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Divisions of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Use of the Term “Natural” in the labeling of Human Food Products; Request for Information and Comments - Docket No. FDA-2014-N-1207

Thank you for the opportunity to comment on the Food and Drug Administration’s request for comments on the use of the term “natural” in the labeling of human food products.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers’ associations, distributors, importers, exporters, consultants, retailers and others. OTA’s Board of Directors is democratically elected by its members. OTA’s mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace (<http://www.ota.com/>).

OTA is pleased to have the opportunity to provide FDA with feedback on whether or not to formally define the term “natural” for use in food labeling. The use and oversight of the term “natural” are of significant importance to the organic sector because of the association that consumers make between the “organic” label and labels utilizing the term “natural.” FDA’s decision on how to define and regulate the term “natural” will inevitably have a real impact on the organic label.

There is a significant amount of data currently available demonstrating that consumers view the two label claims as equal or similar. However, unlike the term “natural,” the organic label is a federally regulated, third-party inspected and enforced term that represents a set of codified standards covering production (farming) and handling (processing and manufacturing) practices and labeling requirements. Based on our analysis of labels in the marketplace and the survey data presented in our comments below, we have concluded that “natural” has no clear meaning and FDA should take action to protect consumers from misleading claims.

OTA’s comments are structured to first express the direction OTA believes FDA should take if the end goal is to eliminate confusion and protect consumers from misleading claims on labels. We have also included a list of outcomes we believe absolutely **must not** occur under any circumstance, followed by actions that **must** occur should FDA decide to pursue formal rulemaking and define the term “natural” according to consumer beliefs and expectations. OTA’s comments are based on aggregated consumer data and the identification of actions that may undermine the meaning of the “organic” label and/or duplicate or conflict with existing definitions within the organic regulations.

Directly below is a summary of our comments. Our more detailed comments follow thereafter.

Summary of OTA's Position

Consumers are misled by the term natural

OTA has collected and aggregated a range of available data from consumer research (see Page 4). The data demonstrate that many to most consumers incorrectly believe that “organic” and “natural” have similar meaning or at least share several attributes. More specifically, consumers incorrectly believe that the term “natural,” when used on food labels, comprises **multiple** attributes, such as “no toxic pesticides/fertilizers,” “no GMOs,” “no artificial colors or flavors,” “no artificial ingredients,” “minimally processed,” and “enforced according to a government standard.” The survey data in totality clearly indicate that consumers are confused by the term “natural” and they are misled by its use.

FDA action is needed

FDA has the statutory obligation to protect consumers from misleading claims on food labels. Therefore, we agree that something should be done. However, given the complexity of the situation and limited agency resources, we are uncertain how FDA will be able to: 1) create a definition for “natural” that meets all of consumers’ expectations; **and** 2) be able to **adequately** carry out compliance and enforcement of its use on food labels. Consumer perception and expectation of “natural” are largely consistent with the USDA’s organic regulations, and efforts to create an FDA definition through rulemaking would not only be extremely time-consuming and resource-intensive, it would also be duplicative of the organic regulations and could create regulatory conflicts if definitions and requirements are not aligned.

The term “natural” should be replaced on labels with single-attribute claims

OTA believes the most workable approach for FDA to take is to clarify through **guidance** its preference that, except where already provided for in FDA regulations (e.g. natural flavors), the term “natural” **should not be used** on food labels. Instead we urge FDA to focus its efforts on identifying and defining the ‘single attribute’ claims that may be used on food labels (e.g. “no artificial colors or flavors,” “no synthetic ingredients,” “minimally processed,” “produced without the use of GMOs”) and engage in labeling guidance for the use of each of those single attribute claims on labels and marketing materials. If the term “natural” is to be used, then we request that FDA, in the same guidance, identify and define the single attributes the term “natural” may be associated with and **require** a statement on the package label explaining its meaning. For example: “Natural – no artificial flavors or colors.”

This would be the clearest way to eliminate consumer confusion surrounding the interplay between the terms “natural” vs. “organic” and the misleading use of the term “natural” in the marketplace.

Actions that will negatively impact the organic label and create further consumer confusion

OTA has explored the various directions that stakeholders may want FDA to take and analyzed each one according to its potential impact on both the USDA organic label and certified organic operations. We have identified several potential actions we believe would undermine the meaning of the “organic” brand and ultimately create further confusion in the marketplace. This process has resulted in a list of actions that must and must not occur in order to maintain interagency regulatory consistency, depending on the course of action FDA decides to take.

Under NO CIRCUMSTANCE should the following be allowed:

- FDA must not extend the meaning of “natural,” when used on food labels, to include production methods (i.e. how something is grown). OTA **strongly opposes** such an action because it would

be duplicative of the production standards already covered under USDA's National Organic Program (NOP), potentially create interagency regulatory conflict, and only create increased consumer confusion. Furthermore, we do not believe adequate compliance and enforcement could exist without the establishment of a certification program at FDA similar to the USDA National Organic Program (which would be resource-intensive and duplicative). **For labeling regarding attributes related to production methods (including growing and raising practices), FDA should direct consumers to the organic label.**

- The term “natural” should not be allowed on or associated with ingredients or food products that were genetically modified through the use of modern biotechnology (i.e. GMOs).
- When used on food labels, the term “natural,” and the attributes used to describe it, should not extend beyond the scope of: 1) the source of the ingredient/product (plant, animal, mineral); 2) the composition or content of the ingredient/product; & 3) the extent to which the ingredient/product is processed.
- Terms and subsequent definitions used to describe or define the term “natural” must not conflict or be inconsistent with the same terms and definitions found in the USDA organic regulations. Potential examples include “synthetic,” “processing” and “genetic engineering/GMOs.” This would only create additional consumer confusion and inconsistency between federal agencies.

The following MUST occur should FDA decide to pursue a formal definition for “natural:”

- Any policy, guidance or regulatory definition offered by FDA should specify that all labels utilizing the term “natural” must include a statement explaining the meaning (such as “no artificial flavors or colors,” “minimally processed,” “no artificial ingredients”). By requiring such clarification, “natural” will be understood in its particular context—reflecting whatever single attribute applies to that product.
- Should FDA decide to revise its policy and define “natural” beyond its current scope or the scope of USDA Food Safety and Inspection Service’s (FSIS) policy, then advocates and FDA should proceed through program establishment and rulemaking and ensure that processes are set up that include verification and enforcement mechanisms, including third-party certification, similar to the National Organic Program (NOP) for “certified organic.” Anything less would create an unfair market advantage for “natural” over “organic,” and undermine the validity of the “natural” claim.

Again, OTA strongly believes consumer confusion would best be eliminated if clearly defined single-attribute claims, such as “contains no artificial ingredients” or “produced without the use of genetic engineering” appeared on product labels **instead** of the term “natural.”

We offer the following more detailed comments:

I. Do consumers associate, confuse or compare the term “natural” with “organic?”

FDA is asking whether the term “natural,” when used on food labels, is perceived by consumers the same way as “organic” and also whether “natural” is perceived by consumers to be “better” (or not as

good) as “organic.” In order to answer these questions, OTA has aggregated a range of available data from consumer research. We also fielded a consumer study on these questions in December 2015 with May Media, publisher of *Kiwi Magazine* and research partner for OTA’s *U.S. Families’ Organic Attitudes and Beliefs Study*. The following is a summary of the data:

MAY MEDIA

Background: We conducted a survey in December 2015 with May Media, publisher of *Kiwi Magazine* and research partner for OTA’s *U.S. Families’ Organic Attitudes and Beliefs Study*. The survey looks at parents’ understanding and perception of the meaning of the terms “natural” and “organic.”

- More than 3,400 parents responded to the survey.
- This particular group is highly knowledgeable about the attributes found in organic foods, although they indicate a lesser degree of knowledge about natural foods – often conflating attributes of organic products with those of natural products.
- Almost all of the respondents had purchased organic (97%) or natural (99%) products in the past six months.
- 71% of respondents think that natural products are “grown without the use of toxic pesticides or fertilizers,” 70% believe that they are “produced without the use of genetically modified organisms” and 54% think that they are “inspected, certified and enforced according to government standards.” 82% of those surveyed admitted that they confused organic and natural products at least some of the time.
 - **Methodology:** *The target audience consisted of KIWI Magazine’s “Moms’ Meet Ambassadors” community. The survey population of more than 3,400 respondents completed the online questionnaire in December 2015.*

Open-ended comments yielded some interesting insights as well:

- “I had no idea there was a difference. I always assumed they were the same thing!”
- “When I shop for natural and organic foods, I sometimes find it hard to see the difference between natural and organic products. The food labels are confusing.”
- “It can be very confusing between organic and natural. I think the term natural is used too freely and without clarifications. People see that term and assume it is organic.”

OTA’s U.S. ORGANIC FAMILIES’ ORGANIC ATTITUDES AND BELIEFS STUDY

Background: OTA has been conducting a consumer survey annually since 2009, but only in the 2010 and 2013 studies did we ask questions specific to consumer perception of “natural.” These results, however, support the findings from the May Media Group study above and the additional surveys below, that consumer confusion about the difference between organic and natural has remained or even increased.

- 2010 Study:
 - On average, eight in ten parents believe foods labeled as “natural” also follow each of the standards and requirements established for the organic foods category.

- 36% believe that “natural” fruits and vegetables are grown without synthetic pesticides or fertilizers.
- 38% believe that “natural” foods are not genetically engineered.
- Four in ten parents “agree strongly” that natural “food products do not contain artificial ingredients” (42%) or natural “foods are produced without the use of antibiotics or synthetic hormones” (40%.) These are two of the highest rated requirements for organic foods as well.
- Many parents also believe systems are in place to certify natural foods, including a system to “certify that specific practices are used for food products” (32% “agree strongly”), and to “certify label claims” (32% “agree strongly”) or “certify growers” (30% “agree strongly”) by an organization accredited by USDA.
 - **Methodology:** *The target audience consists of KIWI Magazine’s Parents’ Advisory Board (PAB), supplemented with a national online panel of U.S. households. The total sample of 763 reflects the target population of U.S. households online at a confidence interval of +/- 5% at the 95% confidence level.*
- 2013 Study:
 - Most parents (68%) feel natural foods are on par with organic foods nutritionally. One quarter (24%) “strongly agree” that “foods labeled as ‘all natural’ are just as nutritious as organic foods,” and four in ten (44%) “agree somewhat” with this statement.
 - **Methodology:** *The target audience consists of KIWI Magazine’s Parents’ Advisory Board (PAB), supplemented with a national online panel of U.S. households. The total sample of 1,239 reflects the target population of U.S. households online at a confidence interval of +/- 3% at the 95% confidence level.*

CONSUMER REPORTS NATIONAL RESEARCH CENTER *Natural Food Labels Survey – 2015*
Nationally Representative Phone Survey

- **Background:** Formed as an independent, non-profit organization in 1936, Consumer Reports serves consumers through unbiased product testing and ratings, research, journalism, public education, and advocacy*.
- According to research conducted by Consumer Reports in December 2015, most consumers think that the natural label on meat and poultry currently means that no artificial ingredients or colors were added to the meat or poultry (65%), no artificial growth hormones were used (64%), the animals' feed contained no artificial ingredients or colors (61%), the animals' feed contained no GMOs (59%), and no antibiotics or other drugs were used (57%). A greater percentage feel that this label should mean that no artificial ingredients or colors were added to the meat or poultry (85%), no artificial growth hormones were used (87%), the animals' feed contained no artificial ingredients or colors (83%), the animals' feed contained no GMOs (81%), and no antibiotics or other drugs were used (82%).
- While half think that the natural label on meat and poultry currently means that the animals went outdoors, nearly 7 out of 10 think that this label should mean this. Many consumers think that the

natural label on packaged/processed foods currently means that no toxic pesticides were used (63%), no artificial materials or chemicals were used during processing (62%), no artificial ingredients or colors were used (61%), and no GMOs were used (60%). An even greater percentage feel that this label should mean that no toxic pesticides were used (84%), no artificial materials or chemicals were used during processing (85%), no artificial ingredients or colors were used (84%), and no GMOs were used (82%).

- Forty-five percent of consumers believe that the “natural” label is verified.
 - **Methodology:** *This survey was fielded by Opinion Research Corporation on behalf of Consumer Reports. The survey was conducted in December 2015. A representative sample of 1,005 U.S. adults was selected by means of random-digit dialing, and they were invited to interview by phone. The data were statistically weighted so that respondents in the survey are demographically and geographically representative of the U.S. population. The margin of error is +/- 3 percentage points at a 95% confidence level.*
**According to information gathered from the organization’s website (www.consumerreports.org) on April 18, 2016.*

ORGANIC & NATURAL HEALTH ASSOCIATION

Background: The Organic & Natural Health Association was created to provide collaborative leadership in this dynamic market, creating standards, facilitating research and being an industry advocate through a partnership between companies and consumers*.

- Thirty-six percent of American adults do not believe there is any difference between “organic” and “natural”
- Forty-six percent think that natural is a term regulated by the U.S. government.
- About half of U.S. consumers perceive that “natural” means “no pesticides,” or “no-GMOs.”
 - **Methodology:** *The Natural Marketing Institute (NMI) conducted an online research study among a representative sample of 1,005 U.S. consumers. The margin of error at 95% confidence was +/- 3.1%.*
**According to information gathered from the organization’s website (www.organicandnatural.org) on April 18, 2016*

ANALYSIS OF CONSUMER DATA

The survey data in totality demonstrates that consumers are confused by the term “natural,” they associate the term “natural” with “organic,” and they are misled by its use.

The data reveal that many to most consumers are being misled because they inaccurately believe that “organic” and “natural” have similar meaning or at least share several attributes. More specifically, consumers inaccurately believe that the term “natural,” when used on food labels, comprises **multiple** attributes, such as:

- “No toxic pesticides/fertilizers”
- “No GMOs”
- “No artificial colors or flavors”
- “No artificial/synthetic ingredients”

- “Minimally processed”
- “Regulated and enforced according to a government standard.”

However, these beliefs are not consistent with FDA’s informal policy on the use of the term natural, which is “to mean that nothing artificial or synthetic (including colors regardless of source) is included in, or has been added to, the product that would not normally be expected to be there.” (56 FR 60421 at 60466) The informal policy on the use of the term “natural” falls significantly short of what consumers think it means.

Consumers have clearly and repeatedly communicated confusion and frustration over the “natural” label. As food companies and marketers currently utilize it, the term has misled consumers by implying a slate of benefits that are simply not borne out by current regulations or verified under a product certification program.

II. Should FDA define, through rulemaking, the term “natural?”

Consumer perception and expectation of the term “natural” are largely consistent with the USDA’s organic regulations (7 CFR 205). Efforts to create regulations for “natural” with equal meaning, including adequate compliance (third-party certification) and enforcement, would not only be extremely time-consuming and resource-intensive, it would be duplicative of the organic regulations and could create regulatory conflicts if definitions and requirements are not aligned.

FDA does, however, have the statutory obligation to protect consumers from misleading claims on food labels. Therefore, we believe that something must be done.

OTA believes the most workable approach for FDA to take is to clarify through **guidance** its preference that, except where already provided for in FDA regulations (e.g. natural flavors), the term “natural” **should not be used** on food labels. Instead, we urge FDA to identify and define the ‘single attribute’ claims that may be used on food labels (see Page 10).

Defining the term “natural” in and of itself is extremely challenging and will always be met with differences in opinion. An equally needed but more manageable approach – and one that would go further to alleviate consumer confusion – is to provide guidance on the use of the following (or similar) single attribute claims that may be used in place of the term “natural”:

- “Produced without the use of genetically modified ingredients”
- “No artificial colors or flavors”
- “No artificial/synthetic ingredients”
- “Minimally processed”

The USDA organic regulations provide certified organic food companies with a transparent set of codified, third-party inspected and enforced standards by which to produce, handle and label food products. The regulations also include definitions for “processing,” “non-synthetic,” “synthetic,” and “excluded method.” This allows companies to label their products “100% organic,” “organic,” or “made with organic (ingredients or food groups)” and, if they choose, to spell out the attributes the organic label represents. This can be done according to codified standards and definitions with regulatory oversight.

This entire system provides industry and consumers with clarity around the meaning of the organic label and the attributes the organic claim represents.

Companies that are not certified, on the other hand, do not have the same guidance or oversight. Accordingly, OTA strongly urges FDA to focus its efforts on identifying and defining the ‘single attribute’ claims that may be used on food labels, and on engaging in labeling guidance for the use of those claims on labels and marketing materials.

If the term “natural” is to be used, then we strongly urge FDA in that same guidance to identify and define a narrow scope of attributes that the term may be associated with (see Pages 10 -11) and **require** a accompanying statement on the package label explaining its meaning.

- Example: “Natural – no artificial flavors or colors.”

This approach would give companies and marketers greatly needed guidance on the use of single attribute claims that can be monitored by FDA through label and ingredient deck review. We also believe this would be the most definite way to eliminate the misleading use of the term “natural” in the marketplace, and also to eliminate consumer confusion surrounding the terms “natural” vs. “organic.”

III. What actions must FDA absolutely not pursue?

FDA is asking whether certain production practices used in agriculture (e.g. genetic engineering, mutagenesis, hybridization, the use of pesticides, or animal husbandry practices) should be a factor in defining “natural.” As mentioned earlier, our primary desire is that no FDA regulatory action in this area undermine the meaning of the USDA “organic” label and/or duplicate or conflict with existing definitions within the organic regulations. OTA has carefully considered existing consumer data on the meaning of “natural” alongside the scope of USDA’s organic regulations and the definitions and standards contained therein. Accordingly, we have identified four outcomes that **must not occur** given any course of action that FDA might pursue.

a. FDA should not extend the meaning of “natural” to include production (farming) methods

FDA should not extend the meaning of “natural,” when used on food labels, to include production methods (i.e. how something is grown). OTA **strongly opposes** such an action because it would be duplicative of the production standards already covered under USDA’s National Organic Program, potentially create interagency regulatory conflict, and only create increased consumer confusion. Furthermore, we do not believe adequate compliance and enforcement could exist without the establishment of a certification program at FDA similar to USDA NOP with third-party accredited certifiers and annual on-site inspections of each operation and site (which would be resource-intensive and duplicative).

Survey data demonstrate that many to most consumers think the “natural” label represents several attributes related to production practices. We know, however, from a regulatory perspective, this is not true.

The organic label, on the other hand, does represent those attributes related to production practices. The organic label was established through a ten-year public process that led to a federal regulation managed under a designated USDA certification and enforcement program. The organic label is

unique in that it is the only federally enforced food label claim that comprises a suite of attributes covered under both farming and processing standards.

The following production (farming) practices are codified in the federal **organic** regulations:

- Applies to agricultural products only {7 CFR 205.102}
- “Organic Production” is defined as “A production system that is managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity. {7 CFR 205.2 – Terms defined}
- Operators are required to maintain or improve the natural resources of the operation including soil and water quality {7 CFR 205.200}
- Operators are required to maintain and build healthy soil {7 CFR 205.203}
- Prohibits the use of synthetic inputs unless they have been reviewed against the Organic Foods Production Act (OFPA) criteria (not harmful to human health or the environment and necessary because of the unavailability of wholly natural substitutes) and appear on the National List of Approved or Prohibited Substances {OFPA SEC. 2118 [7 U.S.C. 6517 and 6518] and 7 CFR 205.601 and 205.602}
- Prohibits the use of pesticides or fertilizers that are harmful to human health or the environment {OFPA SEC. 2118 [7 U.S.C. 6517 and 6518]}
- Prohibits the use of excluded methods (genetic engineering/genetically modified organisms) {7 CFR 205.105}
- Requires outdoor access for all livestock and access to pasture for ruminants {7 CFR 205.239 and 205.240}
- Prohibits the use of antibiotics, growth hormones and mammalian or poultry slaughter by-products {7 CFR 205.237 and 205.238}

If natural is to comprise those production practices, FDA would need to create a duplicative and resource-intensive regulatory scheme and enforcement program, including public input. Rather than do that, OTA concludes that for attributes related to production (growing and raising) practices, FDA should direct consumers to the existing USDA organic label and the public process established to maintain and uphold the organic standards.

b. The term “natural” should not be allowed on genetically modified products

The term “natural” should not be allowed on or associated with ingredients or food products that were genetically modified through the use of modern biotechnology (i.e. Genetically Modified Organisms (GMOs)). Defining genetically modified products as “natural” would not only contradict the beliefs and expectations of consumers, it would create a conflict with the organic regulations and the basis for prohibiting GMOs in organic agriculture.

Consumer data over the past five years demonstrate that *at least* half of consumers believe that “natural” means “non-GMO.” OTA’s recent May Media study shows that 70% of parents think that natural products are “produced without the use of genetically modified organisms” and data from the 2015 Consumer Reports National Research Center study show that 85% of consumers expect the term

“natural” to mean GMOs were not used. Data also demonstrate that the consumers believe “natural” approaches GMOs in the same way as “organic.”

FDA can learn from the lesson the organic sector learned on this topic when USDA’s NOP received over 250,000 comments on its first proposed rule that would have allowed the use of genetic engineering in foods certified as organic. After learning that consumers did not expect “organic” foods to be made using GMOs, the proposed rule was withdrawn and a second proposed rule followed explicitly prohibiting the use of excluded methods¹ (GMOs) in the production and handling of NOP certified products. That prohibition has always been in the final rule.

The basis of the prohibition on GMOs found in the organic regulations, consistent with public outcry, is that the methods used to genetically modify organisms are not possible under **natural** conditions or processes and therefore are not compatible with organic farming and handling. To say that the term “natural” may be applied to genetically modified products would imply that genetically modified products are produced under natural conditions. Consistent with consumer preference and the organic regulations, OTA believes that the term “natural” may only be associated with products that are produced using traditional breeding and selection techniques. We do not anticipate that consumers and/or organic stakeholders will respond favorably to a proposal that would allow for the use of genetic engineering in products labeled as “natural” any differently than was experienced by USDA’s National Organic Program in 1997.

c. The scope of “natural” when used on food labels should not extend beyond the FSIS policy

The most critical consideration when developing a formal definition for the term “natural” is how FDA will be able to provide adequate regulatory oversight. The more complex the definition and the wider it is in scope and meaning, the more agency resources will be needed to ensure effective compliance and enforcement.

OTA does not believe the agency should create a definition of “natural” that is similar to the “meaning” and/or labeling requirements of the National Organic Program without also creating a compliance and enforcement program of the same caliber as USDA NOP. However, this would duplicate regulatory resources, because, as stated earlier, most of the attributes consumers associate with “natural” are already covered under the organic regulations.

Instead, OTA urges FDA to clarify that the term “natural,” when used on a food label, may be associated only with the **source** and/or **content** of the ingredient or product it is referring to and how it was processed. More specifically, the scope of the term “natural” and the single-attribute claims associated with it should be limited to the following:

- 1) The source of the ingredient(s) (e.g. plant, animal, mineral);
- 2) The composition or content of the ingredient/product (e.g. no artificial colors); and

¹ *Excluded methods.* A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

- 3) The extent to which the ingredient/product is processed (e.g. minimally processed).

Limiting the scope of “natural” and associated claims to “**source**” and “**product content**” is consistent with USDA’s FSIS, and it would allow FDA to effectively determine compliance through label review and desk audit. We believe this is a realistic path forward and one that will avoid duplication or conflict with the organic standards.

This, in turn, would allow FDA to pursue OTA’s preferred course of action as follows:

1. FDA explains, in guidance, its preference that the term “natural” should not be used.
2. FDA identifies and defines the ‘single attribute’ claims that may be used instead (according to the scope above) and engages in labeling guidance for their use on labels and marketing materials.
 - o “No artificial colors or flavors”
 - o “No artificial ingredients”
 - o “Minimally processed”
 - o “Produced without the use of biotechnology/genetic engineering”
3. FDA explains that *IF* companies choose to use the term “natural,” then the term must be connected to a statement on the package label explaining its meaning.
 - a. Example: Natural – No artificial colors or flavors.

OTA agrees that “natural” is extremely difficult to define. We believe that its derivatives, the single-attribute claims associated with “natural,” are also in need of further definition and offer the most reasonable place for FDA to focus its efforts. Moreover, they are clearly responsive to consumer demands and confusion. Within the scope of meaning we have described above, we believe that consumer confusion will best be eliminated if companies plainly and simply state the attribute(s) they wish to communicate. Accordingly, we believe FDA should develop definitions and guidance on the use of the single attribute claims, which will allow food companies to send – and consumers to receive – a clear and consistent message that can be easily understood and adequately enforced.

d. FDA terms and definitions must be consistent with USDA’s organic regulations

In the course of defining or providing guidance on the term “natural” and its associated attributes, FDA will likely use terms that are already defined in the organic regulations. In order to avoid additional consumer confusion and regulatory inconsistency between federal agencies, it is critical that terms and subsequent definitions used to describe or define the term “natural” are consistent with the same terms and definitions found in the organic regulations.

OTA respectfully requests that FDA utilize the definitions found in the organic regulations at 7 CFR 205.2. We respectfully request that any guidance or rulemaking pursued remain consistent with the following:

Excluded methods. A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the

positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

(Organic) Processing. Mechanical or biological methods, including but not limited to cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, distilling, extracting, slaughtering, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing, and the packaging, canning, jarring, or otherwise enclosing food in a container may be used to process an organically produced agricultural product for the purpose of retarding spoilage or otherwise preparing the agricultural product for market.

Non-synthetic (natural). A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, non-synthetic is used as a synonym for natural as the term is used in the Act.

Synthetic. A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

IV. What actions MUST occur should FDA decide to pursue a formal definition for “natural?”

OTA strongly believes consumer confusion would best be eliminated if clearly defined single-attribute claims, such as “contains no artificial ingredients” or “produced without the use of genetic engineering” appeared on product labels **instead** of the term “natural.”

Should FDA be persuaded to pursue rulemaking, the following outcomes must occur:

1. Labels must include a statement explaining the meaning of the term “natural”

As explained earlier, **any policy, guidance or regulatory definition** offered by FDA should specify that all labels utilizing the term “natural” must include a conjunctive statement explaining the meaning (e.g. natural - “no artificial flavors or colors”). By requiring such clarification, “natural” will be understood in its particular context – reflecting whatever single attribute it in fact means on that package.

2. Third-party certification and a enforcement program

Should FDA decide to revise its policy and define “natural” beyond its current scope or the scope of USDA’s FSIS policy, then legitimate oversight of the term must be fully established. To simply define “natural” and establish labeling guidelines without a proactive and robust compliance system would not respond to consumers’ belief that “natural” should be “inspected, certified and enforced according to government standards.” Moreover, it would create a “natural” label without any of the rigors of existing food certification, such as the organic label and the National Organic Program certification process.

If FDA is persuaded to offer a formal definition consistent with consumer beliefs and expectations, then advocates and FDA should proceed through program establishment and rulemaking and ensure that processes are set up that include verification and enforcement mechanisms, including third-party certification, similar to the National Organic Program for “certified organic.” Anything less would create further consumer confusion and undermine the validity of the “natural” claim.

V. What can be done to ensure that consumers have a consistent and accurate understanding of the term “natural” in food labeling to ensure that it is not misleading?

The organic sector has the experience to know that the use of a single term, such as “organic,” to represent multiple attributes and practices on a wide range of products, requires trust in a label that must be supported and backed by transparent standards, product certification and federal enforcement. It also requires significant consumer education. The organic sector has spent over 20 years educating consumers on the meaning of the organic label, and unfortunately, consumer confusion persists.

Our efforts to educate consumers on the term “organic” are constantly impeded by the prolific use of the term “natural”, and the fact that consumers inaccurately conflate the term “natural” with the “organic” label. The lack of clarity and education on the term “natural” not only misleads consumers into thinking they are getting more than they are paying for when they buy a product labeled “natural,” it creates an unfair situation for the certified organic farmers and handlers who go the distance to offer a product that is certified and enforced to a set of codified standards.

Consumers need to have a clear understanding of the meaning behind “organic” vs. the meaning behind “natural.” They need to be able to recognize each label claim for what it is and what it is not. The organic sector and USDA’s National Organic Program will continue to educate consumers on the meaning of the organic label. OTA strongly believes that the best action FDA can take to ensure that consumers have a consistent and accurate understanding of the term “natural” is to eliminate or significantly narrow its use in the marketplace in favor of single attribute claims, or, go the full distance and create a standard and robust third-party certification program similar to the National Organic Program.

OTA recognizes that whatever FDA decides to do will take a great deal of time. Given the amount of consumer confusion that exists in the marketplace, OTA respectfully requests that FDA immediately invest in education and outreach to help consumers and marketers understand the current regulatory status of the term “natural.” In the absence of a formal definition, FDA should issue guidance expressing its preference that the term not be used as expressed in Section III(c) of our comments and summarized below.

Conclusion

The Organic Trade Association’s *2014 Organic Industry Survey* shows the industry has grown from \$11.6 billion in 2004 to \$39 billion in 2014, with an annual growth rate of about 12 percent. This growth is made possible by consumer trust in the “organic” label and the fact that is tied to a codified and transparent set of standards that are verified through third-party certification and enforced by USDA. Allowing companies to use the term “natural” in a way that can be conflated with “organic” by consumers, misleads consumers about the nature of the food they purchase for their families, and free-rides on the hard work of the certified organic industry in creating, abiding by, and educating consumers about a robust set of standards.

OTA respectfully requests that FDA address the situation as follows:

1. FDA explains, in guidance, its preference that the term “natural” should not be used.
2. Instead, companies should use ‘single attribute’ claims that are associated with the term “natural” in accordance with the following scope of meaning:
 - o The source of the ingredient/product (e.g. plant, animal, mineral);
 - o The composition or content of the ingredient/product (e.g. no artificial colors); and
 - o The extent to which the ingredient/product is processed (e.g. minimally processed).
3. FDA engages in labeling guidance (including definitions) for the use of the following single-attribute claims on labels and marketing materials:
 - o “No artificial colors or flavors”
 - o “No artificial ingredients”
 - o “Minimally processed”
 - o “Produced without the use of biotechnology/genetic engineering”
4. FDA explains, in the same guidance, that **IF** companies choose to use the term “natural” according to the scope defined in #2 above, then the term must be connected to a statement on the package label (as per #3 above) explaining its meaning.

Example: Natural – No artificial colors or flavors.
5. FDA ensures that any terms and definitions used to describe or define the attributes associated with “natural” are consistent with the same terms and definitions found in the organic regulations.
6. FDA immediately invests in consumer education and outreach to help consumers and marketers understand the current regulatory status of the term “natural.”

In closing, OTA appreciates the opportunity to provide comments on behalf of our members across the supply chain and the country.

Respectfully submitted,



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