



**IDFA**

**International  
Dairy Foods Association**

# Introduction to Dairy Product Labeling

October 14-15, 2020

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# An Introduction to Dairy Product Labeling – Day 1 Agenda

- Jurisdiction
- Label components
  - Identity statement
  - Flavor Labeling
  - Net quantity of contents
  - Information panel
  - Ingredient statement
  - Allergen labeling
  - Name and address of manufacturer
- Special labeling requirements
- Bioengineered Foods Disclosure Standard



# Jurisdiction

- Federal vs State
- FDA Enforces
  - **Interstate** Shipment of Products
    - Any part of food or packaging that has crossed state lines
  - Adulteration and Misbranding
  - Code of Federal Regulations
- State Enforces
  - Not sold in Interstate Commerce
  - State Standards
    - Where no federal standard exists
    - Frozen Yogurt, Feta, Ricotta
  - Exemption from Preemption



- FDA granted CA exemption from preemption minimum milk fat and milk solids non fat (msnf) of 8.25%
- California Department of Food & Agriculture Code
- [http://leginfo.legislature.ca.gov/faces/codes\\_display\\_expandedbranch.xhtml?tocCode=FAC&division=15.&title=&part=&chapter=&article=](http://leginfo.legislature.ca.gov/faces/codes_display_expandedbranch.xhtml?tocCode=FAC&division=15.&title=&part=&chapter=&article=)
- Part 35601-388892 Dairy Standards
  - Whole milk higher milk fat (3.5%) and 8.7% msnf
  - Fat free milk – 9.0% msnf
  - Low-fat milk – 11.0% msnf
  - Reduced fat milk – 10.0% msnf



CALIFORNIA DEPARTMENT OF  
FOOD AND AGRICULTURE





# Label Components

# The Label

- Principal Display Panel (PDP)
- Alternate PDP
- Information Panel (IP)





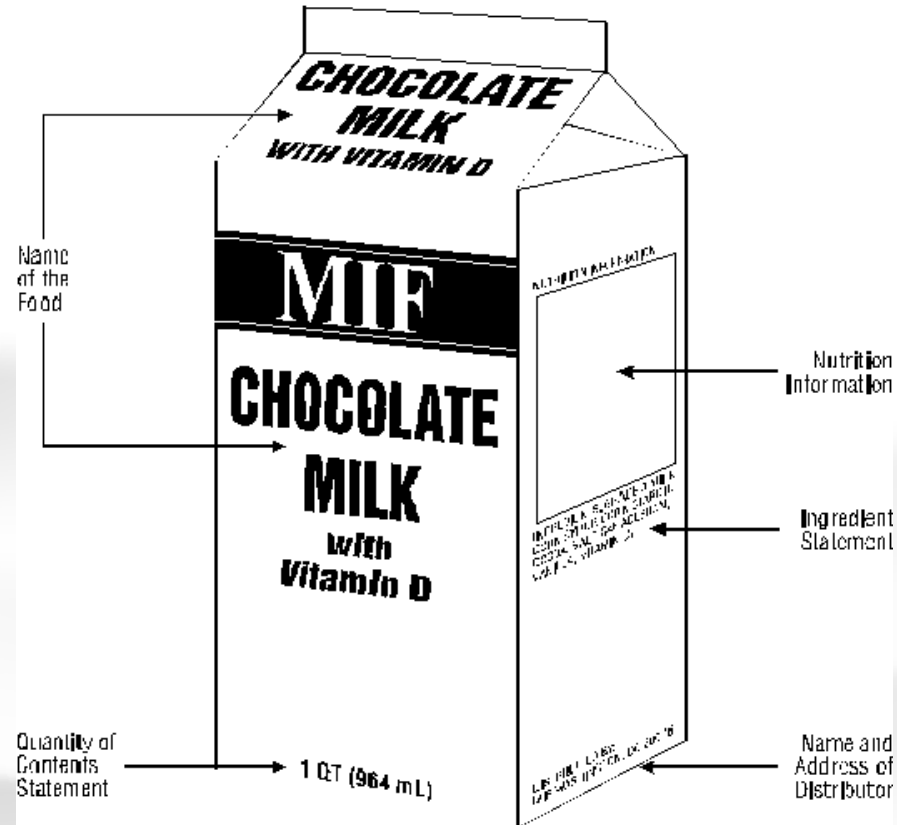
- Part of the label most likely to be displayed
- Mandatory
  - Name of the Food
  - Net Contents
- All mandatory information must be displayed on all PDPs and alternate PDPs



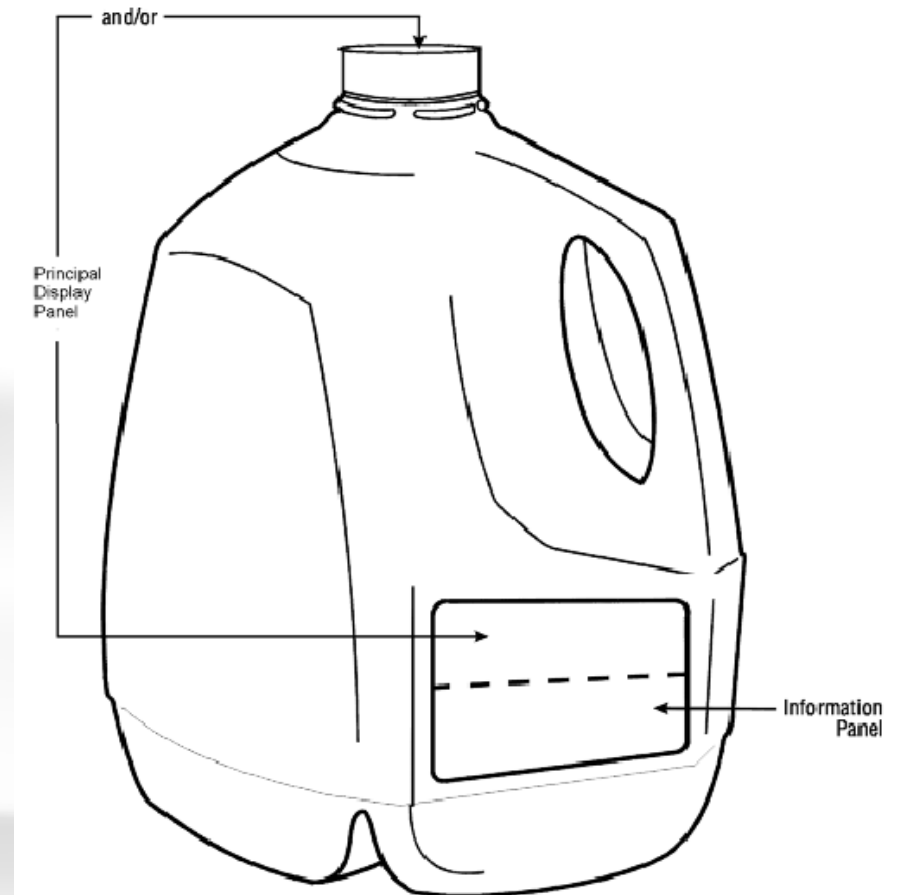
# Five Mandatory Label Components

- Identity Statement
- Net Quantity of Contents
- Ingredient Statement (including allergen declaration, if appropriate)
- Nutrition Information
- Name and Address of Business
  - If a language other than English is used then ALL mandatory information must be presented in BOTH languages

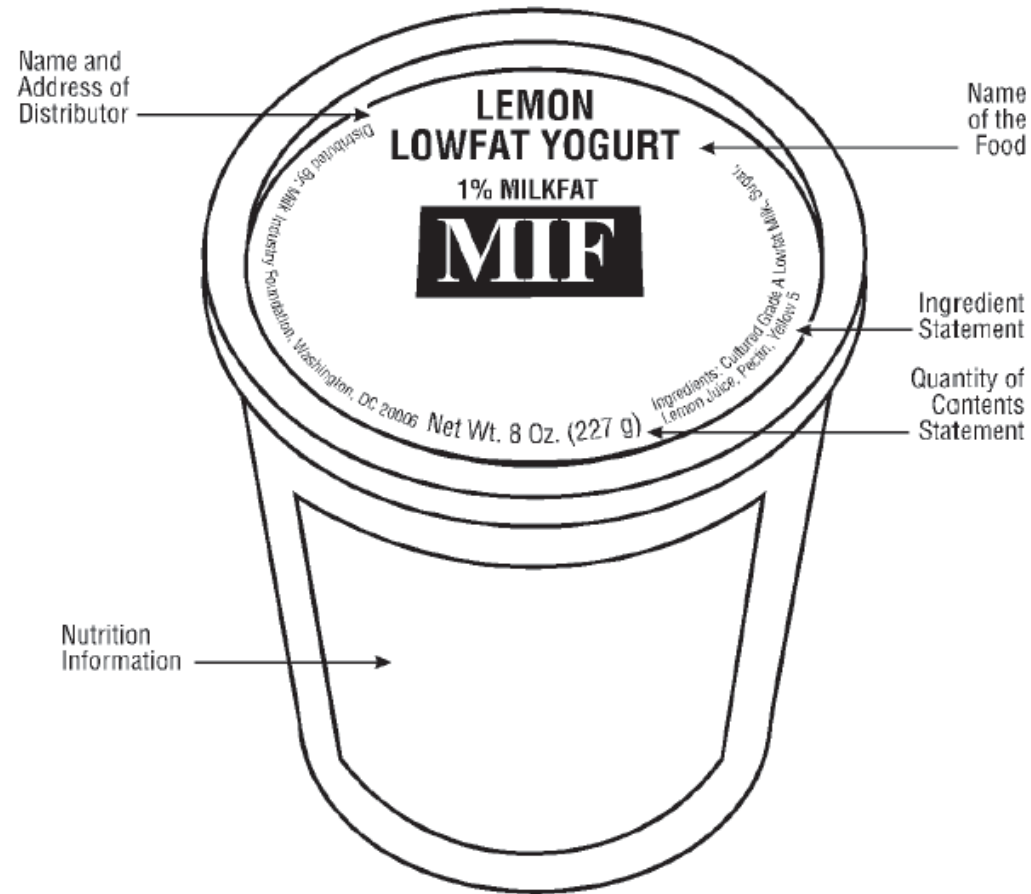
# Principal Display and Information Panels



# Principal Display and Information Panels



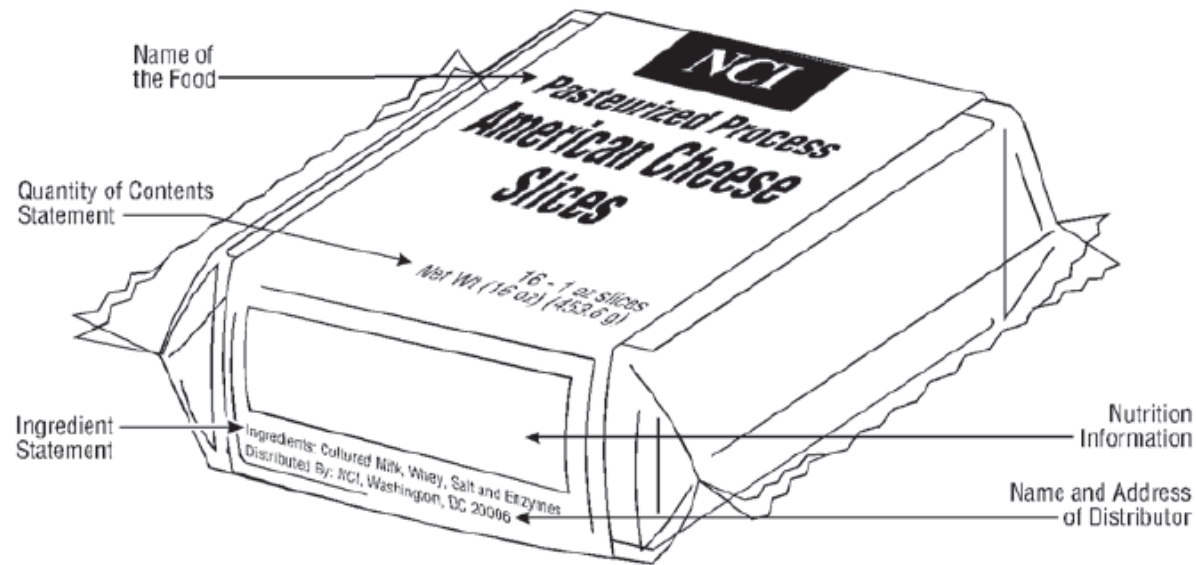
# Principal Display and Information Panels



# Principal Display and Information Panels



# Principal Display and Information Panels







# Mandatory Label Components -Exemptions

- Bulk Containers
  - Shipping containers used solely for transporting a commodity in bulk to packer, processor or warehouse – Shipper for cottage cheese packages or display tray
  - No requirements for labeling
- Institutional and Food Service Containers
  - Identity Statement
  - Net Quantity of Contents
  - Ingredient Statement
  - Name and Address of Business
  - Nutrition Information, if claim is made



# Mandatory Label Components -Exemptions

- Multiunit Packages – two or more individual packaged units of identical commodity in the same quantity
  - Outer package must have full required labeling, unless it is a clear wrap that allows for full view of fully labeling units inside



- Multiunit Packages: Inner Units
  - No printed information
  - Full labeling
  - Some printed statements, with “this unit not labeled for retail sale” not less than 1/16 inch
    - Ingredient list
    - Name and place of business
    - Nutrition labeling
  - Some labeling will require full labeling on units
    - Statement of identity
    - Quantity of contents
    - Allergen labeling

# Identity Statement



# Identity Statement 21 CFR § 101.3

- Standard of Identity – Cultured Lowfat Buttermilk
- Common or Usual Name - Feta Cheese
- Appropriate Descriptive Name – Spreadable Cheese, Yogurt and Juice
- Fanciful Name – Vanilla Wafers





Statement of Identity

Fanciful Name





Statement of Identity



Pasteurized Prepared  
Cheese Product



Soft Spreadable  
Cheese

Statement of Identity for non-standard food  
(appropriate descriptive term)



Dairy Snack



Milk Beverage



Statement of Identity for non-standard food  
(appropriate descriptive term)



# Identity Statement

- Form of Food (bars, slices, sticks)
- Combination or Multi Food
  - “with” or “and”
- Imitation
  - Nutritionally inferior
- Substitute Food
  - Not nutritionally inferior
  - Common or usual name not false or misleading



# Identity Statement

- Size and Location
  - Bold type
  - Reasonably related in size
  - Parallel to base of package
- No printed matter may appear larger than twice the size of the Identity Statement



# Questions?

Type your questions in the text  
chat box area at the bottom of  
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Presenters will answer questions without  
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# Flavor Labeling



- Part of the statement of identity
- First determine if the flavoring is natural or artificial
- Artificial Flavor or Flavoring:
  - Any substance that functions to impart flavor, which is NOT derived from:
    - Spices
    - Fruit or fruit juice, vegetable or vegetable juice
    - Herbs, bark, roots, buds, leaf or plant materials
    - Meat
    - Seafood
    - Poultry, eggs, dairy products or fermented products

- Determine if the flavor is a food (peaches, strawberries, chives), or a flavoring “from the bottle”
- Determine if the flavor is characterizing or simulating
  - Characterizing flavor
    - Primary recognizable flavor of the finished food
    - Independently characterizes the flavor of the food
  - Simulates, resembles or reinforces
    - Round out, modifies, extends, or increases intensity
- What is source of flavoring (characterizing source or another source)?

- Chocolate flavor labeling may require standardized chocolate: cocoa, chocolate liquor, cocoa butter
- Does consumer expect standardized chocolate in product/ingredient?
- Chocolate chips
- Chocolate milk or ice cream



- 6 Category System 21 CFR § 101.22
  - Artificial Flavor / Artificial Flavoring
  - Natural Flavor / Natural Flavoring
  - With Other Natural Flavors (WONF)
- Most products, including milk, yogurt, cheese, non-standard frozen desserts



- 6 Category System 21 CFR § 101.22
  - A – Primary characterizing flavor solely natural, no artificial flavor = **“Vanilla Yogurt”**
  - B - Primary natural flavor, with other natural flavors that simulate, resemble or reinforce = **“Coffee Yogurt with Other Natural Flavors”**
  - C - Natural Flavor not derived from the ingredient that it characterized or food contains an artificial flavor = **“Artificially Flavored Strawberry Milk”**
  - D - Contains insufficient food ingredient to characterized the product, and contains added natural flavor = **“Peach Flavored Yogurt”** or **“Natural Peach Flavored Yogurt”**
  - E – Contains insufficient food ingredient, added natural flavors not derived from the characterizing flavor = **“Peach Yogurt with Other Natural Flavors”**
  - F = Contains sufficient level of food ingredient to characterize the flavor and no artificial or added natural flavors = **Peach Yogurt**

A - Primary characterizing flavor solely natural, no artificial flavor = **“Vanilla Yogurt”**





B – Primary characterizing natural flavor, with other natural flavors that simulate, resemble or reinforce = “**Coffee Yogurt with Other Natural Flavors**”



Cultured grade A reduced fat milk,  
sugar, **natural flavor**, pectin.  
Contains active yogurt cultures  
including *L. acidophilus*.

with other natural flavors



C - Natural flavor not derived from the characterizing ingredient or food contains an artificial flavor =  
**“Artificially Flavored Rootbeer Milk”**



Artificially flavored



D - Contains insufficient food ingredient to characterize the product, and contains added natural flavor =  
**“Peach Flavored Yogurt” or “Natural Peach Flavored Yogurt”**



**Ingredients:** Cultured Pasteurized Grade A Low Fat Milk, Sugar, Peaches, Modified Corn Starch, Nonfat Milk, Kosher Gelatin, Citric Acid, Tricalcium Phosphate, Natural Flavor, Pectin, Colored with Annatto Extract, Vitamin A Acetate, Vitamin D<sub>3</sub>.



E – Contains insufficient food ingredient, added natural flavors  
not derived from the characterizing flavor =  
**“Peach Yogurt with Other Natural Flavors”**



Lowfat milk, sugar, high fructose corn syrup,  
**peaches**, modified corn starch, **natural flavor**,  
Contains active yogurt cultures



F = Contains **sufficient level** of food ingredient to characterize the flavor and no artificial or added natural flavors = “**Peach Yogurt**”



Cultured grade A lowfat milk, **peaches**, sugar, fructose syrup, high fructose corn syrup, contains less than 1% of pectin, modified corn starch, kosher gelatin, potassium phosphate, calcium phosphate. Contains active yogurt cultures

# Flavor Labeling - Ice Cream

- 3 Category System 21 CFR § 135.110 (Ice Cream Standard of Identity)
- Cat II if  $\geq 2\%$  citrus, 2% nut meats, 6% berries, 10% other fruits by wt.

Category	Description
I	Those products which contain <u>no artificial characterizing flavor</u>
II	Contains both natural characterizing flavor and artificial flavor in which the <u>natural flavor intensity predominates</u>
III	Flavored exclusively with artificial flavor or with a combination of artificial and natural flavors in which the <u>artificial flavor intensity predominates.</u>

Flavored  
with natural  
vanilla

Category I

"Vanilla  
Ice Cream"



Flavored with vanilla extract  
and vanillin (vanilla extract  
predominates)

Category II

"Vanilla Flavored  
Ice Cream with Maraschino  
Cherries"

Subsidiary statement "Artificial  
Flavors Added"





Flavored  
with Vanillin

Category III

"Artificially  
Flavored  
Vanilla"



# Flavor Labeling Examples – Non standardized frozen desserts

- Uses 6 category system like milk and milk products
- Frozen yogurt, fruit bars, sorbet, gelato
- Also components of a novelty such a wafer, cone, coating, cookie part of an ice cream sandwich use 6-category labeling



# Flavor Labeling - Putting Them Together

Product	Component	Flavor Labeling
Ice Cream Bar (uncoated)	Ice Cream	3 Category
Ice Cream Sandwich	Ice Cream	3 Category
	Cookie or Wafer	6 Category
Coated Ice Cream Bar	Ice Cream	3 Category
	Coating	6 Category
Frozen Yogurt Bar (uncoated)	Frozen Yogurt	6 Category
Ice Cream Cone	Ice Cream	3 Category
	Cone and Toppings	6 Category

Cream Cheese  
Flavored  
Ice Cream

Strawberry swirl

Vanilla Wafers





# Vanilla Flavor Labeling

- Ice cream or yogurt that is flavored only with natural vanilla-derived flavorings (vanilla bean, vanilla extract, natural vanilla flavoring derived from vanilla) should be labeled as "vanilla ice cream" or "vanilla yogurt."
  - Ingredient labeling "natural flavor(s)" or list the specific flavoring ingredients by name (e.g., vanilla bean)
- Vanilla flavored product that uses artificial vanilla flavor (e.g., vanillin) would be labeled as “artificially flavored vanilla yogurt,” “artificially flavored vanilla ice cream” or “vanilla flavored ice cream, artificial flavors added.”
  - Ingredient labeling: “artificial flavor(s)” or list the specific flavoring ingredients by name (e.g., “vanillin”)
- Vanillin or other artificial flavors would not be considered a natural flavor for the purposes of labeling "with other natural flavors." "WONF" on the front panel of the vanilla yogurt could refer to another naturally-derived flavor that is not derived from a vanilla bean.





# Net Quantity of Contents

# Net Contents 21 CFR § 101.7

- Weight Measure, Fluid Measure, or Numerical Count
- Contains both U.S. Customary and Metric Units
- Must Appear on PDP and alternate PDP



- Weight or Mass
  - Solid, Semi-Solid, Viscous, Mixture of Solid and Liquid
  - Cheese, Yogurt, Butter, Ice Cream Cake
- Fluid Measure
  - Liquid
  - Milk, Cream, Ice Cream, Ice Cream Novelties
- FDA issued opinion on pelletized ice cream & frozen desserts
  - Quantity should be declared in terms of weight
  - Adopted by National Conference on Weights & Measures effective on April 17, 2010



Net Quantity	U.S. Customary Units	Metric Units	Example
Weight	Pounds Ounces	Kilogram Gram Milligram	1 lb (453 g) 12 oz (340 g)
Fluid	Gallon, Half Gallon, Quart, Pint, Half Pint, Fluid Ounce	Liter Milliliter	12 fl oz (354 ml) 2.5 gal (9.46 L)

- Placement
  - Bottom 30% of the PDP
  - May appear on more than one line
- Font Size: Depends on size of PDP
  - PDP area of 5 square inches or less: not less than 1/16"
  - PDP area 5 to 25 square inches: not less than 1/8"
  - PDP area 25 to 100 square inches: not less than 3/16"
  - PDP area more than 100 square inches: not less than 1/4"
  - 1/16" larger when net contents molded into plastic or glass container

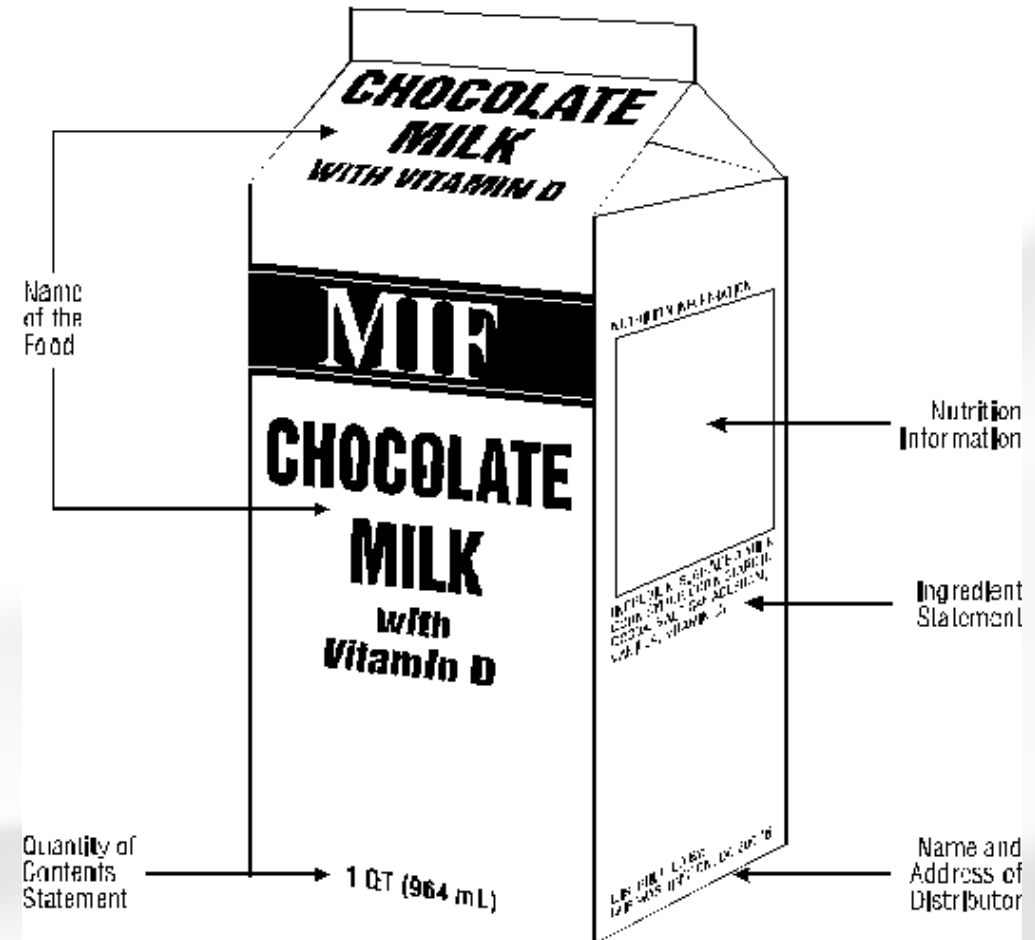


- Multiunit retail package
  - # of individual units
  - Quantity of each individual unit
  - Total quantity of contents in multiunit package
  - Metric equivalent only required on total package amount
  - “6-2.3 fl oz. Bars (13.8 fl oz.) (408 ml)”



# Information Panel

- Ingredient Statement
- Nutrition Information
- Name and Address of Manufacturer, Packer or Distributor
- If applicable:
  - Nutrient Content Claim Information
  - Warning Statements
  - Allergen Labeling



- Immediately to the right of the PDP
- All required information must appear in one place without other non-mandatory information intervening
  - Intervening material is information presented on the Information Panel that is not mandated by the regulations (any information, other than nutrition information, comparative information required for claims, ingredient list, allergens statement, manufacturer's address)
  - UPC code, 800 number would be intervening, should not appear between the required labeling elements



# Ingredient Statement



- Required with two or more ingredients
- Ingredients listed using common or usual name (not the scientific or brand name)
- Descending order of predominance by weight of ingredient
- Multicomponent ingredients must declare all subingredients: two options
  - Grouping
    - Ingredients: Yogurt (cultured milk, raspberries, sugar gelatin), granola (rolled oats, puffed rice, sugar)
  - Dispersion
    - Ingredients: Cultured milk, sugar, rolled oats, raspberries, puffed rice, gelatin

- 2% rule
  - Ingredients present in 2% or less maybe listed as collectively not in order of predominance
  - “Contains\_\_\_\_% or less of \_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_.”
  - Rounding to nearest 0.5%

Ingredients: Cultured grade A lowfat milk, peaches, sugar, fructose syrup, high fructose corn syrup, **contains less than 1% of pectin, modified corn starch, kosher gelatin, potassium phosphate, calcium phosphate.** Contains active yogurt cultures

- No non-mandatory information allowed (brand names, etc)
- Some exemptions from declaration for processing aids or incidental additives, but any allergenic ingredients must be declared

- Spices, Flavorings, Colorings and Chemical Preservatives\* 21 CFR § 101.22 (j)
- The collective term “spices” can be used instead of each spice or herb, but it does not include substances traditionally regarded as food, e.g. onion, garlic, or celery
- Flavorings may be grouped together as “artificial flavor” or “natural flavor” or declared by their common and usual name

- Certified color additives must be declared as: “FD&C Blue No. 1”, “Blue 1 Lake”
  - Ice cream, cheese and butter are **exempt** from color labeling, the voluntary declaration of all colorings in the ingredient statement is recommended and encouraged by FDA.
  - All foods, including ice cream, cheese and butter are **required** to declare the presence of the certified color FD&C Yellow No. 5, as well as carmine and cochineal extract, in the ingredient statement.
- All other colors “Non Certified Colors” such as titanium dioxides, annatto, beta-carotene, etc. **may be declared as one of these options:**
  - “Artificially colored,” “artificial color,” “artificial color added,”
  - Name of color “Annatto (for color),” “Colored with\_\_\_\_(name of color),” “Color added”
- A mixture of natural colors or alternate use of a natural colors like annatto and beta-carotene to color cheese may use the term “color added”
- Juice or juice concentrate solely added for color must have (for color)
- Since all added color results in an artificially colored food, FDA doesn't allow using the terms, “food color” or “natural color.”



**INGREDIENTS:** Contains: Milk, Cream, Sugar, Buttermilk, Whey, Corn Syrup, Chocolate Chips (sugar, chocolate liquor, coconut oil, soy lecithin, vanilla, salt), Mono & Diglycerides, Guar Gum, Artificial Flavor, Sodium Phosphate, Cellulose Gum, Sodium Citrate, Polysorbate 80, Carrageenan, Annatto (for color).



- Spices, Flavorings, Colorings and Chemical Preservatives\* 21 CFR § 101.22 (j)
- Chemical Preservatives: Parenthetical description of function required
  - Preservatives – (to retard spoilage) (a mold inhibitor) (to help protect flavor) (to promote color retention)
- Parenthetical declaration of purpose, other than preservatives, is voluntary: (stabilizer), (emulsifier)
  - Cannot use solely class name, must use common and usual name for ingredient



INGREDIENTS: CULTURED PASTEURIZED SKIM MILK, MILK, CREAM, WHEY PROTEIN CONCENTRATE, SALT, WHEY, NATURAL FLAVOR, XANTHAN GUM, LOCUST BEAN GUM, GUAR GUM, SORBIC ACID AND CARBON DIOXIDE (TO MAINTAIN FRESHNESS).

## Ingredients exempt from being listed in ingredient statement

- Incidental additives - 21 CFR § 101.100
  - No functional or technical effect in finished foods
  - Insignificant amount
  - Processing aids
  - Substances migrating to food from equipment or packaging
- Examples: Strawberry puree with preservative (potassium sorbate) used to retard spoilage during refrigeration of ingredient. When used in ice cream, preservative is nonfunctional, so potassium sorbate is not declared.



- And/or Labeling Provisions - 21 CFR § 101.4 (b)(14)
- Class names - 21 CFR § 101.4(b)(3-12)
  - Allows skim milk, concentrated skim milk, reconstituted skim milk and nonfat dry milk to be declared as “skim milk” or “nonfat milk”
  - Milk and whey labeling is similar
  - Bacterial cultures may be declared by the word “cultured” followed by the name of the substrate “cultured milk”
  - Cream, reconstituted cream, dried cream, plastic cream (CMF) may be declared as “cream”
  - Butteroil, AMF, may be declared as “butterfat”
  - Reconstituted dairy can include the amount of water to obtain single strength. Excess water must be declared as “water”
- “Non Dairy” product containing caseinate must declare “(milk derived ingredient)” in ingredient statement

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# Allergen Labeling



- Food Allergen Labeling and Consumer Protection Act
  - Requires declaration of all major food allergens (milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat and soy) contained in the product, including flavors, colors, spices and incidental additives, on food labels in one of two ways:
    - In the ingredient statement, follow the name of the allergenic ingredient with the plain English name of the allergen. (e.g., “casein (milk)”)
    - Follow the ingredient statement with a statement of the allergens found in the product. (e.g., “Contains: milk, eggs and soy.”)
  - Tree nuts, fish and shellfish must be individually declared by species name (e.g., hazelnut, cod, shrimp)

- Food Allergen Labeling and Consumer Protection Act
  - Exemptions (if parenthetical declaration in ingredient statement is used):
    - 1) if the ingredient's name states the known food allergen in plain English such as "Peanut Butter Ice Cream", the label would not have to restate peanuts in the ingredient statement, and/or
    - 2) if the known allergen has appeared elsewhere in the ingredient list
  - These exemptions do not apply if "Contains" statement is used.



Ingredients: cream, skim milk, rum  
raisins (raisins, sugar, water, rum),  
sugar, egg yolks, rum

- Highly Refined Oils are specifically exempt from declaration under FALCPA
  - Peanut oil that is highly refined would be exempt. Peanut oil, not highly refined (cold pressed), must be labeled as an allergen.
- No threshold levels for allergenic ingredients: any amount of allergenic protein requires labeling
- Codify FDA guidance - color, flavoring or spice contains an allergenic ingredient disclosure in the ingredient statement using the named food source
- FDA has a process that companies can petition to request an exemption from food allergen labeling.
  - One example is soy lecithin used as a release agent

- "May Contain" statements
  - Food Allergy Issues Alliance voluntary guidance
  - Be careful not to use "may contain" too often-- could dilute warning to consumers
  - Use only if it meets four conditions
    - Presence of allergen has been documented
    - Present in some but not all product
    - Cannot be controlled through GMPs
    - Poses a danger to health
- No FDA regulations regarding "May Contain"



# Name and Address of Manufacturer

# Name and Address of Manufacturer

## 21 CFR § 101.5



- Location
  - PDP or IP
- Required Information
  - Name of manufacturer, packer, or distributor
  - Street Address
  - City or Town
  - State
  - Zip

- Company location may be either:
  - Where product is manufactured or packed
  - Principal place of business of company
    - Corporate Name
    - Particular Division
- If name of actual manufacturer is not listed:
  - “Manufactured for\_\_\_\_\_”
  - “Distributed by\_\_\_\_\_”
- If product is made outside US, must declare "Product of \_\_\_\_\_" adjacent to manufacturer address.



# Special Labeling Requirements



- PMO Requirements for Grade A Products
- Seals
- State requirements
- Warning Statements
- UPC Codes

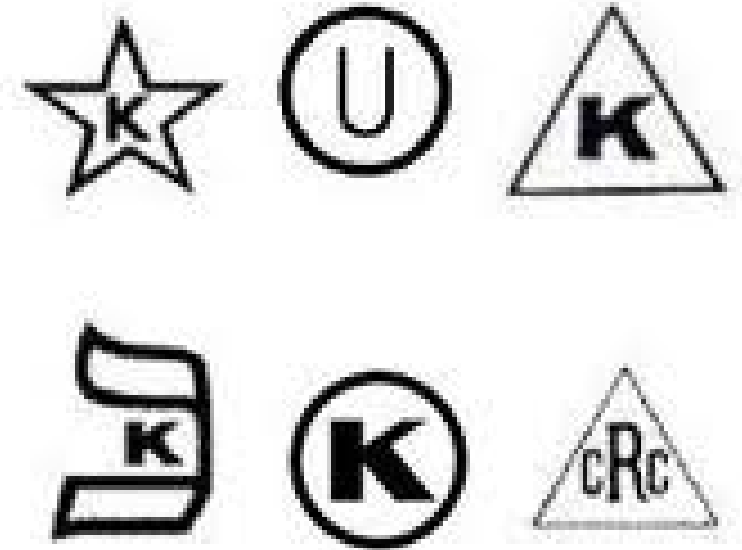
- PMO labeling only applies to Grade A products: milk, cream, yogurt, cottage cheese, cultured products
- “Grade A” - PDP, IP, Cap, or Cover
- Plant Code where Pasteurized
- "Keep Refrigerated After Opening" Statement: for aseptic products
- Where Applicable:
  - “Reconstituted” or “Recombined”
  - For Concentrated Milk - Volume/portion of water to add when reconstituting or recombining

- Real Seal
  - National Milk Producers Federation
  - [www.realseal.com](http://www.realseal.com)
- Heart-Check Mark
  - American Heart Association
  - Criteria updated for Jan. 2014
- Live and Active Cultures Seal
  - Managed by IDFA
  - [Aboutyogurt.com](http://Aboutyogurt.com)



# State Requirements

- No Federal criteria established - enforced by state
- “Kosher” or “Kosher style”
  - Meet the dietary requirements of Jewish Religion
- Code Date
  - Sell by date



- 21 CFR 101.17
  - Nutritive and Non-nutritive Sweeteners
- Specified Ingredients
  - Aspartame (21 CFR 172.804)
    - **“Phenylketonurics: Contains Phenylalanine”**
    - IP or PDP
  - Sorbitol (21 CFR 184.1835) – if greater than 50 grams
    - If sugar alcohols are present in a product making a sugar claim ("no sugar added") then sugar alcohols must be declared in the Nutrition Facts panel.



# Universal Product Code (UPC)

- Location
  - Bottom of container of IP
- Size based on:
  - package surface area
  - print quality
  - symbol location
  - Minimum size = 1.75 inch wide x 0.817 inch high
- GS1 US source of bar codes
- Website: <http://barcode.gs1us.org>



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# National Bioengineered Food Disclosure Standard

# National Bioengineered Food Disclosure Standard – BE Rule

- Broadly applies to all foods and ingredients, including milk, processing aids, food additives, bulk foods, enzymes and dietary supplements
- Applies only to foods labeled for retail sale
- Preempts state and local BE labeling standards
- Narrowly defines “bioengineered” foods and ingredients
- Establishes mandatory and voluntary disclosure criteria and labeling options
- Describes foods and ingredients exempt from labeling
- Describes recordkeeping requirements, audit and enforcement procedures



# What is a BE Food or Ingredient?

- Foods or ingredients on (or derived from) the BE Food List, OR actual knowledge that a food or ingredient is from a BE source

*AND*

- Detectable amount of genetic material modified through in vitro rDNA technology



Mandatory BE label unless it qualifies for exemption



# What is on the USDA BE Food List

Alfalfa, Apple (Arctic™), Canola, Corn, Cotton, Eggplant (BARI Bt Begun varieties), Papaya (ringspot virus-resistant varieties), Pineapple (pink flesh), Potato, Salmon (AquAdvantage®), Soybean, Squash (summer) and Sugar beet



Crop	Examples of food ingredients
Soybeans	Soybean oil, partially hydrogenated soybean oil, modified soybean oil (e.g., high-oleic), soy protein, textured vegetable protein, tofu, soy lecithin
Corn	Corn meal, corn flour, corn oil, corn starch, modified food starch, dextrose, corn syrup, high-fructose corn syrup
Cotton	Cottonseed oil, partially hydrogenated cottonseed oil
Sugar Beets	Sugar
Canola	Canola oil

## EXEMPTIONS

- Animal products (milk) are not BE solely because the animal's feed contained BE substances or was a BE variety
- USDA Certified Organic
- Incidental additives (as defined by FDA regulations)
- Below threshold for unintentional, inadvertent and unavoidable presence

**No BE disclosure label allowed**

# Exemption – Animal Derived Products

- Rule and 2016 statute prohibit labeling animal products such as milk and eggs as BE *solely* because the cow consumed feed from, containing or consisting of a BE substance
- Food and ingredients derived from an animal that did not consume BE feed do not automatically qualify for an absence claim



# Exemption - USDA Certified Organic

USDA categories (100% Organic and Made with Organic) and ingredients (organic and conventional) within each label category

- Excludes products with less than 70% organically produced ingredients (regulations allow BE ingredients)
- No additional recordkeeping or disclosure requirements
- Statute authorizes use of terms “non-GMO” and “not bioengineered”



# Exemption-Incidental Additives

Processing aids with detectable modified rDNA that meet FDA's definition of "Incidental additives" do not require a BE label.

**Provided:**

1. BE incidental additive is detectable in food;
2. Present at an insignificant level;
3. Has no technical or functional affect in the food; and
4. Is exempt from inclusion in a food label's ingredient statement under FDA regulations at 21 CFR 101.100(a)(3)



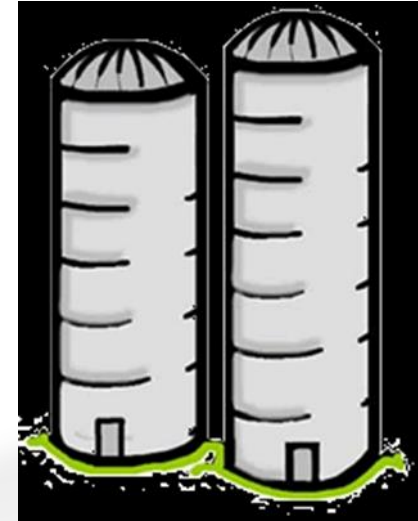
*Enzymes used in cheese are not incidental additives*



# Exemption -- Below Threshold

Each of the following required-

1. No ingredient intentionally contains a BE substance;
2. Presence of BE substance is inadvertent and technically unavoidable; and
3. BE substance is less than 5% of any individual ingredient by weight



On BE Food List or known to be from a BE source

+

Detectable levels of modified rDNA and no applicable exemption

- Highly refined and processed ingredients: HFCS, Corn, Soybean & Canola Oil, soy lecithin, corn starch and
- Other ingredients developed through fermentation with the use of BE inputs - enzymes

1. Records to verify that the food is sourced from a non-bioengineered crop or source;
2. Records to verify that the food has been subjected to a refinement process validated to make the modified genetic material in the food undetectable; or
3. Certificates of analysis or other records of testing appropriate to the specific food that confirm the absence of modified genetic material

1. Actual documentation of the “validating refining processes” and how it has been verified to remove detectable levels of modified genetic material
2. Testing methods to confirm non-detectable levels of modified genetic material
  - Certificate of Analysis
  - Documentation that testing was appropriate, validated, accurate for product being tested and for what is being measured – name test and standard

- Supplier letters with conclusory statements are not enough – need actual documentation/substantiation
- Terminology can be important: BE and not GE or GMO
- Information on testing and validated refinement process should cite to compliance with AMS July 2020 Guidance and BE Rule
- Absent records confirming absence of detectable modified genetic material, USDA presumes food/ingredient on the BE Food List requires mandatory disclosure
- Maintain records for 2 years after product is labeled for retail sale



1. Exempt entities
  - Very small manufacturers
  - Restaurants and similar retail food establishments
2. Food or ingredient on BE Food List, but records show no detectable modified rDNA as a result of a validated refinement process – highly refined ingredients



## Mandatory

- “bioengineered food” (raw food or all BE ingredients)
- For multi-ingredient foods - “contain(s) a bioengineered food ingredient(s)” (may not specify which ingredient)

## Voluntary - Refined Foods and Exempt Entities Only

- “derived from bioengineering” or
- “ingredient(s) derived from a bioengineered source”
- “ingredient(s)”: maybe replaced with the name of the specific crop(s) or food ingredient(s)





# Electronic/Digital Link (QR Code) + Phone Number

**On package: directly above or below the digital link: “Scan anywhere on package for more food information” or “Scan here/icon for more food information.”**



***Plus “Call [1-000-000-0000] for more food information” in close proximity to the digital link***

- Scan must send customer directly to product landing/information page: symbol or “bioengineered food” “contains a bioengineered food ingredient”
- No marketing or information collection
- URL embedded in electronic or digital link
- Telephone number must provide access 24/7 “regardless of the time of day” (may be prerecorded)



**On package: “Text [command word] to [number] for bioengineered food information”**

- Number and short code immediately send a one-time response to consumer’s device
- Response text must be, “bioengineered food” or “contains bioengineered food ingredient” or voluntary disclosure
- No marketing or information collection allowed
- Dairy and food manufacturers may coordinate to centralize an automated text message



Annual receipts between \$2.5 - \$10 million. Additional disclosure options:

- (1) “call [1-000-000-0000] for more food information + telephone number providing access 24/7 “regardless of time of day” (may be prerecorded)
- (2) Visit [URL of website] for more information consistent with mandatory disclosure language and digital link product information page requirements

Small Packages – packages with total surface area less than 40 square inches.

Disclosure options: abbreviated words + all other requirements

(1) Electronic digital link: “scan for info” + all other

(2) Text message: “text [number] for info”

(3) Telephone: “call [1-000-000-0000] for info”

Very Small Packages – packages with total surface area less than 12 square inches. May use preexisting URL for a website or telephone number for consumer access to BE information, consistent with all other disclosure option requirements

# Where is the Disclosure Placed?

Options include:

- Information panel (IP) directly adjacent to statement identifying name and location of manufacture/distributor (below Nutrition Facts)
- On the principal display panel (PDP) (front) if not enough space on IP or
- On alternative panel if not enough space on IP and PDP
- No specific type size – must be sufficient for clarity, easy to read under normal shopping conditions



- BE Rule does not address absence claims
- By statute, only certified organic foods may bear a “non-GMO” label
- No mandatory BE label requirement does not mean food is “non- GMO”
- 3<sup>rd</sup> party verification standards do not always align with BE Rule (but documentation may assist with compliance)
- Follow FDA guidance – truthful and not misleading

- No private right of action against a manufacturer – complaints filed with USDA
- USDA may investigate complaints, request records and audit, but will not test products – company documentation is basis for compliance
- Company may request hearing and provide supporting documentation
- USDA concludes investigation by publishing public summary of investigation final results, subject to judicial review
- No AMS recall authority





**Yes, the ingredient contains detectable modified genetic material.**

**Does the bioengineered substance in the ingredient fall below the threshold amount?**

**Yes, the bioengineered substance in the ingredient falls below the threshold amount.**

**No, the bioengineered substance in the ingredient does not fall below the threshold amount.**

If an ingredient includes an inadvertent or technically unavoidable amount of a bioengineered substance, in an amount less than five percent, then that specific ingredient does not trigger disclosure.

Any intentional use of a bioengineered ingredient requires disclosure.

# Compliance Dates

Nutrition Facts Panel  
Compliance: January 1, 2020  
Enforcement discretion until  
January 1, 2021  
January 1, 2022 for small  
entities

BE Food Disclosure  
Compliance: Jan 1, 2022



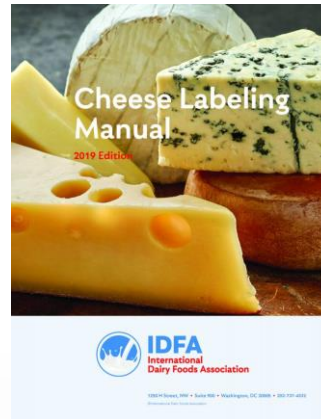
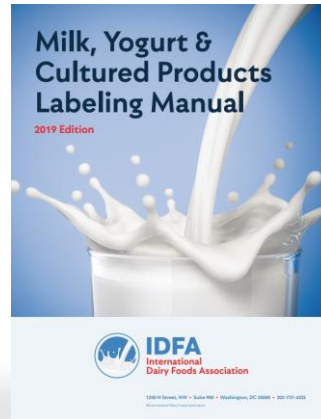
# Questions?

Type your questions in the text  
chat box area at the bottom of  
the window

Presenters will answer questions without  
attribution to your name or company as time  
allows or email back a response after the  
webinar



- Updated IDFA Labeling Manuals – order at IDFA’s website [www.idfa.org](http://www.idfa.org)



- IDFA Member Support
  - Joe Scimeca (202)220-3516, [jscimeca@idfa.org](mailto:jscimeca@idfa.org)
  - Michelle Albee Matto (202) 431-6864 [amfoodnutrition@gmail.com](mailto:amfoodnutrition@gmail.com)
  - Danielle Quist (202) 220-3508 [dquist@idfa.org](mailto:dquist@idfa.org)
- FDA webpage on Labeling & Nutrition - Food Labeling and Nutrition Overview

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/default.htm>

- Code of Federal Regulations Title 21 part 100-169
- [Guidance for Industry: A Food Labeling Guide](#) (Revised 2013)