December 14, 2006

FSIS Holds Public Meeting on the Definition of the Term "Natural"

On December 12, 2006, the U.S. Department of Agriculture's ("USDA" or "the Agency") Food Safety and Inspection Service ("FSIS") held a public meeting to solicit comments on the meaning of the term "natural" in the labeling of meat and poultry products.[1] The purpose of the meeting was to gain public input, in advance of rulemaking, on the meaning of "natural" as well as the definition of the term requested in a petition by Hormel Foods.[2] Food industry representatives provided oral comments to USDA representing a diverse range of views and positions on the meaning and use of the term "natural" in the labeling of USDA-regulated foods.

I. Key Issues Raised in the Public Meeting

At the outset, USDA officials explained that the meaning of the term "natural" in the labeling of meat and poultry products is a significant and controversial issue that is ripe for public discourse. The Agency's policy for "natural" claims has not substantially changed in over 20 years, since the first USDA Policy Memo 055 was introduced in 1982 and subsequently revised and replaced in 2005.[3] USDA's stated goal is to clarify the meaning of the "natural" claim through rulemaking, beginning with comments and information received from Wednesday's meeting. The Agency specifically sought comments and information on (1) whether a definition of "natural" should incorporate a "minimally processed" criterion; (2) the implications and/or conflicts arising from current and new food processing methods and technologies (e.g., high pressure processing, multi-purpose ingredients, and modified atmosphere packaging); (3) consumer research on views, perceptions, and beliefs about the meaning of terms such as "natural," "minimal processing," "artificial," "synthetic," and "preservatives"; and (4) whether food safety and public health interests outweigh any conflict in a definition of "natural."[4]

The major themes throughout the public meeting focused on consistency, transparency, and accountability in USDA's definition, application, and enforcement of the "natural" claim. Many industry representatives expressed concern that USDA's current case-by-case approach has led to a state of confusion and unknown risks in the development and marketing of their food products.

[1] USDA, FSIS Notice of petition and public meeting; request for comments; 71 Fed. Reg. 70503 (Dec. 5, 2006), *available at* http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2006-0040.pdf.

[2] *See* Hormel Foods, Petition for the Issuance of a Rule Regarding Natural Label Claims (Oct. 9, 2006), *available at* http://www.fsis.usda.gov/regulations_&_policies/Petition_Natural_Label_Claims/index.asp.

[3] *See* USDA, FSIS, Food Standards and Labeling Policy Book (Aug. 2005), *available at* http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf.

[4] *See* 71 Fed. Reg. at 70504-70505.

The following summary highlights the key issues raised in oral comments at the meeting:

Consumer Expectations

Although there was general consensus that the definition of "natural" must account for consumer understanding and expectations, widely differing views were expressed with respect to current consumer perceptions concerning the meaning of "natural" claims. Some groups urged USDA to conduct its own consumer study to evaluate consumer understanding of "natural" and use the findings to inform any future agency action to define the term.

Scope of the Claim

"Production" versus "Processing": Many comments proposed that "natural" claims encompass and/or distinguish between production and processing methods. In addition to considering the utility of a "minimally processed" criterion for "natural" foods, comments explained that (1) "natural" is more closely tied to livestock production practices than to the processing of or ingredients used in the finished meat or poultry product, and (2) consumers view foods more holistically, from "conception to consumption." As such, some comments requested that a definition of "natural" include criteria pertaining to the production or raising of livestock (e.g., that an animal be raised in a natural environment, under humane standards, and without growth stimulants, hormones, or antibiotics). To this end, it was suggested that USDA consider creating different types of "natural" claims, such as "naturally produced" and "naturally processed."

"Organic": Some comments suggested that "natural" claims should be consistent with existing regulations for "organic" claims. One industry representative recommended that USDA even consider implementing a scheme for "natural" claims similar to the one implemented for "organic" claims (e.g., "100% natural"; "Natural"; and "Made with natural ingredients").

"Minimal Processing"

USDA has specifically questioned whether the "minimally processed" criterion is reasonable in light of advances in food processing technologies. On this issue, comments primarily focused on and questioned whether certain processes should be permitted for a "natural"-labeled food. Many comments, however, expressed manufacturer and consumer confusion over the meaning and application of "minimal processing."

Multifunctional Ingredients

According to several comments, any new definition of "natural" should not preclude naturally-derived ingredients that have multiple functions, such as taste, increasing shelf life, or having an antimicrobial or preservative effect. Some comments opposed Hormel Foods' position that lactates are refined chemical preservatives, and contended that such ingredients should be recognized as natural in origin.[5] One comment asked that USDA also consider ingredient constituents (e.g.,

[5] Following the receipt of the Hormel Foods petition, USDA revised its 2005 policy by deleting the note that deemed sodium lactate acceptable for "natural" claims. USDA explained that the note was originally added for sodium lactate that was derived from a natural source, not more than minimally processed, and provided a flavoring, not antimicrobial, effect. In light of questions about the status of multifunctional ingredients as "natural," USDA has explained that the issue is complicated and best addressed in rulemaking. In the meantime, the Agency has advised that it intends to evaluate "natural" claims food foods containing lactates on a case-by case-basis. *See supra* note 3.

anticaking agents or ethylene oxide) in any new definition of "natural." Another comment explained that naturally-derived ingredients should be permitted in foods labeled as "natural" even if such ingredients (e.g., annatto, paprika, turmeric) impart color to the finished food product; this position runs counter to the current FDA position classifying all approved color additives as "artificial color," and precluding a natural claim for foods with added color.[6]

Food Safety

One of the specific issues on which USDA sought comments was the manner and extent to which food safety policy considerations should play a role in defining the conditions of use for "natural" claims. For example, should antimicrobial agents that do no meet the current standard for "minimally processed" be allowed for use in "natural" meat and poultry products under certain conditions? There was general consensus that a USDA policy concerning "natural" claims should support food safety, but differing views were expressed concerning whether such policy should validate the use of antimicrobial ingredients that are more than "minimally processed," and whether "natural" alternatives would be preferable.

Federal and International Harmonization

A few comments noted that a separate petition to define "natural" by regulation is pending with the U.S. Food and Drug Administration ("FDA"). A number of groups urged that USDA policy concerning "natural" claims be developed in a manner that accounts for FDA and Federal Trade Commission ("FTC" or "the Commission") policies, to promote greater consistency in U.S. federal policy. Some comments encouraged USDA to work with FDA to establish a uniform definition for "natural" claims. Others expressed support for the current FDA natural policy. In addition, a couple comments suggested that USDA consider the implications of the definition on foreign or international companies that import or export foods bearing the "natural" claim.

Procedural Issues

In light of USDA's recent revision to its 2005 policy, including its stated intention to evaluate lactate ingredients on a case-by-case basis, comments requested that USDA provide a coherent interim process for regulating "natural" claims. At least one comment asked that the Agency make no changes to the pre-existing 2005 policy until a new rule is issued. Another comment requested that USDA clarify the meaning of "natural" through policy or guidance instead of a regulation. Finally, a few comments requested that USDA return to and uphold its original 1982 Policy Memo 055 and make no further changes.

There was general consensus among industry representatives that USDA should extend the comment period by an additional 60 days, in consideration of the diversity of views, intervening holidays, and nature of the issue. There was no indication by the Agency whether this request would be met. Currently, the deadline to submit written comments to USDA is January 11, 2007.

II. Significant Issues for Further Consideration

In addition to the key substantive and procedural issues raised during USDA's public meeting, other regulatory and legal factors may affect the use and meaning of this claim, including other federal policies and definitions, consumer issues and litigation, and the First Amendment.

[6] *See* note 8, *infra.*

A. Federal Policies and Definitions of "Natural"

The Hormel Foods petition and USDA's public meeting are only the latest steps in a long history of federal agency actions regarding the "natural" claim. Federal efforts date back to the 1970s, when the FTC nearly defined "natural foods" by regulation, but instead opted to evaluate "natural" claims on a case-by-case basis,[7] which the Commission still does today.

USDA and FDA also have a long history with the regulation of "natural" claims. Today, there are petitions pending before both agencies requesting that they each define "natural" by regulation.[8] USDA's public meeting is a significant step in the Agency's intended regulation of the "natural" claim. The petition pending before FDA, submitted by The Sugar Association in February 2006, requests that FDA define "natural" by adopting USDA's policy in a regulation.[9] In the past, FDA has denied requests to define "natural" by regulation; however, FDA has yet to rule on the current petition, which remains pending. In light of the petitions before USDA and FDA, the recent calls for more uniformity or consistency between the agencies' definitions may spur a cooperative effort. A definition by one agency (whether by regulation or guidance) will necessarily impact the other.

B. Consumer Expectations

Consumer understanding and expectations about "natural" claims were a significant issue in USDA's public meeting; however, the discussion was limited to the label claim as defined by a federal authority. Because "natural" claims are often challenged and litigated outside of the federal regulatory arena, it is important to consider the meaning and definition of the term, as well as consumer understanding, from these additional contexts. These sources provide potentially new understanding about the meaning of "natural." For example, the National Advertising Division ("NAD") has considered several cases challenging the use of a "natural" claim in food advertising. In many of these, the NAD has referenced or relied upon federal definitions and policies to inform its decisions.[10] The NAD's evaluation of such claims, however, is typically context-dependent, because "the reasonable takeaway of an advertisement requires the evaluation of the entire advertisement instead of the meaning of the words or phrases standing alone."[11]

[7] *See* 48 Fed. Reg. 23270 (May 24, 1983).

[8] Since the 1980s, FDA has maintained a policy for "natural" claims that it will not restrict the use of the term except for added color, artificial or synthetic substances, and artificial flavors, as defined in 21 C.F.R. § 101.22, and that "natural" means that "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." *See* 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993); 56 Fed. Reg. 60421, 60466-67 (Nov. 27, 1991).

[9] *See* The Sugar Association, Citizen Petition re Definition of the term "Natural" for making claims on foods and beverages regulated by the Food and Drug Administration (Feb. 28, 2006) [Docket No. 2006P-0094/CP1], *available at* http://www.fda.gov/ohrms/dockets/dockets/06p0094/06p-0094-cp00001-toc.htm.

[10] *See, e.g.,* NAD Case No. 4289, Sanderson Farms Chicken (Mar. 8, 2005) (finding that it is not misleading to use the claim "100% Chicken. Naturally." when the chicken complies with USDA's labeling policy); NAD Case No. 3499, Procter & Gamble (Olean Fat Substitute) (Oct. 1, 1998) (referencing USDA's policy to determine whether a product is "natural"); NAD Case No. 4442, Swiss Research, Inc. (Shugr Sweetener) (Jan. 20, 2006) (referring to FDA's policy to evaluate whether "shugr" is natural).

[11] *See* NAD Case No. 4289, *supra*, note 10 (citing *Pizza Hut, Inc. v. Papa John's Int'l, Inc.*, 227 F.3d 489, 495 (5th Cir. 2000), *cert. denied*, 532 U.S. 920 (2001); *Am. Home Products Corp. v. FTC*, 695 F.2d 681, 687 (3d Cir. 1982).

In a 2004 case in California, a consumer advocacy group sued Tyson Foods, Inc., for injunctive relief, alleging, in part, that magazine and television advertisements claiming that Tyson chicken products are "all natural" constituted false advertising and unfair businesses practices under state law. The plaintiffs did not base these allegations on any violation of USDA's "natural" policy, but instead alleged that the conditions in which Tyson chickens were raised or produced made them unnatural.[12] Although the case was dismissed without prejudice, it stands for the proposition that "natural" should be defined to include livestock production practices.

C. First Amendment

In the regulation of any commercial speech, including "natural" claims on food labels, the USDA, and any other governmental agency, must consider the constitutional protection of such speech. Under the First Amendment, in order to restrict the freedom of expression in food labeling or other commercial speech, the government has the burden of proof to establish that the restriction is needed to alleviate a genuine harm to a material degree, and that the particular regulatory strategy it has imposed is not unduly burdensome. By defining "natural" by regulation, the USDA definition would constitute a restriction on the freedom of expression in commercial speech and the restriction must be justified in accordance with First Amendment standards.[13] A definition based on a finding that use of the "natural" term differing from the definition is false or misleading, based on consumer research about consumer perception and understanding, would pass muster under *Central Hudson's* recognition that false or misleading commercial speech is not protected.

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[12] *Physicians Committee for Responsible Medicine v. Tyson Foods, Inc.*, 119 Cal. App. 4th 120 (June 1, 2004).

[13] *See* Central Hudson Gas & Electric Corp. v. Public Service Comm'n, 447 U.S. 557, 563-64 (1980).