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FSIS and FDA Policy on the Definition of “Natural” and the Qualification for Use on Food and Meat/Poultry Labeling

What does it mean to be “organic” or “natural”? The answer is different depending on whom you ask. Perhaps because many people have their own ideas about what the terms “organic” and “natural” should mean, the regulatory conditions for the terms have been difficult to pin down precisely. Nevertheless, as public health awareness has increased and consumers demand healthier foods and the terms “organic” and “natural” have gained traction and appeal with the public, the demand for greater clarity in this area has increased.

The United States Department of Agriculture’s Food Safety and Inspection Service (“FSIS”) held a public meeting on December 12, 2006 in anticipation of rulemaking “to discuss the voluntary claim ‘natural’ and to delineate the conditions under which the claim can be used on the labels of meat and poultry products.”¹ The comment period for this meeting has been extended to March 5, 2007.² This proceeding was initiated in part in response to a petition filed by the Hormel Foods Corporation. The Food and Drug Administration (“FDA”) has also received a petition from the Sugar Association to codify the conditions under which a “natural” claim can be used.³

Market Trend—Movement of Food and Meat/Poultry Industry to Natural and Organic Labeling to Meet Consumer Demands

Consumer interest has steadily driven the expansion of the natural and organic markets. According to the National Marketing Institute, 63% of consumers in 2004 reportedly preferred natural foods and beverages.⁴ Food sales in natural product stores reached a reported \$11.4 billion in 2003.⁵ The U.S. organic food industry grew 16.2% to reach \$13.8 billion (2.5% of total U.S. food sales) in consumer sales in 2005.⁶ According to Iowa State University Agricultural Marketing Resource Center, “The combination natural/organic food category has grown significantly since 1990, increasing four-fold in the decade after and averaging 14% annual growth (compared to the historic growth rate of 4% in the overall food industry).”⁷

1 71 Fed. Reg. 70,503 (December 5, 2006).

2 72 Fed. Reg. 2257 (January 18, 2007).

3 See Letter from Sugar Association to FDA, dated February 28, 2006 (Docket No. 2006P-0094), available at http://www.cspinet.org/new/pdf/sugar_fda_petition.pdf. FDA has responded with a letter stating that it has not been able to reach a decision within 180 days. See FDA letter to the Sugar Association, dated August 22, 2006, available at <http://www.fda.gov/ohrms/dockets/dockets/06p0094/06p-0094-let0001-vol2.pdf>.

4 E. A. Sloan, “Gourmet & Specialty Food Trends,” *Food Technology* 58 no. 7 (2004): 26-38.

5 *Id.* at 9.

6 OTA’s 2006 Manufacturer Survey, U.S. Organic Industry Overview, available at <http://www.ota.com/pics/documents/short%20overview%20MMS.pdf> (last visited December 7, 2006). By way of comparison, in 1997, the organic food industry comprised \$3.6 billion in consumer sales, or 0.8% of total U.S. food sales.

7 J. Norwood, “Natural Products,” Agricultural Marketing Resource Center, Iowa State University, January 2004, available at <http://www.agmrc.org/NR/rdonlyres/61DAD87B-9BE8-41C0-8161-0391DD070917/0/naturalfoodsnorwood.pdf> (last visited December 8, 2006).

As this indicates, the organic and natural food producers positioned themselves in a significant and growing niche in the overall food market. Before investing in processing facilities and product development, these companies relied on certain FDA and USDA/FSIS interpretations and policy determinations of when and how the claims should be used based on regulations and guidances, interpretations and policy determinations that have, at least in the use of “natural,” become increasingly confusing and unpredictable.

Lack of Clarity Creates Confusion

This in turn has led to growing tension between government agencies that are mandated to protect the public from false and misleading claims and an industry that believes it has relied in good faith on established regulations and guidances in providing the consumer with a quality product with appropriate and accurate “natural” claims.

The primary issue has been how to clarify the regulatory definition in a way that makes sense to the public (both the consumer and the industry). Further, the government needs a clear definition such that agency staff can consistently determine whether a “natural” claim is accurate. An ill-defined term loses relevance to the consumer and accuracy of claim is difficult to ascertain for terms with amorphous boundaries. For companies that have invested millions of dollars in processing facilities and product development, ambiguously defined terms and conditions of use, and resulting inconsistent application of enforcement, have proven extremely costly. Various segments of the industry have requested clarity on the terms, and the agencies are beginning to respond.

Organic

Prior to 2002 and the implementation of USDA National Organic Standards, the definition of and standards for “organic” varied widely. Organic certification was voluntary in most states, and the requirements for organic production and handling were different from certifying agency to agency. In 2002, USDA set forth the organic standards that must apply to all agricultural commodities or products, whether raw or processed, including any commodities or products derived from livestock. As of October 21, 2002, these products must be in compliance with the national organic standards in order to be labeled “organic.”

USDA organic standards, as mandated by the Organic Foods Production Act of 1990, were developed and are administered by USDA’s National Organic Program. The regulations limit the use of “organic” on products for sale in the U.S. to ingredients and production methods that have been verified by a USDA-accredited certification agency as meeting USDA standards for organic production. The organic standards offer a uniform national definition for the term “organic,” and they detail the methods, processes, practices, and substances that can be used in producing and handling organic crops and livestock, as well as processed products. The organic standards also establish clear organic labeling criteria.

Therefore, the “organic” definition has been clarified in a manner which seems to work sufficiently well from both a consumer and industry standpoint.

Natural

The term “natural,” however, is an entirely different matter. Various agencies have attempted to clearly define “natural” over the past 20 years. In the mid-1970s, the Federal Trade Commission (“FTC”) proposed to define “natural” foods as “those with no artificial ingredients and only minimal processing.”⁸ FTC abandoned this effort in 1983,⁹ noting that it would still scrutinize “natural” claims on a case-by-case basis.

FDA attempted to define the term “natural” in 1989.¹⁰ Citing resource limitations and other priorities, FDA formally abandoned this effort in 1993.¹¹ In the same Federal Register notice, however, FDA stated that it would “maintain its policy regarding the use of ‘natural’ as meaning 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 in food.” Despite not having a formal regulatory definition of “natural,” FDA still refers to its general guidelines put forth in the

8 39 Fed. Reg. 39,842 (November 11, 1974); 40 Fed. Reg. 23,686 (May 28, 1975); 41 Fed. Reg. 8980 (March 2, 1976).

9 48 Fed. Reg. 23,270, 23,271 (May 24, 1983).

10 54 Fed. Reg. 32,610 (August 8, 1989). While FDA does not have a premarket label review program, FDA still maintains a policy with respect to “natural” labeling, and it enforces this policy by taking action against misbranded and mislabeled products, including those products that make false or misleading statements on their labels.

11 58 Fed. Reg. 2302 (January 6, 1993).

1993 Federal Register notice.¹² FDA's only codified definition of "natural" is in the FDA natural flavor regulation. This definition focuses on the source and the processing method of natural flavors.

FSIS defines the term more broadly in a guidance document. To coincide with FTC's efforts, FSIS issued a natural policy on November 22, 1982 in the form of a Policy Memo ("FSIS Policy Memo 55"). This Policy Memo forms the basis for FSIS's policy on "natural" and guides FSIS's interpretative decision making with respect to label reviews. In May 2003, FSIS also outlined its definition of "natural" and the conditions for its use in the Food Standards and Labeling Policy Book ("Policy Book") that officially cancelled FSIS Policy Memo 55. The 2003 "natural" definition required that: 1) the product 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 be not more than minimally processed. Minimal processing included: a) traditional processes used to make food edible or to preserve it or make it safe for human consumption, e.g., smoking, roasting, freezing, drying, and fermenting; or b) 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. Relatively severe processes, e.g., solvent extraction, acid hydrolysis, and chemical bleaching, would be considered more than minimal processing.

Like FDA's natural flavor regulation, the FSIS guidance definition focuses on the source and processing method, but the factors and conditions, e.g., "minimally processed," have eluded precise definition. Further complicating things, FSIS does not appear to consistently follow its own guidance. For example, although not stated in any written policy,

12 See FDA Warning Letter to Oak Tree Farm Dairy, Inc. (dated August 16, 2001), available at www.fda.gov/foi/warning_letters/g1644d.htm ("The term 'all natural' on the 'OAKTREE ALL NATURAL LEMONADE' label is inappropriate because the product contains potassium sorbate. Although FDA has not established a regulatory definition for 'natural,' we discussed its use in the preamble to the food labeling final regulations (58 Fed. Reg. 2407, January 6, 1993). FDA's policy regarding the use of 'natural,' means nothing artificial or synthetic has been included in, or has been added to, a food that would not normally be expected to be in the food.").

FSIS maintains that multi-function ingredients that have an antimicrobial effect defeat an end-product's natural status.

The 2003 definition of "natural" was amended by a note in the August 2005 revision of the Policy Book that indicated that "sugar, sodium lactate (from a corn source), and natural flavorings from oleoresins or extractives are acceptable for 'all natural' claims." In its announcement for the December 12, 2006 meeting, under pressure from several members of the industry that cited FSIS inconsistency in granting sodium lactate from corn sources a free ticket, FSIS removed the reference to sodium lactate in the Policy Book pending finalization of rulemaking. Coincident with this change, FSIS has issued letters to meat and poultry processors using the ingredient to provide new justification for any "natural" claims.

Today's Regulatory Landscape

USDA/FSIS maintains a premarket approval system for labels. Each label is evaluated against FSIS policy. With respect to natural claims, given the undefined boundaries of the term, FSIS must make a case-by-case determination of what ingredients, processes, and uses qualify for the claim being used. FSIS officials have at times indicated that they do not consider the case-by-case determinations "policy." These decisions are generally made without any written explanation for the conclusion. Perhaps predictably under these circumstances, label approvals in this area are inconsistent.

Without adequate transparency, consistency, or accountability, companies have frequently been unable to develop products or invest in processing methods. Further, companies must function in a regulatory environment that arbitrarily has favored some ingredients and processing methods over others. This is the regulatory landscape within which companies function today.

Rulemaking is a long, time-consuming, and complicated process. Even if a rulemaking on this topic eventually leads to a more clearly codified definition of natural, companies will still face FSIS's pre-market label approval system with day-to-day interpretative rulemaking.

Current and Future Strategies

Interested parties, especially those in the meat and poultry industries, need to develop strategies on the “natural” issue for the long, intermediate, and short terms.

In the long term, the focus for USDA-regulated companies should be on the comment process, which has been extended to March 5, 2007. It bears emphasis that this rulemaking is at a preliminary stage and that, if it leads to a specific regulatory proposal, an additional round of public comment will occur. The current process, therefore, enables interested parties to effectively get in on the ground floor of the formation of a policy which may (or may not) undergo significant change.

In the intermediate term, it is important to recognize that rulemaking is frequently an uncertain and always a time-consuming exercise. Given the reality that

no new formal policy change will emerge for many months, if not years (if at all), it is critical for FSIS to establish a workable interim policy. Efforts toward this end have been complicated by some of the procedural and substantive inconsistencies noted in this document. One major focus, as reflected in FSIS’s issuance of letters to various ingredient users, is the continued “natural” status of products using such ingredients. In addition to technical responses, various legal and procedural arguments can be offered in favor of preservation of the status quo during an ongoing rulemaking process.

In the short term, processors, with the support of the ingredient suppliers, have products to market and labels to be approved. All such parties have a right to insist upon the highest possible level of consistency, accountability, and transparency in the label review and approval process.

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