Nutritional Criteria for Labeling Claims

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Presentation Outline

- Regulatory Framework for Nutrition Labeling
- Current activities and priorities
- Challenges for consideration by the Committee

Approaches FDA has used to define nutrient criteria for claims

- Nutrient content claims
- Implied nutrient content claims
- Nutrient levels for disclosure statement with nutrient content claims
- Nutrient levels to disqualify products from bearing health claims
- Questions raised by FDA in a 2003 ANPRM* about dietary guidance statements

*Advanced Notice of Proposed Rulemaking

Legal Authority for Food Labeling

- Federal Food, Drug and Cosmetic Act (FFDCA)
- Fair Packaging and Labeling Act
- Public Health Service Act

Purpose of Labeling

- Informs consumer at point of purchase about, among other things:
  - The basic nature of the food
  - Ingredients used to make the food
  - Nutritional attributes about the food
  - Other *material*/*essential* information about the food (i.e., warnings/clarifications)

Mandatory Label Requirements for foods, including dietary supplements

- The label must contain:
  - Identity of food
  - Ingredient statement
  - Amount of food in package
  - Name and place of business
  - Nutrition information (unless exempt)
  - Information disclosing material facts about the food
  - Allergen labeling

Nutrition Labeling

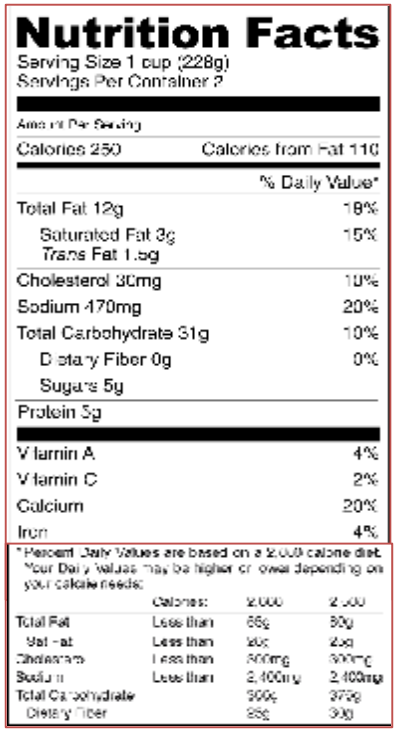
- Nutrition Labeling and Education Act - 1990
  - Amended the FFDCA and made nutrition information mandatory on most packaged foods
  - Specified format and content for nutrition labeling
    - Nutrition Facts
  - Shifted emphasis toward macronutrients associated with chronic disease risk
  - Allowed nutrient content claims and health claims on foods

Goals of NLEA, 1990

- To make available nutrition information that can assist consumers in selecting foods that can lead to healthier diets,
- To eliminate consumer confusion by establishing definitions for nutrient content claims that are consistent,
- To help consumers maintain healthy dietary practices and to protect these consumers from unfounded health claims, and
- To encourage product innovation through the development and marketing of nutritionally improved foods.
- Federal pre-emption

Goals of NLEA

Mandatory Information



Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving

Calories 250	Calories from Fat 110
	% Daily Value*
Total Fat 12g	18%
Saturated Fat 3g	15%
Trans Fat 1.5g	
Cholesterol 30mg	10%
Sodium 470mg	20%
Total Carbohydrate 31g	10%
Dietary Fiber 0g	0%
Sugars 5g	
Protein 5g	
Vitamin A	4%
Vitamin C	2%
Calcium	20%
Iron	4%

*Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values 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

Voluntary Information

Authorization of Health Claims
and
Nutrient Content Claims

Claims Related to Health and Nutrition on Foods and/or Dietary Supplements that do not require pre-approval

- Dietary Guidance
  - Message that refers to a general category of foods and health
- Nutrition Support Statements
  - Statements of well-being
  - Structure Function Claims
  - Classical nutrient deficiencies (+prevalence)

Claims Related to Health and Nutrition on Foods and/or Dietary Supplements that require pre-approval

- Nutrient Content Claims
  - Reference to the nutrient level in a product
- Health Claims
  - Characterizes a relationship between a food or food component and reducing risk of disease or health-related condition

Expressed Nutrient Content Claims

- Describe the level of a nutrient or dietary substance
  - *Free; high; low; contains*
  - *Good or excellent source*
- Compare the level of nutrient or dietary substance to another food
  - *More; reduced; light (lite)*
- Percentage Claims for dietary supplements
  - Simple percent claims with amount
  - Comparative percent claims

Examples of Expressed Claims

Type of claim	Criteria	Synonyms	Comments
"Good" source	At least 10% of RDI or DRV (i.e. DV)	provides, contains etc.	Cannot use without an established DV.
"High" source	At least 20% of the RDI or DRV (i.e. DV)	excellent, etc.	
Free or low	Grams or mg per RACC or labeled serving based on nutrient	Zero, without, insignificant; little, small amount etc.	See regulations for additional terms and criteria.
Reduced	At least 25% less per RACC than an appropriate reference food	Less, fewer etc.	

Terms: RDI=Reference Daily Intake, DRV=Daily Reference Value; DV=Daily Value
RACC=Reference Amount Customarily Consumed

Implied Nutrient Content Claims

- Suggests that a nutrient is present or absent in a certain amount
  - *e.g. "contains no oil"; "only"*
- Equivalence claims
  - *e.g."as much vitamin C as an 8 oz of orange juice"*
- Claims that a food may be useful in maintaining healthful dietary practices
  - *e.g. Healthy*

Criteria for use of "healthy"

	Individual Food* (RACC is ≥ 30 g)	Seafood/Game Meat	Main Dish/Meal Product
Total Fat	3 g or less /RACC (low)	Less than 5 g per RACC & 100g	3 g or less/100g & no more than 30% of calories (low)
Saturated Fat	1 g or less/RACC & 15% or less calories (low)	Less than 2 g per RACC and 100g	1 g or less/100 g & <10% of calories (low)
Sodium	480 mg or less/RACC & /labeled serving	480 mg or less/RACC & /labeled serving*	600 mg or less per labeled serving
Cholesterol	60 mg or less/RACC & /labeled serving	Less than 95 mg/RACC & 100g	90 mg or less per labeled serving
Beneficial Nutrients	At least 10% RDI or DRV per RACC for one or more of vitamins A, C, iron, calcium, protein, or fiber‡		Main dish: 2 nutrients; Meal: 3 nutrients

*For foods with a RACC of 30 g or less or 2 tablespoons or less, the criteria refer to the amount per 50 g of food.
‡Except raw fruits and vegetables; frozen or canned single ingredient/mixture fruits and vegs, except that ingredients whose addition does not change the nutrient profile of the fruit or veg may be added; enriched cereal-grain products that conform to a standard of identity.
RACC = Reference amount customarily consumed, which is the basis of serving size on food labels.

Health Claims

- To allow foods (including dietary supplements) to bear certain science-backed claims about reducing disease risk in their labeling without being regulated as drugs
- Risk reduction claims
  - Health claims are about reducing the risk of a disease or health-related condition, not treating, mitigating, or curing diseases.
- Elements of a Health Claim
  - Substance: A specific food or component of food, whether in conventional food or dietary supplement form. 21 C.F.R. 101.14(a)(2).
  - Disease or health-related condition as described in 21 CFR 101.14(a)(5).

Use of disclosure and disqualifying statements with claims

- Disclosure: Requirement for disclosure levels with *nutrient content claims*.
  - If a product exceeds certain levels for fat, saturated fat, cholesterol, or sodium
  - "See nutrition information for ____ content."
- Disqualifying Criteria: For use of *health claims*, a product must meet certain criteria, including:
  - Food contains, without fortification, 10% or more of the DV for one or more of vitamin A, vitamin C, iron, calcium, OR fiber
  - Food contains less than a specified level for total fat, saturated fat, cholesterol, or sodium.

Minimum levels for disclosure or disqualifying requirements on claims

	Individual food*	Main Dish product	Meal Product
	per RACC	per labeled serving	
Fat, g	13.0	19.5	26.0
Saturated fat, g	4.0	6.0	8.0
Cholesterol, mg	60	90	120
Sodium, mg	480	720	960

*If RACC is 30 g or less, the criteria are based on amount per 50g.
RACC=Reference amount customarily consumed.

Questions raised in the 2003 ANPRM*

- Definition of dietary guidance statements; approaches to distinguish from nutrient content and health claims
- Dietary guidance statements on substitution or replacement of foods
- Development of dietary guidance statements by Federal agencies
- Criteria for assessing the scientific validity of these statements.
- Criteria needed to so that statements are truthful and not misleading

*Part of activity from Task Force on Consumer Information for Better Nutrition Initiative.

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Factors considered by FDA in developing nutrient criteria for claims

- Public health significance
- Reference values for intake
- Distribution among food groups
- How do reference values for daily intake apply to individual foods, meals, or main dishes?

Questions related to nutritional criteria

- How can the nutritional criteria developed by FDA be used in front-of pack labeling systems?
  - Which criteria are applicable?
  - Does the current approach apply to front-of-pack systems?
- Are there additional nutrients or factors that should be considered?
  - What is the evidence base for these factors?
  - Some examples: added sugars, nutrients to encourage, food categories to encourage.

FDA Activities Related to Front-of-Pack Labeling

- Docket No. 2007N-0277 Food labeling: Use of Symbols to communicate Nutrition Information, Consideration of Consumer Studies and Nutritional Criteria.
- Guidance on front-of-pack symbols or logos that can be considered nutrient content claims (Dear Manufacturer letter) December 2008
- Letter to Industry regarding point-of-purchase food labeling. October 2009
- Consumer studies regarding the use and understanding of front-of-pack claims