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100% ALL NATURAL AMBIGUITY: A COMPARATIVE APPROACH TO FOOD LABELING REQUIREMENTS FOR THE TERM “NATURAL” BY THE FOOD AND DRUG ADMINISTRATION AND THE EUROPEAN UNION

In his best-selling book, *In Defense of Food: An Eater's Manifesto*,¹ Michael Pollan invites the reader to embrace the eating habits of our grandparents. In a criticism of complicated and difficult-to-interpret food labels, Pollan argues, “Imagine your grandmother or your great-grandmother picking up this tube, holding it up to the light . . . and then imagine her reading the ingredients. Yogurt is a very simple food. It’s milk inoculated with a bacterial culture. But Go-Gurt has dozens of ingredients.”² Consider the nutritional list of Go-Gurt,³ Orville Redenbacher’s Popcorn,⁴ Del Monte Fruit Naturals,⁵ Alexia Sweet Potatoes Fries,⁶ and Kraft Natural Cheese⁷ for a moment. All five of these food products share one common label on their packaging: “natural.” Across the market, “natural” is one of the most popular terms used on

1 MICHAEL POLLAN, *IN DEFENSE OF FOOD: AN EATER’S MANIFESTO* 148 (2009).

2 *Talk of the Nation: Author Comes to Natural Food’s ‘Defense,’* NAT’L PUB. RADIO (Jan. 4, 2008), <https://www.npr.org/templates/story/story.php?storyId=17850369>; see also Pollan, *supra* note 1.

3 *Yoplait® Simply Go-Gurt® Yogurt Single Serve Tube Strawberry 2oz*, GENERAL MILLS, <https://www.generalmills.com/products/category/yogurt/yoplait-portable/go-gurt-strawberry> (last visited Oct. 31, 2018).

4 *Orville Redenbacher’s Microwave Popcorn, Naturals, Simply Salted*, SMARTLABEL PRODUCT SEARCH, <http://smartlabel.orville.com/product/4389550/nutrition> (last visited Oct. 31, 2018).

5 Andrea Rock, *Peeling Back the “Natural” Food Label*, CONSUMER REPORTS (Jan. 29, 2016), <https://www.consumerreports.org/food-safety/peeling-back-the-natural-food-label/>.

6 *Id.*

7 *Id.*

product labeling for food products and beyond.⁸ Americans spend over \$40 billion dollars on “natural” food products each year, making it clear that consumer demand for “natural” foods is strong.⁹

But what does “natural” mean? No one is quite sure.¹⁰ “Natural” seems to evoke health and wellness, an image that American consumers clearly respond well to.¹¹ And yet, both consumers and manufacturers are puzzled as to what “natural” really means, because the Food and Drug

8 Nicole E. Negowetti, *A National “Natural” Standard for Food Labeling*, 65 ME. L. REV. 581, 582 (2013); see also Press Release, PR Newswire, New Mintel data highlights most frequent on-package claims for new products in the food and beverage industry (June 11, 2012) (available at <https://www.prnewswire.com/news-releases/new-mintel-data-highlights-most-frequent-new-product-on-package-claims-in-food--beverage-industry-158486945.html>).

9 Alan Levinovitz, *What is ‘Natural’ Food? A Riddle Wrapped in Notions of Good and Evil*, NAT’L PUB. RADIO (May 8, 2016), <https://www.npr.org/sections/thesalt/2016/05/08/477057872/what-is-natural-food-a-riddle-wrapped-in-notions-of-good-and-evil>; see also Mary Avant, *Consumers Care More About Natural Foods Than Organic*, QSR Magazine (Aug. 22, 2013), <https://www.qsrmagazine.com/news/consumers-care-more-about-natural-foods-organic> (noting that consumers are more likely to purchase a “natural” product versus an “organic” one partially because “organic” has become “watered-down” as a labeling term).

10 See Chase Purdy, *No One Knows What the Words “Healthy” or “Natural” Mean in Food-Including the US Government*, QUARTZ (Sept. 28, 2016), <https://qz.com/793639/no-one-knows-what-the-words-healthy-or-natural-means-in-food-including-the-us-government/> (noting that the FDA has been recently investigating and working on new definitions for both “natural” and “healthy” terms); see also Rock, *supra* note 5. In its 2015 survey, the Consumer Reports National Research Center discovered that two-thirds of the adults surveyed incorrectly believed that the “natural” term referred to something more than what the term actually means. The survey also demonstrated that almost half of the 1,005 individuals falsely believed that the “natural” label on food packaging is independently verified. When asked about what the term should mean, an overwhelming 85% reported “[n]o chemicals were used during processing,” “84% No artificial ingredients or colors,” “84% No toxic pesticides,” “82% No GMOs,” and “87% of shoppers who buy foods labeled ‘natural’ said they would pay more if the term met all of their expectations.” *Id.*; see also Michael Pollan, *Why ‘Natural’ Doesn’t Mean Anything Anymore*, N.Y. TIMES (Apr. 28, 2015), <https://www.nytimes.com/2015/05/03/magazine/why-natural-doesnt-mean-anything-anymore.html>. Mr. Pollan argues that “any food product that feels compelled to tell you it’s natural in all likelihood is not,” instead preferring a common sense-based approach to “natural.” *Id.*

11 *Healthy, “Natural” and the FDA: A Definition Problem. We’ve seen this Before*, HARTMAN GROUP (May 24, 2016) [hereinafter HARTMAN GROUP], <https://www.hartman-group.com/hartbeat/651/healthy-natural-and-the-fda-a-definition-problem-we-ve-seen-this-before->

Administration has not formally defined the term “natural” despite having the power to establish definitions for food product labeling.¹² In the absence of a formal definition for the term or its derivatives,¹³ consumers have turned to class action lawsuits against corporations such as Arizona Beverages¹⁴ and Nature Valley¹⁵ for misleading consumers through deceptive labels.¹⁶

Food labeling requirements function as a critical guide between the consumer and the producer. They mandate guidelines for when producers may use a certain term on their products, protect the consumer from misleading claims, and ultimately empower consumers with accurate and appropriate labels to make informed choices when purchasing and consuming a product. However, these requirements must be clear and specific in order to accomplish these goals. A company needs to be able to understand the requirements, and a consumer needs to be able to trust that the claims on the products accurately reflect their content.

This Note will examine the term “natural” by comparing the different approaches to the food labeling requirements in the United States through

12 *Id.*

13 See Lesley Fair, *Are Your “All Natural” Claims All Accurate?*, FED. TRADE COMM’N: BUS. BLOG (Apr. 12, 2016), <https://www.ftc.gov/news-events/blogs/business-blog/2016/04/are-your-all-natural-claims-all-accurate>. Throughout this Note, derivatives of “natural” refers to “all-natural,” “100% natural,” and similar variations to the term; see also Caitlin Dewey, *The Raging Legal Battle Over What Makes a Food ‘Natural,’* WASH. POST. (Aug. 30, 2017), https://www.washingtonpost.com/news/wonk/wp/2017/08/30/the-raging-legal-battle-over-what-makes-a-food-natural/?utm_term=.f9050e122701.

14 See Anthony J. Anscombe & Mary Beth Buckley, *Jury Still Out on the ‘Food Court’: An Examination of Food Law Class Actions and the Popularity of the Northern District of California*, BLOOMBERG BNA (June 28, 2013), <https://www.bna.com/jury-still-out-on-the-food-court/?amp=true>.

15 See *Janney v. Mills*, 944 F. Supp. 2d 806, 817 (N.D. Cal. 2013) (citing the consumer-plaintiffs’ allegation that General Mills “falsely represented that its Nature Valley® products are ‘All Natural’ or ‘100% Natural,’ despite knowing that they contain processed sweeteners”).

16 See HARTMAN GROUP, *supra* note 11.

the Food and Drug Administration (“FDA”)¹⁷ and in the European Union (“EU”).¹⁸ First, it will examine the origins of each body and early shortcomings. Then it will outline the current state of the regulations and the general public response to labeling requirements and legislation.

From there, it will argue that the FDA’s requirements are too generic to protect consumers and effectively guide producers on standards for their products.¹⁹ The FDA should issue a final definition for “natural” and its derivatives²⁰ to standardize the term for consumers and manufacturers. The FDA’s reluctance to fully define the term only halts further progress on consumer protection and public health. A functional and enforceable definition of “natural” would ensure that consumers have more knowledge of products and can make more informed decisions. Further, consumers could be more confident in their purchases and trust companies more that the labels on the products are accurate and appropriate based on FDA requirements. A final ruling on the definition would also serve to reduce the number of class action lawsuits that have stemmed from consumer and many food corporations’ confusion surrounding labeling requirements for “natural.”

This Note will examine two critical problems with the FDA’s approach, especially compared to that of the EU and its member states: (1) mounting litigation without federal preemption that results in increasing class action lawsuits from frustrated consumers²¹ and (2) growing distrust

17 *See infra* Part I.

18 *See infra* Part II.

19 *See infra* Part III. The FDA’s reluctance to establish a definition has forced consumers to turn to the judicial system for remedies and relief.

20 *See Fair, supra* note 13.

21 *Id.*

of both the FDA and American food manufacturers.²² While this Note will refrain from offering a formal definition for the term “natural,” it will explore crucial components of EU member states’ approach to food product labeling and suggest key elements of European agencies’ definitions for the FDA to consider when issuing a final rule.

I. FOOD LABELING REQUIREMENTS IN THE UNITED STATES THROUGH THE FDA

A. *Colonial Origins to the Pure Food and Drug Act of 1906*

Food labeling practices in the United States have existed in some form since colonial times²³ but became more common in the early twentieth century with the onset of greater production technology and transportation advances during the Industrial Revolution.²⁴ This change increased consumer access to products and pre-packaged foods and allowed for greater distribution of goods.²⁵ Out of necessity, producers began to mark their products as a way of identifying the product as their own and

22 See Marc T. Law & Gary D. Libecap, The Determinants of Progressive Era Reform: The Pure Food and Drugs Act of 1906, in *CORRUPTION AND REFORM: LESSONS FROM AMERICA'S ECONOMIC HISTORY* 319, 331 (Edward L. Glaeser & Claudia Goldin, eds., 2006).

23 Marc T. Law, *History of Food and Drug Regulation in the United States*, EH.NET ENCYCLOPEDIA (Oct. 11, 2004), <http://eh.net/encyclopedia/history-of-food-and-drug-regulation-in-the-united-states/> (“These regulations were generally targeted toward specific food products. For instance, in 1641 Massachusetts introduced its first food adulteration law, which required the official inspection of beef, pork and fish; this was followed in the 1650s with legislation that regulated the quality of bread.”).

24 See Mira Wilkins, *When and why brand names in food and drink?*, in *ADDING VALUE: BRANDS AND MARKETING IN FOOD AND DRINK* 15, 18 (Geoffrey Jones & Nicholas J. Morgan eds., 1994). While the labeling was not necessary when consumers purchased their food fresh and directly from the local shopkeeper or farmer, a label or marker became more necessary when producers sold items in bulk or to distant consumers. Previously, consumers formed a personal relationship with food producers by exclusively purchasing weekly goods from local farmers and shopkeepers. *Id.*

25 *Id.* at 17.

drawing a distinction between their goods with those of their competitors.²⁶

Absent legislation and regulation on food production, food manufacturers had free rein to include whatever they wanted in the goods without having to include any labeling information, creating an asymmetry of information.²⁷ While this posed many increasing public health concerns for consumers, food manufacturers enjoyed this privilege for several years without the federal government's intervention because states still controlled food-related issues until the beginning of the twentieth century.²⁸ Although large food manufacturers strongly resisted government interference and food laws,²⁹ a well-publicized series of reports and publications, known as the Shattuck Report, increased awareness of the health risks associated with adulterated foods,³⁰ propelling public health legislation throughout the end of the nineteenth century and beyond.³¹

26 *Id.* at 18. These advances simultaneously increased food access and destroyed the direct relationship between a food producer and his consumer.

27 Marc C. Sanchez, *Understanding the Ancestry of the Food Safety Modernization Act*, FOODSAFETY MAGAZINE (Aug./Sept. 2011), <https://www.foodsafetymagazine.com/magazine-archive1/augustseptember-2011/understanding-the-ancestry-of-the-food-safety-modernization-act/>.

28 INST. OF MED.: COMM. ON STATE FOOD LABELING, FOOD LABELING: TOWARD NATIONAL UNIFORMITY 41 (Donna V. Porter & Robert O. Earl, eds., 1992).

29 MELANIE WARNER, PANDORA'S LUNCHBOX: HOW PROCESSED FOOD TOOK OVER THE AMERICAN MEAL 26 (Scribner 2013). Food companies' resistance to any government regulations related to the food industry is best noted in an appearance by a representative for one large food distribution company before the House Committee on Interstate and Foreign Commerce where the official famously declared that forcing producers to "call [their] products by the right name . . . [would] bankrupt every food industry in the county." *Id.*

30 INST. OF MED.: COMM. ON STATE FOOD LABELING, *supra* note 28, at 37; *see also* LEMUEL SHATTUCK ET AL., REPORT OF THE SANITARY COMMISSION OF MASSACHUSETTS (Harvard Univ. Press 1948) (1850).

31 PUBLIC HEALTH: THE DEVELOPMENT OF A DISCIPLINE, FROM THE AGE OF HIPPOCRATES TO THE PROGRESSIVE ERA 207 (Dona Schneider & David E. Lilienfeld eds., 2008).

As a final push to persuade the United States government to pass these regulations, notable critics and muckrakers³² such as Upton Sinclair in his 1906 book, *The Jungle*,³³ increased public awareness to common food producers' poor hygienic conditions and production methods. Several months after publication, *The Jungle*'s graphic and horrific account of meatpacking conditions³⁴ pressured the federal government to finalize food production and mislabeling laws, resulting in the passage³⁵ of the Pure Food and Drug Act of 1906³⁶ ("the Act") and the Meat Inspection Act.³⁷ While the Act only prevented mislabeling of products without requiring specific information about the content or ingredients,³⁸ it is

32 Law & Libecap, *supra* note 22, at 331 ("Muckraking journalists like Samuel Hopkins Adams, Ray Stannard Baker, Henry Demarest Lloyd, Upton Sinclair, Lincoln Steffens, Charles Edward Russell, and Ida Tarbell were hired by these periodicals to write articles exposing unscrupulous business practices, slum urban conditions, and political corruption.").

33 See UPTON SINCLAIR, *THE JUNGLE* 38 (Doubleday, Page & Co., 1906) ("They use everything about the hog except the squeal."); see also *All Things Considered: Impact of Sinclair's 'The Jungle' on Food Safety*, NAT'L PUB. RADIO (Jan. 2, 2004), <http://www.npr.org/templates/story/story.php?storyId=1580844>.

34 See Adam Cohen, Opinion, *100 Years Later, the Food Industry Is Still 'The Jungle'*, N.Y. TIMES, Jan. 2, 2007, at A16. Upton Sinclair was disappointed by the public's reaction to *The Jungle*. He wanted to capture the struggles of the working class and was dismayed to find that readers focused on his horrific accounts of meat packaging. Mr. Sinclair notably remarked, "I aimed at the public's heart . . . and by accident I hit it in the stomach." *Id.*

35 Law & Libecap, *supra* note 22, at 320.

36 Federal Food and Drugs Acts of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906), *repealed by* Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 341 .

37 Federal Meat Inspection Act of 1906, Pub. L. No. 59-242, 34 Stat. 1256 (1906) (current version at 21 U.S.C. § 601 (2018)).

38 See Donna M. Byrne, *Cloned Meat, Voluntary Food Labeling, and Organic Oreos*, 8 PIERCE L. REV. 31, 35 (2009) (noting the limited requirements of the Pure Food and Drugs Act of 1906); See also Frederick H. Degnan, *The Food Label and the Right-to-Know*, 52 FOOD & DRUG L.J. 49, 50-51 (noting that the Act did not include any requirements for food product labels).

known as one of the first American consumer protection laws that banned the inclusion of ingredients that would pose health risks to consumers.³⁹

Despite the ambiguous nature of the Act, courts declined to apply a test of “chemical, scientific, or technical accuracy” and instead broadly interpreted labels based on what an ordinary person would understand the label to mean, looking to the commonplace usage of the terms.⁴⁰ Early cases⁴¹ emphasized that food producers could not include deleterious ingredients that may cause harm to consumers.⁴² In the midst of the Act’s passage, Congress also approved the Bureau of Chemistry, better known today as the FDA, to administer the Act and ensure its success.⁴³

B. The Passage of the Food, Drug, and Cosmetic Act

However, after six amendments to the Act from 1906 to 1938 and a tragic mislabeling incident that resulted in the death of over one hundred

39 *Part I: The 1906 Food and Drugs Act and Its Enforcement*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/History/FOrgsHistory/EvolvingPowers/ucm054819.htm> (last updated Feb. 1, 2018).

40 *Legislation: The Consumer’s Protection Under the Federal Pure Food and Drugs Acts*, 32 COLUM. L. REV. 720, 723-25 (1932) (discussing early judicial interpretation of the Pure Food and Drugs Act).

41 *See* *United States v. Ninety-Five Barrels*, 265 U.S. 438, 444-45 (1924) (holding that a food label can be misleading if the food product is not identical to what the manufacturer claims it is); *United States v. Schider*, 246 U.S. 519, 522-23 (1918) (affirming that improper labels “exhale deceit”); *United States v. Coca Cola Co.*, 241 U.S. 265, 284 (1916) (noting that the caffeine included in the beverage is an “added ingredient”); *United States v. Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914) (“[T]he Government need not prove that this flour or food-stuffs made by the use of it would injure the health of any consumer. It is the character -- not the quantity -- of the added substance, if any, which is to determine this case.”); *Weeks v. United States*, 224 F. 69, 70 (2d Cir. 1915) (affirming that the focus of Pure Food and Drug Act cases is whether the added ingredient “reasonably ha[s] a tendency to injure health”).

42 NEAL D. FORTIN, *FOOD REGULATION: LAW, SCIENCE, POLICY, AND PRACTICE* 167 (2d ed. 2017) (noting that the Act’s scope does not require added deleterious ingredients to actually injure consumers but instead that it might cause injuries).

43 *Part I: The 1906 Food and Drugs Act and Its Enforcement*, *supra* note 39.

consumers, including children,⁴⁴ President Roosevelt repealed the Pure Food and Drug Act and signed the Food, Drug, and Cosmetic Act (“FDCA”) of 1938.⁴⁵ Congress intended to “promote honesty and fair dealing in the interests of consumers” by focusing on misrepresentation via labeling and packing,⁴⁶ which still left consumers unprotected from unchecked and unregulated health claims on labels.⁴⁷ Although bare-boned in its approach, Congress under 21 U.S. Code § 343(k) stipulated that “any artificial flavoring, artificial coloring, or chemical preservatives” were to be labeled on the product.⁴⁸ Following this trend in the mid-twentieth century, Congress later passed labeling requirements for specific products,

44 *Part II: 1938, Food, Drug, Cosmetic Act*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/History/FOrgsHistory/EvolvingPowers/ucm054826.htm> (last updated Feb. 1, 2018); *see also* Julian G. West, *The Accidental Position that Founded the Modern FDA*, THE ATLANTIC (Jan. 16, 2018), <https://www.theatlantic.com/technology/archive/2018/01/the-accidental-poison-that-founded-the-modern-fda/550574/>. S.E. Massengill Co.’s head chemist, Harold Watkins, concocted a more palatable version of sulfanilamide and accidentally create diethylene glycol, a toxic compound, in the experimentation process. S.E. Massengill labeled Watkins’s creation “Elixir Sulfanilamide” and sold the product. In the meantime, an estimated 107 users of the “elixir” perished while many others suffered from kidney failure and other serious disorders. While S.E. Massengill continuously denied responsibility for the horrific outcome, this public health disaster propelled the passage of a much stricter regulation, the Food, Drug, and Cosmetics Act of 1938. *Id.*

45 Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 341 (2018) (repealing Federal Food and Drugs Acts of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906)).

46 *Part II: 1938, Food, Drug, Cosmetic Act*, *supra* note 44.

47 *The 1938 Food, Drug, and Cosmetic Act*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/History/ProductRegulation/ucm132818.htm> (last updated Feb. 1, 2018). Manufacturers still had discretion to establish standards for their products “whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interests of consumers.” *Id.*

48 21 U.S.C. § 403(k).

such as poultry in 1957⁴⁹ and a federal preemption statute on food labeling in 1966.⁵⁰

While Congress continued to pass public health legislation, the relationship between food labeling and consumer protection remained on the minds of the American public. President John F. Kennedy directly addressed this in a consumer protection focused speech⁵¹ in 1964 where he famously noted the importance of “truth in packaging” and the need to focus more legislation on it in order to protect four basic consumer rights.⁵² Following his address, President Kennedy (and later, President Johnson) created the Consumer Advisory Council and the President’s Committee on Consumer Affairs, with Esther Peterson appointed as the Special Assistant.⁵³ As consumer protection and food labeling take on a larger role in legislation, critics of the FDCA have noted that it assumes that food products are affirmatively deemed safe and that “the statute

49 Poultry Products Inspection Act of 1957, Pub. L. No. 85-172, 71 Stat. 441 (codified as amended at 21 U.S.C. § 451 (2018)).

50 Fair Packaging and Labeling Act, Pub. L. No. 89-755, 80 Stat. 1296 (codified as amended at 15 U.S.C. §§ 1451-1461 (2018)).

51 John F. Kennedy, Special Message to the Congress on Protecting the Consumer Interest (Mar. 15, 1962) (available at THE AMERICAN PRESIDENCY PROJECT, <https://www.presidency.ucsb.edu/documents/special-message-the-congress-protecting-the-consumer-interest>). In his special message, President Kennedy recognized four consumer rights: “the right to safety,” “the right to be informed,” “the right to choose,” and “the right to be heard.” *Id.*

52 *Id.* (“Misleading, fraudulent or unhelpful practices such as these are dearly incompatible with the efficient and equitable functioning of our free competitive economy. Under our system, consumers have a right to expect that packages will carry reliable and readily useable information about their contents.”)

53 Esther Peterson, *The Consumer’s Interest*, 21 FOOD DRUG COSM. L.J. 92, 93-95 (1966). Peterson further expanded on the four consumer rights and noted that while the FDA’s efforts offer significant protection to consumers, additional cooperation between agencies and non-governmental bodies is necessary. *Id.*

holds producers responsible for the safety of their produce, but imposes no premarket inspection regime for foods it covers.”⁵⁴

C. Defining “Natural”

The movement to define “natural” first began with an effort by the Federal Trade Commission (“FTC”) in the early 1970s, where the agency’s proposed rule was to define natural food products as those “with no artificial ingredients and only minimal processing.”⁵⁵ However, these efforts were abandoned in 1983 when the FTC decided to focus on advertising issues instead and abandoned the rule.⁵⁶

While the FDA and other agencies did not continue to pursue a final rule or expand the FTC’s proposed definition, additional labeling issues arose from the ambiguous nature of the FDCA.⁵⁷ Most notably, only a little more than half of food products included a version of nutritional facts,⁵⁸ prompting Congress to amend the original FDCA through the introduction of the Nutritional Labeling Education Act (“NLEA”) of 1990.⁵⁹ The NLEA establishes mandatory nutritional labeling

54 Martha Dragich, *Grass-Fed Americans: Sick of Lax Regulation of Food Additives*, 49 IND. L. REV. 305, 306 (2016); see *infra* note 192. In contrast to the FDA’s regulation, the USDA requires pre-approval on meat products before manufacturers are allowed to begin any marketing campaigns.

55 Termination of Proposed Trade Regulation; Rule on Food Advertising, 48 Fed. Reg. 23270 (proposed May 24, 1983) (to be codified at 16 C.F.R. pt. 437).

56 *Id.* (“It is unlikely that consumers expect the same thing from a natural apple as they do from natural ice cream. The proposed rule assumes . . . that ‘natural’ means the same thing in every context. We should concentrate our resources on more serious consumer protection problems.”)

57 Erik Benny, “Natural Modifications:” *The FDA’s Need to Promulgate an Official Definition of “Natural” that Included Genetically Modified Organisms*, 80 GEO. WASH. L. REV. 1504, 1509 (2012).

58 *Id.*

59 Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended at 21 U.S.C. § 343 (2018)). The NLEA established requirements for nutritional labels on all products intended for human consumption under the FDA’s jurisdiction and stipulated that the “[t]otal fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars,

requirements and mandates that nutritional claims meet the FDA's established guidelines.⁶⁰ At the present, the FDA along with the United States Department of Agriculture ("USDA")⁶¹ are the two administrative agencies that are able to issue final rules and regulations concerning food labeling, including when the term "natural" (or its derivatives) may be used to describe a food product.⁶²

Currently, the FDCA is still the leading statute for nearly all food products in the United States with the NLEA and other amendments supplementing it.⁶³ As mandated by the NLEA, the FDA is tasked with defining nutrient descriptors and ensuring that food products are "safe, wholesome and properly labeled."⁶⁴ The NLEA empowered the FDA to

dietary fiber, and total protein," must be displayed on the product. *Id.* Along with these requirements, labels should include any additional nutrients that the Secretary of Health and Human Services deemed necessary in guiding consumers in "maintaining healthy dietary practices." *Id.*

60 Virginia Wilkening, *The Nutrition Labeling and Education Act of 1990*, in NAT'L NUTRIENT DATABASE CONF. 227, 227-28 (1992), https://www.nutrientdataconf.org/PastConf/NDBC17/8-2_Wilkening.pdf. The NLEA accomplishes the FDA's regulatory goals with three objectives related to product labeling: "1. [t]o clear up consumer's confusion about food labels, 2. [t]o aid consumers in making health food choices, and 3. [t]o encourage product innovation so that manufacturers are given an incentive to improve the quality of the food and make more healthy food choices available to consumers." *Id.* at 227; see also *Nutritional Labeling and Education Act (NLEA) Requirements (8/94 - 2/95)*, U.S. FOOD & DRUG ADMIN. (Feb. 2015), <https://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074948.htm>.

61 *What Does FDA regulate?*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm> (last updated Aug. 22, 2018). The Food Safety and Inspection Service (FSIS) within the USDA is responsible for "aspects of the safety and labeling of traditional (non-game) meats, poultry, and certain egg products." *Id.* While the USDA and the FSIS regulate food products in the US, specifically meat and poultry products, this Note will solely focus on the efforts of the FDA.

62 *Id.*

63 See *Laws Enforced by the FDA*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/default.htm> (last updated Mar. 29, 2018).

64 U.S. Dep't of Health & Human Servs., *A Food Labeling Guide: Guidance for Industry*, U.S. FOOD & DRUG ADMIN. 4 (2013),

define “natural” and other nutrient content claims, and the FDA began to provide definitions in final rules for certain “core terms” like “fat free” and “low sodium” but declined to provide even insight for nonspecific terms like “natural.”⁶⁵

D. The American Public’s Reaction to the FDA’s Failure to Define “Natural”

While the FDA has recognized the importance of defining the term “natural,”⁶⁶ the agency has not provided a clear definition nor included a Final Rule to address the term.⁶⁷ The FDA provides an informal definition for “natural” as “nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in that food” but has long since declined to commit to a formal definition.⁶⁸ In attempts to

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Labeling/Nutrition/ucm2006828.htm>.

65 F. Edward Scarbrough, *Perspectives on Nutrition Labeling and Education Act*, in NUTRITION LABELING HANDBOOK 29, 44 (Ralph Shapiro, ed., 1995). It remains unclear why the FDA has not addressed “natural” when it has standardized health claims and nutritional labeling for other terms.

66 “Natural” on Food Labeling, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Labeling/Nutrition/ucm456090.htm> (last updated Oct. 22, 2018). The FDA recognizes that it has not established a formal definition for “natural” and instead uses an informal policy. However, due to “the changing landscape of food ingredients and production, and in direct response to consumers who have requested that the FDA explore the use of the term ‘natural,’” the FDA requested the American public to comment on the term and provide suggestions on defining it. *Id.*

67 *Id.*; see also Paul Greenberg & Jason J. Czarnetzki, *It’s Time for the FDA to Define ‘Natural,’* TIME MAG. (May 4, 2016), <http://time.com/4317988/fda-natural-definition/> (“The Food and Drug Administration has never formally defined the term. The word is a kind of orphan child, undefined by government, misused by industry and without a provenance or a use for the average American consumer.”).

68 “Natural” on Food Labeling, *supra* note 67. The FDA also has declined to establish “whether the term ‘natural’ should describe any nutritional or other health benefit.” *Id.*; see also Marion Nestle, *Food politics Semantics: The Meaning of “Natural,”* FOOD POL. (Nov. 8, 2011), <https://www.foodpolitics.com/2011/11/food-politics-semantics-the-meaning-of-natural/> (noting that under the FDA’s “non-definition, High Fructose Corn Syrup is ‘natural’ even though to make it, corn

justify this policy, the agency stated that “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.”⁶⁹

Despite public outcry,⁷⁰ the FDA has yet to establish a formal definition.⁷¹ While large food manufacturers have issued several petitions for the FDA to establish a definition, the Consumer Union requested that the FDA prohibit manufacturers from utilizing the term on any product labels,⁷² including the numerous companies that have derivatives of “natural” in their name.⁷³

However, following four citizen petitions⁷⁴ asking the FDA to either define the term “natural” or ban companies from putting it on labels, the

refiners must extract the starch from corn, treat the starch with an enzyme to break it into glucose, and treat the glucose with another enzyme to turn about half of it into fructose”).

69 Paul Greenberg & Jason J. Czarnetzki, *supra* note 68.

70 See Monica Watrous, *Trend of the Year: Clean Label*, *FOODBUSINESSNEWS*, <http://features.foodbusinessnews.net/corporateprofiles/2015/trend-index.html> (last visited Jan. 27, 2018). On the need for an industry change regarding food labeling, President and CEO of Campbell Soup Co., Denise Morrison said, “The demand for transparency has given rise to distrust of large food companies.” *Id.* at 4. From this distrust, companies have responded with providing “clean labels,” or labels with easily recognizable ingredients. *Id.*

71 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, 405-06 (2010).

72 Levinovitz, *supra* note 9.

73 *Id.* at 3 (noting that this would affect food manufacturers such as “Nature Valley, Back to Nature, Amy’s Naturals, Organic by Nature, and the countless other companies whose names incorporate derivations of ‘natural’”).

74 Request for Information and Comments and Extension of Comment Period Regulations, 80 Fed. Reg. 69905, 69906-07 (Nov. 12, 2015) (noting the four citizen’s petitions from the Sugar Association, the Grocery Manufacturers Association, the Sara Lee Corporation, and the Consumer Union); see also MICHAEL T. ROBERTS, *FOOD LAW IN THE UNITED STATES* 270-71 (Cambridge Univ. Press 2016) (citing Lorraine Heller, *‘Natural’ will remain undefined, says FDA*, *FOOD NAVIGATOR-USA.COM* (Jan. 4, 2008), <https://www.foodnavigator-usa.com/Article/2008/01/04/Natural-will-remain-undefined-says-FDA#>). The Sugar Association and the Grocery Manufacturers Association filed their

FDA in 2015 formally requested the public to comment on the term “natural” and make recommendations for the FDA.⁷⁵ In particular, consumers were asked to address three questions: (1) “Whether it is appropriate to define the term “natural;” (2) If so, how the agency should define “natural;” and (3) how the agency should determine appropriate use of the term on food labels.”⁷⁶ The response was more robust than the FDA likely anticipated; the 7,690 comments demonstrated a clear public outcry for stricter regulations on food labeling and harsher punishments for companies in violation of the FDA’s standards.⁷⁷ However, since the comments period closed in May 2016, the FDA has not addressed the food labeling requirement for the “natural” term, has not addressed the public comments and the overwhelming response, and has not mentioned a new proposed rule for a formal definition of the term.⁷⁸

citizens petition in 2006 and 2007 respectively, requesting a formal definition for “natural” and providing suggestions for a uniform term. In response, the FDA announced that it would not pursue a formal definition nor restrict the term to certain food products. *Id.*

75 “Natural” on Food Labeling, *supra* note 67.

76 *Id.*

77 Diana Winters, *Are the FDA’s New Definitions and Labeling Requirements Good for Us, or Just Empty Calories?*, HEALTHAFFAIRS (June 24, 2016), <https://www.healthaffairs.org/doi/10.1377/hblog20160624.055546/full/>; see also Report, Consumer Union, Comments of Consumers Union to the Food and Drug Administration on Use of the Term “Natural” in the Labeling of Human Food Products (May 10, 2016) [hereinafter Consumer Union Report], https://www.consumerreports.org/content/dam/cro/news_articles/health/PDFs/ConsumerReports-Letter-to-FDA-Natural-Food-Label.pdf. Beyond its 2014 citizen petition, Consumer Union also submitted a sixteen-page report to FDA during the open comment period. Consumer Union Report. Within the report, Consumer Union continued to advocate for the ban of the term “natural” and included charts and statistics from past surveys. *Id.* Alternatively, the FDA “should define the term via rulemaking in a manner that is consistent with consumer expectations for the word when it appears on food, and require third-party verification.” *Id.* at 15.

78 Richard M. Blau & Anna M. Wiand, *FDA’s Next Action on Defining “Natural” For Food Labeling Purposes Remains Unclear*, LEXOLOGY (July 21, 2016), <https://www.lexology.com/library/detail.aspx?g=efaabaec-227f-43fd-9462-09396bd2a1eb>.

[/library/detail.aspx?g=efaabaec-227f-43fd-9462-09396bd2a1eb](https://www.lexology.com/library/detail.aspx?g=efaabaec-227f-43fd-9462-09396bd2a1eb).

II. THE EU'S APPROACH TO FOOD LABELING REQUIREMENTS

A. *Historical Background*

In contrast, by virtue of a much longer and more extensive history, food historians recognize one of the earliest written European food laws in the 1266 Assize of Bread and Ale (“the Assize”).⁷⁹ While individual European countries eventually established their own regulations and standards for food laws, food historians consider England to be the first to enact a law⁸⁰ that outlawed the adulteration of food and drink.⁸¹ As a regional bloc, the European community united to create the European Economic Community (better known today as the European Union), spurring a collaborative approach to food laws and consumer protection.⁸² The European Economic Community’s initial approach to food law and product labeling focused on agriculture and eventually the internal EU food industry.⁸³ When establishing the European Economic Community,

79 See CAOIMHÍN MACMAOLÁIN, *FOOD LAW: EUROPEAN, DOMESTIC AND INTERNATIONAL FRAMEWORKS* 3-4 (Bloomsbury 2015). Even as an early food regulation, the Assize introduced standards for pricing, minimum weight requirements, and quality of bread and beer in order to protect consumers from deceptive shopkeepers. *Id.*

80 Adulteration of Food and Drink Act 1860, 23 & 24 Vict., c. 84 (UK).

81 Jillian London, *Tragedy, Transformation, and Triumph: Comparing the Factors and Forces that Led to the Adoption of the 1860 Adulteration Act in England and the 1906 Pure Food and Drug Act in the United States*, 69 *FOOD DRUG L.J.* 315, 315 (2014).

82 TAMARA K. HERVEY & JEAN V. MCHALE, *EUROPEAN UNION HEALTH LAW: THEMES AND IMPLICATIONS* 31 (Cambridge University Press 2015).

83 Bernd M.J. van der Meulen, *The Structure of European Food Law*, 2 *LAWS* 69, 73 (2013).

the six original member states⁸⁴ to the Treaty of Rome in 1957 came together to create a shared and central European market.⁸⁵

After a number of food safety concerns and growing distrust of the food producers in Europe in the late 1990s,⁸⁶ the European Commission published a White Paper on Food Safety⁸⁷ which set out to address mounting food safety concerns for the European community and increase transparency for consumers.⁸⁸ Following this publication two years later, the European Commission then adopted Regulation 178/2002, better known as the General Food Law Regulation.⁸⁹ The General Food Law largely jumpstarted the EU's collaborative approach to food law and safety and famously defined food for the first time in European legislation.⁹⁰

84 The original six countries were Belgium, West Germany, France, Italy, Luxembourg, and the Netherlands. See Treaty Establishing the European Economic Community, Mar. 25, 1957, 298 U.N.T.S. 11, at 1.

85 *Id.* at 3. See also van der Meulen, *supra* note 83, at 73-74. To create this shared market, the member states noted four freedoms in order to foster a prosperous European community: "the free movement of labour, the free movement of services, the free movement of capital and the free movement of goods." *Id.*

86 See Jovana Tulumovic, *Food Law of European Union*, 18 REV. EUR. L. 83, 84 (2016). A particularly horrific crisis resulted from the spread of bovine spongiform encephalopathy (BSE), better known as "Mad Cow Disease." The World Health Organization eventually discovered a link between "BSE and food contamination which caused a lot of financial damage to farmers and also caused fear to European consumers." *Id.*; see also Rose Troup Buchanan, *Mad Cow Disease in the UK: What is BSE and What Are the Symptoms?*, THE INDEPENDENT (Oct. 1, 2015), <http://www.independent.co.uk/news/uk/home-news/mad-cow-disease-in-the-uk-what-is-bse-and-what-are-the-symptoms-a6675351.html>.

87 EUR. COMM'N, WHITE PAPER ON FOOD SAFETY (2000), <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:51999DC0719>.

88 *Id.*

89 Commission Regulation 178/2002, 2002 O.J. (L 31) 1 (EC).

90 Van der Meulen, *supra* note 83, at 78-79. The General Food Law define[s] food or foodstuff as "any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. 'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation

While on the surface, the European Union as a collective body seems to have taken the same approach to food labeling as the FDA,⁹¹ individual member states have taken approaches to further define the term “natural.”⁹²

Currently, the European Commission allows food producers to use the term “natural” when “a food naturally meets the condition(s) laid down in [the] Annex for the use of a nutritional claim.”⁹³ While the EU does not regulate food labels, the EU passed Reg. (EC) 1334/2008,⁹⁴ which provides more precise requirements for “natural flavouring.”⁹⁵ Food producers are specifically instructed to not use the label “natural” if such usage will mislead the consumer or if the flavor component is not at least 95% of natural origin.⁹⁶ In Article 7 (Fair Information) of the Regulation

or treatment.” *Id.* at 79. Unlike the United States, the European Union determined that “animal feed” is not considered food under this definition. *Id.*

91 See Corinna Hawkes, *Government and Voluntary Policies on Nutrition Labeling: A Global Overview*, in *INNOVATIONS IN FOOD LABELING* 37, 41 (Janice Albert ed., 2010).

92 See *infra* Part 2(B); see also USDA FOREIGN AGRIC. SERV., <https://www.fas.usda.gov/> (last visited Feb. 10, 2018). The USDA regularly publishes a Food and Agricultural Import Regulations and Standards (FAIRS) report for each country and summarizes its food laws and the relevant EU provisions. The FAIRS reports also include food laws that are not covered under EU regulations. See, e.g., *FAIRS Reports*, USDA, <https://www.usda-eu.org/trade-with-the-eu/eu-import-rules/fairs-reports/> (last visited on Nov. 17, 2018).

93 *Nutrition Claims*, EUROPEAN COMMISSION, https://ec.europa.eu/food/safety/labelling_nutrition/claims/nutrition_claims_en (last visited on Feb. 10, 2018).

94 Regulation 1334/2008, of the European Parliament and of the Council of 16 December 2008 on Flavourings and Certain Food Ingredients with Flavouring Properties for Use in and on Foods and Amending Council Regulation 1601/91/EEC, Regulation 2232/96 (EC), Regulation 110/2008 (EC), and Directive 2000/13 (EC) 1, 3 (EC).

95 *Id.*

96 *Id.*

No. 1169/2011,⁹⁷ the EU further elaborates on “natural.”⁹⁸ The EU mandates in 7.1(c) and (d) that food labels shall not “suggest that the food possesses special characteristics when in fact all similar foods possess such characteristics, in particular by specifically emphasizing the presence or absence of certain ingredients and/or nutrients”⁹⁹ or “suggest, by means of the appearance, the description or pictorial representations, the presence of a particular food or an ingredient.”¹⁰⁰

B. More Specific Guidance from the United Kingdom, France, Ireland, and Germany

The ambiguous nature of these EU regulations spurred several member states to more strictly define “natural” and related terms to apply to companies in their country.¹⁰¹ In 2000, the UK established the Food Standards Agency (“FSA”), an organization not under the European Union, that works to establish clear and standardized policies relating to food production and consumption for England, Wales, and Northern Ireland.¹⁰²

97 Regulation 1169/2011, of the European Parliament and of the Council of 25 October 2011 on the Provision of Food Information to Consumers 1, 10 (EU).

98 *Id.* at art. 2(2)(i). Food labeling here refers to “any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a food and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such food.” *Id.* at art. 2(2)(j).

99 *Id.* at art. 7(1)(c).

100 *Id.* at art. 7(1)(d).

101 See Nicola Aporti & Cesare Varallo, “Natural” Claim in China: Overview and Comparison with EU and US, 2017 EUR. FOOD & FEED L. REV. 2, 10.

102 *The FSA in Europe*, FOOD STANDARDS AGENCY, <https://www.food.gov.uk/about-us/agencyandeurope> (last visited Feb. 10, 2018).

In 2008, the FSA published a series of guidelines that clearly articulate food descriptors and claims.¹⁰³ The FSA explains that the term “natural” may only be used without qualification to describe “single foods . . . to which nothing has been added” and foods that have undergone processing like smoking, fermentation, or freezing.¹⁰⁴ Food producers are not permitted to describe compound foods (food products composed of multiple ingredients) as “natural” and instead may only use the term “made from natural ingredients” when all the ingredients can be classified as “natural.”¹⁰⁵ Like the EU’s approach, producers should not describe their food products as “natural” to deceive consumers; however, the UK (by way of the FSA) applies this to “natural” and its derivatives and also bans the use of the term where the product is really just “plain or unflavoured,” attempting to imply to the consumer that the product is “natural,” or as part of the brand name.¹⁰⁶ Further, the FSA stipulates that food producers should not attempt to deceive consumers through indirect means by implying the “naturalness” (or any of its derivatives) of a food product.¹⁰⁷

103 FOOD STANDARDS AGENCY, CRITERIA FOR THE USE OF THE TERMS FRESH, PURE, NATURAL ETC. IN FOOD LABELLING 1, 10-12 (2008) [hereinafter FSA], <http://www.foodlaw.reading.ac.uk/pdf/uk-08017-guidance-marketing-terms.pdf>. The FSA recognized the complexity of using the terms “natural” and “natural flavoring” and wrote extensive criteria for specific instances, such as dairy products and bottled water. *Id.* at 16-19. The FSA defined “natural” to refer to a product of “ingredients produced by nature, not the work of man or interfered with by man.” *Id.* at 15. In addition, “it is misleading to use the term to describe foods or ingredients that employ chemicals to change their composition or comprise the products of new technologies, including additives and flavourings that are the product of the chemical industry or extracted by chemical processes.” *Id.*

104 *Id.* at 16.

105 *Id.* at 16-17.

106 *Id.*

107 Ignacio Carreno & Paolo Vergano, *Uses and Potential Abuses of Negative Claims in the EU: The Urgent Need for Better Regulation*, 5 EUR. J. RISK REG. 469, 484 (2014) (noting that the FSA’s guidelines on both direct and indirect claims are intended to discourage food producers from using confusing or misleading labels on their products).

France and Ireland have likewise followed the UK's approach with the creation of La Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (“DGCCRF”)¹⁰⁸ in 2009 and the Food Safety Authority of Ireland (“FSAI”)¹⁰⁹ in 2015.¹¹⁰ In an advisory note¹¹¹ to French producers, the DGCCRF recommends using the term “natural origin” to describe food products that are “stabilized (refrigeration, freezing, freezing), condition[ed] under a protective atmosphere, heat treatment (pasteurization, sterilization, cooking), or fermentation-renneting - roasting or brewing.”¹¹² However, these guidelines from the DGCCRF are not legally binding,¹¹³ leaving consumers still vulnerable to deceptive food labeling and misinformation. Turning to Ireland, the FSAI addressed “natural” in a similar guidance report to the FSA by comparing single ingredient foods to compound foods and indicated how to clearly and appropriately use the term “natural.”¹¹⁴

108 DGCCRF, ECONOMIE.GOUV.FR, <https://www.economie.gouv.fr/dgccrf> (last visited Feb. 10, 2018).

109 FOOD SAFETY AUTHORITY OF IR., <https://www.fsai.ie/> (last visited Feb. 10, 2018).

110 See Aporti & Varallo, *supra* note 101, at 11 (noting that the term “natural” in food labeling should only be used “on a food product which has been subjected to a transformation that does not modify essential characteristics of the food”).

111 Pierre Christen, *Naturalité: la tendance de fond*, PROCESS ALIMENTAIRE (Jan. 8, 2013) (quoted text translated from French using Google translate) (citing Note d'information No 2009-136, La Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes, (Aug. 18, 2009)), <http://www.processalimentaire.com/Ingredients/Naturalite-la-tendance-de-fond-22709>.

112 *Id.*

113 E. Stich, Food Color and Coloring Food: Quality, Differentiation and Regulatory Requirements in the European Union and the United States, in HANDBOOK ON NATURAL PIGMENTS IN FOOD AND BEVERAGES 3, 7 (Reinhold Carle & Ralf M. Schweiggert eds., 2016).

114 FOOD SAFETY AUTH. OF IR., GUIDANCE NOTE 29: THE USE OF FOOD MARKETING TERMS (May 15, 2015) [hereinafter GUIDANCE NOTE 29], available at https://www.fsai.ie/news_centre/press_releases/marketing_terms_14052015.html. Under this standard, compound food products are allowed to be labeled “made with natural ingredients” when they meet the following criteria:

The United Kingdom, France, and Ireland’s separate approaches to the term “natural” are all united efforts with government agencies, food scientists and experts, and food producing companies in order to best fit the needs of their respective food markets.¹¹⁵ Likewise, the Bundesministerium für Ernährung und Landwirtschaft (“BMEL”),¹¹⁶ the Federal Ministry for Food and Agriculture in Germany, addresses food product labeling in a collaborative approach by working with representatives from “food monitoring, science, consumer and food industry” groups to create the Deutsche Lebensmittelbuch-Kommission (“DLMBK”), also called the German Food Book Commission.¹¹⁷ The DLMBK produces guidelines for consumers and food producers alike on individual products divided up into categories, including honey, fruit juices, ice cream, and pastas.¹¹⁸

C. *The EU’s Collaborative Approach*

1. The ingredients are formed by nature and are not significantly interfered with by man 2. The ingredients and the final food are: a) additive-free or b) contain flavourings that are natural as defined in European law or c) contain other food additives that are obtained from natural sources, e.g. plants, by appropriate physical processing (including distillation and solvent extraction) or traditional preparation processes.

Id.

¹¹⁵ See FSA, *supra* note 103; see also Christen, *supra* note 111; see also GUIDANCE NOTE 29, *supra* note 114.

¹¹⁶ *Food Labelling*, Bundesministerium für Ernährung und Landwirtschaft, https://www.bmel.de/EN/Food/Food-Labeling/food-labeling_node.html (last visited Jan. 9, 2018).

¹¹⁷ *International cooperation*, Bundesministerium für Ernährung und Landwirtschaft [hereinafter Bundesministerium für Ernährung und Landwirtschaft], https://www.bmel.de/EN/Ministry/InternationalCooperation/international-cooperation_node.html (last visited Nov. 17, 2018); see also *Aufbau der Deutschen Lebensmittelbuch-Kommission (Structure of the German Book Commission)*, Deutsche Lebensmittelbuch Kommission, <https://www.deutsche-lebensmittelbuch-kommission.de/> (last visited Nov. 1, 2018) (explaining that the DLMBK works with its 32 members to create guidelines to “describe how certain foods are compounded, manufactured, labeled, labeled or made up” to ultimately bolster “fair manufacturing and trade as well as the legitimate consumer expectation”) (translated from German using Google translate).

¹¹⁸ Bundesministerium für Ernährung und Landwirtschaft, *supra* note 117.

As a collective body in 1982, the European Union also took a more collaborative approach to food labeling with the foundation of the Confederation of the Food and Drink Industries of the EU, better known today as FoodDrinkEurope.¹¹⁹ FoodDrinkEurope is a coordinated effort with agencies of EU member states, companies, European sectors, and experts on Europe's food and drink industry, united to address "food and consumer policy (food safety and science, nutrition and health), environmental sustainability and competitiveness."¹²⁰ In response to Regulation 1334/2008, FoodDrinkEurope further elaborated on "natural" by recommending the 95/5 rule, where "at least 95% by weight of the flavouring components must be from X" in order to use the term "natural X flavouring" or "natural."¹²¹ FoodDrinkEurope also provides illustrations and the food industry's common understanding of the regulation's articles.¹²² As the EU continues to develop public health policies as a collective body, individual member state action and the EU's overall collaborative approach demonstrate the European Union's commitment to improving the food system for all parties involved.

III. ABSENT AN OFFICIAL DEFINITION, THE US COURTS ARE

¹¹⁹ *Role and Mission*, FOODDRINKEUROPE [hereinafter FOODDRINKEUROPE], <http://www.fooddrinkeurope.eu/about-us/role-and-mission/> (last visited Jan. 2, 2018).

¹²⁰ *Id.*

¹²¹ CONFÉDÉRATION DES INDUSTRIES AGRO-ALIMENTAIRES DE L'UE, CIAA GUIDELINES ON REGULATION EC 1334/2008 ON FLAVOURING AND CERTAIN FOOD INGREDIENTS WITH FLAVOURING PROPERTIES FOR USE IN AND ON FOODS 8 (2008) [hereinafter CIAA], http://www.fooddrinkeurope.eu/uploads/publications_documents/Flavourings_guidelines.pdf.

¹²² *Id.* at 8-11. For example, when using "natural flavouring substances," the CIAA recommends including information about the name of the flavouring substance to help the consumer understand what the label means. On its flavouring guide, the CIAA explains how food producers should approach food labeling for individual food products and food categories. *Id.* at 11. As an illustration, under individual food products, the CIAA includes a non-exhaustive list of permissible labeling examples such as "natural raspberry flavouring" and "natural pear (and) apricot flavouring." *Id.* at 9. For food categories, the CIAA also provides the food industry's common understanding of labeling and provides examples, including "natural citrus flavouring" and "natural herb flavouring." *Id.*

EXPERIENCING A SURGE IN “NATURAL” LAWSUITS

In the absence of the FDA’s guidance and regulatory enforcement of product labeling, consumers have not been silent about the FDA’s relaxed regulatory approach and have sought relief in the judicial system.¹²³ Tasked with interpreting the FDA’s informal definition and taking over food regulatory duties, courts such as the Northern District of California are now experiencing a surge of class action suits.¹²⁴ Colloquially known as the “Food Court,”¹²⁵ the Northern District of California has seen an influx of consumer-driven lawsuits and litigation asserting claims of false advertisement and deceptive business practices.¹²⁶ Due to the FDA’s

123 NICOLE E. NEGOWETTI, *FOOD LABELING LITIGATION: EXPOSING GAPS IN THE FDA’S RESOURCES AND REGULATORY AUTHORITY* 1 (2014), https://www.brookings.edu/wp-content/uploads/2016/06/Negowetti_Food-Labeling-Litigation.pdf (noting that class actions suits related to food labeling have increased from 19 cases in federal court in 2008 to 102 in 2012).

124 *See* Anscombe & Buckley, *supra* note 14.

125 *Id.* Class action lawsuits are especially common in California due to the large consumer population and plaintiff-friendly precedence established by the Ninth Circuit and California state laws. *Id.* (“Thus, even when a California federal court denies certification of a nationwide class, a California-only class will still contain over 38 million consumers—roughly 12 percent of the U.S. population.”).

The popularity of this particular court probably rests on a combination of factors: a state consumer protection law that is not preempted by the federal Food Drug and Cosmetic Act but, unlike federal law, creates private right of action; a perception that Northern California’s foodie culture will be hospitable to these claims; and the Ninth Circuit’s reputation for being friendly to class actions.

LAWRENCE O. GOSTIN & LINDSAY F. WILEY, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT* 240 (3d ed. 2016).

126 *See, e.g.*, *Rosillo v. Annie’s Homegrown, Inc.*, No. 17-cv-02474-JSW, 2017 U.S. Dist. LEXIS 190130, at *3 (N.D. Cal. Oct. 17, 2017) (alleging that having “natural” in the company’s name is misleading advertisement); *Romero v. Flowers Bakeries, LLC*, No. 14-cv-05189-BLF, 2015 U.S. Dist. LEXIS 59498, at *2-3 (N.D. Cal. May 6, 2015) (discussing whether using the brand name “Nature’s Own” and imagery of wheat stalks on the packaging when the bread products contain azodicarbonamide is misleading); *Musgrave v. ICC/Marie Callender’s Gourmet Prods. Div.*, No. 14-cv-02006-JST, 2015 U.S. Dist. LEXIS 14674, at *3 (N.D. Cal. Feb. 5, 2015) (alleging that the corn bread mix and other products were mislabeled as “natural” when they contain sodium acid pyrophosphate); *Garrison v. Whole Foods Mkt. Grp., Inc.*, No. 13-cv-05222-VC, 2014 U.S. Dist.

reluctance to provide a clear definition for “natural,” the term has been the subject of class action litigation in recent years, particularly for companies like Naked Juice,¹²⁷ General Mills,¹²⁸ and Bear Naked Granola.¹²⁹ Given consumers’ attraction to products labeled “natural” or its derivatives,¹³⁰ food producers face an interesting dilemma: without clear guidance from the FDA, corporations may use the term “natural” liberally on their products but but risk false advertising and deceptive business practice lawsuits from eager plaintiffs.¹³¹ With increasing consumer interest in

LEXIS 75271, at *1 (N.D. Cal. June 2, 2014) (arguing that several Whole Foods’ products are misleadingly labeled “natural” when they contain sodium acid pyrophosphate); *Surzyn v. Diamond Foods, Inc.*, No. C 14-0136 SBA, 2014 U.S. Dist. LEXIS 73352, at *2 (N.D. Cal. May 28, 2014) (discussing whether tortilla chips that contain maltodextrin and/or dextrose should be labeled “natural”); *Kane v. Chobani, Inc.*, 973 F. Supp. 2d 1120, 1124 (N.D. Cal. 2014) (arguing that the “all natural” and “only natural ingredients” labeling on Chobani’s yogurt products was false and misleading when it contains artificial coloring); *Werdebaugh v. Blue Diamond Growers*, No. 12-CV-02724-LHK, 2013 U.S. Dist. LEXIS 144178, at *7 (N.D. Cal. Oct. 2, 2013) (alleging that it is misleading and false to label the products “natural” when there are “artificial ingredients and flavorings, artificial coloring[,] and chemical preservatives”); *Kosta v. Del Monte Corp.*, No. 12-cv-01722-YGR, 2013 U.S. Dist. LEXIS 69319, at *5 (N.D. Cal. May 15, 2013) (discussing whether Del Monte’s fruit cup and other packaged produce products are misleading when labeled natural); *Campen v. Frito-Lay N. Am., Inc.*, No. 12-1586 SC, 2013 U.S. Dist. LEXIS 47126, at *32-33 (N.D. Cal. Apr. 1, 2013) (arguing that Lay’s potato chip products are inappropriately labeled “Made with ALL Natural Ingredients” when it uses “artificial and unnatural maltodextrin, ascorbic acid[,] citric acid, and caramel color”); *Larsen v. Trader Joe’s Co.*, 917 F. Supp. 2d 1019, 1021 (N.D. Cal. 2013) (alleging that various Trader Joe’s products are inappropriately labeled “All Natural Pasteurized” when they contain ascorbic acid); *Astiana v. Ben & Jerry’s Homemade, Inc.*, No. C 10-4387 PJH, 2011 U.S. Dist. LEXIS 57348, at *2 (N.D. Cal. May 26, 2011) (discussing whether it is misleading to label the two ice cream companies’ as “natural” when they use either alkalized cocoa and/or potassium carbonate).

127 *Pappas v. Naked Juice Co. of Glendora, Inc.*, No. LA CV11-08276 JAK, 2012 U.S. Dist. LEXIS 76067, at *3-4 (C.D. Cal. May 14, 2012).

128 *Lam v. Gen. Mills, Inc.*, 859 F. Supp. 2d 1097, 1102 (N.D. Cal. 2012).

129 *Thurston v. Bear Naked, Inc.*, No. 3:11-CV-02890-H (BGS), 2013 U.S. Dist. LEXIS 151490, at *2-3 (S.D. Cal. July 30, 2013); *see also* NEGOWETTI, *supra* note 123.

130 Benny, *supra* note 57, at 1508 (noting that in a 2007 consumer preferences study, 63% of consumer-respondents voiced a preference for foods labeled “natural”).

131 Watrous, *supra* note 70.

“natural” products and the resulting increase in major food corporations’ use of the label, the number of products touted as “natural” is increasing without clear regulation.¹³² As a result of increasing litigation and mounting consumer skepticism over truthfulness in food product labeling, a recent study from the Hartman Group¹³³ indicates that American consumers tend to view “natural” and derivative terms as “potentially a marketing gimmick.”¹³⁴ While the term “natural” remains unregulated, uncertainty for consumers and producers alike over what should be classified as “natural” has led to increasing lawsuits¹³⁵ from competing

Natural claims came under such heavy fire because many food companies gave the term a broad meaning while class-action attorneys and activists had room to argue a much narrower meaning In other words, problems may arise when broad statements are used in questionable contexts. Accordingly, food companies must understand their product, its ingredients and its processing so labeling statements narrowly tailor claims to properly reflect the product.

Id.

132 *Id.*

133 ELAINE WATSON, FOODNAVIGATOR-USA.COM, WHAT ‘CLEAN’ FOOD CUES ARE SHOPPERS LOOKING FOR? HARTMAN GROUP WEIGHS IN (Nov. 21, 2017), <https://www.hartman-group.com/acumenPdfs/Consumers%20look%20for%20cues%20for%20%E2%80%98natural%E2%80%99%20and%20%E2%80%98clean%E2%80%99%20food,%20says%20Hartman%20Group%20at%20FOOD%20VISION%20USA.pdf>. (“When seen on-pack, ‘natural’ continues to be regarded with skepticism. Four in five consumers have clear ambivalence or outright distrust of the ‘All Natural’ label”).

134 *Id.*

135 In the last decade, websites such as ClassAction.org and TopClassAction.com have begun to emerge. The primary purpose of these websites is to inform consumers of class actions lawsuits and to connect potential class members with class action attorneys. *See About Us, CLASSACTION.ORG*, <https://www.classaction.org/about-us> (last visited Feb. 10, 2018) (“ClassAction.org is a group of online professionals who are committed to exposing corporate wrongdoing and giving consumers the tools they need to fight back. We’ve . . . built relationships with class action and mass tort attorneys across the country.”). ClassAction.org even has a regularly updated section on natural foods law where they provide images and lengthy descriptions of products and which ingredients might be considered unnatural. As of February 2018, ClassAction.org has seventy-two different products with updated statuses about the case along with allegations from the class members. *See Natural Foods Lawsuits, CLASSACTION.ORG*, <https://www.classaction.org/natural-foods> (last visited Feb. 10, 2018).

food producers and class action lawsuits without any formal guidance from the FDA.¹³⁶

Most famously, Snapple Beverages faced a class action lawsuit over the term “all natural” on many of its beverages sweetened with processed high fructose corn syrup.¹³⁷ In the case, the consumer argued that it was misleading of Snapple to call the product “all natural” and that “Snapple advertised some products as containing juice that was not in the beverages.”¹³⁸ The issue of state versus federal preemption ultimately decided the case, but the Third Circuit did comment on the FDA’s decision to not establish a formal definition, stating, “[T]he record demonstrates that the FDA arrived at its policy without the benefit of public input.¹³⁹ Additionally, after requesting comments on the use of the term ‘natural,’ the FDA did not appear to consider all the comments received.”¹⁴⁰ Another beverage corporation, Pom Wonderful LLC, faced similar claims when it labeled Pom Wonderful, its pomegranate juice product, “all natural” despite the fact that it also included high fructose corn syrup.¹⁴¹ Finally, only a year after the Pom Wonderful lawsuit, yet another beverage corporation, Hornell Brewing Co., was sued for including the same culpable ingredient, high fructose corn syrup, in its “all natural” iced tea products.¹⁴² Without a final rule and formal definition on

136 See Anscombe & Buckley, *supra* note 14.

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

138 *Id.* at 333.

139 *Id.* at 341.

140 *Id.* The Court declined to define the term for the FDA.

141 See generally *Pom Wonderful LLC v. Organic Juice USA, Inc.*, 769 F. Supp 2d 188 (S.D.N.Y. 2011).

142 *Robinson v. Hornell Brewing Co.*, No. 11-2183 (JBS-JS), 2012 U.S. Dist. LEXIS 176699, at *1 (D.N.J. Dec. 12, 2012).

“natural” food products, additional lawsuits can be expected from consumers and competing corporations alike.

Since the FDA has declined to provide a formal definition, there is no federal preemption for claims based on “natural” product labeling; a formal definition from the FDA would preempt state laws.¹⁴³ The absence of the definition will continue to flood the courts with similar litigation because “federal preemption will never be achieved so long as the FDA refrains from issuing a rule.”¹⁴⁴ Turning back to the NLEA, Congress clearly intended on establishing nutritional standards in order to best protect the consumer and the food production market as a whole.¹⁴⁵ Under the NLEA, Congress established a way for the FDA to establish federal preemption once the FDA implements a final rule on preemption by defining these controversial and confusing product labels;¹⁴⁶ however, the FDA must enact this final rule in order to fully reclaim their regulatory powers from the judiciary.¹⁴⁷ As soon as the FDA establishes a formal definition for “natural” through a final rule, its definition would finally preempt state law claims.¹⁴⁸ However, under the FDA’s current approach to “natural,”¹⁴⁹ the definition cannot be legally enforced since it is only an informal definition and not a binding, final rule.¹⁵⁰ The FDA’s current

143 Benny, *supra* note 57, at 1513.

144 Farris, *supra* note 71, at 416.

145 *See* Wilkening, *supra* note 60.

146 *Id.*

147 *Id.*

148 *See* Allyson Weaver, *Natural Foods: Inherently Confusing*, 39 J. CORP. L. 657, 670 (2013); *see also* Benny, *supra* note 58, at 1513.

149 *See* Negowetti, *supra* note 8, at 584-85 (noting that while the FDA has the regulatory power to establish an enforceable definition, it instead relies upon enforcement letters that are not legally binding).

150 *See* Benny, *supra* note 57, at 1511 (“[T]he Third Circuit recently held that the FDA’s definition of ‘natural’ does not have the force of law.”); *see also* *Holk*, 575 F.3d at 340 (“We conclude

approach to enforcing products mislabeled with “natural” is to send a warning letter to the food manufacturer and ask for it to amend the labeling claim or to respond to the letter within 15 days.¹⁵¹ A warning letter alone without additional regulatory enforcement is insufficient to protect consumers from deceptive labeling.

In response to the sheer volume of class action lawsuits, corporations have petitioned the FDA to clarify “natural” and other related product labeling terms.¹⁵² KIND LLC, a maker of granola bars and other snack products, received a warning letter from the FDA due to KIND’s usage of

that the FDA’s policy statement regarding use of the term ‘natural’ is not entitled to preemptive effect. First, the FDA declined to adopt a formal definition of the term ‘natural.’

151 See Negowetti, *supra* note 8, at 588-89. In recent years, the FDA has sent several warning letters to food manufacturers for “misbranding” their products by using the term “natural” or its derivatives. See Letter from Michael W. Roosevelt, Acting Dir., Office of Compliance, Ctr. for Food Safety & Applied Nutrition, Food & Drug Admin., to Alex Dzieduszycki, CEO and President, Alexia Foods, Inc. (Nov. 16, 2011), <http://fda-warning-letters.blogspot.com/2011/11/alexia-foods-inc-111611.html> (noting that Roasted Red Potatoes & Baby Portabella Mushrooms cannot be classified as “All Natural” when they contain “disodium dihydrogen pyrophosphate, which is a synthetic chemical preservative”); Letter from Roberta F. Wagner, Dir., Office of Compliance, Ctr. for Food Safety & Applied Nutrition, Food & Drug Admin., to John Stranger, Technical Manager, Waterwheel Premium Foods Pty Ltd. (July 26, 2013), <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm364729.htm> (finding that the cracker wafer cannot be labeled “all natural” because it is made with artificial rye flavor); Letter from Mutahar S. Shamsi, New Eng. Dist. Dir., Food & Drug Admin., to Leopoldo Guggenheim, President & Co-Owner, Middle East Bakery, LLC (Sept. 18, 2014), <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm415564.htm> (explaining that gluten-free blueberry pancakes are not considered “all natural” because they contain sodium acid pyrophosphate, which is a synthetic substance); Letter from Kathleen Lewis, S.F. Dist. Dir., Food & Drug Admin., to Emilio Sandoval, Owner & President, Helados La Tapatia, Inc., (Oct. 24, 2014), <https://www.fda.gov/iceci/enforcementactions/warningletters/2014/ucm421463.htm> (determining that Natural Creamy Fruit Bar All Natural Esquimal (3 OZ) and Natural Creamy Fruit Bar All Natural Cookies “N” Cream (3 OZ) product labels misleadingly declare “Natural” and “All Natural” when containing “chemical preservatives (calcium sorbate) and other synthetic ingredients (polysorbate 40) and artificial colors (Yellow 5 and Red 4)).

152 See ROBERTS, *supra* note 74. In particular, the Sara Lee Corporation has been especially vocal on this topic. In its citizen’s petition, the manufacturer requested that the FDA formally define the term with the USDA’s Food Safety and Inspection Service (FSIS) agency and that the definition includes the term “natural preservatives.” *Id.*

the term “healthy” on its products.¹⁵³ In response, KIND replied to the FDA and noted that the amount of nuts and other nutritious fats used in products would exceed the FDA’s outdated regulatory policies.¹⁵⁴ KIND later filed a citizen petition to the FDA, requesting an update to food labeling, especially for “healthy,” to reflect current nutritional views on types of fats.¹⁵⁵ While “healthy” and “natural” have different labeling requirements,¹⁵⁶ corporations are becoming more vocal about their concerns related to product labeling and the potential legal repercussions they face due to the FDA’s informal definitions.

IV. RECOMMENDATIONS FOR THE FORMAL DEFINITION OF “NATURAL”

Under the FDA’s current approach to “natural” and other product labeling, both consumers and corporations are unclear as to what the terms

153 Letter from William A. Correll, Jr., N.Y. Dist. Dir., Ctr. for Food Safety & Applied Nutrition, Food & Drug Admin., to Daniel Lubetsky, CEO, Kind, LLC (Mar. 17, 2015), <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm440942.htm>. In the warning letter, District Director William Correll wrote that several of Kind’s nut-based bars are misbranded and improperly used the label “healthy” when the bars exceed the saturated fat guidelines stipulated by the FDA. Mr. Correll also notes that Kind’s marketing on its website and product packaging implies healthiness, inappropriately suggesting to consumers that they can incorporate Kind bars into their daily diets.

154 Poncie Rutsch, *Nut So Fast, Kind Bars: FDA Smacks Snacks on Health Claims*, NAT’L PUB. RADIO (Apr. 15, 2015), <http://www.npr.org/sections/thesalt/2015/04/15/399851645/nut-so-fast-kind-bars-fda-smacks-snacks-on-health-claims>.

155 Beth Kowitz, *In Reversal, the FDA Says ‘Healthy’ Can Return to Kind Bar Packaging*, FORTUNE (May 20, 2016), <http://fortune.com/2016/05/10/kind-bar-healthy-fda/>; see also Use of the Term “Healthy” in the Labeling of Human Food Products; Request for Information and Comments, 81 Fed. Reg. 66562 (Sept. 28, 2016).

156 *Compare* Use of the Term “Healthy” in Labeling Human Food Products: Guidance for Industry, 81 Fed. Reg. 66527 (Sept. 28, 2016) (noting products with “fat profile of predominantly mono and polyunsaturated fats, but do not meet the regulatory definition of ‘low fat’, or that contain at least 10 percent of the Daily Value (DV) per reference amount customarily consumed (RACC) of potassium or vitamin D” should not be labeled “healthy”), with “Natural” on Food Labeling, *supra* note 76 (suggesting “natural” to refer to “nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in that food”).

mean and when they can be appropriately used.¹⁵⁷ The FDA's reluctance to establish a formal definition¹⁵⁸ has resulted in an increase in consumer protection class action litigation, presenting the judiciary with the task of interpreting regulatory policies and labels.¹⁵⁹ The FDA needs to take a firm approach to product labeling and look to other countries' agencies for guidance on how to make the American food system more efficient and transparent for all parties involved. While this Note will not suggest a formal definition for "natural," it will propose several crucial elements that should be included, all inspired by EU member states' approach to food labeling. Ultimately, the FDA should work on establishing a final rule and definition for "natural" and consider the collaborative work of non-US organizations,¹⁶⁰ particularly in Europe.

Before promulgating an official definition of "natural," the FDA should consider the coordinated efforts of several European countries and agencies. Working with food producing companies, government agencies, experts, and the American consumer would allow for all parties within the food industry to create a transparent and functional definition. The FDA could follow the lead of various European organizations, such as the DLMBK¹⁶¹ or FoodDrinkEurope,¹⁶² and create a collaborative working group to draft a definition for "natural." By taking a more united approach to the consumer/producer relationship like that of EatDrinkEurope,¹⁶³ the

157 See ROBERTS, *supra* note 74.

158 See Greenberg & Czamezki, *supra* note 68.

159 See Anscombe & Buckley, *supra* note 14.

160 This Note is particularly inspired by the approaches taken by DLMBK in Germany, EatDrinkEurope, and the FSA in the UK for their multi-partisan approach to food product labeling.

161 See Bundesministerium für Ernährung und Landwirtschaft, *supra* note 117.

162 See CIAA, *supra* note 121.

163 See FOODDRINKEUROPE, *supra* note 119. ("FoodDrinkEurope's mission is to facilitate the development of an environment in which all European food and drink companies, whatever their size, can meet the needs of consumers and society, while competing effectively for sustainable growth.")

FDA can utilize the input of large food corporations in order to clarify regulations with the industry's common understanding of the term. Fostering a closer relationship with food producing companies would help to ensure that the FDA is creating realistic and effective regulations that will benefit the food market as a whole. EatDrinkEurope's approach brings the key players (food corporations, consumers, policymakers, and the legislative agencies) into the conversation and creates an active partnership to benefit the good of European society.¹⁶⁴ The FDA could work with American food producers, corporations, non-governmental advocacy organizations, and consumers to create a subcommittee that assists with the definition process.¹⁶⁵ This can help to ensure that "natural" and other food labeling terms are well understood and functional for all parties in the American food system.

Turning to crucial elements for the definition of "natural",¹⁶⁶ the FDA should include the following crucial components from EU member states' approach to food product labeling: (1) creating a separate "natural" definition for simple and compound foods;¹⁶⁷ (2) utilizing the term

164 *Id.*

165 For example, the FDA could create a collaborative group of large food manufacturers, perhaps first turning to companies like the Sara Lee Corporation or Kind LLC that have already written to the FDA, organizations like the Consumer Union and the Grocery Manufacturers Association, representatives from other governmental agencies such as the USDA, and important individual leaders in the food industry such as food scientists and influential food policy experts. This ad hoc committee could initially provide the FDA with key insights on the food industry and eventually form a permanent consulting committee if the FDA needs to adjust other terms or policies. The FDA does not need to completely follow FoodDrinkEurope (its Board of Directors is made up of CEOs from various food and drink corporations in Europe); however, this Note recommends implementing a subcommittee based on the organization of FoodDrinkEurope's group. See *Structure*, FOODDRINKEUROPE, <http://www.fooddrinkeuropa.eu/about-us/structure/> (last visited Feb. 10, 2018).

166 As noted in the Introduction section, this Note will not suggest a complete definition for the term "natural" or any of its derivatives. Instead, it will explore different approaches taken by EU member states and identify crucial components of other definitions that the Author believes should be included in the FDA's final rule for the term "natural."

167 See FSA, *supra* note 103, at 17.

“natural origin” to refer to food products that have been heated, refrigerated, or tampered with in some way;¹⁶⁸ and (3) introducing the term “made with natural ingredients” when each ingredient in a food product can be classified as “natural.”¹⁶⁹

Unlike the FDA’s current approach, the EU and the UK FSA recognizes the inherent confusion and ambiguity that a term like “natural” or its derivatives poses to consumers and food producers alike.¹⁷⁰ Separating the term “natural” between simple and compound foods and illustrating examples as to when the term is appropriate for a food product provide food producers with clear guidelines to avoid potential litigation. More importantly, this separation of simple and compound foods empowers consumers to make informed decisions when purchasing and consuming foods and to be able to trust both the FDA and food producers.¹⁷¹ American consumers are currently dissatisfied and wary of the FDA’s ability to regulate food products,¹⁷² and implementing this distinction could provide greater clarity about the requirements for labeling, which will benefit consumers and food corporations alike.

In addition, the FDA could also consider implementing the term “natural origin” to describe food products that originated in nature and have been tampered with only by some sort of heating or stabilization

168 See Christen, *supra* note 111. In guidance note 2009-136, the DGCCRF proposed using the term “natural origin” when referring to food products that have been “stabilized (refrigeration, freezing, freezing), condition[ed] under a protective atmosphere, heat treatment (pasteurization, sterilization, cooking), or fermentation- renneting - roasting or brewing.” *Id.*

169 See FSA, *supra* note 103.

170 See Aporti & Varallo, *supra* note 101, at 10.

171 This approach could be a useful solution in the United States because American consumers should be able to readily understand the difference between “simple” natural foods (e.g. an apple) versus “compound” natural foods (e.g. apple sauce made only of apples and cinnamon).

172 See WATSON, *supra* note 133.

process.¹⁷³ In France, the DGCCRF proposed “natural origin” to narrowly describe food products that were “stabilized” via refrigeration or “condition[ed] under a protective atmosphere, heat treatment . . . or fermentation.”¹⁷⁴ Because American consumers associate “natural-origin ingredients as natural,”¹⁷⁵ the FDA should consider a distinction between “natural” and “natural-origin” and other derivatives in order to avoid confusion for consumers and producers. Further, international organizations such as the Natural Food Colours Association (“NATCOL”) have already proposed a distinction between “natural” and its derivatives, including “natural origin,” as a way of establishing labels that are “truthful and not misleading to consumers.¹⁷⁶ Utilizing the “natural origin” term can help eliminate deceptive product labeling because consumers are intuitively able to “assess[] the naturalness of foods”¹⁷⁷ once given appropriate labels.

¹⁷³ See Christen, *supra* note 111. This proposed use would be based off of the DGCCRF’s definition for “natural origin.”

¹⁷⁴ *Id.*

¹⁷⁵ Donna Berry, *Defining ‘Natural:’ Ingredient Suppliers Weigh in*, FOOD BUSINESS NEWS (Nov. 28, 2017), http://www.foodbusinessnews.net/articles/news_home/Supplier-Innovations/2017/11/Defining_natural_Ingredient_su.aspx?ID=%7B2B57FA58-895B-4E2A-9053-E4D4601F78E3%7D&cck=1.

¹⁷⁶ NATCOL, NATCOL POSITION ON THE TERM ‘NATURAL COLOUR’ AND THE CATEGORISATION OF FOOD COLOURS (Apr. 19, 2013), <https://natcol.org/wp-content/uploads/2016/02/Updated-NATCOL-Position-Paper-on-Natural-Colours-Final-2015.pdf>. Though NATCOL’s position paper was intended for the European market, the international organization recognizes the efforts of the FDA on food labeling, and so NATCOL’s policies can still be applied to the United States food market. *Id.* Further, NATCOL proposes classifications based on “‘natural’ related voluntary labeling options such as “natural”, “natural origin” or “non-artificial.” *Id.* NATCOL distinguishes between terms by considering the follow questions: “1. Does the colour occur as such in nature? 2. Is the colour sourced from a naturally occurring starting material or derived therefrom?” *Id.* Depending on the answers to these questions, a “natural” or “nature-identical” label may be more appropriate.

¹⁷⁷ Sergio Román et al., *The Importance of Food Naturalness for Consumers: Results of a Systematic Review*, 67 TRENDS IN FOOD SCI. & TECH. 44, 45 (2017), <https://www.sciencedirect.com/science/article/pii/S092422441730122X>. Of the 85,348 consumers

Turning to compound foods, the FDA should also introduce the term “made with natural ingredients”¹⁷⁸ to refer to food products where each individual ingredient is deemed “natural.” This approach is similar to the FSA in the UK, which proposed separating compound and simple food products and creating separate “natural” terms to apply.¹⁷⁹ The term “made from natural ingredients” indicates to consumers that the food product in question is not inherently “natural” or from “nature” by itself, but rather, the product is composed of “natural” ingredients.¹⁸⁰ This clarification would allow consumers to understand the product labeling and have a clear idea as to what the terms on the labels mean. The FDA should strive for this level of clarity and consumer confidence in order to protect consumers from misleading and deceptive labeling practices and to provide corporations with the ability to correctly label their products. Further, the FDA’s use of the term “made with natural ingredients” would acknowledge the fact that the “natural” term should only be used when a food product truly fits the appropriate definition.¹⁸¹

Presently, however, it is unclear if the federal government will either follow or draw inspiration from the approach of the European Union (and its member states). The United States was highly critical of the European

from thirty-two countries surveyed, “[t]he results clearly show that for the majority of consumers in developed countries, naturalness in food products is important . . . [a] further insight is that preference for food naturalness is high in almost all of the reviewed studies.” *Id.* at 49.

178 See FSA, *supra* note 103.

179 *Id.* The FSA proposes the following definition for compound foods: Compound foods (i.e. foods made from more than one ingredient) “should not themselves be described directly or by implication as ‘natural’, but it is acceptable to describe such foods as ‘made from natural ingredients’ if all the ingredients meet the criteria.” *Id.*

180 *Id.*

181 See “*Natural*” on Food Labeling, *supra* note 66. Under the FDA’s current definition, there is not a distinction between “natural” and “made with natural ingredients.” Instead, food manufacturers seem to be using the following terms interchangeably: natural, all-natural, purely natural, 100% natural, and made with natural ingredients. See also Rock, *supra* note 5.

Parliament when it established strict labeling requirements for genetically modified foods.¹⁸² While the US condemned the EU's ban on hormone-treated meats in 2003,¹⁸³ it is possible that the FDA's criticism was limited to the European Parliament's approach to labeling genetically modified foods. The FDA took a more collaborative approach with other nations and international food manufacturers to assist with NLEA compliance.¹⁸⁴ The FDA distributes information and regulatory materials with its equivalent regulatory agency for European countries and other nations to exchange ideas about how to approach nutritional labeling.¹⁸⁵ Further, since 1963, the United States has been a member of the Codex Alimentarius,¹⁸⁶ a "collection of internationally adopted food standards and related texts" that addresses food safety, fair food practices, and food product labeling.¹⁸⁷ While the Codex Alimentarius defers to individual member states to establish a definition for "natural" and its derivatives,¹⁸⁸

182 *EU, US Beef Dispute Intensifies*, BRIDGES (Jan. 21, 2009), <https://www.ictsd.org/bridges-news/bridges/news/eu-us-beef-dispute-intensifies>. At a World Trade Organization meeting, the United States publicly criticized the European Union's ban on hormone-enhanced meat and continued its trade restrictions. United States Trade Rep. Susan Schwab noted that "in this time of worldwide financial problems, it is important to emphasize that the purpose of the action announced today is not to raise trade barriers, but to lower them." *Id.*

183 *Id.*

184 Linda R. Horton, *International Harmonization and Compliance*, in *NUTRITION LABELING HANDBOOK* 85, 90 (Ralph Shapiro, ed., 1995) ("FDA has undertaken many educational and compliance activities . . . that will aid domestic and foreign food firms in following NLEA.").

185 *Id.* (noting that the FDA has "participated in NLEA training programs in a number of countries, including . . . the European Union . . . , provided copies of NLEA regulations to embassies and regulatory counterparts abroad . . . , provided special briefing in meetings of the Codex Committee on Food Labeling . . . , [and] sen[t] a letter to representatives of other governments reminding them of the impending effective date of regulations implementing NLEA").

186 *Members Detail: United States of America*, CODEX ALIMENTARIUS, <http://www.fao.org/fao-who-codexalimentarius/about-codex/members/detail/en/c/15600/> (last visited Feb. 9, 2018).

187 *About Codex Alimentarius*, CODEX ALIMENTARIUS, http://www.fao.org/fao-who-codexalimentarius/about-codex/en/#jfmulticontent_c453296-1 (last visited Feb. 9, 2018).

188 ODEX ALIMENTARIUS, CODEX GENERAL GUIDELINES ON CLAIMS (1991), <http://www.fao.org/docrep/005/y2770e/y2770e05.htm> ("Terms such as "natural", "pure", "fresh",

the leadership team is focused on providing safer and more appropriately labeled products for consumers.¹⁸⁹ Given the FDA's openness to establishing a definition of "natural" and their recent open comment period for the American public,¹⁹⁰ the FDA appears to be at least receptive to taking a more collaborative approach to food labeling or possibly follow other nations' approach to food labeling.

Alternatively, the FDA could seek guidance from the USDA. In the context of animal meat, USDA established an official definition for "natural."¹⁹¹ During the process of establishing this definition, the USDA also hosted an extended comment period for consumers to discuss concerns and issues related to the "natural" term.¹⁹² However, it seems less likely that the FDA will utilize a similar definition because the USDA's definition is tailored for meat and poultry products.¹⁹³ Despite the USDA's different approach¹⁹⁴ to labeling, the FDA may still reference the basic

"home made", "organically grown" and "biologically grown" when they are used, should be in accordance with the national practices in the country where the food is sold.").

189 *About Codex: Consumers*, CODEX ALIMENTARIUS, <http://www.fao.org/fao-who-codexalimentarius/about-codex/consumers/en/> (last visited Feb. 9, 2018).

190 See Request for Information and Comments and Extension of Comment Period Regulations, 80 Fed. Reg. 69905, 69906-07 (Nov. 12, 2015).

191 *Meat and Poultry Labeling Terms*, U.S. DEP'T OF AGRIC. (2015), <https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/food-labeling/meat-and-poultry-labeling-terms/meat-and-poultry-labeling-terms> (The USDA's "natural" definition: "A product containing no artificial ingredient or added color and is only minimally processed. Minimal processing means that the product was processed in a manner that does not fundamentally alter the product. The label must include a statement explaining the meaning of the term natural (such as 'no artificial ingredients; minimally processed')").

192 Notice of Meeting and Extension of Comment Period, 72 Fed. Reg. 2257 (Jan. 18, 2007).

193 BRUCE SILVERGLADE & ILENE RINGEL HELLER, *FOOD LABELING CHAOS: THE CASE FOR REFORM 6* (2010), https://cspinet.org/sites/default/files/attachment/food_labeling_chaos_report.pdf.

194 *Id.* The USDA utilizes a pre-approval process where manufacturers must first have their meat labels approved before distribution. In addition, as the Center for Science in the Public Interest notes, the USDA has less strict labeling requirements and allows for poultry products that have been "injected with a salty broth" to be labeled "all natural." *Id.*

outline of the USDA's definition by including a section on minimal processing and clarifying when and how a product may fit this definition. It would most likely benefit consumers and food manufacturers if the FDA collaborated with the USDA on a definition for "natural" and its derivatives because this would help to standardize the term.

While companies may support the FDA's decision not to establish a formal definition for "natural" and instead categorize their product labeling as commercial speech,¹⁹⁵ this argument is limited. Corporations can argue that "natural" is a health claim and as such is only subject to FDA regulations surrounding health claims. While health claims on drugs have separate and stricter regulations, the FDA allows these statements on food products.¹⁹⁶ Following court cases surrounding commercial speech claims,¹⁹⁷ the FDA established additional categories for health claims and clarified when producers may use qualified and unqualified health claims

195 See Caroline Q. Shepard, "Natural" Food Labeling: False Advertising and the First Amendment, 16 MARQ. ELDER'S ADVISOR 173 (2014) (quoting Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 566 (1980)) (When considering if the government may limit commercial speech, courts consider the following four-inquiry test: "(1) it must concern lawful activity and not be misleading; (2) the government's interest must be substantial; (3) the regulation must directly advance the government's interest; and (4) it must not be more extensive than necessary to serve the interest."); see also Robert Lustig & Marsha Cohen, *F.D.A. Must Define, and Enforce, the Term "Natural,"* N.Y. TIMES: THE OPINIONS PAGE, ROOM FOR DEBATE (Nov. 11, 2014), <https://www.nytimes.com/roomfordebate/2014/11/10/should-the-fda-regulate-the-use-of-natural-on-food-products-15/fda-must-define-and-enforce-the-term-natural>.

196 See Monika Jankowska, *U.S. Food Labeling Regulations vs. Freedom of Speech - Creation of Qualified Health Claims*, 2017 EUR. FOOD & FEED L. REV. 142, 145. The commercial speech doctrine later applied to nutritional claims on products in *Whitaker v. Thompson*, 248 F. Supp. 2d 1, 17 (D.D.C. 2002) (citing to *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999)) where the Court ordered the FDA "to draft and submit one or more such appropriately short, succinct, and accurate disclaimer." This decision forced the FDA to establish additional categories for health claims and to clearly clarify when producers may use qualified and unqualified health claims in their product labeling. *Id.* The court in *Whitaker* remanded the case to the FDA and proposed that the FDA clearly define nutritional claims. ("The Court strongly suggests that, at a minimum, the agency consider the two disclaimers suggested by the Court of Appeals in *Pearson I* ('The evidence in support of this claim is inconclusive' and 'The FDA does not approve this claim.')." *Id.*

197 *Whitaker*, 248 F. Supp. 2d at 17.

in their product labeling.¹⁹⁸ But, the commercial speech argument is only viable in the absence of an official definition;¹⁹⁹ when the FDA promulgates a formal definition, food manufacturers will need to comply with the FDA's requirements for the term.²⁰⁰ In the interim, the commercial speech doctrine, along with the increasing number of class action lawsuits, remain the reality for consumers, food manufacturers, and the American judicial system.

V. CONCLUSION

Due to other FDA requirements on packaged food, such as nutritional facts,²⁰¹ consumers are accustomed to having access to this information and being able to rely on the accuracy of food labels.²⁰² The large public response during the comment period indicates that the FDA recognizes the need to define "natural"²⁰³ or at least, explore how best to proceed with food labeling. The growing number of class action lawsuits, particularly in the Northern District of California,²⁰⁴ and distrust of food product labeling indicates that American consumers are unhappy with the informal definition. The FDA needs to establish a formal definition in order to

198 See Jankowska, *supra* note 196, at 148. The Court requested that the FDA clarify their regulations and provide more explicit standards when evaluating health claims on food labels so as not abridge the free speech via commercial speech of producers.

199 See Lustig & Cohen, *supra* note 195. ("Without a government definition, 'natural' is inherently misleading because consumers purchase products under misconceptions about their contents. But as companies oppose banning the use of the word 'natural' as a violation of 'commercial speech,' the F.D.A. has no choice but to issue an industry-wide definition and then enforce it.").

200 *Id.*

201 See 21 U.S.C. § 343 (2018).

202 See Wilkening, *supra* note 60.

203 See Request for Information and Comments and Extension of Comment Period Regulations, 80 Fed. Reg. 69905, 69906-07 (Nov. 12, 2015).

204 See Anscombe & Buckley, *supra* note 14.

protect American consumers from ineffective or inappropriate labels on food products and to provide food manufacturers with enforceable guidelines.²⁰⁵ Beyond protecting the American public, establishing a formal definition for “natural” also positively benefits companies. By establishing a narrow definition, the FDA would clarify labeling requirements for companies to ensure that “natural” is used appropriately. This change would also serve to reward companies that are forthcoming and transparent with their food labels.²⁰⁶

The FDA can turn to the European Union and its member states for guidance on how to define “natural” and how to work with food manufacturers and consumers to have a more efficient food system. The FDA can use crucial elements of select European nations’ definition for “natural,” such as creating a separate definition for compound and simple foods.²⁰⁷ The FDA can also utilize parts of the FSA and FoodDrinkEurope’s approach to defining “natural”²⁰⁸ and related terms while still ensuring that the definition is applicable to the American food market.

However, if the FDA continues to resist implementing new changes, this action will heavily impact consumers’ ability to accurately and efficiently select products, which only increase the public’s distrust of the FDA as a regulatory agency. The FDA has authority to issue a formal definition of “natural” and its derivatives,²⁰⁹ which can protect consumers

205 See Purdy, *supra* note 10.

206 See Watrous, *supra* note 70.

207 See FSA, *supra* note 103.

208 See CIAA, *supra* note 121.

209 See Scarbrough, *supra* note 65.

from mislabeled products²¹⁰ and ensure that the labeling on products is not meaningless.²¹¹

The FDA is the only regulatory agency empowered to issue a definition for “natural,”²¹² and identify any labeling requirements for related terms; in its reluctance to establish a formal definition, the FDA has failed to protect American consumers and manufacturers.

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210 See Levinovitz, *supra* note 9.

211 See Pollan, *supra* note 10.

212 See Request for Information and Comments and Extension of Comment Period Regulations, 80 Fed. Reg. 69905, 69906-07 (Nov. 12, 2015).

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