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*BY ELECTRONIC SUBMISSION*

FSIS Docket Room  
FSIS Docket Clerk  
U.S. Department of Agriculture  
Food Safety and Inspection Service  
12<sup>th</sup> Street, S.W., Room 102 Cotton Annex  
Washington, D.C. 20250

**RE: Docket No. FSIS 2006-0040**  
**Product Labeling: Definition of the Term “Natural”**  
**71 Fed. Reg. 70503 (Dec. 5, 2006)**

Dear Sir or Madam:

The American Frozen Food Institute (AFFI) appreciates this opportunity to offer comments concerning regulation of the term “natural.” AFFI is the national trade association representing frozen food manufacturers and their marketers and suppliers. AFFI’s nearly 500 members are responsible for approximately 90 percent of the frozen food processed annually in the United States, valued at more than \$60 billion. AFFI members are located throughout the country and are engaged in the manufacture, processing, transportation, distribution, and sale of products, both nationally and internationally. AFFI members have a substantial interest in the manner in which the term “natural” is regulated on food labels.

### **Summary**

AFFI respectfully disagrees with the Food Safety and Inspection Service’s (FSIS) recent decision to engage in rulemaking on “natural” claims. In addition to a number of procedural concerns with the agency’s actions, substantively, AFFI does not believe a codified regulatory definition is the best approach to govern use of the word “natural.” We believe this is a word whose meaning is context dependent. As such, we urge the agency to maintain its previous approach to “natural claims.” This approach is enshrined in the Food Standards and Labeling Policy Book in which a set of general principles guides both industry and regulators and allows for case-by-case label review so that the context of the claim may be considered.

In addition, AFFI believes that any reconsideration of the agency's "natural claims" policy should be consistent with the agency's food safety mission. As such, any new "natural" policy should permit the use of non-synthetic ingredients that exhibit anti-microbial properties. AFFI's specific recommendations follow.

### **Procedural Concerns with Recent FSIS Actions**

On December 5, 2006, the Food Safety and Inspection Service (FSIS) announced receipt of a petition, filed on behalf of Hormel Foods Corporation (Hormel or the Petitioner), requesting the agency initiate rulemaking to codify a definition of "natural" and take certain interim actions. <sup>1/</sup> Concurrently, the agency revised its longstanding "natural claims" policy, expressed in the Food Standards and Labeling Policy Book, and announced its intention to initiate rulemaking on the subject. AFFI believes the agency's actions in response to the Petition create substantial procedural concerns.

In revising the "natural claims" policy, FSIS removed the reference to sodium lactate derived from corn, as well as the reference to ingredients on the National Organic Program's National List, as allowable ingredients in "natural" meat and poultry products. As these two changes were expressly requested in the Petition, FSIS in effect has indicated that the agency agrees with the Petitioner's contention that use of natural preservatives conflicts with a "natural" claim. These decisions were made by agency officials even before the Notice announcing the public meeting was published. Moreover, FSIS appears to accept the Petitioner's position despite the agency's longstanding policy and prior label approvals to the contrary. FSIS stated in the Notice announcing receipt of the petition and the decision to engage in rulemaking, "[t]he value and integrity of the 1982 policy is challenged further by new uses of ingredients that have previously been used for flavoring purposes, for example, as antimicrobial agents." <sup>2/</sup>

The agency's actions raise a number of concerns. The agency's decision to change the "natural claims" policy, yet at the same time engage in rulemaking on the term "natural" creates great uncertainty in the food industry. As a practical matter, AFFI members are in a technological predicament: they do not know which technologies to invest in because the direction of the "natural" policy is unclear. Capital investment and product development decisions are in doubt as use of the word "natural" could be further altered in the future. As a more general matter, the decision to codify one entry in the Food Standards and Labeling Policy Book into a regulation creates confusion over the continued existence of other such policies. More specifically, AFFI is concerned that FSIS has apparently sent out numerous letters to firms advising them that label approvals may be revoked due to the recent shifts in FSIS policy.

Consistency and predictability are important components of any federal policy. In an area of food regulation in which technology is evolving, consumer interest is increasing, and where policy choices can have significant food safety implications, these elements are even more important. Thus, if FSIS intends to fundamentally change the method by which it conveys its labeling policies, it should do so in an orderly fashion. Revising a longstanding policy and simultaneously engaging in rulemaking does not give the impression of rational decision making.

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<sup>1/</sup> Product Labeling: Definition of the Term "Natural." 71 Fed. Reg. 70503 (Dec. 5, 2006).  
<sup>2/</sup> 71 Fed. Reg. at 704504.

AFFI is also troubled by the agency’s decision, unilaterally, to conclude that rulemaking is appropriate, without first soliciting input from other stakeholders. The hallmark of transparent federal policy development and implementation is the ability of the public to have confidence that federal agency policies are fair and have a rational basis. Yet, in this instance, FSIS’s decision to commit to rulemaking and substantially revise its longstanding “natural claims” policy with reliance on little more than a single petition will lead stakeholders to question the opportunity to provide meaningful input.

Finally, AFFI is concerned by the Petitioner’s urging of FSIS to enact a new “natural” policy in advance of action from the Food and Drug Administration (FDA). <sup>3/</sup> AFFI believes the two agencies should work together with stakeholders to fashion any new “natural” policy. The sheer diversity of products regulated by the two agencies reinforces the need for an open, transparent process that ensures a flexible context-specific approach. Many of AFFI member products contain both USDA and FDA regulated ingredients. Moreover, consumers do not recognize the division in jurisdiction between the two agencies. As such, unilateral action will only add unnecessary complexity and will confuse industry, consumers, and regulators alike. Instead, any policy guiding the use of “natural” should be consistent across the agencies. <sup>4/</sup>

### **A Codified Regulation Defining “Natural” is Not the Best Approach**

AFFI disagrees with the agency’s decision to initiate rulemaking to define “natural” by regulation. “Natural” is a context dependent term that necessitates regulation by policy, rather than by a rigid and codified rule. We find the history of previous attempts to define “natural” to be instructive. In repeated attempts to define the term, FSIS, FDA, and the Federal Trade Commission (FTC) have each concluded that a case-by-case claim evaluation is the best approach. Moreover, we do not believe a static regulation will be able to adequately capture the varied meanings of “natural,” nor will it be able to accommodate technological innovation in the years to come. Accordingly, AFFI believes the best approach for regulating use of the term “natural” is to maintain a policy that the agency can apply on a case-by-case basis through the prior review label approval process. A uniform, one-size-fits-all approach is appealing, but the varied uses and meanings of “natural” across a broad spectrum of product categories renders the establishment of a static, rational regulation defining “natural” unachievable.

#### “Natural” is a Context Dependent Term

In the December 5, 2006 Notice, FSIS asked about consumer perception regarding the meaning of the term “natural.” <sup>5/</sup> AFFI does not believe the meaning of the term “natural” can be determined absent the context of the claim. Moreover, the proliferation of the claim in the marketplace and the variety of products bearing the term illustrate that it would be exceedingly difficult to develop and test consumer understanding of all the different ways the word is used.

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<sup>3/</sup> Petition at 12.

<sup>4/</sup> To that end, AFFI believes that the minimal processing requirement should be removed from the FSIS “natural claims” policy. This will achieve consistency with FDA and ensure product innovation in the food industry.

<sup>5/</sup> 71 Fed. Reg. at 70505.

Because context determines the meaning of “natural,” a single regulatory definition for the term would either conflict with consumer understanding, or be so complex so as to be unworkable.

The range of products bearing the term “natural” in the marketplace is evidence of its context dependent meaning. For example, consumers do not expect the same thing from a “natural” frozen pizza as they do from “natural” bread, or “natural” yogurt. The broad range in meaning for “natural” is also evident upon examination of a dictionary. “Natural” has been defined to mean several things, including “[p]resent in or produced by nature,” “[n]ot altered, treated, or disguised,” “[f]aithfully representing life or nature,” and “[b]eing in a primitive or unregenerate state.” <sup>6/</sup> Dictionaries reflect common understanding and usage of terms. Accordingly, the number of definitions for the term “natural” demonstrates that consumers use the word in a variety of ways and that its meaning is, therefore, context specific.

Not surprisingly, the agency’s longstanding “natural claims” policy recognizes the importance of evaluating the context in which “natural” appears on a product label. The entry in the Foods Standards and Labeling Policy Book states that “[t]he decision to approve or deny the use of a natural claim may be affected by the specific context in which the claim is made.” <sup>7/</sup> The agency goes on to distinguish a “natural” claim from an “all natural ingredients” claim. Via this distinction, the agency recognizes that context is critical to the evaluation of a “natural” claim. Moreover, the agency has long “granted [exceptions to the minimal processing requirement] on a case-by-case basis if it could be demonstrated that the use of such an ingredient would not significantly change the character of the product to the point where it can no longer be considered a ‘natural’ product.” <sup>8/</sup> Hence, the agency appropriately considers the context in which the word “natural” is used and whether it is suitable for the product in question.

### Prior Attempts at Rulemaking Have Failed

In AFFI’s view, FSIS should continue to recognize the context dependent meaning of “natural,” which is best accomplished by maintaining its current approach, not by trying to establish a single regulatory definition by regulation. Over the past several decades, FSIS, the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) have examined use of the term “natural” to describe food. The agencies have repeatedly attempted to define “natural” in a codified regulation and have failed to do so. It is not apparent, given the context dependent nature of the term, that FSIS will this time be able to reach a different result. <sup>9/</sup>

The statement issued by Chairman James C. Miller, III in the FTC’s notice terminating rulemaking to define “natural” is telling. As he stated, “a fundamental problem exists by virtue of the fact that the context in which ‘natural’ is used determines its meaning.” <sup>10/</sup> He further explained, “[i]t is unlikely that consumers expect the same thing from a natural apple as they do

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<sup>6/</sup> Webster’s II New College Dictionary 729 (2001)

<sup>7/</sup> United States Department of Agriculture, Food Standards and Labeling Policy Book, “Natural Claims” (Revised late November 2006).

<sup>8/</sup> 71 Fed. Reg. at 70504.

<sup>9/</sup> In addition, given the regulatory history of previous unsuccessful attempts to define “natural,” AFFI urges the agency to direct its resources to more critical matters – matters that must be addressed through notice and comment rulemaking.

<sup>10/</sup> Termination of Proposed Trade Regulation; Rule on Food Advertising, 48 Fed. Reg. 23270, 23270 (May 24, 1983) (statement of Commission Chairman James C. Miller, III).

from natural ice cream. The proposed rule assumes, without any evidence, that natural means the same thing in every context.” [11/](#)

Over the past several decades, USDA has regulated the use of “natural” claims through the prior approval label review program. [12/](#) In 1982, FSIS outlined the “natural claims” policy in Policy Memorandum 055. FSIS has, over the years, modified this guidance document “on occasion to make it consistent with prevailing policies, to reflect case-by-case decisions made by the agency and to update references to regulations.” [13/](#) The agency has applied the policy on case-by-case basis for decades, rather than adopt a formal regulation, thereby enabling it to properly consider the context of each claim.

### Consumer Interests Not Served by a Static Regulation

Given previous unsuccessful attempts to define “natural” by regulation and the context dependent nature of the word, a single regulatory definition is not feasible. Moreover, a static regulatory definition will neither be able to account for the varied meanings of the word, nor be able to adjust to technological innovations in the food industry. Accordingly, AFFI believes the best approach to regulating use of the term “natural” is to maintain a policy for use of the word that the agency can apply on case-by-case basis through the prior review label approval process. This approach allows the agency to review the term in the context in which it appears on the product label.

Regulations are, by their very nature, difficult to change. The rulemaking process is inherently time consuming, even when technological innovations, dietary practice, or consumer perception warrant modification to a given rule. We believe the number of food standard petitions awaiting action at the Food Drug Administration is illustrative of the problems created by rigid regulatory definitions. Even when science supports revision, the agencies are unable to effect change in an efficient and meaningful way.

A regulatory definition for “natural” could have a detrimental impact on food safety because a static definition simply will not be able to take into account technological developments that can make products safer and better for consumers. In contrast to a static regulation, a “natural” policy based on a set of fundamental principles can provide the necessary consistency for the industry, consumers, and regulators, and yet can be updated outside of the notice and comment rulemaking process. As such, this is the approach to regulation of the term “natural” that AFFI urges FSIS to take.

### **“Natural” Should Comport with the Agency’s Food Safety Mission**

AFFI believes any reconsideration of FSIS’s approach to use of the term “natural” should be consistent with the agency’s food safety mission. As the agency stated in the Notice, “FSIS is the public health regulatory agency in the USDA responsible for ensuring that the nation’s commercial supply of meat, poultry and egg products is safe, wholesome, and truthfully labeled

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[11/](#)

*Id.*

[12/](#)

*See* Food Labeling, Tentative Positions of the Agencies, 44 Fed. Reg. 75990, 76012 (Dec. 21, 1979).

[13/](#)

71 Fed. Reg. at 70504.

and packaged.” <sup>14/</sup> Natural ingredients such as salt, vinegar, and spices have been used for hundreds of years to improve food safety. As such, there is no inherent conflict between the inclusion of ingredients that exhibit antimicrobial properties and a “natural” claim. Repositioning the definition of “natural” to exclude any ingredient that “serves to retard product deterioration” <sup>15/</sup> is contrary to public health policy. AFFI urges FSIS to return to the previous version of the “natural claims” policy and permit the use of natural preservation techniques like sodium lactate derived from corn.

FSIS’s “natural claims” policy has always provided that “natural” may be used if a 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.” <sup>16/</sup> AFFI believes the meaning of “chemical preservatives” is clear. It excludes the use of “chemical” preservatives from “natural” products, not all preservatives. Moreover, the phrase “or any other artificial or synthetic ingredient” in the policy reveals the targeted ingredients of exclusion. The purpose of the first prong of the “natural claims” policy is to prevent the inclusion of “artificial or synthetic ingredients” in “natural” products. Accordingly, “chemical preservatives” is to be understood as a kind of “artificial or synthetic” ingredient.

The use of natural preservatives in products positioned as “natural” is consistent with other elements of the “natural claims” policy. The second prong of the “natural claims” policy provides that the product and its ingredients must not be more than minimally processed. <sup>17/</sup> Included in the definition of minimal processing are “those traditional processes used to make food edible, to preserve it, or to make it safe for human consumption.” <sup>18/</sup> This ensures that “natural” foods are safe and that the term is not misleading to consumers. To that end, AFFI believes FSIS’s “natural claims” policy encompasses the use of non-synthetic ingredients that make food safer for consumers. To hold contrary would be in conflict with public health policy and the agency’s food safety mission.

For these reasons, AFFI is concerned by the agency’s recent repositioning with respect to use of sodium lactate derived from corn in “natural” products. FSIS previously determined that sodium lactate (from a corn source) is consistent with the “natural claims” policy. The agency specifically amended the policy in August 2005 to state that “sugar, sodium lactate from a corn source), and natural flavorings from oleoresins or extractives are acceptable for ‘all natural’ claims. <sup>19/</sup> In addition, the agency approved many product labels with “natural” claims and the ingredient sodium lactate. Now the agency apparently questions the allowance for sodium lactate because of its antimicrobial properties. <sup>20/</sup>

The agency’s apparent position that sodium lactate when used for flavoring purposes is consistent with a “natural” claim, but not when it is found to exhibit anti-microbial properties, is

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<sup>14/</sup> 71 Fed. Reg. at 70503.

<sup>15/</sup> Petition at 14.

<sup>16/</sup> Policy Memo 055 (Nov. 22, 1982); United States Department of Agriculture, Food Standards and Labeling Policy Book, “Natural Claims” (Revised late November 2006).

<sup>17/</sup> *Id.*

<sup>18/</sup> *Id.*

<sup>19/</sup> 71 Fed. Reg. at 70504.

<sup>20/</sup> *Id.* See also United States Department of Agriculture, Food Standards and Labeling Policy Book, “Natural Claims” (Revised late November 2006).

troubling. Dual purpose ingredients that otherwise comport with the “natural claims” policy and that make food safer for consumers should not be excluded from “natural” products. FSIS should continue to provide for their use so as to carry out its mission of providing “safe, wholesome, and truthfully labeled and packaged” products to consumers.

In sum, AFFI questions the agency’s assumption that preservatives from a naturally-derived source are incompatible with a “natural” claim. We urge FSIS to reconsider its tentative conclusions in light of its food safety mission.

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## **Conclusion**

AFFI believes the best approach for regulating use of the term “natural” is for FSIS to maintain a policy that can be applied on a case-by-case basis during the prior review label approval process. Static regulation will not be able to capture the context dependent meaning of “natural,” nor will it be able to accommodate technological innovations in the food industry. Above all, the agency’s approach to “natural” claims should be consistent with its food safety mission. In AFFI’s view, that should include the use of natural ingredients, even if those ingredients exhibit antimicrobial properties.

Respectfully submitted,

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