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What's in a Name? FDA Working to Define “Natural” and Redefine “Healthy”

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October 14, 2016

farmdoc daily (6):194

Recommended citation format: Schlessinger, L., and A. B. Endres. “What's in a Name? FDA Working to Define ‘Natural’ and Redefine ‘Healthy’.” *farmdoc daily* (6):194, Department of Agricultural and Consumer Economics, University of Illinois at Urbana-Champaign, October 14, 2016.

Permalink: <http://farmdocdaily.illinois.edu/2016/10/whats-in-a-name-fda-working-to-define-natural.html>

2016 has been an active year for food regulations. From the implementation of the Food Safety Modernization Act to the revision of the Nutrition and Supplement Facts Labels, the FDA has been finalizing rules meant to modernize and make our food supply safer, while also helping consumers stay informed and make healthier choices. While the FDA has not yet issued a final rule on the definitions of “natural” and “healthy,” the recent request for public comments on the two terms is a promising step towards clarification of an often litigated claim (“natural”) and an outdated FDA definition of “healthy.”

Natural is the most commonly used claim on new U.S. food products—a \$40 billion a year market. However, the FDA (unlike the USDA with respect to meat products¹) has never formally defined parameters for use of the term on general (non-meat) food products.² Consumer preferences are behind the labeling trend, with sixty-two percent of surveyed consumers responding with a preference for a product labeled natural.³ Historically, the FDA has provided a policy statement about the term natural, but has refused to define the term with an official rule.⁴ The FDA’s policy statement defines natural as no artificial or synthetic ingredients added to a food that would not normally be expected in the food item.⁵ The agency’s reluctance to provide an official rule defining natural has led to near constant private and class action litigation over

¹ USDA, FSIS, Meat and Poultry Labeling Terms,

http://www.fsis.usda.gov/wps/wcm/connect/e2853601-3edb-45d3-90dc-1bef17b7f277/Meat_and_Poultry_Labeling_Terms.pdf?MOD=AJPERES

² A. Bryan Endres et al., *United States Food Law Update: Shrouded by Election-Year Politics, State Initiatives and Private Lawsuits Fill in the Gaps Created by Congressional and Agency Ossification*, 9 J. FOOD L. POL’Y 99 (2013);

<https://www.washingtonpost.com/news/wonk/wp/2014/06/24/the-word-natural-helps-sell-40-billion-worth-of-food-in-the-u-s-every-year-and-the-label-means-nothing/>

³ GreenerChoices.org & Consumer Reports, Food Labeling Poll 9 (July 11, 2007), available at http://greenerchoices.org/wp-content/uploads/2016/08/CR_2015_Natural_Food_Labels_Survey.pdf

⁴ Endres *supra* note 2 at 109.

⁵ <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm456090.htm>

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natural claims on a variety of processed, multi-ingredient food products.⁶ In response, a variety of consumer groups have relied on state consumer protection statutes to bring lawsuits for deceptive and misleading use of the term “natural” on various products.⁷ The result of this ubiquitous litigation is a confusing, piecemeal, state-by-state construction of what may be labeled as a “natural” product—a result that is problematic for both producers and consumers.⁸

Recently, federal courts frustrated with ongoing litigation and several citizen-based petitions have asked the FDA to officially define the term “natural,” including one request seeking to prohibit the term on food labels.⁹ In response, the FDA recognized the troubled state of the “natural” claim, noting that the policy was not intended to address food production methods (i.e. the use of pesticides), nor did it address food processing or manufacturing methods (i.e. how much processing is too much including thermal technologies, pasteurization or irradiation). Additionally, there is no official policy on whether genetically modified organisms can be labeled natural, or whether the term “natural” should describe any specific nutritional or other health benefit.¹⁰

On December 28, 2015, FDA initiated the rule making process by requesting comments on the use of the term “natural” in labeling of human food products.¹¹ Specifically, the FDA was interested in information and comments on questions including whether it is appropriate for the FDA to define natural, how the agency should define natural, and when the use of the term was appropriate on food labels.¹² The comment section closed May 10, 2016 and received 4,148 comments. Comments may be viewed [here](#). Since the comment section closed, the FDA has not offered any proposed rules for the use of term “natural,” in food labeling.

Unlike the term “natural,” the term “healthy” has an official FDA definition. Twenty-six years ago, congress passed the Nutrition Labeling and Education Act of 1990, which amended the Federal Food, Drug, and Cosmetic Act to give the agency the authority to regulate the use of nutrient content claims in the labeling of food.¹³ The current rule, implemented in 1994, states that the term “healthy,” and all related terms, may only be used if the food meets certain requirements for nutrients including low fat, low saturated fat, low sodium, and low cholesterol.¹⁴ To illustrate how this definition is outdated, under the current law’s requirements, foods such as almonds, avocados, and salmon cannot be labelled “healthy” because of the fat content, while fat-free puddings and sugary cereals can carry a “health” label.¹⁵

In March of 2015, the FDA sent a warning letter to KIND, LLC, the producer of KIND Fruit & Nut Bars.¹⁶ In the warning letter, the FDA noted that KIND Bars advertise on the label that they are healthy, although they contain more than 1g of saturated fat, which exceeds the maximum of 15% of calories from saturated fat in the “low saturated fat” definition for healthy.¹⁷ Additionally, the bars contained more than 3g of total fat, which exceeds the levels set for the “low fat” definition for healthy.¹⁸ In December of 2015, in response to the FDA, KIND submitted a petition asking the agency to reconsider the outdated definition of “healthy” to conform with the 2015 Dietary Guidelines Advisor Committee Report, which shifted its focus from individual

⁶ April L. Farris, *The “Natural” Aversion: The FDA’s Reluctance to Define a Leading Food-Industry Marketing Claim, and the Pressing Need for a Workable Rule*, 65 FOOD & DRUG L. J. 4013 (2010).

⁷ Endres *supra* note 2, at 110.

⁸ *Id.*

⁹ <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm456090.htm>

¹⁰ <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm456090.htm>

¹¹ <https://www.regulations.gov/document?D=FDA-2014-N-1207-1827>

¹² <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm456090.htm>

¹³ <http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074948.htm>

¹⁴ 21 CFR 101.65(d)(2)

¹⁵ <https://s3.amazonaws.com/kind-docs/citizen-petition.pdf>

¹⁶ <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm440942.htm>

¹⁷ *Id.*

¹⁸ *Id.*

nutrients in foods to encouraging consumption of whole foods, such as the nuts contained in the KIND Bars.¹⁹ In its petition, KIND asks the FDA to update the definition to allow food items that contain minimally processed fruits, vegetables, nuts, seeds, legumes, whole grains, and seafood to be labelled as “healthy.”²⁰

In response to the petition and to provide consumers with information to enable them to more easily make good food choices consistent with public health recommendations, the FDA began the process to redefine “healthy.”²¹ On the request for comment page, the FDA noted that public health recommendations for various nutrients have evolved, including focusing on the type of fat rather than total amount, as well as the amount of added sugars in the diet.²² The comment period began on September 28, 2016 and is currently open. Interested persons can provide their comments to the agency [here](#). To focus the discussion, the FDA has supplied a list of issues to consider when commenting, including what types of food, if any, should be allowed to be labeled “healthy,” is “healthy” the best term to characterize foods that should be encouraged to build healthy diets, what other terms may be more appropriate, and what nutrient criteria should be considered for the definition of the term “healthy?”²³

The implications of redefining “healthy” and establishing an initial definitional requirement for “natural” could reverberate through the food processing industry and have some impact on demand for commodity products as manufacturers consider adjusting ingredients to meet strong consumer demand for products bearing these labels. In addition, a clear definition could impart a needed degree of certainty in decision making for food companies confronting a variety of lawsuits challenging individual labeling claims on products.

¹⁹ <https://s3.amazonaws.com/kind-docs/citizen-petition.pdf>

²⁰ *Id.*

²¹ <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm520695.htm>

²² <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm520695.htm>

²³ <https://www.regulations.gov/document?D=FDA-2016-D-2335-0001>