



# Food Labeling: Nutrient Content, Health and Other Claims

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# Agenda

- “Misbranding” & Federal Preemption
- Nutrient Content Claims
- Health Benefit Claims
  - Health Claims & Structure-Function Claims
- Other Marketing Claims
  - Natural, Organic, Gluten-free



# **“MISBRANDING” & FEDERAL PREEMPTION**

## How Does FDA Regulate Claims?

- Statute & Key Amendments: Federal Food Drug & Cosmetic Act (FDC Act), as amended by:
  - Nutrition Labeling & Education Act of 1990 (NLEA)
  - Dietary Supplement Health & Education Act of 1994 (DSHEA)
  - Food Allergen Labeling & Consumer Protection Act of 2004 (e.g., Gluten Free)

# How Does FDA Regulate Claims?

## FDA's Misbranding Authority

- FDC Act 403(a)(1) – “A food shall be deemed to be misbranded – [] If [] its labeling is false or misleading in any particular . . .” or fails to conform with requirements specified in section 403.
- FDC Act 201(n) – Labeling claims that fail to disclose “material facts” cause a food to be misbranded.
- FDC Act 403(r): Use of unapproved nutrient content or health claims in labeling causes food to be “misbranded.”

# Federal Preemption

- The NLEA prohibits states from imposing requirements relating to food labeling that are not identical to an applicable federal food labeling standard.
- State and consumer actions under state law incorporating FDC Act.
- Compliance important.

# How Does FSIS Regulate Claims?

- FSIS regulations and procedures provide for FSIS clearance of product labeling and claims.
- FSIS policies are similar to FDA policies but have significant differences:
  - Procedures: FSIS premarket clearance of labeling & claims
  - Claims: FSIS “authorizes” various animal husbandry claims (e.g., “free-range” eggs) and does not authorize health claims.
- Broad Federal Preemption.



## NUTRIENT CONTENT CLAIMS, OTHER “NUTRITIONAL ATTRIBUTE” CLAIMS



## What claims concerning the nutrient amounts provided by a food are permitted?

- “Nutrient content claims”:
  - FDC Act 403(r) –A food is misbranded if labeling includes a claim that is not approved/authorized by FDA which “**expressly or by implication characterizes the level of any nutrient** which is of the type [required in nutrition labeling]”.
- Notified nutrient content claims.

# Express Nutrient Content

- Explicit statements about the level or range of a nutrient in food.
  - Absolute claims: e.g., low fat, cholesterol free, good source of vitamin D, high in antioxidant vitamin E.
  - Relative claims: e.g., Lower fat, enriched, more ...

# Implied Nutrient Content Claims

- “Implicitly characterize” a nutrient level and are permitted if the food qualifies for the nutrient content claim implied.
  - Describes the food or an ingredient in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., high in oat bran); or
  - Suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., healthy, contains 3 g of fat).<sup>21</sup> CFR 101.13

# Nutrient Content Claims

- May not be made unless:
  - Authorized by FDA.
    - 21 CFR Part 101, Subpart D (authorized nutrient content claims)
  - Notified: Through petition or FDAMA notification (claims based on authoritative statement of U.S. government or NAS).

# What claims are not nutrient content claims?

- Non-nutritional Ingredient claims: Claims that convey no express or implied claim characterizing the level of a nutrient in the food.
  - Avoidance Claims (e.g., “gluten-free”);
  - Nonnutritive Claims (e.g., “no preservatives”);
  - Added Value Claims (e.g., “100% whole grain oatmeal”);
  - Statements of Special Dietary Usefulness (e.g., weight control); and
  - Non-quantitative Statements of Identity (e.g., “oat bran muffins,” “corn oil”)

See 21 CFR 101.13, 101.65.

# Types of Nutrient Content Claims

- General Principles 21 CFR 101.13.
- “Good Source,” “high,” “more,” high potency” and antioxidant claims. 21 CFR 101.54.
- “Light” or “lite.” 21 CFR 101.56.
- Sodium content of foods 21 CFR 21 CFR 101.61.
- Fat, fatty acid, and cholesterol content of foods. 21 CFR 101.62.
- Implied nutrient content claims and related label statements (healthy) 21 CFR 101.65.
- Use of nutrient content claims for butter. 21 CFR 101.67.

# Express Nutrient Content Claims

- Good source/Contains/Provides/With
  - 10-19% of the DRV or RDI per RACC.
- High/Rich in/Excellent Source of:
  - 20% or more of the DRV or RDI per RACC.

Beware of use of terms such as “packed with,” “loaded,” “source of” ... not defined by FDA.

# Express Nutrient Content Claims (continued)

- Free/Zero/No/Without/Trivial Source of/Dietary Insignificant Source of:
  - Defined for calories, fat, sat. fat, sodium, cholesterol, and sugar.
  - Must qualify for claim based on RACC and per labeled serving.
- Low/Little/Few/Contains a Small Amount of/Low Source of:
  - Defined for calories, fat, sat fat, sodium, and cholesterol.
  - There is no regulation defining low sugar!



# Express Nutrient Content Claims (cont'd)

- High potency (for vitamins and minerals).
- Antioxidant: for antioxidant vitamins (carotene, C and E).

# Express Nutrient Content Claims; Relative Claims

- Relative Claims: Statements that compare the level of a nutrient in a food with the level of a nutrient in a reference food.
  - More/fortified/Enriched/Added/Extra/Plus:
    - Must have 10% or more of the RDI or DRV per RACC and disclose reference food, detailed requirements.
  - Reduced/Less/Lower/Fewer:
    - 25% less per RACC.
    - Defined for calories, fat, sat. fat, sodium, cholesterol, and sugars.

# “Relative” nutrient content claims?

- Reference Food: May compare against regular brand, competitor’s brand, or a representative nutrient value for a market-basket category of food (required for light claims).
- Disclosure Statements:
  - PDP “Reduced fat – 50 % less fat than regular ice cream.”
  - PDP/IP “4 grams of fat compared with 8 grams fat per serving of regular ice cream.”

# Implied Nutrient Content Claims; 21 CFR 101.65

- High in oat bran.
- Contains as much fiber as an apple (requires disclosures).
- Contains no oil.
- Healthy.

# Implied nutrient content claims

- Claims that a food contains or is made with an ingredient associated with a particular nutrient are authorized where the food is either “low in” or a “good source” of the nutrient associated with the ingredient or type of preparation.
  - “Baked, Not Fried”
  - “Made with oat bran”
    - » 21 CFR 101.13 & 101.65

# Healthy as an Implied Nutrient Content Claim

- 21 CFR 101.65(d) governs the use of the term “health” or similar terms such as “healthful.” Applies to:
  - The use of the term characterizes the level of a nutrient in food; or
  - Implies a judgment of the food itself.

# Healthy as an Nutrient Content Claim

- For a food to bear an implied “healthy” nutrient claims it must generally:
  - not exceed certain FDA established levels for fat, sat. fat, sodium and cholesterol;
  - Provide at least 10% of the recommended daily value for vit. A, C, calcium, iron protein or fiber; and
  - Comply with FDA’s fortification policy.
- But FDA guidance following KIND WL/Petition.
- FDA is considering rule making.

# Quantity and Percentage Claims

- Amount or percentage claims are permitted if they do not “characterize” the level of a nutrient in food (factual statements).

**“100 Calories Per Serving”**

**NOT:**

**“Only 100 Calories  
Per Serving”**

Section 101.13(i)

- Unless expressly prohibited by regulation, statements describing the percentage contribution of vitamins and minerals in a conventional food or dietary supplement in relation to the RDI are permitted.
- E.g., 25% of the RDI for vitamin C.



# “Disclosure levels”

- If a food for which a nutrient content claim is made contains fat (13 g), saturated fat (4g), cholesterol (60mg), or sodium (480mg) in excess of specified “disclosure levels” per RACC and per labeled serving (or for foods with small RACCS, per 50 g) labeling must highlight the nutrient(s) that exceed(s) the level(s). 21 CFR 101.13(h).
- Mandatory disclosure statement must accompany nutrient content claim when disclosure levels are exceeded.

**“See nutrition information for (e.g., fat content)”**

# Lean and Extra Lean (meat, game and seafood)

21 C.F.R. § 101.62(e); 9 CFR 317.362(e)

- Lean: Product contains less than 10 grams of fat, 4.5 grams or less of sat. fat, and less than 95 mg of cholesterol per 100 grams and per RACC.
- Extra Lean: Product contains less than 5 grams of fat, less than 2 grams of sat. fat, and less than 95 mg. of cholesterol per 100 grams and per RACC.

# Percentage Lean Claims

- Can only be used on a low-fat food (3g of fat per RACC).
- Synonym for % fat free.

# Nutrient content claims and standardized food

- Compliance with the formulation and labeling requirements of 21 CFR 130.10 permits a standard of identity food to be nutritionally modified and maintain standardized status for legal purposes.
  - High Calcium Cottage Cheese.
  - Low fat milk.

## Special case:

### Nutrient claims foods for infants and children < two

- Infant formula:
  - See 21 CFR Part 107.
- Percentage Daily Value claims for vitamins and minerals:
  - “100% vitamin C per serving.”
- Taste claims:
  - Unsweetened.
  - Unsalted.

# Carbohydrate, Whole Grain, Keto Friendly Claims

- FDA has not defined nutrient content claims for carbohydrates, whole grains, or keto friendly.
  - May make factual statements such as x g of carbohydrates per serving under 21 CFR 101.13(i)(3).

# Requirements for Whole Grain Claims

*Contains Nonbinding Recommendations  
Draft – Not for Implementation*

## Guidance for Industry and FDA Staff

### Whole Grain Label Statements

*Additional copies are available from:  
Food Labeling and Standards Staff (HFS-820)  
Office of Nutritional Products, Labeling and Dietary Supplements  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740  
(Tel) 301-436-2371  
<http://www.fda.gov/ohrms/dockets/default.htm>*

U.S. Department of Health and Human Services  
Food and Drug Administration

[February 2006]

**Answer:** Manufacturers can make factual statements about whole grains on the label of their products, such as “10 grams of whole grains,” “½ ounce of whole grains,” (21 CFR 101.13(i)(3)) and “100% whole grain oatmeal” (as percentage labeling under 21 CFR 102.5(b)), provided that the statements are not false or misleading under section 403(a) of the Act and do not imply a particular level of the ingredient, i.e., “high” or “excellent source.”

In addition, labels may bear a health claim based on an authoritative statement of a scientific body relating whole grains with a reduced risk of heart disease and certain cancers if the food meets the qualifications of one of the notifications submitted under section 403(r)(3)(C) of the Act (see <http://www.cfsan.fda.gov/~dms/labfdama.html>).

# Notified Nutrient Content Claims

- See FDA website:  
<http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm2006874.htm> (NCC claims for choline and linoleic acid).



# Quiz

- High in monounsaturated fat.
- No artificial colors.
- As much calcium as an 8 ounce glass of milk.
- Bursting with vitamin E.
- 300 g omega-3 fatty acids per serving.
- Eat fruits and vegetables.
- 0 grams of trans fat (note 21 CFR 101.9(c)(7)).

# Front-of-Package Nutrition Labeling

- **Front-of-Package (FOP) Labeling:**
  - Nutrition representations must be consistent with Nutrition Facts and nutrient content claim standards.
    - Express and implied nutrient content claims must be authorized.
    - Express and implied health claims must be authorized.
  - Nutrition information and health promotion claims (i.e., structure function) must be:
    - Accurate.
    - Not Misleading.
    - Substantiated.

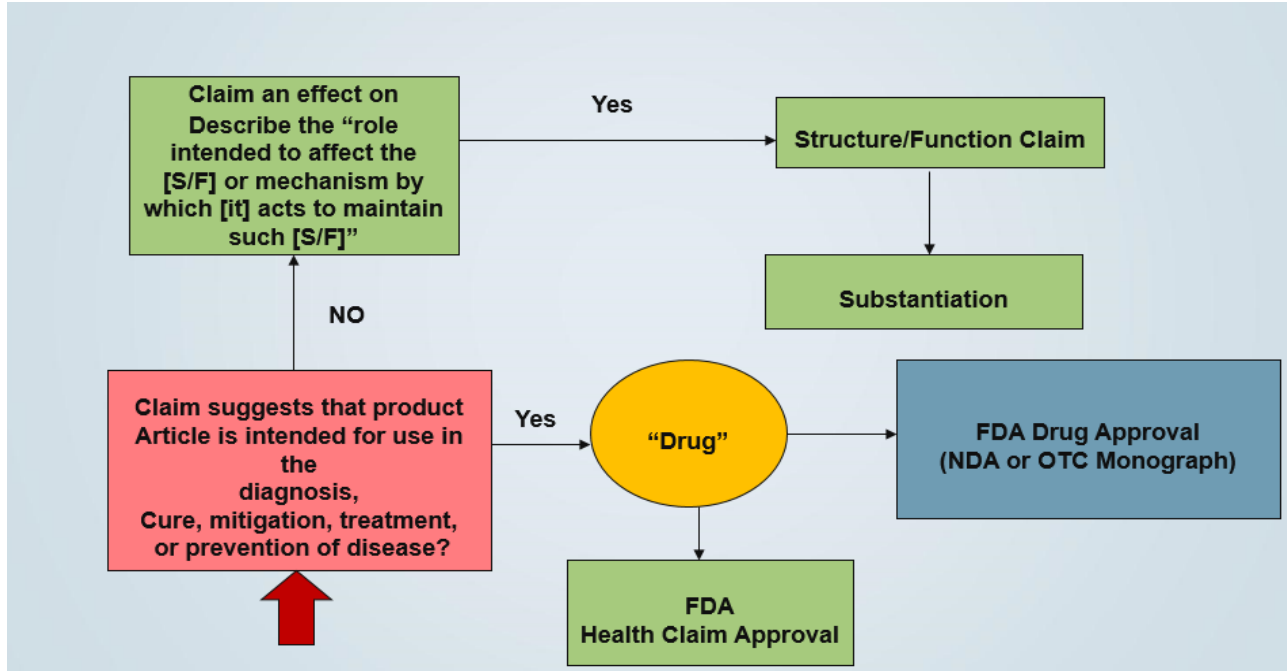


## **STRUCTURE-FUNCTION CLAIMS & HEALTH CLAIMS**

# Health benefit claims

- Structure Function Claims:
  - “Calcium helps build strong bones and teeth.”
- Health Claims:
  - “Calcium and vitamin D helps reduce the risk of osteoporosis.”
- General Dietary Guidance Claims:
  - Consuming 3 dairy servings per day helps ensure that your diet provides enough calcium and vitamin D to meet your needs.

# Framework for Health Benefit Claims



# What are “structure-function claims?”

- Structure function claims are claims that tout a food’s effect on the structure or function of the body.
- For (conventional) food they are “permitted” under FDC Act 201(g)(1)(C) carve-out.
  - Defines a Drug as “articles (**other than food**) intended to affect the structure or any function of the body of man or other animals.
  - Example: Fiber helps maintain bowel regularity.

# Structure/function claims for dietary supplements

- DSHEA amended the FDC Act to expressly authorize structure/function claims for dietary supplements. See FDC Act 403(r)(6).
- FDA developed regulations re structure/function claims, 21 C.F.R. § 101.93.

# What requirements apply to structure-function claims?

- Structure-function claims must be:
  - Truthful and Accurate.
  - Substantiated by competent and reliable scientific evidence.
- Structure-function claims:
  - Include health promotion, wellness, and dietary guidance claims.
  - Do not include express or implied disease prevention claims.



# Structure/Function Claims vs. Drug Claims

- S/f claim may not imply or express usefulness in the diagnosis, cure, mitigation, treatment, or prevention of disease.
  - Disease: Damage to an organ, part, structure, or system of the body such that it does not function properly, or a state of health leading to such dysfunctioning; except (for dss) diseases resulting from essential nutrient deficiencies not included (provided certain disclosures included).

# Structure/Function Claims

- FDA regulation for dietary supplements, 21 C.F.R. § 101.93, provides guidance.
- Preamble to the final regulation
- FDA Courtesy Letters (and Company's notifications).

# Health Claims

- FDA definition: Claim expressly or impliedly characterizes the relationship between a “substance” and a disease or health-related condition.
  - Include disease prevention claims.
- Implied health claims may include:
  - Third party certification symbol (AHA Heart Check).
  - Brand names.
  - Vignettes.

# Health claims

- FDC Act 403(r) – Requires FDA approval of health claims:
  - A food is misbranded if labeling includes a claim that is not approved by FDA which “expressly or by implication characterizes the relationship of any nutrient” in food “to a disease or health related condition.”
- A health claim may not be made expressly or impliedly on the label or in labeling unless specifically authorized by FDA or notified health claim (FDAMA) or....

# Limitations on Health Claims

- **The “Jelly Bean Rule”** --Food products bearing a health claim (with notable exceptions for sugar alcohol/dental caries health claims) must contain, before any nutrient addition, 10 percent or more of the DV for vitamin A, C, iron, calcium, protein, or dietary fiber per RACC.
  - Exceptions granted on a case-by-case basis.
- **“Disqualifying Levels”** of “risk increasing” nutrients.
  - Same as “disclosure levels” for nutrient content claims.

# FDA Authorized Health Claims

- FDA issues regulation pursuant to Petition.
- **“Significant Scientific Agreement Health Claims”** – FDC Act 403(r) requires FDA to issue a health claim regulation authorizing health claims supported by scientific evidence meeting the “significant scientific agreement” standard. (SSA Health Claims).
  - Scientific evidence establishes validity of a diet/disease relationship.
  - Approved health claims are codified at 21 CFR Part 101, subpart E.

# SSA Health Claim Requirements & Model Claims

Requirements for Health Claims Made in Labeling			
Approved Claims	Requirements for the Food	Claim Requirements	Model Claim, Statements
<p>Calcium and Osteoporosis and calcium, vitamin D, and osteoporosis</p> <p>(21 CFR 101.72)</p>	<p>For calcium and osteoporosis claim-high in calcium</p> <p>For calcium, vitamin D and osteoporosis claim-high in calcium and vitamin D</p> <p>-assimilable (Bioavailable)</p> <p>Supplements must disintegrate and dissolve, and</p> <p>Phosphorus content cannot exceed calcium content</p>	<p>The claim makes clear the importance of adequate calcium intake, or when appropriate, adequate calcium and vitamin D intake, throughout life, in healthful diet, are essential to reduce osteoporosis risk. The claim does not imply that adequate calcium intake, or when appropriate, adequate calcium and vitamin D intake, is the only recognized risk factor for the development of osteoporosis.</p> <p>The claim does not attribute any degree of reduction in risk of osteoporosis to maintaining an adequate dietary calcium intake, or when appropriate, an adequate</p>	<p>Calcium and Osteoporosis: Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.</p> <p>Calcium, vitamin D and osteoporosis: Adequate calcium and vitamin D, as part of a well balanced diet, along with physical activity, may reduce the risk of osteoporosis.</p>

# Qualified Health Claims

- **“Qualified Health Claims”** - SSA standard was successfully challenged on First Amendment grounds in *Pearson v. Shalala* (D.C. Cir. 1999) and subsequent litigation.
  - When health claim petition shows that claim is supported by “credible” evidence, FDA issues letter of enforcement discretion declining to object to the claim under defined conditions.



# Qualified Health Claim Criteria for FDA Enforcement Discretion

<p><b><i>Walnuts &amp; Heart Disease</i></b></p> <p><i>Docket No. 2002P-029</i> 03/09/2004 enforcement discretion letter</p>	<p>Whole or chopped walnuts</p>	<p>Walnuts do not need to comply with the total fat disqualifying level in <a href="#">21 CFR 101.14(a)(4)</a>.</p> <p>Walnuts do not need to comply with the requirement in § 101.14(e)(6) that the food contain a minimum of 10 percent of the Daily Value per RACC of vitamin A, vitamin C, iron, calcium, protein, or dietary fiber.</p> <p>The disclosure statement about total fat content (i.e., See nutrition information for fat content) is placed immediately following the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself.</p>	<p>Supportive but not conclusive research shows that eating 1.5 ounces per day of walnuts, as part of a low saturated fat and low cholesterol diet and not resulting in increased caloric intake, may reduce the risk of coronary heart disease. See nutrition information for fat [and calorie] content.</p> <p>Notes: The bracketed phrase "and calorie" is optional in that FDA does not intend for the presence or absence of such phrase to be a factor in whether it considers enforcement discretion for the use of the qualified health claim. FDA considered this additional information beneficial to consumers to heighten their awareness of the caloric contribution from walnuts and encourages companies to include it in product labeling.</p>
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# Notified Health Claims

- “Notified Health Claims” pursuant to FDAMA: Claim relies on an “authoritative statement” published by a “scientific body of the U.S. government with official responsibility for public health protection or research directly relating to nutrition” and represents the statement accurately in the context of a healthy diet.
- Notification filed 120 days before first introduction of labeling claim for the food. Unless FDA objects, claim is permissible.

# Notified Health Claims Based on Authoritative Statement of Scientific Body

- <http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm2006874.htm>.
  - Choline.
  - Fluoride and the risk of dental caries.
  - Potassium and the risk of high blood pressure and stroke.
  - Sat. fat, cholesterol, and trans fat and the risk of heart disease.
  - Substitution of Sat. Fat with Unsat. fat and risk of heart disease.
  - Whole grain foods and the risk of heart disease and certain cancers.

# Health Claims vs. Dietary Guidance

- Dietary guidance statements focus on general dietary patterns, practices, and recommendations that promote health.
- They may refer to either a food substances of a disease or health related condition but not both:
  - Diets rich in fruit and vegetables may reduce the risk of coronary heart disease.
  - Drink low-fat milk for a healthy diet.

**MARKETING CLAIMS: NATURAL, ORGANIC, GLUTEN-FREE**

# When can natural claims be used?

- Natural Claims:
  - “Natural,” “All Natural.”
  - “Made With Natural” Ingredient.
  - “Made From Natural” Source (plant or animal).
  - FDA will “not restrict the use of the term ‘natural’ except for added color, synthetic substances, and flavors . . .” 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993)(citing “natural flavor” definition as guideline for permissible sources and processing methods).
  - USDA/FSIS limits “natural” claims to foods containing no artificial flavor, color, chemical preservative, or other artificial or synthetic ingredients and are not more than “minimally processed.”
  - Much litigation.

# Long-Pending FDA Evaluation

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DEPARTMENT OF HEALTH AND  
HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA-2014-N-1207]

**Use of the Term “Natural” in the  
Labeling of Human Food Products;  
Request for Information and  
Comments**

**AGENCY:** Food and Drug Administration,  
HHS.

**ACTION:** Notification of request for  
comments.

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**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the establishment of a docket to receive information and comments on the use of the term “natural” in the labeling of human food products, including foods that are genetically engineered or contain ingredients produced through the use of genetic engineering. We are taking this action in part because we received three citizen petitions asking that we define

- Response to 3 Citizen Petitions and requests from Federal courts in false advertising cases involving “natural” claims.
- FDA requested comment on whether & how FDA should define “natural.”
- 80 FR 69905 (Nov. 12, 2015)

# Organic claims

- Organic Foods Production Act of 1990 and NOP (AMS) implementing regulations 7 CFR Part 205.
- Uniform standard re production and handling of organically produced agricultural products.
- Requires third-party certification by USDA accredited certifiers
- Organic claims are prohibited for food ingredients produced using “excluded methods”:
  - Synthetic fertilizers, pesticides, or herbicides.
  - Genetically engineering.
  - rDNA, cloning, etc.
  - Sewage sludge.
  - Ionizing radiation.
- National List.





# Organic Claims

- Four categories of labeling:
  - 100 percent organic: Excluding salt and water 100% organic, may use seal.
  - Organic: At least 95% organically produced ingredients, remaining 5% on National List.
  - Made with organic: Contains at least 70 percent organic ingredients.
  - Less than 70%, identify organic ingredients in ingredient statement and may include % organic on information panel.

# Gluten-free



## 21 C.F.R. § 101.91

Less than 20 ppm gluten (i.e., a threshold, “free” is not free),  
BUT

- May not contain a “gluten-containing grain” (any species of wheat, rye, barley, or any of their crossbred hybrids, such as triticale), even if the product contains less than 20 ppm.
- May not contain an ingredient that is derived from a gluten-containing grain that has not been processed to remove gluten, such as wheat flour.
- If any gluten is present in the food, that presence must be unavoidable and the gluten must be below 20 ppm.

# Gluten-free

- Regulation allows labeling gluten content, i.e., “gluten-free, less than 10 ppm gluten.”
- Free is not free. 20 ppm is analytical limit.

# Gluten-Free Fermented Products

- FDA has struggled with fermented products prepared from gluten containing products.
- Final regulation (from 2020) relies on the gluten content of the raw materials before fermentation; if they contain more than 20 ppm gluten or gluten-containing cereals, fermented product may not be labeled gluten-free.
- A product may be gluten-free but still require allergen warning for wheat, e.g., wheat starch (specially processed to remove gluten).

# Questions?

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