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FSIS Docket Room
Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th Street, N.W.
Room 102 Cotton Annex
Washington, DC 20250

Re: Product Labeling: Definition of the Term "Natural"
Docket No. FSIS 2006-0040

Dear Sir or Madam:

The Corn Refiners Association ("CRA") respectfully submits these comments in response to the U.S. Department of Agriculture ("USDA"), Food Safety and Inspection Service's ("FSIS" or "the Agency") request for comments regarding the definition of the term "natural" in the labeling of meat and poultry products.

I. Introduction.

CRA is the national trade association representing the corn refining industry in the United States.¹ CRA and its predecessors have served this important segment of American agribusiness since 1913. Corn refiners manufacture sweeteners, ethanol, starch, bioproducts, corn oil, and feed products from corn components such as starch, oil, protein, and fiber. Corn sweeteners, including corn syrups, dextrose, high fructose corn syrup ("HFCS") and crystalline fructose, are the most important category of refined corn products. Many refined corn products are used as ingredients in meat and poultry products regulated by the USDA.

¹ CRA's member companies include Archer Daniels Midland Co., Cargill, Inc., Corn Products International, Inc., National Starch and Chemical Co., Penford Products Co., Roquette America, Inc., and Tate & Lyle Ingredients Americas, Inc.

As explained in these comments, USDA's "minimally processed" criterion for natural claims should be revised and updated, and natural claims should be permitted for nutritive sweeteners, starches, and fermentation products derived from natural sources.

A. FSIS's "Natural" Labeling Policy.

Since 1982, FSIS policy guidance has defined the term "natural" for meat and poultry products to mean:

- 1) The product "does not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative (as defined in 21 CFR 101.22), or any other artificial or synthetic ingredient; and
- 2) the product and its ingredients are not more than minimally processed.²

The first element in USDA's "natural" policy is identical to the Food and Drug Administration's ("FDA") existing policy for "natural" claims for FDA-regulated foods.³ However, the second element of the USDA policy, the "minimally processed" criterion, is not an FDA requirement. The USDA policy defines "minimally processed" to mean "traditional processes" to make food edible, safe, or to preserve it, or "physical processes" which do not fundamentally alter the product or which only separate the whole product into component parts. Meat and poultry products subjected to "relatively severe processes" may not be labeled as "natural" because they are considered more than minimally processed.⁴

In August 2005, based on modifications and case-by-case decisions since 1982, FSIS revised its "natural" policy. The revised policy guidance was published in FSIS's "Food Standards and Labeling Policy Book." In relevant part, the revised policy retained the two requisite criteria (described above), but noted that meat and poultry products containing sugar, sodium lactate (from a corn source), and/or natural flavorings from oleoresins or extractives may bear a "natural" claim. The 2005 guidance also referred to USDA's regulations under the National Organic Program ("NOP")⁵ for a list of ingredients acceptable for "natural" claims.

² USDA Standards and Labeling Policy Memorandum (Memo) 055 (Nov. 22, 1982). *See also* FSIS, USDA, Food Standards and Labeling Policy Book, Natural Claims (August 2005), available at http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf.

³ 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993). *See also, e.g.*, 56 Fed. Reg. 60421, 60466-67 (Nov. 27, 1991); 62 Fed. Reg. 49826, 49841 (Sept. 23, 1997).

⁴ *See* USDA Standards and Labeling Policy Memo 055, *supra* note 2.

⁵ *See* 7 C.F.R. §§ 205.601 – 205.606.

The revised policy was issued without explanation of the basis for the changes or opportunity for public comment.

On December 5, 2006, FSIS published a notice in the Federal Register announcing receipt of a petition from Hormel Foods regarding “natural” claims and inviting comments on the Hormel petition and the definition of “natural” generally.⁶ With only one week’s notice, FSIS held a public meeting regarding “natural” labeling on December 12, 2006. The short interval between the published notice and the public meeting did not allow adequate time for public comment. In response to the Hormel Foods petition, FSIS published a “correction” to its “natural” policy.⁷ FSIS explained that it was removing the reference to “sodium lactate (from a corn source)” as acceptable for a “natural” claim due to questions about lactates having preservative effects at levels of use associated with flavoring. FSIS also removed the reference to USDA’s NOP regulations “because it was confusing users ... who thought that any ingredient that is ‘organic’ could be used in a ‘natural’ product, which is not the case.”⁸ These policy revisions were made without stakeholder input or meaningful opportunity for public comment.

II. USDA Requirements For “Natural” Labeling Should Take Into Account The Unique Characteristics Of Meat And Poultry Products And The Flexibility Afforded By USDA’s Prior Label Approval Requirement.

A. USDA’s Regulation Of “Natural” Labeling Should Recognize The Unique Nature Of Meat And Poultry Products.

Meat and poultry products regulated by USDA are a unique category of foods. USDA-regulated food products are typically understood to be less processed or manufactured than food products regulated by FDA. However, USDA’s jurisdiction over meat and poultry products ranges from single ingredient products such as raw chicken to multiple ingredient products such as corn dogs. Any definition of “natural” should account for the unique characteristics of meat and poultry products.

⁶ 71 Fed. Reg. 70503 (Dec. 5, 2006).

⁷ See FSIS, USDA, Food Standards and Labeling Policy Book, Natural Claims, *supra* note 2.

⁸ *Id.*

B. Any New Definition Of “Natural” Should Not Undermine The Flexibility Provided By USDA’s Prior Review And Approval Requirement For Meat And Poultry Product Labels.

Unlike FDA, FSIS reviews and approves all labels for meat and poultry products on a premarket basis.⁹ Consequently, FSIS is uniquely positioned to maintain flexibility in the application of its “natural” policy. Any new definition of the term “natural” should preserve the Agency’s flexibility in evaluating label claims, including any “minimally processed” criterion.

III. The “Minimally Processed” Criterion Should Be Clarified And Modernized For Processed Meat And Poultry Products.

FSIS’s revised policy provides that “minimal processing” may include:

(a) those traditional processes use 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 (b) those physical processes which do not fundamentally alter the raw product and/or which only separate a whole, intact food into components 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 clearly be considered more than minimal processing.¹⁰

This criterion has been applied since the Agency’s initial 1982 policy for “natural” labeling of meat and poultry products.

A. The Current USDA “Minimally Processed” Requires Updating And Is Unduly Restrictive.

The definition of “minimal processing” must be revised to account for advances in food processing methods and technologies, and to provide a clear and consistent meaning for meat and poultry product manufacturers and consumers. FSIS’s “minimally processed” requirement for meat and poultry products labeled as “natural” was first imposed nearly 25 years ago. Since that time, new food processing technologies and methods have been developed to increase efficiency and product quality without compromising the “natural” nature of the food. The

⁹ 9 C.F.R. § 317.4.

¹⁰ See FSIS, USDA, Food Standards and Labeling Policy Book, Natural Claims, *supra* note 2.

current “natural” policy does not adequately account for these advancements in food processing methods or technologies, to the detriment of both consumers and the food industry.

In addition, there is no clear consensus or common understanding about the meaning of the term “minimally processed”. This was clearly evidenced by comments at the Agency’s public meeting on December 12, 2006. Furthermore, even FSIS’s “natural” policy is internally inconsistent with respect to the meaning of “minimally processed.” The policy explains that the use of a “natural flavor” that complies with FDA’s regulation in 21 C.F.R. § 101.22 would place it outside the scope of the Agency’s policy if the flavoring has undergone more than minimal processing. Yet, FSIS defines “natural flavors” identical to FDA’s definition,¹¹ and expressly states that “natural flavorings from oleoresins or extractives are acceptable for ‘all natural’ claims.”¹² Any definition of “minimal processing” must be clear and consistent, and appropriately account for advances in food processing methods and technologies.

B. The “Minimally Processed” Criterion Should Be Revised To Accommodate New Natural Processing Methods And Technologies, Including Enzymatic Processing.

If FSIS decides to retain a “minimally processed” requirement, it should be defined to include all natural food processing methods and technologies, including processing with enzymes. Nothing is more natural than processing foods, including meat and poultry products, with the fundamental catalysts of chemical reactions in living systems (i.e., enzymes). Many foods which are routinely regarded as “natural” foods use added enzymes in their processing. For example, enzymes are added during fruit juice processing to remove (through enzymatic hydrolysis) cloudiness caused by pectins.¹³ They are also used in the production and flavoring of cheese.¹⁴ In the context of meat product processing, enzymes have been used to tenderize meats.¹⁵

¹¹ Cf. 21 C.F.R. § 101.22 (FDA’s “natural flavor” definition) and 9 C.F.R. §§ 317.2(f)(1)(i)(B) and (ii); 381.118(c) (USDA’s definitions for “natural flavor” for meat and poultry products).

¹² See FSIS, USDA, Food Standards and Labeling Policy Book, Natural Claims, *supra* note 2.

¹³ Martin Chaplin & Christopher Bucke, *Enzyme Technology*, Ch. 4, “Enzymes in the fruit juice, wine, brewing and distilling industries,” (Cambridge Univ. Press 1990), available at <http://www.lsbu.ac.uk/biology/enztech/index.html>.

¹⁴ *Id.* at Ch. 4, “Applications of proteases in the food industry.”

¹⁵ *Id.*

C. “Natural” Claims Should Be Permitted For Nutritive Sweeteners Derived From Natural Sources And Not Subjected To Chemical Processing, Including Sucrose, Glucose And HFCS, As Well As Starches And Fermentation Products Derived From Natural Sources.

FSIS’s definition of “natural” for meat and poultry products should include products and ingredients that are derived from natural sources (e.g., plants or animals) and that are not subjected to chemical processing. This includes any nutritive sweeteners, such as sucrose, glucose, and HFCS, as well as starches and fermentation products, that are naturally-derived and not chemically processed. Nutritive sweeteners, starches, and fermentation products can all be derived from natural sources. For example, sucrose is derived from sugar cane or sugar beets; HFCS is derived from corn. The processing of these ingredients relies on fundamental physical processes such as steeping, pulping, milling, filtration, and evaporation. Their processing also utilizes enzymes for starch hydrolysis and clarification. A chart comparing sucrose and HFCS processes is attached. Because FSIS has already expressly stated that sucrose is acceptable for a “natural” claim, FSIS should make clear that other nutritive sweeteners, as well as starches and fermentation products, using the same processing methods are also eligible to bear a “natural” claim.

IV. USDA’s Definition Of “Natural” Claims Should Be Consistent With Consumer Expectations.

A. Consumer Studies Supporting New Or Revised “Natural” Labeling Must Be Unbiased And Carefully Designed.

Hormel Foods states that the definition of “natural” should “comport with already-established consumer beliefs regarding ‘natural’ foods.”¹⁶ Hormel relies heavily on a study conducted by The Sugar Association and submitted in support of the Sugar Association’s recent petition to FDA to define “natural” claims.¹⁷ The Sugar Association Petition included a consumer survey purportedly showing, among other things, that (1) consumers believe that a “natural” food should not contain artificial or synthetic ingredients; and (2) “consumers do not consider a food or ingredient in which the fundamental raw material is altered through processing as ‘natural.’”¹⁸ Although the first assertion is consistent with federal policies

¹⁶ Hormel Foods Petition, *supra* note 17, at 8.

¹⁷ 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 [hereinafter “The Sugar Association Petition”], *available at* <http://www.fda.gov/ohrms/dockets/dockets/06p0094/06p-0094-cp00001-toc.htm>.

¹⁸ See *id.* at 8-9; Attachment 4.

regarding the meaning of “natural”, the survey does not support the second assertion. According to the survey, there was a nearly even split among survey respondents, showing 52 percent believing that “processing matters for a natural claim” and 48 percent answering that it does not matter or that they do not know or are not sure. With regard to consumer beliefs about whether “processing that alters the raw material” should be permitted for “natural” claims, the survey question and example are flawed because they fail to disclose material information to survey respondents.

B. Additional Research Is Needed Regarding Consumer Perceptions And Attitudes About The Meaning Of The Term “Natural.”

In its notice and request for comments, FSIS asked for “available data, in addition to the data provided in the [Hormel Foods] petition, from consumer studies on views, perceptions, and beliefs about what the claim ‘natural’ means” on the labels of meat and poultry products.¹⁹ As noted above, the data cited by Hormel Foods is inadequate to document current consumer beliefs about the meaning of “natural” or “minimal processing.” Credible and reliable empirical data is needed to determine actual consumer understanding and expectations about the meaning of “natural” as that term describes meat and poultry products.

V. USDA’s Approach To Regulating “Natural” Claims Should Be Open, Transparent, And Internally Consistent.

Since the inception of USDA’s “natural” policy 25 years ago, this is the first formal public opportunity for stakeholders to provide their views regarding the appropriate meaning of “natural” for meat and poultry products. An open, transparent and deliberate process is necessary to afford stakeholders an opportunity to provide the best possible comments and information on this important issue. Transparency throughout the process will help ensure that the resulting definition of “natural” is clear to meat and poultry product manufacturers and consumers, and consistent with other USDA regulations and policies.

Respectfully submitted,



Audrae Erickson
President

Attachment

¹⁹ 71 Fed. Reg. at 70505.