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**Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852**

CITIZEN PETITION

Consumer Reports Food Safety and Sustainability Center and the undersigned submit this petition under 5 USC 553(e) and 21 CFR 10.25 and 10.30, and the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to issue an interpretive rule prohibiting the “natural” label on foods.

We believe consumers are being misled by the “natural” label and are providing recent national poll data, conducted by the Consumer Reports National Research Center, that underscores this assertion.

The Federal Food, Drug and Cosmetics Act (FFDCA) states that “a food shall be deemed to be misbranded” if “its labeling is false or misleading in any particular” (21 USC §343(a)(1)).

The current policy regarding “natural” used by the FDA, as stated in a 1993 policy, is “nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food.” Yet there is no formal definition and no rule, no verification and virtually no oversight and enforcement of the FFDCA’s requirement for labeling that is truthful and not misleading.

We believe that the difference is drastic between the FDA’s extremely limited policy statement regarding “natural” labeling and what people think the “natural” label should mean.

We have also submitted a citizen petition to the United States Department of Agriculture, which regulates the labeling of meat and poultry products, requesting that the “natural” label be prohibited on those foods as well. Both the Federal Meat Inspection Act and the Poultry Products Inspection Act state, like the FFDCA, that products shall be deemed “misbranded” if labels are

“false and misleading in any particular” (21 USC §601(n)(1)) and 21 USC §453(h)(1)). We believe that the use of the “natural” label on any food currently misleads consumers.

As outlined in detail below, results from our nationally representative survey of consumers, conducted in April 2014 by the Consumer Reports National Research Center, strongly suggest that a majority of U.S. consumers are misled by the “natural” label. Sixty six percent of consumers think “natural” processed food products mean no toxic pesticides were used, 66% think no artificial ingredients or colors were used, 65% think no chemicals were used during processing and 64% think no GMOs were used.

Our survey also covers consumer beliefs and expectations regarding the “natural” label on meat and poultry, which we believe to be relevant since FDA regulates labeling of products with ingredients derived from animal agriculture, including dairy and eggs. Our survey shows that 68% of U.S. consumers think that the “natural” label means that the animal was not given growth hormones, 60% think no antibiotics and other drugs were given to the animals, 64% think that feed did not contain genetically engineered organisms and 60% think the feed contained no artificial ingredients.

When asked what they thought the “natural” label *should* mean, 87% believe no artificial materials or chemicals should be used during processing, 86% believe no artificial ingredients or colors should be used, 86% believe no toxic pesticides should be used, and 85% believe no GMOs should be used.

Eighty nine percent believe no growth hormones should be given to animals raised for food labeled “natural,” 85% believe the animals’ diet should have no artificial ingredients and no GMOs, 81% believe the animal should not be given antibiotics or other drugs, and 66% believe that the animals should not be confined indoors.

These survey results suggest that nearly two-thirds of U.S. consumers are currently misled by the “natural” label on food and nearly 90% expect it to mean much more than it does. We believe that foods with misleading “natural” labels are “misbranded,” as outlined by the FFDCFA.

Our survey results also show that there is widespread consumer interest in foods produced without toxic pesticides, without artificial ingredients, and without genetically modified organisms (GMOs). Given that the FDA currently allows the “natural” label to be used without following any standards and without verification, it is one of the most popular labels. And because there is virtually no enforcement of 21 USC §343 to prevent false and misleading labeling with regards to the “natural” label, there is no limit to the types of foods that can carry the “natural” label.

As a result, consumers have resorted to class action lawsuits. By some estimates, there have been over 200 lawsuits filed in the past several years against food companies making allegedly false

and misleading “natural” claims. Many companies have settled, with settlements as high as \$9 million.

When three judges involved in such cases individually requested clarification from the FDA, the FDA responded that “if FDA were inclined to revoke, amend, or add to this policy, we would likely embark on a public process, such as issuing a regulation or formal guidance, in order to determine whether to make such a change.”

Meanwhile, we have observed a push from the industry to allow the use of the “natural” label on foods that do not represent what consumers believe “natural” should mean. We are aware that our petition follows on the heels of a citizen petition filed by the Grocery Manufacturers Association (GMA) on March 14, 2014, requesting the FDA to issue a regulation authorizing statements such as “natural” on foods that are or contain foods derived from biotechnology. We believe that the GMA petition is out of line with consumer expectations and that consumers demand far more from the “natural” label, in line with what they expect from the “organic” label. As such, we believe that the “natural” label should be banned altogether.

Our survey results reveal that an overwhelming majority of Americans believe that the “natural” label *should* mean that artificial substances or GMOs were not used during the production and processing of the food, and that no antibiotics, growth hormones and artificial feed ingredients were used in animal agriculture . We hereby formally petition the FDA to issue an interpretive rule to ban the misleading practice of labeling foods “natural.”

A. ACTION REQUESTED

We request that the “natural” label be prohibited on food by issuing the following interpretive rule:

The term “natural,” or any derivation of the term, such as “naturally grown,” “naturally sourced” or “from nature,” is vague and misleading and should not be used.

B. STATEMENT OF GROUNDS

To determine whether consumers are currently misled by “natural” labels, and what consumers expect from the label, the Consumer Reports National Research Center conducted a nationally representative survey of U.S. consumers in April 2014. Survey findings support our petition, showing that a majority of consumers are currently misled by the “natural” label, and the vast majority of consumers expect foods labeled “natural” to meet certain requirements, from how they are grown in the field to what ingredients they contain.

For foods derived from animals, survey findings also support our petition. A vast majority of consumers reasonably expect the “natural” label to cover how the animal was raised, its diet, drugs it was administered, whether artificial growth hormones were used, and outdoor access.

Toxic pesticides

There is widespread interest among consumers in reducing pesticide use in agriculture or avoiding pesticide residues. Eighty-nine percent of shoppers say that it is “important” or “very important” to protect the environment from chemicals such as pesticides, and 86% believe that reducing exposure to pesticides in food is either “important” or “very important.”

Our survey results show that consumers are misled by the “natural” label as it is currently used on packaged and processed foods. Sixty-six percent of consumers think that the “natural” label means that no toxic pesticides were used, yet currently, there are no restrictions on the use of pesticides for foods labeled “natural.” Pesticides that are linked to human and environmental health problems, air and water pollution, and endocrine disruption are routinely and widely used on farms growing food that will eventually be sold as “natural.”

The use of industrial, synthetic pesticides in food production is not “natural.” The overwhelming majority of pesticides applied to farm fields are chemicals that have been designed to kill targeted living organisms. These chemicals are not “natural,” neither should farming with these chemicals be considered “natural.”

According to our 2014 survey, 86% of consumers believe that packaged and processed foods sold as “natural” should mean that no toxic pesticides were used.

No artificial ingredients or colors were used

Sixty-six percent of consumers think that the “natural” label on packaged or processed foods means no artificial ingredients or colors were used. Although this consumer perception of the “natural” label is in line with the FDA’s 1993 informal definition of “natural,” the lack of oversight means that many of the foods labeled “natural” contain artificial ingredients and colors.

While the FDA considers all color additives, including caramel color, carmine and annatto, to be “artificial colors,” it is clear that food manufacturers often use these “artificial” color additives in foods labeled “natural.” While these colors may include materials that are “natural” (e.g., corn for caramel color, beetles for carmine, seeds from a tropical tree for annatto), they are often highly processed with synthetic processing aids. Even when no synthetic processing aids are used, the presence of these color additives means that the food does not have its “natural” color.

The FDA already has a policy in place prohibiting the use of any color additives in foods labeled “natural,” although it is not clear how well this is enforced. Consumers Union has a pending petition with the FDA on the use of artificial caramel color in some “natural” labeled foods.

According to our 2014 survey, 86% of consumers think that the “natural” label on packaged and processed foods should mean that no artificial ingredients or colors were used.

No artificial materials or chemicals were used during processing

Our 2014 survey results show that a majority of consumers are misled about the meaning of the “natural” label as it pertains to artificial materials or chemicals used during processing: 65% think that the “natural” label on foods means no artificial processing aids were used.

Yet ingredients in packaged and processed foods, which may appear “natural” when listed on the ingredients list, are routinely processed with chemicals. Canned fruit can be processed with synthetic materials such as potassium hydroxide, to easily peel fruit. Fruits and vegetables can also be treated in storage with chemicals such as chemical ripening agents.

Ingredients that appear in many processed foods are often chemically processed. For example, the vast majority of cooking oils have been extracted with the use of synthetic solvents. Some ingredients in processed foods, such as soy protein isolates and concentrates, are byproducts of cooking oil production and have also been processed with synthetic solvents. All these foods can currently be labeled “natural,” misleading consumers.

These are just a handful of examples of synthetic processing aids that are routinely used in food processing. When foods are labeled “natural,” it suggests to consumers that no chemicals were used during processing. When asked whether the “natural” label should mean that no artificial materials or chemicals were used during the processing, 87% of consumers agreed.

No GMOs were used

Nearly two-thirds of consumers think that the “natural” label on foods means no genetically modified ingredients (GMOs) were used. Again, this shows that the majority of consumers are currently misled by the “natural” label, since GMOs do appear in foods labeled “natural.”

93% of soybeans and 85% of corn in the United States are grown from genetically engineered seed. Genetic engineering is different from conventional breeding: it requires intensive genetic overwriting to allow for genetic changes that cannot occur in nature, such as combining genes of bacteria and viruses with genes of plants, or combining genes from different species of animals.

Genetically engineered crops in processed foods are not “natural.” The vast majority of consumers agree: 85% believe that the “natural” label on processed and packaged foods should mean no GMOs were used.

No antibiotics, growth hormones and other drugs were used

For foods containing ingredients from animals, our survey results show that consumers are misled by the “natural” label as it is currently used. Sixty-eight percent of consumers think that animals raised for meat and poultry sold as “natural” were not given artificial growth hormones, and 60% believe no antibiotics or other drugs were used. This is not the case, and shows consumers are currently misled.

A number of steroid hormone drugs are approved in beef production. These hormones are implanted in beef cattle to speed up growth, and some of the approved drugs are synthetic versions of natural hormones. Products containing meat from these animals can be sold as “natural.” However, consumers reasonably believe that they cannot be since implanting artificial growth hormones to speed up growth is not a “natural” way to raise beef cattle.

Animals raised for “natural” meat and poultry may also be fed sub-therapeutic doses of antibiotics and other drugs daily, regardless of whether they are ill. More than 13.5 million kilograms (nearly 30 million pounds) of antimicrobial drugs were sold and distributed for use in food-producing animals in 2011.

As expressed by the Centers for Disease Control and Prevention (CDC) in a September 2013 report, feeding antimicrobial drugs, including those that are critical to human medicine such as tetracyclines and penicillins, gives rise to antibiotic-resistant human pathogens and raises serious public health concerns.

In a 2007 Consumer Reports National Research Center poll, nearly 9 out of 10 consumers indicated that meat labeled “natural” should come from animals that were raised on a diet without drugs and chemicals.

According to our 2014 survey, 89% of consumers believe that meat sold as “natural” should come from animals that were not given artificial growth hormones, and 81% believe that meat and poultry sold as “natural” should come from animals that were not given antibiotics or other drugs.

No artificial ingredients and GMOs were used in animal feed

Consumers are also misled about the meaning of the “natural” label and the feed of the animals. Currently, feed given to animals whose meat will eventually be sold as “natural” may include genetically engineered corn and soybeans and artificial ingredients. Yet 64% of consumers very reasonably believe that meat and poultry sold as “natural” means the animals were not fed a diet containing genetically engineered organisms, and 60% think that their feed contained no artificial ingredients or colors.

A large portion of livestock feed consists of corn and soybeans, including feed for dairy cows and finishing rations for beef cattle. Not only is a grain-based diet not the natural diet of cattle, which are ruminants that naturally feed on forage and pasture, but the grain in the rations is likely genetically engineered. We do not believe that genetically engineered crops used in animal feed qualifies as “natural.”

The FDA also allows a long list of artificial ingredients in animal feed. By definition, these artificial ingredients are not “natural.” It is also worth noting that many of the artificial substances in the feed can be transferred to the meat, and can end up in the final product that the consumer buys. Artificial ingredients allowed in animal feed include formaldehyde, which can be a component of beef and non-lactating dairy cow feed, propylene glycol, butane, ammonium hydroxide, propylparaben, sulfur dioxide and many others.

Artificial ingredients are even allowed as energy sources for the animals, such as 1,3-butylene glycol, which is allowed as an energy source in pig feed, or protein sources, such as synthetic methionine in poultry feed. Even polyethylene plastic pellets that replace natural sources of fiber and roughage in the diet, can be used in cattle feed.

In poultry feed, some artificial feed additives are used for the purpose of coloring the final product, such as artificial carotenoids that lead to consistently dark yellow or light orange yolk color in eggs laid by confined hens which would otherwise have pale yolks.

In our 2007 survey results, nearly 9 out of 10 consumers indicated that meat labeled “natural” should come from animals that were raised on a diet without artificial ingredients.

According to our 2014 survey, 85% of consumers believe that the “natural” label on meat and poultry should mean that the animals were given a diet that contained no genetically engineered organisms and no artificial ingredients or colors.

Living conditions

Our 2014 survey results show that nearly half of consumers are misled about the meaning of the “natural” label as it pertains to outdoor access of animals raised for “natural” labeled food: 48% think that the animals went outdoors.

Chickens and pigs labeled as “natural” may be raised in crowded barns without outdoor access. This means that the animals were not able to engage in natural behaviors. Animals are routinely physically altered to compensate for destructive behavior that results from unnatural, stressful and crowded living conditions. This includes beak trimming of laying hens, dehorning or disbudding of beef cattle, and tail docking and teeth filing of pigs.

For chickens, foraging and pecking are natural behaviors, and outdoor runs have a much higher number and diversity of stimuli that allow for these natural behaviors than any indoor environment can provide. Outdoor runs also allow the animals to exercise, which benefits their health, and gives the animals access to fresh air and sunshine that are not available in indoor confinement.

When given the opportunity, domestic pigs will spend several hours per day rooting and foraging, feeding on grass, roots, tubers, acorns, nuts, berries and small animals. When confined indoors, the animals are not able to engage in these natural behaviors. Tail docking and teeth filing are common management practices to prevent tail biting, which likely results from frustration due to living in a stressful environment and the inability to engage in natural behaviors.

In our 2007 survey, 83% of consumers expect meat and poultry labeled “natural” to come from an animal that was raised in a natural environment.

According to our 2014 survey, two-thirds of consumers believe that meat and poultry labeled “natural” should come from an animal that was able to go outdoors.

Competition with other labels

Very few foods appearing on supermarket shelves are truly “natural” in ways that consumers expect. Yet, without standards and without verification, the “natural” label is one of the most widely used labels, appearing on foods that are grown with synthetic pesticides and processed with synthetic materials, and that contain genetically engineered and artificial ingredients. The label is essentially meaningless, in addition to being contrary to consumer expectations.

Meanwhile, there are labels that are backed by rigorous standards, oversight, verification and enforcement, and that do aim to reduce the use of toxic pesticides, artificial processing aids, and synthetic ingredients.

The most common of these labels is “organic,” which is regulated by the USDA. Yet even the federal organic standards, which are rigorous, comprehensive and meaningful, allow some synthetics to be used. Our survey also shows that more consumers look for the “natural” label than the “organic” label, likely because they are unaware of the important differences in standards, verification and enforcement between the two labels, yet they expect comparable benefits when it comes to both labels. We believe this widespread confusion and deception can be prevented if the use of the “natural” label were to be prohibited.

Conclusion

The FDA stated in its January 2014 letter to three district judges¹ that “priority food public health and safety matters are largely occupying the limited resources that FDA has to address food matters,” and that dealing with the “natural” label is not a priority for the agency. We believe that both of these things should be a priority for the agency, and urge the FDA to consider addressing the “natural” label.

The FFDCA (21 USC §343) states that labels on food must not be false and misleading, and our survey results show that consumers are currently widely misled by the “natural” label.

A majority of U.S. consumers currently believe the “natural” label means certain requirements were met, such as no toxic pesticides, no GMOs, no antibiotics, no artificial growth hormones, no artificial ingredients, and no chemical processing aids, and a vast majority of U.S. consumers believe that the “natural” label *should* mean no toxic pesticides, no GMOs, no antibiotics, no artificial growth hormones, no artificial ingredients, no chemical processing aids and no indoor confinement of animals.

Rather than setting standards to ensure the “natural” label is truthful and not misleading, as required by the FFDCA, we urge the FDA to prohibit the use of the “natural” label, since other label programs are already in place that come much closer to meeting these consumer expectations and have frameworks for continuous improvement to be made in the standards.

Given the widespread confusion among consumers about the label, and increasing pressure from food manufacturers to use the label in ways that do not meet consumer expectations (i.e. on foods containing GMOs), we urge the FDA to issue an interpretive rule to prohibit the use of the “natural” label on foods.²

C. Environmental Impact

The action requested is subject to a categorical exclusion under 21 CFR 25.30 and 25.32 and therefore does not require the preparation of an environmental assessment.

D. Economic Impact

No statement of the economic impact of the requested action is presented because none has been requested by the Commissioner.

¹ Letter from Food and Drug Administration, Leslie Kux, Assistant Commissioner for Policy, to The Honorable Yvonne Gonzalez Rogers, Jeffrey S. White and Kevin McNulty. January 6, 2014.

² Regardless of whether FDA grants this petition, we believe that the use of the “natural” label on any food misleads consumers and may therefore be actionable under state and federal laws prohibiting misleading labeling and marketing. By filing this petition, we do not give up our right to pursue any remedies available to us under state or federal law.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully Submitted,

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