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The “Natural” vs. “Natural Flavors” Conflict in Food Labeling: A Regulatory Viewpoint

MATTHEW J. GOODMAN*

ABSTRACT

Food branded with a Natural label can be found in any grocery store across the United States. Consumers consider this label to be an important attribute when making a purchasing decision and billions of dollars are spent annually on these products. While many consumers believe Natural foods are healthier, heavy reliance on that assumption is misguided as “Natural” has no formal legal definition—it’s merely defined pursuant to an FDA approved informal policy.

Another important health attribute in a consumer’s purchasing decision is the presence of natural flavors in food. However, unlike the term Natural, FDA has promulgated legally binding regulations for natural flavors. These flavors are currently the fourth most common food ingredient listed on food labels. In reality, “natural flavors” are a far cry from what consumers might expect, as they can contain both artificial and synthetic chemicals (often used as processing aids). Nonetheless, without a legally binding Natural regulation, there has been little opportunity to contest the naturalness of natural flavors in the past.

Recently, FDA has initiated a notification of request for comments on use of the term Natural, so an attempt to promulgate regulations may be underway. Thus, it is appropriate to consider where natural flavors will fall if binding regulations are set forth. This article looks at the Natural debate, its history, and model regulatory standards worth considering. Within that context, it also provides a critical discussion concerning a misunderstood, yet federally regulated, ingredient that our society so heavily consumes: natural flavors.

INTRODUCTION

Whether in Whole Foods, Safeway, or Target, consumers often search for the healthiest food for themselves and their families. While many buyers know unprocessed, whole foods are the items falling into the “healthy” category, exclusively sticking to those foods is not always viable. So we search for more accommodating options and rely on the food’s label to aid us in our purchasing decision.

Upon inspecting these foods, what the consumer finds is a host of claims ensuring the product’s legitimacy as healthy. A claim that frequently appears is “Natural,” “All

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Natural,” or other derivatives of the term.¹ Consumers consider these types of claims to be an important health attribute that influences their purchasing decision.² Moreover, consumers are willing to pay a premium for products carrying the label,³ making the Natural food market a \$40 billion industry.⁴

The popularity of these foods may come from the label’s ability to create a “health halo” effect, which causes consumers to overestimate the healthfulness of the Natural food item.⁵ And while some naturally labeled products may be healthier than products not donning the claim, all-out reliance on Natural as an indicia of healthfulness is misguided because the term is not heavily regulated in the United States.

In fact, “Natural” has no formal legal definition despite being considered at various times by a trio of administrative agencies.⁶ The only regulation of Natural comes by way of an FDA approved informal policy and a USDA guideline.⁷ And while these policy statements generally define natural as not containing anything artificial or synthetic,⁸ they do not establish a legal requirement for manufacturers to follow.⁹ Myriad problems for both consumers and food manufacturers result from this void. This includes consumer confusion, lawsuits,¹⁰ and manufacturer liability—externalities of the inconsistent application of the term by companies.¹¹

¹ See Nicole E. Negowetti, *A National Natural Standard for Food Labeling*, 65 ME. L. REV. 581, 582 (2013) (finding that “all-natural” was the second most used claim on American food products in 2011).

² NIELSEN, WE ARE WHAT WE EAT: HEALTHY EATING TRENDS AROUND THE WORLD, 7–8 (Jan. 2015), <http://www.nielsen.com/content/dam/nielsen-global/eu/nielseninsights/pdfs/Nielsen%20Global%20Health%20and%20Wellness%20Report%20-%20January%202015.pdf>.

³ Efsthimios Parasidis et al., *Addressing Consumer Confusion Surrounding “Natural” Food Claims*, 41 AM. J.L. & MED. 357, 357 (2015).

⁴ Nicole E. Negowetti, *Defining Natural Foods: The Search for a Natural Law*, 26 REGENT U.L. REV. 329, 329 (2014).

⁵ See John Tierney, *Health Halo Can Hide the Calories*, N.Y. TIMES, Dec. 2, 2008, at D1; 5 *Most Confusing Health Halo Food Terms*, HEALTH (July 25, 2014) <http://news.health.com/2014/07/25/5-most-confusing-health-halo-food-terms/> (last visited Oct. 12, 2016).

⁶ See Erik Benny, “Natural” Modifications: The FDA’s Need to Promulgate an Official Definition of “Natural” That Includes Genetically Modified Organisms, 80 GEO. WASH. L. REV. 1504, 1510 (2012) (“The FDA has not used notice and comment rulemaking procedures to promulgate a formal definition of ‘natural.’”).

⁷ See Food Labeling: Nutrition Content Claims, General Principles, Petitions, Definition of Terms; Definition of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2,302, 2,397 (Jan. 6, 1993) (to be codified at 21 C.F.R. pts. 5, 101, 105); USDA, *Food Standards and Labeling Policy Book* (Aug. 2005), http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf.

⁸ *Id.*

⁹ 21. C.F.R. § 10.85(j) (2014); see also *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 342 (3d Cir. 2009) (holding that FDA policy statement regarding the use of the term natural does not have the force of law).

¹⁰ Negowetti, *supra* note 4, at 332–33 (explaining that over one hundred lawsuits have been filed in the last couple years challenging natural claims on foods, with Plaintiff’s alleging violations of “state consumer statutes on false advertising, unfair trade practices, consumer protection, fraud, and breach of warranty.”). Consumers routinely allege that Natural foods are mislabeled because they contain artificial or synthetic ingredients. See Parasidis, *supra* note 3, at 358.

¹¹ See Negowetti, *supra* note 4, at 356–57 (explaining that there is little consensus among food manufacturers regarding Natural’s meaning).

Another important attribute consumers consider when purchasing food is the presence of natural flavors in products.¹² Unlike the term Natural, however, FDA has promulgated regulations for natural flavors.¹³ A search of natural flavors in the Environmental Working Group's food database—containing over 80,000 food products—reveals natural flavors as the fourth most common food ingredient listed on food labels.¹⁴ In recent years, companies have turned to using natural flavors more frequently because of consumer apprehension towards artificial flavors.¹⁵

Natural flavors are essentially anything you extract from a plant or animal source; in contrast to artificial flavors, which are chemicals originating in a lab.¹⁶ But despite being derived from a single natural source, the resulting natural flavor complex buyers eventually consume is far different from the derivative.¹⁷ In the end, the flavors “are mixtures of chemicals obtained by applying physical separation methods” to natural sources, and the result of a lengthy, complex process.¹⁸ Once ready for consumption, these natural flavor mixtures can contain as many as 250 chemically identified constituents, some of which are artificial and synthetic.¹⁹

Natural flavors and the amalgamation of chemical constituents that comprise the ingredient can often be found on the back of products labeled as “Natural.” While there is much commentary online²⁰ questioning the naturalness of these “natural flavors,”

¹² NIELSEN, *supra* note 2, at 8 (finding 31% of North Americans believe the presence natural flavors in their foods is very important in their purchasing decisions).

¹³ The regulation defines natural flavor in the following way:

The term natural flavor or natural flavoring means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional

21 C.F.R. § 101.22(a)(3) (2013) [hereinafter Natural Flavor].

¹⁴ The Environmental Working Group has found that the only other ingredients more commonly found in food are salt, water, and sugar. David Andrews, *Synthetic ingredients in Natural Flavors and Natural Flavors in Artificial flavors*, ENVIRONMENTAL WORKING GROUP, <http://www.ewg.org/foodscores/content/natural-vs-artificial-flavors> (last visited Oct. 15, 2016); *see also* Gabriel S. Sinki & Robert J. Gordon, *Flavoring Agents*, in FOOD ADDITIVES 349, 365 (A. Larry Branen et al. eds., 2d ed. 2001) [hereinafter FOOD ADDITIVES] (discussing how the flavor industry has gone full-circle with natural flavors being the most prominent flavor in the late 19th century, then 90% artificial in the 50's, now to 70% natural).

¹⁵ *See* NIELSEN, *supra* note 2, at 7 (stating that 42% of consumers say the absence of artificial colors is very important in their purchasing decisions and that 41% say the absence of artificial flavors is very important to them).

¹⁶ *Is natural flavoring natural?*, NEW HOPE, <http://newhope.com/ingredients-general/is-natural-flavoring-natural> (last visited May 11, 2016).

¹⁷ Robert L. Smith et al., *A procedure for the safety evaluation of natural flavor complexes used as ingredients in food: essential oils*, 43 FOOD & CHEMICAL TOXICOLOGY 345, 348 (2005).

¹⁸ Robert L. Smith et al., *Safety Evaluation of Natural Flavour Complexes*, 149 TOXICOLOGY LETTERS 197, 198 (2004).

¹⁹ *See* Robert L. Smith et al., *Criteria for the Safety Evaluation of Flavoring Substances: The Expert Panel of the Flavor and Extract Manufacturers Association*, 43 FOOD & CHEMICAL TOXICOLOGY 1141, 1144 (2005) (finding that natural flavors can contain ingredients like BHA and ethyl alcohol).

²⁰ *See e.g.*, David Andrews, *Synthetic ingredients in Natural Flavors and Natural Flavors in Artificial flavors*, ENVIRONMENTAL WORKING GROUP, <http://www.ewg.org/foodscores/content/natural-vs-artificial-flavors>

there is no legal issue with pairing the two together because a formal Natural definition does not exist. But “as the industry works to define natural the ‘fluff’ that is natural flavorings will likely be in trouble.”²¹ In other words, because natural flavors may contain artificial and synthetic ingredients and undergo a complex chemical process, natural flavors may fall outside the bounds of a circumscribed Natural regulation.

The time to cut the fluff *may*²² be imminent. FDA has recently initiated a notification of request for comments²³ on use of the term Natural, and an attempt to promulgate regulations is underway.²⁴ Of the close to 5,000 comments that have been submitted, almost 100 specifically mention natural flavors; many of which highlight the artificial components in the ingredient and suggest that natural flavors are not Natural.²⁵ The vast commentary online and the recognition of the Natural–natural flavors tension in the comments, signifies that the time is ripe to consider where natural flavors will fall if a Natural regulation is promulgated.

This essay seeks to shed light on this tension. It ultimately concludes that the permissibility of pairing a natural flavor ingredient with a Natural claim largely depends on the type of Natural regulation that FDA promulgates and whether certain issues inherent in the natural flavors regulation are neglected or, instead, considered. Part I discusses the current legal landscape revolving around the term Natural, the various agencies’ current positions on the term and their history with Natural, the requests from the judiciary to define the term, and other countries’ and Congress’s consideration of the term.²⁶ Part II introduces FDA’s natural flavors regulation and its regulatory scheme²⁷; it also outlines the specifics of the flavor industry, the natural flavor production process, and the suspect chemicals found in natural flavors.²⁸ Part III forecasts potential Natural regulations, drawing from the Natural policies of other countries, FDA’s and USDA’s informal policy, and the rules FDA has promulgated in

artificial-flavors (last visited Oct. 15, 2016); *The Gross Truth About Natural Flavors*, CARE2, <http://www.care2.com/greenliving/reasons-vegans-read-labels-natural-flavorscastoreum.html> (last visited Oct. 15, 2016).

²¹ Lisa Marshall, *Is Natural Flavoring Natural?*, NEW HOPE (Dec. 19, 2014), <http://newhope.com/ingredients-general/is-natural-flavoring-natural>.

²² There is no guarantee that FDA will begin the rulemaking process, they may decline as they have numerous times before. See generally Negowetti, *supra* note 1, at 584–88.

²³ See 5 U.S.C. § 553(c) (2012). The purpose of the public notice is to allow public citizens to participate effectively in the rulemaking process—submission of written data, views, or arguments regarding the proposed rule. See generally R. PIERCE, S. SHAPIRO & P. VERKUIL, *ADMINISTRATIVE LAW AND PROCESS*, §6.46 (6th ed. 2013).

²⁴ See Use of the Term ‘Natural’ in the Labeling of Human Food Products; Request for Information and Comments, 80 Fed. Reg. 69,905, 69,908 (proposed Nov. 12, 2015).

²⁵ Josie Peper, Comment on the Food and Drug Administration (FDA) Proposed Rule: Use of the Term ‘Natural’ in the Labeling of Human Food Products; Request for Information and Comments; Extension of Comment Period, <https://www.regulations.gov/#!documentDetail;D=FDA-2014-N-1207-3910> (citing research that finds natural flavors contains solvents and preservatives) (last visited Oct. 16, 2016); Jack Sparacino, Comment on the Food and Drug Administration (FDA) Proposed Rule: Use of the Term ‘Natural’ in the Labeling of Human Food Products; Request for Information and Comments; Extension of Comment Period, <https://www.regulations.gov/#!documentDetail;D=FDA-2014-N-1207-4199> (arguing that natural flavors may not be natural because they are processed in laboratories and broken down in chemical compounds) (last visited Oct. 16, 2016).

²⁶ See discussion *infra* Part II.

²⁷ See discussion *infra* Part IIIA.

²⁸ See discussion *infra* Part IIIB–C.

regard to other health claims.²⁹ It also includes an analysis of the implications each individual regulation poses for natural flavors and whether natural flavors can still be considered Natural in light of the proposed models.³⁰

I. THE NATURAL BACKGROUND

A. Natural in Today's Economy

It doesn't take long to notice a Natural labeled product when visiting a grocery store. In fact, the Natural market has experienced an upward trend in the last couple of years.³¹ And in 2014, research concluded that attaching a Natural claim to products helps sell over \$40 billion worth of food every year.³² This rise in Natural's importance in food consumption is traced to the consumer's increased awareness about health.³³ A recent survey found that 59 percent of respondents desire to eat more natural foods in an attempt to live a healthier lifestyle.³⁴

Recent studies have also found 51 percent of Americans specifically search for natural products while shopping,³⁵ and 43 percent consider Natural to be an important health attribute that affects their decision to purchase.³⁶ Natural also fares well against other food labels: 31 percent of consumers choose Natural as the most desirable label, when only 14 percent select 100 percent organic.³⁷ Some speculate that the perceived absence of any artificial ingredients in Natural products drives the demand.³⁸ Or, that "natural" indicates the product contains certain vague, yet valuable, characteristics—i.e., that the product is pure, clean, and healthy.³⁹ Regardless of the reasons consumers are attracted to the claim, it's clear that consumers are willing to rely heavily on the claim when purchasing food products and pay a premium for the label.⁴⁰ These elements create a risk of economic harm to the consumer.

This risk is exacerbated when, in the absence of a formal definition of the term, many manufacturers are able to apply the label inconsistently.⁴¹ All too often, the consumer's reasonable expectations of natural conflicts with the manufacturer's

²⁹ See discussion *infra* Part IV.

³⁰ See discussion *infra* Part IV.

³¹ Roberto A. Ferdman, *The word "Natural" Helps sell \$40 Billion Worth of food in the U.S. each year - and the Label Means Nothing*, WASH. POST, June 24, 2014, <https://www.washingtonpost.com/news/wonk/wp/2014/06/24/the-word-natural-helps-sell-40-billion-worth-of-food-in-the-u-s-every-year-and-the-label-means-nothing/> (finding a 3% year-over-year growth for natural health-claims).

³² *Id.*

³³ *Hormel Foods Corp. v. USDA*, 808 F. Supp. 2d 234, 237 (D.D.C. 2011).

³⁴ *A Healthy Salute to New Year's Resolutions*, NIELSEN, <http://www.nielsen.com/us/en/insights/news/2016/a-healthy-salute-to-new-years-resolutions.html> (last visited Oct. 16, 2016).

³⁵ See Negowetti, *supra* note 4, at 330.

³⁶ NIELSEN, *supra* note, at 8.

³⁷ Parasidis, *supra* note 3, at 364.

³⁸ Allyson Weaver, *Natural Foods: Inherently Confusing*, 39 J. CORP. L. 657, 659 (2014).

³⁹ *Id.*

⁴⁰ Parasidis, *supra* note 3, at 357 ("Studies have consistently found that [Natural] claims influence consumer behavior—consumers seek out and are willing to pay a premium for products that make Natural claims.").

⁴¹ See Negowetti, *supra* note 1, at 356–57.

conception of the label. Moreover, many consumers remain unaware that the term natural is not regulated by the food industry, and has no definition of any legal significance.⁴² Thus, it is no surprise that Natural claims have attracted attention from consumer protection groups, as well as the class action bar.⁴³ And this has led to over a hundred actions being filed in the Northern District of California—dubbed the “Food Court”—in the last couple years.⁴⁴ These consumer-plaintiffs typically challenge Natural labels as misleading and in violation of consumer protection statutes when the Natural items contain artificial and synthetic ingredients.⁴⁵ This potential for Natural-related liability has led many companies to drop the word from their labels entirely in order to avoid subsequent suits.⁴⁶

Fortunately, for consumers and food manufacturers alike, there are administrative agencies designed to oversee and regulate the complicated problems and externalities that arise from food labeling, such as the nebulous Natural label.⁴⁷ In fact, one of the theoretical interests served by administrative regulation is improving product information to consumers to prevent harm; another, “to address market outcomes that are inconsistent with social values.”⁴⁸ Both interests are furthered by increased regulation of Natural: (1) consumers will avoid the economic harm that results from buying Natural products that fail to live up to their expectations; and (2) consumers won’t eat food inconsistent with their values, primarily, maintaining a healthy lifestyle free of consuming undesirable ingredients. Nevertheless, FDA and the other administrative agencies have repeatedly declined to define “Natural,” and the resultant externalities remain.

B. The Natural Consideration in Administrative Agencies and Congress

1. The Federal Trade Commission on Natural.

The Federal Trade Commission (FTC) holds the honor of being the first administrative agency to attempt to define “natural food.” The agency proposed a rule defining Natural foods as those which were minimally processed and free of artificial ingredients.⁴⁹ In 1983, the agency eventually terminated this proposal, citing the need

⁴² Weaver, *supra* note 38, at 659.

⁴³ *Mother Nature’s Perfect Storm: “Natural” Claims*, AMERICAN BAR ASSOCIATION, (Dec. 12, 2012), http://www.americanbar.org/content/dam/aba/publications/antitrust_law/20121211_at12122_materials.authcheckdam.pdf.

⁴⁴ Negowetti, *supra* note 4, at 332–33.

⁴⁵ See Parasidis, *supra* note 3, at 356; Negowetti, *supra* note 4, at 329.

⁴⁶ Mike Esterl, *Some Food Companies Ditch ‘Natural’ Label*, WALL ST. J., Nov. 6, 2013, <http://www.wsj.com/articles/SB10001424052702304470504579163933732367084>.

⁴⁷ See David Zaring & Elena Baylis, *Sending the Bureaucracy to War*, 92 IOWA L. REV. 1359, 1367 (2007) (“[T]he purpose of agencies [is] to provide expert supervision of the complicated problems and externalities presented by the modern economy.”).

⁴⁸ R. Pierce, S. Shapiro & P. Verkuil, ADMINISTRATIVE LAW AND PROCESS, §§ 1.5–1.7 (6th ed. 2013).

⁴⁹ Negowetti, *supra* note 1, at 582 (finding that “all-natural” was the second most used claim on American food products in 2011).

to address more serious consumer protection problems.⁵⁰ However, FTC stated that it would continue to scrutinize natural claims on a case-by-case basis.⁵¹ The Natural issue came up in 2010, but FTC declined to adopt a formal definition once again because it “may be used in numerous contexts and may convey different meanings depending on that context.”⁵² In effect, FTC has left the Natural question to the other agencies.

2. *The Food and Drug Administration on Natural*

The agency most frequently encountering the term is the Food and Drug Administration (FDA); the agency authorized by the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA) to “promulgate regulations fixing and establishing for any food . . . a reasonable definition . . . standard identity [and] . . . standard of quality.”⁵³ The FDCA prohibits misbranding food when the food label neither accurately nor adequately describes the food itself.⁵⁴ The agency first addressed Natural on the heels of Congress’ passage of the Nutrition Labeling Education Act (NLEA), which amended the FDCA in 1989.⁵⁵

Although the amendment required FDA to explicitly define certain nutritional terms, i.e., “Light,” Natural was not one of them.⁵⁶ FDA did eventually adopt a formal policy in 1991, stating a food is Natural when “nothing artificial or synthetic (including colors regardless of source) is included in, or has been added to, the product that would not normally be expected to be there.”⁵⁷ FDA noted that there was evidence of consumer confusion regarding Natural and that the agency would consider promulgating a definition through rulemaking.⁵⁸

The next attempt to provide consumers with a Natural definition of some legal efficacy was in 1993. FDA requested comments upon initiating rulemaking to implement the NLEA.⁵⁹ Upon receiving comments and suggestions, FDA recognized—once again—that defining Natural is of considerable interest to

⁵⁰ Termination of Proposed Trade Regulation; Rule on Food Advertising, 48 Fed. Reg. 23,270 (May 24, 1983) (“We should concentrate our resources on more serious consumer protection problems than addressing whether a claim that ‘milk is natural,’ is deceptive.”).

⁵¹ *Id.*

⁵² Negowetti, *supra* note 4, at 344.

⁵³ 21 U.S.C. § 341 (2012).

⁵⁴ 21 U.S.C. § 343(a) (2012).

⁵⁵ See Parasidis, *supra* note 3, at 361–62 (explaining that with the Act, Congress intended to prompt FDA to achieve national uniformity in food labeling through preemption of state regulations concerning labeling of health claims and nutritional content).

⁵⁶ *Id.*

⁵⁷ Food Labeling: Nutrient Content Claims, General Principles Petitions, Definition of Terms, 56 Fed. Reg. 60,421, 60,466 (proposed Nov. 27, 1991).

⁵⁸ *Id.* There are two different types of Rulemaking recognized under the APA: informal and formal. The type of rulemaking FDA would initiate in defining Natural is informal rulemaking. Formal rulemaking is required “[w]hen rules are required by statute to be made on the record after opportunity for an agency hearing.” Informal rulemaking, which is commonly called notice-and-comment rulemaking, is less demanding and the APA only requires that interest parties be allowed the notice and opportunity to comment. See BERNARD SCHWARTZ, ADMINISTRATIVE LAW § 4.12 (3d ed. 1991).

⁵⁹ Food Labeling: Nutrition Content Claims, General Principles, Petitions, Definition of Terms; Definition of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2,302, 2,397 (Jan. 6, 1993).

consumers and the food industry, and that defining the term could resolve the ambiguity around the term⁶⁰; thus, decreasing the amount of misleading claims regarding Natural labeled food.⁶¹ Nonetheless, FDA declined to move past the comment period and engage in a rulemaking process to define natural, citing lack of resources and more imperative agency priorities.⁶² FDA would maintain its informal policy on natural, which is of little help to consumers and manufacturers because it does not set a legal standard.⁶³ The informal policy is also insufficient because FDA has never defined or issued guidance on the terms artificial or synthetic; the critical components in the informal policy.⁶⁴

In 2006, the Natural issue was brought to FDA's attention when a Citizen Petition requested rulemaking. The Petition, brought by the Sugar Association, requested that FDA "establish specific rules and regulations governing the definition of natural before a natural claim can be made on food and beverages regulated by FDA."⁶⁵ The petition highlighted the augmented need for a definition in today's economy, citing the increased consumer interest in Natural labels. The lack of any definition has "engendered a great deal of ambiguity," the petitioners claimed.⁶⁶

The Sugar Association also asserted that the introduction of new food technologies since FDA last attempted to address the "Natural issue" necessitated strict guidelines to define the term.⁶⁷ In 2007, the Sara Lee corporation filed a similar Petition requesting that FDA work with the Food Safety Inspection Service (FSIS)—a public health agency in the USDA—to create a uniform definition for Natural.⁶⁸ In the end, neither of these requests prompted FDA to initiate any rulemaking. In 2008, the supervisor of the Product Evaluation and Labeling team at FDA's office of nutrition determined that "the agency had not put the 'natural' issue on its priority list because there is not enough evidence that the current situation means consumers are being misled."⁶⁹

This may no longer be the case. Since the petitions in the mid 2000's, additional evidence highlight that consumers are being sufficiently misled. As mentioned above, there has been an influx of controversies over the Natural label.⁷⁰ The frequency of

⁶⁰ *Id.* at 2,407.

⁶¹ Negowetti, *supra* note 1, at 584.

⁶² Definition of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. at 2,407.

⁶³ 21. C.F.R. §§ 10.85(d), (e), (j) (2014); *see also* *Holk v. Snapple Beverage Corp.*, 575 F.3d 329, 342 (3d Cir. 2009) (explaining that FDA's definition of Natural does not have the force of law).

⁶⁴ *See* Benny, *supra* note 6, at 1511.

⁶⁵ *Citizen Petition*, SUGAR ASS'N 1 (Feb. 28, 2006) http://www.cspinet.org/new/pdf/sugar_fda_petition.pdf.

⁶⁶ *Id.* at 3.

⁶⁷ *Id.* at 4. To resolve the ambiguity around natural, the Association proposed the following definition for Natural: 1) a food that does not contain anything artificial or synthetic and 2) a food or food ingredient that is not more than minimally processed, meaning that the molecular structure inherent in the raw material is left intact. *Id.* at 4–5.

⁶⁸ Weaver, *supra* note 38, at 664.

⁶⁹ Lorraine Heller, 'Natural' will Remain Undefined, Says FDA, FOOD NAVIGATOR-USA (Jan. 4, 2008), <http://www.foodnavigator-usa.com/Financial-Industry/Natural-will-remain-undefined-says-FDA>.

⁷⁰ Negowetti, *supra* note 4, at 332–33.

filed cases raises an inference that consumers are so misled by Natural claims that they may feel resorting to litigation is their only option to effect regulatory reform.

In addition, several courts have requested administrative determinations from FDA on using the claim—by way of the primary jurisdiction doctrine.⁷¹ For instance, in the midst of a natural controversy, the court in *Cox v. Gruma Corp.* referred to FDA the question of “whether and under what circumstances food products containing ingredients produced using bioengineered seeds may or may be labeled ‘Natural’”⁷² Likewise, the court in *Barnes v. Campbell Soup Company* stayed its Natural controversy and designated the question to FDA for administrative determination.⁷³ The underlying tensions inherent in the primary jurisdiction doctrine recognize that agencies are expected to be experts in technical matters, and that courts are not always up to this task.⁷⁴ That expertise is desperately needed here, and the court’s use of the doctrine acknowledges that the Natural question can—and should—be answered by FDA.

Moreover, the fact that FDA has repeatedly declined to define Natural is disconcerting, as the original policy that the agency still adheres to was developed in 1993. Since then, the food industry has undergone substantial industrialization and food is more processed than ever before.⁷⁵ Biotechnology and other complex technologies are increasingly applied to food and its ingredients.⁷⁶ Notwithstanding the increased use of these technologies, natural claims continue to rise exponentially—a seemingly contradictory scenario.⁷⁷ All in all, advanced food production technology, explicit requests from the judiciary, and a marked increase in filed cases litigating Natural suggest FDA should promulgate a Natural regulation.

3. *The United States Department of Agriculture on Natural*

The United States Department of Agriculture’s (USDA) relationship with Natural provides important background to this article’s contribution. USDA has made more headway on setting a workable definition of Natural than FDA. However, like its administrative counterpart, it too only has an informal policy.⁷⁸ USDA implemented its policy in 1982, and it has remained in effect with little to no change.⁷⁹ The guidelines limit the use of the term Natural to those products that contain no artificial ingredients or chemical preservatives, and require that the products and ingredients be

⁷¹ A court will refer an issue to FDA when it determines that the doctrine of primary jurisdiction applies, and this doctrine “allows courts to stay proceedings or to dismiss a complaint without prejudice pending the resolution of an issue with the special competence of an administrative agency.” *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008).

⁷² *Cox v. Gruma Corp.*, No. 12-CV-6502-YGR, 2013 WL 3828800, at *2 (N.D. Cal. July 11, 2013).

⁷³ *Barnes v. Campbell Soup Co.*, No. 12-CV-05185-JSW, 2013 WL 5530017, at *9 (N.D. Cal. July 25, 2013).

⁷⁴ William F. Fox, Jr., *ADMINISTRATIVE LAW* § 11.02 (6th ed. 2012).

⁷⁵ Parasidis, *supra* note 3, at 362.

⁷⁶ *FOOD ADDITIVES*, *supra* note 14, at 358 (explaining how biotechnology is being used in a variety of food processing).

⁷⁷ Parasidis, *supra* note 3, at 362.

⁷⁸ Negowetti, *supra* note 1, at 589–90.

⁷⁹ Weaver, *supra* note 38, at 664.

minimally processed.⁸⁰ They also mandate that the manufacturer include a descriptive factor of what makes the food Natural on the label.⁸¹

The inclusion of a minimally processed requirement is the most distinctive quality in USDA's policy vis-à-vis FDA's. Minimally processed refers to traditional processes used to preserve food, to make food edible, or to make food safe for human consumption.⁸² Minimally processed also refers to processes that "do not fundamentally alter the raw product and/or separate a whole, intact food into counterparts"⁸³

In 2006, Hormel petitioned USDA to implement rulemaking and define Natural. Hormel posited that a 2005 revision created inconsistencies within USDA's policy by permitting products containing artificial ingredients and preservatives to be labeled natural.⁸⁴ Hormel advocated for a regulation prohibiting exemptions for certain chemical preservatives and synthetic ingredients.⁸⁵ In response, USDA initiated a notice and comment period and solicited comments from the public.⁸⁶ Unfortunately, this did not result in a Natural definition and USDA decided to maintain its informal policy.⁸⁷ USDA did issue an advanced notice of proposed rulemaking in 2009, citing a lack of consensus on the general understanding of what is natural and how the agency should define the term, but there has been no further action since the issuance.⁸⁸

4. Legislative Attempts Concerning Natural

In 2013, the Food Labeling Modernization Act (FLMA) was introduced in the House and Senate.⁸⁹ This ultimately unsuccessful bill would have amended the FDCA to establish a standard definition for the term Natural.⁹⁰ In 2015, the FLMA was revived with an effort to accomplish the same goal as its failed predecessor by requiring the Secretary of Health and Human Services to promulgate a final rule on Natural no later than two years of enactment of the bill.⁹¹ It further requires that the term natural will "exclude at minimum, the use of any artificial food or ingredient (including any artificial flavor or added color) or any synthetic substance."⁹²

⁸⁰ FOOD SAFETY AND INSPECTION SERVICE, U.S. DEP'T OF AGRIC., FOOD STANDARDS AND LABELING POLICY BOOK, (2005), http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf [hereinafter Labeling Policy Book]. The full definition provides the following: (1) the product does not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative (as defined in 21 C.F.R. § 101.22), or any other artificial or synthetic ingredient; and (2) the product and its ingredients are not more than minimally processed. *Id.*

⁸¹ *Id.*

⁸² *Id.*

⁸³ *Id.*

⁸⁴ Weaver, *supra* note 38, at 665.

⁸⁵ Negowetti, *supra* note 1, at 590-91.

⁸⁶ *Id.* at 591.

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ Food Labeling Modernization Act of 2013, S. 1653, 113th Cong. (2013) (proposing amendment of 21 U.S.C. § 343 (2010) titled "Misbranded food").

⁹⁰ *Id.*

⁹¹ Food Labeling and Modernization Act of 2015, H.R. 4061, 114th Cong. § 4(a)(1) (2015).

⁹² *Id.* at § 4(a)(2).

Importantly, synthetic and artificial are defined under the new bill,⁹³ whereas the terms are not explained in FDA informal policy.⁹⁴ A food is artificial if it “is synthetically produced but has the same chemical structure as a naturally occurring food or ingredient” or has “undergone chemical changes through the introduction of synthetic chemicals or processing aids”⁹⁵ Synthetic is defined as “a substance that is formulated or manufactured by chemical process or by a process that chemically changes a substance extracted from a naturally occurring plant, animal . . . except that such a term does not apply to a substance created by naturally occurring biological processes.”⁹⁶ The FLMA is set to be finalized in early 2016.⁹⁷

C. Natural Abroad: Canada, Israel, and the United Kingdom

Although our nation’s various administrative agencies have failed to undertake rulemaking to define natural, other countries have developed a regulatory standard.⁹⁸ In contrast to the various informal policies and proposed legislation in the United States, which have focused on the presence of artificial and synthetic ingredients in Natural products,⁹⁹ the regulations in other jurisdictions move the inquiry to the effect processing and food technology has on the food or food ingredient.¹⁰⁰

For instance, Canada confines the use of a Natural label to a food or food ingredient that has not “been submitted to processes that have significantly altered their original physical, chemical or biological state.”¹⁰¹ Canada categorizes various processes into two groups: the first includes processes that have a minimum alteration effect on food or food ingredients, which are considered natural, while the second lists processes that have a maximum alteration on food or food ingredients, which are considered unnatural.¹⁰² Israel similarly focuses on the process used in making the food.¹⁰³ It defines Natural as “a single food product or its fragment, which is not a blend of foods, which is free of additional Ingredients and which has not passed different

⁹³ *Id.* at § 11(b).

⁹⁴ See Food Labeling: Nutrient Content Claims, General Principles Petitions, Definition of Terms, 56 Fed. Reg. 60,421, 60,466 (proposed Nov. 27, 1991).

⁹⁵ H.R. 4061, 114th Cong. § 11(b)(ss) (2015) (listing a number of processing aids including: corn syrup, high-fructose corn syrup, high-maltose corn syrup, maltodextrin, chemically modified starch, and cocoa processed with alkali).

⁹⁶ *Id.* at § 11(b)(tt).

⁹⁷ Rick Lingle, *How Brand Owners can Leverage Nutritional Labeling Changes*, PACKAGING DIGEST (Jan. 26, 2015), <http://www.packagingdigest.com/labels/flma-labeling-law-update-advice150126>.

⁹⁸ See Negowetti, *supra* note 1, at 600–01 (summarizing different countries’ Natural policies, which focus on the level of processing).

⁹⁹ See Food Labeling: Nutrient Content Claims, General Principles Petitions, Definition of Terms, 56 Fed. Reg. 60,421, 60,466 (proposed Nov. 27, 1991).

¹⁰⁰ See Negowetti, *supra* note 1, at 600–01.

¹⁰¹ *Food Labelling for Industry*, CANADIAN FOOD INSPECTION AGENCY (Aug. 10, 2016), <http://www.inspection.gc.ca/english/fssa/labeti/guide/ch4ae.shtml>.

¹⁰² *Id.*; see also Negowetti, *supra* note 1, at 601.

¹⁰³ Gilad Shachar, *Food and Agricultural Import Regulations and Standards- Narrative. FAIRS Country Report*, USDA FOREIGN AGRIC. SERV. (July 26, 2010) http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Food%20and%20Agricultural%20Import%20Regulations%20and%20Standards%20-%20Narrative_Tel%20Aviv_Israel_7-26-2010.pdf.

processes”¹⁰⁴ The regulations also provide a definition of Natural ingredients that hones in on one of the same requirements mandated in the Canadian rules: the prohibition on labeling an ingredient as Natural when it has chemically changed during the production process.¹⁰⁵

In addition, there is the United Kingdom who may have the most restrictive definition of Natural and Natural ingredients. Like Israel and Canada, the UK’s definition focuses on both the processing involved and the chemical changes in the food or ingredient.¹⁰⁶ For a food to be considered Natural, the item must be comprised of natural ingredients, e.g., “ingredients produced by nature, not the work of man or interfered with by man.”¹⁰⁷ The regulation contains a prohibition as well and states: “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 . . . flavourings that are the product of the chemical industry or extracted by chemical processes.”¹⁰⁸

In essence these countries focus on two inquiries when determining if a food or food ingredient is natural: (1) whether traditional, minimal processes are used; and (2) whether the chemical composition of the food or ingredient is altered or changed significantly. This stands in contrast to the Natural policies in the United States. To be sure, USDA’s policy does mention the process involved, but the interlocking inquiry for FDA and USDA revolves around the presence of natural or synthetic ingredients. In any event, these foreign regulations provide useful guidance and may be suggestive of a rule FDA may promulgate.¹⁰⁹

II. THE NATURAL FLAVORS BACKGROUND

A. FDA’s Natural Flavors Regulatory Scheme

At present, a definition of “natural flavors” is the only promulgated regulation concerning the term Natural.¹¹⁰ The regulation contains a list of chemical substances that a natural flavor ingredient may contain,¹¹¹ as well as a list of sources in which the chemical substance may originate.¹¹² One of the hallmarks of this regulation is that in

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Criteria for the use of the terms, Fresh, Pure, Natural etc.*, FOOD STANDARDS AGENCY 15–19 (July 2008), <http://www.food.gov.uk/sites/default/files/multimedia/pdfs/markcritguidance.pdf>.

¹⁰⁷ *Id.* at 15.

¹⁰⁸ *Id.*

¹⁰⁹ See discussion, *infra* Part IV.B.

¹¹⁰ Lauren E. Handel, *A Practitioner’s Guide to Defending “Natural” Food Label Litigation*, 7 KY. J. EQUINE, AGRIC. & NAT. RESOURCES L. 255, 259 n.23 (2014–15) (“[T]here is no federal statute or regulation regarding the use of the term ‘natural’ to describe food or ingredients other than ‘natural flavors.’”).

¹¹¹ 21 C.F.R. § 101.22(a)(3) (“The term natural flavor or natural flavoring means the essential oil, oleoresin, essence or extractive, protein, hydrolysate, distillate, or any product of roasting, heating or enzymolysis”).

¹¹² *Id.* (“The term natural flavor or natural flavoring . . . contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products”). The

defining natural, the rule only refers to ingredients affecting flavor as natural; it doesn't specify the extent to which an ingredient that does not affect flavor is natural or unnatural.¹¹³ If the ingredient satisfies the requirements listed above, it may be deemed a natural flavor in the ingredient statement.¹¹⁴

Section 101.22 also discusses different types of flavorings besides natural flavors and different uses for the term natural flavor—e.g., labeling a product as “naturally flavored” or an ingredient as a “natural vanilla flavor.”¹¹⁵ A detailed look at each provision is beyond the scope of this article, and I will only discuss the provisions relevant to natural flavors as listed in the ingredient statement.¹¹⁶ In particular, I will detail how these provisions are capacious and leave room for manufacturers to include artificial and synthetic chemicals in their natural flavors.¹¹⁷

The first relevant provision is the subsection setting forth the standard for artificial flavors, which is any flavor not derived from a spice, herb, vegetable, and so forth; in other words, artificial flavors are flavors not derived from something natural.¹¹⁸ This provision is significant because it establishes a dichotomy suggesting one type of flavor is free of artificial flavors and the other—natural flavors—is not. The regulation also defines the colors or color additives listed in §70.3(f) as artificial. Lastly, there is the section making reference to chemical preservatives, which “means any chemical that, when added to food, tends to prevent or retard deterioration thereof”¹¹⁹

In sum, the two provisions defining artificial flavors and natural flavors establish that it is *only* the flavoring ingredient that qualifies as something natural or artificial; it does not refer to the permissibility of using ingredients (synthetic or artificial) that *do not* have an effect on flavoring. And if a synthetic color additive is not listed in §70.3(f), or an artificial chemical preservative does not sufficiently prevent or retard deterioration of the food, those chemicals are not required to be listed even if used in a natural flavor.

But the provision that most generously enables manufacturers to include artificial and synthetic chemicals in their natural flavors is §101.22(h)(2). This section exempts

regulation also includes a cross reference to various other subsections of plants that a natural flavor's essence or extraction may be derivable from. *Id.*; see also §§ 182.10, 182.20, 182.40, and 182.50.

¹¹³ 21 C.F.R. § 101.22(a)(3).

¹¹⁴ See 21 C.F.R. § 101.4(a)(1) (specifying the requirements manufacturers must follow when designating ingredients in the ingredient statement).

¹¹⁵ See e.g., 21 C.F.R. §§ 101.22(i)(1)(iii) (“If the food contains both a characterizing flavor from the product whose flavor is stimulated and other natural flavor which stimulates . . . the food shall be immediately followed by the words ‘with other natural flavor’”), 101.22(i)(2) (“If the food contains any artificial flavor which simulates, resembles or reinforces the characterizing flavor . . . the name of the characterizing flavor shall be accompanied by the word(s) ‘artificial’ or ‘artificially flavored’ . . .”).

¹¹⁶ See 21 C.F.R. § 101.4(a)(1) (specifying the requirements manufacturers must follow when designating ingredients in the ingredient statement).

¹¹⁷ Note, I am referring to natural flavors that would be listed in the ingredient list, as opposed to natural flavor labeling represented more generally on the front of the product. See 21 C.F.R. § 101.22(i) (setting forth the regulations for labeling a product as naturally flavored when the product contains both natural flavors, pursuant to 101.22(a)(3), and artificial flavors).

¹¹⁸ *Id.* at § 101.22(a)(1).

¹¹⁹ *Id.* at §§ 101.22(a)(4), (a)(5).

all incidental additives from labeling.¹²⁰ Chemicals qualifying as incidental additives include substances that have no technical or functional effect in the food, but are still present due to being incorporated into the food as an ingredient of another food.¹²¹ Processing aids used in food production may also qualify as incidental additives if (1) they are removed from the food before it is in its finished form, (2) they are converted into constituents typically found in the food and do not significantly increase the number of constituents naturally found in the food, or (3) they are “added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.”¹²² Lastly, manufacturers can also exclude chemical preservatives from the ingredient list if it qualifies as an incidental additive.¹²³

These regulations make two points clear regarding the regulation of natural flavors: (1) FDA only bars ingredients that are artificial or synthetic when they are an artificial flavor, a designated artificial color, or a sufficiently retarding chemical preservative; and (2) if a synthetic chemical is present in the food at incidental levels, with no technical or functional effect in the food, it is exempt from being listed in the ingredient statement.

As to the first point, this leaves open the possibility that natural flavors could contain artificial processing aids, as long as they are not chemical preservatives and do not have an impact on flavor or color. And to the latter, processing aids, chemical preservatives, and other artificial or synthetic substances used in natural flavors don’t have to be listed in the ingredient statement of natural flavors, so long as they don’t have any technical or functional effect in the finished product.

Before further examining the tension between natural flavors that contain artificial chemicals and a potential Natural regulation, a preliminary discussion of the industry that develops natural flavors and the processes used to make the ingredient is necessary.

B. The Flavor Industry

The flavor industry consists of a small and elite group of scientists—deemed flavorist or flavor chemists—who develop the flavors in most of the food consumed in the United States.¹²⁴ The flavor industry is incredibly secretive, with even more secrecy going into the protection of these flavors.¹²⁵ For instance, it’s not atypical for

¹²⁰ *Id.* at § 101.22(h)(2) (“The label of a food to which flavor is added shall declare the flavor in the statement of ingredients in the following way An incidental additive in a food, originating in a spice or flavor used in the manufacture of the food, need not be declared in the statement of ingredients”).

¹²¹ 21 C.F.R. § 101.100(a)(3)(i).

¹²² *Id.* at § 101.100(a)(3)(ii); see *Sea Snack Foods, Inc. v. United States*, No. 87-3229 (D.D.C. Dec. 22, 1987), reprinted in Vincent A. Kleinfeld & Alan H. Kaplan, *Federal Food, Drug, and Cosmetic Act 1987–1988*, 212 (1989); see also *Food Drug Cosm. L. Rep.* ¶ 50, 163 (stating that processing aids are exempt from satisfying the labeling requirements of the FDCA if they are in insignificant amounts and play no technical or functional part).

¹²³ 21 C.F.R. § 101.22(j) (“A food to which a chemical preservative is added shall, except when exempt pursuant to § 101.100 bear a label declaration stating both the common name of the ingredient(s) and a separate description of its function”).

¹²⁴ ERIC SCHLOSSER, *FAST FOOD NATION: THE DARK SIDE OF THE AMERICAN MEAL* 125–29 (Houghton Mifflin 2001).

¹²⁵ *Id.*

flavor formulas to only be disclosed to a single individual in an entire food processing company, in order to protect their proprietary information.¹²⁶

This secrecy stems from the importance of natural flavors in our food economy. Much of what gives the foods we consume today such appealing flavor are the manufactured flavors within a food,¹²⁷ and “natural flavors” make up a significant portion of this \$24 billion global flavor industry.¹²⁸ In the 1960s, the flavor industry primarily manufactured synthetic and artificial flavors, a practice that was more lucrative for the flavor industry.¹²⁹ But with today’s health conscious consumers preferring natural ingredients, there has been a marked switch to a preference for natural flavors.¹³⁰

To keep up with this demand, food processors now make an effort to use only natural flavors in their products.¹³¹ This demand has led to a corresponding increase in natural flavors research and the use of new complex technological processes to manufacture these ingredients.¹³² For example, advances in flavor manufacturing are coming from the field of biotechnology, which seeks to replicate nature’s biogenetic pathways.¹³³

C. The Natural Flavor Creation Process

The natural flavor production process begins with a flavor chemist picking a natural flavor target to recreate.¹³⁴ The chemist then draws upon a natural raw material (i.e., spice or food),¹³⁵ as §101.22(a)(3) mandates, to develop the natural flavor. It is very rare, however, that this natural raw material will be used in its native form¹³⁶ because the goal is to produce the densest concentration of aromatic chemicals.¹³⁷ The starting point for maximizing this aromatic effect frequently involves the use of various physical separation methods including extraction, distillation, or cold pressing the natural material.¹³⁸

To elucidate the natural flavor manufacturing process, we’ll look at the most common type of natural flavor, the essential oil, which is harnessed through a steam

¹²⁶ Telephone Interview with Mary Mulry, Managing Partner, FoodWise One (Mar. 7, 2016) [hereinafter Interview].

¹²⁷ *Id.*

¹²⁸ David Andrews, *Synthetic ingredients in Natural Flavors and Natural Flavors in Artificial flavors*, ENVIRONMENTAL WORKING GROUP, <http://www.ewg.org/foodscores/content/natural-vs-artificial-flavors> (last visited May, 11, 2016).

¹²⁹ FOOD ADDITIVES, *supra* note 14, at 350.

¹³⁰ *Id.* at 351.

¹³¹ ERIC SCHLOSSER, *FAST FOOD NATION: THE DARK SIDE OF THE AMERICAN MEAL* 125–29 (Houghton Mifflin 2001).

¹³² FOOD ADDITIVES, *supra* note 14, at 358.

¹³³ *Id.*

¹³⁴ *Id.*

¹³⁵ *Id.* at 364–65.

¹³⁶ Robert L. Smith et al., *A Procedure for the Safety Evaluation of Natural Flavor Complexes Used as Ingredients in Food: Essential Oils*, 43 FOOD & CHEMICAL TOXICOLOGY 345, 348 (2005) [hereinafter Smith].

¹³⁷ FOOD ADDITIVES, *supra* note 14, at 365.

¹³⁸ Smith, *supra* note 136, at 348.

distillation extraction method.¹³⁹ After the steam distillation extraction process, a crude oil is obtained; but this oil is not normally used as a natural flavor.¹⁴⁰ The oil needs to be subjected to numerous other processes intended to purify the chemical and produce a sufficiently flavorful product.¹⁴¹ Additional processing methods include “fractional distillation, topping (removal of volatile parts), solvent extraction, supercritical extraction, thin-film evaporation and molecular distillation.”¹⁴²

The processing does not end there: once the oil is evaluated for its technical function as a flavor, additional redistillation may be used to remove color, water, resinous material and unpleasant aromas or taste perceptions.¹⁴³ Then, the oil may be combined with other sources of the same oil or chemical constituents isolated from the oil to create a suitable flavor.¹⁴⁴ When all the flavor-parts have been combined, any given natural flavor complex may contain as many as 250 chemically identified constituents.¹⁴⁵ These combinations not only contain components made through the natural flavor process just described, but also synthetic and artificial substances.¹⁴⁶ These substances, which do not impart flavor, serve several functions and have significant uses in the food supply.¹⁴⁷

D. Preservatives and Other Chemicals that Perform Non-Flavor Functions in Natural Flavors

As discussed earlier, §101.22(a)(3) explicitly requires that the flavorings used in natural flavorings be natural. The regulation, however, makes no mention of whether any other ingredients that perform non-flavor functions must be natural.¹⁴⁸ We also learned that incidental additives that have no form or function in the finished product need not be mentioned in the ingredient list. Thus, it is no surprise that a natural flavor complex can contain many chemicals that don’t perform a flavor function, some of which are artificial or synthetic.¹⁴⁹ These ingredients include “preservatives (BHA),

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

¹⁴² Robert L. Smith et al., *Safety Evaluation of Natural Flavour Complexes*, 149 TOXICOLOGY LETTERS 197, 198 (2004).

¹⁴³ *Id.*

¹⁴⁴ Smith, *supra* note 136, at 348.

¹⁴⁵ Robert L. Smith et al., *Criteria for the Safety Evaluation of Flavoring Substances: The Expert Panel of the Flavor and Extract Manufacturers Association*, 43 FOOD & CHEMICAL TOXICOLOGY 1141, 1144 (2005).

¹⁴⁶ *Id.* (explaining that natural flavor complexes contain other ingredients that perform non-flavor functions).

¹⁴⁷ *Id.*

¹⁴⁸ *Supra* note 113 and accompanying text.

¹⁴⁹ See Robert L. Smith et al., *Criteria for the Safety Evaluation of Flavoring Substances: The Expert Panel of the Flavor and Extract Manufacturers Association*, 43 FOOD & CHEMICAL TOXICOLOGY 1141, 1144 (2005).

solvents (ethyl alcohol), modifiers (neohesperidin dihydrochalcone), emulsifiers,” and more.¹⁵⁰ In fact, non-flavor chemicals can comprise 80 to 90 percent of the mixture.¹⁵¹

Section 101.22 permits the use of artificial or synthetic emulsifiers, modifiers, and solvents because they do not have an impact on flavor, they are not considered color additives, or they are not classified as chemical preservatives.¹⁵² In addition, chemical preservatives that do prevent or retard deterioration may still remain unmentioned if they are considered incidental additives. This latter point is often the case because by time the natural flavor is added to the product intended for consumption, the artificial ingredient is in such trace amounts that it does not affect flavor.¹⁵³

To provide an example, we can look at propylene glycol.¹⁵⁴ This is a synthetic chemical that is used as a solvent to disperse and transfer other substances, but eventually evaporates.¹⁵⁵ Hence, by the time you mix the natural flavor into the finished product, the propylene glycol, having already performed its intended function and since evaporated, has no presence in the finished product. Propylene glycol used in this way is a permissible incidental additive.¹⁵⁶

Admittedly, the use of synthetics like propylene glycol doesn't negate the fact that artificial flavors are still *less* natural than natural flavors.¹⁵⁷ But it does suggest that “[t]he distinction between artificial and natural flavors [is] somewhat arbitrary and absurd . . . ,”¹⁵⁸ as the flavors can sometimes contain many of the same chemicals.¹⁵⁹ Put differently, because the real weight behind the FDA definition of natural flavors stems from how the flavor is derived—not the process used¹⁶⁰—the regulation presents somewhat of a superficial dichotomy, and can be characterized as more of a euphemism rather than an aid to understanding what is contained in a natural flavor.¹⁶¹ The commentary online and the concern with natural flavors in the proposed

¹⁵⁰ *Id.*

¹⁵¹ *EWG's Dirty Dozen Guide to Food Additives: The FDA Failed Us*, ENVIRONMENTAL WORKING GROUP (Nov. 12, 2014), <http://www.ewg.org/research/ewg-s-dirty-dozen-guide-food-additives/fda-failed-us>.

¹⁵² Remember, the two provisions defining artificial flavors and natural flavors make clear that it is *only* the flavoring ingredient that qualifies as something natural or artificial; it does not refer to the permissibility of using ingredients (synthetic or artificial) that *do not* have an effect on flavoring. And if a color additive is not listed in §70.3(f) or a chemical preservative does not sufficiently prevent or retard deterioration of the food it is being added to, those chemicals are not required to be listed even if used in a natural flavor.

¹⁵³ Interview, *supra* note 26.

¹⁵⁴ Lisa Marshall, *Is natural flavoring natural?*, NEW HOPE (Dec. 19, 2014), <http://newhope.com/ingredients-general/is-natural-flavoring-natural>.

¹⁵⁵ *Chemical Classes of Concern*, SIX CLASSES, <http://www.sixclasses.org/wp-content/uploads/2013/11/Solvents-Fact-Sheet-Harriman.pdf> (last visited May 11, 2016).

¹⁵⁶ Interview, *supra* note 26.

¹⁵⁷ See FOOD ADDITIVES, *supra* note 14, at 394–96.

¹⁵⁸ SCHLOSSER, *supra* note 124, at 126.

¹⁵⁹ *Id.*

¹⁶⁰ MICHAEL SABISCH & DAVID SMITH, *The Complex Regulatory Landscape for Natural Flavor Ingredients*, SIGMA-ALDRICH, <http://www.sigmaaldrich.com/technical-documents/articles/white-papers/flavors-and-fragrances/natural-flavor-ingredients-regulations.html#standardization> (last visited May 5, 2016).

¹⁶¹ Lisa Heinzerling, *The Varieties and Limits of Transparency in U.S. Food Law*, 70 FOOD & DRUG L.J. 11, 19 (2015).

rulemaking comments recognizes the superficiality between the distinction, and suggests consumers seek transparency regarding natural flavors.

E. Legal Challenges to Natural Flavors

Despite the commentary online and elsewhere, natural flavors that contain artificial or synthetic chemicals are not currently challenged in litigation as misleading because if those chemicals don't impact flavor or affect the form of function of the food, they don't need to be listed in the ingredient statement. Contrastingly, natural flavors challenges have been brought when a manufacturer labels the product as being "Naturally Flavored" or containing "all Natural Ingredients," although the product contains artificial or synthetic ingredients.¹⁶² The permissibility of this type of labeling depends on which chemicals give the natural flavor its original taste.¹⁶³ If the artificial chemicals do not give the natural flavor its original taste, but instead, the flavors come from extracts of natural flavors defined as natural under §101.22(a)(3), the branding does not run afoul of FDA's regulations.¹⁶⁴ For example, in *Viggiano v. Hansen* the court held that there is no issue with using synthetic ingredients that sweeten or amplify a characterizing flavor that comes from a natural source.¹⁶⁵ In other words, FDA regulations allow the phrase "natural flavor" or "naturally flavored" to be used even when a product includes artificial ingredients, as long as the characterizing flavor is natural.¹⁶⁶

While the legal challenges mentioned above concerned natural flavor labeling and artificial chemicals *alongside* natural flavors, and did not address the issue of ascertaining the specific chemicals *contained within* natural flavors, there have been attempts to effectuate transparency by legal groups. In 1999, the Vegetarian Legal Action Network (VLAN) submitted a Citizen Petition to FDA requesting that the agency require food manufacturers to list the specific sources of the natural flavors.¹⁶⁷ The VLAN was concerned with natural flavors containing animal by-products; thus, violating vegetarian dietary restrictions.¹⁶⁸ Had FDA implemented this requirement, consumers would have been alerted to the unsuspecting origins of certain natural flavors—such as Castoreum, a Beaver secretion derived from a sac between the anus and extra genitals of the beaver.¹⁶⁹

A 2003 proposed amendment to the FDCA would have done exactly what the VLAN requested and required food processors to list the specific raw material the

¹⁶² See e.g., *Lam v. Gen. Mills, Inc.*, 859 F. Supp. 2d 1097, 1102 (N.D. Cal. 2012) (challenging a "naturally flavored" label as deceptive because the product contained artificial food dyes and other artificial substances).

¹⁶³ *Viggiano v. Hansen Natural Corp.*, 944 F. Supp. 2d 877, 889 (C.D. Cal. 2013).

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

¹⁶⁷ Sarah Kaltsounis, *Vegetarian Law Finds Fertile Grounds*, KARR TUTTLE CAMPBELL (Nov. 5, 2005), <http://www.karrtuttle.com/news/vegetarian-law-finds-fertile-ground.aspx>.

¹⁶⁸ *Id.*

¹⁶⁹ Natural flavors that are derived from "Natural" sources like Castoreum are startling, yet generally Recognized as Safe (GRAS) by FDA and the Flavor and Extract Manufacturers Association (FEMA); see George A. Burdock, *Safety Assessment of Castoreum Extract as a Food Ingredient*, 26 INT. J. TOXICOLOGY 51, 55 (2007).

natural flavor originates from.¹⁷⁰ Although this failed amendment would not have required any disclosure of synthetic or artificial flavors used during processing, it would have clued consumers into the fact that the natural flavors in our foods aren't necessarily what they seem.

The path towards the transparency of natural flavors is unsettled, but there is at least one published book,¹⁷¹ countless literature online,¹⁷² and numerous comments¹⁷³ calling attention to the unnaturalness of natural flavors. And though attempts from legal action groups like VLAN have subsided,¹⁷⁴ FDA's decision to look into promulgating a Natural definition presents an opportunity to analyze natural flavors and their supposed "naturalness." Hence, a discussion of whether natural flavors may still be considered Natural, in the event a rule is promulgated, follows.

III. AN ANALYSIS OF NATURAL FLAVORS IN LIGHT OF A LEGALLY ENFORCEABLE NATURAL REGULATION

FDA has repeatedly declined to promulgate regulations defining the term Natural for labeling in human food products, despite acknowledging both the potential deception for consumers and the ambiguity for companies manufacturing natural foods.¹⁷⁵ Nonetheless, with FDA's most recent notification of request for comments, issued on November 12, 2015 and closed on May 10, 2016, it may finally issue a rule. A variety of different routes are available for constructing a definition. These range from (1) giving full legal effect to the current informal policy, (2) implementing a process-based criterion exemplified by the USDA, Canada, Israel, and Great Britain, (3) creating detailed criteria for different categories of products, such as raw fruits and vegetables, grain products, and seafood or game meat, or (4) setting forth a list of ingredients that *cannot* be used on a Natural labeled product. Each of these options will be examined below, as well as the corresponding effect that option would have on natural flavors.

A. Adopting the Current Policy as the Regulation

The current policy states that "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 the food." This option, which does not address the processing of foods, would be the easiest type of promulgation for an already overburdened, underfunded, and understaffed FDA.¹⁷⁶ It also provides courts and state legislatures with a sizeable amount of discretion in interpreting the regulation.

¹⁷⁰ Kaltsounis, *supra* note 167.

¹⁷¹ See SCHLOSSER, *supra* note 124, at 125.

¹⁷² See *e.g.*, Andrews, *supra* note 14; Flinn, *supra* note 20.

¹⁷³ See *e.g.*, Sparacino, *supra* note 25 (arguing that natural flavors may not be natural because they are processed in laboratories and broken down in chemical compounds).

¹⁷⁴ Kaltsounis, *supra* note 167.

¹⁷⁵ Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2,302, 2,407 (Jan. 6, 1993).

¹⁷⁶ See Joseph G. Hoflander, *A Red Bull Instead of a Cigarette: Should the FDA Regulate Energy Drinks*, 45 VAL. U. L. REV. 689, 730-31 (2011) (explaining that critics of more expansive FDA regulatory power commonly assert that FDA is overburdened, underfunded, and understaffed).

Although this definition would not resolve the issue of processing in Natural foods, some have noted that this would be an added benefit because it would avoid potential safety concerns.¹⁷⁷ An emphasis on the process used may lead to companies avoiding some safe and socially desirable food manufacturing methods because they cannot be applied to “Natural” foods.¹⁷⁸ FDA’s insistence on the process used can also create absurd results, as illustrated by the “Fresh” regulation adopted in the early 1990s.¹⁷⁹ Thus, FDA may be better off transforming its own policy statement into a rule and ignoring the degree of processing involved all together.¹⁸⁰

If this were the case, it is likely that some Natural Flavors would no longer be considered Natural. This is because some natural flavors contain ingredients like artificial preservatives, emulsifiers, solvents, and modifiers.¹⁸¹ Although these chemicals may be in trace amounts, they are nonetheless used in natural flavors. Thus, in the scenario a natural flavor contains a preservative like BHA, the food it is added to will no longer contain “nothing artificial or synthetic.”

This outcome comports with the consumer expectation portion of the policy, as a consumer would not expect BHA to be in its Natural-labeled granola. In regard to this clause, it is possible manufacturers can argue that infinitely small levels of BHA may actually be expected to be in foods that are moderately-to-heavily processed. But because of the prohibition on anything artificial or synthetic, it seems those natural flavors containing synthetic preservatives and the like, would undoubtedly bar a food containing those ingredients from being labeled as Natural. Still, it would not disallow other artificial and synthetic ingredients used in the *processing* of the natural flavor that have since dissolved; as examined above, the processing used in natural flavors can be extensive and the use of synthetic processing aids prevalent.¹⁸²

Additionally, it’s possible the promulgation will make reference to incidental additives and exclude any incidental additive from affecting the Natural determination. If this occurred, artificial and synthetic ingredients in natural flavors would not prevent a Natural label from containing those flavors. This, too, is a possibility.

B. Adopting a Process-Based Regulation and Reaching Uniformity with USDA

To quell litigation that arises from the absence of a processing standard in FDA informal policy—brought by the likes of the Sugar Association and Sara Lee Corporation—FDA may factor USDA’s “minimal processing” language into the new standard. This would create uniformity between USDA’s and FDA’s Natural definition. And many other countries have integrated a processing element into their natural definition. At bottom, these countries’ Natural definitions make clear that a

¹⁷⁷ See April L. Farris, *The “Natural” Aversion: The FDA’s Reluctance to Define a Leading Food-Industry Marketing Claim, and the Pressing Need For a Workable Rule*, 65 FOOD & DRUG L.J. 403, 421 (2010).

¹⁷⁸ *Id.*

¹⁷⁹ *Id.* (explaining that FDA’s regulation of Fresh led to some food that would objectively be considered un-fresh to be labeled as such, while food that would comport with what people believe to be fresh could not be labeled as such).

¹⁸⁰ *Id.*

¹⁸¹ See *supra* notes 148–50 and accompanying text.

¹⁸² See *supra* notes 148–51 and accompanying text.

food processing method should not be so extraordinary that it divorces a product from a naturally occurring state.¹⁸³

These nations have also created detailed, extensive lists of permitted Natural processes. This reduces ambiguity for manufacturers when making a Natural label decision, as they can exclude certain unnatural processes when manufacturing their products. One initial observation must be made when focusing on the process: is it the food alone that must not be subject to extraordinary process, or the food *and* the ingredients. If only the former, a natural flavor in it of itself probably doesn't subject the food to the level of processing necessary to transform its essence into something "unnatural." But if the ingredients are also required to be minimally processed, a natural flavor, regardless of it containing something artificial or synthetic, may still bar a food from being labeled as Natural if it divorces the ingredient from its naturally occurring state.

USDA's guidelines in its Food Standards and Labeling Policy book applies the minimally processed standard to both the food product and its ingredients.¹⁸⁴ The guidelines make note of various minimal processing methods as well as certain severe processes that would overstep the boundaries of minimal processing—e.g., solvent extraction, acid hydrolysis, and chemical bleaching.¹⁸⁵ The guidelines also explicitly address the possibility that some natural flavors, which have undergone more than minimal processing, may render the food unnatural.¹⁸⁶

Notably, in 2005, USDA added a note to the policy book stating that natural flavors from oleoresins and extractives are acceptable for all natural claims. This revision, though, does not include natural flavors from essential oils, the most common type of natural flavor.¹⁸⁷ There was no explanation for this apparent shift from considering natural flavors made from severe processes as potentially incompatible with a Natural claim, to outright acceptance for natural flavors. While there have been no other attempts by FSIS to add policy guidance to this 2005 revision or clarify its natural flavors exemption, on August 19, 2015, the FSIS announced its intent to revise the Labeling and Policy.¹⁸⁸

Canada's labeling guidelines may provide a useful template for FDA, as it is similar to both FDA informal policy and USDA policy. In addition to prohibiting the presence of anything artificial as a flavoring agent, Canada also bars affixing a Natural claim to any food that has had its physical, biological, or chemical state significantly changed

¹⁸³ See e.g., FOOD STANDARDS AGENCY, *supra* note 106, at 15–19.

¹⁸⁴ (1) the product does not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative (as defined in 21 CFR § 101.22), or any other artificial or synthetic ingredient; and (2) the product and its ingredients are not more than minimally processed. Minimal processing may include: (a) those traditional processes used to make food edible or to preserve it or to make it safe for human consumption, e.g., smoking, roasting, freezing, drying, and fermenting, or (b) those physical processes which do not fundamentally alter the raw product and/or which only separate a whole, intact food into component parts, e.g., grinding meat, separating eggs into albumen and yolk, and pressing fruits to produce juices. U.S. DEP'T AGRIC. FOOD SAFETY & INSPECTION SERV., *supra* note 7, at 116.

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ Smith, *supra* note 17, at 348.

¹⁸⁸ *Availability of Updated FSIS Food Standards and Labeling Policy Book*, FOOD DRUG COSM. L. REP. P. 44751 (C.C.H.) (2015) ("The Food Safety And Inspection Service (FSIS) is announcing the Agency's intent to revise the Standards and Labeling Policy Book.").

by processing.¹⁸⁹ And like the USDA policy, these requirements apply to both food *and* ingredients.¹⁹⁰ Most significantly, Canada disallows a natural label even when the product contains a natural additive—i.e., natural flavor—because they are an added component that makes the food no longer natural.¹⁹¹ Thus, Canada allows *ingredients* to be labeled as natural but prohibits the *product* from being labeled as natural.

This policy, which categorically excludes all Natural labeled foods from containing natural flavor, seems to be less driven by the fact that there are potential artificialities lurking in natural flavors, and instead is due to the fact that a process that interjects an additive into the food inherently makes a product unnatural. Regardless of the purpose behind Canada's pragmatic regulation, there is bound to be less confusion for the consumer and the manufacturer alike if this type of regulation is promulgated.

Israel also lists a number of processes—Article C-1—a manufacturer may use in processing the food, while still allowing the product to don the Natural claim.¹⁹² Israel considers an ingredient to be Natural if it was produced using the same processes detailed in Article C-1, “and also by using sometimes, extraction or reconstruction or redefining, during the production process, conditioned that the ingredient has not chemically changed during the production process.”¹⁹³

Adding extractions to the list of permissible processes is important because natural flavors are commonly processed using extraction methods.¹⁹⁴ But, Israel only permits a Natural label when that food's ingredients have remained chemically unchanged by the production process.¹⁹⁵ Hence, a food product with an ingredient that has undergone a significant chemical change of the type banned by Israel's regulations cannot carry a Natural label. And a food product that contains a non-natural ingredient, like an artificial flavor, cannot be described as Natural either.¹⁹⁶

The regulations, however, are deficient in one respect: they do not make clear what transmutes an ingredient into an artificial flavor. So, one question remains unanswered: whether an artificial preservative qualifying as an incidental additive—and added to a natural flavor—would make an otherwise natural flavor artificial. Without clearing this up, if FDA were to adopt a regulation modeled on the process-based approach of Israel, processes that do not chemically change the natural flavor, yet add a preservative, may *still* be considered natural.

The United Kingdom's regulations provide another template useful in analyzing the Natural–natural flavors question. As was mentioned earlier, the UK has a very strict conception of natural, and defines natural as something produced by nature, not by man or interfered with by man.¹⁹⁷ Further, it criticizes use of the term to describe foods *or ingredients* that use chemicals to alter their composition or comprise the product of new technologies, “including . . . flavourings that are the product of the chemical

¹⁸⁹ CAN. FOOD INSPECTION AGENCY, *supra* note 101.

¹⁹⁰ *Id.*

¹⁹¹ Canada would still allow a claim that the product contains “natural ingredients,” but the food itself cannot be described as Natural because it contains an added component. *Id.*

¹⁹² Shachar, *supra* note 103, at 27–29.

¹⁹³ *Id.*

¹⁹⁴ See *supra* notes 138–41 and accompanying text.

¹⁹⁵ See Shachar, *supra* note 103.

¹⁹⁶ *Id.*

¹⁹⁷ FOOD STANDARDS AGENCY, *supra* note 106, at 15–19.

industry or extracted by chemical process.”¹⁹⁸ This latter proclamation would seem to sound the death knell for manufacturers wanting to label a food product with natural flavors as Natural. But, the regulations do permit usage of the term “[t]o describe permitted food additives that are obtained from natural sources (e.g. food or plant) by appropriate physical processing (*including distillation and solvent extraction*) or traditional food preparation processes.”¹⁹⁹

Therefore, the United Kingdom uses language that would seem to bar using a Natural claim on foods with natural flavors. But because of a qualification, the determination would ultimately depend on whether the processing method does not use chemicals to alter their composition. Also important is whether the process is either an appropriate physical process (distillation and solvent extraction) or a traditional food preparation process. If the answer to these questions is yes, the natural flavor of interest will not prevent a Natural claim from being on the product.

In evaluating the naturalness of natural flavors, the most substantial difference between these foreign countries and the United States is that the former define Natural by examining whether the process alters the chemical composition of the ingredient. Because these Natural regulations also apply to ingredients, they apply to natural flavors. FDA natural flavors regulation, however, is strikingly different from these other regulations. §101.22(a)(3) merely names various concentrations (essential oils, oleoresins, essence, or extractive) obtained for certain natural derivatives (spice, fruit, meat, or herb), and does not make mention of the process used or the effect altering composition would have on the naturalness of the flavor.²⁰⁰ This regulation is only concerned with where the flavor originally comes from and how it is derived, not what happens to the concentration once it’s derived.²⁰¹ A promulgated Natural definition may help address this issue.

To summarize, if FDA’s Natural definition adopts characteristics of the process-based regulations examined above, the use of a natural flavor that undergoes a sufficient alteration of chemical composition or undergoes a prohibited process may prevent the food from being labeled as Natural.

C. Designating Detailed Standards for Natural Labels by Food Category

Other scholarship has suggested that FDA develop distinct Natural definitions for different food categories.²⁰² In the past, FDA used this technique to regulate the use of the word healthy.²⁰³ The regulation designated specific levels of fat, saturated fat, and cholesterol that different types of food could contain and still carry a “healthy” label.²⁰⁴

¹⁹⁸ *Id.* (emphasis added).

¹⁹⁹ *Id.* (emphasis added).

²⁰⁰ Natural Flavor, *supra* note 13.

²⁰¹ SIGMA-ALDRICH, *supra* note 160.

²⁰² See Farris, *supra* note 177, at 421–22; Negowetti, *supra* note 1, at 602.

²⁰³ Farris, *supra* note 177, at 421.

²⁰⁴ See 21 C.F.R. § 101.65 (2014). The different categories of food are: A raw fruit or vegetable; a single-ingredient or a mixture of frozen or canned fruits and vegetables; an enriched cereal-grain product; a raw, single ingredient seafood or game meat; a meal product or main dish; and a food not specifically listed in the table. *Id.*

The allure of categorizing natural by food type is in the ability to designate a different definition of naturalness to products that require more processing. This would be preferable to a one-size-fits-all definition because of the different expectations consumers may have for products. That is, if a consumer understands that an enriched dairy product like yogurt or cottage cheese undoubtedly requires more processing than a raw fruit or piece of meat, this methodology can reflect that consideration and manufacturers can proceed accordingly.

The effect of this type of regulation on natural flavors would of course depend on the category of food in which the natural flavor is a constituent. The regulation would also have to explicitly mention the naturalness applies to both the food and the ingredient. But in the end, the processing of a natural flavor and the presence of accompanying preservatives or processing aids may limit the use of that flavor in heavily-processed products while allowing it in less processed products. This approach is appealing from a practical standpoint, but may be costly, as promulgating regulations for different types of food would require serious FDA resources.

D. Promulgating a Regulation of Natural that Lists and Excludes Unnatural Ingredients

FDA could alternatively promulgate a regulation that sets forth a list of ingredients that *cannot* be used on a Natural labeled product. The effect on natural flavors will depend on their inclusion or exclusion from the list. And exclusion from the unnatural list is possible, if not likely, as USDA has completely approved of the use of natural flavors on Natural products in its 2005 labeling policy book.²⁰⁵

Tension could remain, however, if ingredients used within natural flavors are found on the exclusion list, i.e., BPA. Because the BPA has no form or effect on the finished product, it would not need to be listed in the ingredient breakdown. But unless there is a separate provision addressing the use of incidental additives in ingredients within Natural products, it's unclear whether incidental, synthetic chemicals would be excluded.

In addition, FDA has also not clearly articulated what constitutes synthetic or artificial means, which further obfuscates the permissibility of using such chemicals in natural flavors.²⁰⁶ But with the upcoming finalization of the FLMA, it's possible that the statute's definitions of artificial and synthetic will have an influence on potential FDA regulation.²⁰⁷

At bottom: an approach that excludes unnatural ingredients might be possible, but unless more detailed issues are considered—i.e., incidental additives and what specifically is artificial or synthetic in Natural products—the naturalness of natural flavors problem won't be resolved in one fell swoop. Nonetheless, the unnatural ingredients exclusion remains an option for FDA in promulgating a Natural rule.

IV. CONCLUSION

It is entirely possible that FDA will decline to define Natural after reviewing the information received from its request for comments. Still, with the flood of recent

²⁰⁵ See *supra* notes 184–88 and accompanying text.

²⁰⁶ Benny, *supra* note 6, at 1511.

²⁰⁷ See *supra* notes 90–98 and accompanying text.

cases filed in the Northern District Court of California, the advancements in food technology, and the judiciary referring the Natural question to FDA, enough evidence may now exist for FDA to finally promulgate a legally binding rule. This essay also inserted a new, but related, element into the Natural question: the relationship between Natural and natural flavors. With the public's recognition of this relationship—by way of commentary online and the recent submissions published in response to FDA's request for comments—natural flavors, too, may be considered if FDA promulgates a rule. But as this essay highlights, there is still much indeterminacy regarding the naturalness of natural flavors. Nonetheless, consideration of the Natural–natural flavors relationship is still warranted, and this essay aspires to serve as a mainspring for the discussion.