



DIVISION OF AGRICULTURE
RESEARCH & EXTENSION

University of Arkansas System

Labeling and Allergens

Mandatory Food Label Elements

Federal FD&C Act and FPLA

Big 5 Requirements:

- Statement of identity
- Net quantity of contents
- Nutrition labeling
- Ingredient statement
- Name and place of business of the manufacturer, packer or distributor

Anatomy of a Label

- **Principal Display Panel (PDP)**
 - Portion of the package label that is most likely to be seen by the consumer at the time of purchase
- **Information Panel (IP)**
 - Immediately to the right of the PDP, as displayed to the consumer

Principal Display Panel

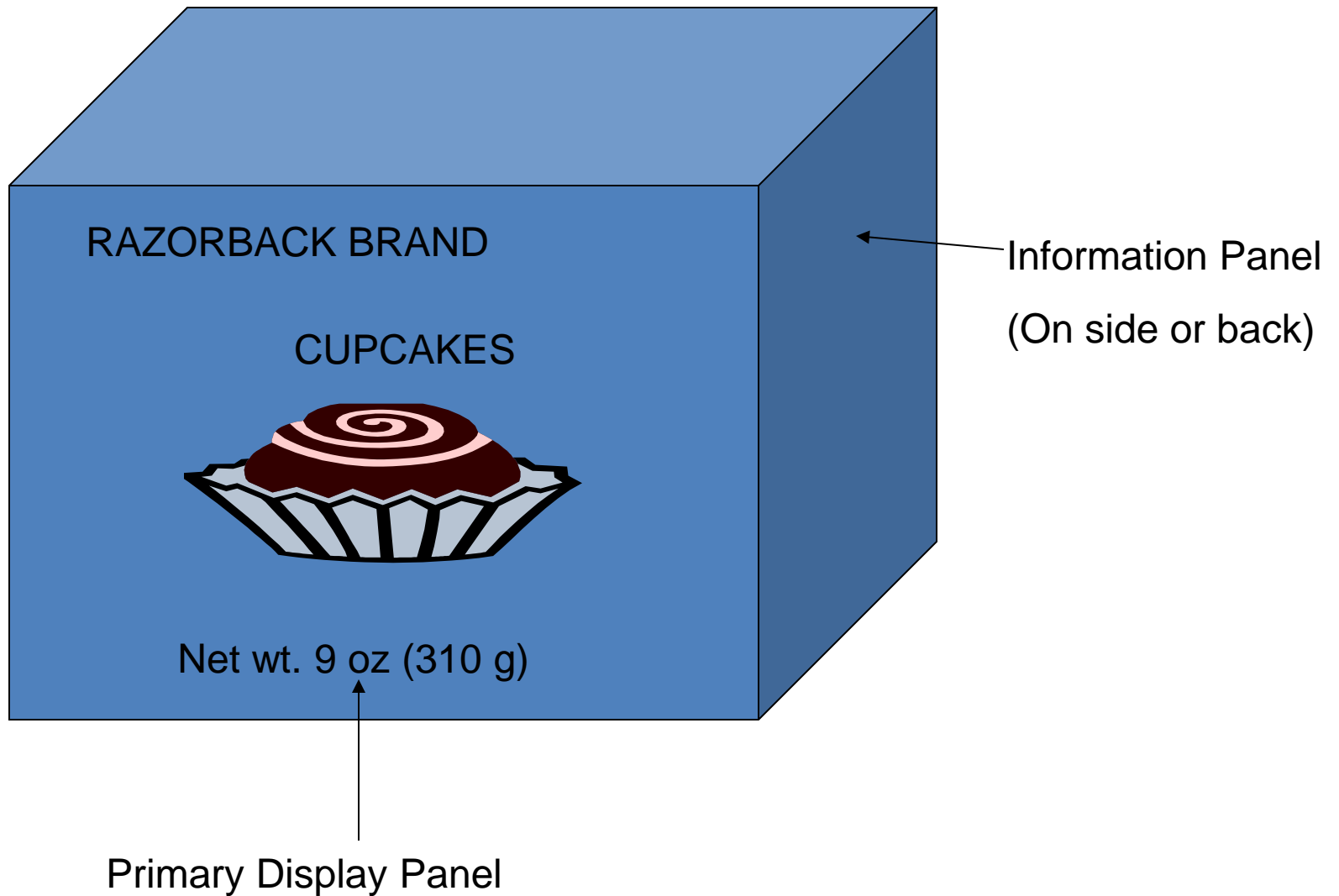
- That part of the label most likely to be seen by the consumer at the time of purchase
- Must include:
 - Statement of identity
 - Net quantity of contents

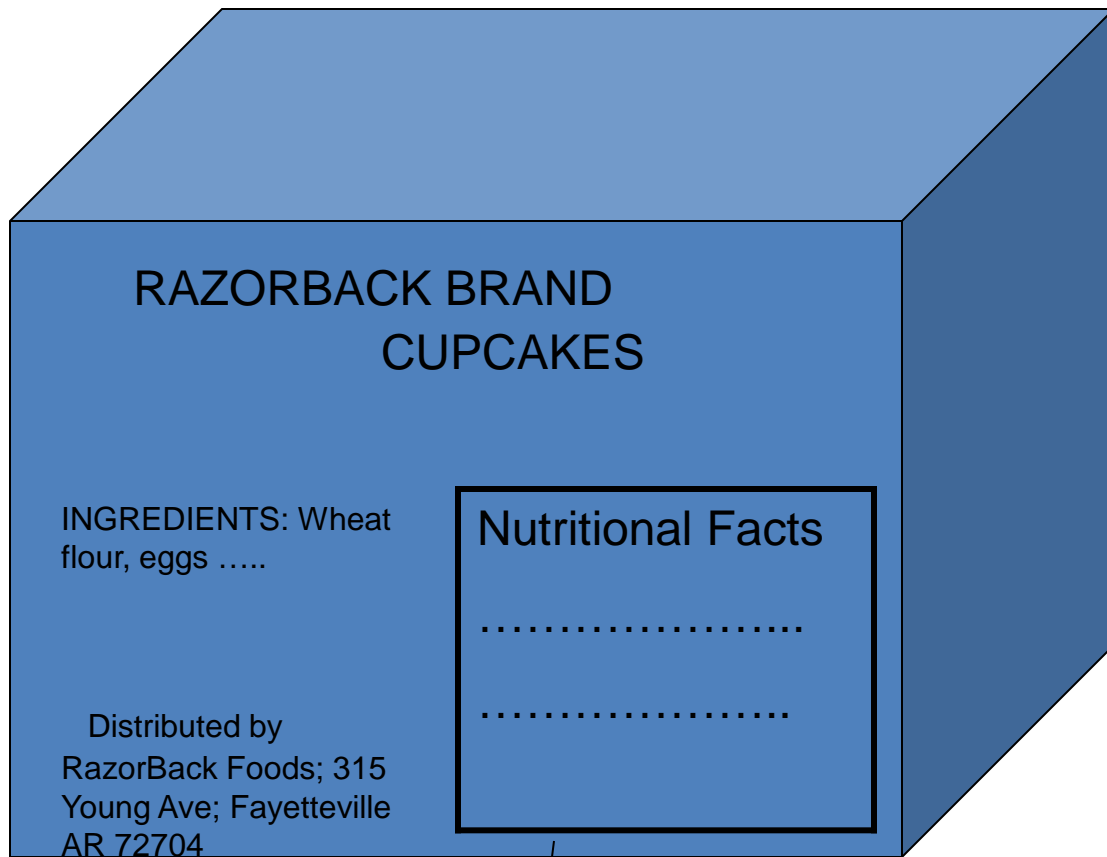
(21 CFR 101.1)

Information Panel

- That part of the label immediately contiguous and to the right of the PDP
- Includes:
 - Nutrition labeling
 - Ingredient statement
 - Name and place of business of the manufacturer, packer or distributor

(21 CFR 101.2)

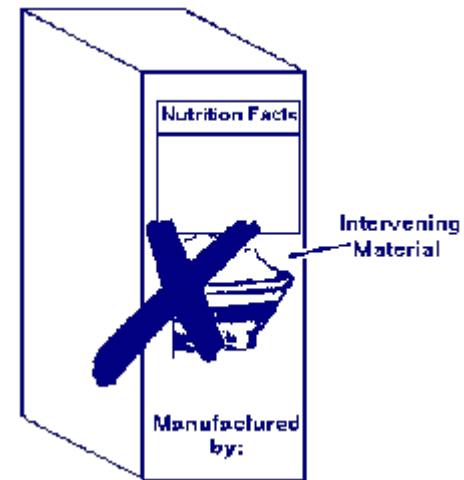




Information Panel on back
(can also be on right side)

Information Panel

- All three label elements must appear together without intervening material
- Nutrition labeling may move to another panel
(21 CFR 101.2)



What Goes Where on a Label

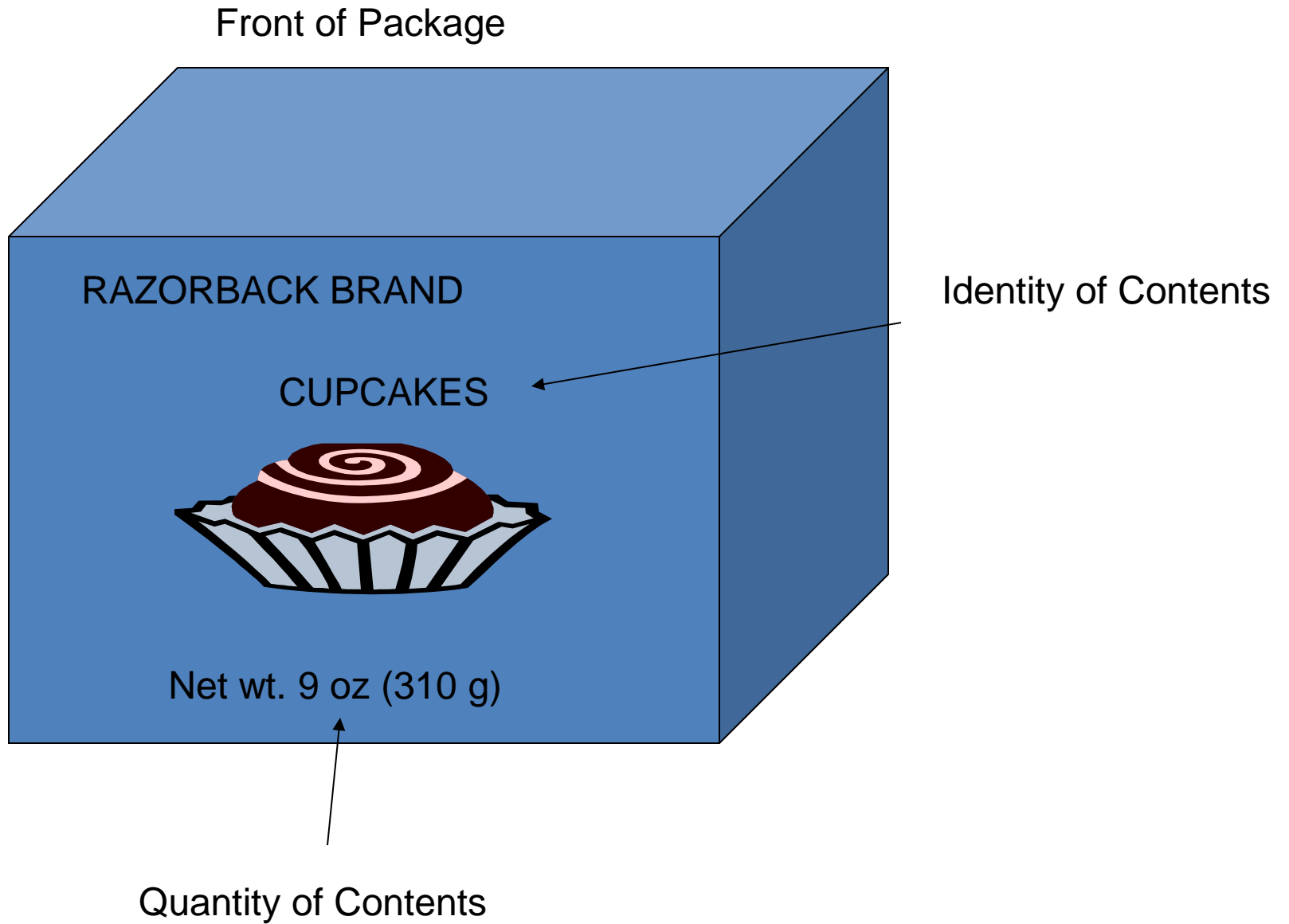
Information

- Identity of Contents
- Ingredient Listing
- Name and address of manufacturer, packer or distributor
- Quantity of Contents
- Nutritional Label

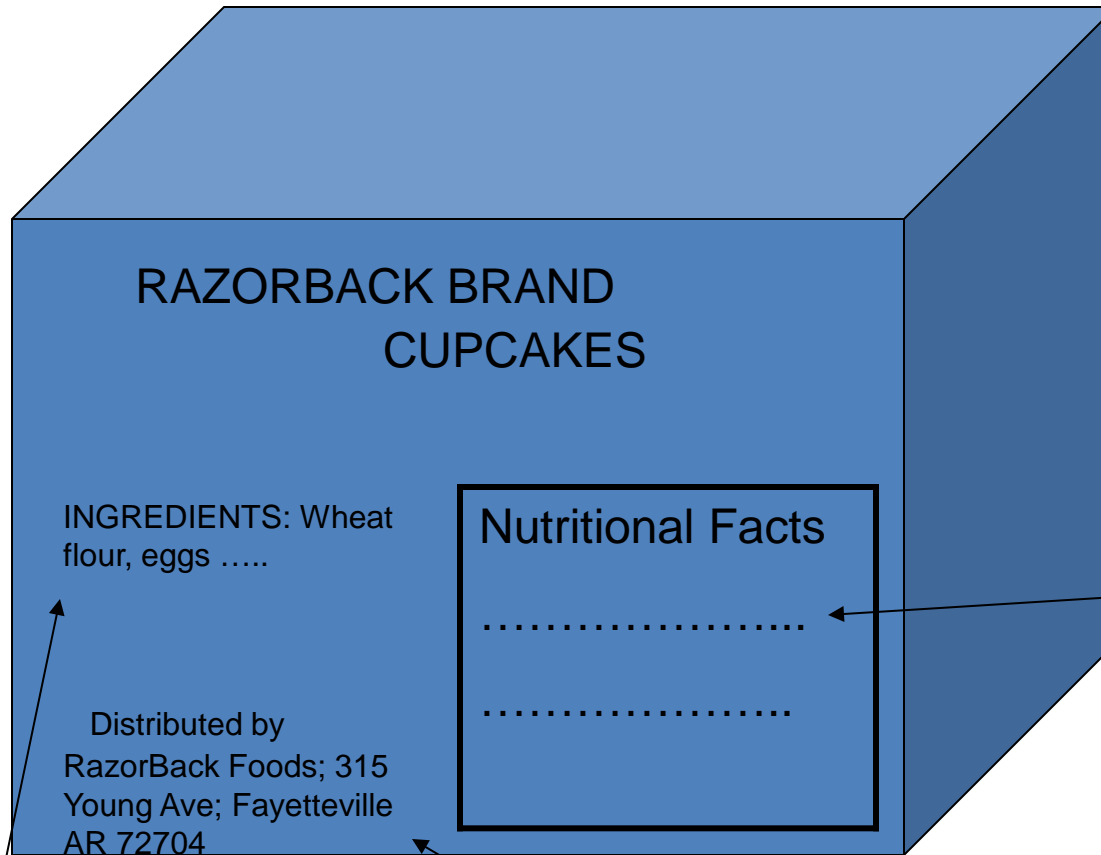
Location

- PDP
- PDP or IP
- PDP or IP

- PDP
- PDP or IP



Back of Package



Nutritional Label

Ingredient Listing

Name and address of
manufacturer, packer or
distributor.

Other Label Parts

- Depending on the product and situation, labels may also be required to contain the following;
 - 1) Code Dates
 - 2) Handling instructions
 - 3) Sulfites
 - 4) Percentage Juice
 - 5) If meat, must contain inspection bug
 - 4) Although not required, a food label usually contains a UPC code.

Statement of Identity

- Must be one of the principal features on the PDP
- Must appear in bold type
- Should be at least one half the type size of the largest printed matter on the PDP

Statement of Identity

1. Name specified by law or regulation
(21 CFR parts 130-169)
2. Common or usual name
3. Appropriately descriptive name or fanciful term

Mueller's[®]

hearty
egg noodles

ENRICHED

MADE FROM 100% DURUM FLOUR

®

GOYA®

Small White Beans Habichuelas Blancas



NET WT.
PESO NETO
15.5 OZ. (439g)

PREMIUM

18

FAT FREE
SEE BACK PANEL FOR
NUTRITION INFORMATION

THE CANDY WITH THE HOLE[®]

LIFE SAVERS[®]

FIVE FLAVOR

ARTIFICIALLY FLAVORED



LARGE SIZE PIECES
INDIVIDUALLY WRAPPED

NET WT. 6.25 OZ. (177g)

Nutrition Facts

Serving Size 4 candies (16g)
Servings Per Container about 11

Amount Per Serving

Calories 60

% Daily Value*

Total Fat 0g 0%

Sodium 0mg 0%

Total Carbohydrate 16g 5%

Sugars 15g

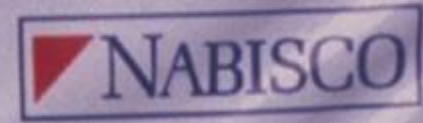
Protein 0g

Not a significant source of Calories from Fat, Saturated Fat, Cholesterol, Dietary Fiber, Vitamin A, Vitamin C, Calcium or Iron.

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

INGREDIENTS: SUGAR, CORN SYRUP, HIGH FRUCTOSE CORN SYRUP, CITRIC ACID (FOR TARTNESS), NATURAL AND ARTIFICIAL FLAVOR, ARTIFICIAL COLOR (CONTAINS RED 40, YELLOW 5, BLUE 1).

593221A



© NABISCO INC.
LIFESAVERS COMPANY
P.O. BOX 41
WINSTON-SALEM, NC 27102 USA

Ruker Garden Eggs



Ruker Außerginen Art

Made in Ghana by TINET VENTURES
P.O. Box 113106, Tema, Ghana
Tel: No. 033-044-4400

ZUTATEN: Garden Eggs, Salz und Wasser
GEEIGNET FUER: Suppe oder Sauce

• Net Weight • Netto Gewicht: 400g

USAGE: Garden Eggs may be used for soup or sauce

INGREDIENTS: Garden Eggs in brine. 261/186

© 2011 TINET VENTURES • Made in Ghana • Halbes Bitter Melon • DECA 00

Net Quantity of Contents

- Metric and U.S. customary inch-pound system declaration required
- Amount of food in a package exclusive of wrappers and packing material
 - Weight or mass
 - Dry or fluid measure
 - Numerical count
 - Combination (numerical count and weight or measure)
- Qualifying phrases or terms not permitted, e.g., “large”, “jumbo”

Net Quantity of Contents Format

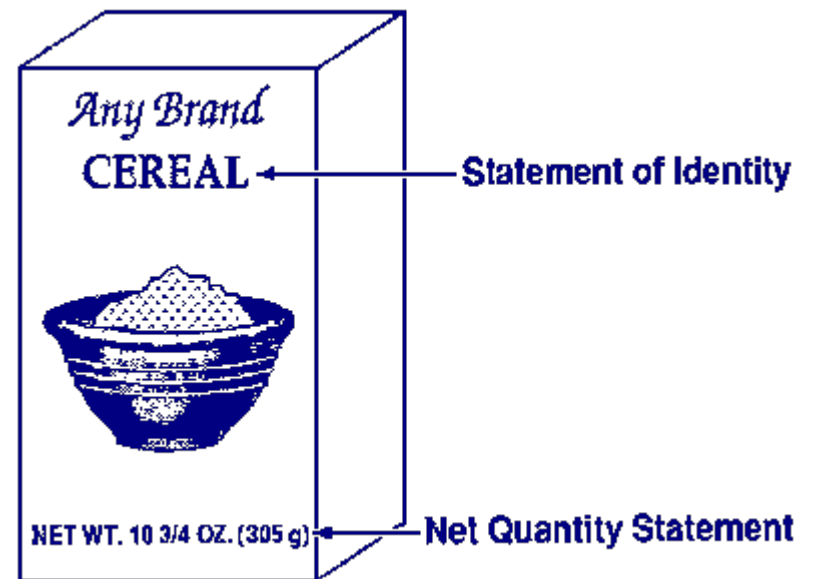
- Must be prominent and conspicuous
- Must appear in bold type
- Must be in distinct contrast to other label information
- Must be in proportion to the area of the PDP

Net Quantity of Contents Size

Area of PDP	Minimum Type Size
$\leq 5 \text{ in}^2$ (32 cm ²)	1/6 in (1.6 mm)
5 in ² to 25 in ²	1/8 in (3.2 mm)
25 in ² to 100 in ²	3/16 in (4.8 mm)
100 in ² to 400 in ²	1/4 in (6.4 mm)
$> 400 \text{ in}^2$	1/2 in (12.7 mm)

Net Quantity of Contents Placement

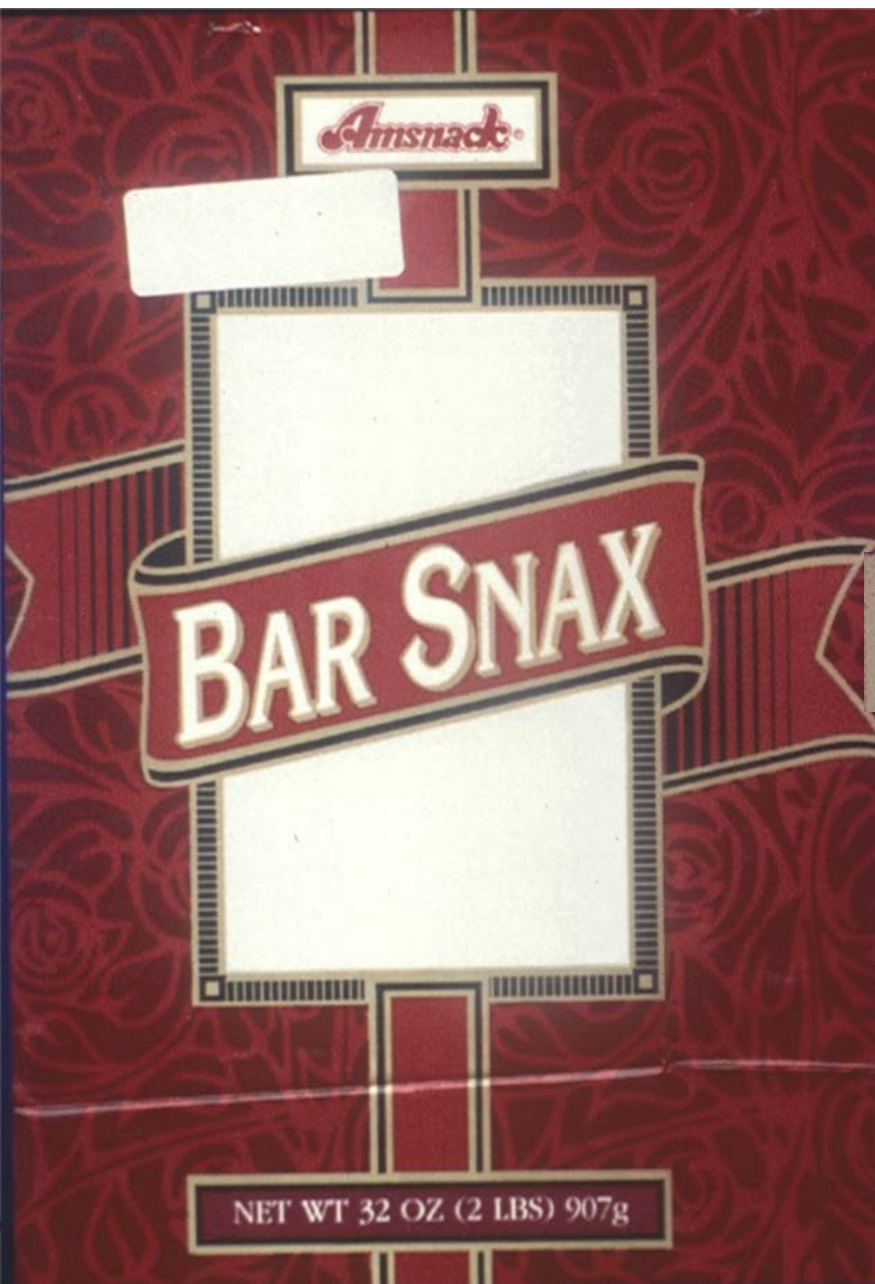
- Must appear on the PDP
- Located in lower 30 percent of PDP
- Lines generally parallel to the base



Net Quantity of Contents Examples

- Net Mass 425 g (15 oz)
- Net Wt 15 oz (425 g)
- Net 12 fl oz (355 mL)
- Net contents 1 gal (3.79 L)
- 500 mL (1 pt 0.9 fl oz)
- 1 L (1 qt 1.8 fl oz)

FR May 21, 1993



NET WT 32 OZ (2 LBS) 907g

NET WT 32 OZ (2 LBS) 907g

New heading signals a new label.

More consistent serving sizes, in both household and metric measures, replace those that used to be set by manufacturers.

Nutrients required on nutrition panel are those most important to the health of today's consumers, most of whom need to worry about getting too much of certain items (fat, for example), rather than too few vitamins or minerals, as in the past.

Conversion guide helps consumers learn caloric value of the energy-producing nutrients.

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

New mandatory component helps consumers meet dietary guidelines recommending no more than 30 percent of calories from fat.

% Daily Value shows how a food fits into the overall daily diet.

Reference values help consumers learn good diet basics. They can be adjusted, depending on a person's calorie needs.

Ingredient Labeling

- All ingredients used to fabricate a food must be listed in the ingredient statement by their common or usual name
- Except, if covered by an exemption

Ingredient Labeling Requirements

- All ingredients must be listed in descending order of predominance by weight
- EXCEPT ingredients present in amounts of 2% or less may be listed at the end of the ingredient statement followed by a qualifying statement:
 - *“contains # percent or less of...”*



CRANBERRY TRAIL MIX

Ingredients: Virginia Blanched Peanuts(peanuts, peanut oil, salt), Sunflower Seeds(sunflower seeds, vegetable oil, salt), Candy Buttons(sucrose, partially hydrogenated palm kernel oil, cocoa, whey solids, gum acacia, lecithin, vanillin, color added: Red #40, Red #40 Lake, Yellow #5, Yellow #5 Lake, Yellow #6 Lake, Blue #1, Blue #1 Lake, Blue #2 Lake, Carnauba Wax), Dried Cranberries (sugar, cranberries, citric acid).

Net Weight 10 oz.

JC2/82002

SNYDER KITCHENS, INC.
Millersburg, Ohio 44654

Ingredients: Virginia Blanched Peanuts(peanuts, peanut oil, salt), Sunflower Seeds(sunflower seeds, vegetable oil, salt), Candy Buttons(sucrose, partially hydrogenated palm kernel oil, cocoa, whey solids, gum acacia, lecithin, vanillin, color added: Red #40, Red #40 Lake, Yellow #5, Yellow #5 Lake, Yellow #6 Lake, Blue #1, Blue #1 Lake, Blue #2 Lake, Carnauba Wax), Dried Cranberries (sugar, cranberries, citric acid).

Name and place of business of the manufacturer, packer, or distributor

- Must appear on PDP or IP
- Must include:
 - Name of manufacturer, packer or distributor
 - Street Address (if not in current directory)
 - City
 - State
 - Zip Code

(21 CFR 101.5)

Name and place of business of the manufacturer, packer or distributor

- Principal place of business may be listed if the food is manufactured at a site other than the principal place of business
- Terms that may be used if the food is not manufactured by the company named on the label:
 - *“Manufactured for”*
 - *“Distributed by”*
 - *“Imported by”*

カモ井の **本格** つくだに

桜てんぷ

SEASONED CODFISH GRINDED

(SAKURA DENBU)

Mes 11-4-94

NET WT. 16 OZ. (1 LB.)

(453 g)

INGREDIENTS: COD FISH,
SUGAR, SALT & ARTIFICIAL
COLOUR (COCHINEAL
EXTRACT) ADDED.

IMPORTED BY
JFC INTERNATIONAL INC
S. SAN FRANCISCO, CA 94080

PRODUCT OF JAPAN

Country of Origin

- U.S. Bureau of Customs and Border Protection (CBP) requirement (19 CFR)
- No smaller than U.S. name and address
- No abbreviations except as permitted by CBP
- Multiple countries listed in any order

Country of Origin

- Repackers must mark repackaged imports with English name of the country of origin, e.g.:
 - “Product of Spain”
 - “Product of Spain and USA”

Inspections are mandatory

FIGURE 8-6 USDA inspection stamps.



U.S. Department of Agriculture

FIGURE 8-9 USDA quality grade stamps for specific food types.



- **Grade:** The voluntary process in which foods are evaluated for yield (a 1 to 5 grading for meats only) and quality (Prime, Choice, AA, A, Fancy, etc.).

FOOD ALLERGIES

Food Sensitivities

- FOOD INTOLERANCE
- FOOD ALLERGY

FOOD INTOLERANCE

- A response to a food other than a true protein reaction.
- **EXAMPLE; Lactose intolerance;**
 - *Mother Nature's method of weaning where the carbohydrate in milk (lactose) is not readily digested by the offspring.
 - *Generally starts in people in their 30s & 40s. Lack enzyme to break down milk sugar (lactose) so bacteria do it.



FOOD ALLERGIES

- True food allergies are the body's rejection of a foreign protein.
- There almost has to be a protein involved.
- Hay fever in humans is a true allergy caused by protein-containing pollen and animal hair and feathers..

HAY FEVER

- Certain cells around the eyes and sinuses perceive the protein from certain tree and plant pollen, animal hair, feathers, and possible other natural occurring proteins as foreign.
- The body's defense mechanism is set in motion to remove the protein from entering the body. Tears form around the eyes and sneezing to blow out the foreign protein are examples.

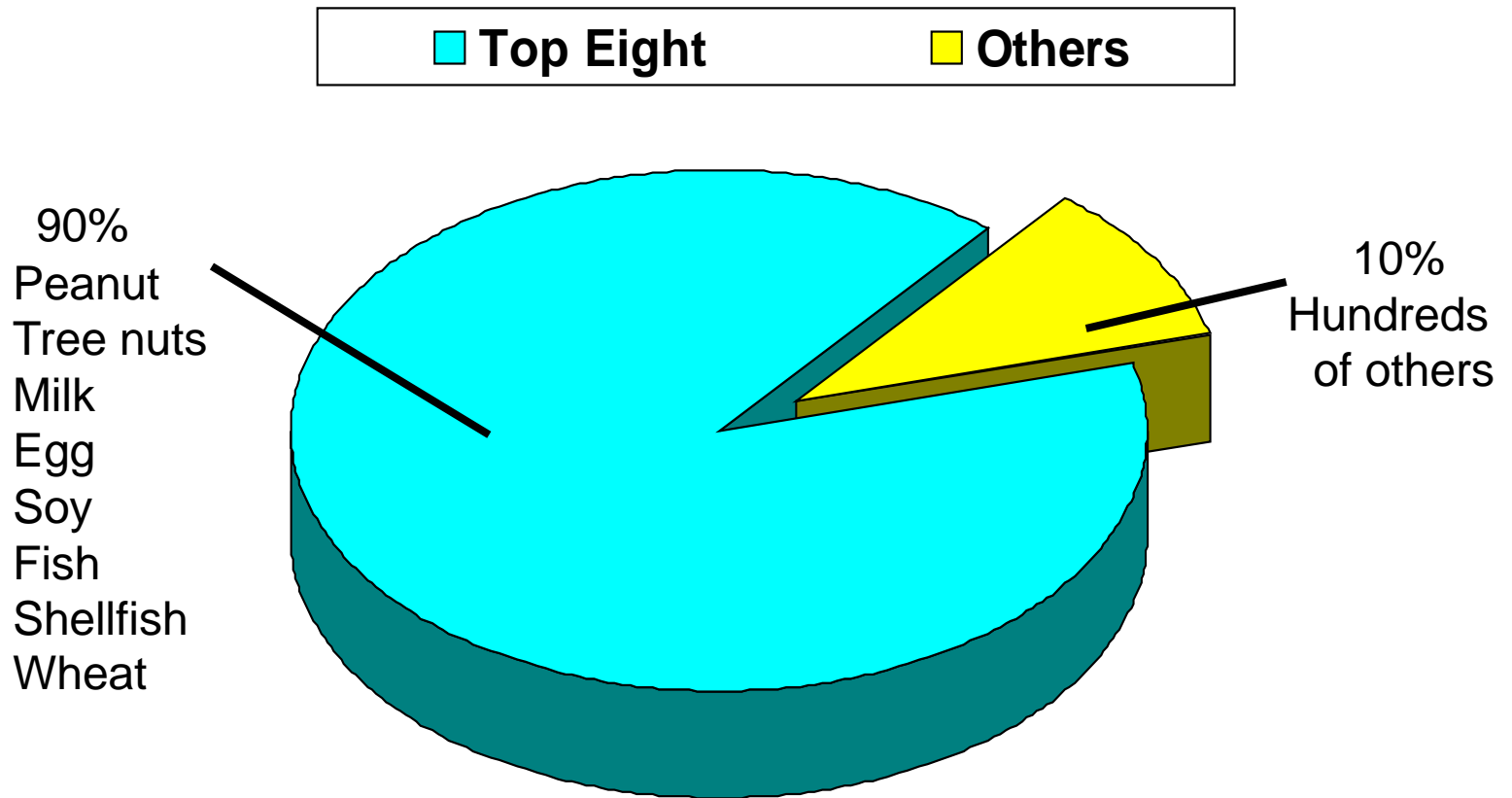
PREVALENCE

Between 2-2.5% of the U.S. population (or 6-7 million Americans) have food allergies.

Typical Symptoms of Food Allergies

- Gastrointestinal
 - *Nausea
 - *Vomiting
 - *Abdominal pain
 - *Diarrhea
- Systemic
 - *Anaphylactic shock
- Cutaneous
 - *Urticaria
 - *Angioderma
 - *Atropic dermatitis
- Respiratory
 - *Rhinitis
 - *Laryngeal edema
 - *Asthma

Food Allergies Prevalence









Other Foods

- There are 160+ other foods that can cause allergic reactions.
- Strawberries- the protein in the seed.

ANAPHYLACTIC SHOCK

- All the previous symptoms of food allergies such as nausea, vomiting, rhinitis etc are discomfoting but not “life threatening”.
- Anaphylactic shock is life threatening.
 - *Can be caused by food proteins

Anaphylaxis

- Defined as a hypersensitivity to a foreign substance, especially in animals, induced by a small preliminary or sensitizing injection of the substance.
- A generalized shock reaction.
- Can have multiple organ failures.
- Can have many symptoms including severe loss of blood pressure and cardiac arrhythmia.
- If not treated immediately, can be fatal.

TREATMENT FOR TRUE FOOD ALLERGIES

- Specific avoidance diets.
 - *People have to learn what they are allergic to.
 - *What is their tolerance level? (milligrams, ppm)-No peanuts on airlines anymore.
 - *What is in the food as an ingredient in trace amounts?

Ingredients Derived from Commonly Allergic Sources

- Edible oils
- Hydrolyzed proteins
- Lecithin
- Flavors
- Lactose
- Starch
- Gelatin
- Lysozyme
- Lactoferrin
- Soy Sauce
- Worcestershire Sauce
- Fermented ingredients.

LABELING

- Best solution for people with food allergies is knowledge via labeling.
- Major challenge to food industry is to label products with increased emphasis on source of additives.
 - *Old method “hydrolyzed protein”
 - *New method “hydrolyzed protein derived from wheat”.



Approaches to Precautionary Labeling

- “may contain....”
- “may contain the occasional nut”
- “may contain nut traces”
- “not suitable for nut allergy sufferers”
- “containstraces”

Approaches to Precautionary Labeling

- “contains traces of ...”
- “contains one or more of the following ingredients:....”
- “on rare occasions this product contains traces of....”
- manufactured on the same equipment as....”
- manufactured in the same facility as....”

SOUP BASE INGREDIENTS:

SALT, DEHYDRATED VEGETABLES (MUSHROOM, ONION, GARLIC, CHIVE), SUGAR, MONOSODIUM GLUTAMATE, HYDROLYZED CORN, WHEAT AND SOY PROTEIN, SOUP CREAM POWDER (CREAM, NONFAT MILK, CULTURES), DEHYDRATED SOY SAUCE (WHEAT, SOYBEANS, SALT, MALTODEXTRIN), POWDERED COOKED CHICKEN, SPICES, TURMERIC, DISODIUM INOSINATE, DISODIUM GUANYLATE.

CONTAINS WHEAT, SOY AND MILK INGREDIENTS.

INGREDIENTS: ENRICHED PASTA (WHEAT FLOUR, NIACIN, IRON, THIAMIN MONONITRATE, RIBOFLAVIN, FOLIC ACID), CORN STARCH, SALT, ENRICHED FLOUR (WHEAT FLOUR, NIACIN, IRON, THIAMIN MONONITRATE, RIBOFLAVIN, FOLIC ACID), HYDROLYZED SOY AND CORN PROTEIN, *ONION, DEXTROSE, NATURAL FLAVOR (CONTAINS SOY SAUCE [WHEAT, SOYBEANS, SALT] AND YEAST), *GARLIC, MONOSODIUM GLUTAMATE, PARTIALLY HYDROGENATED SOYBEAN OIL, YELLOWS 5&6 AND OTHER COLOR ADDED, SPICES, MONO AND DIGLYCERIDES, BEEF EXTRACT, NONFAT MILK, AUTOLYZED YEAST EXTRACT, SUGAR, BEEF FAT, CITRIC ACID, DISODIUM GUANYLATE, DISODIUM INOSINATE, EGG. *DRIED CONTAINS WHEAT, SOY, MILK AND EGG INGREDIENTS.

A hamburger Extender

INGREDIENTS: ENRICHED FLOUR [WHEAT FLOUR, MALTED BARLEY FLOUR, NIACIN, REDUCED IRON, THIAMIN MONONITRATE (VITAMIN B1), RIBOFLAVIN (VITAMIN B2), FOLIC ACID], WATER, HIGH FRUCTOSE CORN SYRUP. CONTAINS 2% OR LESS OF EACH OF THE FOLLOWING: YEAST, PARTIALLY HYDROGENATED SOYBEAN OIL, SALT, WHEAT GLUTEN, SOY FLOUR, DOUGH CONDITIONERS (MAY CONTAIN ONE OR MORE OF THE FOLLOWING: MONO- AND DIGLYCERIDES, CALCIUM AND SODIUM STEAROYL LACTYLATES, CALCIUM PEROXIDE), AMYLASE, YEAST NUTRIENTS (MONOCALCIUM PHOSPHATE, CALCIUM SULFATE, AMMONIUM SULFATE), CALCIUM PROPIONATE ADDED TO RETARD SPOILAGE, CORNSTARCH. "MAY BE TOPPED WITH SESAME SEEDS"

5600 5000 708

Hamburger Buns

Ingredients: Walnuts, Sugar, Corn Syrup, Sesame Seeds, Partially Hydrogenated Soybean Oil, Salt, Soy Lecithin (an emulsifier), Natural Flavors.

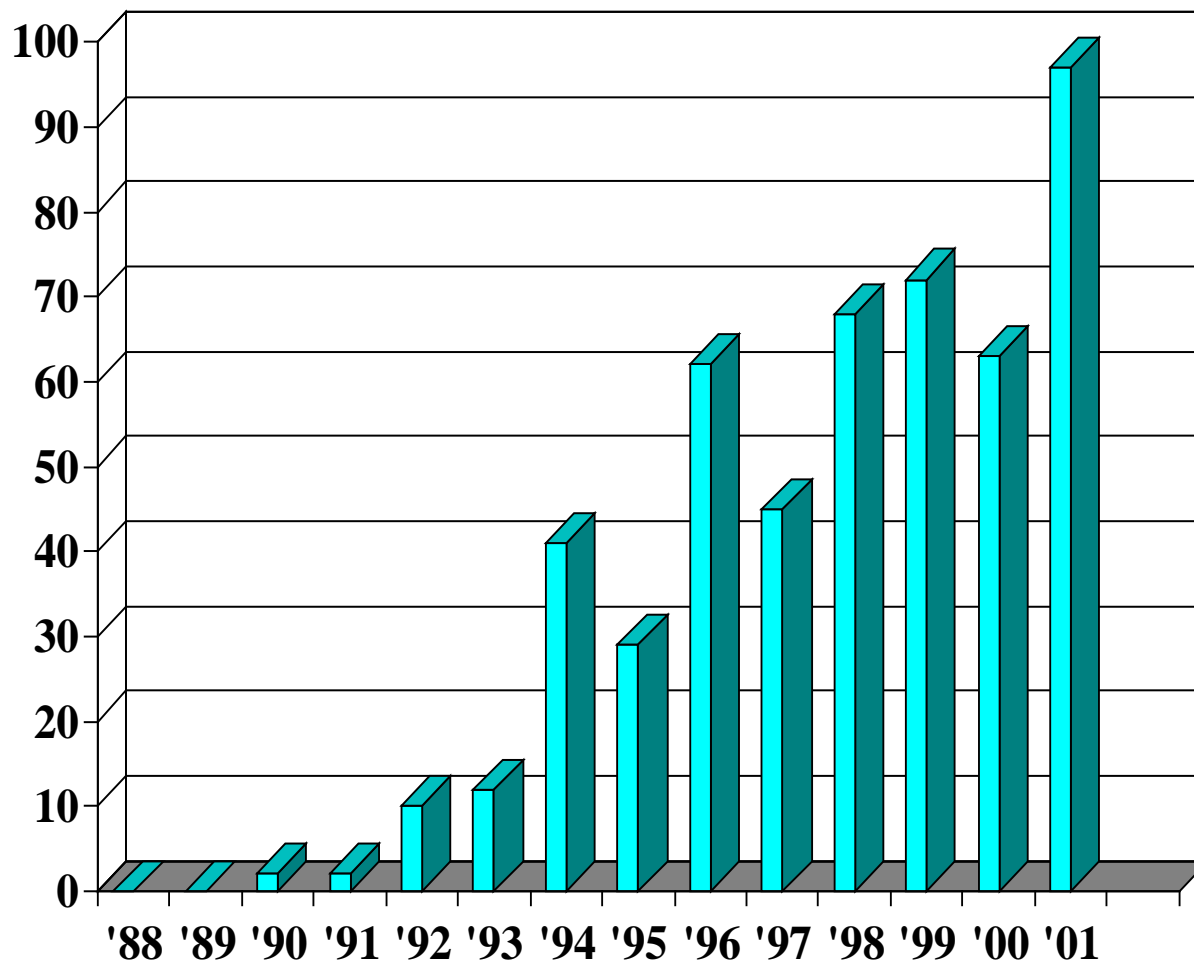
Produced in a facility that also handles peanuts.

A package of Glazed Walnuts

LABELING CHALLENGES

- Industry concern over increase in lawsuits.
- Hard to pin down where trace amounts can come from. They can come from other processed ingredients or contact surfaces in a plant. This is a major challenge to the food industry since the tolerance levels are so small.
- 20 ppm seems to be growing standard

U.S. FDA Food Allergen Recalls 1988-2001



CONCLUSIONS

An issue of growing concern

An issue that is here to stay

An issue that has increasing international aspects

An issue that can be controlled



Photo courtesy of IFS&E

Food Safety, Food Allergens, Nutrition and Labeling: Legal Issues

First Nations Webinar Series

October 2014

Janie Simms Hipp, J.D., LL.M.

Indigenous Food and Agriculture Initiative

University of Arkansas School of Law

Why are labeling, nutrition, allergens and food safety related?

- If you are allergic to a food, you look on the product label to identify what is in the food
- Some allergies to foods and ingredients can be mild; other reactions can be lethal
- What is on the label is the consumer's guide to what is in the product
- “Undeclared allergens” are the leading cause of food recalls by FDA
- Labeling also tells the consumer about your product and has general concerns associated with what you place on the label
- Nutrition and health claims need to be based on some sort of claims or you are merely misleading the consumer

Why do we care

- Heightened consumer interest in nutrition and nutrition labeling, allergens and allergen labeling
 - Consumer “right to know”
 - Medical concerns
- Heightened attention to allergens and the affect on consumers
- Link to legal liability of food producers, food processors, and food retailers
 - Always been present; heightened focus has been building

Health Claims

- Health claims are the relationship between a food and a reduced risk of a disease or health-related condition
- 1990 Nutrition Labeling and Education Act (NLEA)
 - Gives FDA authority to issue regulations authorizing health claims after reviewing and evaluating scientific evidence
- 1997 Food and Drug Administration Modernization Act (FDAMA)
 - Allows health claims based on authoritative statements of the National Academy of Sciences or a scientific body of the US
- Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements
 - FDA can review petitions for qualified health claims if the science falls below that required to issue an authorizing regulation

Examples of #1 and #2 Claims

- Authorized/approved claims
 - Sodium and Hypertension (21 CFR 101.74)
 - Food must be low sodium
 - Required terms: “sodium”, “High blood pressure”
 - Model Claim, Statements: “Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors”
- FDAMA Health Claims
 - Whole Grain Foods and Risk of Heart Disease and Certain Cancers
 - Contains 51% or more whole grain ingredients by weight and dietary fiber content of certain levels
 - Required wording of the claim: “Diets rich in whole grain foods and other plant foods and low in total fat, saturated fat...”

Exemptions

- Manufactured by small businesses
- Served in restaurants or delivered to homes ready for immediate consumption
- Deli-type food, bakery products and confections sold directly to consumers from the location where prepared
- Foods that provide no significant nutrition such as instant coffee or most spices
- Infant formula and foods for children up to 4 years of age
- Dietary supplements (but they must comply with another regulation)
- Medical foods
- Bulk foods

Exemptions, cont.

- Fresh produce and seafood
 - A voluntary nutrition labeling program covers these foods through shelf labels, signs and posters
- Packaged single-ingredient fish or game meat labeled on the basis of 3-oz cooked portions
- Custom-processed fish and game are exempt from nutrition labeling
- Certain egg cartons (look inside the lid or on insert in the carton)
- Packages labeled “This unit not labeled for retail sale” within multiunit packages when outer wrapper bears all required label statements
- Self-service bulk foods
- Donated food that is given free (not sold) to the consumer
- Game meats may have to provide nutrition info under another regulation – 21 CFR 101.9(a)(2)

Nutrition

- Nutrition and Labeling
- More people look at labels
 - To avoid products
 - To seek products
 - To avoid allergens
 - To calculate calories and nutrients
 - To lose weight
 - To gain weight
 - To make more informed choices
 - To choose within their own values systems

Nutrition Facts

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

1 **Start Here** →

Amount Per Serving

Calories 250 Calories from Fat 110

2 **Check Calories**

% Daily Value*

Total Fat 12g	18%
Saturated Fat 3g	15%
<i>Trans</i> Fat 3g	
Cholesterol 30mg	10%
Sodium 470mg	20%
Total Carbohydrate 31g	10%

3 **Limit these Nutrients**

6

Quick Guide to % DV

Dietary Fiber 0g	0%
Sugars 5g	
Protein 5g	
Vitamin A	4%
Vitamin C	2%
Calcium	20%
Iron	4%

• 5% or less is Low

• 20% or more is High

4 **Get Enough of these Nutrients**

5 **Footnote**

* 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



UNIVERSITY OF
ARKANSAS

SCHOOL OF LAW

Nutrition labeling

- Is the food producer, processor, retailer, distributor's responsibility
- If the food you produce makes it into the marketplace without a proper label, you will be held liable for illness or deaths it causes
- You also could be held responsible for violations of guidance documents, regulations, laws
- If the food you produce never makes it outside the home or the direct consumer, perhaps that liability will never be sought
- But your responsibility as a producer and seller of foods requires you to consider the legal landscape

Small Business Exemption

- Small business nutrition labeling exemption for foods (21 CFR 101.9(j)(1) and 21 CFR 101.9 (j)(18)
 - Retailers with annual gross sales of not more than \$500k or with annual gross sales of foods or dietary supplements to consumers of not more than \$50k - - no notice needs to be filed with FDA
 - Low-volume products exemptions apply if the person claiming the exemption employs fewer than an average of 100 FTE and fewer than 100k of the product are sold in the US in a 12-month period - - NOTICE MUST BE FILED WITH FDA
 - If not an importer and less than 10 FTE, don't have to file a notice for any food product with annual sales of less than 10,000 total units

Small Business Exemption

- “Product” “unit” and “firm” are all defined terms
- If any nutrient content claim (e.g., “sugar free”), health claim, or other nutrition information is provided on the label, or in labeling or advertising, the small business exemption is NOT APPLICABLE for the product
- There are still mandatory information requirements (statement of identity, net quantity of contents, ingredient statement, and name and address of manufacturer, packer or distributor)
- Annual notice required
- Public notice of firms that have applied for small business labeling exemption (listed on FDA website)

Nutrition labels

- Bottom line, there are very specific requirements for nutrition labels
- Anyone selling foods **MUST** determine the requirements that cover their foods
- Anyone giving foods must determine whether the requirements cover their specific circumstances
- You are responsible for the accuracy of the label required for your food
- You are also responsible for the truthfulness of the language on your label and that it is not misleading to the consumer

Nutrition Labels Proposed Changes

- Require information about “added sugars”
- Update daily values for nutrients like sodium, dietary fiber and vitamin D
- Require manufactures to declare the amount of potassium and vitamin D
- “calories from fat” would be removed - - but “total fat” “saturated fat” and “trans fat” would remain
- Change serving size requirements to reflect how people eat and drink today
- Require that packaged foods eaten in one sitting be labeled as a single serving
- Refreshed design of the label
- Comment period closed August 1, 2014 (changes aren’t final yet)

Additional Labeling Information

- FDA also has additional guidance documents or information on their website on the following additional products:
 - Adding new/novel ingredients to conventional foods
 - Genetically engineered salmon
 - Biotechnology
 - BSE (Mad Cow Disease)
 - Eggs/shell eggs
 - Food allergens (covered in more detail in this session)
 - “Fresh”

Additional Labeling Information

- Also...
 - Food Irradiation
 - Gluten-Free
 - Honey
 - Juice
 - Trans Fatty Acids
 - Whole Grains
 - Foods that need refrigeration
 - Raw Fruits, Vegetables and Fish
 - Food Standards
 - Cheeses
 - Frozen Desserts and Parmesan Cheese
 - White Chocolate
 - Yogurt

Allergens and the Law

- Because FDA has such a number of “undeclared allergens” involved in food recalls it is focusing on:
 - Research to determine cause in errors of labels
 - Working with industry on best practices
 - Developing new ways to test for presence of allergens
- FEDERAL LAW requires labels of FDA-regulated foods marketed in the US identify “major food allergens” -- 8 major food allergens -- 90% of food allergic reactions
 - **Milk**
 - Eggs
 - Fish (e.g., bass, flounder, cod)
 - Crustacean shellfish (e.g., crab, lobster, shrimp)
 - Tree nuts (e.g., almonds, walnuts, pecans)
 - **Wheat**
 - Peanuts
 - **Soybeans**

Life-Threatening Reactions

- Anaphylaxis
 - Constricted airways in the lungs
 - Lowering of blood pressure and shock
 - Suffocation by swelling in the throat
 - 30,000 emergency room visits/year
 - 2,000 hospitalizations/year
 - 150 deaths/year

Allergens and Manufacturing

- If “cross contact” can occur because of shared equipment or processing lines, FDA guidance states that food allergen advisory statements should not be used as a substitute for good manufacturing practices and must be truthful and not misleading
- Possible advisory statements: “may contain...” or “produced in a facility that also uses....”
- But even if these advisory statements are included, the manufacturer may not escape liability

Allergens and the Law

- If a product label does not list the potential allergen information
 - It is deemed “misbranded”
 - Can be seized by the FDA
- Firms (or individuals) marketing the foods normally do voluntary recalls as opposed to waiting for the federal government to seize their products from the shelves
- There are substantial costs associated with recalls (either voluntary or seized)

Allergens and complaints

- FDA has a consumer complaint coordinator in every district
- These offices receive consumer complaints regarding food products
- From September 2009 – September 2012
 - 1/3 of food reported to FDA involved undeclared allergens
 - 5 food types most often involved in recalls were
 - Bakery products
 - Snack foods
 - Candy
 - Dairy products
 - Dressings (salad dressings, sauces, gravies)

Allergens and labeling

- Pre-January 1, 2006
 - Federal law did not require relabeling of food products labeled before January 1, 2006
- FALCPA – Food Allergen Labeling and Consumer protection Act of 2004
 - Applies to all foods whose labeling is regulated by FDA (domestic and imported)
 - Doesn't apply to poultry, most meats, certain egg products, and most alcoholic beverages (covered by other agencies and laws)

Allergens and law

- Before FALCPA
 - Labels of food with 2+ ingredients required to list all ingredients by their common/usual name
- After FALCPA
 - Labels must clearly identify food source names of all ingredients that are, or contain any protein derived from, the 8 most common food allergens (see previous slide)
 - Example: “lecithin (soy)” – “flour (wheat)” – “whey (milk)” OR “Contains Wheat, Milk and Soy”

Recent Recalls: as of October 23, 2014

- www.foodsafety.gov/recalls/recent
- **JFC International Inc. Issues Allergy Alert on Undeclared Milk in 'Hapi Pudding'**
- Oct 17, 2014 10:34 PM
- JFC International Inc. of Los Angeles, CA is voluntarily recalling all lot codes of its 3-pack Hapi Pudding with a net weight of 8.46 ounces (UPC 11152 13417), because they may contain undeclared milk. People who have allergies to milk run the risk of a serious or life-threatening allergic reaction if they consume the products.

Recent Recalls

- [United Natural Trading LLC dba/ Woodstock Farms Manufacturing Issues Allergy Alert for Undeclared Peanuts in Asian 7 Rice Cracker Mix](#)
- Oct 17, 2014 3:07 PM
- United Natural Trading LLC dba/ Woodstock Farms Manufacturing, Edison, New Jersey are recalling 22lb. bulk cases only (Lot# YOU103) and Market Basket 12oz. tubs only (Lot# 14248) because they may contain undeclared peanuts. People who have allergies to peanuts run the risk of serious or life-threatening allergic reaction if they consume these products.

Recent Recalls

- **Publix Issues Voluntary Recall of Publix Asian Mix**
- Oct 17, 2014 2:51 PM
- Out of an abundance of caution, Publix Super Markets is issuing a voluntary recall for Publix Asian Mix because the product contains peanuts that are not declared on the packaging.

Recent Recalls

- **Massachusetts Firm Recalls Chicken Products Due to Possible Misbranding and Undeclared Allergen**
- Oct 16, 2014 12:00 AM
- Shop Packaging LLC, a New Bedford, Mass. establishment, is recalling approximately 115,505 pounds of chicken wing products due to misbranding and an undeclared allergen.

FDA Recalls

- First Alert:
 - FDA hears about the product problems
 - Company notification, agency inspections, adverse event reports, CDC
 - State health departments that report to CDC or other agencies
- Alerting the Public
 - FDA posts updates on its website and in weekly enforcement reports
- Effectiveness Checks
 - FDA reviews the company's corrective actions

Recall Classifications

- Class I
 - Dangerous or defective products that could cause serious health problems or death
 - Botulinum toxin; undeclared allergens; label mix-up; defective products
- Class II
 - Products that cause temporary health problem or slight threat of a serious nature
 - Drug that is under-strength but not used in life threatening situations
- Class III
 - Not likely to cause health reaction, but do violate FDA labeling or manufacturing laws
 - Minor container defect or lack of English language on labeling of a retail food

Recalls

- FDA-regulated products subject to recall:
 - Human drugs
 - Animal drugs
 - Medical devices
 - Radiation-emitting products
 - Vaccines
 - Blood and blood products
 - Transplantable human tissue
 - Animal feed
 - Cosmetics
 - **About 80% of the foods eaten in the US**

Recalls: meat or poultry

- USDA laws/regulations govern meat and poultry but they use a similar approach:
- If the FSIS Recall Committee recommends a recall of a meat or poultry product, the Committee classifies the recall based on the relative health risk, as follows:

Class I - A Class I recall involves a health hazard situation in which there is a reasonable probability that eating the food will cause health problems or death.

Class II - A Class II recall involves a potential health hazard situation in which there is a remote probability of adverse health consequences from eating the food.

Class III - A Class III recall involves a situation in which eating the food will not cause adverse health consequences.

Meat and Poultry Recalls

- All meat or poultry recalls are voluntary. They may be initiated by the manufacturer or distributor of the meat or poultry or at the request of FSIS.
- If a company refuses to recall its product, then FSIS has the legal authority to detain and/or seize meat and poultry products in commerce when there is reason to believe they are hazardous to public health or if other consumer protection requirements are not met.
- Costs associated with recalls can be very high

Food Safety: General Legal Issues

- Contract law
 - The purchase and sale of food involves buyers and sellers
 - Contracts for the purchase and sale of food can be written or oral
 - At your farmers market, you are engaging in a contract to buy or sell food
 - At a mobile market you are engaging in a contract for the sale of food; at a booth at a conference you are also engaging in a contract
 - What are the rights and duties of the parties in those “contractual relationships”
- Uniform Commercial Code (UCC)
 - The UCC deals with commercial transactions
 - It includes sections dealing with transactions in “goods”
 - Foods are “goods”

Food Safety: General Legal Issues

- Product Liability law
 - Food is a product
 - What happens when the product doesn't meet expectations
- The “business transaction” related to buying and selling food
- When buying and selling food you are engaging in a business transaction, whether you like it or not
- You also engage in a transaction when you give food
- There is a different way of examining the legal issues in giving food (donating food)
- We will address those at a later date
 - www.law.uark.edu
 - Nicole Cevita – at our law school – is a noted expert in this area

Food Safety

- Livestock, feed, seed, pesticides and food are also “goods”
- Sales and other transactions of goods result in the creation of “warranties”
- **Express Warranties**
 - Stated as part of the sales agreement
- **Implied warranties**
 - Are “read into” or “implied” in the sales agreement by the UCC, unless there is specific language or circumstances that exclude the warranties
 - Sales agreements may result in the creation of two types of implied warranties:
 - Implied warranty of merchantability
 - Implied warranty of fitness for a particular purpose

Food Safety

- Express warranties
 - Explicit statements made by the seller
 - Once the express warranty is made, it is very difficult to disclaim the warranty
 - Created in usually three possible ways:
 - Seller makes an affirmation of fact or a promise that relates to the goods and becomes part of the bargain
 - The warranty is that the goods will conform to the promises made
 - Oral or written statements concerning the goods that the buyer relies upon when purchasing the goods
 - “all my cows are bred”
 - “all my hay is of the highest quality”
 - “all my onions are organic”
 - “all my tomatoes are natural”
 - Statements made on the **product label**

Food safety

- Express warranties can also be made if the seller provides “any description of the goods” that becomes part of the bargain
 - The warranty is that the goods will conform to the description
 - Description of the goods on a label, a sign, an advertisement in the newspaper, magazine or on-line
- Express warranties can also be created if the seller displays a “sample or model” of the goods
 - The warranty is that the rest of the goods will conform to the sample or model

Food safety

- Express warranties can be created by statements
- Statements do not create express warranties if they are statements of opinion, honestly held, or merely commendation of the goods (“puffing talk”)
 - “these okra are the best”
 - “my beans are better than his beans”
- Statements can be oral or written or both
- But if the statement is first oral, then later is reduced to writing, the writing will likely control

There are also food labeling laws re: claims on labels

Food labels are statements

If you have a food safety product problem, you can have problems with the federal (or state/local) agency involved AND problems in the legal system (lawsuits brought by the consumers of the products)

Food safety

- Representations by the food business and its employees
- Any representations made by a company, its employees, consultants or agents pertaining to a product, whether oral or written, can be treated as an express warranty
- Must closely monitor any representations made by your employees
- Must also provide training concerning appropriate representations to your employees

Food Safety

- Implied Warranties
 - Imposed by law to assure a fair result and fulfill the buyer's expectations that an acceptable product is being purchased
 - Two types of implied warranties
 - Implied warranty of merchantability
 - Implied warranty of fitness for a particular purpose
- Implied warranty of merchantability
 - Merchants are held to a higher standard of business conduct than others who participate in business transactions
 - Merchants = those who deal in the goods of the kind sold
 - Are you a merchant???
 - Where merchants are involved, there is an implied warranty that the goods are merchantable
 - Exists even if the seller made no statements or promises and didn't know of the defect in the goods

Food Safety

- In order for goods to be merchantable:
 - Pass without objection in the trade under the contract description
 - In the case of fungible goods, are of fair average quality within the description
 - Fungible goods can be food; fungible goods are those that are interchangeable and of like kind
 - Are fit for the ordinary purposes for which the goods are used
 - Run, within variations permitted by the sales agreement, of an even kind, quality and quantity within each unit and among all units (involves bulk purchases)
 - Are adequately contained, packaged, and labeled as the agreement may require (if sold in containers)
 - Conform to the promises or affirmations of fact made on the container or label (if sold in containers)

Food Safety

- Standards of merchantability also involve standards of the particular trade
- If a product fails to comply with industry standards, an implied warranty of merchantability may arise
- Known product defects must be disclosed to a potential buyer
- Every seller with knowledge of defects must disclose those to the buyer
- Underlying rationale: the buyer is getting what is being paid for and that market participants are acting in “good faith”

Food Safety

- Special rules apply in some states concerning livestock sales transactions
- Some states exempt livestock sellers from implied warranties if
 - The seller knew the animals were sick at the time of the sale
 - Some state statutes exempt the livestock seller from implied warranties for all sales
 - Some statutes provide an exemption from implied warranties if certain conditions are met
 - It depends on where you are
 - Express warranties can still be made
- Also, cannot usually hide behind an exclusion if the seller knows the animals are diseased or sick and sells them anyway
- In the area of livestock sales it may come down to whether the seller knew or should have known the animals were diseased, sick or unable to breed

Food Safety

- Implied warranty of fitness for the buyer's particular purpose
- Seller has reason to know of the buyer's particular purpose for purchasing the goods and the buyer relies on the seller's skill or judgment to select or furnish the goods
- Doesn't matter whether the seller is a merchant or not
- Questions tend to revolve around the expertise of the buyer and seller and the relative skill or knowledge of either

Lawsuits Involving Food Safety

- Food and drink cases usually focus on three issues:
 - Is the food or drink wholesome or defective
 - Is the condition of the food or drink the cause of the plaintiff's harm
 - Plaintiff is the one who is harmed
 - Is the food or drink condition attributable to the defendant
 - Defendant is the one who allegedly caused the harm

Lawsuits involving food safety

- Lawsuits involving food safety usually fall into categories:
 - Disgusting things in food
 - Who is responsible for things in the food - - food tampering
 - Ordinary things in food
 - Invisible things in food
 - Uneaten things
 - Bottle – things in bottled foods
 - Damages – who gets paid for finding the things & what about damages when things are missing?
 - Regulations – failure to follow regulations regarding food safety
 - The Delaney Clause (tolerances in foods – related to cancer deaths)
 - Violation of specific statutes

Cases - Examples

- Disgusting things in food
 - Rocks in box of Grape Nuts (Elliott v. Kraft Foods)
 - Cockroach in biscuit and gravy breakfast (CEF Enterprises v. Betts)
 - Cockroach in chili dog (Bullara v. Checker's Drive-In)
 - Condom in soft drink (Hagan v. Coca-Cola)
 - Metal in meatball (Jones v. GMRI)
 - Hypodermic needle point in steak (Kroger v. Beck)
 - Decomposed human toe in chewing tobacco (Pillars v. RJ Reynolds)



Cases - Examples

- Responsibility for things found in Food – Tampering
 - Tin plate sliver in bowl of soup (Mears v. Heinz)
 - Maggots in soup (Campbell Soup v. Gates)
 - Deliberately putting things in food
 - Pin in Baby Ruth candy bar (Tardella v. Nabisco) – when did pin get into the candy bar
 - Finger in the Wendy’s chili (2005)
 - Syringe in Diet Pepsi (innocently deposited there by diabetic relative, but ended in 60 copycat cases and a videotape of a woman planting a syringe)
 - Finger in frozen chocolate custard (2005)



Resources

- *Products Liability and Safety Cases and Materials*; Owen, Montgomery and Davis (book)
- *Agricultural and Food Policy*; Knutson, Penn and Flinchbaugh (book)
- *Agricultural Law Cases and Materials*; Meyer, Pederson, Thorson and Davidson (book)
- *Principles of Agricultural Law*; McEowen and Harl (book)
- www.fda.gov
- www.usda.gov
- www.fsis.usda.gov
- www.ams.usda.gov