
Panel on Defining Healthy and Natural

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IFT Food Laws and Regulations Division



“Natural”

What is “Natural?”

- From a food science perspective, it is difficult to define a food product that is ‘natural’ because the food has probably been processed and is no longer the product of the earth. That said, FDA has not developed a definition for use of the term natural or its derivatives. However, the agency has not objected to the use of the term if the food does not contain added color, artificial flavors, or synthetic substances.



“Natural” – What Does It Mean?

- Perceptions:
 - Healthier or more nutritious?
 - More wholesome?
 - Safer?
 - Fresh or unprocessed?
 - Organic?
 - Better for the environment?

Regulation of Natural – Background

- USDA FSIS “Natural” Claims

- 1982 Policy Memo:
 - Does the product contain an artificial flavor/flavoring, a coloring ingredient, a chemical preservative, or any other synthetic or artificial ingredient?
 - Is the product, and its ingredients, only minimally processed?

	United States Department of Agriculture	Food Safety and Inspection Service	
			POLICY MEMO 055
To:	Branch Chiefs, SLD		NOV 22 1982
From:	 Robert G. Hibbert, Director, SLD		
Subject:	Natural Claims		

USDA FSIS “Natural” Claims

- Change to FSIS Policy in 2005
- If product contained sugar, sodium lactate from a corn source at certain levels, or natural flavorings from oleoresins or extracts, a “natural” claim could be made
 - FSIS was challenged on this; FSIS reversed the determination
- 2006 - Notice of petition and public meeting; request for comments: Definition of the term “Natural”
 - 71 Fed. Reg. 70503 (Dec. 5, 2006)

USDA FSIS “Natural” Claims

- December 2006 FSIS Public Meeting:
 - ~12,000 comments received
 - FSIS takeaways:
 - Need for rulemaking
 - Multifunctional ingredients
 - Nontraditional food processing methods
 - Enhanced products
- Proposed Rule on Natural Labeling – “around the corner” since 2008

FDA and “Natural”

- 1988 - FDA informally articulated its opinion on the use of the term “natural”
- The Agency considers “natural” 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. For example, the addition of beet juice to lemonade to make it pink would preclude the product from being called “natural.”

FDA and “Natural”

- 1993 - FDA announced its decision to not define the term “natural” due to limited resources and other priorities. FDA maintained its 1988 policy:
 - Not to restrict the use of “natural” except for added color, synthetic substances, and flavors
 - “Natural” meaning nothing artificial or synthetic (including all color additives regardless of source) has been included in or added to a food that would not normally be expected to be in the food
 - 1993 Federal Register - 58 Fed. Reg. 2407 (Jan. 6, 1993)

FDA and “Natural”

- 1993 Federal Register - 58 Fed. Reg. 2407 (Jan. 6, 1993)
- “Minimal processing” includes
 - Processes that are familiar to consumers and can be performed at home (grinding, baking)
 - Traditional processes (smoking, roasting, freeze-drying, fermentation, separation of components)
 - Processes that do not fundamentally alter a raw food or material
- FDA’s regulations on natural flavor should remain unchanged
- Note: refers only to processing – not origin of ingredient

FDA Long-standing View on “Natural”

- FDA does not encourage use of “natural” because:
 - It could be potentially ambiguous and/or
 - It may unjustifiably imply superior quality or safety
- FDA evaluates appropriateness of use of “natural” on a case-by-case basis
 - FDA recognizes complexity of issue
 - Application of FDA’s policy
 - Presentation in the context of entire label

Codex's Efforts to Develop Guidelines for the Use of "Natural"

- Terms such as "natural," "pure," "fresh," "homemade," "organically grown," and "biologically grown," when they are used, should be in accordance with the national practices in the country where the food is sold. The use of these terms should be consistent with the prohibitions set out in Section 3.
(CAC/GL 1-1979 (Rev. 1-1991), Section 5.1(iii))
- **1990** Discussion on "natural" is initiated at the Codex Coordinating Committee for North America and the Southwest Pacific (CCNASWP)
- **1990** Executive Committee of the CAC endorses CCNASWP proposal and forwards the issue to CCFL
- **1990** CCFL considered draft guidelines
- **1993** CCFL continued its consideration of revised draft guidelines
- **1994** CCFL decided to discontinue consideration of the issue

Back to the Future ...

- Three district courts requested FDA issue an administrative determination on the question of whether food products containing ingredients produced using bioengineering may be labeled as “Natural,” “All Natural,” and/or “100% Natural.”
- Four citizen petitions have been filed requesting FDA to define or prohibit the term:
 - 2006: Sugar Association
 - 2007: Sara Lee
 - 2014: GMA
 - 2014: Consumers Union

Two BIG Questions by FDA

- Should we define, through rulemaking, the term “natural?” Why or why not?
- Should we prohibit the term “natural” in food labeling? Why or why not?

Questions for Panel

- What are the public health benefits of defining the term “natural?”
- Should “natural” have some nutritional benefit associated with it? If so, what should be the benefit?

Questions for Panel

- If we define the term "natural," what types of foods should be allowed to bear the term?

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- If we define the term "natural," what types of foods should be allowed to bear the term?
 - Only raw agriculture commodities?
 - Single ingredient foods (e.g. bottled water)?
 - Multi-ingredient foods?

Questions for Panel

- If multi-ingredient foods should be able to bear the term, what type(s) of ingredients would disqualify the food from bearing the term?

Questions for Panel

- Should manufacturing processes be considered when a food can bear the term “natural?”
- Should certain production practices used in agriculture, for example, genetic engineering, mutagenesis, hybridization, the use of pesticides, or animal husbandry practices, be a factor in defining “natural”?
- Should the term only apply to “unprocessed” or “minimally processed” foods?

“Healthy”

Definition of healthy

- The definition in 21 CFR 101.65(d) establishes the parameters for use of the implied nutrient content claim “healthy” or related terms (such as “health”, “healthful”, “healthfully”, “healthfulness”, “healthier”, “healthiest”, “healthily”, and “healthiness”) on the label or in labeling of a food to suggest that a food, because of its nutrient content, may be useful in creating a diet that is consistent with dietary recommendations, if the food meets certain nutrient conditions, and the claim is made with an explicit or implicit claim or statement about a nutrient (e.g., “healthy, contains 3 grams of fat”).

Current Conditions for the Use of “Healthy”

Food	Seafood/Game Meat	Meal/Main Dish
Low Fat	TOTAL FAT < 5 g fat/RACC & /100g	Low fat
Low Saturated Fat	SATURATED FAT < 2 g sat fat /RACC & /100g	Low Sat fat
<480 mg/RACC & l.s.; or /50 g, if RACC is small	SODIUM <480 mg/RACC & low sodium; or /50 g, if RACC is small	< 600 mg/l.s.
<disclosure level	CHOLESTEROL < 95 mg/RA & /100 g	< 90 mg/l.s.

l.s.=labeled serving;RACC=Reference Amounts Currently Consumed per eating occasion

Current Requirements for a “Healthy” Claim

	Individual Food	Seafood/Game Meat	Meal/Main Dish
<i>TOTAL FAT</i>	low fat	< 5 g fat /RACC & /100g	low fat
<i>SATURATED FAT</i> >	low sat fat	< 2 g sat fat /RACC & /100g	low sat fat
<i>SODIUM</i>	≤ 480 mg /RACC and /l.s.; or /50 g, if RACC is small	≤ 480 mg /RACC and /l.s.; or /50 g, if RACC is small	≤ 600 mg /l.s.
<i>CHOLESTEROL</i>	≤ disclosure level	< 95 mg /RACC & /100 g	≤ 90 mg /l.s.
<i>BENEFICIAL NUTRIENTS</i>	Contains at least 10% of DV /RACC for vitamins A, C, calcium, iron, protein, or fiber except: raw fruits and vegetables; or a single ingredient or mixture of frozen or canned single ingredient fruits and vegetables (may include ingredients whose addition does not change the nutrient profile of the fruit or vegetable); enriched cereal-grain products that conform to a standard of identity in <i>21 CFR 136, 137, or 139</i> .	Contains at least 10% of DV /RACC for vitamins A, C, calcium, iron, protein, or fiber	Contains at least 10% of the DV /l.s. of two nutrients (for a main dish product) or of three nutrients (for a meal product) of vit. A, vit. C, calcium, iron, protein, or fiber.
<i>FORTIFICATION</i>	Per 21 CFR 104.20	Per 21 CFR 104.20	Per 21 CFR 104.20

Don't forget the Mandatory Disclosure Statements

- Required when:
 - > 13 g fat
 - > 4 g sat fat
 - > 60 mg cholesterol
 - > 480 mg sodium
- These are same levels used to disqualify food from bearing a “health” claim

Healthy: Consumers' Description

- Food and Health Survey, International Food Information Council (IFIC), 2016

Food and Health Survey, 2016*

- For one-third of consumers, a healthy food is defined, in part, by what it does not contain.
- A healthy eating style is most often defined by moderation and including certain “healthy” foods.

*International Food Information Council; FoodInsight.org

Food and Health Survey, 2016*

- How much of an impact do the following have on your decision to buy foods and beverages?
- *Taste*---84%
- *Price*---71%
- *Healthfulness*---64%
- *Convenience*---52%
- *Sustainability*---41%

*International Food Information Council; FoodInsight.org

Food and Health Survey, 2016*

How do you define a Healthy eating style?

The right mix of different foods	51
Limited or no artificial ingredients or preservatives	41
Natural foods	37
Can easily be incorporated into my daily routine	36
Flexible and easy to maintain over time	26
Organic foods	25
Eating only foods I define as healthy	23

*International Food Information Council; FoodInsight.org

Request for Information and Comments

- **Use of the Term “Healthy” in the Labeling of Human Food Products; Request for Information and Comments**
- [Food and Drug Administration on 09/28/2016](#)
- Comment period has been extended into April, 2017

Implied Claims

- Claims about a food or ingredient or method of preparation that suggests that the nutrient or ingredient is absent or present in a certain amount
 - or
- Claims about a food that suggests a food may be useful in maintaining healthy dietary practices and which are made with an explicit claim (e.g., “healthy, contains 3 grams of fat”)

What is the basis for the proposed update

- Strategic Plan to update of Food labeling
- Citizens Petitions request that FDA amend the regulation defining the nutrient content claim “healthy” with respect to total fat intake and amend the regulation to emphasize whole foods and dietary patterns rather than specific nutrients.

SIDE-BY-SIDE COMPARISON

Original Label

Nutrition Facts			
Serving Size 2/3 cup (55g)			
Servings Per Container About 8			
Amount Per Serving			
Calories 230	Calories from Fat 72		
		% Daily Value*	
Total Fat 8g			12%
Saturated Fat 1g			5%
<i>Trans</i> Fat 0g			
Cholesterol 0mg			0%
Sodium 160mg			7%
Total Carbohydrate 37g			12%
Dietary Fiber 4g			16%
Sugars 1g			
Protein 3g			
Vitamin A			10%
Vitamin C			8%
Calcium			20%
Iron			45%
* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.			
	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

New Label

Nutrition Facts	
8 servings per container	
Serving size	2/3 cup (55g)
Amount per serving	
Calories	230
	% Daily Value*
Total Fat 8g	10%
Saturated Fat 1g	5%
<i>Trans</i> Fat 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	13%
Dietary Fiber 4g	14%
Total Sugars 12g	
Includes 10g Added Sugars	20%
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%
* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.	

Note: The images above are meant for illustrative purposes to show how the new Nutrition Facts label might look compared to the old label. Both labels represent fictional products. When the original hypothetical label was developed in 2014 (the image on the left-hand side), added sugars was not yet proposed so the “original” label shows 1g of sugar as an example. The image created for the “new” label (shown on the right-hand side) lists 12g total sugar and 10g added sugar to give an example of how added sugars would be broken out with a % Daily Value.

“Healthy” Criteria based on the old Nutrition Facts Label

- The nutrient conditions for bearing a “healthy” nutrient content claim:
 - Criteria for nutrients to limit in the diet
 - total fat, saturated fat, cholesterol, sodium,
 - Requirements for nutrients to encourage in the diet
 - Vitamin A, vitamin C, iron, and calcium.
- The nutrient criteria to use the claim can vary for different food categories, e.g., fruits and vegetables, or seafood and game meat

Linked to elements in the Nutrition Facts label and serving size regulations
21 CFR §§ 101.9, 101.65(d)(2), and 101.12

FDA's Enforcement Discretion

- “...this guidance is intended to advise food manufacturers of our intent to exercise enforcement discretion relative to foods that use the implied nutrient content claim “healthy” on their labels which:
 - (1) Are not low in total fat, but have a fat profile makeup of predominantly mono and polyunsaturated fats; or
 - (2) contain at least ten percent of the Daily Value (DV) per reference amount customarily consumed (RACC) of potassium or vitamin D.

Questions for Panel

- Is the term “healthy” most appropriately categorized as a claim based only on nutrient content? If not, what other criteria (*e.g.*, inclusion of foods from specific food categories) would be appropriate to consider in defining the term “healthy” for use in food labeling?

Questions for Panel

- What types of food, if any, should be allowed to bear the term “healthy?” Should all food categories be subject to the same criteria?

Questions for Panel

- If nutrients for which intake is encouraged are included in the definition, should these nutrients be restricted to those nutrients whose recommended intakes are not met by the general population, or should they include those nutrients that contribute to general overall health?
 - Should the nutrients be intrinsic to the foods, or could they be provided in part—or in total—via fortification?

Questions for Panel

- How will the food industry and consumers regard a change in the definition of “healthy?”
- What would be the costs to industry?

Questions for Panel

- Are there current dietary recommendations (*e.g.*, the *Dietary Guidelines for Americans*) or nutrient intake requirements, such as those provided by the Dietary Reference Intakes (DRI) that should be reflected in criteria for use of the term “healthy?”

Questions for Panel

- Is the term “healthy” most appropriately categorized as a claim based only on nutrient content?
 - If not, what other criteria (*e.g.*, inclusion of foods from specific food categories) would be appropriate to consider in defining the term “healthy” for use in food labeling?