

IT'S ONLY NATURAL

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FOOD REGULATION IN THE UNITED STATES

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INTRODUCTION

How does the Food and Drug Administration (FDA) define the term natural when applied to food products? Although I consider myself to be an educated consumer and am also an industry professional, I find myself without an answer to this question, because unfortunately, and shockingly, the FDA doesn't have a definition. With the exponentially growing number and variations of classifications used on labels, primarily for foods in the "organic" and "natural" realms, consumers are more confused than ever about just how unadulterated the foods they're purchasing are. Therefore, the FDA needs to put forth a clear and concise definition of the term natural, much like the United States Department of Agriculture (USDA) has done for foods under its jurisdiction, to assuage customer consternation.

This paper serves to demonstrate the need for the FDA to define the term natural. The first section will discuss the terminology associated with and confused with the term natural, namely, "fresh" and "organic". The next section will explore some of the controversial "natural" claims and their associated cases, and the final section will establish the consumer and industry need for a formalized definition of the term natural. Overall, this paper will propose that the FDA present a formal stance on the definition and use of the term natural.

I. BACKGROUND AND DEFINITIONS

This section will discuss and define the multitude of “green” or “healthy” terminology currently used on food labels and will also explore the USDA’s stance on the term natural. In highlighting these buzzwords and by presenting the USDA’s position regarding the term natural, it should be evident that the FDA should follow suit by putting forth a “natural” definition of their own.

A. Definition/Regulation of “Fresh” Foods

Comprehension of food in general, its labeling, and how to make informed and wise nutritional choices may never have been as bewildering to the average consumer as it is today. A primary cause of this puzzlement is the overwhelming amount of “healthy” terminology popping up on food labels. The intent of food labels and their claims is to provide consumers with scientific and legitimate information about the foods they consume. It appears, unfortunately, that this method of information sharing may actually be misleading to consumers as the waters continue to be muddied by more and more ambiguous terminology.

The scope of these terms is wide and appears to be growing exponentially along with customer confusion, particularly surrounding the use of the term natural and its many pseudo-synonyms, such as local food, slow food, free-range, cage-free, hormone-free, grass-fed, and community supported. The two terms most frequently associated and confused with the term natural are “fresh” and “organic,” which will be the focus of the following discussion. The key fundamental difference among these three descriptors is that “natural” is the only term left undefined by the FDA, and it is therefore officially not regulated in foods other than those under the USDA’s jurisdiction.

The descriptor “fresh” and its related terms are regulated by the FDA.¹ The FDA’s regulation of the term fresh includes its use in a brand name or as a sensory modifier (describing such attributes as texture, color, flavor, or taste) whenever the term is used to suggest or imply a lack of processing or preservation methods. *Id.* The use of the term fresh in a way that does not attempt to suggest the food is unprocessed, such as “fresh milk,” is not subject to the formal fresh definition. The aforementioned use is, however, subject to section 403(a) of the Federal Food Drug and Cosmetic Act,² therefore, the FDA may pursue action against products that use the term fresh in a misleading way.

The term fresh is defined by the FDA to generally mean foods that have not been frozen, thermally processed, or chemically processed in any way,³ however, the addition of specific pesticides, waxes, etc.,⁴ and the use of refrigeration⁵ are acceptable within the confines of the definition. Furthermore, a food may not carry the term fresh if it is made with concentrated or processed ingredients. *Id.*

With regard to the use of the term fresh when used to describe ingredients that comprise a processed food, the FDA is taking a case-by-case approach to regulation, by taking action only when such use is found to be misleading. The FDA has noted, however, that “consumers generally are not misled when such statements are made provided that the statements clearly refer to the ingredients and to not imply that the

¹ See 21 C.F.R. § 101.95.

² See 21 USC 343.

³ See 21 C.F.R. § 101.95(a).

⁴ See 21 C.F.R. § 101.93(c)(1).

⁵ See 21 C.F.R. § 101.95(c)(2).

food itself is unprocessed.”⁶

B. Definition/Regulation of “Organic” Foods

Organic foods have an ever-increasing presence in the food industry and on grocery store shelves as consumer demand for foods that are healthy and environmentally friendly continues to grow. Organic foods can be found in more than 72% of retail grocery stores and are also stocked in over 20,000 natural food stores.⁷ Half of all shoppers in the U. S. purchase organic foods, 81% of those do so based on concern for nutritional value, 77% cite freshness as the driver to purchase organic, and 67% feel organic foods will promote their long-term health. *Id.* Perhaps the principal reason that even more consumers don't purchase organic foods is that they tend to be higher priced, although, with farmers devoting more acreage to organics and mass production being perpetuated, organic foods will increasingly become competitively priced.

Pursuant to the Organic Foods Production Act of 1990 (OFPA), the USDA is the agency responsible for defining and regulating the use of the term organic. The USDA's Agricultural Marketing Service (AMS) put forth regulations for the implementation of OFPA on December 21, 2000, which included the establishment of uniform national standards for governing the production, handling, and marketing of foods bearing organic claims.⁸ These regulations were issued after a 10-year rulemaking period in which the USDA determined how to most effectively implement OFPA, with the final decision being the establishment of the National Organic Program (NOP), which was

⁶ See 58 Fed. Reg. 2405.

⁷ FMI Backgrounder, *Natural and Organic Foods*, <http://www.fmi.org> (June, 2007).

⁸ See 65 Fed. Reg. 80548 (Dec. 21, 2000).

implemented on October 21, 2002.⁹

Organic certification through the NOP is available only for agricultural products, including livestock, crops, and certain processed products containing agricultural commodities. Operations intending to produce or handle organic products or ingredients must obtain certification through a USDA-accredited certification agent, and must submit an organic plan that demonstrates their compliance with the USDA's standards for organic production and handling. *Id.*

The fundamental principle of the NOP is that a product's organic composition, or the percentage of organic ingredients in the product, dictates not only the marketing terms that can be associated with the product, but also the non-organic ingredients that may be found in the product. The regulations set forth four categories of products that are allowed to represent themselves as organic, to varying degrees, as calculated exclusive of water and salt:

- 100% organic products may be marketed as "100% organic"
- Products with at least 95% organic ingredients may be represented as "organic"
- Products with at least 70% organic ingredients may be marketed as "made with organic" (specified ingredients/foods), up to 3 specific organic ingredients/food groups may be name
- Products in packaged form that contain less than 70% organic ingredients may identify specific organic ingredients in their ingredient declaration
Id.

The USDA has limited the non-organic ingredients and circumstances with which they may be used in "organic" or "made with organic" food items via the National List of

⁹ FMI Backgrounder.

Allowed and Prohibited Substances and by declaring that these ingredients must also be commercially available¹⁰ or individually listed via the National List procedures.¹¹

C. Definition/Regulation of “Natural” Foods

Despite the fact, or perhaps because of the fact, that the FDA has not issued a specific definition of what a “natural” food is, the market for such food items is growing, as is consumer confusion and skepticism over just what the word natural means when found on a food label. Although the FDA has not put forth specific regulations for “natural” foods, it has adopted an informal policy pertaining to the use of the term which states that “natural” means:

nothing artificially or synthetic has been included in, or has been added to, a food that would not normally be expected to be in the food.¹²

Natural flavors and colors, however, are defined by the FDA and serve to provide for additional guidance regarding the use of the term natural.^{13 14}

Unlike the FDA, the UDSA, along with the Food Safety and Inspection Service (FSIS), has made significant strides in the definition and regulation of the term natural for food items in their jurisdiction. FSIS has issued a Policy Memo that expresses its position in regard to the conditions under which the use of the term natural is appropriate. The FSIS policy states that “natural” may be used on food labels of meat and poultry products if:

- the product does not contain any artificial flavor or flavoring, coloring ingredient,

¹⁰ See 7 C.F.R. § 205.606.

¹¹ See 72 Fed. Reg. 2167 (January 18, 2007).

¹² See 58 Fed. Reg. 2407 (January 6, 1993).

¹³ See 21 C.F.R. § 101.22(a)(3) (Natural Flavors).

¹⁴ See 21 C.F.R. § 101.22(a)(4); see also Compliance Policy Guide No. 7127.01 (Natural Colors).

or chemical preservative (as defined in 21 C.F.R. § 101.22) or any other artificial or synthetic ingredient; and

- the product and its ingredients are not more than minimally processed.¹⁵

Further, and according to the Policy Memo, minimal processing may include:

- 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
- physical processes that do not fundamentally alter the raw product and/or that only separate a whole, intact food into component parts, *e.g.*, grinding meat, separating eggs into albumen and yolk, and pressing fruits to produce juices. *Id.*

For severe processes such as solvent extraction, acid hydrolysis, and chemical bleaching, the FSIS's position is that these fall outside the definition of minimally processed. *Id.* The presence of an ingredient that has been more than minimally processed does not necessarily place this food outside of the FSIS "natural" policy, however. FSIS considers exceptions of this type on a case-by-case basis. If it can be shown that the processed ingredient does not significantly change the character of the product to a degree that it could no longer be considered a "natural" product, FSIS requires the "natural" claim be qualified to identify the ingredient in question (*e.g.*, contains high fructose corn syrup). *Id.*

FSIS regulates "natural" claims by requiring that they are accompanied by a brief statement on the principal display panel directly beneath or beside the claim elaborating on what is meant by the term, *i.e.*, that the product is a "natural" food because it contains no artificial ingredients and is minimally processed. *Id.* Additionally, the FSIS may approve or deny the use of a "natural" claim based on the specific context in which

¹⁵ See FSIS Standards and Labeling Policy Memo #055.

the claim is made. For example, a product may not claim to be “natural” if it contains beet powder that artificially colors the product, however, this food may instead claim to contain “all natural ingredients.” *Id.*

CONTROVERSIAL “NATURAL” CLAIMS

This section will discuss the practical application of the USDA’s definition of the term natural and how this definition has been challenged and contended with in the food industry. Specifically, the controversial subjects of injected chickens and the “natural” status of high fructose corn syrup will be explored. This section will serve to demonstrate the complexity of defining the word natural by divulging specific examples of the challenges associated with regulating its use.

A. Crying Fowl over “Natural” Chickens

Increasing consumer demand for healthy food options is an undeniable fact, and is a trend that savvy businesses aim to cater to and capitalize on. This is evident not only in the exponentially increasing number of new food products popping up on store shelves, but also in the way these foods are marketed and labeled. One segment of the food industry where a product’s freshness and wholesomeness is particularly important is the meat industry.

As previously mentioned, the USDA defines “natural” as being minimally processed with no chemical preservatives, no artificial flavorings, and no artificial coloring. This definition, perhaps intentionally so, is a broad one that is often dictated by marketing, often times resulting in customer confusion and skepticism. As a result, the meat industry may be doing itself an injustice because it stands to reason that more consumers would purchase, and more retailers would carry, “natural” lines of meat products if consumer confidence was well established.

That being said, consumer demand for “natural” meat is on the rise, even while the consumer may not have a firm grasp on what that terminology realistically implies. The 2007 Power of Meat study, conducted by the American Meat Institute and the Food Marketing Institute indicated that more than one in five shoppers buy “natural” or “organic” meat.¹⁶ Of those shoppers with a preference for “natural” protein, 73% purchased “natural” chicken, while 50% bought “natural” beef. *Id.* In addition, FreshLook Marketing, an Illinois-based firm, indicates that the natural/organic segment of the meat industry is growing at a faster rate than overall sales of beef, chicken, and pork, with “natural” proteins accounting for the majority of unit volume and sales dollars. *Id.*

With so many consumers showing interest in “natural” proteins, particularly chicken, unscrupulous poultry producers have set out to capitalize on this desire by injecting their “natural” or “enhanced” chickens with up to 15% of a solution of such ingredients as salt, broth, and seaweed extract.¹⁷ Not only does this appear to be a relatively unethical means of increasing profit by charging the consumer for saltwater rather than protein, but adding insult to injury is the fact that these products are much less healthy than the “natural” varieties they purport to be due to the additional salt content.

The USDA has, in fact, addressed this issue by way of approving labels for these injected chickens, specifically for Tyson Foods and Pilgrim’s Pride, the world’s largest

¹⁶ Meg Major, “No Uncertain Terms,” *Progressive Grocer*, July, 2007.

¹⁷ Cindy Skrzycki, “Crying Foul in Debate over ‘Natural’ Chicken,” *The Washington Post*, November 6, 2007, Financial Section: D02.

poultry processor.¹⁸ FSIS supports the USDA's action by stating that these chickens are considered minimally processed because a chef can duplicate similar marinades at home with a fork and plastic bag. *Id.*

The USDA began dealing with additives in "natural" meats after Hormel Foods petitioned them claiming that its competitors were labeling their deli meats as "natural," even though they contained chemical preservatives. Further petitions have been issued more recently on behalf of Foster Farms, Sanderson, and Gold'n Plump, who started the Truthful Labeling Coalition. *Id.* The Center for Science in the Public Interest's (CSPI) Executive Director Michael Jacobson has also weighed in on the issue by urging the USDA to "put an end to this deceptive labeling practice and allow consumers to make informed, healthful decisions."¹⁹

B. The Sweet Science: The High Fructose Corn Syrup Debate

Capitalizing on, and potentially exploiting, consumer demand for healthy food options to select from is not a tactic that is exclusive to the meat industry. This practice is apparent in literally every section of the supermarket by the proliferation of "natural" and "organic" foods, as well as their shrewdly marketed and labeled counterparts. It is also clear from the previous section that even with the USDA's formal stance on the issue of the use of the term natural, let alone in the absence of one as is the case with those products under the FDA's jurisdiction, there is an abundance of room for interpretation and controversy.

The consumer quest for "natural" foods and beverages is at an all-time peak and

¹⁸ Skrzycki.

¹⁹ Center for Science in the Public Interest, *Pumped-Up Poultry Not 'Natural,'* <http://www.cspinet.org> (May, 2007).

continues to burgeon. “Natural” and “organic” foods and beverages soared to sales of over \$30 billion in 2007, up from \$26.2 billion in 2006, and \$22.9 billion in 2005.²⁰ According to the Mintel Global New Products Database, “All Natural” was the second most frequent claim, after “Kosher”, for new foods and beverages launched in the U.S. in 2007, appearing on 2,617 products.²¹ In addition, “All Natural” was the fourth most frequently used claim for beverages, appearing on 542 products. *Id.*

The term natural is clearly attractive and enticing to consumers, however, without a formal definition from the FDA, the food and beverage industry is rather free to engage in deceptive behavior regarding its usage. One seemingly grey area that has been ripe for debate and riddled with concerns of subjective interpretation is the practice of labeling foods and beverages as “natural” when they contain the ingredient high fructose corn syrup.

High fructose corn syrup (HFCS) is an ingredient, used primarily to sweeten beverages, which is derived from corn. The debate over whether HFCS can be considered “natural” is based on the processing methods utilized in its production, which consists of a high dextrose equivalent corn starch hydrolysate undergoing a partial enzymatic conversion of glucose (dextrose) to fructose by way of an insoluble glucose isomerase enzyme preparation. The Corn Refiners Association has long maintained the HFCS is a “natural” ingredient, primarily due to the fact that it is derived from corn.²² The Sugar Association and CSPI, however, emphatically oppose this viewpoint due to the fact that chemical bonds are broken and rearranged during the

²⁰ Susan Salisbury, “It’s Only Natural-Or Is It?” *Tribune Business News*, June 14, 2008.

²¹ Lorraine Heller, *HFCS is not ‘Natural’ says FDA*, <http://www.nutraingredients-usa.com> (April 2, 2008)

manufacture of HFCS. *Id.*

Initially, Geraldine June, Supervisor of the Product Evaluation and Labeling team at FDA's Office of Nutrition, Labeling, and Dietary Supplements had this to say on behalf of the FDA in April, 2008:

“The use of synthetic fixing agents in the enzyme preparation, which is then used to produce HFCS, would not be consistent with our policy regarding the use of the term ‘natural’. Moreover, the corn starch hydrolysate, which is the substrate used in the production of HFCS, may be obtained through the use of safe and suitable acids or enzymes. Depending on the type of acid(s) used to obtain the corn starch hydrolysate, this substrate itself may not fit within the description of ‘natural’ and therefore, HFCS produced from such corn starch hydrolysate would not qualify for a ‘natural’ labeling term.” *Id.*

Although the FDA issued what seemed like a formal decision on this issue, a mere two months later the agency amended their stance in what appeared to be a reversal of their original statement, much to the dismay of the Sugar Association and CSPI. With Geraldine June again acting as the voice of the FDA, the following statement was issued in July, 2008:

“When HFCS is made using the process presented by Archer Daniels Midland (ADM) Company, it can be considered ‘natural.’ This process sees the enzymes for making HFCS being fixed to a column by the use of a synthetic fixing agent called glutaraldehyde. However, this agent does not come into contact with the high dextrose equivalent corn starch hydrolysate and so it is not considered to be included or added to the HFCS. We would, however, object to the use of the term ‘natural’ on a product containing HFCS that has a synthetic substance such as a synthetic fixing agent included in or added to it. We would also object to the use of the term ‘natural’ on any product containing HFCS if the acids used to obtain the starch hydrolysate do not fit within our policy on ‘natural’.”²³

It is clear from the seemingly divergent aforementioned statements that the

²² Heller, (April, 2008).

debate over the use of the term natural is not easily settled and will perhaps continue for some time. It is also apparent that while this debate is vast in scope, there are an infinite number of subtle nuances that must be taken into consideration as well.

THE NEED FOR AN FDA DEFINITION

Having explored some “healthy” terminology and examined two hot button issues surrounding the use of the term natural, this section will provide an overview of cases brought against industry powerhouses based upon their use of the characterization. In addition, industry petitions requesting FDA’s intervention in this matter will be highlighted. Finally, consumer data and statistics surrounding the desire for FDA clarification of the term natural will be underscored.

A. “Natural” Claims Catalyze Cases and Petitions

Consumers are not the only faction that appears to find difficulty in discerning what the term natural means and how it should be applied, as cases and petitions emerge in the food industry itself, demonstrating confusion and frustration. One of the first complaints lodged was on behalf of CSPI, requesting that the FDA take action against Ben & Jerry’s for the use of the phrase “All Natural.” CSPI claimed that Ben & Jerry’s products contained “artificial flavorings” and other man-made ingredients such as partially hydrogenated soybean oil, alkalized cocoa powder, corn syrup, and corn

²³ Laura Crowley, *HFCS is Natural, says FDA*, <http://www.foodnavigator-usa.com> (July, 2008).

syrup solids.²⁴ Although the FDA has no official stance on the use of the term natural, Ben & Jerry's "All Natural" claim was barred due to the FDA's policy of not allowing the term natural to be used unless "nothing artificial or synthetic has been included in, or has been added to, a food that would normally not be expected to be in the food."²⁵

CSPI made waves once again by threatening to sue Cadbury Schweppes, manufacturer of 7-Up soda, for deceptive advertising. Cadbury Schweppes came under attack after reformulating its 7-Up beverage to contain what it termed "100% natural" ingredients: filtered water, high fructose corn syrup, natural citric acid, natural flavors, and natural potassium citrate.²⁶ As previously discussed, HFCS is an extremely controversial ingredient where the use of the term natural is concerned, as was the case in this scenario. CSPI ultimately dropped its planned lawsuit, however, upon the decision of Cadbury Schweppes to change the labeling of 7-Up.

In a similar case, with a similar result, CSPI threatened to sue Kraft over the mislabeling of their Capri Sun juice product, which is labeled as "All Natural" even though it contains high fructose corn syrup.²⁷ Despite the fact that Kraft had been labeling this product in the same fashion for over 25 years, the company decided to avoid the impending legal battle by altering its labels to read "no artificial colors, flavors,

²⁴ Letter from Michael F. Jacobson, Executive Director, Center for Science in the Public Interest, to Christine Lewis Taylor, Director of Office of Nutritional Products, Labeling and Dietary Supplements HFS-800, Food and Drug Administration, (July 30, 2002).

²⁵ See 58 Fed. Reg. 2302, 2407.

²⁶ Lorraine Heller, *7-Up Changes Label to Avoid Misleading 'Natural' Claims*, <http://www.nutraingredients-usa.com> (January 15, 2007).

²⁷ Julie Jargon, "Is Kraft Crossing the Line?", *Crain's Chicago Business*, February 5, 2007, News Section: pg 1.

or preservatives.”²⁸

Finally, in addition to formalized legal action, there have been two noteworthy petitions filed asking the FDA to define natural; one on behalf of Sara Lee Corporation and the other on behalf of the Sugar Association.²⁹ These petitions request that the FDA formalize a definition for natural, or specifically, that the agency adopts the USDA definition used for meat and poultry products. *Id.*

B. The Confused Consumer

As previously discussed, the propagation of “healthy” terminology on food labeling, particularly the use of the term natural, has been exponentially multiplying. Consumer consciousness, often accompanied by confusion, of food labeling appears to be increasing as well. A recent Nielsen study showed that 65% of US consumers pay attention to nutritional information on food packaging more often than they did two years ago.³⁰ Another study, conducted by Consumer Reports National Research Center, revealed that consumers expect more from foods labeled “natural” than they do from other foods.³¹ In fact, 86% indicated that they expect the “natural” label to mean that the food contains no artificial ingredients. *Id.*

Consumer expectations coupled with a “natural” foods industry that is estimated to reach \$129 billion in sales in the year 2008 make the “natural” segment of the food

²⁸ Heller, (January 15, 2007).

²⁹ Salisbury, June 14, 2008.

³⁰ Sarah Hills, *Nutrition Labels Seen as a Marketing Tool*, <http://www.foodnavigator-usa.com> (August 5, 2008).

³¹ Consumer Reports, *Food Labeling Poll shows Consumers Expect Higher Label Standards*, <http://www.greenerchoices.org> (July, 2007).

industry a lucrative one, and one that is ripe with the potential for exploitation.³² Consumers are becoming increasingly skeptical of the use of the term natural as well, with 83% of US consumers expressing the desire for the FDA to put forth regulations governing “natural” claims.³³

The Association of Food & Drug Officials (AFDO) has weighed in on the need for FDA involvements as well by stating their concerns and stipulations for the use of the term natural, and has also advised several issues that the FDA should take into consideration when developing a definition.³⁴ One of the central concerns expressed by ADFO is that consumers may interpret foods labeled as “natural” to be safer or healthier for consumption. *Id.*

Unfortunately, the FDA has no plans in the foreseeable future to establish a definition for the term natural due to limited resources and conflicting priorities, such as reviewing health claims, nutrient claims, allergen declarations, and irradiation labeling.³⁵ Furthermore, according to Geraldine June of the FDA’s Labeling and Standards Department, the Agency is “not sure how high of an issue it is for consumers.” *Id.* Despite the fact that June recognizes the fact that a growing array of products carry the “natural” claim, she asserts that “even if people interpret it in different ways, it doesn’t mean there is confusion out there. If there was, then we would definitely raise it

³² Anonymous, *Manufacturers and Consumers Lose Faith in Natural Label Claims*, <http://www.foodnavigator-usa.com> (September 11, 2008).

³³ Barry Estabrook, *Politics of the Plate: “Natural Lies,”* <http://www.gourmet.com> (August 19, 2008).

³⁴ USDA FSIS, *Comments from ADFO on Product Labeling-Definition of the term “Natural,”* Docket No. FSIS 2006-0040, January 9, 2007.

³⁵ Lorraine Heller, *Natural Will Remain Undefined, says FDA*, <http://www.foodnavigator-usa.com> (January 4, 2008)

as a priority.” *Id.*

CONCLUSION

This paper began by asking a question that has no decisive answer, namely, how does the FDA define the term natural when applied to food products? Initially the FDA’s lack of a formal characterization for “natural” and its uses may seem like a quick fix, and it is clearly a challenge the FDA must tackle, but the complexity surrounding this issue is evident upon closer examination.

Having explored the terminology most often mistakenly viewed as synonymous with “natural,” having examined various controversial “natural” claims, and having delved into court cases, petitions, and consumer data pertaining to the use of the term natural, now would be an ideal time to propose a definition that the FDA could adopt. Unfortunately, this task that the FDA has cited as being outside the realm of its priorities and too labor intensive, is also far too substantial in scope for me to provide a remedy for. Accordingly, until the FDA defines and regulates the term natural, one simple suggestion to perplexed consumers will have to suffice; as one notices, and perhaps is confused by, the explosion of food and beverage labels claiming to be “natural,” it’s wise to interpret these claims with a grain of salt, or in this case, a grain of natural sea salt may be more appropriate.