

ESSAY

“Natural” Modifications: The FDA’s Need to Promulgate an Official Definition of “Natural” that Includes Genetically Modified Organisms

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ABSTRACT

Consumer demand for “natural” food and beverage products has never been higher. In response to this demand, U.S. companies have made “natural” the most frequently used descriptive claim on new U.S. food products. Yet, despite the immense importance placed on this term, “natural” has no legal meaning. The FDA has not exercised its authority over product labeling to officially define the term, but instead issued an informal and unbinding definition of “natural” that has led to consumer confusion, food and beverage industry uncertainty, and countless lawsuits across the country. The most recent lawsuits have been brought against companies whose products are labeled “natural” and contain Genetically Modified Organisms (“GMO”). GMOs have changed the world of food production and now represent a major portion of America’s food supply.

As the extent of GMOs in the market and consumer demand for “natural” products simultaneously continue to increase, the time is ripe for FDA interpretation. Absent FDA action, food and beverage companies will con-

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tinue to be placed in a no-win situation and judges across the country will eventually be forced to define “natural,” potentially resulting in several inconsistent and unworkable definitions. This Essay argues that the FDA should initiate notice and comment rulemaking to define “natural” and that, when it does, consistency and predictability dictate that the term include products containing GMOs.

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INTRODUCTION

Consumers entering any supermarket or convenience store are bombarded with products labeled “Natural,” “All Natural,” or “100%

Natural.”¹ “Natural” is the most frequently used claim on new U.S. food products,² and “natural” foods constituted a roughly \$22 billion industry in 2008.³ Despite the importance that consumers and, therefore, the food industry, places on this descriptive term, the Food and Drug Administration (“FDA”) has not exercised its congressionally delegated authority over product labeling to initiate notice and comment rulemaking to officially define “natural” and regulate its use. The FDA’s lack of interpretation has led to numerous lawsuits alleging that the food industry misleads consumers by using a term that has no legal definition.⁴ These lawsuits do little more than create uncertainty in the food industry, line the pockets of plaintiffs’ attorneys, and, eventually, place the definition of “natural” in the hands of judges across the country who lack the necessary expertise to define such a term.

Most recently, plaintiffs have brought suits against companies for labeling their products “natural” when those products are in fact created from genetically modified (“GM”) base ingredients⁵—Genetically Modified Organisms (“GMO”).⁶ The development of GMOs has changed the world of food production over the last twenty years and is now vital to America’s food supply. For example, in 2009, ninety-five percent of all sugar beets grown in the United States were of the GM variety.⁷ In 2010, eighty-six percent of corn⁸ and ninety-

¹ This Essay uses “natural” to refer to any similar descriptive term such as “100% natural” and “all natural.”

² Karlene Lukovitz, ‘Natural’ Claims Most Common on New F&B Products, MEDIAPOSTNEWS (Jan. 19, 2009, 11:16 AM), http://www.mediapost.com/publications/?fa=Articles.showArticle&art_aid=98562.

³ “Natural” Beats “Organic” in Food Sales According to Nielsen’s Healthy Eating Report, NIELSENWIRE (Jan. 21, 2009), <http://blog.nielsen.com/nielsenwire/consumer> (search for “natural beats organic” in search bar) [hereinafter *Natural Beats Organic*].

⁴ See, e.g., *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 332 (3d Cir. 2009).

⁵ See Complaint at 1–2, *Gengo v. Frito-Lay N. Am., Inc.*, No. CV1110322 (C.D. Cal. filed Dec. 14, 2011); Complaint at 1, *Briseño v. ConAgra Foods, Inc.*, No. CV11-05379 (C.D. Cal. filed June 28, 2011); see also Jill Ettinger, *Naturally... GMO Foods Labeled ‘Natural’ Land Manufacturers in Court*, ORGANICAUTHORITY.COM (Sept. 22, 2011), <http://www.organicauthority.com/blog/organic/naturally-gmo-foods-labeled-natural-land-manufacturers-in-court>.

⁶ This Essay uses GM and GMO interchangeably to refer to crops that have been produced with the help of genetic modification. See *infra* Part III.A for a description of genetic modification.

⁷ USA: Cultivation of GM Plants, 2009: Maize, Soybean, Cotton: 88 Percent Genetically Modified, GMO COMPASS (July 30, 2009), http://www.gmo-compass.org/eng/agri_biotechnology/gmo_planting/506.usa_cultivation_gm_plants_2009.html.

⁸ NAT’L AGRIC. STATISTICS SERV., AGRIC. STATISTICS BD., U.S. DEP’T OF AGRIC., ACREAGE 24, June 30, 2010, available at <http://usda.mannlib.cornell.edu/usda/nass/Acre/2010s/2010/Acre-06-30-2010.pdf> [hereinafter ACREAGE].

three percent of soybeans⁹ were GM products. A large number of companies taking advantage of the new GM technology label their products “natural.”¹⁰ In fact, even Whole Foods Market, a health foods store whose entire business model is based upon offering the “most flavorful and natural foods,”¹¹ uses a substantial amount of GMOs in its own brand name products, which the company labels as “natural.”¹² These lawsuits will likely continue to proliferate until the FDA preempts them by initiating rulemaking to officially define “natural.”

The combination of the demand for “natural” products, the massive presence of GMOs in various food products throughout the market, and the refusal by the FDA to define “natural” has created the proverbial “perfect storm.” Food producers want to take advantage of the market for “natural” products but are unsure as to what qualifies as such. They can guess, but rather than facing enforcement by the agency responsible for regulating food labeling, producers must answer to class action attorneys and various judges across the country.

This Essay argues that it is essential for the FDA to initiate notice and comment rulemaking to define “natural,” and that an appropriate definition should include products containing GMOs.¹³ Part I introduces the controversy surrounding “natural” labels, including the FDA’s unwillingness to officially define “natural” and the resulting legal uncertainty. Part II explains why the FDA should initiate rulemaking to define “natural.” Finally, Part III argues that, when the FDA finally defines the term, consistency and predictability dictate that the definition of “natural” should include products containing GMOs.

⁹ *Id.* at 25.

¹⁰ See, e.g., *No Official Definition for “Natural” Food*, UPI.COM (Oct. 13, 2011, 1:09 AM), http://www.upi.com/Health_News/2011/10/13/No-official-definition-for-natural-food/UPI-36821318482586/?spt=hs&or=hn (stating that brands—including Kashi, Mother’s, Nutritious Living, Barbara’s Bakery, and Whole Foods Market’s 365—advertised as “natural” contain high levels of GM ingredients).

¹¹ See *About Whole Foods Market*, WHOLE FOODS MARKET, <http://www.wholefoodsmarket.com/company> (last visited May 21, 2012).

¹² See *No Official Definition for “Natural” Food*, *supra* note 10.

¹³ This Essay does not argue that GM foods are, in fact, “natural,” whatever that term may mean in a non-legal sense. Instead, this Essay argues that, because of the FDA’s and USDA’s current positions surrounding the term, GM products are “natural” for the purposes of labeling. See *infra* Part III.

I. THE “NATURAL” CONTROVERSY

Use of the term “natural” in food and beverage labeling has dramatically increased throughout the last decade. “Natural” is now the most-used descriptive term on new U.S. food products.¹⁴ “Natural”-labeled food and beverages constituted an over \$22 billion industry in 2008,¹⁵ which represents a ten percent increase from 2007 sales and a thirty-seven percent increase from 2004 sales.¹⁶ Moreover, approximately 55,000 products have the term “natural” on their labels.¹⁷ This universe of products includes well-known brands that contain between fifty and one hundred percent genetically engineered ingredients.¹⁸ There is good reason for the proliferation of “natural” labels: a recent consumer poll shows that sixty-three percent of consumers prefer a product labeled “natural.”¹⁹ Whatever the cause of this “natural” phenomenon—either a product of consumer preference or a response to the food industry’s marketing of natural products—increasing demand, and therefore, the supply, for “natural” products is likely to continue into the foreseeable future.

According to a 2006 study, approximately eighty-three percent of consumers want the FDA to define “natural.”²⁰ Yet, the FDA has not used its congressionally delegated authority to officially define the term. This inaction has caused much uncertainty in the food industry and litigation in the courts.

¹⁴ Lukovitz, *supra* note 2.

¹⁵ *Natural Beats Organic*, *supra* note 3.

¹⁶ *Id.*

¹⁷ Adam C. Schlosser, *A Healthy Diet of Preemption: The Power of the FDA and the Battle Over Restricting High Fructose Corn Syrup from Food and Beverages Labeled “Natural,”* 5 J. FOOD L. & POL’Y 145, 167 (2009).

¹⁸ *No Official Definition for “Natural” Food*, *supra* note 10; see also CORNUCOPIA INST., CEREAL CRIMES: HOW “NATURAL” CLAIMS DECEIVE CONSUMERS AND UNDERMINE THE ORGANIC LABEL—A LOOK DOWN THE CEREAL AND GRANOLA AISLE 7, 29 (Oct. 2011), available at http://cornucopia.org/cereal-scorecard/docs/Cornucopia_Cereal_Report.pdf [hereinafter CEREAL CRIMES] (explaining that cereal brands with high levels of GMO ingredients include General Mills’ Kix).

¹⁹ GREENERCHOICES.ORG & CONSUMER REPORTS, FOOD LABELING POLL 9 (July 11, 2007), available at http://greenerchoices.org/pdf/Food%20Labeling%20Poll-final_rev.pdf.

²⁰ 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, 418 (2010) (referring to a 2006 Harris Interactive study indicating that consumers want the FDA to define the term “natural”); Citizen Petition from Andrew C. Briscoe III, President & Chief Exec. Officer, Sugar Assoc., to Docket Mgmt. Branch, FDA, at 9 (Feb. 28, 2006), available at http://www.cspinet.org/new/pdf/sugar_fda_petition.pdf [hereinafter Citizen Petition from Sugar Association] (requesting that the FDA “undertake rulemaking to establish rules and regulations governing the definition of ‘natural’”).

A. The FDA’s Authority to Regulate Labeling

For more than one hundred years, Congress has regulated food and beverage labeling.²¹ The Pure Food and Drug Act of 1906²² established labeling standards and prohibited misbranding of foods sold in interstate commerce.²³ These regulations, however, did not vest Congress and the FDA with sufficient power to protect consumers.²⁴ In 1938, Congress responded to mounting public concern regarding manufacturing and marketing of dangerous food and drug practices by passing the Federal Food, Drug, and Cosmetic Act (“FDCA”).²⁵ The FDCA grants the FDA the power to “promulgate food definitions and standards of food quality.”²⁶ This power includes requiring nutritional labeling if the manufacturer makes nutritional or health claims about the product such as “low fat” or “high in fiber.”²⁷ Under the original FDCA, only about sixty percent of food labels in the U.S. disclosed nutritional information.²⁸ Thus, the FDA needed further regulatory power to require more disclosure.

Congress passed the Nutrition and Labeling Education Act (“NLEA”)²⁹ in 1990, which amended the FDCA to require more detailed nutritional information to be included on product labels.³⁰ The NLEA introduced several reforms including requiring nutritional labeling for nearly all food products under the purview of the FDA, changing the requirements for ingredient labels on food packages, and imposing and regulating health claims on packages.³¹ Congress enacted the NLEA to curb the abundance of inconsistent and poorly

²¹ *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 331 (3d Cir. 2009).

²² Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768, *repealed by* Act of June 25, 1938, ch. 675, § 902(a), 52 Stat. 1059.

²³ *Holk*, 575 F.3d at 331.

²⁴ *Id.* (explaining that the Pure Food and Drug Act “lacked affirmative requirements to guide compliance”).

²⁵ Federal Food, Drug, and Cosmetic Act (FDCA), Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301–399); *Holk*, 575 F.3d at 331.

²⁶ *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 251 (3d Cir. 2008) (citing 21 U.S.C. §§ 341, 346 (2006)).

²⁷ See Emily J. Schaffer, *Is the Fox Guarding the Henhouse? Who Makes the Rules in American Nutrition Policy?*, 57 FOOD & DRUG L.J. 371, 404 (2002).

²⁸ BRUCE SILVERGLADE, CTR. FOR SCI. PUB. INT., USING FOOD LABELING TO IMPROVE DIET AND HEALTH: AN EXAMINATION OF THE U.S. NUTRITION LABELING AND EDUCATION ACT, <http://www.cspinet.org/reports/codex/labeling.htm>.

²⁹ Nutrition Labeling and Education Act (NLEA) of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified at 21 U.S.C. § 343).

³⁰ *The Impact of the Nutrition Labeling and Education Act of 1990 on the Food Industry*, 47 ADMIN. L. REV. 605, 606 (1995).

³¹ *Id.*

defined terms used to describe nutrient content.³² To promote this end, the NLEA required the FDA to set comprehensive standards for nutrition claims such as “low fat,” “light,” and “healthy.”³³ Although the FDA regulates the majority of terms that appear on food and beverage labels,³⁴ the agency has not exercised its authority with regard to “natural” labels.

B. The FDA’s Current “Natural” Policy

The FDA has not used notice and comment rulemaking procedures to promulgate a formal definition of “natural.” Originally, the FDA recognized the importance of formally defining this term and believed that an adequate definition could prevent consumer confusion and ambiguity.³⁵ Unfortunately, however, the FDA backtracked on this goal. After receiving an initial set of public comments regarding the proper definition of “natural,” the FDA blamed “resource limitations and other agency priorities” for its ultimate decision to forgo notice and comment rulemaking to define “natural.”³⁶ The FDA continues to stand by this decision.³⁷

In the place of an official definition, the FDA has an informal definition of the term “natural.” The agency stated in the 1993 preamble to a rulemaking for nutrient content claims that “natural” means that “nothing artificial or synthetic . . . has been included in, or has been added to, a food that would not normally be expected to be in the food.”³⁸ To be legally binding, the FDA’s policy regarding “natu-

³² See *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 332 (3d Cir. 2009).

³³ SILVERGLADE, *supra* note 28.

³⁴ Schlosser, *supra* note 17, at 147 (noting that terms such as “reduced fat” and “high fiber” must meet strict requirements).

³⁵ Food Labeling: Nutrient Content Claims; General Principles, Petitions, Definitions of Terms, 56 Fed. Reg. 60,421, 60,466 (proposed Nov. 27, 1991); Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993) (to be codified at 21 C.F.R. pts. 5, 101).

³⁶ Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. at 2407.

³⁷ Letter from Margaret O’K. Glavin, Assoc. Comm’r for Regulatory Affairs, FDA, to Antonio Zamora (Dec. 12, 2005), *available at* <http://www.fda.gov/ohrms/dockets/dockets/04p-0009/04p-0009-pdn0001-vol1.pdf> (stating that the FDA intended to adhere to its current policy); *see also* Lorraine Heller, “Natural” Will Remain Undefined, Says FDA, FOOD NAVIGATOR-USA.COM (Jan. 4, 2008), <http://www.foodnavigator-usa.com/Business/Natural-will-remain-undefined-says-FDA> (stating that the natural issue is not a priority for the FDA). Moreover, requests by the Sugar Association, Sara Lee, and Hormel to define “natural” have failed to prompt the FDA to initiate rulemaking. *See* Farris, *supra* note 20, at 406–07, 409–11.

³⁸ See Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition

ral” must be a legislative rule rather than an interpretative rule or policy statement.³⁹ To determine whether a rule is substantive or legislative, rather than nonlegislative, courts look at whether the rule has the “force of law.”⁴⁰

While distinguishing between legislative and nonlegislative rules is sometimes “enshrouded in considerable smog,”⁴¹ the Third Circuit recently held that the FDA’s definition of “natural” does not have the force of law.⁴² The court’s conclusion stemmed from the fact that (1) the FDA did not undertake a formal process or receive public input on the term; (2) the FDA admitted in 1993 that it was not officially defining the term because there were still many facets that the agency needed to consider before making a definition; (3) the FDA’s enforcement letters to food and beverage manufacturers telling them to remove “natural” labels were insufficient to accord the policy the weight of federal law; and (4) the FDA reissued the preexisting “natural” policy after soliciting public comments, which proves that the agency did not take any of the comments they received into account.⁴³

Satisfying the notice and comment procedures in § 553 of the Administrative Procedure Act (“APA”)⁴⁴ would give binding force to the FDA’s definition of “natural.”⁴⁵ But because the FDA’s “natural” policy is nonbinding, neither the agency nor the courts can compel compliance. Adding to the difficulty, the FDA has not defined or issued guidance regarding the two key terms in the informal “natural” policy—“synthetic” and “artificial”—so the policy does little to inform the food industry or consumers as to what “natural” actually means. The lack of a clear and binding definition of “natural” has led to countless lawsuits across the country.

of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. at 2407.

³⁹ See *Chrysler Corp. v. Brown*, 441 U.S. 281, 301–02 (1979).

⁴⁰ *Id.* at 302; see also *Cement Kiln Recycling Coal. v. EPA*, 493 F.3d 207, 216 (D.C. Cir. 2007); *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1109 (D.C. Cir. 1993). Courts will look at factors such as whether the agency needs the rule to be able to initiate an enforcement action, whether the agency published the proposed rule in the Code of Federal Regulations, whether the agency says that the rule is legislative, and whether the rule amends a preexisting legislative rule. *Am. Mining Cong.*, 995 F.2d at 1112.

⁴¹ *Noel v. Chapman*, 508 F.2d 1023, 1029–30 (2d Cir. 1975).

⁴² See *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 342 (3d Cir. 2009). The Third Circuit is the only circuit court to address the force of the FDA’s “natural” definition.

⁴³ *Id.* at 340–41.

⁴⁴ 5 U.S.C. § 553(b)–(c) (2006).

⁴⁵ *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 245 (3d Cir. 2008) (stating that an agency rule will have the effect of law when it is the result of a formal procedure).

C. Legal Uncertainty Surrounding “Natural” Labeling

Because the FDA has not officially defined the term “natural,” companies use the term at will, but at their own risk. Over the last ten years, food companies choosing to advertise their products as “natural” have faced a growing number of lawsuits from competing companies,⁴⁶ consumer groups,⁴⁷ and consumers in the form of class action lawsuits.⁴⁸ Initially, the majority of these lawsuits involved food and beverage products labeled as “natural” and containing High Fructose Corn Syrup (“HFCS”).⁴⁹ Within the last year, however, these lawsuits have evolved. Class action lawsuits are now being brought against companies for labeling their products “natural” despite containing citric acid,⁵⁰ sodium benzoate,⁵¹ or GMOs.⁵²

Lawsuits over the legality of labeling products made from GMOs as “natural” are particularly important for two reasons. First, most of the controversy thus far has concerned using “natural” to describe products containing HFCS.⁵³ Because the vast majority of corn grown

⁴⁶ Complaint at 2–3, Sugar Assoc., Inc. v. McNeil-PPC, Inc., No. CV 04 10077 (C.D. Cal. Dec. 10, 2004); Complaint at 3, 5, Pom Wonderful LLC v. Organic Juice USA, Inc., No. 09 CV 4916 (S.D.N.Y. May 26, 2009).

⁴⁷ The consumer group Center for Science in the Public Interest threatened or backed litigation prompting several companies to change their labels. See, e.g., *7UP Drops “All Natural” Claim*, CTR SCI. PUB. INT. (Jan. 12, 2007), <http://www.cspinet.org/new/200701121.html>; *Food Company Kraft Dump “All Natural” Label From Juice-Free Capri Sun Drink*, MAILONLINE (Jan. 9, 2007, 10:29 PM), <http://www.dailymail.co.uk/news/article-427697/Food-company-Kraft-dump-natural-label-juice-free-Capri-Sun-drink.html>.

⁴⁸ See, e.g., *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 332 (3d Cir. 2009); *Williams v. Gerber Prods. Co.*, 552 F.3d 934, 936 (9th Cir. 2008); *Lockwood v. ConAgra Food, Inc.*, 597 F. Supp. 2d 1028, 1029 (N.D. Cal. 2009).

⁴⁹ See, e.g., *Von Koenig v. Snapple Beverage Corp.*, 713 F. Supp. 2d 1066, 1070 (E.D. Cal. 2010); Complaint at 2, *Coyle v. Hornell Brewing Co.*, No. 08-2797 (D.N.J. July 31, 2009); Complaint at 7, *Covington v. Ariz. Beverage Co.*, No. 08-21894 Civ (S.D. Fla. Sept. 30, 2009); see also *Holk*, 575 F.3d at 332; *Williams*, 552 F.3d at 936; *Lockwood*, 597 F. Supp. 2d at 1029.

⁵⁰ Complaint at 6, *Ries v. Hornell Brewing Co.*, No. CV10-01139 (N.D. Cal. Mar. 17, 2010).

⁵¹ Alison Frankel, *Class Action Claims Skinnygirl Margaritas Not “All Natural”!*, THOMSON REUTERS NEWS & INSIGHT (Sept. 7, 2011), <http://newsandinsight.thomsonreuters.com/Legal/News/ViewNews.aspx?id=26962&terms=%40ReutersTopicCodes+CONTAINS+%27ANV%27>.

⁵² See, e.g., Complaint at 1–2, *Gengo v. Frito-Lay N. Am., Inc.*, No. CV1110322 (C.D. Cal. filed Dec. 14, 2011); Complaint at 1, *Briseño v. ConAgra Foods, Inc.*, No. CV11-05379 (C.D. Cal. filed June 28, 2011). The Panel on Multidistrict Litigation recently consolidated six class action suits against ConAgra Food. See *In re Wesson Oil Mktg. & Sales Practice Litig.*, 818 F. Supp. 2d 1383 (J.P.M.L. 2011).

⁵³ See generally Josh Ashley, *A Bittersweet Deal for Consumers: The Unnatural Application of Preemption to High Fructose Corn Syrup Labeling Claims*, 6 J. FOOD L. & POL’Y 235 (2010); Farris *supra* note 20; Schlosser, *supra* note 17.

in the United States is genetically modified,⁵⁴ discussing only whether companies can label foods containing HFCS as “natural” misses the point. That is, even if the process used to create HFCS does not render the product unnatural, the next logical question is whether the product is unnatural because of its underlying GM base ingredients. Second, the market share of GM products is increasing dramatically.⁵⁵ This increase will likely result in more products made from GMOs and, subsequently, more products labeled “natural” that contain GMOs. When a similar increase occurred with products containing HFCS, the number of lawsuits filed also increased.⁵⁶ It appears likely that this phenomenon will repeat itself.

The majority of the “natural” lawsuits are class actions alleging deceptive business practices and false advertising.⁵⁷ Essentially, plaintiffs’ attorneys bring putative class actions against companies that claim their products are “natural” because, no matter what the product contains, the lack of a formal definition permits an argument that the product does not fit consumers’ conceptions of “natural.” Significantly, the Third Circuit, in *Holk v. Snapple Beverage Corp.*,⁵⁸ recently held that the FDA’s informal policy regarding “natural” does not preempt these lawsuits.⁵⁹ The court made clear, however, that a “natural” definition promulgated after notice and comment rulemaking would have this preemptive effect.⁶⁰ This is because, under the NLEA, a definition of “natural” would preempt all state laws that are not identical to the federal definition.⁶¹ A California district court—

⁵⁴ See *supra* note 8 and accompanying text.

⁵⁵ See *infra* Part III.A.

⁵⁶ See Farris, *supra* note 20, at 411–12; Schlosser, *supra* note 17, at 168–72.

⁵⁷ See, e.g., *Von Koenig v. Snapple Beverage Corp.*, 713 F. Supp. 2d 1066, 1070 (E.D. Cal. 2010); *Lockwood v. ConAgra Foods, Inc.*, 597 F. Supp. 2d 1028, 1029–30 (N.D. Cal. 2009).

⁵⁸ *Holk v. Snapple Beverage Corp.*, 575 F.3d 329 (3d Cir. 2009).

⁵⁹ *Id.* at 340.

⁶⁰ See *id.* (citing *Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 245 (3d Cir. 2008)). The issue of express preemption was not properly before the court in *Holk*, so the court only considered field and implied preemption. *Id.* at 336. Based on the court’s discussion, however, implied conflict preemption is sufficient to preempt conflicting state law if the FDA formally defines “natural.” *Id.* at 339–42. More importantly, a promulgated definition would expressly preempt all non-identical state law claims. See *infra* note 61.

⁶¹ See *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 510 (1996) (explaining that Congress intended the FDCA to preempt state law if the state law contains any language different from the FDCA). The FDCA does not grant a private right of action. 21 U.S.C. § 337(a) (2006). A provision added to the FDCA by the NLEA, however, permits a private party to enforce a violation of the NLEA, if and only if the state enacts a law that imposes requirements *identical* to those in the NLEA. See 21 U.S.C. § 343-1(a)(5); *Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011) (holding that state law claim alleging deceptive advertising regarding the amount of fiber in a granola bar was expressly preempted because requirements for the labeling of fiber content were

where most of these cases tend to be filed⁶²—recently echoed the Third Circuit’s sentiment.⁶³

In response to the Third Circuit’s opinion in *Holk*, multiple courts stayed actions and referred the issue of whether HFCS qualifies as a “natural” ingredient to the FDA in hopes that the agency would respond to the Third Circuit’s preemption determination.⁶⁴ Unfortunately, however, the FDA declined to make a determination in each case, prompting the courts to lift stays they issued earlier.⁶⁵ Because of the FDA’s inaction, the number of cases filed has increased, creating further uncertainty in the food industry and wasting scarce judicial resources. Plaintiffs will continue to file suits until the FDA preempts them by initiating notice and comment rulemaking to define “natural.”

II. THE FDA SHOULD DEFINE “NATURAL” THROUGH NOTICE AND COMMENT RULEMAKING

Forcing agency action is a near impossible feat.⁶⁶ Therefore, the FDA should voluntarily initiate notice and comment rulemaking to define “natural” to avert the problems discussed above. Defining “natural” is worthy of FDA action because (1) defining the term comports with the FDA’s responsibility delegated under the FDCA and NLEA; (2) it requires the FDA to utilize its expertise in defining the complex term, which is preferable to leaving it in the hands of a variety of judges across the country; and (3) an official definition of “natural” will relieve the burden on consumers, the food industry, and courts.

expressly laid out in 21 U.S.C. § 343(q)(1)(D) and 21 C.F.R. § 101.54(d)). Therefore, by promulgating a definition, the FDA would effectively preempt all of the state law claims currently pending (unfair business practices, false advertising, etc.), except those specifically attempting to enforce compliance with the FDA’s definition.

⁶² See, e.g., *Von Koenig*, 713 F. Supp. 2d at 1070; Complaint at 1, *Briseño v. ConAgra Foods, Inc.*, No. CV11-05379 (C.D. Cal. June 28, 2011); Complaint at 1, *Ries v. Hornell Brewing Co., Inc.*, No. CV10-01139 (N.D. Cal. Mar. 17, 2010).

⁶³ See, e.g., *Lockwood v. ConAgra Foods, Inc.*, 597 F. Supp. 2d 1028, 1033–34 (N.D. Cal. 2009).

⁶⁴ See Order at 1–2, 14, *Coyle v. Hornell Brewing Co.*, No. 08-02797 (D.N.J. Sept. 23, 2012); Order at 1, *Holk v. Snapple Beverage Corp.*, No. 07-3018 (D.N.J. Oct. 14, 2010).

⁶⁵ See Order Lifting Stay at 1, *Coyle*, No. 08-2797; Order at 1, *Holk*, No. 07-3018.

⁶⁶ See *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 64 (2004) (explaining that a plaintiff’s claim “can proceed only where a plaintiff asserts that an agency failed to take a *discrete* agency action that it is *required to take*”).

A. The FDA Is Ignoring Its Congressionally Delegated Responsibility

Congress enacted the FDCA not only to protect consumer health and safety,⁶⁷ but also to prevent the misbranding and false advertising of food.⁶⁸ Moreover, Congress also passed the NLEA because, due to competitive pressures and a lack of regulatory guidance, many companies used misleading claims on their labels.⁶⁹ By creating a uniform system for when certain claims can be made, Congress intended the NLEA to stop companies from using misleading claims.⁷⁰ It is impossible, however, to prevent misbranding and protect the public without an official definition of “natural.” Finally, Congress enacted the NLEA to create uniform federal labeling standards.⁷¹ Yet, the use of “natural” in labeling is anything but uniform.⁷² By relying on an informal policy statement rather than officially defining “natural,” the FDA has not only failed to properly exercise the authority delegated to it by Congress, but has failed the consumers and industries Congress intended the FDA to protect.⁷³

B. The FDA Has the Necessary Expertise to Define “Natural”

An agency’s expertise is the primary reason for agencies, rather than courts, to make decisions that will have significant policy implications.⁷⁴ The FDA has admitted the difficulty in defining “natural.”⁷⁵

⁶⁷ See 21 U.S.C. § 393(b) (2006).

⁶⁸ S. REP. NO. 91, at 1 (1937).

⁶⁹ See SILVERGLADE, *supra* note 28.

⁷⁰ See H.R. REP. NO. 101-538, at 7 (1990), reprinted in 1990 U.S.C.C.A.N. 3336, 3337.

⁷¹ See *id.*; MARION NESTLE, FOOD POLITICS: HOW THE FOOD INDUSTRY INFLUENCES NUTRITION AND HEALTH 245, 249–50 (rev. and expanded ed. 2007).

⁷² See *supra* notes 46–52 and accompanying text.

⁷³ Potential methods of defining “natural” include (1) the FDA harmonizing its definition of “natural” with the USDA’s definition, (2) determining “natural” foods by listing and excluding “unnatural” ingredients, and (3) creating different natural standards based on different categories of food. Farris, *supra* note 20, at 421–22; Schlosser, *supra* note 17, at 175.

⁷⁴ See, e.g., Am. Elec. Power Co. v. Connecticut, 131 S. Ct. 2527, 2539 (2011) (stating that an “expert agency is surely better equipped to do the job than individual district judges . . .”). Although the Court said this in the context of the Environmental Protection Agency setting limits on greenhouse gas emissions, the basic tenet remains the same: when Congress delegates a responsibility to an expert agency, the agency, rather than judges, should exercise this responsibility.

⁷⁵ See Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definitions of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993) (to be codified at 21 C.F.R. pts. 5, 101) (noting that the solicited comments it received regarding “natural” “provided a wide range of ideas for the agency to consider on the issue of developing a definition for ‘natural’” and did not provide the “FDA with a specific direction to follow”).

In fact, the FDA's lack of resources was likely a problem because of the potential complexity of the term.⁷⁶ A definition of "natural" is so complex that the FDA would need to devote a significant amount of time and resources to address it appropriately.⁷⁷ Given that an agency specifically delegated this responsibility has trouble defining "natural," it is likely that judges, who lack expertise in this area, will have an even more difficult time attempting to define the term.

Moreover, because of the complicated nature of the term "natural," judges are likely to disagree on both the definition itself and the food products and ingredients that qualify under the definition.⁷⁸ The inevitable result is a patchwork of "natural" definitions across the country.⁷⁹ This patchwork, in turn, would result in an unnecessary and illogical burden on the food industry.⁸⁰ For example, companies may be permitted to label their products "natural" in New York but not in New Jersey.⁸¹ This would result in a complete lack of uniformity in labeling, something Congress sought to avoid.⁸²

Judges also lack the benefit of notice and comment rulemaking to assist them in formulating a definition that is best for consumers and food and beverage companies. Therefore, when defining a term that principally affects food and beverage companies and consumers, the courts would not receive input from either group. Federal agencies, on the other hand, have the advantage of soliciting comments from those most knowledgeable about the potential effects of each possible

⁷⁶ See *id.*

⁷⁷ Limited agency resources are always a hurdle when an agency attempts to promulgate a new rule. However, the FDA recently received a \$335 million increase in discretionary funding, Farris, *supra* note 20, at 419, and "President Obama has indicated renewed commitment to the FDA," Schlosser, *supra* note 17, at 174. Moreover, minimal resources are required for FDA enforcement of a definition of "natural" because the NLEA permits private parties to enforce state laws that have definitions that are identical to the federal definition. Farris *supra* note 20, at 419 (citing 21 U.S.C. §§ 337(b), 343(k), 343-1(a)(3) (2006)). Thus, a binding definition of "natural" promulgated through notice and comment rulemaking and subsequent state laws that mimic this definition would allow private parties, rather than the FDA, to ensure compliance with the definition.

⁷⁸ See *Coyle v. Hornell Brewing Co.*, No. 08-02797, 2010 WL 2539386, at *4 (D.N.J. June 15, 2010).

⁷⁹ See *id.*

⁸⁰ See *id.*

⁸¹ See *id.* The Seventh Circuit also recently pointed out that Congress enacted the NLEA and its preemption provisions to prevent states from imposing their own disclosure requirements. *Turek v. Gen. Mills, Inc.*, 662 F.3d 423, 426 (7th Cir. 2011). If states imposed their own disclosure requirements, manufacturers would have to create and "print 50 different labels, driving consumers who buy food products in more than one state crazy." *Id.* The same result would likely stem from allowing judges to define the term "natural."

⁸² See *Coyle*, 2010 WL 2539386, at *3; see also *NESTLE*, *supra* note 71, at 250.

definition, facilitating an informed decision. Courts would have to define “natural” without the advantages of notice and comment rulemaking if the FDA’s inaction continues.⁸³ The onus is on the FDA to preempt this judicial action to protect food and beverage companies and consumers.

C. Negative Effects on Companies and Consumers

The increasing demand for “natural” products combined with the uncertainty surrounding the term puts companies in an awkward position: use the term and risk litigation, or omit the term and lose out in the market to competitors who do label their products as “natural.” Evidence suggests that food and beverage companies have chosen to use the “natural” label and simply pass the litigation costs on to consumers.⁸⁴

Moreover, a lack of an official definition of “natural” means companies do not know in which technology to invest to ensure the future success of their business.⁸⁵ For example, if companies cannot label products containing GMOs as “natural,” and a company wants to take advantage of the public demand for “natural” products, then the company will want to structure its business so that it no longer relies on GMOs. Additionally, the cost of doing business will likely increase dramatically if the FDA again declines to define “natural,” because different courts throughout the country will create competing definitions.

Consumers are also affected negatively by the lack of an official definition. Currently, consumers are under the false impression that a product labeled “natural” signifies “healthy” or “organic,”⁸⁶ unaware that the FDA has let them down in this regard. There is no excuse for

⁸³ Thus far, failure to satisfy class certification requirements, such as predominance and typicality, has prevented courts from reaching the merits of “natural” lawsuits. See *Coyle v. Hornell Brewing Co.*, No. 08-02797, 2011 WL 2147218, at *6 (D.N.J. May 26, 2011) (lacking adequacy of representation); *Weiner v. Snapple Beverage Corp.*, No. 07 Civ. 8742, 2010 WL 3119452, at *5 (S.D.N.Y. Aug. 5, 2010) (lacking predominance); see also FED. R. CIV. P. 23. As plaintiffs modify the proposed classes to satisfy the class action requirements and competing companies continue to bring claims, judges will have no choice but to define the term.

⁸⁴ See *CEREAL CRIMES*, *supra* note 18, at 6 (“Although ‘natural’ products are conventional (both in crop production and processing methods), they often are priced at a premium, closer to organic prices,” which can be more expensive in some cases).

⁸⁵ *Farris*, *supra* note 20, at 410.

⁸⁶ Many consumers believe that foods labeled “natural” are healthier than similar products without the label. Karen Collins, *What a “Natural” Label Really Means*, AM. INST. FOR CANCER RES. (Apr. 13, 2009), http://preventcancer.aicr.org/site/News2?abbr=pr_hf_&page=NewsArticle&id=14740&news_iv_ctrl=1089.

the “natural” market to remain unregulated. With a more than \$22 billion industry at stake,⁸⁷ companies use the term as “meaningless marketing hype” designed to cash in on consumer desire for healthier products.⁸⁸ With this extensive presence in the market, it is no wonder that eighty-three percent of consumers want the FDA to define “natural.”⁸⁹ The FDA should accede to this demand.

III. GENETICALLY MODIFIED PRODUCTS SHOULD QUALIFY AS “NATURAL” UNDER THE FDA’S PROMULGATED DEFINITION

In addition to initiating notice and comment rulemaking to define “natural,” the FDA should define the term in such a way as to include GMOs. Before explaining why products made from GMOs should qualify as “natural,” however, it is important to keep a distinction in mind. This Essay does not argue that GM foods are, in fact, “natural.” Whatever that term may mean in a non-legal sense is beyond this Essay’s scope. Instead, this Essay argues that the FDA’s definition of “natural” for the purposes of labeling should include GM products based on the FDA and USDA’s current positions surrounding the term.

This approach is similar to what the FDA and other agencies routinely do when defining terms. For example, under the FDA’s definition of “fresh,” a loaf of bread that just came out of the oven may not be labeled “fresh” if it contains a certain chemical used to inhibit mold, but a loaf of bread without this chemical sitting out for two full days may be labeled as such.⁹⁰ This is seemingly contrary to consumers’ everyday understanding of “fresh,” but the FDA found the definition proper for the purpose of labeling.

In short, there is often a difference between a lay definition and a legal definition, and “natural” is no different. Although this may, admittedly, be counter to some consumer expectations of the term “natural,” as is apparent from the definition of “fresh,” the purpose of the NLEA is not to satisfy consumer expectations. Instead, the purpose of the NLEA is to “establish the circumstances under which claims may be made about nutrients in foods.”⁹¹ In other words, rather than promulgating definitions of terms in ways that correspond with consumers’ current understanding, the FDA creates the consumer expec-

⁸⁷ *Natural Beats Organic*, *supra* note 3.

⁸⁸ CEREAL CRIMES, *supra* note 18, at 5.

⁸⁹ Citizen Petition from Sugar Association, *supra* note 20 at 9.

⁹⁰ See Farris, *supra* note 20, at 419; see also 21 C.F.R. § 101.95 (2011).

⁹¹ H.R. REP. No. 101-538, at 7 (1990), reprinted in 1990 U.S.C.C.A.N. 3336, 3337.

tation by providing a baseline requirement from which to make those claims. The remainder of this Essay will discuss why the definition of “natural” should include products containing GMOs.

A. *The Impact and Regulation of Genetically Modified Foods in America*

For centuries, farmers, ranchers, and even animals have used selective breeding to influence the genes of future generations.⁹² For example, farmers may breed two of their largest animals so that the offspring will inherit these desirable genes. The only difference between these “traditional” techniques and genetic modification is that, rather than a random or uncontrolled combination of parent cells, genetic engineering allows for specific segments of one or more pieces of DNA to be combined to produce the desired genetic sequence.⁹³ In this way, the best characteristics of different species of plants are combined.⁹⁴ Rather than *creating* new characteristics, GM plants merely *combine* traits that are already exhibited in nature.⁹⁵

Despite some criticisms,⁹⁶ GMOs have had a tremendous impact on the world’s food supply. In 2006, 10.3 million farmers planted 252 million acres of GM crops in twenty-two countries.⁹⁷ Most of these

⁹² Sheryl Lawrence, Comment, *What Would You Do with a Fluorescent Green Pig?: How Novel Transgenic Products Reveal Flaws in the Foundational Assumptions for the Regulation of Biotechnology*, 34 ECOLOGY L.Q. 201, 209 (2007).

⁹³ *Id.* at 209–10.

⁹⁴ See *id.* at 209 (explaining that scientists can target genes to create “[c]rops that resist frost, and fish that grow bigger, healthier, and faster than previous varieties”); see also Christopher A. Isham, Comment, *Caveat Venditor: Products Liability and Genetically Modified Foods*, 2 J. FOOD L. & POL’Y 85, 114 (2006).

⁹⁵ See Lawrence, *supra* note 92, at 209–10.

⁹⁶ The criticisms generally concern the uncertainty regarding long-term health, environmental, agricultural, and ecological consequences. See Sarah Butcher, *Fraud-on-the-FDA and Genetically Modified Foods: Will the Action Stand?*, 22 REV. LITIG. 669, 695–96 (2003); Isham, *supra* note 94, at 114–15. Several European Union countries, including France, Germany, Greece, Austria, Luxembourg, and Hungary, forbid the cultivation of GMOs. Alistair Driver, *France Upholds GM Maize Ban Despite Court Ruling*, FARMERS GUARDIAN (Jan. 18, 2012), <http://www.farmersguardian.com/home/arable/france-upholds-gm-maize-ban-despite-court-ruling/44204.article>. The French government continues to uphold the ban despite a ruling by the country’s highest court that the ban on GMOs was improper because the government had insufficient evidence that GMOs posed any risk to one’s health or the environment. *Id.* This difference in opinion from across the Atlantic is irrelevant for two reasons. First, the French ban is based on a lack of evidence that GMOs do not cause harm rather than on any evidence that GMOs cause some sort of harm. See *id.* Second, the rapid growth of GMOs in the food markets of the United States is evidence that GMOs are here to stay, which is important for United States administrative agency policies. See *infra* notes 97–105 and accompanying text.

⁹⁷ *Genetically Modified Foods and Organisms*, HUM. GENOME PROJECT INFO., http://www.ornl.gov/sci/techresources/Human_Genome/elsi/gmfood.shtml (last modified May 12, 2012).

crops were soybeans, corn, cotton, canola, and alfalfa.⁹⁸ Although not used for large-scale cultivation until the mid 1990s, GMOs now account for the vast majority of America's staple crops.⁹⁹ Benefits of GMOs include food with higher nutritional value, insect and disease resistance, and higher crop yields, which some commentators see as a potential solution to world famine.¹⁰⁰

The amount of GMOs in the marketplace is astounding. As of 2009, ninety-five percent of all sugarbeets grown in the United States were of the GM variety.¹⁰¹ As of 2010, eighty-six percent of corn¹⁰² and ninety-three percent of soybeans¹⁰³ were GM products. There is no doubt that these GMOs reach the consumer in the form of food and drinks labeled "natural."¹⁰⁴ For example, a recent survey found that numerous cereal brands labeled "natural," including Kashi, Mother's, Nutritious Living, General Mills' Kix, Barbara's Bakery, and Whole Foods Market's 365, contain high levels of GM ingredients—between fifty and one hundred percent.¹⁰⁵

The FDA, EPA, and USDA each have a role in the regulatory oversight of GMOs.¹⁰⁶ The FDCA authorizes the FDA to evaluate the safety and marketing of GM products when they are intended for human or animal consumption.¹⁰⁷ The FDA will approve a genetically modified food product if the modification did not create an adulteration of a "valuable constituent" of that food.¹⁰⁸ This is the test for all new plant species, regardless of whether the species was created

⁹⁸ *Id.*

⁹⁹ *GMO Education*, INST. FOR RESPONSIBLE TECH., <http://www.responsibletechnology.org/gmo-education> (last visited May 20, 2012).

¹⁰⁰ Isham, *supra* note 94, at 113.

¹⁰¹ *USA: Cultivation of GM Plants, 2009: Maize, Soybean, Cotton: 88 Percent Genetically Modified*, *supra* note 7.

¹⁰² *ACREAGE*, *supra* note 8, at 24.

¹⁰³ *Id.* at 25.

¹⁰⁴ See *supra* note 5.

¹⁰⁵ *CEREAL CRIMES*, *supra* note 18, at 29. This study likely reveals only the tip of the iceberg because the government does not require that companies label GM foods. See Butcher, *supra* note 96, at 697.

¹⁰⁶ Isham, *supra* note 94, at 90. The EPA's role consists of monitoring the environmental risk of GMOs. See *id.* at 92; see also Lawrence, *supra* note 92, at 219. The USDA monitors the growth of GMOs and plants containing and produced using "biological organisms" under the Plant Protection Act. See 7 U.S.C. §§ 7702(2), 7712(g) (2006); Isham, *supra* note 94, at 91–92; Lawrence, *supra* note 92, at 219. Extensive details of the EPA's and USDA's authority are outside the scope of this Essay.

¹⁰⁷ Lawrence, *supra* note 92, at 219.

¹⁰⁸ See *id.* at 223–24; see also 21 U.S.C. § 342(a)–(b) (2006). Unfortunately, Congress did not define "valuable constituent" in the statute and the FDA has not promulgated binding regulations for clarification. Lawrence, *supra* note 92, at 223–24. For the purposes of this Essay,

through traditional breeding or genetic engineering.¹⁰⁹ Significantly, the FDA generally recognizes that food produced through recombinant DNA processes—the dominant method used to create GMOs—is safe.¹¹⁰

B. The FDA’s Definition of “Natural” Should Permit Foods Produced from GMOs to Be Labeled as “Natural”

In addition to the immense growth of GMOs in the United States, GM products should qualify as “natural,” if and when the FDA promulgates a binding definition, for two reasons. First, GMOs qualify as “natural” under the FDA’s current informal policy and the formal definition should remain as consistent as possible with the informal policy. Second, GMOs are analogous to cloned animals, which the USDA currently permits companies to label as “natural” and “naturally raised.”¹¹¹

1. Foods Produced Using GMOs Qualify as “Natural” Under the FDA’s Informal Policy

GMOs qualify under the FDA’s current informal policy regarding “natural.” As stated above, this policy prohibits a company from labeling a product as “natural” when it contains a “synthetic” or “artificial” ingredient.¹¹² GMOs, however, do not contain any “synthetic” or “artificial” ingredients;¹¹³ in fact, the FDA has even stated that the

however, it is sufficient to note that the extent of GMOs in the marketplace shows that this issue is not a significant hurdle to overcome. *See supra* note 101 and accompanying text.

¹⁰⁹ See Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,984 (proposed May 29, 1992).

¹¹⁰ Lawrence, *supra* note 92, at 224.

¹¹¹ This Essay does not consider whether the company’s product label should also inform consumers that the company used GMOs to produce the product. The FDA does not currently require such labeling. Butcher, *supra* note 96, at 704. The author of this Essay believes that a rule permitting companies to label foods containing GMOs as “natural” is best coupled with a requirement that foods containing GMOs be labeled as such so that the consumer can make an informed purchasing decision.

¹¹² See Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993) (to be codified at 21 C.F.R. pts. 5, 101).

¹¹³ The FDA has not defined “artificial” and “synthetic.” *See supra* Part I.B. Therefore, this argument is based on the colloquial meaning of these terms. The FDA has, however, expressed a willingness to interpret these terms broadly, stating that processed HFCS can be considered “natural.” Letter from Geraldine A. June, Supervisor, Product Evaluation & Labeling Team, FDA, to Audrae Erickson, President, Corn Refiners Ass’n. (July 3, 2008), available at <http://www.corn.org/wp-content/uploads/2008/07/FDAdecision7-7-08.pdf> (stating that the FDA “would not object to the use of the term ‘natural’” to describe a product containing HFCS that was created using an enzyme that “is fixed to a column by the use of the synthetic fixing agent,

only thing added to GMOs is nucleic acids.¹¹⁴ Nucleic acids are essential to the existence of every living organism, are safe as a component of food, and are not considered a food additive by the FDA.¹¹⁵ An essential element to the existence of all living things is highly unlikely to qualify as “synthetic” or “artificial.” Moreover, even if the added nucleic acids were considered “synthetic” or “artificial,” this would not lead to the conclusion that GMOs do not qualify as “natural” because nucleic acids are normally expected to be in food.¹¹⁶ In short, rather than adding scientifically created components to GM plants, genetic engineers simply combine and enhance traits and characteristics that already occur naturally in plants.¹¹⁷ Therefore, under the FDA’s current, albeit unbinding, policy, a company could label a product made from GMOs as “natural.”

Although the current definition is not binding, it is important that, when the FDA does promulgate an official definition, it ensures that the new definition is as close as possible to the informal policy for two reasons. First, the informal policy conforms to the USDA’s definition of “natural”¹¹⁸ and should remain this way to prevent confusion and promote regulatory clarity. Second, food and beverage companies have adapted and relied on this informal policy and it would be inequitable for them to be penalized by a complete reworking of the term. The current definition is inadequate not because of its substance, but because of its informal nature and lack of preemptive authority. Although the definition will likely undergo some changes as the FDA incorporates public comments, the agency should nonetheless keep the basic structure to ensure consistency and predictability.

glutaraldehyde” as long as the glutaraldehyde “does not come into contact with the high dextrose equivalent corn starch hydrolysate”).

¹¹⁴ See Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,990. Nucleic acids carry genetic information for living things. Richard J. Roberts, *Nucleic Acid*, ENCYCLOPEDIA BRITANNICA, <http://www.britannica.com/EBchecked/topic/421900/nucleic-acid> (last visited May 20, 2012). There are two types: deoxyribonucleic acid (“DNA”) and ribonucleic acid (“RNA”). *Id.*

¹¹⁵ See Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,990 (“Nucleic acids are present in the cells of every living organism . . . ”). Because of the safety of the nucleic acids, FDA has chosen not to regulate GM products as a food additive. *Id.*

¹¹⁶ See Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. at 2407; *supra* text accompanying note 38.

¹¹⁷ See *supra* notes 94–95 and accompanying text.

¹¹⁸ See *infra* Part III.B.2.

2. *Genetically Modified Products Are Analogous to Cloned Animals, Which Companies May Label as “Natural” or “Naturally Raised” Under Current USDA Rules*

Cloning of animals is essentially equivalent to genetic modification of plants.¹¹⁹ Because it is possible for companies to label meat from a cloned animal as “natural” or “naturally raised” under the current USDA rules, it follows that, in order to maintain interagency consistency, products made from GMOs should also be permitted to bear “natural” labels.

Animal cloning is a process by which scientists can make an exact copy of the genetic traits of an animal.¹²⁰ Cloning is accomplished through a process called somatic cell nuclear transfer,¹²¹ where scientists take an immature egg from a female animal, remove the nucleus, and replace it with the nucleus from the “donor” animal with the desired traits.¹²² After the donor nucleus fuses with the egg, the egg divides and forms an embryo, which scientists then implant into the uterus of a surrogate to carry to term.¹²³ Similar to GMOs, the purpose of cloning is to create more animals with desirable characteristics such as disease resistance and suitability to certain climates.¹²⁴

The FDA has concluded that meat and milk from clones are as safe to eat as food from conventionally bred animals.¹²⁵ Moreover, while the predominant use for these cloned animals is breeding, the FDA admits that cloned animals, and their offspring, enter the human food chain.¹²⁶ When cloned animals do enter the human food chain,

¹¹⁹ See *A Primer on Cloning and Its Use in Livestock Operations*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/animalveterinary/safetyhealth/animalcloning/ucm055513.htm> (last updated Oct. 28, 2009) [hereinafter *Primer on Cloning*].

¹²⁰ *Id.*

¹²¹ Jennifer E. F. Butler, *Cloned Animal Products in the Human Food Chain: FDA Should Protect American Consumers*, 64 FOOD & DRUG L.J. 473, 474 (2009).

¹²² *Primer on Cloning*, *supra* note 119.

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ Press Release, U.S. FDA, FDA Issues Documents on the Safety of Food from Animal Clones: *Agency Concludes that Meat and Milk from Clones of Cattle, Swine, and Goats, and the Offspring of All Clones, Are as Safe to Eat as Food from Conventionally Bred Animals* (Jan. 15, 2008), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116836.htm>; Andrew Martin & Andrew Pollack, *F.D.A. Says Food from Cloned Animals Is Safe*, N.Y. TIMES (Jan. 16, 2008), <http://www.nytimes.com/2008/01/16/business/16clone.html?ref=cloning>.

¹²⁶ See Butler, *supra* note 121, at 477. Cloned animals have also entered the food chain in the United Kingdom. *Meat of Cloned Cow Offspring in UK Food Chain, FSA Says*, BBC NEWS (Aug. 4, 2010, 11:10 AM), <http://www.bbc.co.uk/news/uk-10859866>.

the FDA does not require companies to label food products as such.¹²⁷ Although the FDA has fully approved the consumption of cloned animals, the USDA governs the labeling of meat and poultry products.¹²⁸

The USDA has two relevant definitions of “natural.” In 2006, in response to a public petition, the USDA initiated notice and comment rulemaking to define “natural.”¹²⁹ Even though the USDA has received extensive comments, the Department has yet to issue an official definition.¹³⁰ Instead, the USDA continues to maintain an informal policy regarding “natural” that is strikingly similar to the FDA’s definition and focuses on the absence of “artificial” and “synthetic” ingredients.¹³¹ Despite the USDA’s similar informal policy regarding the term “natural,” the USDA’s policy does not encounter the same troubles of “lack of understanding and agreement within the food industry” as the FDA’s informal policy because the USDA regulations require producers to seek approval of labeling before a product enters the market.¹³²

The solicited comments regarding “natural” have, however, been of some assistance to the USDA; they helped lead to a published definition of “naturally raised” for the meat and poultry industries.¹³³ Under this definition, a “naturally raised” animal is one that has not been given growth hormones or antibiotics and has never been fed animal byproducts.¹³⁴ Because cloned animals do not contain anything “synthetic” or “artificial” and do not require growth hormones

¹²⁷ U.S. FDA CTR. FOR VETERINARY MED., ANIMAL CLONING: FAQS ABOUT CLONING FOR CONSUMERS, available at <http://www.fda.gov/AnimalVeterinary/DevelopmentApproval-Process/GeneticEngineering/GeneticallyEngineeredAnimals/ucm113605.htm>.

¹²⁸ The USDA’s Food Safety and Inspection Service regulates domestic and imported meat and poultry product labeling, standards, and ingredients under the Federal Meat Inspection Act, 21 U.S.C §§ 601, 607 (2006), and the Poultry Products Inspection Act, 21 U.S.C. §§ 451, 457 (2006). See *Acts & Authorizing Statutes*, FOOD SAFETY & INSPECTION SERV., U.S. DEPARTMENT AGRIC., http://www.fsis.usda.gov/Regulations_&_Policies/Acts_&_Authorizing_Statutes/index.asp (last modified July 20, 2010).

¹²⁹ Farris, *supra* note 20, at 409–10.

¹³⁰ *Id.* at 411.

¹³¹ FOOD SAFETY & INSPECTION SERV., U.S. DEP’T OF AGRIC., FOOD STANDARDS & LABELING POLICY BOOK 116–18 (2005), available at http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_book_082005.pdf (defining “natural” identically to the FDA definition but additionally requiring that “the product and its ingredients are not more than minimally processed”).

¹³² Carolyn Fisher & Ricardo Carvajal, *What Is Natural?*, 62 FOOD TECH. 24, 30–31, (2008).

¹³³ United States Standards for Livestock and Meat Marketing Claims, Naturally Raised Claim for Livestock and the Meat and Meat Products Derived from Such Livestock, 74 Fed. Reg. 3541, 3545 (Jan. 21, 2009).

¹³⁴ *See id.*

or antibiotics,¹³⁵ companies can label them as “natural” or “naturally raised” under USDA regulations.

Cloned animals are analogous to GMOs.¹³⁶ Both are “created” by scientists and seek to enhance characteristics that already occur in nature.¹³⁷ Genetic sequences and the uncertainties surrounding traditional breeding are admittedly manipulated in both circumstances, but in neither case is anything “synthetic” or “artificial” added to the plant or animal. It follows that, if companies can label cloned animals as “natural” or “naturally raised” under USDA regulations, companies should also be able to label products made from GMOs as “natural” when the FDA eventually defines the term.

The FDA should, therefore, define “natural” in a way that comports with the USDA definitions of “naturally raised” (which has been promulgated through the USDA’s notice and comment proceedings) and “natural.” Interagency consistency is integral to ensuring that the regulated food industry can comply without a substantial burden. This is especially true when both agencies regulate food labeling. Multiple players in the food industry have already requested that the FDA define “natural” similarly to the USDA for the sake of consistency and predictability.¹³⁸ Also, during the comment period for the USDA’s proposed rulemaking concerning the definition of “natural,” food industry members specifically requested a definition that accounts for FDA policies and allows the food industry to plan for the future and invest in the appropriate technology.¹³⁹

In short, GMOs and cloned animals are parallel in both purpose and method of creation. Therefore, because meat from cloned animals can be labeled as “natural” or “naturally raised” under current USDA rules, and interagency consistency is desirable when agencies have overlapping regulatory authority, FDA regulations should permit companies to label products made from GMOs as “natural” as well.

¹³⁵ See *supra* notes 120–24 and accompanying text.

¹³⁶ Compare *supra* Part III.A, with *supra* Part III.B.2. While the presence of cloned animals in the market is likely not nearly as extensive as GMOs, the analogy provides an example of how the regulatory system responds to scientific advancement.

¹³⁷ See *supra* Part III.A, B.2.

¹³⁸ Citizen Petition from Sugar Association, *supra* note 20, at 1; Letter from Robert G. Reinhard, Director, Food Safety/Regulatory, Sara Lee Corp., to Division of Dockets Mgmt., FDA, U.S. Dep’t Health & Human Servs. 1 (Apr. 9, 2007), available at <http://www.fda.gov/ohrms/dockets/dockets/07p0147/07p-0147-cp00001-02-vol1.pdf>.

¹³⁹ See Farris, *supra* note 20, at 410–11; Transcript, U.S. Dep’t Agric., Public Meeting on Product Labeling: Definition of the Term “Natural” at 54–55 (Dec. 12, 2006), available at http://www.fsis.usda.gov/pdf/natural_claims_transcripts.pdf.

CONCLUSION

A formal definition of “natural” is necessary. The supply and demand of “natural” products is too high for the current market to remain unregulated. Courts should not define “natural” because this outcome would result in inconsistent “natural” labels throughout the country. Instead, the FDA should use notice and comment rulemaking to promulgate an official definition of “natural,” and this definition should include products made from GMOs. Products made from GMOs qualify as “natural” under the FDA’s current informal policy and they are indistinguishable from cloned animals, which companies can label as “natural” or “naturally raised” under current USDA standards. To provide clear labels for the consumer and to provide a uniform and consistent definition for the food industry, the FDA should exercise its congressionally delegated responsibility and define “natural” to include GM products.