

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



Docket No. FDA-2014-N-1207
Use of the Term “Natural” in the Labeling of Human Food Products
May 9, 2016

Re: Use of the Term “Natural” in the Labeling of Human Food Products; FDA-2014-N-1207

Dear Sir or Madam:

These comments respond to the U.S. Food and Drug Administration’s (FDA’s) request for information and public comment regarding the use of the term “natural” in the labeling of human food products, 80 Fed. Reg. 69905 (Nov. 12, 2015). These comments demonstrate that, the use of the term “natural” in meat and poultry product labeling is inherently misleading and has a history of deceptive use; thus, in order to protect consumers from “false or misleading”¹ food labels, the FDA should prohibit the use of the term “natural” in meat and poultry product labeling. However, should the FDA decline to prohibit the use of the label, then it should at minimum prohibit use of the label when those products are derived from animals raised unnaturally, i.e., indoors and unable to perform their natural behaviors, fed subtherapeutic antibiotics and other veterinary drugs, or injected with growth hormones.

170 East Cotati Avenue
Cotati, California 94931

T 707.795.2533
F 707.795.7280

info@aldf.org
aldf.org

I. About the Commenters

The Animal Legal Defense Fund (ALDF) was founded in 1979 to protect the lives and advance the interests of animals through the legal system. To accomplish this mission, ALDF files high-impact lawsuits to protect animals from harm; provides free legal assistance and training to prosecutors to assure that animal abusers are punished for their crimes; supports tough animal protection legislation and fights harmful legislation; and provides resources and opportunities to law students and professionals to advance the emerging field of animal law.

The Center for Biological Diversity (Center) is a non-profit environmental organization dedicated to the protection of native species and their habitats through science, policy, and environmental law. The Center has more than one million members and online activists dedicated to the protection and restoration of endangered species and wild places. The Center has worked for twenty-six years to protect imperiled plants and wildlife, open space, air and water quality, and overall quality of life. The Center is committed to

¹ 21 U.S.C. 343(a)(1).

protecting the environmental and public health, including by engaging in matters about the appropriate and non-deceptive use of human food labels.

II. FDA Should Define the Term “Natural” to Prevent Significant Consumer Confusion

The FDA, in tandem with the United States Department of Agriculture (USDA),² should define the term “natural” as used in meat and poultry product labeling because of the importance of the term “natural” to consumers, as well as the clear evidence that consumers have been misled by use of the term in product labeling. Per the USDA Food Safety Inspection Service, a “natural” product is one “containing no artificial ingredient or added color and is only minimally processed,” where “[m]inimal processing means that the product was processed in a manner that does not fundamentally alter the product.”³ A meat or poultry company need only “include a statement explaining the meaning of the term natural (such as ‘no artificial ingredients; minimally processed’)” in order to label its product “100% Natural” or “All Natural.”⁴ However, recent consumer surveys have demonstrated that consumers have a much different idea of what “natural” means with regard to meat and poultry, and thus are being misled by a label claim that does not meet their reasonable expectations.

In 2007, the FDA declined to define the term “natural” in response to petitions asking it to do so because it was “not sure how high of an issue it [wa]s for consumers.”⁵ The FDA noted there was insufficient proof of consumers being misled by the term.⁶ Yet market research firms have since identified the increasing importance of the “natural” label to consumers. A 2015 food & beverage-focused consumer survey by global business advisory firm AlixPartners found that “the attributes ‘all-natural’ and ‘organic’”⁷ increased in importance to respondents as compared to the 2013 survey; 21% of consumers cited “all-natural” in the most recent survey as most important (up from 10% who said that in the survey of a year ago) and 15% cited “organic” as most important (up from 5% in the year-ago survey).⁸ Additionally, consumers’ self-reported

² Given the FDA and USDA’s shared jurisdiction over meat and poultry products, the FDA and USDA should have a unified policy concerning the use of the term “natural” in meat and poultry labeling. To this end, the FDA and USDA should work together to amend the definition of “natural” in the USDA Food Safety Inspection Services (FSIS) Food Standards and Labeling Policy Book such that the FSIS definition is consistent with the FDA’s definition.

³ FSIS, Meat and Poultry Labeling Terms, <http://www.fsis.usda.gov/wps/wcm/connect/fsis-content/internet/main/topics/food-safety-education/get-answers/food-safety-fact-sheets/food-labeling/meat-and-poultry-labeling-terms/meat-and-poultry-labeling-terms> (last visited April 7, 2016).

⁴ *See id.*

⁵ Lorraine Heller, ‘Natural’ will remain undefined, says FDA, Food Navigator (Jan. 4, 2008).

⁶ *Id.*

⁷ Establishing a definition of “natural” as used in meat and poultry product labels would help to clarify differences between “natural” and “organic” meat and poultry, as one out of every three Americans do not differentiate at all between foods labeled as “natural” versus foods labeled “organic.”⁷ Moreover, there is considerable overlap between consumers’ understanding of the two terms, as the majority of consumers think that *both* “natural” and “organic” label on meat and poultry means that no artificial ingredients, growth hormones, genetically modified ingredients, or antibiotics were used.

⁸ Alix Partners, *Companies May Be Leaving Money on the Table’ in Health & Wellness, Says AlixPartners Food & Beverage Consumer Survey* (Feb. 2015), <http://www.alixpartners.com/en/MediaCenter/PressReleases/tabid/821/articleType/ArticleView/articleId/1552/Com>

willingness to pay more increased by the following amounts for these attributes: “organic” (an 11% premium, up from 9.3% in the 2013 survey) and “all-natural” (a 9.9% premium, up from 5.7%).”

While consumer surveys have broadly demonstrated consumers’ growing affinity for the “natural” label, the potential for consumers to be misled by the term, particularly as applied to meat and poultry products, has also been increasingly documented. A 2014 Consumer Reports survey of 1,000 consumers found that while nearly 60% of consumers seek out the “natural” label when purchasing meat and poultry products, the label’s perceived meaning stands in stark contrast to what the standard actually requires of meat and poultry.⁹ According to the report, “[t]he majority of consumers think that the natural label on meat and poultry currently means that...no growth hormones were used (68%), the animals’ feed contained no GMOs (64%) or artificial ingredients (60%), and no antibiotics or other drugs were used (60%).” Nearly half (48%) also believe that the natural label means that the animals went outdoors, and 57% think that the “organic” label means “the animals’ living space met some meaningful minimum size requirements.”¹⁰

Industry-conducted surveys have reached similar conclusions. The 2015 Power of Meat survey, for example, published by the North American Meat Institute, reported, “[t]he number one reason for buying natural/organic meat and poultry in 2015 is shared between the desire to avoid certain substances and the better health/treatment of the animals.”¹¹

Yet, as discussed further below, companies frequently employ the term “natural” on meat and poultry product labels when those products are derived from animals raised *in direct conflict* with consumers’ reasonable understanding of the term. A regulatory definition of “natural” that accurately reflects consumer expectations for meat and poultry products so labeled, in conjunction with an adequate enforcement regime, would alleviate consumer confusion in this area.

III. Production Practices Incompatible with Consumer Understanding of the Term “Natural” Must be Prohibited from Using the Label

The FDA should define and regulate the term “natural” to prohibit production practices incompatible with any reasonable understanding of the term, including but not limited to keeping large numbers of animals intensively confined in indoor facilities with no meaningful access to the outdoors, and routinely dosing animals with antibiotics and other drugs in order to speed their growth.

panies-May-Be-Leaving-Money-on-the-Table-in-Health-Wellness-Says-AlixPartners-Food-Beverage-Consumer-Survey.aspx#sthash.keIbrQBS.XflclTfu.dpbs.

⁹ Consumer Reports National Research Center, Food Labels Survey (April 2014), <http://www.greenerchoices.org/pdf/consumerreportsfoodlabelingsurveyjune2014.pdf> (hereinafter, “Consumer Reports survey”).

¹⁰ In light of the interchangeability of “natural” and “organic” among a significant portion of the population (see fn. 4), it is likely that a substantial percentage of consumers expect a similarly meaningful minimum living space requirement for animals raised for meat and poultry labeled as “natural.”

¹¹ North American Meat Institute, *Top Findings of the Power of Meat 2015*, <https://www.fmi.org/docs/default-source/research/power-of-meat---top-ten-findings.pdf?sfvrsn=2>.

As the aforementioned Consumer Reports survey illustrates, consumers perceive the term “natural” as used in meat and poultry product labeling to mean that no growth hormones were used in production, and that products were derived from animals who were not fed antibiotics¹² or other drugs, or from animals confined without access to the outdoors or sufficient space to perform natural behaviors.

Companies that sell meat and poultry products derived from animals fed growth hormones, subtherapeutic antibiotics, or other veterinary drugs, and given no meaningful access to the outdoors, must be prohibited from labeling such products “natural,” so as to prevent a likelihood of consumer deception. Consider, for example, the labels on Hormel’s “Natural Choice” line of lunchmeat products, which inform consumers that the products are “100% Natural,”¹³ despite the fact that Hormel itself confirms that it raises its hogs and turkeys indoors.¹⁴ Additionally, Hormel has not committed to ending the routine subtherapeutic dosing of antibiotics for disease prevention, and also uses ractopamine – a beta agonist commonly used to increase growth – in its hog production.

Indeed, meat and poultry producers are themselves aware of the likelihood of consumer confusion created by the use of the term “natural” on product labeling. Hormel, for example, in its 2006 petition for rulemaking, acknowledged that “some consumers or animal raisers may confuse natural products with those that are free of antibiotics or growth stimulants.”¹⁵

And it is not just consumers and animals who are adversely affected by a definition of “natural” that does not exclude products derived from animals raised indoors in extreme confinement and pumped with subtherapeutic antibiotics and other drugs, contrary to consumers’ expectation of what that term means. A definition of “natural” bearing only on artificial ingredients and minimal processing, and with no relation to how the animals were raised, also harms competitors

¹² Regulations should allow producers to employ the term “natural” in the labeling of meat and poultry derived from animals who have not been fed subtherapeutic levels of antibiotics, but may have received treatment for illness. For clarification of antibiotic claims in particular, ALDF calls for the implementation of USDA’s 2002 proposed labeling requirements which would have established various classes of antibiotics claims with accompanying standards, including: “no antibiotics used” or “raised without antibiotics” for livestock that have never received antibiotics from birth to harvest; and “no subtherapeutic antibiotics added” or “not fed antibiotics” for livestock that have not been fed subtherapeutic levels of antibiotics, but may have received treatment for illness. *See* United States Standards for Livestock and Meat Marketing Claims, 67 Fed. Reg. 79552, 79552-56 (Dec. 30, 2002).

¹³ The “100% Natural” claim is featured prominently just below the name “Natural Choice,” followed by a double asterisk that directs consumers to considerably smaller print in the bottom left corner that reads “no artificial ingredients” and “minimally processed,” disclaimers required by FSIS for use of the “100% natural” claim.

¹⁴ Hormel, *Animal Care*, <https://www.hormelfoods.com/About/CorporateResponsibility/Animal-Care.aspx> (last visited Jan. 2, 2016). That Hormel confines animals indoors is further confirmed by two undercover investigations of Hormel suppliers in Iowa; the first, a September 2008 investigation of MowMar Farms conducted by PETA, and the second, a February 2012 investigation of Hawkeye Sow Center conducted by Compassion Over Killing. Both investigations, of breeding centers housing sows and piglets, illustrate the crowded and unnatural, conditions common in industrial pig farming. Hormel employs other breeding and production practices, including the use of gestation and farrowing crates,¹⁴ genetic manipulation for fast growth and efficient production, and routine amputations and mutilations for production purposes (as seen in the undercover videos).

¹⁵ Hormel, Petition for the Issuance of a Rule Regarding Natural Label Claims, (Oct. 2006), http://www.fsis.usda.gov/wps/wcm/connect/808518d9-0d50-4a8a-96a9-2b4c1750f700/Petition_Natural_Label_Claims.pdf?MOD=AJPERES.

who spend significant resources to provide truly “natural” living conditions for animals. As Mack H. Graves, CEO of Panorama Meats, stated, producers like Hormel have succeeded in “dilut[ing] the term ‘natural’ by codifying it in its current confusing and mistrusted form.”¹⁶

IV. Defining the Term “Natural” Will Benefit Both Public Health and the Environment

Defining and regulating the term “natural” as described above will not only protect consumers from false and misleading advertising, but will also provide a net positive benefit to the public health and the environment. Significantly, it will further the FDA’s mission to “protect[] the public health by assuring the safety, effectiveness, quality, and security of human and veterinary antibiotics.”¹⁷

By defining the term “natural” in meat and poultry labeling to exclude products derived from animals routinely fed subtherapeutic doses of antibiotics, producers seeking to leverage the popularity and profitability of the “natural” claim will then cease the subtherapeutic dosing of antibiotics. Given the public health threat posed by the overuse of antibiotics in animals raised for food,¹⁸ a reduction in such use has been recommended by the Centers for Disease Control.¹⁹ Indeed, antibiotic resistance is one of the greatest public health threats of our generation, and their overuse in animals raised for food is widely seen as a major contributor to this crisis.²⁰ Thus, as producers eliminate the routine administration of subtherapeutic antibiotics in order to take advantage of the “natural” claim, such a reduction would have tangible public health benefits.

Similarly, by defining the term “natural” in meat and poultry labeling to exclude products derived from animals given other drugs, companies employing the term in meat and poultry labeling will no longer be able to administer beta agonists like ractopamine, which is commonly used in the pork and turkey industries to boost fast, lean growth in the “finishing” stage. Ractopamine has been shown to cause elevated heart rates in humans²¹ and has been banned or limited in China, Russia, Taiwan, and the European Union.²² Thus, defining “natural” for meat

¹⁶ Panorama, *Department of Agriculture - Food Safety and Inspection Service Product Labeling: Definition of the Term “Natural”*: Comments submitted by Mack H. Graves, CEO, Panorama Meats, <http://www.panoramameats.com/resources/archives>.

¹⁷ FDA, *FDA Fundamentals*, <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm192695.htm> (last visited May 9, 2016).

¹⁸ The Pew Charitable Trusts, *Record-High Antibiotic Sales for Meat and Poultry Production* (Feb. 6, 2013), <http://www.pewtrusts.org/en/research-and-analysis/analysis/2013/02/06/recordhigh-antibiotic-sales-for-meat-and-poultry-production>; Tom Philpott, *CDC Reveals Scary Truth About Factory Farming and Superbugs*, Mother Jones (Sept. 18, 2013), <http://www.motherjones.com/tom-philpott/2013/09/cdc-meat-industry-yes-you-contribute-antibiotic-resistance>.

¹⁹ Centers for Disease Control, *Antibiotic Resistance Threats in the United States, 2013*, <http://www.cdc.gov/drugresistance/threat-report-2013/>.

²⁰ See note 18, *supra*.

²¹ *Safety Evaluation of Ractopamine, Scientific Opinion of the Panel on Additives and Products or Substances Used in Animal Feed*, 7 Euro. Food Safety Auth. J., at 18 (April 2009).

²² Center for Food Safety, *Ractopamine Fact Sheet*, (Feb. 2013) http://www.centerforfoodsafety.org/files/ractopamine_factsheet_02211.pdf.

and poultry could help lessen the public health threat posed by ractopamine in U.S. pork and turkey products, by encouraging companies to move away from its use.

Current production practices in the meat and poultry industries – including for many of the products labeled and advertised as “natural” – are having a devastating impact on the environment. Global meat and dairy production alone emits more greenhouse gases than all forms of transportation or industrial processes combined,²³ while waste runoff from Concentrated Animal Feeding Operations (CAFOs)²⁴ pollutes both groundwater and surface water nationwide.²⁵ Perhaps even worse are the direct local impacts from CAFOs. Children who live near CAFOs are more likely to suffer from asthma as a result of the air pollutants that CAFOs release, through open manure lagoons, excessive land application of manure, and ventilation systems in the CAFO buildings.²⁶ A study by Iowa State University found that just two CAFO chicken houses emitted over 10 tons of ammonia in a single year.²⁷ In sum, neither the human body nor the environment are equipped to tolerate the devastating impacts of CAFOs’ unnatural production methods.

By requiring companies labeling meat and poultry as “natural” to ensure that animals were given meaningful access to the outdoors, producers catering to the lucrative “natural” market will be forced to deviate from the extreme confinement and crowding typical of CAFOs, which will have direct environmental health benefits. Reducing the number of animals raised in CAFOs will reduce the waste generated, and thereby lessen both the environmental and public health impacts of meat production.²⁸

V. The FDA Must Establish Specific Criteria and Procedures for Determining Whether Products May Bear the “Natural” Label

After defining the term “natural” to align with existing consumer perception of the term as applied to meat and poultry products, the FDA should collaborate with USDA’s National Organic Enforcement program, through which USDA certifying agents already conduct on-site inspections of USDA organic-certified facilities.²⁹ Pooling resources in this manner will enable more efficient administration of the new “natural” program, as well as the existing USDA organic program. The inspections should be unannounced to ensure meaningful observation and enforcement.

²³ Nathan Fiala, *How Meat Contributes to Global Warming*, SCI. AM. (Feb. 4, 2009), <http://scientificamerican.com/article.cfm?id=the-greenhouse-hamburger>.

²⁴ As defined by the Environmental Protection Agency (EPA).

²⁵ National Association of Local Boards of Health (2010), *Understanding Concentrated Animal Feeding Operations and Their Impact on Communities*, http://www.cdc.gov/nceh/ehs/docs/understanding_cafos_nalboh.pdf.

²⁶ See note 18, *supra*.

²⁷ Burns, R., Xin, H., Gates, R., Li, H., Hoff, S., Moody, L., et al., Tyson broiler ammonia emission monitoring project: Final report (2007) <http://www.sierraclub.org/environmentallaw/lawsuits/docs/ky-tysonreport.pdf>.

²⁸ Smil, Vaclav, *Eating Meat: Constants and changes*, Global Food Security (June 2014) http://www.vaclavsmil.com/wp-content/uploads/Smil_2014.pdf.

²⁹ USDA, *Organic Enforcement*, <http://www.ams.usda.gov/services/enforcement/organic> (last visited Jan. 2, 2016).

It is important, however, to differentiate between “natural” and “organic” labels on meat and poultry. ALDF advocates that the definition of natural “go beyond [current] organic standards,”³⁰ in accordance with the Organic & Natural Health Association’s “initiative to set the standard for the term “natural.”³¹

Specifically, in accordance with the Guides for the Use of Environmental Marketing Claims established by the Federal Trade Commission,³² the FDA should establish comprehensive, species-specific standards that better comport with consumer understanding of the term “natural” (requiring, at minimum, that animals had consistent outdoor access and sufficient space to perform their natural behaviors, but did not receive subtherapeutic antibiotics, other veterinary drugs, or growth hormones). The development of such standards would be eminently feasible, as evidenced by the success of the Animal Welfare Approved (AWA) certification program,³³ which is currently the only independent third-party certifier with “highly meaningful” specific requirements for animal raising.³⁴ AWA also demonstrates that there is great consumer demand for meaningful, species-specific standards for humane animal care and environmental stewardship. Thus, the FDA should implement a program whereby producers who use the “natural” label in meat and poultry must be certified as having met species-specific requirements, and AWA is one potential model for how such a program could be implemented.

ALDF opposes employing the USDA Agricultural Marketing Service (AMS) Process Verified Program (PVP) as the mechanism for certifying “natural” claims on meat and poultry labeling. As currently administered, the PVP certification means only that USDA has audited a producer for compliance with the producer’s own standards whereas consumers may reasonably misconstrue the USDA shield as a certification of compliance with substantive federal standard (a problem noted not just by animal advocates, but meat producers as well³⁵). Indeed, facilities’ food safety procedures been PVP certified by the USDA within days of being cited for serious food safety violations by the FDA.³⁶

³⁰ While current organic standards under the USDA Agricultural Marketing Service’s National Organic Program (NOP) would provide a useful baseline for defining standards for the use of the term “natural,” those standards alone are insufficient to remedy consumer deception. For example, while the NOP requires that animals have “outdoor access,” there is little in the way of specifics as to the duration and quality of outdoor access. *See Organic Foods Production Act of 1990, U.S. Code 7 (2005), §§ 6501 et seq.*

³¹ Organic & Natural Health Association, *New ‘Natural’ Definition Will Go Beyond Organic Standards*, <http://organicandnatural.org/new-natural-definition-will-go-beyond-organic-standards/> (emphasis added).

³² 16 CFR 260, https://www.ftc.gov/sites/default/files/documents/federal_register_notices/guides-use-environmental-marketing-claims-green-guides/greenguidesfrn.pdf

³³ Animal Welfare Approved, *Standards*, <http://animalwelfareapproved.org/standards> (last visited Jan. 2, 2016).

³⁴ Consumer Reports, Greener Choices, *Label Index*, <http://animalwelfareapproved.org/standards> (last visited Apr. 15, 2016).

³⁵ *See* Petition by Tyson Foods, Inc. to USDA to Rescind the Use of Process Verified Labels on Point of Sale Materials (2011), *available at* http://www.fsis.usda.gov/PDF/Petition_Tyson_031811.pdf.

³⁶ *See* Warning Letter, U.S. FDA to Sparboe Farms, Inc. (Nov. 16, 2011); AMS PVP Audit Reports for Sparboe Facilities in Hudson, CO (June 1, 2011), Goodell, IA (May 3, 2011), Litchfield, MN (April 19, 2011), and Humboldt, IA (April 20, 2011).

VI. Conclusion

Given the importance of the term “natural” to consumers as used in meat and poultry product labeling and the likelihood of consumer confusion created by the existing minimal requirements for companies using the term, ALDF and the Center request that the FDA establish species-specific standards for companies who employ the “natural” label. Specifically, the undersigned urge the FDA to prohibit the use of the term “natural” where meat and poultry products are derived from animals that are fed subtherapeutic doses of antibiotics, fed other veterinary drugs for nontherapeutic uses, injected with growth hormones, or confined without outdoor access in spaces that prevent them from performing their natural behaviors.

Respectfully submitted,

Animal Legal Defense Fund
170 E. Cotati Ave
Cotati, CA 94931
info@aldf.org

Center for Biological Diversity
P.O. Box 710
Tucson, AZ 85702-0710
center@biologicaldiversity.org