROID POISONING (2009), *available at* <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FoodbornePathogensContaminants/ScombrotoxinPoisoningDecomposition/default.htm>.

2. Parasites

A second health risk associated with the consumption of sushi is the ingestion of parasites. In the absence of controls, infection from parasites is a hazard that is reasonably likely to occur when a species that is prone to parasites is consumed raw.⁵⁶ Two of the more common parasitic diseases caused by seafood consumption are Anisakiasis⁵⁷—caused by round worms—and Diphyllbothriasis⁵⁸—caused by tape worms.⁵⁹ Parasites are present in many water supplies and appear in food sources through the natural food chain.⁶⁰ The parasites enter human bodies through the humans' consumption of raw or undercooked pieces of fish.⁶¹ “Within hours of ingestion, the parasite larvae cause violent abdominal pain, nausea, and vomiting.”⁶² In the case of tapeworm consumption, weight loss and massive infections may result from intestinal obstruction.⁶³

3. Bacterial and Viral Contaminants

When proper food processing and handling procedures are not followed, bacterial⁶⁴ and viral⁶⁵ contaminants are a concern for

56. Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, 60 Fed. Reg. 65,120 (Dec. 18, 1995) (to be codified at 21 C.F.R. pt. 123, 1240).

57. DIVISION OF PARASITIC DISEASES, CENTER FOR DISEASE CONTROL, ANISAKIASIS (2009), available at <http://www.dpd.cdc.gov/dpdx/HTML/Anisakiasis.htm>. The Center for Disease control has found that:

Anisakiasis is caused by the accidental ingestion of larvae of nematodes or roundworms. Occasionally larvae are coughed up. If the larvae pass into the bowel, a severe eosinophilic granulomatous response may also occur one to two weeks following infection, causing symptoms mimicking Crohn's disease. In severe cases, physical removal of the worms by endoscopy or surgery is needed to reduce the pain.

Id. Anaphylactic shock may result in rare but serious cases. Ingrid Khoo, Ph.D., *Sushi Scares—Infectious Diseases Associated with Sushi or Raw Fish*, (April 15, 2009), <http://infectiousdiseases.about.com/od/g/a/Sushi.htm> (last visited Sep. 14, 2010).

58. *Diphyllobothrium latum*, the largest human tapeworm, causes diphyllbothriasis. DIVISION OF PARASITIC DISEASES, CENTER FOR DISEASE CONTROL, DIPHYLLOBOTHRIASIS (2009), available at <http://www.dpd.cdc.gov/dpdx/HTML/Diphyllobothriasis.htm> (last visited Sep. 14, 2010). Adult tapeworms can reach ten meters in length and can last for decades. *Id.*

59. SEAFOOD NETWORK INFORMATION CENTER, *supra* note 46.

60. ANISAKIASIS, *supra* note 57; DIPHYLLOBOTHRIASIS, *supra* note 58.

61. *Id.*

62. ANISAKIASIS, *supra* note 57.

63. *Id.*

64. *Vibrio parahaemolyticus* is a bacterium found in brackish saltwater and has been associated with consumption of raw or undercooked fish and shellfish. NAT'L CTR. FOR ZOONOTIC, VECTOR-BORNE, AND ENTERIC DISEASES, VIBRIO PARAHAEMOLYTICUS (2009), available at <http://www.cdc.gov/nczved/divisions/dfbmd/diseases/vibriop/> (last visited

consumers of raw fish.⁶⁶ The bacteria most common to raw fish are salmonella and certain vibrio species.⁶⁷ The FDA also has identified three main viral contaminants that are common to seafood: Hepatitis A, Norwalk Virus, and Poliovirus.⁶⁸

The preceding discussion shows that there is an inherent risk associated with consuming sushi. With proper regulation and consumer knowledge, however, the health benefits associated with consuming raw fish easily can outweigh its risks.

C. *Globalization: Sushi and Its Risks Reach the United States*

As previously stated, technology, transportation, and emerging changes in tastes each have played a part in sushi's "globalization." When a fish is caught offshore, now it can be flash-frozen almost immediately onboard long-distance boats.⁶⁹ Once the boats reach their ports, the frozen fish can be transported anywhere in the world via cargo jet, all while preserving the freshness of the product.⁷⁰

The inventiveness of sushi chefs also has allowed the food to adapt to the unique tastes found at each corner of the globe.⁷¹ For example, California added the avocado, Brazil added the mango, and New York contributed "the 'Nixon roll,' [made] of grilled eel, cucumber, and cream cheese."⁷² Local ingredients have a familiar and welcome presence but

Sep. 14, 2010). Infection by these bacteria can cause symptoms including diarrhea, abdominal cramps, nausea, vomiting, headache, fever, and chills, which usually occur within 24 hours of ingestion. *Id.* "An estimated 4500 cases of *vibrio parahaemolyticus* infection occur each year in the United States, but the number of cases reported is much lower due to underreporting." *Id.* *Vibrio vulnificus* is a "halophillic" bacterium, which requires salt and normally lives in warm saltwater. NAT'L CTR. FOR ZOONOTIC, VECTOR-BORNE, AND ENTERIC DISEASES, *VIBRIO VULNIFICUS* (2009) available at <http://www.cdc.gov/nczved/divisions/dfbmd/diseases/vibriov/> (last visited Sep. 14, 2010). In healthy people, ingestion of this microbe can cause vomiting, diarrhea, and abdominal pain, but in people with liver disease or weakened immune systems, the microbe can enter the bloodstream, causing the life-threatening condition of septicemia. *Id.*

65. Viruses are infectious particles that live outside host organisms as a protein called a capsid, which encloses DNA or RNA elements of the virus. Cesare Emiliani, *Extinction and Viruses*, 31 *BIOSYSTEMS* 155, 155-59 (1993) available at <http://www.ucmp.berkeley.edu/alllife/virus.html>. Upon contact with a host cell, a virus takes over the host's functions, using the host to produce more viral proteins. *Id.* As production of viral proteins increases, the host cell bursts and the virus spreads, infecting other cells. *Id.*

66. SEAFOOD NETWORK INFORMATION CENTER, *supra* note 47.

67. *Id.*

68. *Id.*

69. ISSENBERG, *supra* note 1, at xi-xiv.

70. *Id.*

71. *Id.* at xxii-xxiii.

72. *Id.* at xxiii.

also add the flair and taste craved by high-end palates.⁷³ One chef who was interviewed in *Entrepreneur Magazine* stated that he prefers traditional sushi, but he knows the fusion sushi rolls get the biggest buzz in the United States.⁷⁴ “In the U.S., however, the evolution of sushi will continue to be a product of its environment, advancing with the local tastes and popular trends.”⁷⁵

In the late 1800s, the Japanese migrant population in the United States boomed, especially in California.⁷⁶ These migrants, perhaps feeling homesick, searched for familiar ingredients from Japan and prepared “rice balls” covered with slices of fish.⁷⁷ California migrants formed a trading company to supply the increasing demand for tastes of home.⁷⁸ This trading company eventually became the channel through which sushi traveled to the United States.⁷⁹

Years later, the Post-World War II era boasted growing business traffic between Tokyo and the West Coast. Japanese corporations sent their executives to the United States,⁸⁰ and the Immigration Act of 1965 liberalized immigration laws, further opening California’s doors to Japanese immigrants.⁸¹ As a result, the Japanese presence on the West Coast drastically increased, and the sushi restaurants of California satisfied the demographic’s culinary demands.⁸² During relatively the same period, a West Coast movement in favor of simple, fresh ingredients led other consumers to indulge in sushi.⁸³

The appeal of sushi to Americans grew for primarily two reasons: sophistication and health. Americans were drawn to the air of affluence that surrounded sushi diners.⁸⁴ Furthermore, sushi’s simple ingredients supported an era of diets and self-image perfection.⁸⁵ Innovative Japanese chefs created sushi dishes that embraced the tastes of their new culinary brethren. A new trend, or an American obsession, was born.

73. *Id.*

74. *See* Chen, *supra* note 8.

75. *Id.*

76. CORSON, *supra* note 9, at 44.

77. *Id.*

78. *Id.* at 43.

79. *Id.*

80. ISSENBERG, *supra* note 1, at 186-87.

81. *Id.*

82. *Id.* at 87-89.

83. *Id.* at 96-99.

84. *Id.*

85. *Id.*

D. “Sushi Grade” Labeling

Sushi has established itself in the United States, but with the cuisine comes unregulated health concerns. Furthering the inherent health risks are the effects of a marketing ploy known as “sushi grade” labeling. Some retailers attempt to self-regulate by providing their own definitions for products that bear the label “sushi grade.”⁸⁶ This form of self-regulation, however, does little to standardize the label’s definition, which ultimately varies with each retailer.⁸⁷ Retailers provide their own definitions and standards that are based on the freshness of a piece of fish, in comparison to the freshness of other fish sold by the same retailer.⁸⁸ In some cases, retailers offer “sushi grade” fish but do not provide their own definition of the term.⁸⁹ Sasha Issenberg, author of *The Sushi Economy*, stated that “[s]ushi-grade fish can be only as good as the last person to own it says it is.”⁹⁰ Consequently, use of the term acts as a marketing ploy on unsuspecting consumers who believe that they are getting a regulated product with some safety guarantees.⁹¹ Furthermore, the lack of government-issued standards provides no guidance to restaurants in purchasing their seafood.⁹² As depicted by the situation of the owner in the story above,⁹³ restaurants may be unaware that their products pose potential health risks.⁹⁴ Ultimately, any reduction in the health risks posed to the consumer is left to the honesty and self-regulation of fish producers and retailers, who may or may not arbitrarily label their products as “sushi grade.”

86. See AKVACOBIA BY MARINE FARMS, *Sashimi Grade*, <http://akvacobia.com/cobia-sashimi-grade.html> (last visited Oct. 5, 2010); CATALINA OFFSHORE PRODUCTS, *Sushi/Sashimi Grade Seafood*, http://www.catalinaop.com/help_answer.asp?ID=19#126 (last visited Oct. 5, 2010).

87. Compare AKVACOBIA BY MARINE FARMS, *supra* note 85, with CATALINA OFFSHORE PRODUCTS, *supra* note 86.

88. See AKVACOBIA BY MARINE FARMS, *supra* note 85; CATALINA OFFSHORE PRODUCTS, *supra* note 86.

89. See SUSHI FISH MARKET, <http://www.sushifishmarket.com/> (last visited Oct. 5, 2010); MING HONG INTERNATIONAL, <http://www.minghongfood.com/index.php/company/> (last visited Oct. 5, 2010).

90. ISSENBERG, *supra* note 1, at xiv.

91. *Sushi Grade Fish*, SUSHI GUY’S DIY SUSHI RECIPES, <http://www.diy-sushi-recipes.com/sushi-grade-fish.html> (last visited Oct. 5, 2010).

92. See Burros, *supra* note 4.

93. See *supra* Part I.

94. See Burros, *supra* note 4.

III. ANALYSIS

A. *Current Sushi Law*

1. The Food and Drug Administration's Authority

The Food and Drug Administration, as it is known today, was created by the passage of the Food, Drug, and Cosmetic Act (FDCA or Act) in 1930.⁹⁵ The FDA is the oldest comprehensive consumer protection agency in the federal government, tracing its roots back to 1848.⁹⁶ Currently, Congress has authorized the FDA to issue regulations for seafood under various sections of the FDCA, specifically, Sections 342(a)(1), 342(a)(4), and 371(a).⁹⁷

Section 371(a) delegates authority to the Secretary of Health and Human Services⁹⁸ to promulgate regulations to promote the efficient enforcement of the Act.⁹⁹ The FDA aids the Secretary in creation and enforcement of regulations as an agency within the Department of Health and Human Services.¹⁰⁰ The FDCA specifically addresses food in its Section 331 prohibition of “the introduction or delivery for introduction of any food . . . that is adulterated” and “the adulteration or misbranding of any food . . . in interstate commerce.”¹⁰¹ In clarifying these prohibitions, Section 342(a)(1) of the Act states that a food is adulterated “if it bears or contains any poisonous or deleterious substance that may render the food injurious to health.”¹⁰² Section 342(a)(4) further explains that a food is adulterated “if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.”¹⁰³ In section 343, the FDCA also defines when a food is deemed “misbranded;”¹⁰⁴ misbranding, however, will be addressed later in this Comment.¹⁰⁵ Under this authority and that of the Department of Health and Human Services, the FDA has been charged with protecting the public health by

95. See U.S. FOOD AND DRUG ADMIN., WHAT WE DO: HISTORY (2010), available at <http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm>.

96. *Id.*

97. See 21 U.S.C. § 342 (2000); 21 U.S.C. § 371 (2000).

98. *Id.* § 321(d).

99. *Id.* § 371.

100. U.S. FOOD AND DRUG ADMIN., ABOUT THE FDA (2010) available at <http://www.fda.gov/AboutFDA/CentersOffices/default.htm>.

101. 21 U.S.C. § 331(a) & (b) (2000).

102. *Id.* § 342(a)(1).

103. *Id.* § 342(a)(4).

104. *Id.* § 343.

105. See *infra* Part III.B.2.

assuring the safety, efficacy, and security of the nation's food supply among other things.¹⁰⁶

2. Federal Regulations: The Seafood HACCP Plan

The FDA has promulgated numerous regulations that appear to govern, or at least advise, the seafood industry.¹⁰⁷ Whether these regulations have any effect on raw sushi fish is unclear. Under the Fish and Fishery Products chapter of the Code of Federal Regulations, every processor¹⁰⁸ is required either to conduct or have conducted a hazard analysis identifying likely safety hazards and establishing preventative measures that the processor can apply.¹⁰⁹ The chapter further mandates that every processor have a written Hazard Analysis Critical Control Point Plan (HACCP Plan or "Plan") that includes certain provisions.¹¹⁰ The first step under the Plan is to identify and to list food safety hazards that are likely to occur.¹¹¹ The second step under the Plan is to list the "critical control points" for each of the hazards identified.¹¹² Critical control points include those "designed to control food safety hazards introduced inside or outside of the processing plant environment, which may include hazards that occur before, during, [or] after harvest."¹¹³ The HACCP Plan must include a list of critical limits,¹¹⁴ monitoring procedures, corrective action plans, verification, and other administrative requirements.¹¹⁵ When a processor deviates from an established critical limit, the processor is required to take corrective action.¹¹⁶ In spite of these requirements, the measures established through the implementation of an HACCP Plan remain constantly subject to human error and oversight. Additionally, while the broad commands of HACCP Plans

106. See ABOUT THE FDA, *supra* note 99.

107. See 21 C.F.R. § 123 (2010); 21 C.F.R. § 101.45 (2010).

108. "Processor" means any person engaged in commercial, custom, or institutional processing of fish or fishery products, either in the United States or in a foreign country. A processor includes any person engaged in the production of foods that are to be used in market or consumer tests. 21 C.F.R. 123.3(l) (2010).

109. 21 C.F.R. § 123.6(a) (2010).

110. 21 C.F.R. §§ 123.6(b)-(c) (2010).

111. See 21 C.F.R. §§ 123.6(b)-(c). Food safety hazards, applicable to sushi, may be caused by natural toxins, microbiological contamination, decomposition in scombroid toxin-forming species, and parasites. *Id.* See also *supra* Section II.B.

112. See 21 C.F.R. § 123.6(c)(2) (2010).

113. *Id.*

114. "Critical limit means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." 21 C.F.R. § 123.3(c) (2010).

115. 21 C.F.R. §§ 123.6(c)(3)-(7) (2010).

116. 21 C.F.R. § 123.7 (2010).

appear to encompass a majority of the health risks associated with raw fish, verification, validation, and mere implementation issues remain.¹¹⁷ Verification problems arise when the processor does not follow the HACCP Plan that has been implemented.¹¹⁸ While the critical controls the processor adopts may be the best in existence, there is simply no guarantee that individuals within the organization will follow the Plan.

The issue of validation addresses whether the Plan actually will work if it is followed.¹¹⁹ The implication here is that, even if a processor has a HACCP Plan in place, the limits and controls established may not ensure elimination of the identified seafood hazards. Another validation issue that may arise is a poor hazard analysis.¹²⁰ A poor hazard analysis produces HACCP Plans that fail to establish adequate controls for the risks because the risks have not been identified. The likely result of this type of error is the entrance of adulterated foods into commerce because the lack of adequate controls under-represents risk. For example, in a recent inspection of a New Hampshire seafood processor, an FDA inspector found numerous HACCP Plan violations and informed the seafood processor that it needed to do a better job of monitoring temperatures to control bacteria growth and toxin formation.¹²¹ While the processor responded to the inspection, it “did not document its temperature monitoring devices, provided no data, and gave no evidence that personnel are appropriately monitoring temperatures.”¹²² This story is just one instance of a validation problem that led to HACCP Plan failure.¹²³

Finally, some processors simply may choose not to implement HACCP Plans. Section 123.6(b) of the Code of Federal Regulations requires that an HACCP Plan be implemented only if “a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur. . . .”¹²⁴ The preceding HACCP section states that a processor can conduct a hazard analysis or have one conducted for it.¹²⁵ When

117. Pascal Yvon, *HACCP Programs and Practices Evolve*, FOOD QUALITY (Dec./Jan. 2009), available at http://www.foodquality.com/details/article/807907/HACCP_Programs_and_Practices_Evolve.html.

118. *See id.*

119. *See id.*

120. *See id.*

121. Dan Flynn, *Seafood Processors Have HACCP Issues*, FOOD SAFETY NEWS (Feb. 3, 2010), available at <http://www.foodsafetynews.com/2010/02/seafood-processors-with-seafood-haccp-issues/>.

122. *Id.*

123. *See* Dan Flynn, *FDA Finds Seafood Importers Have HACCP Problems*, FOOD SAFETY NEWS (Aug. 22, 2010), available at <http://www.foodsafetynews.com/2010/08/fda-finds-seafood-importers-with-haccp-problems/>.

124. 21 C.F.R. § 123.6(b) (2010).

125. 21 C.F.R. § 123.6(a) (2010).

processors conduct their own hazard analyses, conflict of interest issues can arise. The Seafood HACCP Alliance (Alliance) conducts a “Seafood HACCP Encore Course.”¹²⁶ Within the course materials, the Alliance identifies a number of “common compliance problems,”¹²⁷ all of which may stem from a poor hazard analysis. In summary, a poor analysis resulting from intentional misrepresentation by a processor or untrained inspectors ultimately can result in the implementation of a sub-par HACCP Plan, or worse, no plan at all.

3. The FDA’s Food Code

Another body of regulation that appears to govern sushi is the FDA’s Food Code (the Code). The FDA created the Code as a model to assist state and local governments in initiating and maintaining effective programs for the prevention of food borne illnesses.¹²⁸ The Food Code is neither federal law nor federal regulation; the Code is merely the FDA’s best advice “for a uniform system of regulation to ensure that food at retail is safe and properly protected and presented.”¹²⁹

Two sections within the Food Code seem to apply specifically to sushi and its associated risks. Chapter 3, Section 4 of the Code discusses the destruction of organisms of public health concern.¹³⁰ Specifically, Section 3-402.11 recommends a process for parasite destruction that is essentially “super-freezing.”¹³¹ In its “super-freezing” process, the FDA recommends that:

[B]efore service or sale in ready-to-eat form, raw . . . fish shall be:
(1) Frozen and stored at a temperature of -20°C (-4°F) or below for a minimum of 168 hours (7 days) in a freezer; (2) Frozen at -35 C (-31 F) or below until solid and stored at -35°C (-31°F) or below for a minimum of 15 hours; (3) Frozen at -35°C (-31°F) or below until solid and stored at -20°C (-4°F) or below for a minimum of 24 hours.¹³²

126. SEAFOOD HACCP ALLIANCE, ENCORE HACCP MANUAL (2010) *available at* [http://seafood.ucdavis.edu/haccp/encore%20 manual2.pdf](http://seafood.ucdavis.edu/haccp/encore%20manual2.pdf).

127. *Id.* “Summary of Common Compliance Problems: No written HACCP plan when one is needed; Hazard not listed in plan; Appropriate critical limits not listed; Adequate monitoring procedures not listed; Monitoring Procedures not followed; Corrective action in plan not adequate; Inadequate sanitation monitoring; Inadequate sanitation monitoring records.” *Id.*

128. FDA FOOD CODE iii (2009), *available at* <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/default.htm>.

129. *Id.*

130. *Id.* § 3.

131. *Id.* § 3-402.11.

132. *Id.* §§ 3-402.11(A)(1)-(3).

However, even when this provision has been adopted, the FDA subsequently exempts from the “Super-freezing” requirement:

(2) [t]una of the species *Thunnus alalunga*, *Thunnus albacares* (Yellowfin tuna), *Thunnus atlanticus*, *Thunnus maccoyii* (Bluefin tuna, Southern), *Thunnus obesus* (Bigeye tuna), or *Thunnus thynnus* (Bluefin tuna, Northern); or (3) [a]quacultured fish, such as salmon, that: (a) [i]f raised in open water, are raised in net-pens, or (b) [a]re raised in land-based operations such as ponds or tanks, and (c) [a]re fed formulated feed, such as pellets, that contains no live parasites infective to the aquacultured fish[; and] (4) [f]ish eggs that have been removed from the skein and rinsed.¹³³

The Food Code also requires that “if an animal food such as . . . fish . . . is served raw . . . the permit holder¹³⁴ shall inform the consumer of the significantly increased risk of consuming such foods by way of disclosure and reminder.”¹³⁵ The disclosure must include a description of the animal derived foods¹³⁶ or identification of the foods by “asterisking them to a footnote that states that the items are served raw . . . or contain (or may contain) raw . . . ingredients.”¹³⁷ Another option, a reminder, requires asterisking of the animal-derived foods and a corresponding footnote that provides basic information¹³⁸ regarding the risks of consumption.¹³⁹ These provisions do not protect consumers by regulating the safety of the food, but instead, increase consumer awareness.

While the Food Code provides sound regulations that govern areas of sushi consumption, in application, the Code’s effect on sushi is limited by the Code’s voluntary nature. The preface to the Food Code notes, “[t]he model Food Code is neither federal law nor federal regulation and is not preemptive. Rather, it represents the FDA’s best advice for a

133. *Id.* §§ 3-402.11(B)(2)-(3).

134. “‘Permit holder’ means the entity that: (1) [i]s legally responsible for the operation of the food establishment such as the owner, the owner’s agent, or other person; and (2) [p]ossesses a valid permit to operate a food establishment.” *Id.* § 1-201.10.

135. *Id.* § 3-603.11(A).

136. For example, “‘oysters on the half shell (raw oysters),’ ‘raw-egg Caesar salad,’ and ‘hamburgers (can be cooked to order).’” *Id.* § 3-603.11(B)(1).

137. *Id.* § 3-603.11(B).

138. The footnote must state: “(1) Regarding the safety of these items, written information is available upon request; (2) Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness; or (3) Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions.” *Id.* § 3-603.11(C).

139. *Id.* § 3-603.11(B).

uniform system of regulation.”¹⁴⁰ By the very language of the Code itself, adoption of the Food Code is voluntary.¹⁴¹

The voluntary nature of the Food Code leads to two subsequent problems regarding effectiveness of the Code in regulating sushi. First, state legislatures act at different times, resulting in the adoption of different versions of the Code.¹⁴² Thus, lack of uniformity in food regulation between states results when states adopt the Code at different times and, accordingly, the adopted versions differ from state to state. Most, if not all, processors sell their catch to sushi retailers in more than one state.¹⁴³ Furthermore, advancements in Internet sales and transportation technology support only the multi-state presence of most processors.¹⁴⁴ Currently, pre-1993, 1993, 1995, 1997, 1999, 2001, 2005, and 2009 versions of the Food Code are all in effect somewhere in the United States.¹⁴⁵ This variation can make compliance with each state’s regulations more difficult for processors.¹⁴⁶ The southeast corner of the United States alone is subject to seven different versions of the Code.¹⁴⁷ Further complicating this situation is the fact that different departments within a particular state may adopt different versions of the Code.¹⁴⁸ The result is a greater risk of non-compliance, as the confusion of different versions over-burdens processors and retailers. Furthermore, states may choose to adopt only portions of the Code.¹⁴⁹ Partial adoption may lead to the exclusion of provisions that specifically regulate sushi. Thus, some states that adopt the full version of the Code have safeguards regulating sushi, while other states that adopt only portions of the Code are left with gaps in protection for the sushi consumer.

More specifically, the Code suffers from a defect in its regulations that require the provision of information to consumers. The consumer advisory regulations discussed previously¹⁵⁰ fail because the regulations

140. *Id.* at ii-iii.

141. *Id.*

142. See U.S. FOOD AND DRUG ADMIN., REAL PROGRESS IN FOOD CODE ADOPTIONS (2010), available at <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FederalStateCooperativePrograms/ucm108156.htm>.

143. See, e.g., CATALINA OFFSHORE PRODUCTS, *supra* note 86.

144. See ISSENBERG, *supra* note 1, at xi-xii.

145. REAL PROGRESS IN FOOD CODE ADOPTIONS, *supra* note 142.

146. DONNA V. PORTER, CONGRESSIONAL RESEARCH SERVICE, RL33559, FOOD SAFETY: NATIONAL UNIFORMITY FOR FOOD ACT 7-8 (2007), available at <http://www.nationalaglawcenter.org/assets/crs/RL33559.pdf>.

147. *Id.*

148. REAL PROGRESS IN FOOD CODE ADOPTIONS, *supra* note 142. The Department of Agriculture and Department of Health in each of New York, North Carolina, Oregon, Tennessee, and Wisconsin have adopted differing versions of the Food Code. *Id.*

149. See *id.*

150. See *supra* notes 134-39 and accompanying text.

do not require enough information to allow consumers to make educated decisions. Generally, the regulations require a disclosure only of the nature of the food and an appropriate raw consumption warning.¹⁵¹ Consumers are left with an all-or-nothing proposition: eat and risk illness or go without. This regulation ignores moderation.

The Environmental Protection Agency (EPA) and the FDA recommend eating no more than six ounces of tuna per week as to not exceed the recommended limit of weekly mercury consumption.¹⁵² Unfortunately, the Food Code consumer advisory regulations, in the interest of brevity, ignore the effect of moderation.¹⁵³ If consumers are given more information, they safely can consume sushi while mitigating its risks.

As can be seen, the Food Code provides a number of regulations that are applicable to sushi consumption. These regulations likely would be effective if the Code did not suffer from both procedural and substantive flaws.

B. Why Standardized Federal Regulation is Necessary

1. Sushi's Health Concerns Parallel the Concerns in the Meat Industry

President Abraham Lincoln founded the United States Department of Agriculture (USDA) in 1862.¹⁵⁴ Subsequently, Congress adopted the Federal Meat Inspection Act (FMIA) in 1907,¹⁵⁵ which, by amendment, became the Wholesome Meat Act (WMA) in 1967.¹⁵⁶ The WMA generally requires the inspection of certain animal species¹⁵⁷ before their slaughter and the "meat and meat food products thereof."¹⁵⁸ Pursuant to this requirement, the USDA promulgated regulations that identify

151. FDA FOOD CODE § 3-603.11 (2009), available at <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/default.htm>.

152. U.S. FOOD AND DRUG ADMIN., WHAT YOU NEED TO KNOW ABOUT MERCURY IN FISH AND SHELLFISH (2009) [hereinafter *What You Need to Know*], available at <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FoodbornePathogensContaminants/Methylmercury/ucm115662.htm>.

153. FDA FOOD CODE § 3-603.11.

154. U.S. DEP'T OF AGRIC., AGENCY HISTORY (2007), available at http://www.fsis.usda.gov/About_Fsis/Agency_History/index.asp (last visited Oct. 4, 2011).

155. Meat Inspection Act of 1907, Pub. L. No. 59-242, 34 Stat. 1256, 1260-65 (1907) (prior to 1967 amendment).

156. Wholesome Meat Act of 1967, Pub. L. No. 90-201, 81 Stat. 584, 584-93 (1967).

157. Species include: "cattle, sheep, swine, goats, horses, mules, and other equines." 21 U.S.C. § 603(a) (2000).

158. 21 U.S.C. § 603(a) (2000).

“establishments” that must be inspected¹⁵⁹ and, subsequently, required application for inspection by these “establishments.”¹⁶⁰ Establishments are assigned official numbers¹⁶¹ and each establishment must demonstrate that the facility is in a sanitary condition.¹⁶² When an inspection is conducted, “any product which has not theretofore been inspected, passed, and marked in compliance with the regulations . . . shall not be distributed in commerce.”¹⁶³ Establishments are further required to comply with and adopt all measures the inspectors find necessary for “carrying out the purposes” of the WMA.¹⁶⁴ The WMA’s stated purpose is “preventing the use in commerce of meat and meat food products which are adulterated.”¹⁶⁵ This language, however, does not adequately convey the rationale behind the WMA.

To understand the purposes of the WMA, it is important to look at the circumstances surrounding its adoption. In the late 1800s, railroads were expanding and provided a means of transporting livestock to slaughterhouses.¹⁶⁶ This transportational shift, combined with the introduction of refrigerated rail cars, caused an explosion in the meatpacking industry.¹⁶⁷ The filthy conditions of slaughterhouses and the threat that they posed to meat consumers, all of which were detailed in Upton Sinclair’s *The Jungle*,¹⁶⁸ led to public outrage.¹⁶⁹ As a result, President Theodore Roosevelt, supporting the presence of federal inspectors in meatpacking houses, adopted the Meat Inspection Act of 1907 (MIA).¹⁷⁰ The MIA was subsequently amended in 1967 and became the WMA described above.¹⁷¹ Congress stated in the WMA that “[i]t is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged.”¹⁷² Thus, Congress wished to protect consumers on two different levels: Congress sought to protect consumers’ health and shield them from marketing deception.

159. 9 C.F.R. § 302.1 (2010).

160. *Id.*

161. *Id.* § 305.1.

162. *Id.* § 305.3.

163. *Id.* § 305.4.

164. *Id.* § 305.3.

165. 21 U.S.C. § 603(a) (2000).

166. U.S. DEP’T OF AGRIC., *supra* note 154.

167. *Id.*

168. U.S. DEP’T OF AGRIC., *supra* note 154 (discussing UPTON SINCLAIR, *THE JUNGLE* (1906)).

169. U.S. DEP’T OF AGRIC., *supra* note 154.

170. *Id.*

171. *See supra* Part III.B.1.

172. 21 U.S.C. § 602 (2000).

To do so, Congress clearly indicated in the statute that its intention is to “assur[e] that meat and meat food products distributed to [consumers] are wholesome.”¹⁷³ The Fifth Circuit, in *United States v. Mullens*,¹⁷⁴ further clarified that “[t]he purpose of the Meat Inspection Act of 1907, as amended . . . is to ensure a high level of cleanliness and safety in meat products.”¹⁷⁵ Additionally, Congress evaluated the “wholesomeness” of meat and meat products based on the overwhelming public outcry regarding unsanitary packing conditions.¹⁷⁶ The prevalence of railroads reduced meat costs, which led to an increase in meat product consumption nationally.¹⁷⁷ More importantly, public furor vastly increased the population concerned with proper sanitary practices in meatpacking plants.¹⁷⁸

Like the meat industry, the sushi industry recently has undergone a rapid increase in product demand. Sushi has spread through the United States for reasons discussed above,¹⁷⁹ and it has followed a pattern of expansion that is similar to that of meat products and the meatpacking industry.¹⁸⁰ A technological advancement in transportation—airplane refrigeration units instead of refrigerated rail cars—allowed sushi fish to flow more quickly throughout the United States.¹⁸¹ Subsequently, under the basic principles of supply and demand, the increased availability of the product led to reduced costs. With a new transportation source available and costs in a manageable range, sushi reached new regions, affecting larger numbers of people.¹⁸²

As sushi “rolls” down a path analogous to that taken by meats and the meat industry, the cuisine will expose more individuals to sushi’s unregulated health risks. The health risks associated with sushi¹⁸³ are very similar to those associated with the meat industry. Congress’ health-based rationale behind the WMA supports adoption of similar legislation to protect other food industries that are plagued by similar

173. 21 U.S.C. § 602 (2000). Wholesome is defined as “promoting or conducive to good health or well-being; healthful.” WEBSTER’S NEW UNIVERSAL UNABRIDGED DICTIONARY 2089 (2d ed. 1979).

174. *United States v. Mullens*, 583 F.2d 134, 139 (5th Cir. 1978).

175. *Id.* See also *Federation of Homemakers v. Hardin*, 328 F.Supp. 181, 184 (D.C.D.C. 1971) (stating the primary purpose of the Wholesome Meat Act is to benefit the consumer and to enable him to have a correct understanding of and confidence in meat products purchased).

176. U.S. DEP’T OF AGRIC., *supra* note 154.

177. *Id.*

178. *Id.*

179. See *supra* Part II.C.

180. See *supra* notes 166-72 and accompanying text.

181. See ISSENBERG, *supra* note 1, at 1.

182. See Chen, *supra* note 8; Corson, *supra* note 9, at 132-33.

183. See *supra* Part II.B.1-3.

concerns. To mitigate these parallel risks, Congress should step in and require regulation of sushi to assure consumers that the raw fish “distributed to them are wholesome.”¹⁸⁴

Congress also intended the WMA to protect consumers from marketing deception by processors and retailers. This intent is evidenced by the WMA’s language, stating, “[i]t is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are . . . properly marked, labeled, and packaged.”¹⁸⁵ The court in *Tennessee Valley Ham Co., Inc. v. Bergland*¹⁸⁶ addressed this issue stating, “the authority to promulgate standards of identity was conferred to prevent economic adulteration, the erosion of food ‘integrity’ and the sale of products inferior to those which the consumer expected to receive.”¹⁸⁷ In the case of raw fish, the “sushi grade” label can create a product expectation of superiority when the product itself is actually inferior. This misbranding often occurs when a retailer labels fish “sushi grade” and provides no definition or, alternatively, bases the grade on a comparison of the sushi-grade fish to other fish sold by the retailer.¹⁸⁸ In either situation, the consumer expects to receive a fish that is safe for raw consumption—as the word “sushi” implies “raw” to the ordinary consumer—but the consumer is merely receiving the retailer’s “better” fish. This argument will be explored further in the next section.¹⁸⁹

The implication of the WMA’s second purpose¹⁹⁰ is that sushi is exposed to and suffers from the risks of misleading marketing practices.¹⁹¹ In keeping with the purpose of the Act, Congress also should regulate “sushi grade” labeling in order to prevent “economic adulteration.”

In sum, the risks, both health and economic, that are associated with sushi consumption parallel those risks associated with meat consumption. These risks formed the basis of Congress’ rationale for adopting the MIA and the WMA. Because Congress enacted legislation to protect consumers of meat products when the meat industry was largely unregulated and presented countless health and economic

184. 21 U.S.C. § 602 (2000).

185. *Id.*

186. *Tennessee Valley Ham Co., Inc. v. Bergland*, 493 F.Supp. 1007, 1011-12 (D.C. Tenn. 1980).

187. *Id.*

188. *What is Sushi Grade Fish?*, *supra* note 17.

189. *See infra* Part III.B.2.

190. The purpose is to assure that meat and meat food products distributed to them are properly marked, labeled, and packaged. 21 U.S.C. § 602 (2000).

191. *Id.*

concerns, Congress should act now to protect sushi consumers who face similar health and economic concerns.

2. The Use of “Sushi Grade” is Misbranding Under the FDCA

The Food, Drug and Cosmetic Act (FDCA), discussed above,¹⁹² regulates certain labeling. Under the FDCA, a food is deemed misbranded if “its labeling is false or misleading.”¹⁹³ Section 341 explains the goals of the legislature in enacting such provisions regarding misbranding.¹⁹⁴ The statute states, in pertinent part, “[w]henever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing . . . a reasonable definition and standard of identity, [or] a reasonable standard of quality.”¹⁹⁵ Upon initial inspection, the statutory text requires only that the labeling be either false or misleading, but not both.¹⁹⁶ The Fifth Circuit in *Van Liew v. United States*¹⁹⁷ supported this conclusion, noting, “[subsection (a) of section 343] envisages therefore that there might be a misleading label without its being false and vice versa.”¹⁹⁸ Because “sushi grade” labels are based on the retailers’ own definitions, it is unlikely that such a label is “false” within the confines of section 343(a). However, the “sushi grade” label is likely misleading to the average consumer. That is, raw fish is misbranded under the FDCA if it bears a “sushi grade” label because the “sushi grade” label is “misleading” as to a reasonable definition and reasonable standard of quality.

The Supreme Court defined the concept of “misleading” labeling in *United States v. Ninety-Five Barrels More or Less Alleged Apple Cider Vinegar*.¹⁹⁹ The Supreme Court found a vinegar label describing its contents as “apple cider vinegar made from selected apples” to be misleading to the public because the seized product was made from dehydrated apples rather than from fresh apples.²⁰⁰ The Court reached the decision in spite of the fact that the contested vinegar was similar in color, taste, and consistency to vinegar processed from fresh apple cider, and it was equally wholesome.²⁰¹ The Court explained its holding: “The

192. See *supra* Part III.A.1.

193. 21 U.S.C. § 343(a)(1) (2000).

194. See *id.* § 341.

195. *Id.*

196. See *id.*

197. *Van Liew v. United States*, 321 F.2d 664, 673 (5th Cir. 1963).

198. *Id.*

199. *United States v. Ninety-Five Barrels More or Less Alleged Apple Cider Vinegar*, 265 U.S. 438, 442-43 (1924).

200. *Id.*

201. *Id.* at 443.

statute is plain and direct. Its comprehensive terms condemn every statement, design and device which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true.²⁰² Thus, under section 343(a) of the FDCA, whether a food label is “misleading” tends to turn on deception.

As stated by the Fifth Circuit, deception need not result from false statements.²⁰³ Furthermore, any statement that is likely to be misleading should be read favorably for the consumer to accomplish the goals²⁰⁴ of Section 343.²⁰⁵

The use of “sushi grade” labeling is misbranding because the label is misleading to consumers; they are led to believe that “sushi grade” fish is safe to eat in raw form. While the “sushi grade” label is not necessarily false, it is misleading because it is deceptive to consumers. The deception arises because the “sushi grade” label is “ambiguous and [therefore] liable to mislead.”²⁰⁶ First, the word “sushi,” while not technically translated as raw fish, is commonly understood by consumers to mean raw fish, thus making the label ambiguous. An ambiguous statement alone is often enough to deem an article misbranded under the FDCA.²⁰⁷ Second, when a “sushi grade” label is borne by a piece of fish in raw form, it is liable to mislead the consumer as to the reasonable definition and reasonable standard of quality of that particular fish.

The average purchaser infers that a particular piece of fish bearing this label is meant for, and is thus safe for, raw consumption.²⁰⁸

202. *Id.* at 442-43. The court further explained:

The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. It is not difficult to choose statements, designs, and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the act. The statute applies to food, and the ingredients and substances contained therein. It was enacted to enable purchasers to buy food for what it really is.

Id.

203. *Taylor v. United States*, 80 F.2d 604, 605-06 (5th Cir. 1935).

204. “Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing . . . a reasonable definition and standard of identity, [or] a reasonable standard of quality.” 21 U.S.C. § 341 (2000).

205. *Taylor*, 80 F.2d at 605-06.

206. *Ninety-Five Barrels*, 265 U.S. at 443.

207. *See United States v. Vitasafe Formula M*, 226 F.Supp. 266, 278 (D.N.J. 1964) (holding that any single false, misleading, exaggerated, *ambiguous*, or over-emphasized statement or representation in the labeling of either drug or food misbrands the article within meaning of this section).

208. *Cf. United States v. An Article of Food . . . “Manischewitz . . . Diet Thins”*, 377 F.Supp. 746, 749 (E.D.N.Y. 1974) (holding a front label for food product described as ‘Diet-Thins Matzo Crackers’ was misleading when consumers might be led to believe that the “diet-thins” matzos were lower in calories than ordinary matzo crackers).

Therefore, the label, though not technically false, is indeed likely to mislead consumers. Furthermore, when processors and retailers define their own labels or provide no definition at all, the reasonable purchaser's conclusion of safety is not sound. Accordingly, it may be said that the "sushi grade" label can mislead the purchaser. Because labels that are liable to mislead should be read favorably to the consumer to promote honesty and fair dealing,²⁰⁹ the use of a "sushi grade" label is misbranding under the FDCA.

C. *Defining "Sushi Grade": The Components*

In defining "sushi grade," the aforementioned regulations and techniques²¹⁰ already in place are effective under certain circumstances. The overarching problem for most of the laws or regulations, however, is either the lack of mandatory compliance or the fact that compliance is unsupervised. This section will attempt to synthesize the strengths of the aforementioned alternatives and develop a definition of "sushi grade" that compels mandatory, supervised compliance in order to use the "sushi grade" label. The definition is intended to regulate only those processors and retailers who choose to label their raw fish as "sushi grade."

The first part of the definition of "sushi grade" should include the FDA's definition of "fish" under the Code of Federal Regulations.²¹¹ Affixed to the end of this definition should be the words "in its raw form" to regulate only fish that possess the risks addressed herein. The use of the FDA's existing definition promotes standardization throughout the various food industries and reduces the risk of confusion on the part of processors. For the same reasons, "sushi grade" also should include the FDA's definition of "processing"²¹² in 21 C.F.R. § 123.3.

Second, the definition of "sushi grade" should include mandatory "super-freezing" in compliance with the FDA's Food Code recommendations.²¹³ The purpose of such a standard is to eliminate the

209. See *Taylor*, 80 F.2d at 605-06; 21 U.S.C. § 341 (2000).

210. See discussion *supra* Part III.A.

211. 21 C.F.R. § 123.3 (2010). Fish means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption. *Id.*

212. 21 C.F.R. § 123.3 (2010). Processing means, with respect to fish or fishery products: Handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding. *Id.*

213. FDA FOOD CODE § 3-402.11 (2009), available at <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/default.htm>.

risk of parasites in the raw fish.²¹⁴ While some Japanese purists may argue that freezing goes against the traditional essence of sushi,²¹⁵ the health concerns of an entire population outweigh such a contention. Furthermore, Section 3-402.11(B) of the Food Code regulation²¹⁶ will not be included in order to bring all species of fish within the “sushi grade” definition.

Third, a processor selling fish under the “sushi grade” label should be required to undergo a mandatory hazard analysis, conducted by an outside inspection official. In response to the analysis, a Hazard Analysis Critical Control Point Plan also must be implemented in compliance with 21 C.F.R. § 123.6.²¹⁷ Use of the HACCP regulation within the “sushi grade” standard takes advantage of the benefits of the regulation. Moreover, by making HACCP analysis and planning mandatory, the “sushi grade” definition eliminates the non-mandatory compliance concerns discussed above. The proposed definition also requires that an outside inspector—similar to beef inspectors of the USDA—conduct the HACCP analysis, thus eliminating any bias that would occur from a self-conducted analysis. A requirement that all fish species entering the processor be inspected was also considered at this point of the definition; however, this requirement would be too cumbersome to be effective. The meat industry effectively can require inspection of all species entering slaughterhouses and packing plants, but the fish industry is not the same. Because fish species are far more broad than the “amenable species”²¹⁸ in the meat packing industry, and because the quantity of fish entering processing plants is greater than the number of “amenable species”²¹⁹ in meat packing plants, mandatory inspections are much less feasible for the fish-processing industry. The HACCP requirements, in coordination with adapted Food Code requirements discussed above, already address the risks that pre-entry inspection would encompass.

The “sushi grade” definition should include two specific labeling requirements. First, the definition should include an origin-labeling requirement. This mandate is based on 21 C.F.R. § 123.281, which

214. *Id.*

215. William Hollingworth, *Sushi Chefs in Europe Slam Fish-Freezing Regulation*, THE JAPAN TIMES ONLINE, Aug. 31, 2007, <http://search.japantimes.co.jp/cgi-bin/nn20070831f1.html>.

216. FDA FOOD CODE § 3-402.11(B) (providing freezing procedures to accomplish parasite destruction in ready-to-eat form, raw, raw-marinated, partially cooked, or marinated-partially cooked fish).

217. 21 C.F.R. § 123.6 (2010).

218. 21 U.S.C. § 603(a) (2000).

219. *Id.*

attempts to regulate source controls for raw molluscan shellfish.²²⁰ Origin-labeling requires that processors maintain records and include on the “sushi grade” label: the date of harvest; the location of harvest; the type of fish harvested; the date of receipt by the processor; and the name of the harvester and the name or registration number of the harvester’s vessel.²²¹ The purpose of this requirement is to prevent the harvest of sushi fish from waters highly polluted by mercury and other toxins. The requirement will indeed require more documentation work on the part of the processor; however, many processors work in the business of molluscan shellfish and, therefore, are already set up to handle the required documentation.²²² Furthermore, the health benefits of this requirement substantially outweigh the potential added expense of documentation and any burden on the processor. Second, the definition should include a version of the FDA’s Food Code disclosure requirement.²²³ Under this requirement, the label should be required to include a disclosure that, by way of reminder, informs consumers of the significantly increased risks associated with consuming raw fish. The reminder should disclose that consumption of raw seafood may increase the risk of food-borne illness. The reminder also would include the FDA’s recommended limit on weekly consumption for the particular species of raw fish.²²⁴ Providing this information would allow the consumer to consider the amount of fish he or she already has consumed in a particular week and then evaluate the risk associated with consumption of more fish. The labeling requirements suggested under the “sushi grade” definition promote consumer awareness and independence by allowing consumers to make intelligent decisions.

D. A Recommendation: “Sushi Grade” Fish Is . . .

In attempting to place these components into statutory form, the following represents this author’s version of the “sushi grade” definition.

220. 21 C.F.R. § 123.26 (2010).

221. *Id.*

222. See CONGRESSIONAL SEAFOOD CO., <http://www.congressionalseafood.com/> (last visited Jan. 25, 2011); SUSHI FISH MARKET, *supra* note 89; MING HONG INTERNATIONAL, *supra* note 89.

223. FDA FOOD CODE § 3-603.11 (2009), available at <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2009/default.htm>.

224. See *What You Need to Know*, *supra* note 152 (providing three recommendations for fish consumption that will reduce mercury exposure). See also U.S. FOOD AND DRUG ADMIN., MERCURY LEVELS IN COMMERCIAL FISH AND SHELLFISH (2009), available at <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FoodbornePathogensContaminants/Methylmercury/ucm115644.htm>; WASHINGTON STATE DEPARTMENT OF HEALTH, HEALTHY FISH GUIDE (2009), available at <http://www.doh.wa.gov/ehp/oehas/fish/fishchart.htm>.

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- I. The use of “Sushi Grade” labels shall only be permitted in accordance with this section.
 - A. Definitions—Under this section,
 1. The terms “Fish” and “Processing” shall bear the definitions provided in the Code of Federal Regulations, 21 C.F.R. § 123.3 (2010).²²⁵
 - B. Requirements—A processor or retailer may sell fish products under the label “sushi grade” if:
 1. Parasite destruction is undergone in accordance with 2009 FDA FOOD CODE § 3-402.11;²²⁶ and
 2. An official inspector conducts a hazard analysis and implements a hazard analysis critical control point plan in accordance with 21 C.F.R. § 123.6 (2010).²²⁷
 - C. Labeling—The “sushi grade” label shall include:
 1. Origin-based label notations in compliance with 21 C.F.R. § 123.28(c) (2010).²²⁸
 2. A consumer advisory in compliance with 2009 FDA FOOD CODE § 3-603.11 that includes a notice of the Federal Food and Drug Administration’s weekly consumption recommendations for particular species of raw fish.²²⁹

The use of a unified and regulated “sushi grade” definition will eliminate misbranding issues associated with the label, cure overarching non-mandatory compliance problems, and provide uniformity throughout the United States. First, in the proposed definition, the “sushi grade” label no longer would be misbranding because federal regulation of the definition no longer would mislead consumers. The purchaser would not be subject to the deception of a label, which was liable to mislead; instead, the label would provide all the necessary information for consumers to make intelligent decisions. Furthermore, “sushi grade” fish, under federal regulation, would conform to a uniform standard that the consumer may review.

Second, the new “sushi grade” definition would mandate compliance. Furthermore, processors could no longer skirt HACCP requirements by performing the analyses themselves. Instead, well-trained government inspectors will perform hazard analyses.

225. 21 C.F.R. § 123.3 (2010).

226. FDA FOOD CODE § 3-402.11(A)(1)-(3).

227. 21 C.F.R. § 123.6 (2010).

228. 21 C.F.R. § 123.28(c) (2010).

229. FDA FOOD CODE § 3-603.11(A)(1)-(3).

Finally, a standard definition of “sushi grade” would eliminate uniformity issues amongst states. The Food Code, being voluntary, was adopted at different times, in different forms, by different states. Through implementation of the proposed definition, processors need not worry about multiple compliance programs or adoption of differing Code provisions if they sell in multiple states. A uniform standard also easily may be adopted and enacted within businesses abroad.

There remains, however, an issue that the new “sushi grade” definition does not fully address: human error. While the definition provides safeguards, humans can always deviate, even unintentionally, from the standards imposed. In fish processing and preparation areas, any deviation from such standards increases the health risks posed to consumers. It is certainly a difficult task to completely eliminate human error; however, the definition effectively promotes safe and healthy consumption of raw fish and empowers consumers to make their own intelligent choices.

IV. CONCLUSION

In sum, the popularity of sushi continues to roll through United States and the world.²³⁰ The dish’s recognition can be attributed to a number of factors, and sushi is here to stay.²³¹ As the cuisine becomes a staple of more and more diets, the risks associated with raw fish consumption increase for its consumers.²³² There are a number of recent accounts of individuals who have “felt the effect” of sushi’s health risks.²³³ Unfortunately for the consumer, the federal government is inconspicuously absent from regulating sushi concerns.²³⁴

If the federal government mandated proper procedures, sushi would provide a safe²³⁵ and healthy²³⁶ cuisine for Americans. This procedural mandate could be accomplished by preparing regulations specifically targeted at the raw fish used in sushi. Such regulations, to be effective, must address the problems of voluntary adoption, uniform enactment, and overall wholesomeness.²³⁷ One alternative that addresses each of the aforementioned concerns is a single, uniform definition of “sushi

230. See Chen, *supra* note 8.

231. See *id.*; see also discussion *supra* Part II.C.

232. See Mayton, *supra* note 2.

233. See *id.*; Burros, *supra* note 4.

234. See discussion *supra* Part III.A-B.

235. See discussion *supra* Part III.D.

236. *What You Need to Know*, *supra* note 152. “Fish and shellfish contain high-quality protein and other essential nutrients, are low in saturated fat, and contain omega-3 fatty acids. A well-balanced diet that includes a variety of fish and shellfish can contribute to heart health and children’s proper growth and development.” *Id.*

237. See *supra* Part III.A-B.

grade.”²³⁸ The above definition is effective, not only because it addresses the problems discussed throughout this Comment, but also because it merges current governmental regulations—that would fail to regulate on their own²³⁹—into a workable, effective combination. The use of current governmental tools allows the “sushi grade” definition to grow and adapt as regulations are updated. Furthermore, the combination of current regulations utilizes the governmental knowledge base and experience already in place. Use of governmental expertise eliminates the would-be cost of creating an inspection power in a new agency or branch, as was done by Congress through the adoption of the Wholesome Meat Act.²⁴⁰ The use of this type of definition also benefits the parties involved in the “sushi grade” fish exchange.

A uniform definition of “sushi grade” provides a standard by which consumers and restaurants can judge their raw fish purchases. When faced with the option of two pieces of fish—one labeled “sushi grade” and the other bearing no such label—the purchaser would be more inclined to purchase the fish that complies with governmental standards. The label offers these purchasers assurance of quality and wholesomeness. Second, the uniform definition reduces compliance demands on processors of raw fish:²⁴¹ processors’ sales in multiple states would be required to conform to only one standard under such a system. Third, the uniform definition provided above requires compliance with certain health and safety standards. Conformance with these standards makes sushi consumption safer because it minimizes associated risks. Because this definition of “sushi grade” benefits purchasers and processors and provides for wholesomeness in general, it is the best alternative for federal governmental action.

Eating sushi can be a safe, healthy, and delicious experience when the proper governmental controls are in place. Innovative chefs behind sushi bars abroad continue to create an endless stream of delectable and artful options for the sushi-lover. To properly enjoy these culinary possibilities, consumers should demand assurance that they are consuming fish from processors that have minimized risks to the greatest extent possible. The use of a uniform “sushi grade” definition would provide such assurance. With proper safeguards and an increasing demand, roll sushi, roll; you have something for everyone.

238. See *supra* Part III.D.

239. See *supra* Part III.A-B.

240. 21 U.S.C. § 606 (2000).

241. See REAL PROGRESS IN FOOD CODE ADOPTIONS, *supra* note 142.