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A National "Natural" Standard for Food Labeling

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A NATIONAL “NATURAL” STANDARD FOR FOOD LABELING

Nicole E. Negowetti

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A NATIONAL “NATURAL” STANDARD FOR FOOD LABELING

Nicole E. Negowetti*

I. INTRODUCTION

What do Juicy Juice fruit punch, SunChips, Nature Valley granola bars, and Skinny Girl Margaritas have in common? These products are all branded with the term “natural.” From canned vegetables to cereals to soft drinks, the term “natural” has become one of the most common claims on foods, drugs, dietary supplements, and personal care products. The word “natural” on a label or in advertising brings to mind nature, and things that are pure, clean, healthy,¹ free of artificial additives,² and therefore safe, harmless, and beneficial to overall health. In 2011, “all-natural” was the second-most-used claim on new American food products.³ The food industry’s marketing of such products has been extremely successful. In 2009, sales of products with a “natural” claim reached \$22 billion,⁴ and a recent study found that the “natural” claim is the most popular among consumers. When asked “which is the best description to read on a food label,” 31% of consumers selected “100% natural” and 25% selected “all natural ingredients.”⁵

Although both the Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA) are statutorily mandated to protect consumer interests by prohibiting false and misleading labeling, both agencies have refused to formally

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1. *Naturally Misleading: Consumers’ Understanding of “Natural” and “Plant-Derived” Labeling Claims*, NAT’L CONSUMERS LEAGUE 4, <http://www.nclnet.org/images/PDF/naturalsreport.pdf>. The National Consumers League is America’s oldest consumer organization, representing consumers and workers on marketplace and workplace issues since 1899.

2. *Id.* at 5.

3. Press Release, PR Newswire, New Mintel data highlights most frequent new product on-package claims in food & beverage industry (June 11, 2012) (on file with author), *available at* <http://www.prnewswire.com/news-releases/new-mintel-data-highlights-most-frequent-new-product-on-package-claims-in-food--beverage-industry-158486945.html>.

4. A. Elizabeth Sloan, *Top Ten Food Trends*, INST. OF FOOD TECHNOLOGISTS (2011), <http://www.ift.org/food-technology/past-issues/2011/april/features/food-trends.aspx?page=viewall> (quoting Press Release, The Nielsen Co., U.S. Healthy Eating Trends: Part 1 Commitment Trumps the Economic Pinch (Jan. 26, 2010) (on file with author), *available at* <http://blog.nielsen.com/nielsenwire/consumer/healthy-eating-trends-pt-1-commitment-trumps-the-economic-pinch/>).

5. Press Release, The Shelton Group, National Survey: Green Is Official Mainstream- Consumers Are Confused, Skeptical About Products: Many believe ‘Organic’ is Just a Marketing Claim That Really Means ‘More Expensive’ (June 29, 2009), *available at* <http://www.sheltongroupinc.com/Shelton%20Eco%20Pulse%202011%20Press%20Release.pdf>. In the most comprehensive consumer survey on natural labels in Europe, German company Kampffmeyer Food Innovation commissioned the Clean Label Study of 2012, results of which were released in November 2012. *See generally How to Make a Clean Label*, KAMPFFMEYER FOOD INNOVATION, <http://kfi.kampffmeyer.com/cleanlabelreport/en/index.html> (last visited Jan. 27, 2013). Of 4,000 people in eight European countries, 74% of respondents called “natural” foods products healthier, and 72% said they would pay a premium to get them. *Id.* at 60-61, 48.

define the term. As a result, food manufacturers have been free to use the term as they see fit. As the Food Marketing Institute (FMI)⁶ explains, the term "natural" "applies broadly to foods that are minimally processed and free of synthetic preservatives; artificial sweeteners, colors, flavors and other artificial additives; hydrogenated oils; stabilizers; and emulsifiers."⁷ However, this restrictive definition is merely aspirational. As a wave of recent lawsuits demonstrates, some food manufacturers have taken great liberties with their use of the term. Although the FDA has indicated that the issue is not a priority for the Agency because of limited resources and because there was not enough evidence that consumers were being misled,⁸ this article demonstrates that the meaning of "natural" is of great significance in the marketplace, as indicated by the premium consumers are willing to pay for "natural" foods, recent polls demonstrating consumer concern and confusion over such claims, and an influx of recent lawsuits alleging that "natural" claims do not meet consumer expectations of natural ingredients or minimum processing.

As part of its 2006 petition for a Food and Drug Administration-approved "natural" definition, the Sugar Association commissioned Harris Interactive to conduct a telephone survey regarding the use of the term "natural" in food labeling. When asked whether "the government should provide regulations for food manufacturers to follow when food manufacturers make a natural claim on foods and beverages or do you think the government should not be involved in providing these types of regulations," 83% responded that the government should provide regulations.⁹ The food industry also supports clearer guidance from the FDA. In 2011, FoodNavigator-USA/NutraIngredients-USA conducted an opinion survey of food companies, questioning whether a clearer definition of "natural" was needed for food marketing.¹⁰ The survey revealed that 63% of respondents wanted the FDA to implement a formal definition.¹¹ Less than 1% of respondents believed that the FDA's 1993 guidance was sufficient.¹² The ambiguity of the "natural" claim, coupled with its significance to consumers, has resulted in controversy over its use. This essay argues that a formal and uniform rule adopted and enforced by the FDA and USDA that defines "natural" would benefit consumers and food producers.

6. FMI conducts programs in public affairs, food safety, research, education and industry relations on behalf of its 1,500 food retailers and wholesalers in the United States and around the world. See generally <http://www.fmi.org/>.

7. *Natural and Organic Foods*, FOOD MKTG. INST. (2008), http://www.fmi.org/docs/media-backgroundunder/natural_organic_foods.pdf?sfvrsn=2.

8. Lorraine Heller, *'Natural' Will Remain Undefined, Says FDA*, FOODNAVIGATOR-USA (Jan. 4, 2008), <http://www.foodnavigator-usa.com/Financial-Industry/Natural-will-remain-undefined-says-FDA>.

9. , *Citizen Petition re Definition of the term "Natural" for making claims on foods and beverages regulated by FDA*, SUGAR ASS'N 8-9 (Feb. 28, 2006), http://www.cspinet.org/new/pdf/sugar_fda_petition.pdf [hereinafter *Sugar Ass'n Petition*].

10. Elaine Watson, *Poll Results: We Need a Clearer Definition of Natural... and the FDA Should Come Up With It*, FOODNAVIGATOR-USA (Nov. 7, 2011), <http://www.foodnavigator-usa.com/Regulation/POLL-results-We-need-a-clearer-definition-of-natural-and-the-FDA-should-come-up-with-it>.

11. *Id.*

12. *Id.*

II. REGULATORY ATTEMPTS TO DEFINE “NATURAL”

Since the 1970s, several federal agencies have attempted to define “natural” as it relates to food. The Federal Trade Commission (FTC), which regulates the use of false and misleading advertising, was the first agency to undertake such an effort. In 1974, the FTC proposed the adoption of a rule establishing “natural” foods to be those which were minimally processed and free of artificial ingredients.¹³ However, in 1983 the FTC terminated its rulemaking, concluding that it was unable to establish a definition for “natural” due to the wide variety of products and industries involved in food production.¹⁴ As the FTC explained:

Quite aside from the significant difficulties that would be posed in enforcing this rule, a fundamental problem exists by virtue of the fact that the context in which “natural” is used determines its meaning. It is unlikely that consumers expect the same thing from a natural apple as they do from natural ice cream We should concentrate our resources on more serious consumer protection problems than addressing whether a claim that “milk is a [sic] natural,” is deceptive.¹⁵

The FTC has not attempted to address the “natural” issue since its aborted effort in 1983.

A. FDA’s Informal “Natural” Policy

The Federal Food, Drug, and Cosmetic Act (FDCA) of 1938 grants the FDA the power to “promulgate food definitions and standards of food quality.”¹⁶ This power includes requiring nutritional labeling if the manufacturer makes nutritional or health claims about the product, such as “low fat” or “high in fiber.” In response to growing concern about inconsistent and unclear terms used to describe nutrient content,¹⁷ Congress enacted the Nutrition and Labeling Education Act (NLEA)¹⁸ in 1990, which amended the FDCA for nearly all food products within the FDA’s jurisdiction, to regulate health claims on food packaging, standardize nutrient content claims, and require that more detailed nutritional information be included on product labels.¹⁹ Although the NLEA required the FDA to set comprehensive standards for nutrition claims, such as “healthy,”²⁰ and “low fat,”²¹ as well as the other terms that regularly appear on food and beverage labels, “natural” food claims have escaped definition.

Although the FDA has seemed to recognize the importance of formally

13. Termination of Proposed Trade Regulation; Rule on Food Advertising, 48 Fed. Reg. 23,270 (May 24, 1983). See generally 39 Fed. Reg. 39,842 (proposed Nov. 11, 1974); 40 Fed. Reg. 23,086-23087 (proposed May 28, 1975).

14. Termination of Proposed Trade Regulation; Rule on Food Advertising, 48 Fed. Reg. 23,270.

15. *Id.*

16. *Fellner v. Tri-Union Seafoods*, 539 F.3d 237, 251 (3d Cir. 2008) (citing 21 U.S.C. §§ 341, 346 (2006)).

17. See *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 332 (3d Cir. 2009).

18. Nutrition Labeling and Education Act (NLEA) of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified at 21 U.S.C. § 343 (1990)).

19. *The Impact of the Nutrition Labeling and Education Act of 1990 on the Food Industry*, 47 ADMIN. L. REV. 605, 606 (1995).

20. 21 C.F.R. §101.65(d)(2) (2003).

21. 21 C.F.R. §101.13(e)(1) (2003).

defining this term and has recognized that an adequate definition could prevent consumer confusion and ambiguity,²² the agency nevertheless has declined to adopt a formal definition. In 1991, it adopted an "informal policy," which states that "natural" means merely that "nothing artificial or synthetic (including colors regardless of source) is included in, or has been added to, the product that would not normally be expected to be there."²³ The policy carries only the weight of an advisory opinion, and it does not establish a legal requirement.²⁴ As the Third Circuit recently held, the FDA's definition of "natural" does not have the force of law.²⁵ The court's conclusion stemmed from the fact that (1) the FDA did not undertake a formal process or receive public input on the term; (2) the FDA admitted in 1993 that it was not officially defining the term because there were still many issues that the agency needed to consider before making a definition; (3) the FDA's enforcement letters to food and beverage manufacturers telling them to remove "natural" labels were insufficient to accord the policy the weight of federal law; and (4) the FDA reissued the preexisting "natural" policy after soliciting public comments, which proves that the agency did not take any of the comments it received into account.²⁶

In 1993, when it initiated rulemaking to implement the NLEA, the FDA invited comments on a potential rule regarding the definition of "natural."²⁷ After receiving a variety of suggestions, from banning use of the term, to allowing free use of the term, to harmonizing a definition with the USDA, the FDA recognized that "use of the term 'natural' on [a] food label is of considerable interest to consumers and industry. . . ."²⁸ However, it concluded that "[n]one of the comments provided FDA with a specific direction to follow for developing a definition" for the use of the word "natural."²⁹

After reviewing and considering the comments, the agency continues to believe that if the term "natural" is adequately defined, the ambiguity surrounding use of this term that results in misleading claims could be abated. However, as the comments reflect, there are many facets to this issue that the agency will have to carefully consider if it undertakes a rulemaking to define the term "natural."³⁰

The FDA concluded, "[b]ecause of resource limitations and other agency priorities, FDA is not undertaking rulemaking to establish a definition for 'natural' at this

22. Food Labeling: Nutrient Content Claims; General Principles, Petitions, Definitions of Terms, 56 Fed. Reg. 60,421, 60,466 (proposed Nov. 27, 1991); Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993) (to be codified at 21 C.F.R. pts. 5, 101).

23. Food Labeling: Nutrient Content Claims, General Principles Petitions, Definition of Terms, 56 Fed. Reg. at 60,466.

24. 21 C.F.R. § 10.85(d), (e), (j) (1996).

25. See *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 342 (3d Cir. 2009).

26. *Id.* at 340-41.

27. Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2,302, 2,397 (Jan. 6, 1993).

28. 58 Fed. Reg. 2407 (Jan. 6, 1993).

29. *Id.*

30. *Id.*

time.”³¹ Instead, the FDA has maintained its informal policy.³²

Over the following decade, as consumer interest in “natural” labels grew, the lack of a formal definition “engendered a great deal of ambiguity.”³³ In 2006, the Sugar Association petitioned the FDA to “establish specific rules and regulations governing the definition of ‘natural’ before a ‘natural’ claim can be made on food and beverages regulated by the FDA.”³⁴ The petition asserted that the development of new food technologies since the FDA last attempted to address the “natural” claim issue in the early 1990s warranted “strict [FDA] guidelines that ensure that ‘natural’ claims do not mislead the growing number of consumers who value and wish to purchase natural products.”³⁵

The Sugar Association asked the FDA to “maintain consistency across federal agencies and define the term ‘natural’ based on the definition provided in the USDA *Food Standards and Labeling Policy Book*.”³⁶ It proposed that “natural” be defined as “(1) a food that does not contain anything artificial or synthetic and 2) a food or food ingredient is not more than minimally processed”³⁷

The following year, the Sara Lee Corporation petitioned for the FDA to collaborate with the USDA’s Food Safety and Inspection Service (FSIS) to create a uniform policy for the use of the term “natural.”³⁸ Unlike the Sugar Association, Sara Lee advocated that a uniform definition be prescribed by policy rather than formal regulation, on the basis that flexibility is required to evaluate use of certain ingredients.³⁹ It proposed the following definition:

Use of the term “natural” may be used to describe a food or food ingredient that does not contain any artificial flavor or flavoring, coloring ingredient (regardless of source), or any artificial or synthetic ingredient that is included within or not normally expected to be in the product. The degree of processing necessary to produce the food or food ingredient should be considered in determining consumer expectation.⁴⁰

Unsurprisingly, this manufacturer of packaged meats, baked goods, and coffee⁴¹ argued that “traditional preservative ingredients are consistent with ‘natural’ claims” because many natural preservatives are derived from “natural” ingredients, such as corn, plants, and animals, and these preservatives have “food safety benefit[s].”⁴²

These petitions from Sara Lee and the Sugar Association did not prompt the FDA to take any new rulemaking or policy-amendment actions. Rather, in January

31. *Id.*

32. *See supra* note 23 & accompanying text.

33. *Sugar Ass’n Petition, supra* note 9, at 3.

34. *Id.* at 1.

35. *Id.* at 4.

36. *Id.* at 1.

37. *Id.* at 4-5.

38. Robert G. Reinhard, Sara Lee Corp., Citizen Petition Requesting FDA to Develop Requirements for the Use of the Term “Natural” Consistent with the USDA’s FSIS 12 (Apr. 9, 2007), *available at* <http://www.fda.gov/ohrms/dockets/dockets/07p0147/07p-0147-cp00001-02-vol1.pdf>.

39. *Id.* at 2, 10.

40. *Id.* at 2.

41. *Id.* at 1.

42. *Id.* at 9.

2008, the supervisor of the Product Evaluation and Labeling team at the FDA's Office of Nutrition, Labeling and Dietary Supplements stated in a public interview that "the agency had not put the 'natural' issue on its priority list because there is not enough evidence that the current situation means consumers are being misled."⁴³

In April 2008, the FDA added confusion regarding use of the term "natural" with respect to high fructose corn syrup (HFCS). In response to an inquiry from FoodNavigator-USA.com regarding whether HFCS could be considered a natural ingredient, the FDA stated that the use of the "synthetic fixing agents in the enzyme preparation, which is then used to produce HFCS, would not be consistent with our . . . policy regarding the use of the term 'natural.' Consequently, we would object to the use of the term 'natural' on a product containing HFCS"⁴⁴ Only three months later, in July 2008, the FDA amended its position. In a letter to the Corn Refiners Association, the FDA explained that it would not restrict the use of the term "natural" except on products with added color and synthetic substances and flavors.⁴⁵ In doing so, the FDA would continue to adhere to its position that its "longstanding policy on the use of the term 'natural' is that 'natural' means that nothing artificial (including artificial flavors) or synthetic (including all color additives regardless of source) has been added to a food that would not normally be expected to be in the food."⁴⁶ Whether HFCS could be considered "natural" would depend on the manner in which the corn syrup was made, and products containing HFCS could carry a "natural" label when synthetic fixing agents were not in contact with the product during manufacturing:

[I]t is our understanding that the enzyme used to make HFCS is fixed to a column by the use of a synthetic fixing agent, glutaraldehyde. Any unreacted glutaraldehyde is removed by washing the column prior to the addition of the high dextrose equivalent corn starch hydrolysate, which undergoes enzymatic reaction to produce HFCS. Because the glutaraldehyde does not come into contact with the high dextrose equivalent corn starch hydrolysate, it would not be considered to be included in or added to the HFCS. Therefore, we would not object to the use of the term "natural" on a product containing the HFCS⁴⁷

The FDA further confused matters when it also stated that it would make determinations on a case-by-case basis, as opposed to adopting a consistent, uniform policy:

Consistent with our policy on the use of the term "natural," we have stated in the past that the determination of whether an ingredient would qualify for use of the

43. Lorraine Heller, *'Natural' Will Remain Undefined, Says FDA*, FOOD NAVIGATOR-USA (Jan. 4, 2008), <http://www.foodnavigator-usa.com/Financial-Industry/Natural-will-remain-undefined-says-FDA>.

44. Lorraine Heller, *FDA Comments on HFCS Spark Industry Opposition*, FOOD NAVIGATOR-USA (Apr. 3, 2008), <http://www.foodnavigator-usa.com/Legislation/FDA-comments-on-HFCS-spark-industryopposition>.

45. Letter from Geraldine A. June, Supervisor of the Prod. Evaluation and Labeling Team, FDA, Dep't of Health and Human Servs. (HHS), to Audrae Erickson, President of the Corn Refiners Ass'n (Jul. 3, 2008), available at <http://www.corn.org/wp-content/uploads/2008/07/FDAdecision7-7-08.pdf>.

46. *Id.*

47. *Id.*

term “natural” is done on a case-by-case basis. Further, ingredients with the same common or usual name may be formulated in different ways, where a food containing the ingredient formulated one way may qualify for the use of the term “natural” and another food containing the ingredient with the same common or usual name, which has been formulated in a different way may not be eligible for the use of the term “natural.”⁴⁸

The question of whether HFCS qualifies as a “natural” ingredient has found its way into the courts. In 2010, in a lawsuit against Snapple, the federal court in New Jersey certified to the FDA for administrative determination this very question.⁴⁹ On September 16, 2010, the FDA responded by letter and declined to provide the court with the requested guidance.⁵⁰ Stating that it would take two-to-three years to engage in a transparent proceeding to elicit the proper public participation, the FDA again cited its limited resources and more pressing food-safety concerns. It pointed out that “[c]onsumers currently receive some protection in the absence of a definition of ‘natural’ because the Federal Food, Drug, and Cosmetic Act and FDA’s implementing regulations require that all ingredients used in a food be declared on the food’s label.”⁵¹

Most recently, the FDA, on its website, has provided consumers the following explanation of the meaning of “natural” food labels:

From a food science perspective, it is difficult to define a food product that is “natural” because the food has probably been processed and is no longer the product of the earth. That said, the FDA has not developed a definition for use of the term natural or its derivatives. However, the agency has not objected to the use of the term if the food does not contain added color, artificial flavors, or synthetic substances.⁵²

1. FDA Enforcement: Warning Letters

Although FDA enforcement of “natural” claims has been limited, the FDA has issued publicly available warning letters to companies declaring that use of the term “all natural” is inappropriate if the product contains citric acid, calcium chloride, ascorbic acid, or potassium sorbate.⁵³ For example, on April 3, 2012, the

48. *Id.*

49. *Coyle v. Hornell Brewing Co.*, No. 08-CV-2797, 2011 WL 2147218, at *1 (D.N.J. May 26, 2011).

50. Letter from FDA to Judge Jerome B. Simandle (Sept. 16, 2010) (*on file with author*).

51. *Id.*

52. *What is the meaning of ‘natural’ on the label of food*, FDA, <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm214868.htm> (last updated Apr. 4, 2012).

53. As of Dec. 10, 2012, the following warning letters have been issued to companies for misleading use of the term “natural”: Warning Letter from FDA to Hirzel Canning Co., (Aug. 29, 2001) (Chopped tomato products not natural because products contain calcium chloride and citric acid), *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2001/ucm178343.htm>; Warning letter from FDA to Richard Classey, Oak Tree Dairy Farm (Aug. 16, 2001) (Oaktree All Natural Lemonade misbranded because it contains potassium sorbate; All Natural Oaktree Real Brewed Ice Tea misbranded because it contains citric acid), *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2001/ucm178712.htm>; Warning Letter from FDA to Fresh Made Inc. (Oct. 16, 2007) (Happy Kids Strawberry Farmer’s Cheese and Happy Kids Peach Farmer’s Cheese products are misbranded because the products are labeled as “All Natural,”

FDA issued an import alert against an Israeli "berry juice," citing, among other things, its claim of "natural" despite the inclusion of sulfur dioxide.⁵⁴ In the letter, the FDA explained that although it "has not established a regulatory definition for the term natural[,] . . . the Agency has a long-standing policy that restricts the use of the term natural when a product is formulated with added color, synthetic substances, and flavors . . . that would not normally be expected to be in the food."⁵⁵ Because the product contains "sulfur dioxide, which is listed in the ingredient statement as a preservative, . . . the product name can not [sic] include the term Natural."⁵⁶ It remains to be seen whether the increase in warning letters directed at "natural" claims signals the FDA's interest in addressing this issue. However, until the FDA adopts a more formal policy or regulation on use of the term "*natural*," it is unlikely that the warning letters represent a departure from the Agency's historical reluctance to address "natural" claims.

B. USDA's Attempts to Define "Natural"

The USDA, which regulates meat, poultry products, and "organic" products pursuant to the Organic Foods Production Act of 1990,⁵⁷ has implemented an informal policy regarding "natural" labeling since 1982. No formal rulemaking has

but in fact contain artificial coloring as defined in 21 CFR 101.22(a)(4)), *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2007/ucm076542.htm>; Warning Letter from FDA to Ninth St. Mgmt, Inc. (Aug. 13, 2009) (Cheese ravioli and lobster ravioli products had labels that stated "All Natural Ingredients," but then listed some synthetic substances in the products' ingredients), *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm179558.htm>; Warning Letter from FDA to Nestle U.S. (Dec. 4, 2009) (The principal display panels of Juicy Juice products identify the products as "Orange Tangerine" and "Grape," respectively, in large, bold lettering outlined in black; however, neither orange/tangerine juice nor grape juice is the predominant juice in the products. The statements "All Natural-100% Juice" in close proximity to the words "Orange Tangerine" or "Grape" and vignettes of oranges or grapes also may lead consumers to believe that the products are 100% orange/tangerine juice or 100% grape juice when, in fact, they are not), *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2009/ucm194122.htm>; Warning Letter from FDA to Shemshad Food Prod., Inc. (Mar. 11, 2011) (Lime Juice Natural product cited for natural claim because product had sodium benzoate 1% (chemical preservative)), *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm247908.htm>; Warning Letter from FDA to Bagels Forever, Inc. (July 22, 2011) (Blueberry bagel products deemed misbranded because label used the term "All Natural," when they were manufactured with infused wild dry blueberries that contain potassium sorbate (chemical preservative). Label also misleadingly made the claim "No Preservatives."), *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm265756.htm>; Warning Letter from FDA to Lebanese Arak, Corp. (Sept. 22, 2011) ("Sadaf Natural Lemon Juice" cited for natural claim because product contained sodium benzoate and sodium bisulfite (chemical preservatives)), *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm274047.htm>; Warning Letter from FDA to Alexia Foods, Inc. (Nov. 16, 2011) (Roasted Red Potatoes & Baby Portabella Mushrooms claimed to be "All Natural" but they contained "disodium dihydrogen pyrophosphate, which is a synthetic chemical preservative"), *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm281118.htm>.

54. Warning Letter from FDA to Arza Winery LTD (Apr. 3, 2012), *available at* http://www.accessdata.fda.gov/cms_ia/importalert_264.html.

55. *Id.*

56. *Id.*

57. 7 U.S.C. § 6501 (2006).

been undertaken to establish a definition. Contained in its Policy Memorandum 55, the USDA's guidelines limit use of the term to those foods that contain no artificial ingredients and are minimally processed.⁵⁸ This definition addresses only the ingredients and processes used to make meat or poultry products.⁵⁹ The Policy Memo acknowledges, however, that there are exceptions to this general view, and that the presence of an ingredient that has been more than minimally processed would not necessarily preclude a product from being promoted as "natural." The Policy permits exceptions on case-by-case and contextual bases if the proposed ingredient "would not significantly change the character of the product to the point where it could no longer be considered a natural product."⁶⁰ In such cases, manufacturers must conspicuously identify the excepted ingredient on the label⁶¹ (e.g., "all natural ingredients except dextrose, modified food starch, etc.").⁶² For example, a "turkey roast" cannot be called a "natural" product if it contains beet coloring, but can still bear the statement "all natural ingredients."⁶³ Policy Memo 55 further states that all products claiming to be "natural" or a "natural" food should be accompanied by a brief statement that explains what is meant by the term "natural" (i.e., that the product is a "natural" food because it contains no artificial ingredients and is only minimally processed).⁶⁴

On October 9, 2006, Hormel Foods requested that the USDA institute rulemaking to establish a definition for "natural." In particular, it sought a

58. *Food Standards and Labeling Policy Book*, FSIS, (Aug. 2005), http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf [hereinafter *Labeling Policy Book*]. The *Labeling Policy Book* defines "natural" as meaning (1) the product does not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative (as defined in 21 CFR 101.22), or any other artificial or synthetic ingredient; and (2) the product and its ingredients are not more than minimally processed. Minimal processing may include: (a) those traditional processes used to make food edible or to preserve it or to make it safe for human consumption, e.g., smoking, roasting, freezing, drying, and fermenting, or (b) those physical processes which do not fundamentally alter the raw product and/or which only separate a whole, intact food into component parts, e.g., grinding meat, separating eggs into albumen and yolk, and pressing fruits to produce juices. *Id.* The *Policy Book* contains additional directives on the use of the term "natural," requiring the label to be "accompanied by a brief statement which explains what is meant by the term," and provides additional guidance regarding what forms of processing are too "severe" to be considered minimal. *Id.* Although the August 2005 edition provided that sugar, sodium lactate, and natural flavors from oleoresins are acceptable in "natural" foods, the use of sodium lactate is now considered on a case-by-case basis. *See id.*

59. The FSIS definition of "natural" does not provide guidelines for how an animal can or should be raised. On January 21, 2009, the Agricultural Marketing Service (AMS) division of the USDA released the voluntary "Standards for Livestock and Meat Marketing Claims, Naturally Raised Claim for Livestock and the Meat and Meat Products Derived From Such Livestock" that allows for third-party verification of these claims. *See* 74 Fed. Reg. 12 (Jan. 21, 2009), *available at* <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5075017>. ("Naturally-raised," according to AMS, means that an animal has not received antibiotics or hormones, and that no animal byproducts have been used in animal feed). *Id.* This essay's scope is limited to a discussion only of the term "natural."

60. *Labeling Policy Book*, *supra* note 58.

61. *Id.*

62. Product Labeling: Definition of the Term "Natural", 71 Fed. Reg. 70,504 (Dec. 5, 2006).

63. A. Bryan Endres, *United States Food Law Update: Labeling Controversies, Biotechnology Litigation, and the Safety of Imported Food*, 3 J. FOOD L. & POL'Y 253, 263 (2007).

64. Product Labeling: Definition of the Term "Natural", 71 Fed. Reg. at 70,504.

regulation that would prohibit exceptions for specific chemical preservatives and synthetic ingredients. A public hearing was held on the petition in December 2006⁶⁵ to discuss certain issues raised by the Hormel petition, including consumer expectations of a “natural” label, the types of food processing methods commonplace today versus twenty-four years ago when the policy on “natural” claims was established, and whether a “minimally processed” standard should remain a requirement of the “natural” label.⁶⁶ The public hearing also sought to address whether ingredients or processes that would otherwise disqualify a product from bearing the “natural” label but would enhance food safety—for example, sodium lactate or high-pressure processing—should be excepted.⁶⁷ The public comments submitted to the Food Safety Inspection Service (FSIS)⁶⁸ expressed a wide variety of concerns. For example, some comments highlighted the inconsistency that has resulted from the case-by-case determinations⁶⁹ and stressed the value of predictability and transparency of FSIS’s decision-making.⁷⁰

In September 2009, FSIS issued an Advance Notice of Proposed Rulemaking, which is a continuation of the USDA’s December 2006 request concerning use of the term “natural” in labeling for meat and poultry products. In its notice of proposed rulemaking, the USDA explained that:

The comments indicated there is an overall lack of consensus on both the general or common understanding of what the claim “natural” means to the industry and to the public and on the approach that FSIS should take to address issues associated with the use of “natural” on claims on the labels of meat and poultry products.⁷¹

The FDA has taken no further action since its 2009 request for comments.

III. EFFECTS OF THE INFORMAL “NATURAL” POLICIES

In sum, U.S. agencies have refused to formalize a definition of “natural,” claiming (1) the task is too challenging,⁷² (2) a lack of resources and other

65. Food Safety Inspection Serv. (FSIS), Transcript of Public Meeting, Product Labeling: Definition of the Term “Natural” 1 (Dec. 12, 2006), *available at* http://www.fsis.usda.gov/PDF/Natural_Claims_Transcripts.pdf#page=16.

66. Product Labeling: Definition of the Term “Natural”, 71 Fed. Reg. at 70,504.

67. *Id.*

68. Product Labeling: Definition of the Term “Natural,” 72 Fed. Reg. 2,257 (Jan. 18, 2007). The comments can be found at http://www.fsis.usda.gov/Regulations_&_Policies/2006_Notices_Index/index.asp#Labeling.

69. *See* Letter from Barbara K. Negron, President, N. Am. Natural Casing Ass’n, to FDA, Comments, Docket No. FSIS-2006-0400: Product Labeling: Definition of the term “Natural,” (Mar. 5, 2007), *available at* <http://www.fsis.usda.gov/OPPDE/Comments/2006-0040/2006-0040-25.pdf>.

70. *See* Letter from Robert G. Reinhard, Dir. Food Safety/Regulatory, Sara Lee Food & Beverage Corp., to FDA, Citizen Petition: requesting the Food Safety & Inspection Service to Develop requirements for the Use of the Term “Natural” Consistent with the Food & Drug Administration, (Mar. 5, 2007), *available at* <http://www.fsis.usda.gov/OPPDE/Comments/2006-0040/2006-0040-24.pdf> [hereinafter Sara Lee Petition].

71. Product Labeling: Use of the Voluntary Claim “Natural” in the Labeling of Meat and Poultry Products, 74 Fed. Reg. 46,953 (Sept. 14, 2009) (to be codified at 9 CFR pts. 317 and 381).

72. *See supra* notes 50-51 and accompanying text.

priorities,⁷³ and (3) “there is not enough evidence that the current situation means consumers are being misled.”⁷⁴ Although the FTC, FDA, and USDA have identified valid concerns regarding the difficulties of formally defining the term “natural,” consumers are reasonably confused about the meaning of the word on products, and the food industry is clamoring for consistent and uniform standards for FDA and FSIS-regulated products. The Grocery Manufacturing Association has commented that because such regulatory agencies have not clarified the term, food products are subject to the agencies’ “best current thinking of what constitutes truthful labeling.”⁷⁵

Informal policies that differ by each agency have created uncertainty for both consumers and for the food industry. As Sara Lee stated in its petition to the FDA, the value of a unified policy is evident from the significant number of FDA-regulated foods and ingredients that are used in FSIS-regulated products.⁷⁶ An FDA-regulated food that could be sold and used with a meat or poultry product, such as mashed potatoes in a frozen dinner that contains chicken, should be subject to only one definition of “natural.”⁷⁷ It is unlikely that consumers would differentiate between foods subject to the different agencies’ jurisdictions, and understand that “natural” could be regulated pursuant to different standards.⁷⁸ Predictability and consistency will also benefit food marketers. As the FSIS stated when it adopted regulations parallel to those of the FDA-regulated foods under the Nutrition Labeling and Education Act of 1990 (NLEA), “[h]armonization will ensure consistency of format and content for consumers and, thereby, will encourage use of the new labels, while minimizing the cost of compliance on the food industry.”⁷⁹ The FDA, for its part,

[r]ecognizes the need for consistency between the FDA and FSIS in the development and implementation of food standards that set forth minimum composition requirements. The agency believes that manufacturers will be better able to comply with the requirements of both agencies if similar approaches are used. Thus, to the extent possible, one of the agency’s goals is to harmonize its regulations with those of the FSIS.⁸⁰

73. Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2,407 (Jan. 6, 1993) (to be codified at 21 CFR pts. 5 and 101) (“Because of resource limitations and other agency priorities, FDA is not undertaking rulemaking to establish a definition for “natural” at this time.”).

74. See Lorraine Heller, *‘Natural’ Will Remain Undefined, Says FDA*, FOODNAVIGATOR-USA, (Jan. 4, 2008), <http://www.foodnavigator-usa.com/Financial-Industry/Natural-will-remain-undefined-says-FDA> (FDA representative Geraldine June’s statement to the publication).

75. Press Release, Inst. of Food Technologists, *Is There a Definition for Natural Foods?*, (June 30, 2008), available at <http://www.amfe.ift.org/cms/?pid=1000744>.

76. See Letter from Robert G. Reinhard to FDA, *supra* note 70, at 3.

77. *Id.* at 5.

78. *Id.* at 3.

79. Nutrition Labeling of Meat and Poultry Products, 58 Fed. Reg. 632, 637 (Jan. 6, 1993) (to be codified at 9 CFR pts. 317, 320, and 381); see also Sara Lee Petition, *supra* note 70, at 3-5 for a summary of the FDA and FSIS’s history of developing consistent labeling policies and requirements.

80. Food Standards of Identity, Quality and Fill of Container; Common or Usual Name Regulations; Request for Comments on Existing Regulations 60 Fed. Reg. 67492, 67502 (proposed Dec. 29, 1995) (to

If two companies are using the label on similar or different products, the term “natural” should have the same meaning. As the FTC noted in comments to the FDA, “a consistent and coherent federal policy on food marketing is also important to protect consumers, to avoid conflicting legal standards, and to help stimulate competition to improve products so consumers can improve their diets.”⁸¹

A formal, unified definition is necessary because otherwise, the issue will be up to the manufacturers or the courts to decide, resulting in an even more fractured landscape. “[I]ndividual retailers have come up with their own rules for suppliers, which are slightly different, from Whole Foods Market⁸² to Costco or Trader Joe’s.”⁸³ As the Third Circuit recently held, the FDA’s informal “natural” policy does not preempt lawsuits alleging deceptive business practices and false advertising.⁸⁴ Therefore, inconsistency across different jurisdictions is possible, which would certainly create an issue for food manufacturers that sell food across state borders. Without a consistent definition for food manufacturers to rely upon, some companies face unfair competition from other companies that adopt looser standards for products they call “natural.” Misuse of the term impacts the food companies that are truly committed to producing “natural” food products. For example, a 2011 report compares organic cereals and granolas with cereals labeled “natural.”⁸⁵ The report documents that some cereal companies that started out organic, and built consumer loyalty as organic brands, switched to conventional “natural” ingredients without changing their packaging or marketing while continuing to charge customers as much as or more than many certified organic competitors.⁸⁶

be codified at 21 CFR pts. 102, 130, 131, 133, 135, 136, 137, 139, 145, 146, 150, 152, 155, 156, 158, 160, 161, 163, 164, 165, 166, 168, and 169).

81. Press Release, Fed. Trade Comm’n, FTC Chairman Steiger Discusses Food Advertising: Announces Staff Comments to FDA on Proposed Food Label Regs, in Remarks Before Advertising Agencies (Feb. 25, 1992) available at <http://www.ftc.gov/opa/predawn/F93/steiger-ad.htm>.

82. See *List of Prohibited Ingredients* WHOLE FOODS, <http://www.wholefoodsmarket.com/about-our-products/quality-standards/unacceptable-ingredients-food> (last visited Feb. 5, 2013).

83. Elaine Watson, *Industry Should Develop Working Definition of ‘Natural’ if FDA Won’t*, *Expert*, FOODNAVIGATOR-USA (Oct. 25, 2011), <http://www.foodnavigator-usa.com/Market/Industry-should-develop-working-definition-of-natural-if-fda-won-t-expert>.

84. See *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 340 (3d Cir. 2009); see also Adam C. Schlosser, *A Healthy Diet Of Preemption: The Power of the FDA and The Battle Over Restricting High Fructose Corn Syrup From Food and Beverages Labeled ‘Natural’*, 5 J. Food L. & Pol’y 145, 149-66 (2009) (discussing preemption issued in state tort claims cases attempting to exclude HFCS from foods and beverages labeled “natural”).

85. See generally Charlotte Vallaeys, Mark Kastel, Will Fantle, Lynn Buske, *Cereal Crimes: How “Natural” Claims Deceive Consumers and Undermine the Organic Label—A Look Down the Cereal and Granola Aisle* THE CORNUCOPIA INSTITUTE (Oct. 2011), http://cornucopia.org/cereal-scorecard/docs/Cornucopia_Cereal_Report.pdf.

86. *Id.* at 11. For example, in 2008, the company that owned the Peace Cereal brand, Golden Temple, switched from organic to cheaper conventional ingredients, without lowering its prices. At the time of the switch, the company also did not change its barcode or package design, other than eliminating the USDA Organic seal and the word “organic” from its cereal boxes. *Id.* Some retailers continued to use “organic” in-store shelf tags for Peace Cereal—until Cornucopia publicized its findings showing widespread mistakes. *Id.* The Cornucopia Institute filed a complaint with the Federal Trade Commission, alleging that Hearthsides Food Solutions, which manufactures Peace Cereal, is misleading consumers by suggesting that its “natural” breakfast cereals are grown and processed without pesticides.

As the FSIS and FDA have recognized, the agencies' longstanding policies on "natural" claims have been challenged by advances in food processing and in packaging methods.⁸⁷ The USDA's case-by-case exceptions to its general policy regarding "natural" labeling have resulted in the label being used in a misleading manner.⁸⁸ For example, Hormel's "Natural Choice 100% Natural Deli Turkey" lists the following ingredients: "turkey breast meat, water, salt, turbinado sugar, carageenan (from seaweed), baking soda, natural flavoring and lactic acid starter culture (not from milk)."⁸⁹ That kind of highly processed product barely resembles the turkey that a consumer would cook and slice at home, although the USDA permits other poultry and meat products to be labeled "100% Natural" or "All Natural" even if they contain added chicken or beef broth, which can raise the water and sodium content of the product to decidedly unnatural levels.⁹⁰ Furthermore, the FDA's 1993 policy addressing "added color, artificial flavors or synthetic substances" does not resolve issues regarding HFCS, enriched flour, modified starch, partially hydrogenated vegetable oils, organic solvents such as hexane for extracting certain ingredients, genetically engineered ingredients, and pesticides. A definition by the FDA and USDA must account for these food innovations. As indicated in recent consumer and industry surveys, as well as a proliferation of recent lawsuits (discussed *infra*) alleging misleading labeling and advertising, the "natural" controversy has become too important for the FDA and USDA to ignore.

A. Consumer Expectations

As the Sugar Association contended in its petition to the FDA, consumers' inherent lack of knowledge about food ingredients, food technology, food ingredient terminology, and marketing claims places them at a disadvantage when trying to evaluate when a product or ingredient is "natural."⁹¹ For this reason, consumers should be able to rely on the oversight of regulatory agencies to provide food manufacturers with clear and concise regulations. Although use of the term has been shown to significantly influence food purchases, consumers are thoroughly confused about the meaning of "natural" claims on products.

See Press Release, The Cornucopia Institute, Organic Industry Watchdog Files Complaint with the Federal Trade Commission (Feb. 18, 2011), *available at* <http://www.cornucopia.org/2011/02/peace-cereal-illegally-misleading-consumers/>; Press Release, The Cornucopia Institute, Major Agribusinesses Competing with Organics on the Cheap, "Natural" Food Products with Toxic Chemicals and GMOs Deceiving Consumers (Oct. 12, 2011), *available at* <http://www.cornucopia.org/2011/10/cerealcrimes-pressrelease/>.

87. See *supra* notes 65-66 and accompanying text.

88. See BRUCE SILVERGLADE & ILENE RINGEL HELLER, CTR. FOR SCI. IN THE PUB. INTEREST, FOOD LABELING CHAOS pt. X-4 (2010), *available at* http://www.cspinet.org/new/pdf/food_labeling_chaos_report.pdf.

89. *Id.*

90. For example, Tyson's 100% All Natural Chicken Wing Sections, contain up to 12% chicken broth, or, as the label states "up to 12% Natural Chicken Broth." *Id.* Safeway brand boneless/skinless chicken thighs and breasts have 330 mg of sodium per/100 g and Shady Brook Farms young turkey breast with broth contains 304 mg of sodium per 100 g. *Id.* Both products contain up to 15% added broth. *Id.*

91. *Sugar Ass'n Petition*, *supra* note 9.

For example, the confusion is evident when consumers are asked about preferences regarding "natural" or organic foods. Unlike the term "natural," organic foods are governed by a comprehensive set of requirements. The National Organic Program (NOP)—implemented in 2002 by the U.S. Department of Agriculture (USDA)—holds the industry to strict standards in the production and sale of such foods. The NOP was established by the Organic Foods Production Act of 1990 (OFPA), which "was intended by Congress to create national organic marketing standards, assure consumers that organic foods meet a consistent standard, and facilitate interstate commerce in organic foods."⁹² "Organic" refers not only to the food itself, but also to how it was produced.⁹³ To qualify as organic, crops must be grown without synthetic pesticides (unless that substance is on the National List of Allowed and Prohibited Substances) or bioengineered genes.⁹⁴ Organic foods also may not be irradiated.⁹⁵ Organic livestock must have access to the outdoors and be raised without antibiotics or growth hormones.⁹⁶ All organic production and handling operations must be certified by third parties accredited by the USDA.⁹⁷

Despite the far more precise and stringent standard for organic foods, surveys suggest that consumers express a preference for products labeled "natural" over those labeled "organic."⁹⁸ While 50% of polled consumers in 2009 said the "natural" label on food was either important or very important to them, only 35% believed "organic" carried the same value.⁹⁹ While consumers define the terms in a similar manner, "natural" claims are more strongly associated with the absence of artificial flavors, colors, and preservatives.¹⁰⁰ According to a separate survey of

92. Ricardo Carvajal & Riette van Laack, *Seeing Red over Green: The Fight over "Organic," "Natural," and "Sustainable,"* 18-JUN BUS. L. TODAY 33 (2008-2009).

93. See Agricultural Marketing Service, *Organic Standards*, <http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateN&navID=OrganicStandardsLinkNOPFAQsHome&rightNav1=OrganicStandardsLinkNOPFAQsHome&topNav=&leftNav=&page=NOPOrganicStandards&resultType=&acct=nopgeninfo> [hereinafter *Organic Standards*].

94. See Agricultural Marketing Service, *About the National List*, <http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateJ&navID=AboutNationalListLinkNOPOrganicStandards&rightNav1=AboutNationalListLinkNOPOrganicStandards&topNav=&leftNav=&page=NOPNationalList&resultType=&acct=nopgeninfo>.

95. *Organic Standards*, supra note 93.

96. *Id.*

97. See Agric. Marketing Serv., *Organic Certification & Accreditation*, USDA (Dec. 31, 2012), <http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateN&navID=OrgCertLinkNOPOrganicStandards&rightNav1=OrgCertLinkNOPOrganicStandards&topNav=&leftNav=&page=NOPAccreditationandCertification&resultType=&acct=nopgeninfo>. The regulations require that products labeled: "100% organic" contain only organic ingredients. 7 C.F.R. § 205.102, 205.303 (2010). "Organic" contain at least 95% organic materials. 7 C.F.R. §205.303. Products in this or the first category can (but are not required to) display the USDA Organic seal. *Id.* "Made with organic ingredients" contain 70% to 95% organic ingredients and may list up to three of them. 7 C.F.R. § 205.309. Products with less than 70% organic ingredients may not use the term organic other than to list specific organic ingredients. 7 C.F.R. § 205.305.

98. *Beyond Organic: How Evolving Consumer Concerns Influence Food Purchases*, CONTEXT MARKETING 4 (Oct. 2009), <http://www.contextmarketing.com/foodissuesreport.pdf>.

99. *Id.*

100. *Where Organic Ends and Natural Begins*, HARTMAN GROUP (2010), <http://www.hartman-group.com/hartbeat/where-organic-ends-and-natural-begins>. While 66% of respondents associated

1,006 consumers in 2009, 31% of respondents said “100% natural” is the most desirable eco-friendly product label claim, compared to 14% who chose “100% organic.”¹⁰¹ A majority of respondents in a 2010 poll erroneously believed the term “natural” implied “absence of pesticides,” “absence of herbicides,” and “absence of genetically modified foods.”¹⁰² The FDA has acknowledged that “[t]he word ‘natural’ is often used to convey that a food is composed only of substances that are not manmade and is, therefore, somehow more wholesome.”¹⁰³ These surveys show that marketing of “natural” food has been successful; however, the value of these products has been skewed due to a lack of consistency in the term’s use across a wide variety of products that do not meet a discernable standard. The term is used on products such as SunChips, Snapple Juice Drinks, and Tyson Chicken Wings.¹⁰⁴

B. Controversy in the Courts

Although the FDA’s, USDA’s, and FTC’s enforcement of misleading “natural” claims has been limited, food company practices may be swayed by a wave of lawsuits filed in recent years. Most of these cases allege that “all natural” marketing claims violate state consumer protection statutes that proscribe false and misleading advertising. The cases generally target four categories of products: products containing high fructose corn syrup (HFCS), products containing genetically modified organisms (GMOs), products containing artificial preservatives, and products processed with chemicals or containing other unnatural ingredients.¹⁰⁵ Each of the lawsuits alleges that the defendants are able to charge a premium for their products because the “all natural” claims falsely lead consumers to believe the products do not contain these substances.

For example, since 2007, class action lawsuits have been filed against the makers of AriZona beverages,¹⁰⁶ Snapple Beverage Corp.,¹⁰⁷ ConAgra Healthy

“organic” foods with no artificial flavors/color/preservatives, 73% associated “natural” foods with an absence of these additives. *Id.*

101. Press Release, The Shelton Grp., National Survey: Green Is Officially Mainstream- But Consumers are Confused, Skeptical About Products, (June 29, 2009), *available at* http://www.sheltongroupinc.com/press/ecopulse/press_releases/EcoPulseNewsReleaseNaturalvOrganic.pdf.

102. HARTMAN GROUP, *supra* note 100.

103. Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60,466 (Nov. 27, 1991).

104. *See* Mike Esterl, *Can This Chip Be Saved?*, WALL ST. J., Mar. 24, 2011, *available at* <http://online.wsj.com/article/SB10001424052748704050204576218492608111416.html>; SILVERGLADE & HELLER, *supra* note 88, at Part X-3 to X-5.

105. *See* Dawn Goulet, *Confusion in Court Over “All Natural” Claims*, AM. BAR ASS’N (Apr. 30, 2012), <http://apps.americanbar.org/litigation/committees/classactions/articles/spring2012-0412-all-natural-labels-mean-marketing.html>.

106. *Coyle*, 2011 WL 2147218, at *1. Plaintiff, representing a putative class action, sued Hornell Brewing and Arizona Beverage Company for “deceptive business practices” because they labeled their products “natural” although they contained high fructose corn syrup (“HFCS”).

107. *Holk v. Snapple Beverage Corp.* 574 F.Supp.2d 447 (D.N.J. 2008). On behalf of a proposed nationwide class, the plaintiffs asserted causes of action for violation of New Jersey’s consumer-fraud act, breach of express and implied warranty, and unjust enrichment. *Id.* at 448-49; *see also* *Weiner v. Snapple Beverage Corp.*, No. 07-Civ.-8742, 2011 WL 196930 (S.D.N.Y. Jan. 21, 2011). On behalf of a

Choice pasta sauces,¹⁰⁸ and General Mills Nature Valley products¹⁰⁹ for advertising their products as "100% Natural" when they contained HFCS. Specifically, the Snapple class action complaint alleged that HFCS is "a highly processed sugar substitute that does not exist in nature."¹¹⁰ On behalf of a nationwide class, the plaintiffs in these cases asserted causes of action for violations of state consumer protection acts, breach of express and implied warranty, and unjust enrichment.

The most recent wave of lawsuits has been filed against companies whose products contain GMOs and are advertised as "all natural." For example, class action lawsuits have been filed against General Mills, alleging the company engaged in a widespread marketing campaign to mislead consumers about the nature of the ingredients in its Kix cereals,¹¹¹ against Frito-Lay and Pepsico claiming that the companies' Tostitos and SunChips products were not "made with all natural ingredients" because the corn and oils used to make them were made from genetically modified plants,¹¹² and similarly, against ConAgra Foods, alleging that the inclusion of genetically modified corn and soy in the Wesson line of cooking oils disqualifies its labeling as "all-natural."¹¹³ Most recently, a lawsuit was filed against Pepperidge Farm, Inc., alleging that the company misleads consumers by labeling its Cheddar Goldfish crackers "natural" because they

class of New York purchasers, the complaint asserted claims for violations of New York's deceptive trade practices act, unjust enrichment, and breach of express and implied warranties. Goulet, *supra* note 105. On January 21, 2011, the court granted Snapple's motion for summary judgment, finding the plaintiffs had failed to show that they had paid a premium for the "all natural" label on Snapple beverages. *Id.*

108. *Lockwood v. ConAgra Foods, Inc.*, 597 F.Supp.2d 1028 (N.D. Cal. 2009). The complaint asserted claims for unlawful and deceptive business acts and practices, false advertising, injunctive relief, and restitution on behalf of a class of California consumers. Goulet, *supra* note 105. The parties reached an undisclosed settlement. *Id.*

109. Complaint at 1, *McKendrick v. General Mills*, No. 12-CV-3919 (N.D. Cal. filed July 26, 2012). The complaint alleged violations of California's Unfair Competition Law, False Advertising Law, and unjust enrichment. *Id.*

110. See Goulet, *supra* note 105. As the Center for Science in the Public Interest (CSIP) explains in its report, "[h]igh fructose corn syrup is made through a complex chemical industrial process in which cornstarch molecules are chemically or enzymatically degraded to glucose and oligosaccharides, and then some of the glucose molecules are converted to fructose." SILVERGLADE & HELLER, *supra* note 88, at X-2 to X-3

111. *Lewis v. General Mills, Inc.*, No. BC472451 (Cal. Super. Ct., Los Angeles Co. filed Oct. 28, 2011). The lawsuit alleged that General Mills was able to command a premium for its cereals by deceiving customers into believing they are made with "All Natural Corn," when the corn used in the cereals is actually derived from genetically modified plants. Goulet, *supra* note 105. The plaintiffs asserted claims for unlawful, unfair, and fraudulent business practices; deceptive advertising; and breach of express and implied warranties under California law. *Id.*

112. *Shake v. Frito-Lay North America, Inc.*, No. 12-CV-408 (E.D.N.Y. filed Jan. 27, 2012). On behalf of a nationwide class, the plaintiffs asserted causes of action for violations of New York's consumer-fraud and false-advertising laws and breach of express warranty. Goulet, *supra* note 105.

113. Complaint and Demand for Jury Trial, *Briseno v. ConAgra Foods, Inc.*, No. CV11-05379 (C.D. Cal. filed June 28, 2011). The plaintiff alleged breach of express warranty along with claims under California's false advertising law ("FAL"), California's unfair competition law ("UCL"), and California's Consumer Legal Remedies Act ("CLRA"). *Id.*

contain GMOs.¹¹⁴ Although the FDA does not recognize any meaningful difference between GMOs and foods developed by traditional plant breeding, and therefore does not require labeling of GMOs,¹¹⁵ these lawsuits allege that GMOs are inherently unnatural. To support this allegation, several of the lawsuits cite to bioengineering corporation Monsanto's own definition of GMOs, as "[p]lants or animals that have had their genetic makeup altered to exhibit traits *that are not naturally theirs*. In general, genes are taken (copied) from one organism that shows a desired trait and transferred into the genetic code of another organism."¹¹⁶

Several other lawsuits have been filed against companies whose products are labeled "natural" but contain artificial ingredients and preservatives. For example, consolidated complaints against Kashi and Kellogg's alleged that these companies cultivated a wholesome and healthful image by promoting their products as "all natural" or containing "nothing artificial," when the products contained substances like ascorbic acid, calcium pantothenate, calcium phosphates, potassium carbonate, pyridoxine hydrochloride, sodium acid pyrophosphate, sodium phosphates, tocopherols, and/or xanthum gum.¹¹⁷ Class-action lawsuits have been filed against Ben & Jerry's Homemade, Inc. on behalf of consumers who purchased Ben & Jerry's "all natural" ice cream products containing alkalized cocoa,¹¹⁸ against Bear Naked, Inc., alleging that the company's products labeled "100% Pure & Natural" actually contain synthetic ingredients such as potassium carbonate, glycerin, and lecithin,¹¹⁹ and against South Beach Beverage Co. and Pepsico alleging that the companies market their SoBe beverages as "all natural" when they do not contain juice from any of the fruits described in their names and contain substances created by chemical processing, including ascorbic acid, cyanocobalamin, calcium

114. Class Action Complaint, *Bolerjack v. Pepperidge Farm, Inc.*, No. 12-2918 (D. Colo. filed Nov. 6, 2012). The plaintiff alleged a violation of Colorado's Consumer Protection Act, breach of express warranty and negligent misrepresentation. *Id.*

115. See *Statement of Policy: Foods Derived from New Plant Varieties*, 57 *Fed. Reg.* 22984 (May 29, 1992); *Guidance for Industry Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Draft Guidance, FDA* (Jan. 2001), <http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/foodlabelingnutrition/ucm059098.htm>.

116. See Complaint and Demand for Jury Trial, *Briseno v. ConAgra Foods, Inc.*, No. CV11-05379 (C.D. Cal. filed June 28, 2011); *Glossary, MONSANTO* <http://www.monsanto.com/newsviews/Pages/glossary.aspx#g> (last visited Mar. 28, 2013) [emphasis added].

117. *Bates v. Kashi Co.*, No. 11-CV-1967 (S.D. Cal. filed Aug 24, 2011). The plaintiffs asserted claims for violation of the Magnuson Moss Warranty Act; false advertising; unlawful, unfair, and fraudulent business practices; and common-law fraud under California law. Goulet, *supra* note 105.

118. *Astiana v. Ben & Jerry's Homemade, Inc.*, No. 10-CV-4387 (N.D. Cal. filed Sept. 29, 2010). The complaint asserted claims for unlawful, unfair, and fraudulent business practices; deceptive advertising; and unjust enrichment under California law. Goulet, *supra* note 105. According to the complaint, alkalized cocoa is "a non-natural processed ingredient" containing "potassium carbonate, a man made, synthetic ingredient." *Id.*

119. *Thurston v. Bear Naked, Inc.*, No. 11-CV-4678 (N.D. Cal. filed Sept. 21, 2011). On behalf of a nationwide class, the plaintiffs asserted causes of action for common-law fraud; unfair, unlawful, and deceptive business practices; false advertising; and unjust enrichment under California law. Goulet, *supra* note 105.

pantothenate, niacinamide, and pyridoxine hydrochloride.¹²⁰ More recently, lawsuits allege that Jamba Juice mislabeled its smoothie kits "all natural" when they contain "unnaturally processed, synthetic and/or non-natural ingredients" including ascorbic acid, citric acid, xanthan gum, and steviol glycosides,¹²¹ and that Hansen's Diet Sodas with "all natural flavors" are misbranded because they contain artificial sweeteners.¹²²

IV. ACHIEVING A UNIFIED AND COMPREHENSIVE DEFINITION

In the absence of agency action, consumers have attempted to influence the food industry by filing lawsuits alleging misleading advertising and labeling of "natural" products, and the food industry is attempting to prevent inconsistent use of the term by proposing self-regulation. For example, the Natural Products Association (NPA)¹²³ is developing standards for use of the word "natural" in food marketing to "give consumers confidence that foods featuring the seal adhere to a clear set of standards."¹²⁴ Although a detailed discussion of the merits of "natural" food lawsuits and self-regulation proposals¹²⁵ are beyond the scope of this essay, these efforts signal demand for a uniform, consistent definition of the term. To achieve this, the FDA and USDA should adopt unified, formal regulations governing use of the "natural" claim. The following is an overview of the key points that should inform the development of a uniform and effective "natural" policy.

Although the USDA has been praised for providing a more specific policy statement regarding "natural," its task is easier than the FDA's. The USDA regulates only 20% of the food supply, and most of its products (meat, poultry, and processed eggs) contain only a single ingredient.¹²⁶ Meanwhile, 80% of the U.S. food supply, which equates to \$417 billion worth of domestic food and \$49 billion worth of imported foods,¹²⁷ is regulated by the FDA. These products vary considerably, and include fresh fruits and vegetables, dairy, baked products,

120. *Hairston v. S. Beach Beverage Co.*, No. 12-CV-1429 (C.D. Cal., filed Feb. 21, 2012). The case asserts, on behalf of a California class, causes of action for false advertising and unlawful, unfair, and deceptive trade practices under California law. Goulet, *supra* note 105.

121. *Anderson v. Jamba Juice Co.*, No. 12-CV-01213 (N.D. Cal. filed Mar. 12, 2012).

122. *Viggiano v. Hansen Natural Corp.*, No. 12-CV-10747 (C.D. Cal. filed Dec. 17, 2012).

123. Founded in 1936, the Natural Products Association is the nation's largest and oldest nonprofit organization dedicated to the natural products industry. NPA represents over 1,900 members accounting for more than 10,000 retail, manufacturing, wholesale, and distribution locations of natural products, including foods, dietary supplements, and health/beauty aids. *About the Natural Products Association*, NATURAL PROD. ASS'N, http://www.npainfo.org/NPA/About_NPA/NPA/AboutNPA/AbouttheNaturalProductsAssociation.aspx?hkey=8d3a15ab-f44f-4473-aa6e-ba27ccebcb8 (last visited Feb. 10, 2013).

124. Elaine Watson, *NPA Weighs Into 'Natural' Debate as Natural Seal Initiative for Food Gathers Pace*, NUTRA INGREDIENTS-USA (Nov. 7, 2011), <http://www.nutraingredients-usa.com/Regulation/NPA-weighs-into-natural-debate-as-Natural-Seal-initiative-for-food-gathers-pace>.

125. Self-regulation of the food industry's use of "natural" claims will be discussed in a forthcoming article.

126. See *FDA, USDA, NOAA Statements on Food Safety*, FDA (2011), <http://www.fda.gov/newsevents/publichealthfocus/ucm248257.htm>.

127. *2012 Annual Report on Food Facilities, Food Imports, and FDA Foreign Offices*, FDA (Aug. 2012), <http://www.fda.gov/Food/FoodSafety/FSMA/ucm315486.htm>.

seafood, etc.¹²⁸

The oversight of labeling by the FDA and USDA also differs. Although the USDA pre-approves labels on foods under its jurisdiction, the FDA does not. Therefore, it is much more likely that misleading “natural” claims on USDA products would never reach store shelves. Because the FDA regulates a significant percentage of the nation’s food supply, does not pre-approve labels, oversees a vastly more varied assortment of products, and has a more vague “natural” policy, the following discussion will focus on reforms to be undertaken by the FDA.

A. Processing of the Food Product

The FDA’s informal policy states that “natural” means merely “that nothing artificial or synthetic (including colors regardless of source) is included in, or has been added to, the product that would not normally be expected to be there.”¹²⁹ This policy fails to address the effect processing and other recent food technology advances have on the “naturalness” of the food. In contrast, the USDA’s policy defines “natural” as meaning that “(1) the product does not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative (as defined in 21 CFR 101.22), or any other artificial or synthetic ingredient; and (2) the product and its ingredients *are not more than minimally processed*.”¹³⁰ The USDA further explains what constitutes “minimal processing.”¹³¹ As the Sugar Association has advocated, the FDA should amend and formalize its policy to include not only what it means for an ingredient to be “natural,” but also whether certain processes render the product *unnatural*. This would help to harmonize the FDA and USDA policies.

Although a substance can be found in nature, it should not qualify for a “natural” claim when manufactured by extraordinary processing means that divorce a product from its naturally occurring state.¹³² This approach has been adopted by several other countries. For example, the Canadian Food Inspection Agency defines “natural” to include a list of processes that do or do not alter food significantly enough to affect its labeling as “natural.”¹³³ Canada uses two

128. FDA, *supra* note 126.

129. Food Labeling: Nutrient Content Claims, General Principles Petitions, Definition of Terms, 56 Fed. Reg. 60,421, 60,466 (proposed Nov. 27, 1991) (to be codified at 21 C.F.R. pts. 5, 101, and 105).

130. *Labeling Policy Book*, *supra* note 58 (emphasis added).

131. According to the USDA, “minimal processing” refers to “those traditional processes used to make food edible or to preserve it or to make it safe for human consumption, e.g., smoking, roasting, freezing, drying, and fermenting, or (b) those physical processes which do not fundamentally alter the raw product and/or which only separate a whole, intact food into component parts, e.g., grinding meat, separating eggs into albumen and yolk, and pressing fruits to produce juices.” *Id.*

132. See *Sugar Ass’n Petition*, *supra* note 9, at 7. The petition discusses the National Advertising Division (NAD) of the Council of Better Business Bureau “Tom’s of Maine” case (No. 3470 June 1, 1998) in which NAD concluded that it was misleading for Tom’s of Maine to advertise its product as natural. A competitor of the manufacturer had questioned whether the product was natural based on one of the product’s ingredients. *Id.* While Tom’s of Maine argued that the ingredient in question existed in nature, the assertion was found to be misleading because the ingredient in question underwent extensive processing to obtain the final product.” *Id.*

133. Canada has two requirements for “natural” food: “A “natural” food or ingredient of a food is not expected to contain, or to ever have contained, an added vitamin, mineral nutrient, artificial flavoring agent or food additive. A “natural” food or ingredient of a food does not have any constituent or fraction thereof removed or significantly changed, except the removal of water.” *Chapter 4-*

processing standards to help define "natural." Simply put, food created through processing that has a minimum alteration effect is considered to be "natural" food, and food created through processing that has a maximum alteration effect is considered unnatural.¹³⁴ Israel similarly adheres to a list of processes that may be used to generate "natural" food.¹³⁵ The United Kingdom's Food Standards Agency¹³⁶ developed regulations for applying the term "natural" to food.¹³⁷ Like the standards developed by Canada and Israel, the U.K.'s definition of "natural" refers to the use of certain permissible food processes.¹³⁸

B. HFCS, GMOs, and Preservatives: Understanding Consumer Expectations

Furthermore, as the lawsuits discussed above illustrate, the current FDA and USDA policies are deficient in dealing with food technologies that have become mainstream since the 1980s and 1990s, when these policies were established. Therefore, a comprehensive and effective "natural" policy must address the "naturalness" of HFCS,¹³⁹ GMOs,¹⁴⁰ and preservatives. To shape the definition and resulting policy, both agencies should undertake rulemaking that focuses on consumer expectations. The FDA, in considering "natural" to mean "that nothing artificial or synthetic (including colors regardless of source) is included in, or has been added to, the product *that would not normally be expected to be there*,"¹⁴¹ has recognized the importance of consumer expectation to the inquiry of whether a "natural" label is misleading. Therefore, what a consumer would reasonably

Composition, Quality, Quantity, and Origin Claims, 4.7 *Nature, Natural*, CAN. FOOD INSPECTION AGENCY (Nov. 15, 2012), <http://www.inspection.gc.ca/english/fssa/labeti/guide/ch4ae.shtml>.

134. *Id.*

135. Gilad Shachar, *Food and Agricultural Import Regulations and Standards- Narrative*. FAIRS Country Report, USDA FOREIGN AGRIC. SERV. (July 26, 2010), http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Food%20and%20Agricultural%20Import%20Regulations%20and%20Standards%20-%20Narrative_Tel%20Aviv_Israel_7-26-2010.pdf [hereinafter *GAIN Report*]. Israel's definition of "natural" is: "[A] single food product or its fragment, which is not a blend of foods, which is free of additional ingredients and which has not passed different processes from the processes [this list considers natural]." *Id.*

136. *About Us*, FOOD STANDARDS AGENCY, (Dec. 9, 2010), <http://collections.europarchive.org/tna/20101209122142/http://www.food.gov.uk/aboutus/>.

137. *Criteria for the use of the terms Fresh, Pure, Natural etc.*, FOOD STANDARDS AGENCY 15-19 (July 2008), <http://www.food.gov.uk/multimedia/pdfs/markcritguidance.pdf>.

138. *Id.* The definition for "natural" is: "[A] single ingredient or compound food to which nothing non- "natural" is added. *Id.* at 19. It also is "[n]ot interfered with by man by use of chemicals; [n]ot interfered with by man by use of technology or not normally consumed by man; [n]ot interfered with by man in that treated only with processes that are traditionally used in food preparation, including fermentation. *Id.*

139. See Schlosser, *supra* note 84 (arguing that the FDA should ban use of HFCS in food and beverages labeled "natural").

140. See Erik Benny, "Natural" Modifications: The FDA's Need to Promulgate an Official Definition of "Natural" That Includes Genetically Modified Organisms, 80 GEO. WASH. L. REV. 1504 (2012) (arguing that the FDA's definition of "natural" should permit foods produced from GMOs to be labeled as "natural").

141. Food Labeling: Nutrient Content Claims, General Principles Petitions, Definition of Terms, 56 Fed. Reg. at 60,466 (emphasis added).

expect to be “natural” should be considered when devising the definition.¹⁴² A California district court recently highlighted this issue in a class action lawsuit against Dreyer’s Grand Ice Cream.¹⁴³ The court refused to dismiss state law claims alleging that Haagen-Dazs ice cream was falsely advertised as “All Natural Ice Cream,” although it contained cocoa alkalized with potassium carbonate, a substance alleged to be artificial or synthetic.¹⁴⁴ Among other things, Dreyer’s argued that “because potassium carbonate is commonly used as an alkalizing agent . . . nothing artificial or synthetic has been used in its ice cream.”¹⁴⁵ The court found this argument problematic: “even if potassium carbonate is commonly used, that does not necessarily mean that a reasonable consumer would expect it to be used—*i.e.*, normally used does not necessarily imply normally expected; a reasonable consumer may not have the same knowledge as, *e.g.*, a commercial manufacturer.”¹⁴⁶ Likewise, the FDA should clarify that the presence of an artificial, synthetic, or heavily processed substance is compatible with a “natural” claim only if one can demonstrate that *consumers* normally expect the substance to be present.¹⁴⁷

C. Detailed Criteria or More Descriptive Labels

To deal with the variety of products regulated by the FDA, the Agency could create detailed criteria for different types of products, such as dairy, fruits and vegetables, grain products, main dishes, seafood, and miscellaneous products.¹⁴⁸ Alternatively, the Agency could implement a policy similar to that of the USDA, which requires that the use of the term “natural,” be “accompanied by a brief statement . . . explain[ing] what is meant by the term,” and providing additional guidance regarding what forms of processing are too “severe” to be considered minimal.¹⁴⁹ Therefore, in the absence of a formal definition, the FDA should require companies to qualify all “natural” claims by explaining how the company defines “natural” and how the product meets the criteria. If a label will be used, it must be explained in detail so that consumers cannot misunderstand the claim. By requiring such clarification, “natural” will be understood in its particular context (*i.e.*—the particular product and the other information on the label).

142. Haagen-Dazs has attempted to focus on consumer expectations in formulating its “natural” Haagen-Dazs 5 ingredient ice cream. See Kampffmeyer Food Innovation, *supra* note 5 at 68-69 (quoting Laura Blue, *Why? Why did Haagen Dazs Want to Launch Five?*, TIME HEALTHLAND (Aug. 7, 2009), <http://healthland.time.com/2009/08/07/simple-ingredients/>). The company has adopted a policy called “kitchen friendly” which means they do not use ingredients that would not be found in a consumer’s “well-stocked home pantry.” *Id.*

143. *Astiana v. Dreyer’s Grand Ice Cream, Inc.*, Nos. C-11-2910 EMC, C-11-3164 EMC, 2012 WL 2990766 (N.D. Cal. July 20, 2012).

144. *Id.* at *11.

145. *Id.*

146. *Id.*

147. *Id.*

148. See April L. Farris, *The “Natural” Aversion: The FDA’s Reluctance to Define a Leading Food-Industry Marketing Claim, and the Pressing Need For a Workable Rule*, 65 FOOD & DRUG L.J. 403, 421-22 (2010) (proposing that the FDA create different standards for different food categories, as it did for “healthy” claims).

149. *Labeling Policy Book*, *supra* note 58.

V. CONCLUSION

As demand for "natural" products continues to grow, survey results and recent lawsuits evidence the frustration of consumers and food manufacturers. Both groups are calling for a uniform, clear, and enforceable "natural" food policy. Unless the FDA and USDA attempt to resolve the controversy regarding "natural" products by accounting for innovative food processing techniques, consumer expectations, HFCS, GMOs, and preservatives, the courts or manufacturers will ultimately decide what "natural" means. However, such an outcome will not resolve the inconsistent use or confusion regarding this term. Despite the costs and challenges, the FDA and USDA have the statutory mandate and expertise to codify the term's meaning, identify conditions of its use, and specify labeling requirements for "natural" claims.