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January 31, 2007

Dockets Management Branch
Food and Drug Administration (FDA)
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, MD 20852

Re: Docket No. 2006P-0094; Requesting FDA undertake rulemaking to establish specific rules governing the definition of the term "natural" before a "natural" claim can be made on foods and beverages regulated by the FDA.

Dear Sir or Madam:

The Sugar Association (Association) submits these comments to its above-referenced petition. The Association petition requests that FDA maintain consistency across Federal agencies and define the term "natural" based on the definition provided in the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS), *Food Standards and Labeling Policy Book*. On December 5, 2006 the USDA FSIS published in the Federal Register "Labeling Guidance on the Voluntary Claim "Natural" in response to a Hormel Foods Company petition that asks USDA FSIS to address important inconsistencies in the FSIS *Food Standards and Labeling Policy Book* definition of "natural," specifically related to recent changes to Policy Memo 55.

The Association provided the attached comments to the USDA FSIS docket number 2006P-0040 and requests that these comments be posted as part of the record to it's the Association's petition docket number 2006P-0094.

The Association believes that the accountable regulatory agencies should maintain consistency and harmonize the definition of the term "natural" for all foods and beverages. Further, the Association respectfully requests that the FDA and USDA work cooperatively by undertaking rulemaking on this important consumer issue jointly. Agency collaboration on this issue is essential to eliminate consumer confusion.

Respectfully submitted,

Andrew C. Briscoe
President & CEO

2006 P-0094
Attachment

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THE SUGAR ASSOCIATION, INC.





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January 10, 2007

FSIS Docket Room, Docket Clerk
USDA FSIS
300 12th Street, SW
Room 102 Cotton Annex
Washington, DC 20250
Docket Number 2006-0040

Re: Labeling Guidance on the Voluntary Claim "Natural"

Dear Dr. Post:

The Sugar Association (Association) is pleased to provide comments in response to the USDA Food Safety and Inspection Service (FSIS) December 5, 2006 Federal Register Notice "Labeling Guidance on the Voluntary Claim "Natural." The Association applauds the FSIS decision to undertake rulemaking on this major consumer issue. The steady growth of consumer interest in natural and organic products requires detailed regulations to assure consumer confidence. Further, for those companies deciding to provide natural products for this growing number of consumers, a precise definition of the term "natural" would provide the very continuity such claims require and would help eliminate misleading competitive practices.

On February 28, 2006 the Association submitted a citizen petition to the Food and Drug Administration (FDA) requesting that FDA undertake rulemaking to establish specific rules governing the definition of the term "natural" before a "natural" claim can be made on foods and beverages regulated by the FDA. The Association petition docket number is 2006P-0094 and a copy is provided with these comments.

The Association's petition requests that FDA maintain consistency across Federal agencies and define the term "natural" based on the definition provided in the USDA *Food Standards and Labeling Policy Book*. The Association believes it is important for consumers to have a consistent definition accepted by all government agencies responsible for "natural" claims on foods and beverages. The Association requested that FDA adopt the USDA FSIS *Food Standards and Labeling Policy* definition because the present FSIS definition of "natural" is the most comprehensive for regulating "natural" claims made by food manufacturers.

The Association is please that Hormel Foods petitioned USDA FSIS requesting that important inconsistencies in the FSIS definition be addressed. The Association concurs with Hormel's position that "USDA needs to act quickly to codify a workable definition" prior to any FDA action.

THE SUGAR ASSOCIATION, INC.



Overview of the Sugar Association Petition

Minimally Processed

In its petition the Association contends that the proposed combination of two criteria for allowing a natural claim 1) a food that does not contain anything artificial or synthetic and 2) a food or food ingredient is not more than minimally processed – achieves a level of specificity that will negate much of the current ambiguity associated with a "natural" claim.

The Association petition addresses FDA's concern, expressed in its 1991 Notice of Proposed Rule Making,¹ about the potential for ambiguity in defining minimally processed. To this matter, the Association cites the USDA minimal processing criterion of "those physical processes which do not fundamentally alter the raw product" as the standard for evaluating whether or not a product or ingredient is minimally processed. The Association contends that a minimally processed food or ingredient can claim to be "natural" only when processing does not affect the natural character of the food or its molecular structure is identical to that present in the raw material from which it is separated. Processes where the raw material is fundamentally altered to the extent that these processes manipulate the molecules of one substance to create another and/or the final product is absent in the host substance would preclude a "natural" claim.

The current FSIS definition offers the following examples of processes that would not be considered minimal.

(2) Relatively severe processes, e.g., solvent extraction, acid hydrolysis, and chemical bleaching would clearly be considered more than minimal processing. Thus, the use of a natural flavor or flavoring in compliance with 21 CFR 101.22 which has undergone more than minimal processing would place a product in which it is used outside the scope of these guidelines.

In its petition the Association also provides other examples of processes that fundamentally alter the raw ingredient such as the hydrogenation of oils and flour treated with potassium bromate or chlorine dioxide during milling.

One aspect of the minimally processed standards that has created a difference of opinion is whether the use of individual extracted enzymes instead of traditional chemicals to alter the fundamental molecular structure of an intrinsic component of a raw material is a natural process. Processes using single enzymes, including enhancement in food fermentation, are the result of advances in bioengineering particularly the ability to alter the biocatalyst, these processes are being utilized to create many new products.² These advances in food technology and the new ingredients and products created have a place in the food supply but many of these new products are created through processing and therefore not natural.

¹ Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definitions of Terms, 56 Fed. Reg. 60,466 - 60,467 (November 27, 1991).

² Hyu Y, H, Encyclopedia of Food Science and Technology, Vol 2 Genetic Engineering Part II: Enzyme Cloning pages 1300-1312.

The Association contends that ingredients made from extracted enzymes and any process dependent on an enzyme extracted from a host organism are synthetic. Extracted enzymes differ substantively from an enzyme that is an intrinsic component of the constituent system of enzymes within an intact biological organism. Extracted enzymes are themselves chemically changed when they are chemically attached to the backbone matrix of a commercial polymer structure and manufactured specifically to chemically change a substance by the action of the immobilized enzymes. Purified single enzymes are used solely to accelerate the rate of molecular manipulation above that achievable with chemical systems and with enzymes found in naturally occurring microbes.³ Purified single enzyme processes are not naturally occurring, whole-organism biological processes.

The agencies should endeavor to provide rulemaking that requires strict adherence to a minimal processing criterion consistent with consumer understanding and expectations for natural products and ingredients. The Association contends that products and ingredients that are created by processing methods are not minimally processed and are not natural.

Exists in Nature

Furthermore, the Association contends that a substance's mere presence in nature should not be a qualifying factor for a "natural" claim. A natural claim is exceedingly misleading on substances that may occur somewhere in nature but are generated commercially through extraordinary processing. The National Advertising Division (NAD) of the Council of Better Business Bureau in "Tom's of Maine" case (No. 3470 June 1, 1998) ruled that the amount of processing should be considered when a manufacturer makes a natural claim. The NAD ruling went to the heart of the issue – consumer confidence in a natural claim – with the following statement:

"Given the target markets' significant interest in the naturalness of products ingredients, NAD believes that advertisers of 'natural' products should be very specific when describing ingredients that may be inconsistent with their consumer's expectations."

Consumer Expectations for a Natural Claim

To support its FDA petition, the Association commissioned Harris Interactive to conduct a nationally representative survey of American consumers. When asked whether the government should provide food manufactures with regulations to follow when making a natural claim, 83% of survey participants stated that the government should provide regulations.

Eighty-five percent of the 1000 survey participants said that they would not consider any food that contained anything artificial or synthetic to be natural. The

³ Starch Hydrolysis Products: Worldwide Technology, Production and Application, FW Schenk and RE Hebeda, EDS. VCH Publishers, Inc. 1992. Chapters 3-6.

majority of consumers (52%) agreed that processing influences whether or not a food or food ingredient is natural. When asked whether fundamentally altering a raw material should disqualify a product from making a "natural" claim, 60% said yes. Further, when provided an overview of the FSIS definition, 76% agreed these standards should be adopted to include all foods. A copy of this survey is provided with these comments.

Policy Memo 55

In August 2005, the FSIS published changes to Policy Memo 55 in *Food Standards and Labeling Policy*. These changes corrected inconsistencies and as Hormel articulates in its petition also created inconsistencies.

Sugar

The Association has long disagreed with the 1982 version of Policy Memo 55 that required the qualifying statement "all natural ingredients except refined sugar" in a product that makes a natural claim. Sugar is one of the most natural and purest food ingredients. Sugar refining is a simple extraction process that physically separates sucrose, whose molecular structure is unaltered, from the surrounding plant matter. Although done on an industrial scale and made more efficient due to approved processing aids, the sugar refining process preserves the inherent molecular structure of sucrose. The molecular structure of commercial sugar products is identical to the molecular structure of the sucrose present in sugarcane, sugar beets, peaches, watermelons or the multitude of fruits and vegetables that contain sucrose as a result of photosynthesis.

Sodium Lactate

In its October 9, 2006 petition to FSIS, Hormel questioned whether or not sodium lactate from corn sources should be included in a list of ingredients approved for an all natural claim. The Association does not profess to have expertise in meat and poultry processing methods or have unique expertise regarding preservatives or antimicrobial agents used in meat and poultry processing. Hormel provides information to support its assertion that sodium lactate is an artificial preservative and therefore the use of sodium lactate in a natural food would be contrary to consumer's expectation that a natural product does not contain artificial preservatives.

Further, the process used to manufacture sodium lactate from corn goes far beyond any reasonable interpretation of the FSIS minimally processed standard.⁴ Lactic acid generated from corn requires not only extensive solvent extractions and highly selective catalyzed molecular rearrangements but also a fermentation medium rich in dextrose, itself a product manufactured through the molecular manipulation of corn starch.

Section (2) of the FSIS guidance for making a natural claim for meat and poultry products includes a provision for the exception of ingredients that are more than minimally processed, e.g., "all natural except ..." or "all natural ingredients except ..."

⁴ Eyal et al. Lactic acid processing; methods; arrangements; and products, United States Patent 7,144,977 <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO2&Sect2=HITOFF&p=1&u=%2Feta>

"These exceptions may be granted on a case-by-case basis if it is demonstrated that the use of such an ingredient would not significantly change the character of the product to the point that it could no longer be considered a natural product." At the FSIS December 12, 2006 public meeting seeking public input on issues relating to the Hormel petition, the opinion that sodium lactate is well accepted by the natural community was expressed. Clear identification of the use of sodium lactate as a preservative under the above exception guideline in a natural claim seems appropriate and allows the consumer to make an informed decision.

National Organic Policy

The Hormel concern that reliance on the National Organic Policy (NOP) for a list of allowable ingredients is internally inconsistent is endorsed by the Association. The NOP allows ingredients that are synthetic and more than minimally processed to be used in certified organic foods. One example of internal inconsistency between NOP and FSIS rules is the ingredient dextrose. The FSIS requires an exception statement for the use of dextrose in meat and poultry products that claim to be all natural or to contain all natural ingredients, whereas under the NOP there is currently a certified organic dextrose.

The organic food category is the fastest growing category because a growing segment of the US population wants to consume foods that are grown and produced under certain strict criteria. The Association contends that consumers that purchase organic products have the expectation that these products are natural.

The Organic Foods Production Act of 1990 (Act) provides a definition for synthetic. The National Organic Standards Board (NOSB) is in the process of providing guidance to clarify the term synthetic. The NOSB has proposed a matrix showing different processing techniques that result in a synthetic or non-synthetic product. The program's internal memos use the synonyms "natural" for non-synthetic substances.⁵ The Association contends that this endeavor demonstrates the importance of a workable definition for natural in the organic category.

While the Association fully agrees that consumers who purchase organic products have the expectation that these products are natural, the proposed NOSB matrix broadens the definition of what will be considered non-synthetic. The Act defines a product as synthetic if it is "formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from a naturally occurring plant, animal or mineral sources, except that such term shall not apply to substances that are created by naturally occurring biological process." Thus, the Association cautions that the current NOSB proposal will permit ingredients created through processing using individual extracted enzymes which are not naturally occurring biological processes.

A regulatory framework that harmonizes the definition of natural across all government agencies and their departments responsible for regulating natural claims is

⁵ Recommended Framework to Further Clarify the Definition of Synthetic, Memo from Valerie Frances, USDA National Organic Standards Board, National Organic Program to National Organic Standard Board, March 9, 2006.

essential to eliminate consumer confusion in both the natural and organic categories of foods and beverages.

FSIS Questions

As to the 4 questions introduced in the Federal Register Notice, the Association again wants to be clear that it does not profess to have expertise in the area of meat and poultry safety, processing methods or have unique expertise regarding preservatives or antimicrobial agents used in meat and poultry processing. We would like to provide the following general comments regarding the natural category and concerns raised by these questions.

Many consumers purchase natural products because they feel comfortable and knowledgeable about products made with traditional ingredients. Consumers understand the source of traditional, natural ingredients. The minimally processed criterion is an important integral component of any meaningful definition of natural. A definition that solely relies on the exclusion of artificial or synthetic ingredients will compromise consumer expectations of natural products.

Many of the newer manufactured ingredients are more than minimally processed, have no nutritional, safety, or caloric advantage over the traditional ingredients they often replace and are often less expensive fillers or bulking agents. Therefore, it is important to the integrity of the natural category to maintain a minimally processed standard that provides a meaningful distinction for ingredients used in natural claims.

The Association's consumer survey validates Hormel's assertion that consumers believe natural products should contain no artificial or synthetic ingredients. It is also true food safety is a paramount concern for the agency, but if traditional methods of processing and traditional ingredients are available and do not compromise safety, the FSIS should respect the consumer's desire for natural products that don't contain artificial or synthetic ingredients or undergo more than minimal processing.

As stated earlier, exception guidelines are available for ingredients, such as sodium lactate manufactured from corn dextrose, should FSIS determine it important for the safety of vulnerable food categories.

Consumers understand that they often compromise shelf life when they purchase natural products, e.g. a whole wheat bread without preservatives may have a shorter shelf life and needs to be refrigerated to maintain freshness longer. Furthermore, manufacturers of natural products have the added responsibility to insure that they take extreme care to employ rigorous good manufacturing and food safety practices.

The Association offers that consumer's inherent lack of knowledge about food ingredients, food technology, food ingredient terminology and marketing claim places them at a disadvantage when trying to evaluate when a product or ingredient is natural. Therefore, consumers must rely on the oversight of regulatory agencies to provide food manufacturers with clear and concise regulations.

Conclusion

It is important for the regulatory agencies responsible for food safety and labeling to respect the increasing segment of the American population that has already made the value judgment that natural foods and ingredients are important when purchasing foods and beverages for themselves and their families. The Association is hopeful that this rulemaking process will clarify the issues brought forward in the Hormel petition. The Association believes that the accountable regulatory agencies should maintain consistency and harmonize the definition of the term "natural" for all foods and beverages and a minimal processing criterion is an integral component of any meaningful definition of natural. At the FSIS December 12, 2006 public meeting, there was nearly unanimous agreement among participants that there should be harmonization among accountable regulatory agencies in defining criteria for making a natural claim. The Association respectfully requests that the FDA and USDA work cooperatively by undertaking rulemaking jointly. Agency collaboration on this issue is essential to eliminate consumer confusion.

To summarize:

1. Consumers want the government to provide food manufacturers regulations for making a "natural" claim.
2. To have a meaningful definition of what is natural, maintain a minimally processed criterion.
3. Today many enzymatic processes, including enhancement in food fermentation, are not naturally occurring biological process
4. Extracted enzymes are used to create products that are not in the raw material and therefore not natural.
5. To avoid consumer confusion USDA and FDA need to provide regulations that are consistent for all foods and beverages claimed to be "Natural."

Sincerely,



Andrew C. Briscoe III
President & CEO

Attachments

Cc: FDA Docket # 2006P-0094