Food Directions USA Food Labeling Overview

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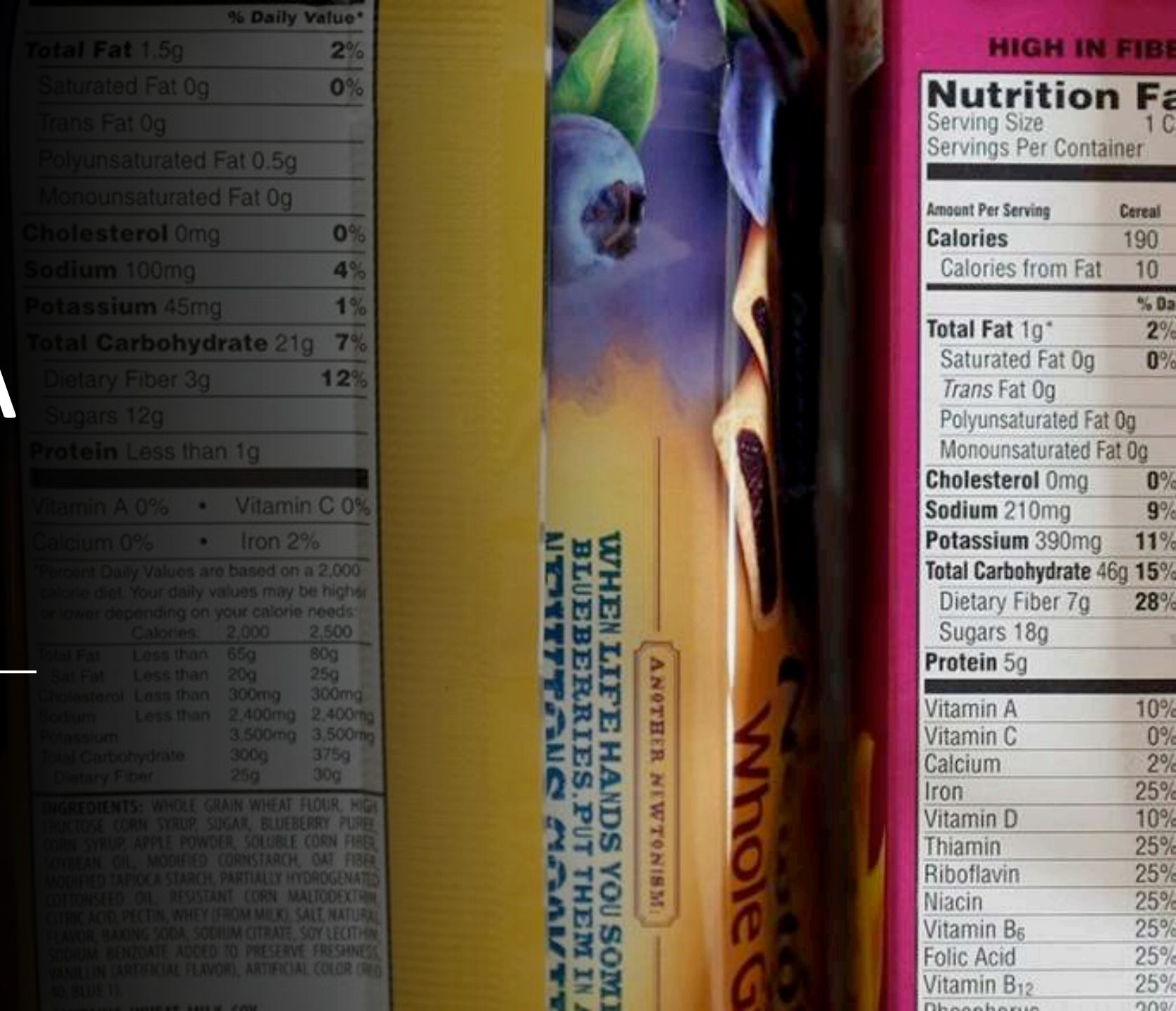
Prepared for:

FOOD SAFETY INTERNATIONAL NETWORK



Overview

Today I will cover:

- General USA Labeling Authorities
- FDA Labeling Requirements
- FDA Nutrition Labeling Updates
- Claims
- Future Directions

General USA Labeling Authorities

US Laws and Regulations for Food Labeling

US Congress

- In the US, Congress passes laws
- Congress may direct a regulatory Agency to develop rules to implement the law

Regulatory Agencies (FDA/USDA)

- Create regulations to implement and enforce the laws

FDA vs USDA

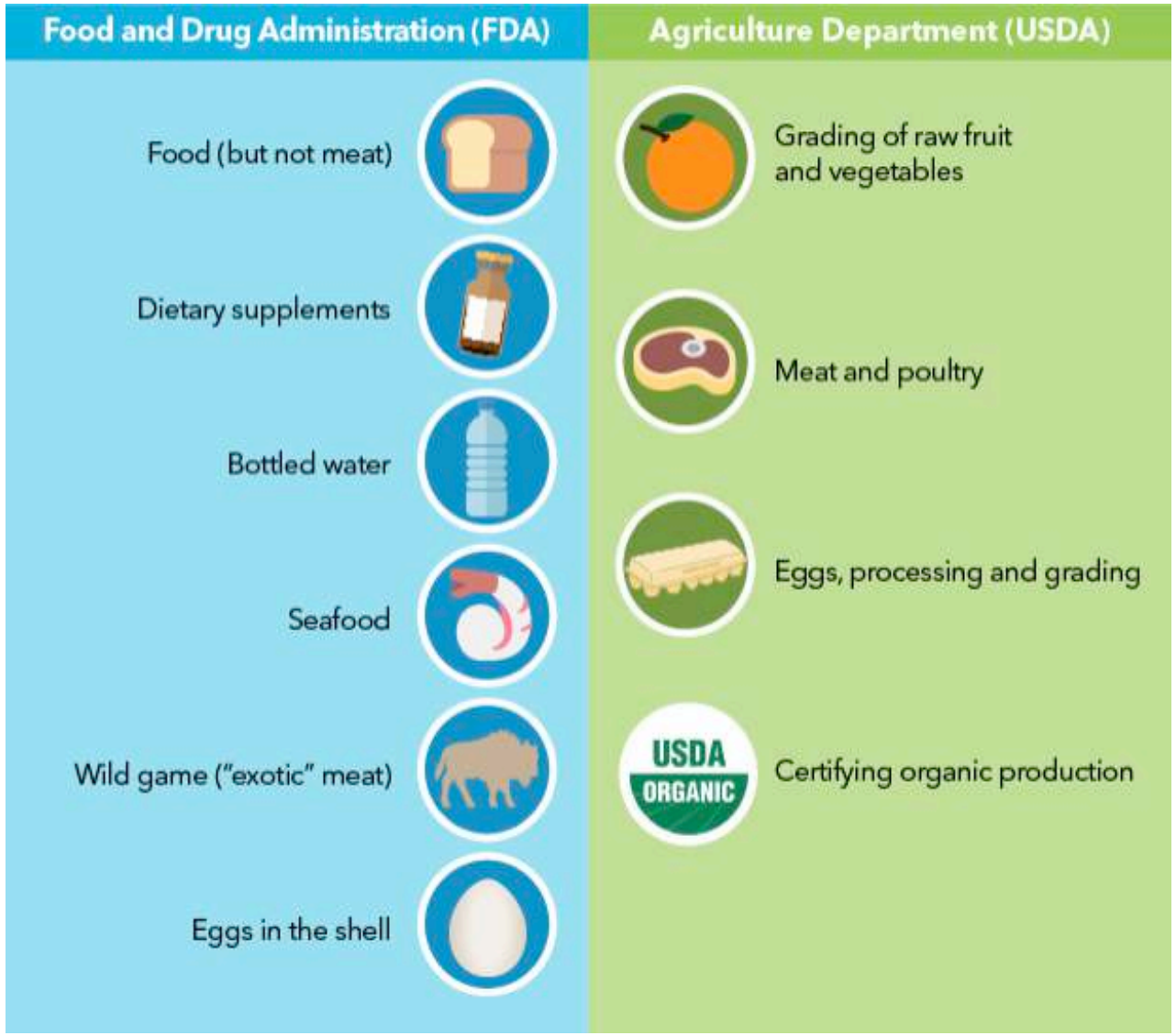
Food and Drug Administration (FDA)

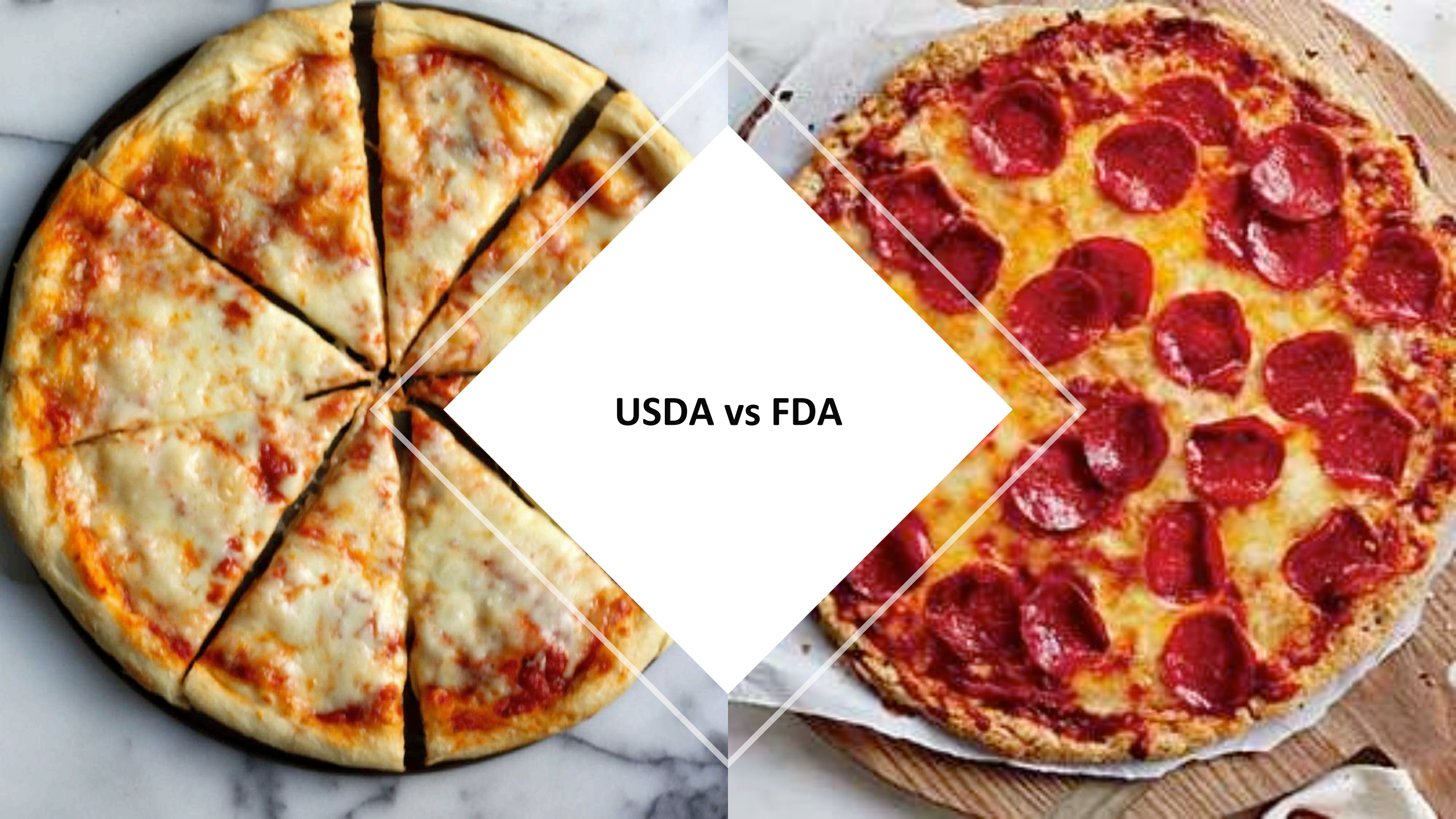
- Regulates 85% of the food supply
- Also regulates drugs and cosmetics

United States Department of Agriculture (USDA)

- Food Safety Inspection Service (FSIS)- regulates meat, poultry, egg products
- Agricultural Marketing Service (AMS)- BE labeling, grade standards and organic

Who Regulates What?





USDA vs FDA

Finding FDA and USDA Regulations

FDA

- Title 21 of Code of Federal Regulations (CFR) Food and Drugs
    - Part 101: General Labeling Requirements
    - Parts 130, 131-169: Standards of Identity

USDA (FSIS)

- Title 9 CFR Animals and Animal Products
    - Meat Labeling: 9 CFR 317
    - Poultry Inspection and Labeling: 9 CFR Part 381

FDA Labeling Requirements

Required Labeling Features

FDA

- Product Name
- Ingredient List
- Allergens
- Net Contents
- Signature Line
- Handling Statement
- Nutrition Facts

Product Names

FDA Standards of Identity

- Requirements regarding the ingredients and composition of products
- These requirements will also influence the name of the product
- Example of FDA Standards of Identity:
  - Yogurt- food produced by culturing one or more optional dairy ingredients with a bacterial culture that contains lactic-acid producing bacteria. Can also add optional ingredients like vitamins, other dairy, sugars, flavors, colors, and stabilizers.
  - If it doesn't meet this standard ≠ yogurt

Product Names/ Statements of Identity

- All products are required to have a product name; this is also called a ‘statement of identity’
- If the product meets a standard of identity then that dictates its product name. If doesn’t meet a standard of identity, then it the product name must be a common or usual name that is easily understood by consumers
- Must be located on the primary display panel (PDP)
- Should be ½ size of largest type on label

Naming Products

Standardized

- Products where there is a standard of identity
- Must meet the requirements to use the product name
- Very clear about requirements

Non-Standardized

- Products that either
  - Don't meet the standard that exists
  - No standard of identity exists for
- Example:
  - What we think of as salad dressing does not usually contain eggs to can't be labeled salad dressing
    - Labeled as dressing

Naming Products Without Standards

- Confirm doesn't meet a standard of identity
- Confirm that name does not include a standard by accident
- Choose name that is adequately descriptive
- Compare with other products on the market
- Write a product name

Fanciful Names

- Products can also have fanciful names
- Fanciful names are known by the general public
- This is used to refer to a product but is not usually appropriately descriptive (E.g., Oreo)
- Should also include a common/usual name on label

Fanciful Names Continued

Fanciful Product Name

- Does not describe the product
- FDA is typically trade marked
  - Allows for greater variety of product name

True Product Name

- Describes what the product is
- Adequately describes the product
- Gives true nature of product

Flavors

- Chemicals that are added to food to intensify or add flavors
- Two types of flavors:
  - Natural-
    - Made from plant, animal or other natural sources
  - Artificial-
    - Made from synthetic or chemical sources
- Must label natural or artificial flavor below the product name if same flavor is used in product name

Summary: Product Naming

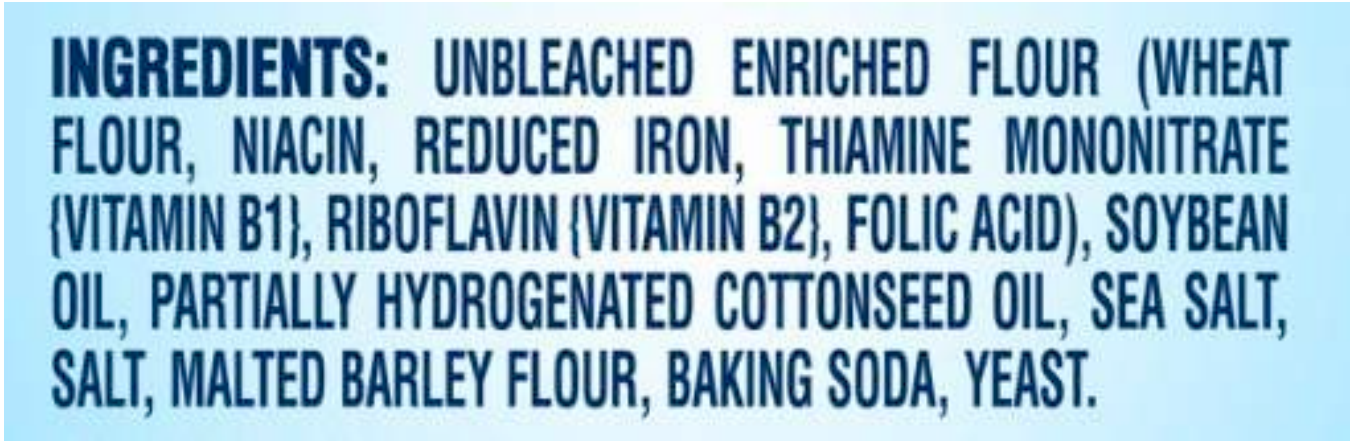
Considerations for naming:

1. Statement of Identity
   - Name specified by law or regulation/standard of identity (if applicable)
   - If no standard of identity: Common or usual name/descriptive
2. Fanciful name (if applicable)
3. Flavor labeling (if applicable)

Ingredient Statements

Ingredient Statement

- Required on label, unless a specific exemption
- Declare all ingredients by common or usual name
- List ingredients in descending order of predominance by weight (Largest to smallest)
  - In paragraph form
  - Must sublist ingredients with more than one component
- Can use ‘less than 2%, 1.5%, 1% or 0.5%’



Ingredient Statement Continued

- Two different format options, pick one to suit labeling desires:
  - Component- Declare ingredient by common name followed by sub-listing
    - I**NGREDIENTS:** BEEF, TOMATO PUREE (WATER, TOMATO PASTE)
  - Composite- Incorporate the sub-ingredients of multi-component ingredients by order of predominance
    - **INGREDIENTS:** BEEF, WATER, TOMATO PASTE
- Can also use a combination of component and composite listing

Ingredient List Size And Placement

- Must be 1/16” tall at the smallest letter o
- Companies can choose to use caps and small letters as desired
  - Bold is allowed as desired
  - Must meet size requirements
- Must be located next to the Nutrition Facts label and signature line

Incidental Additives Or Processing Aid Definition

- Substances that have no technical or functional effect in the finished food
- These ingredients are not declared in ingredients list
  - Examples: substances removed, substances converted during processing, etc.
  - Exception: All incidental additives/processing aids that are also food allergens must be listed in ingredient list

Spices

- May be labeled as
  - Spices
  - Flavoring
  - Natural Flavor
- List of spices provided by FDA:
  - Allspice
  - Anise
  - Basil
  - Bay leaves
  - Caraway seed
  - Cardamon
  - Celery seed
  - Chervil
  - Cinnamon
  - Cloves
  - Coriander
  - Cumin seed
  - Dill seed
  - Fennel seed
  - Fenugreek
  - Ginger
  - Horseradish
  - Mace
  - Marjoram
  - Mustard flour
  - Nutmeg
  - Oregano
  - Parsley
  - Pepper, black
  - Pepper, white
  - Pepper, red
  - Rosemary
  - Sage
  - Savory
  - Star aniseed
  - Tarragon
  - Thyme

Allergen Labeling

Allergen Labeling

- Plain English declaration of major food allergens
- Include in the ingredient statement
- Contains statement
  - Contains:
  - Below the ingredient statement in the same size and font
  - In bold
  - FDA preferred method
- May put in parenthesis after the ingredient in the ingredient statement
  - Example: Whey (milk)
  - Not FDA preferred method
- Both methods combined is not allowed

US Major Food Allergens

- Soy
- Milk
- Wheat
- Eggs
- Tree Nuts
- Peanuts
- Fish
- Shellfish

FDA Considering Adding Sesame as Allergen

- FDA moving towards requiring sesame to be listed as an allergen
- Requested data from the public on this topic
  - Next step is proposed rule
- Expect final rule in 5 to 10 years
- Appropriate to start labeling now
  - With other label changes

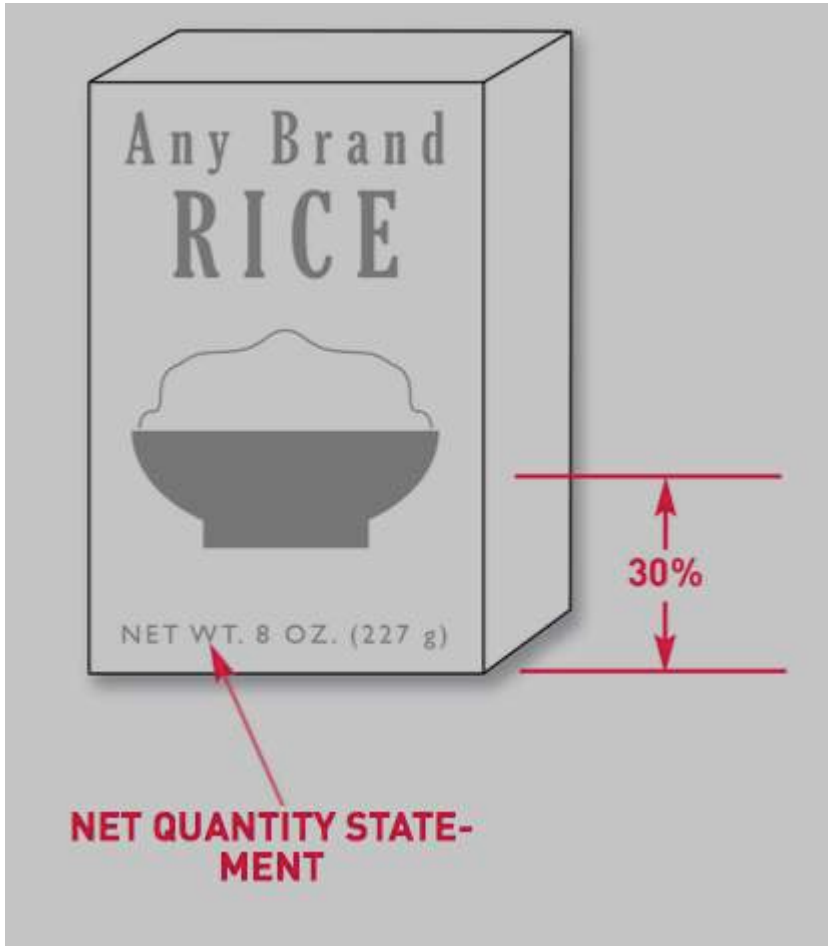
May Contain Statement

- There are not regulations around may contain
- Every effort must be taken by plant to prevent cross-contamination
- Companies must provide allergen information as request to consumers and customers
  - Ingredient suppliers
  - Grocery stores for private label
- Statement does not protect against recall if allergens present

Net Contents Statement

FDA

- Has net weight regulations
- Required to have weight statement on all food packages
- May be weight, liquid or count
- Location, size and format are regulated



Net Content Font Size

Minimum Type Size	Package Area
1/16” (1.6 mm)	5 sq in (32 sq cm) or less
1/8” (3.2 mm)	More than 5 sq in (32 sq cm) but not less than 25 sq in (161 sq cm)
3/16” (4.8 mm)	More than 25 sq in (161 sq cm) but not less than 100 sq in (645 sq cm)
¼” (6.4 mm)	More than 100 sq in (645 sq cm) but not less than 400 sq in (2580 sq cm)
½” (12.7 mm)	Over 400 sq in (2580 sq cm)

Measured at the smallest letter
Do not cheat and go smaller
- Many companies have tried this

Signature Line

Signature Line Or Packer/ Distributor Statement

- FDA requires labeling to identify the company responsible for manufacturing or distributing a food. Generally found on the information panel
- Includes:
  - Name and place of business/location required
  - “Manufactured for” or “Distributed by” if not made by the named company

Signature Line Or Packer/ Distributor Statement

- The following is required in the address line
  - Name
  - City
  - State
  - Zip Code
- The street address is required if the address is not in the local phone book or on the internet
- Must be located directly adjacent to the ingredient statement or Nutrition Facts label
  - No intervening material is allowed
- Distributed by, prepared for, and manufactured by:
  - Used prior to address line
  - Required on co-packed products
  - Common used on other products
  - Other similar statements allowed

Handling Statement

Handling Statements

- FDA
  - Only a regulatory requirement on some foods
  - But should always include to protect company from liability
- Examples
  - Keep Frozen
  - Keep Refrigerated
- Voluntary Statements
  - Refrigerate after opening

Other Labeling Features

General Font Size Rules

- Everything on the label must be 1/16” (1.6 mm) tall
  - Unless required to be bigger
- Font style is not regulated
- Upper and lower case is allowed
- Font size measured at smallest letter o

Foreign Language Labeling

- Any English must be translated if even 1 word appears in another language
- Not allowed to translate only select items; all or nothing
- Both languages must be same size and predominance

Pictures and Vignettes

- Use statement ‘Serving suggestion’ when pictured food is not the same as what is found in the package or has items not in the package
  - Garnishes
  - Prepared items
  - Utensils, etc.
- Required on frozen dinners; and also commonly used on other packages
- Used to legally protect companies
- Other language is sometimes used
  - Enlarged to show texture

Traceability and Code Dating

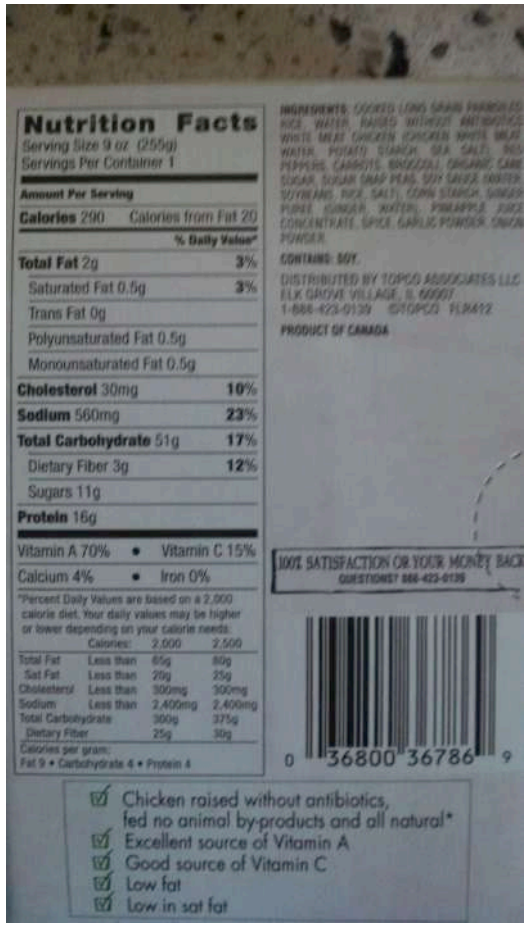
- May be in any format company desires
- Used by, best by and best if used by
  - Not a regulatory requirement
  - Some stores require it (e.g., Walmart)
- Companies must be able to trace product one step forward and one step back
  - Where the ingredients came from
  - Where the finished product went

Country Of Origin

- Regulated by multiple Agencies
- Customs
  - Required on all imported products
  - Located next to address line in same size and type
- USDA AMS
  - Required on all single ingredient meat, produce and nuts
  - Located next to the address line in same size and type

US Customs Country Of Origin

- Require country made in on all products imported into the US
- Require that final purchaser of goods can see the country of origin
- For food products:
  - Industry has come to consensuses on size and location
  - Located with the address line in same size



Bioengineered Labeling (i.e. GMO)

- Rule passed in December 2018
  - Applies to all FDA-regulated foods
  - All other meat, poultry and egg products are excluded
- Compliance by January 1, 2022
- Definition of a BE food
  - *food that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature;* ***provided that: Such a food does not contain modified genetic material if the genetic material is not detectable.***
- Excludes refined ingredients (oils, sugars) from the definition but may be voluntarily declared

BE Foods List

Alfalfa

Apple (Arctic™ varieties)

Canola

Corn

Cotton

Eggplant (BARI Bt Begun varieties)

Papaya (ringspot virus-resistant varieties)

Pineapple (pink flesh)

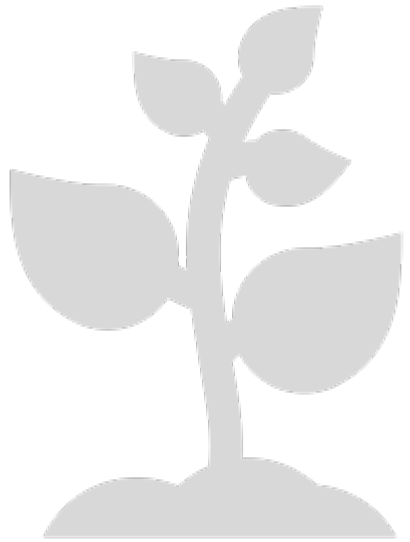
Potato

Salmon (AquAdvantage®)

Soybean

Squash (summer), and

Sugar beet



BE Disclosure Options

- Disclosure method should include one of the following:
- Text disclosure: “bioengineered food” or “contains bioengineered food ingredients”
- Symbol disclosure
- Text message
- Electronic or digital disclosure

Nutrition Labeling Updates

Nutrition Label Reform Update

FDA Final Rules

- Food Labeling: Revision of the Nutrition and Supplement Facts Labels
- Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments

USDA Proposed Rule

- Revision of the Nutrition Facts Panel for Meat and Poultry Products and Updating Certain Reference Amounts Customarily Consumed

FDA Guidance and Technical Updates

Notable Guidance (2018)

- FDA's Final Guidance on Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals
- FDA's Draft Guidance on Serving Sizes, RACCs, Dual-Column Labeling, and Miscellaneous Topics
- Food Labeling; Revision of the Nutrition and Supplement Facts Labels; Technical Amendment, 83 Fed. Reg. 65493 (Dec. 21, 2018).

2018-2020: FDA has continued to publish guidance documents to industry for NFP compliance

https://www.fda.gov/food/food-labeling-nutrition/industry-resources-changes-nutrition-facts-label

Nutrition Labeling

Important points about nutrition labeling:

- Nutrition labeling required for overwhelming majority (about 95%) of packaged foods sold to consumers

- Developing a compliant nutrition label follows a general process:
  - Information about the nutrients – analysis or databases
  - Determine label serving size
  - Convert nutrient data to declaration info
  - Select nutrition label format
  - Adjust for any claims

Impact Beyond Nutrition Panel

- Package Design
- Nutrient Content Claims
- Brand Names
- New Practices for Records Maintenance & Substantiation

Nutrition Labeling Regulations

FDA regulations:

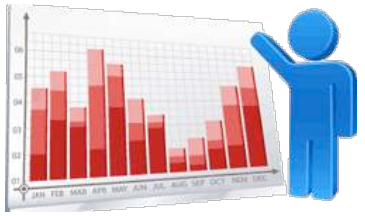
- 21 CFR 101.9(b) – serving size
- 21 CFR 101.9(c) – nutrient declarations
- 21 CFR 101.9(d) – format basics
- 21 CFR 101.9(e – f) – alternate formats
- 21 CFR 101.9(g) – compliance
- 21 CFR 101.9(h – j) – special provisions and exemptions

Major Labeling Changes

- Modernized the format to highlight calories and serving size information; updated footnote
- Updated the Daily Values
- Updated nutrients of public health significance
- *Trans* fat and dietary fiber
- Mandated declaration of added sugars with % DV
- Records requirements
- Changed some reference amounts used to calculate serving sizes
- Require dual-column labeling with nutrition information listed per serving and per package or unit for certain products
- Changed the criteria for single serving packages
- Compliance date

Reference Amounts Customarily Consumed

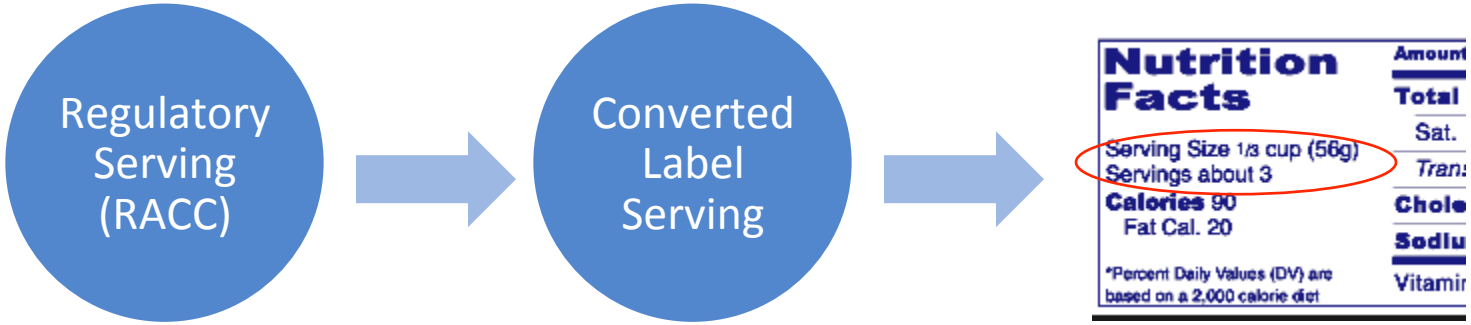
How are Reference Amounts Determined?



Consump-tion Data + Analysis of Data = Proposed RACC

Reference Amounts Customarily Consumed

How are Reference Amounts Used?



Reference Amount Updates

- Consumption Data Showed ± 25%
- ~ 14 updates to RACCs
- Notable updates include:

Beverages

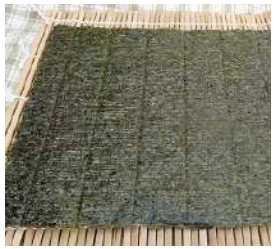
Bulk & Novelties

Yogurt

Reference Amount Updates

- ~19 newly established categories
- Notable new RACCs include:

Dried Vegetables



Seaweed Sheets

Appetizers & Hor d'oeuvres

Seasoning Pastes

Drink Mixes

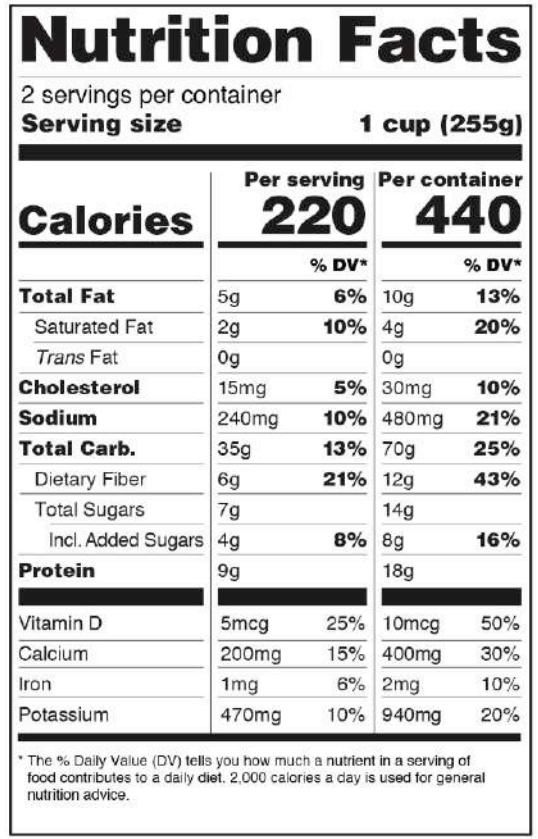
Single Serving Container

- Contains less than 200% of RACC
- The entire contents of package is a “serving”
- Removed large RACC exemption

Packaged Food Sold Individually Containing

≥200% & up to & including 300% of the RACC

- Products of this pack size – dual-column NFP required
- First Column: per serving
- Second Column: per container



Nutrition Facts

2 servings per container

Serving size **1 cup (255g)**

	Per serving		Per container	
Calories	**220**		**440**	
		% DV*		**% DV***
Total Fat	5g	**6%**	10g	**13%**
Saturated Fat	2g	**10%**	4g	**20%**
Trans Fat	0g		0g	
Cholesterol	15mg	**5%**	30mg	**10%**
Sodium	240mg	**10%**	480mg	**21%**
Total Carb.	35g	**13%**	70g	**25%**
Dietary Fiber	6g	**21%**	12g	**43%**
Total Sugars	7g		14g	
Incl. Added Sugars	4g	**8%**	8g	**16%**
Protein	9g		18g	
Vitamin D	5mcg	25%	10mcg	50%
Calcium	200mg	15%	400mg	30%
Iron	1mg	6%	2mg	10%
Potassium	470mg	10%	940mg	20%

* 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.

Serving Size for Products in Discrete Units

- Individual unit weights ≥200% and up to including 300% of RACC
- Serving Size = amount closest to RACC
- Dual-column labeling required
  - Per serving
  - Per unit

NFP Makeover

Nutrition Facts

Serving Size 2/3 cup (55g)
Servings Per Container About 8

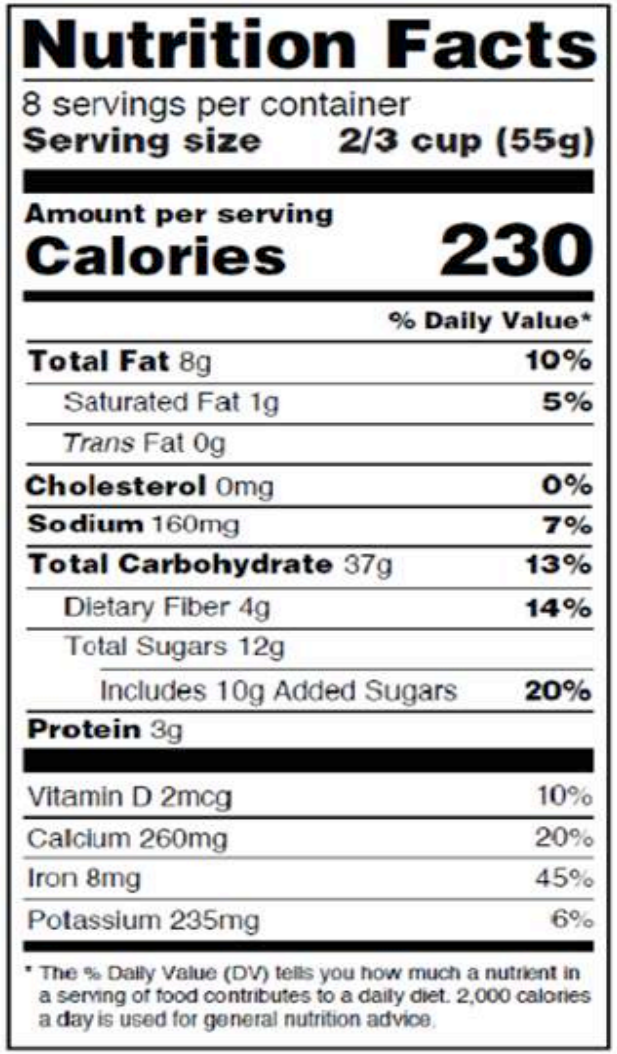
Amount Per Serving

Calories 230	Calories from Fat 72
	% Daily Value*
Total Fat 8g	**12%**
Saturated Fat 1g	**5%**
Trans 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

Current 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%**
Trans 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.

New Label

Design Changes

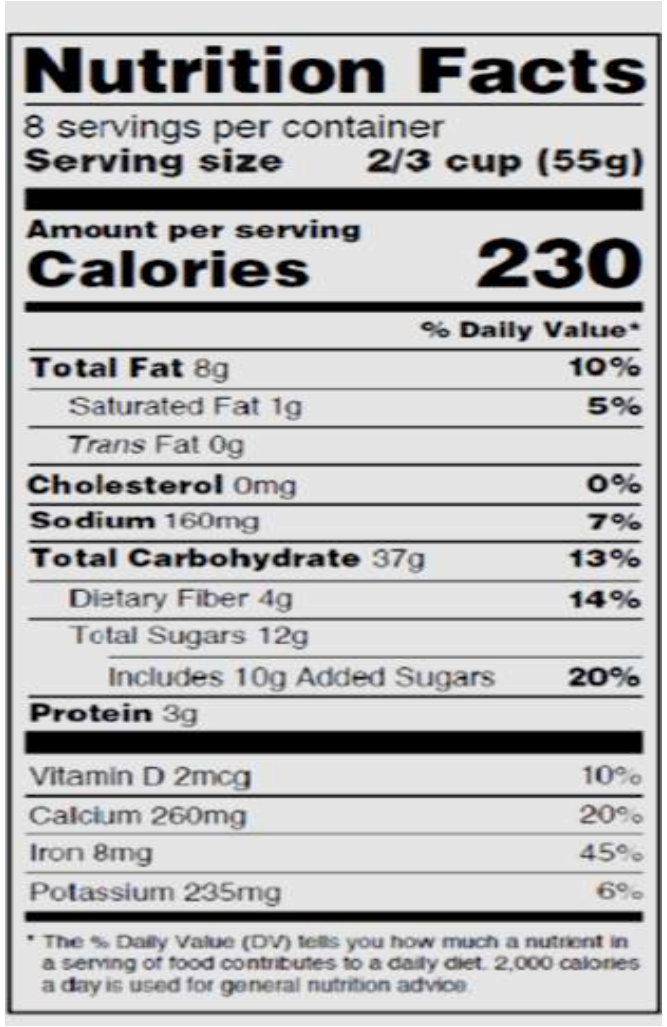
Nutrient Declarations

Changes to Mandatory Nutrients

- Added Sugars
- Vitamin D
- Potassium

Changes to Voluntary Nutrients

- Vitamin A
- Vitamin C



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Amount per serving

Calories **230**

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Vitamins and Minerals

Mandatory:

- Vitamin D, Calcium, Iron and Potassium

Voluntary:

- Vitamin A, Vitamin C, Vitamin E, Vitamin K, Vitamin B_6, Thiamine, Riboflavin, Niacin, Folate, Biotin, Pantothenic Acid, Phosphorous, Iodine, Magnesium, Zinc, Selenium, Copper, Manganese, Chromium, Molybdenum, Chloride, and Fluoride

Daily Value Changes

Total Fat: 65 to 78 g
Total Carbohydrate: 300 to 275 g
Dietary Fiber: 25 to 28 g
Sodium: 2,400 to 2,300 mg
Potassium: 3,500 to 4,700 mg
Calcium: 1,000 to 1,300 mg
Vitamin D: 400 IUs (10 µg) to 20 µg

Other Nutrient Declarations

No longer permitted on Nutrition Facts:

- Calories from Fat
- Other Carbohydrates

Change in terminology used on Nutrition Facts:

- “Sugars” now listed as “Total Sugars”

Revised Footnote

- Removed %DV footnote table
- Amended footnote statement for:
  - Foods for persons 4 years of age and older
  - Foods represented or purported for children 1-3 years of age

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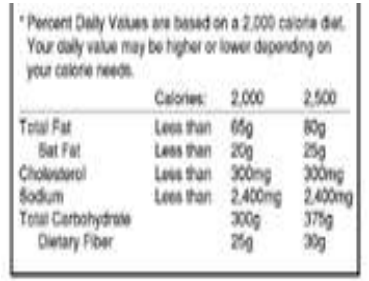

* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.

	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

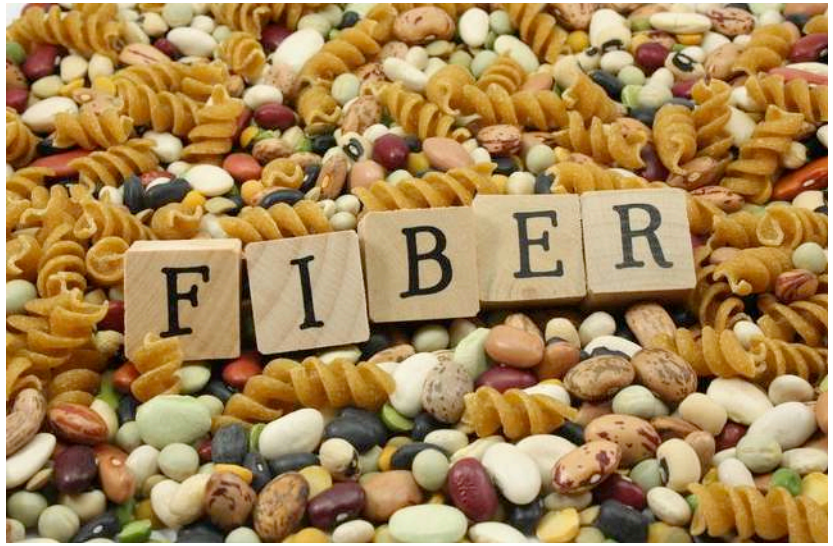
Added Sugar

Inclusions:

- Sugar (free, mono-, and disaccharides)
- Sugars from syrups and honey
- Sugars from concentrated fruit/vegetable juice

Dietary Fiber

Non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units), and lignin that are intrinsic and intact in plants; isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health.



Compliance Timing

FDA extended the compliance dates for updating Nutrition Facts and Supplement Facts labels, from July 26, 2018, to January 1, 2020, for manufacturers with $10 million or more in annual food sales.

Recently, FDA has provided enforcement discretion until January 1, 2021 for updates to NFPs due to the COVID-19 pandemic

CLAIMS

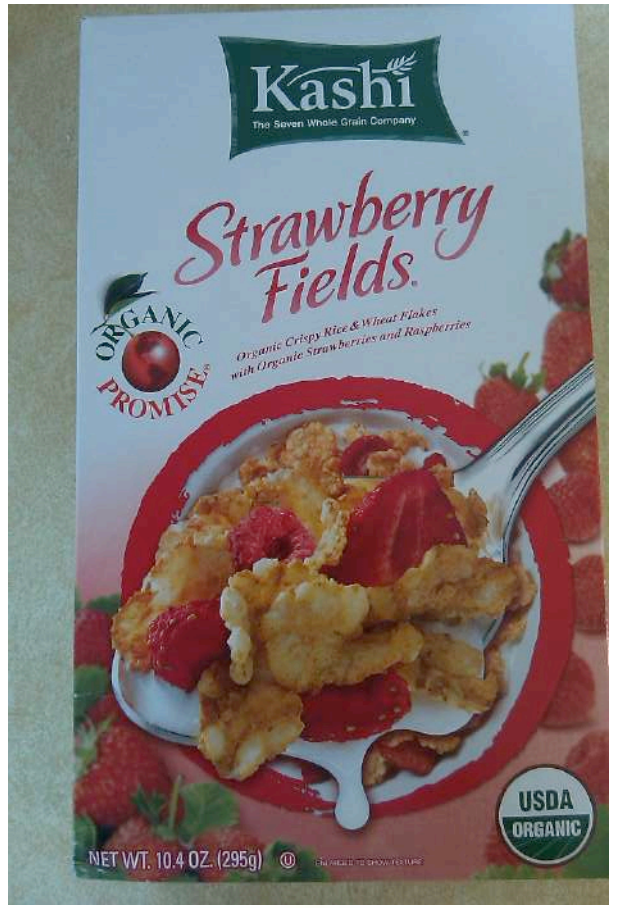
Types of Claims

- Ingredient related claims
  - Natural
  - Organic
  - Religious (Kosher, Hallal)
  - Gluten Free
- Nutrition claims
- Third Party claims (non-GMO)
- Sustainability Claims (recycled content)

Ingredient Claims

Organic

- Defined claim
- USDA Agricultural Marketing Service
- Labeling
  - Organic - >95%
  - Made with Organic – 70 – 95%
  - List organic ingredients - <70%



Fresh

- Defined claim

- FDA definition: “fresh” suggest or implies that the food is unprocessed or unpreserved this means the food is in its raw state and has not been frozen or subjected to any form of thermal processing or any other preservation

Gluten Free

- Defined claim
- Final Rule on August 5, 2013
- Less than 20 ppm of gluten
- May contain small amounts of wheat has been processed to allow this food to meet the Food and Drug Administration (FDA) requirements for gluten-free foods

Natural

- Not well defined
- FDA
  - No synthetic ingredient
  - No colors from any source
- USDA
  - No synthetic ingredients
  - No colors from any source
  - Minimally processed

No Preservative

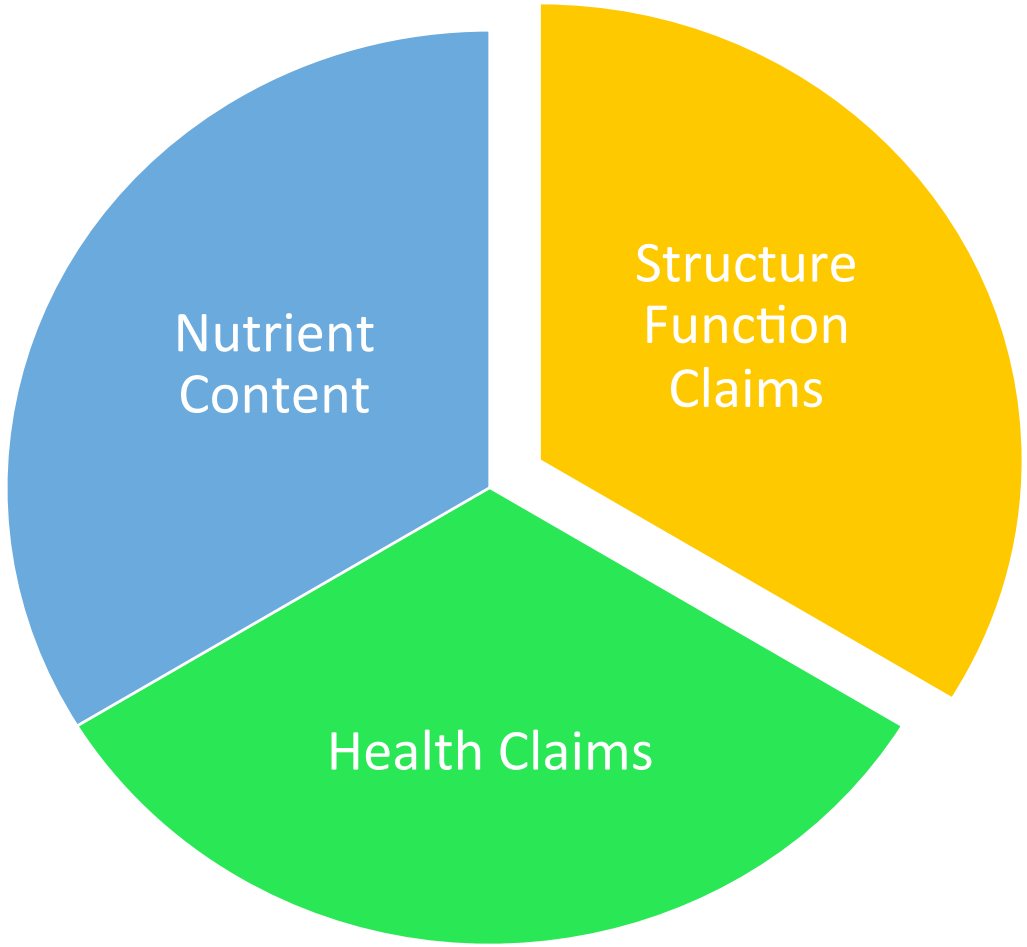
- No a formal regulatory definition for FDA or USDA
- Often used when products don't meet requirements to make a natural claim

Plant-Based

- No regulatory definition
- Variety of definitions
  - Some vegan
  - Some vegetarian
- Must be truthful and not misleading

Nutrition Claims

Types of Nutrition Claims



Nutrient Content Claims (NCC)

- Statements about the amount of a nutrient in the food
- Expressed claims
- Implied claims
- Must meet specific requirements

Expressed vs Implied Claims

Expressed:

- Any direct statement about the level (or range) of a nutrient in the food, e.g., "low sodium" or "contains 100 calories.

Implied:

- Describes the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount
- Suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices

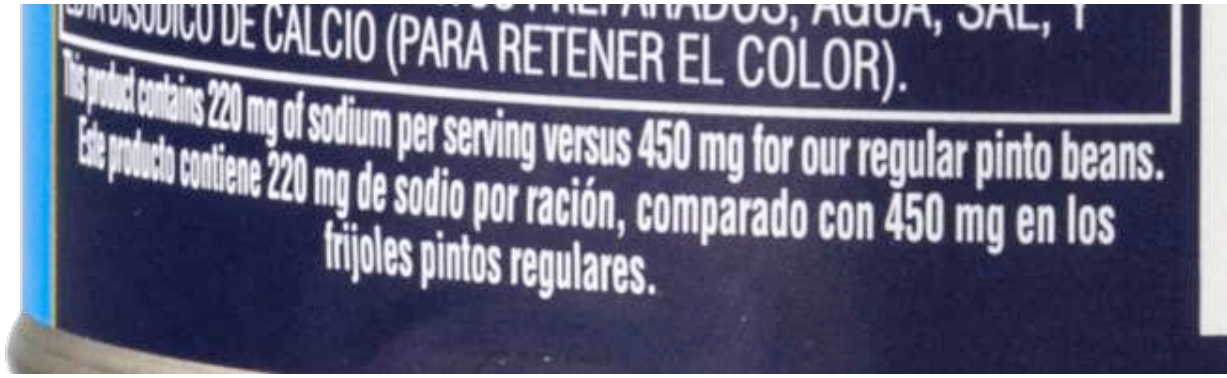
Sample-Regulatory Claims Definition

Claim	Description	Reference
Calorie Free	Less than 5 calories per RACC and labeled serving	21CFR101.60
Low Calorie	40 calorie or less per RACC (and 50 g serving if RACC is small) Meals and Main Dish 120 calories or per 100 g	21CFR101.60
Reduced Calorie	At least 25% fewer per RACC than appropriate reference food Meals and Main Dish 25% fewer calories /100 g Reduced calories claims can't be used on foods the meet low calories Must include comparative statement on back panel	21CFR101.60

Expressed NCC Example

Comparative Claims:

- Appropriate reference food
- Must include reference statement on back panel



Implied NCC Example

- Claims that make consumers believe the product meets a specific nutrition claim without using any words that a regulated
- Must meet all requirements of the original claim to make this statement
- Example: “good source of oat bran”

Implied NCC Example

‘Healthy’ Claim

- FDA Guidance Document, September 2016
- FDA currently looking to update healthy definition and establish a corresponding front of pack symbol

Undefined NCC

- Undefined nutrient content claims are **not** allowed

- Examples:
  - Low Sugar
  - Low Carb

Health Claims

- Codified/Authorized Health Claims
- FDAMA and Qualified Health Claims

FDAMA and Qualified Health Claims

- FDA reviews and defines enforcement discretion
- Example:
  - *Very limited and preliminary scientific evidence suggests that eating about 1 tablespoon (16 grams) of corn oil daily may reduce the risk of heart disease due to the unsaturated fat content in corn oil. FDA concludes that there is little scientific evidence supporting this claim. To achieve this possible benefit, corn oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of corn oil."*

Structure Function Claims

- Claims that talk about the function of a nutrient

- Example:
  - Protein helps build strong bones

Looking Toward the Future

COVID-19 Notable Regulatory Updates

FDA

- Continues to provide temporary flexibility for Food Labeling
- NFP Compliance Date Extension (January 2021)
- Changes in Variety Packs
- Restaurant Foods Sold to Consumers/Menu Labeling
- Ingredient Substitution and Flexibility
- Vending Calorie Labeling

USDA

- USDA Updates Guidance on Inspection and Export Services, Food Safety
- Flexibilities for Food Assistance/School Meals Programs

CDC

- CDC and OSHA release Guidance for Manufacturing Workers and Employers

CISA

- Designate Food and Agriculture as Critical Infrastructure

FDA's 2018 Strategic Policy Roadmap

Healthy Innovation, Safer Families: FDA's 2018 Policy Roadmap

a. Reduce the burden of addiction crises threatening families;

b. Leverage innovation and competition to improve health care, broaden access, and advance public health goals;

c. Empower consumers to make better and more informed decisions about their diets and health; expand opportunities to use nutrition to reduce morbidity and mortality from disease;

d. Strengthen FDA's scientific workforce and its tools for efficient risk management.

FDA Nutrition Innovation Strategy

1. Modernizing Claims
2. Modernizing Ingredient Labels
3. Modernizing Standards of Identity
4. Implementing NFP and Menu Labeling
5. Reducing Sodium

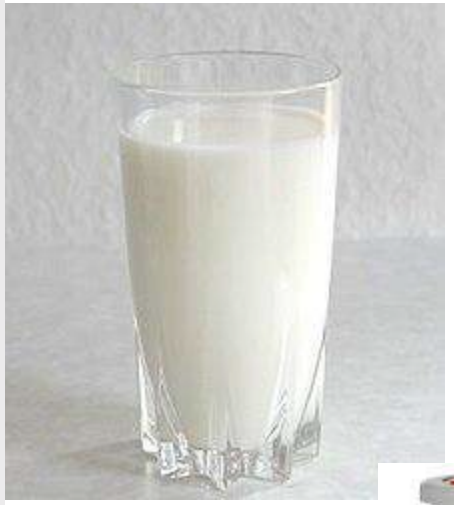
U.S Food and Drug Administration

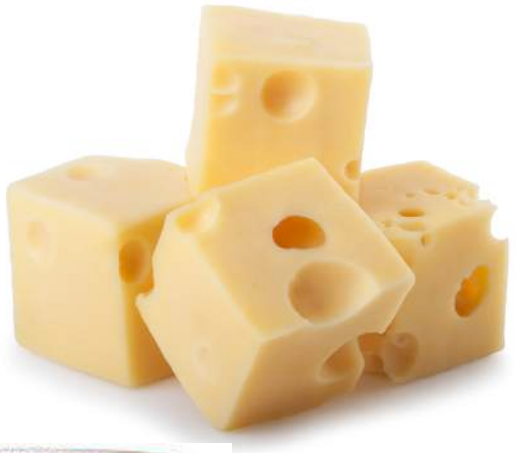
Standards of Identity (SOI)

General Principles:

- In 2005, a proposed rule was issued as a first step in instituting a process to modernize SOI
- This rule proposed a set of 13 general principles to consider when establishing, revising, or eliminating a SOI
- In 2006, US 11 allied trade associations proposed a broad horizontal approach to updating SOIs
- FDA has hosted public meeting to address SOI updates
- FDA reopening general principles in 2019, and recently took more public comments

Plant-Based Products





Naming of Plant-Based Products

- Milk, Yogurt and Cheese
  - Standard of identities from cow or goat
  - Products from nuts, oats, soy, coconut and other
- Meat Replacements
  - Burgers, crumbles, franks
  - Products from soy, pea, wheat and others
- Issues:
  - Product naming
  - Nutritional equivalence
- FDA requested comments in 2018
  - Comments again 2020

Potential FDA Priorities

2020-2021 FDA Priorities:

- Publish a proposed rule on use of the term 'healthy' in food labeling
- Explore ways to help industry use statements or claims that could facilitate innovation to promote healthy eating patterns (could include FDA-sanctioned 'healthy' icon)
- Develop a regulatory strategy for labeling plant-based alternatives to dairy products

Potential FDA Priorities Continued

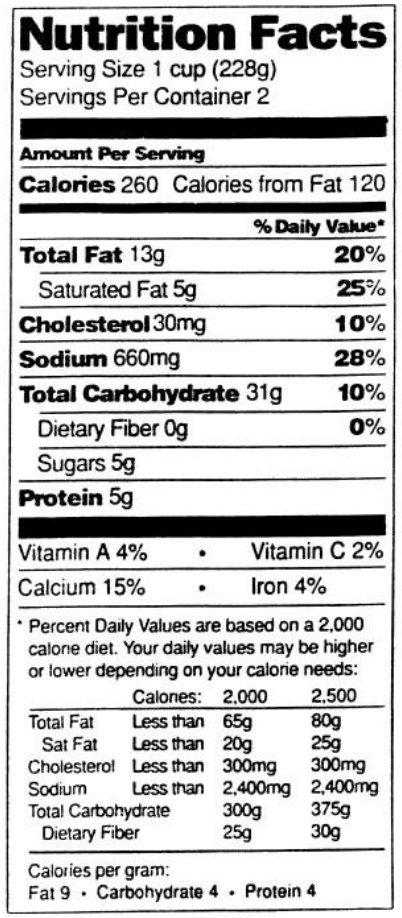
2020-2021 FDA Priorities:

- Review existing standards of identity in light of marketing trends and the latest nutritional science

- Review National Academy of Science, Engineering, and Medicine DRI for sodium and potassium report with regard to FDA's guidance for voluntary short-term sodium reduction goals

- Collaborate with stakeholders to address questions and promote compliance with menu labeling

USDA Proposed Nutrition Facts Label Changes



Nutrition Facts

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

Amount Per Serving

Calories 260 Calories from Fat 120

	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**10%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

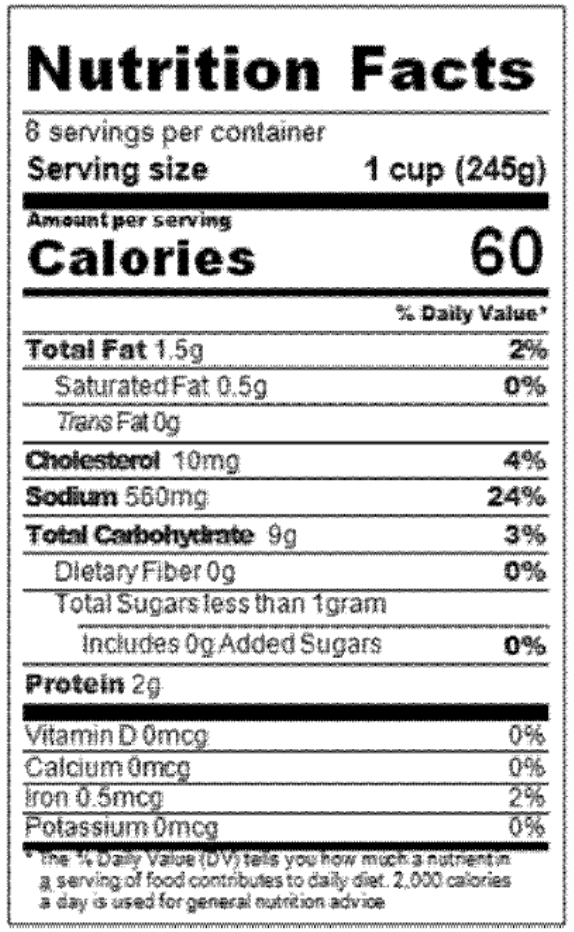
Vitamin A 4% • Vitamin C 2%
Calcium 15% • Iron 4%

* 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

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Current Label



Nutrition Facts

8 servings per container
Serving size 1 cup (245g)

Amount per serving
Calories 60

	% Daily Value*
Total Fat 1.5g	**2%**
Saturated Fat 0.5g	**0%**
Trans Fat 0g	
Cholesterol 10mg	**4%**
Sodium 560mg	**24%**
Total Carbohydrate 9g	**3%**
Dietary Fiber 0g	**0%**
Total Sugars less than 1gram	
Includes 0g Added Sugars	**0%**
Protein 2g	
Vitamin D 0mcg	0%
Calcium 0mcg	0%
Iron 0.5mcg	2%
Potassium 0mcg	0%

* the % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to daily diet. 2,000 calories a day is used for general nutrition advice

New Label

Q+A

I am happy to take any questions you may have.

CONTACT ME

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Beth Johnson, MS, RD

Principal

Food Directions LLC