Truth in Food Labeling: It's Anyone's Guess

University of Arizona Humanities Seminar
Spring 2024
Version – 3-8-24

Week 4

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  - Addressing commonly misunderstood and possibly misleading labeling terms --
    - With manufacturers trying to sell their product, subtle labeling terms may draw consumers to a particular product.
    - Implied healthier food (i.e., “less processed,” “all natural ingredients,” “contains whole grain,” “no added…,” etc.) is the type of subtle catch-phrasing that often is seen on labeling but, more likely than not, is misunderstood.
    - Importantly, some of the most misunderstood terms also cannot be verified by analytical testing (e.g., animal raising claims); trust is all that the consumer (and government) has regarding the truthfulness of the claim..

Slide #2D – commonly misunderstood…sugar and added sugar…

- 2016 changes to the Nutrition Fact panel --
  - Included
    - Added sugar
    - Sugar alcohol
- **First amendment concerns raised**
- Only added more detailed facts
  - Information helps consumers maintain healthy dietary practices

Nutrition Facts

120 servings per container

Serving size **1 Piece (2g)**

Amount per serving

Calories **5**

	% Daily Value
Total Fat 0g	**0%**
Sodium 0mg	**0%**
Total Carbohydrate 2g	**1%**
Total Sugars 0g	
Includes 0g Added Sugars	**0%**
Sugar Alcohol 2g	
Protein 0g	

Not a significant source of other nutrients.

Week 4

…sugar and added sugar…

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- Slide #2D – commonly misunderstood and possibly misleading labels…sugar and added sugar issues…
- Week 4 Topic –
  - In 2016, the FDA published a final regulation that revised certain aspects of the Nutrition Facts label.
    - In particular, the label could no longer simply identify the total amount of sugar in a product.
    - Rather, the label requirement was changed to also specify the amount of added sugar (e.g., sucrose or dextrose; syrups and honey; and concentrated fruit or vegetable juices) and sugar alcohol (e.g., sorbitol and maltitol) .
    - Note: FDA considers the terms “sweetener” and “sugar substitute” to include any ingredient that provides sweetness to a food regardless of whether calories are also provided.
    - Numerous comments were received and addressed, as follows —
      - Sugar legal issues —
        - Commenters questioned the FDA’s ability to compel a declaration of added sugars under the First Amendment.
          - Arguments made included —
            - “There is already a declaration for total sugars and there is no material difference, or scientific rationale, for distinguishing between added and intrinsic sugars, including no sufficient nexus to consumer health;”
            - “Because added sugars are not chemically distinct from natural sugars and do not have different health effects, the declaration of added sugars would be false and misleading, and FDA could not compel it under the First Amendment;”
            - “There is no physiological distinctions between added and naturally occurring sugars, and therefore, no connection to consumer health on which to compel such speech;”
            - “The added sugars declaration would compel misleading labeling because it would mislead consumers into believing that a sweetened dried cranberry is less healthy than a naturally sweetened dried fruit, due to the cranberry’s added sugar content;” and

- An added sugar declaration and percent daily value (% DV) will compel false information on the label because the amount of added sugars will need to be overstated on yeast-leavened products, in violation of the First Amendment."

- The FDA responded, as follows —
  - "The disclosure of added sugars is factually accurate nutrition information;"
  - "Providing consumers information on the amount of added sugars in a serving of food does not offend the core First Amendment values of promoting efficient exchange of information and furthers, rather than hinders, the First Amendment goal of the discovery of the truth and contributes to the efficiency of the marketplace of ideas;"
  - "The disclosure of added sugars is reasonably related to government interests in promoting the public health, preventing misleading labeling, and providing information to consumers to assist them in maintaining healthy dietary practices;"
  - "The comment seems to refer to the consumer research data related to consumer perceptions of 'healthful'…
    - We do not agree that the declaration is misleading labeling…
    - Consumers need more, not less, information about the added sugars content of a food to learn how to understand and use the information in planning a healthy dietary pattern…
    - The term 'unhealthful' when describing a food with added sugars is a relative term and must be viewed in the context of the day's total dietary intake…
    - They need to include a variety of foods in their diet, as part of a healthy dietary pattern, so they can understand how to include added sugars in their diets at levels less than 10 percent of calories to avoid overconsumption…and still achieve a healthy dietary pattern [Note: The Daily Value for added sugars is 50 grams per day based on a 2,000-calorie daily diet];" and
    - "We disagree that an added sugars declaration on yeast-leavened products will need to be overstated and therefore compel false information on the label…we allow for reasonable deficiencies in foods generally for label amounts of calories, sugars, added sugars, saturated fat, trans fat, cholesterol, and sodium…within current good manufacturing practice…and that labeling of added sugars in products that undergo fermentation and non-enzymatic browning may not be exact, but that manufacturers of most products that participate in these reactions should be able to provide a reasonable approximation of the amount of added sugars in a serving of their product based on information in the literature and their own analyses…or else submit a petition to request an alternative means of compliance."

Slide #3D – commonly misunderstood…sugar-free…sugar alcohol…

- Slide #3D – commonly misunderstood and possibly misleading labels…sugar alcohol…
- Week 4 Topic –
  - Also in the 2016, final rule on sugars issued by the Food and Drug Administration (FDA), sugar alcohol amount was required to be added to the Nutrition Facts label.
  - The prior FDA nutrition labeling regulations provided for the voluntary declaration of sugar alcohol (i.e., the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group such as mannitol or sorbitol) on the Nutrition Facts label.
    - Sugar alcohols are also known as the broader group of polyols and are ingredients used as sweeteners and bulking agents.
    - They occur naturally in foods and come from plant products such as fruits and berries.
    - As a sugar substitute, they provide fewer calories (about a half to one-third less calories) than regular sugar;
      - Still, they are a kind of carbohydrate that can raise blood sugar levels though not as much as regular sugar.
  - Commenters questioned why the FDA won't change the name "sugar alcohols" to "polyols" and had concerns about misleading consumers about "alcohol" in food.
    - FDA responded, as follows —
      - The term "polyols" is not accurate for purposes of food labeling because polyols contain a broader group of compounds including low digestible carbohydrates (i.e., sugar alcohols) that are used by the body, as well as non-carbohydrate polyalcohols (e.g., polyesters).
      - In recognition that the term "sugar alcohols" may not be understood by consumers, the labeling requirements allow for the listing of the name of the specific sugar alcohol provided that only one sugar alcohol is present in the food because many sugar alcohols are listed as ingredients –
        - For example, erythritol, hydrogenated glucose syrups, hydrogenated starch hydrolysates, isomalt, lactitol, maltitol, mannitol, sorbitol, and xylitol;
        - Most of which have a different contribution of calories less than 4 kcal/gram) and therefore be more recognizable by consumers.
    - Note — the European Union allows for the term "polyols," contrary to the U.S. labeling requirements.
    - Regarding confusion about alcohol –

        - Sugar alcohol and alcoholic beverages do not have the same chemical structure.
        - Sugar alcohol does not contain ethanol, which is found in alcoholic beverages.
- In the picture of the sugar free imitation honey, the Nutrition Facts panel lists, among other things –
    - Total Carbohydrates – 17 g (6 % Daily Value or DV),
    - Fiber – 0 g (0 % DV),
    - Total sugars – 0 g, including 0 g added sugars (0 % DV),
    - Sugar alcohols – 17 g –
        - Note -- there was no DV provided for sugar alcohols –
            - There is no established DV;
            - However, because the sugar alcohols are a form of carbohydrate, the DV of 17 g was totally provided by the sugar alcohol content.

Slide #4D – commonly misunderstood…imitation sweetener…

- Slide #4D – commonly misunderstood and possibly misleading labels…sugar alcohol…imitation sweetener…
- Week 4 Topic –
  - The common and usual name of this product is "zero sugar" followed by "honey substitute" because the product has natural honey flavoring.
    - The product is not imitation honey, as in the prior slide, which had no natural honey flavoring.
  - Regarding net carbs
    - FDA recommends using total carbohydrates on the Nutrition Fact panel.
    - However, manufacturers are using "net carbs" on other parts of the labeling –
      - "Net carbs" are determined by subtracting any fiber or sugar alcohols from the total carbohydrates.
      - Caution – FDA has not evaluated such net carb claims; if data is presented to show that this phrase is misleading, FDA will issue guidance and pursue enforcement action.

- Slide #5D – commonly misunderstood and possibly misleading labels…sweetener issues…
- Week 4 Topic –
  - In searching individual ingredient database at U.S. FDA "Substances Added to Food (formerly EAFUS) —
    - https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=FoodSubstances
  - The "sugar free" chewing gum "Menthos Pure Fresh Spearmint" was assessed.
    - In total, there are 9 different sweeteners incorporated --
      - 6 are nutritive,
      - 3 are non-nutritive.
    - It is likely that so many different sweeteners are included in order that the different sectors of the taste buds are activated for sweetness.
  - Also, note that there are three warnings on the label –
    - May contain wheat –
      - Although there is no ingredients identified that actually contain wheat components and is, thus, a cautionary statement about potential cross-contact within the facility (i.e., the manufacturer many make other products in the facility that do contain wheat)
      - The statement likely is added as a 'litigation protector" due to other foods manufactured in the facility that may contain wheat.
        - Manufacturers have the ability to prevent cross-contact and reflect this extra care on product labeling; yet the easier path is to say an allergen may be present and then not invest in the proper controls and equipment/structural design to prevent cross-contact.
    - Contains phenylalanine,
    - Xylitol is not safe for dogs.
      - Xylitol is commonly used in reduced- or sugar-free desserts, including chocolate.
      - However, the primary ingredient in chocolate that is harmful to dogs is theobromine.
        - Theobromine is similar to caffeine –
          - Used medicinally as a diuretic, heart stimulant, blood vessel dilator, and smooth muscle relaxant.
          - Dogs cannot metabolize theobromine and caffeine as well as people can.
  - Here is the ingredient list for the gum and the purpose for each ingredient –

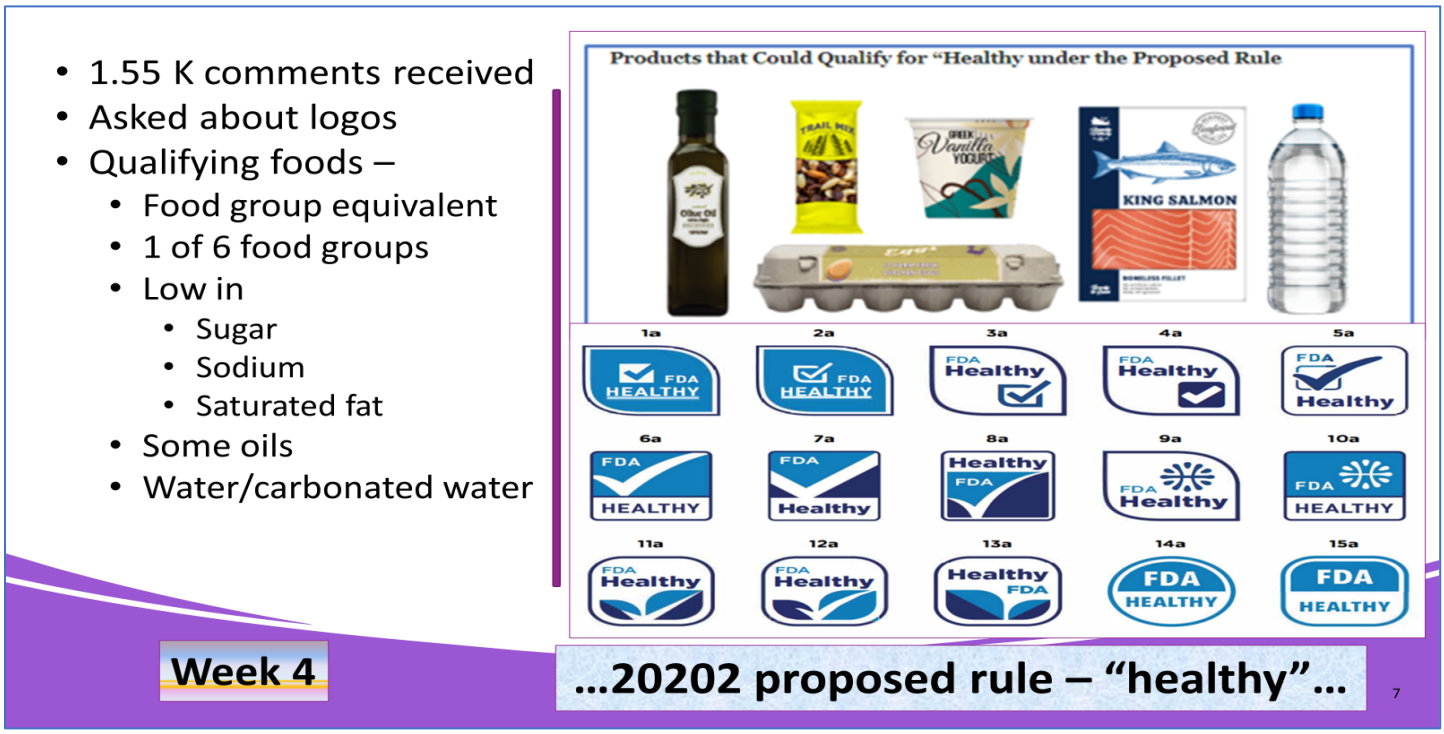
- Xylitol -- nutritive sweetener
- Sorbitol -- nutritive sweetener
- Chewing gum base -- ? as to nutritive impact
- Mannitol -- non-nutritive sweetener
- Glycerin -- nutritive sweetener
- Maltitol syrup -- sugar substitute sweetener
- Maltodextrin -- nutritive sweetener
- Less than 2 % of –
    - Natural and artificial flavors
    - Rice starch -- thickener
    - Sucralose -- nutritive sweetener
    - Sodium carboxymethylcellulose -- texturizer
    - Coconut oil -- texturizer
    - Acesulfame K -- non-nutritive sweetener
    - Aspartame -- non-nutritive sweetener
    - Sucrose fatty acid esters -- texturizer
    - Lecithin (soy) -- texturizer
    - Green tea extract -- ? As to nutritive impact
    - Carnauba wax -- anticaking agent
    - Xanthan gum -- texturizer
    - BHT to maintain freshness
    - Blue 1 lake
    - Colored with –
        - Turmeric oleoresin
        - Blue 1
- May contain –
    - Wheat
    - Phenylketonurics:
        - Contains phenylalanine
- Calories per serving -- < 5 although 1 g sugar alcohol –
    - FDA allows foods with less than 5 calories to be labeled as such;
        - Manufacturers can apply a “calorie free” label to products with less than 5 calories.
        - Note that in this product, 1 piece of gum is a serving and is 4 calories.

Slide #6D – implied nutrient content claim…healthy recommendations…

- Slide #6D – implied nutrient content claim – "healthy"…
- Week 4 Topic –
  - Since 1994, the FDA has recognized that when a manufacturer uses labeling that characterizes the nutritional attributes of a food as "healthy," the manufacturer is making an implicit claim of the level of nutrients of the food.
    - When the 1994 (existing but outdated) definition was established, the state of nutrition science focused on individual nutrients contained in a food.
    - Under the 1994 regulations for claims –
      - Foods bearing the "healthy claim" had to meet specific criteria for nutrients in the food –
        - Cholesterol,
        - Saturated fat,
        - Sodium, and
        - Total fat; and
        - Minimum amounts (10 % of Daily Value – DV of at least one of the following nutrients whose consumption was encouraged based on deficiencies in the general US population –
          - Calcium,
          - Dietary fiber,
          - Iron,
          - Protein,
          - Vitamins A and C.
        - The required nutrient criteria varied for certain food groups, including –
          - Fruit (raw),
          - Game meat,
          - Seafood, and
          - Vegetables (raw).
        - The claim also had to link to an explicit or implicit claim or statement about a nutrient –
          - For example, "healthy, contains 3 grams of fat."
      - The 1994 regulations were based on certain requirements associated with the Nutrition Facts panel, including serving sizes that have since been changed by subsequent regulations.

        - Any of the following terms must meet the criteria for "healthy" –
            - "Healthy,"
            - "Health,"
            - "Healthful,"
            - "Healthfully,"
            - "Healthfulness,"
            - "Healthier,"
            - "Healthiest,"
            - "Healthily," "and
            - "Healthiness."
- By 2022, the *Dietary Guidelines, 2020-2025 (https://www.dietaryguidelines.gov/sites/default/files/2020-12/Dietary_Guidelines_for_Americans_2020-2025.pdf)* no longer identify vitamins A and C as deficient in the general US population.
    - Rather, potassium and vitamin D are identified as deficient and are required to be listing on the Nutrition Facts panel.
    - In addition, rather than focusing on individual nutrients in a food as required for the "healthy" claim since 1994, by 2022, the new recommendation is to follow a healthy dietary pattern at every life stage with a focus on meeting food group needs with nutrient-dense foods and beverages and staying within calorie limits.
        - Foods provide an array of nutrients and other components that have health benefits,.
        - Nutritional needs should be met primarily through a variety of nutrient dense foods.
    - Dietary intake should be increased for food groups with under-consumed dietary components.
    - Guidance stressed that there are no bad foods, just bad habits.

Slide #6D – implied nutrient content claim…proposed rule - "healthy"…



- Slide #7D – implied nutrient content claim…proposed rule – "healthy"…
- Week 4 Topic –
  - A proposed regulation for "healthy" claims, based on the 2020-2025 Dietary Guidelines for Americans was issued by FDA on September 22, 2022.
    - Comments were received from the public through February 16, 2023, with a total of 1.55 K received.
      - 1.55 K individual comments can be viewed at this link -- https://www.regulations.gov/docket/FDA-2016-D-2335/comments.
      - Such a rulemakings likely won't be finalized for at least 2 years, perhaps by 2025.
    - Meanwhile, in anticipation of the proposed changes getting finalized, manufacturers can modify food labels and begin using the proposed criteria at any time.
      - If the proposed rule content changes significantly based on comments, then the proposed rule might be re-proposed.
      - If the comments support the proposed rule and no significant changes are made, then the rule may be finalized.
      - Thus, manufacturers face some risk if they change labeling now, but the risk is likely low.
    - The regulatory focus is on food groups and nutrients to limit, as recommended.
      - Food products would need to contain a certain amount of food (a "food group equivalent") from at least one of the recommended food groups –
        - Dairy
        - Fruits
        - Grains
        - Proteins,
        - Oils
        - Vegetables
      - The proposed incorporation of food group criteria focuses on dietary patterns as a whole and is appropriate for an implied nutrient content claim.
      - Claims that imply a food product contains a certain amount of a food group would in essence, characterize the level of a variety of nutrients important to help consumers maintain healthy dietary practices.

- In addition to the food group criteria, the proposed 2022 “healthy” regulation will require that foods must continue to adhere to certain criteria regarding nutrients to limit to be labeled as “healthy.”
    - Specifically,
        - Added sugars
        - Sodium
        - Saturated fats
- Because of the proposed food group approach, the proposed “healthy” criteria no longer will include minimum amounts of nutrients to encourage (i.e., nutrients that are under-consumed and whose low intake in the general population or in individual subpopulations raise public health concern).
- Sufficient overall nutritional adequacy likely will be attained by the food group approach of consumption to maintain healthy dietary practices.
    - FDA is concerned that including criteria for nutrients to encourage could spur fortification to allow foods that are low in saturated fat, sodium, and added sugars to qualify for the “healthy” claim despite these foods not contributing to a meaningful amount of a food group (e.g., white bread fortified with calcium).
- There are some foods that the proposed regulations explicitly included in the updated criteria for “healthy” including raw, whole fruits and vegetables, and water.
    - These foods will not need to meet requirements for food group equivalent and nutrients to limit.
    - These foods are included in categories of food that can automatically use the “healthy” claim because of their nutrient content and positive contribution to an overall healthy diet.
    - This is not the case for these foods under the 1994 “healthy” regulations.
- Food groups are clarified as follows –
    - Dairy –
        - Including fat-free., low-fat, and/or lactose-free versions, plus a soy alternative –
            - Cheese
            - Fortified soy beverages and soy yogurt alternatives
            - Milk
            - Yogurt
    - Fruits –
        - Especially whole
    - Grains –
        - At least half of which are whole grain
    - Oils –
        - Oils in food such as nuts and seafood
        - Vegetable oils
    - Proteins –
        - Beans
        - Eggs
        - Lentils
        - Meats (lean)
        - Nuts
        - Peas
        - Poultry
        - Seafood
        - Seeds
        - Soy products
    - Vegetables of all types –
        - Dark green
        - Red and orange
        - Beans, peas, and lentils (which also are included as “proteins”
        - Starchy

        - Other vegetables
- Note on the use of the *Dietary Guidelines, 2020-2025* –
    - Foods fit into groups based on how they are consumed and their nutrient content even if this is different from their botanical classification.
        - For example –
            - A bell pepper is considered a vegetable in the *Dietary Guidelines, 2020-2025*, even though it is botanically a fruit.
        - Additionally, foods from the same source may be categorized differently depending on how they are consumed –
            - For example –
                - Soybean oil is classified as an oil, but tofu made from soybeans is classified as a protein.
    - The 2022 proposed regulation adopts the categorizations used in the *Dietary Guidelines, 2020-2025* to determine the appropriate food group for the food.
        - Also, when considering saturated fat content, the saturated fat content from nuts and seeds is excluded in mixed food products due to the positive nutrient dense nature of consuming nuts and seeds. .
        - Foods group equivalent for foods to qualify for a "healthy" claim in the 2022 "healthy" proposed regulations include –
            - Dairy – ¾ cup
            - Fruits – ½ cup
            - Grains – ¾ oz whole grain
            - Protein foods --
                - Beans, peas, and soy products – 1 oz
                - Egg – 1 oz
                - Game meats – 1 ½ oz
                - Nuts and seeds – 1 oz.
                - Seafood – 1 oz
                - Vegetables – ½ cup
        - Eligible products for "healthy" nutrient content claim in the 2022 "healthy proposed regulations include –
            - Fruits – raw, whole – no additional criteria.
            - Main dish (as defined in 21 CFR 101.13(m) – at least 1 food group equivalent each from at least 2 different food groups, and nutrients to limit.
            - Meal (as defined in 21 CFR 101.13(l) -- at least 1 food group equivalent each from at least 3 different food groups, and nutrients to limit.
            - Mixed products – at least ½ food group equivalent each from at least 2 different food groups, and nutrients to limit.
            - Vegetables – raw, whole – no additional criteria.
            - Water – plain and carbonated – no additional criteria.
        - Total fat no longer is included in the criteria for the 2022 proposed regulations on "healthy."
            - Rather, the focus is on the types of fat consumed.
            - Saturated fat is replaced with unsaturated fats, particularly monounsaturated fat and polyunsaturated fats.
        - Meanwhile, FDA is aware of Dietary Guidelines that stress reliance on monounsaturated and polyunsaturated fats, but do not meet the regulatory definition of "low fat," and on foods that contain at least 10 percent of the DV per reference amount customarily consumed (RACC) of potassium or vitamin D.
            - Thus, FDA has informed industry that enforcement discretion will be instituted such that such labeled foods likely will not be targeted by FDA for corrective action.

- The 2022 proposed regulation on “healthy” will require certain recordkeeping requirements for food bearing the claim where compliance cannot be verified through information on the product label.
- For cost-benefit of the 2022 proposed regulation on “healthy,” –
  - In the marketplace, about 5 % of all packaged foods are labeled as “healthy.”
    - From the economic analysis –
      - About 34,000 UPCs, or 14 percent of total Universal Product Codes (UPCs), qualify for the existing “healthy” implied nutrient content claim but only 5 percent (12, 000 UPCs) choose to label.
    - The use of the “healthy” nutrient content claim is voluntary.
  - Diet-related chronic diseases targeted for improvement as a consequence of the proposed rule include –
    - Cardiovascular disease and
    - Type 2 diabetes.
  - Costs for reformulating, labeling, and recordkeeping, discounted at 3 % over 20 years, would result in a mean value of costs estimated at $276 M, or $19 M annualized.
  - Benefits, also discounted at 3 % over 20 years, the mean present value is estimated at $455 M, or $31 M annualized.
  - Net benefits are estimated at $180 M, or $12 M annualized.
- FDA also proposed to conduct research on front of package symbols signifying conformance to any finalized “healthy” criteria for foods from the 2022 proposed regulation on “healthy” claims.
  - Comments were to be submitted by April 27, 2022.

Products that Could Qualify for "Healthy under the Proposed Rule

Proposed Criteria for Certain Food Groups and Sample Foods

Per Reference Amount Customarily Consumed

oz =ounce
g = grams
mg = milligrams
DV = Daily Value

Food Groups	Food Group Equivalent Minimum	Added Sugar Limit	Sodium Limit	Saturated Fat Limit
Grains	3/4 oz whole-grain equivalent	5% DV (2.5 g)	10% DV (230 mg)	5% DV (1 g)
Dairy	3/4 cup equivalent	5% DV (2.5 g)	10% DV (230 mg)	10% DV (2 g)
Vegetable	1/2 cup equivalent	0% DV (0 g)	10% DV (230 mg)	5% DV (1 g)
Fruit product	1/2 cup equivalent	0% DV (0 g)	10% DV (230 mg)	5% DV (1 g)

Proteins	Food Group Equivalent Minimum	Added Sugar Limit	Sodium Limit	Saturated Fat Limit
Game meat	1 ½ oz equivalent	0% DV	10% DV	10% DV
Seafood	1 oz equivalent	0% DV	10% DV	10% DV
Egg	1 egg	0% DV	10% DV	10% DV
Beans, peas, and soy products	1 oz equivalent	0% DV	10% DV	5% DV
Nuts and seeds	1 oz equivalent	0% DV	10% DV	5% DV*

* Excluding saturated fat derived from nuts and seeds

Oils	Food Group Equivalent Minimum	Added Sugar Limit	Sodium Limit	Saturated Fat Limit
100% Oil	N/A	0% DV	0% DV	20% of total fat
Oil-based Spreads	N/A	0% DV	5% DV	20% of total fat
Oil-based Dressing*	N/A	2% DV	5% DV	20% of total fat

* Must contain at least 30% oil and saturated fat level of the oil must be ≤ 20 percent of total fat

Sample Foods	Individual food	Mixed product	Meal
			
Amount of food groups required	6-oz yogurt (1 food group equivalent)*	1/8 cup dried fruit and 1/4 oz nuts (At least 1/2 food group equivalent each from 2 different food groups)	1 oz salmon, 1/2 cup green beans, 3/4 oz brown rice (At least 1 food group equivalent each from 3 different food groups)
Nutrients to Limit (no more than)**	2 g saturated fat 230 mg sodium 2.5 g added sugar	1 g saturated fat*** 230 mg sodium 0 g added sugar	4 g saturated fat 690 mg sodium 2.5 g added sugar

* A food group equivalent is the amount of a food group required

** Amounts based on percentage of the Daily Value for that nutrient

*** Saturated fat from nuts/seeds does not contribute to limit

Under the proposed definition, raw whole fruits and vegetables would automatically qualify for the "healthy" claim because of their nutrient profile and positive contribution to an overall healthy diet. Examples of foods currently ineligible to bear the "healthy" claim based on the existing regulatory definition, but that would qualify under the proposed definition are water, avocados, nuts and seeds, higher fat fish, such as salmon, and certain oils. Products that currently qualify for "healthy" that would not under the proposed definition include white bread, highly sweetened yogurt and highly sweetened cereal.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Slide #8D – take a stretch…

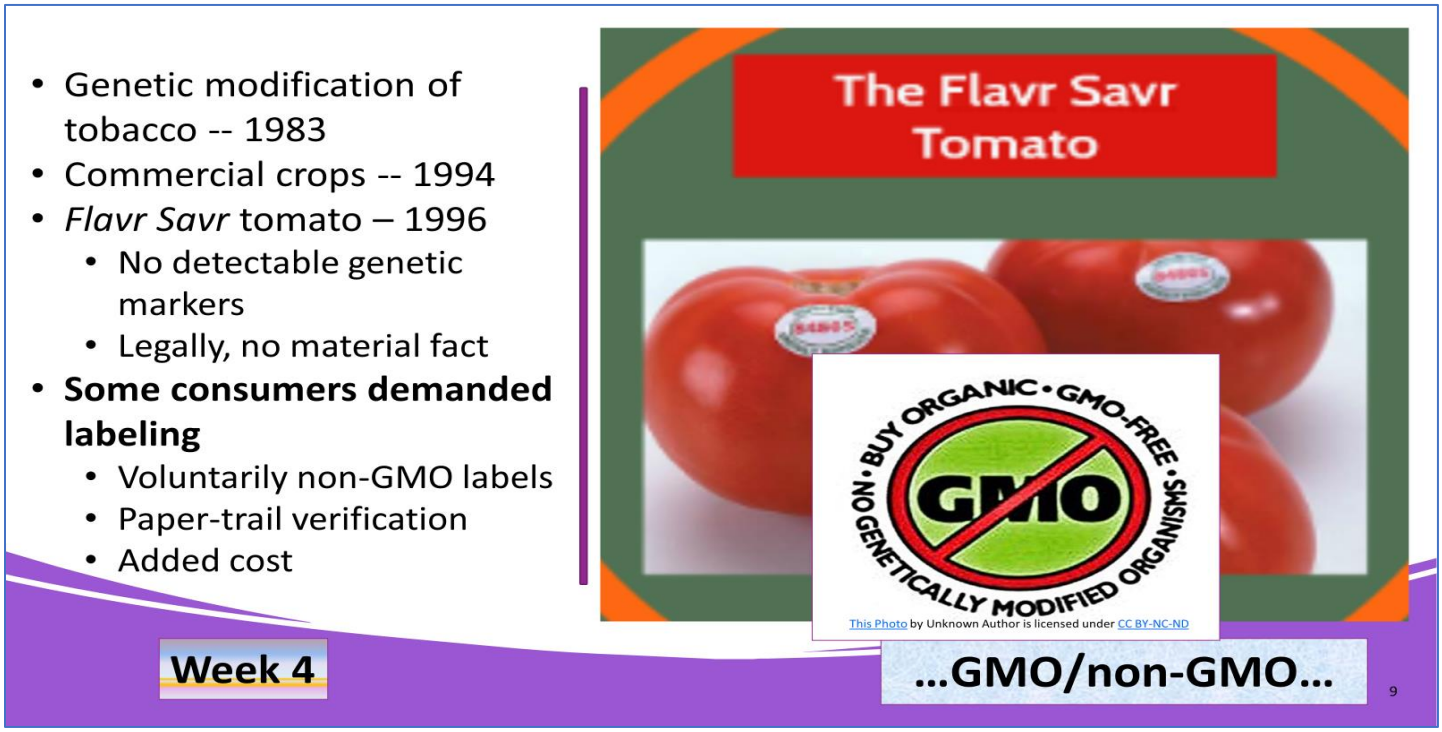
- 10-minute break

Week 4

Take a stretch…

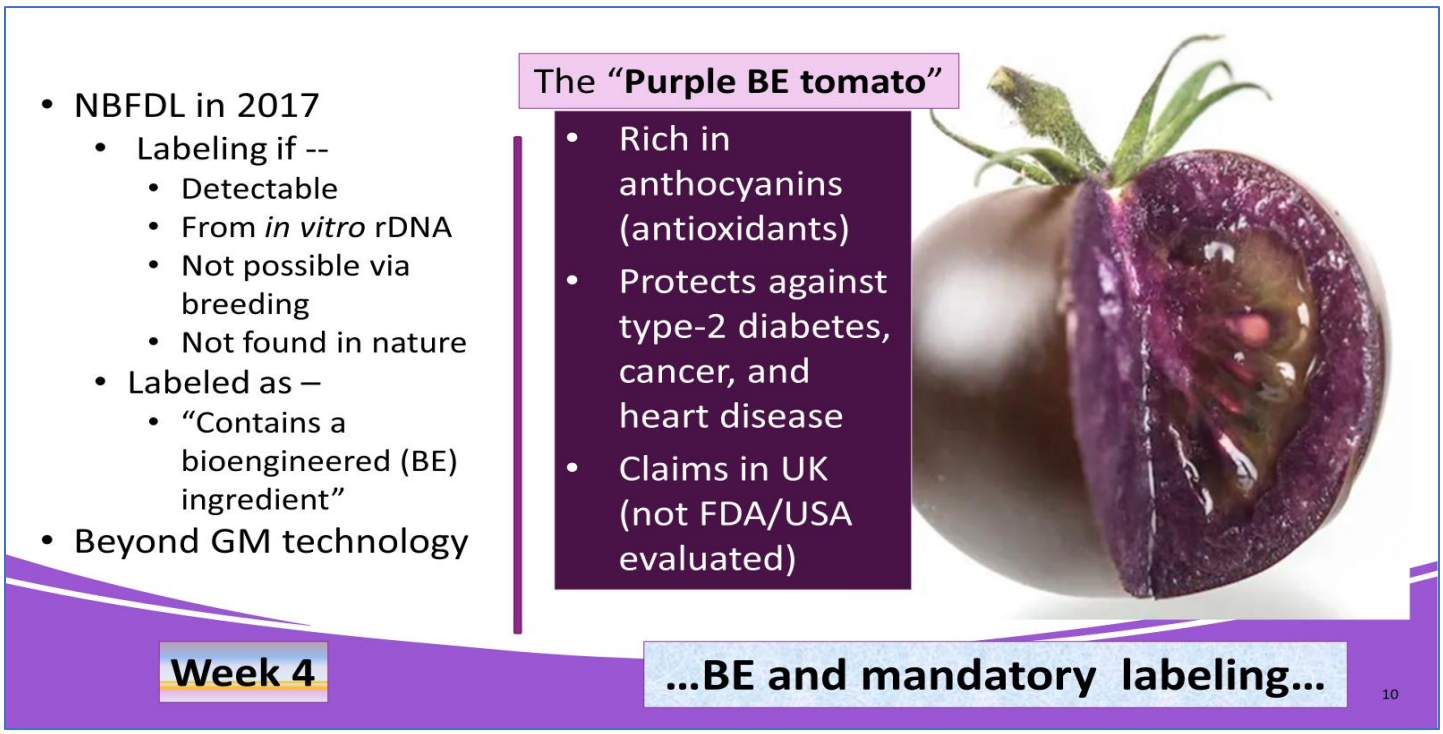
8

- Slide #8D – Take a stretch…
- Week 4 Topic –
  - 10-minute break



- Slide #9D – implied claim…GMO/non-GMO...
- Week 4 Topic –
  - In 1983, the first genetically modified (GM) plant was an antibiotic-resistant tobacco plant.
  - In 1994, the first GM food commercially available to the public was the "Flavr Savr" tomato designed to slow the ripening process.
  - Since 1996, farmers have been growing GM crops.
    - Some consumers have viewed such crops as unsafe, unhealthful, and not natural.
    - Some consumers have demanded that use of such crops in human and animal food be labeled for their presence.
  - Historically, there was no mandatory requirement to label or disclose whether foods came from GM crops.
    - FDA concluded that "bioengineered foods do not differ in any meaningful or uniform way or present any different or greater safety concern than food developed from traditional breeding."
      - Specifically (and, importantly, legally), "the method of development of a new plant variety is generally not material information…and would not usually be required to be disclosed in the labeling of food."
      - Basically, there were no markers in the food that proved that the food was from a GM crop (of which the GM plant itself did have such markers).
    - Manufacturers, on a voluntary basis, could label affected foods with information about whether the food was or was not derived from GM plants.
      - Consequently, many manufacturers voluntarily labeled foods as "non-GMO," but few manufacturers affirmatively labeled foods as containing GM ingredients.
      - A variety of fee-for-service programs emerged to "certify" that ingredients were not GMO.
      - Government auditors were not allowed on-farm to verify such attestations.
      - Labeling was via paper trail and "trust."
    - Many non-GMO foods were more expensive than those not carrying a "non-GMO" logo due to the certification process..
  - The Flavr Savr tomato was advertised with the name "Flavr Savr" and with promotional material stressing the long-lasting freshness of the product.
    - The product did not survive due, in part, to poor management of the business aspects..

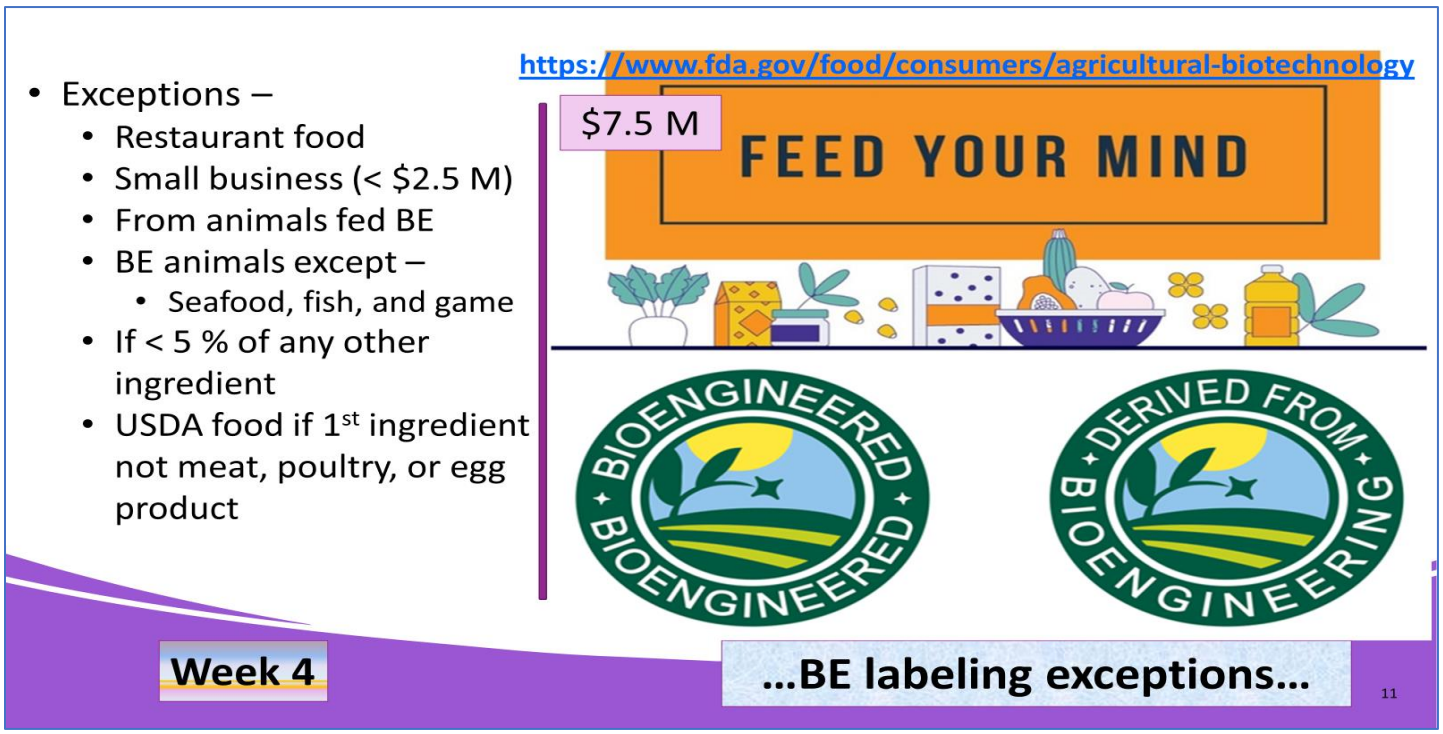
Slide #10D – implied claim…bioengineered (BE) food and mandatory labeling…



- Slide #10D – implied claim…bioengineered (BE) food and mandatory labeling...
- Week 4 Topic –
  - Labeling initiatives driven by advocates opposing genetic engineering have explicitly prohibited inclusion of GM ingredients (e.g., organic), pushing for labeling of such material.
  - Three States (Vermont, Maine, and Connecticut) moved to mandate labeling of foods containing a GM ingredient.
    - This state-by-state push created a potential problem with distribution systems since manufacturers do not produce and market products for specific States.
  - In 2017. Congress issued a new law that supersedes and applies uniformly to all States – the National Bioengineered Food Disclosure Law – NBFDL. --
    - Through surveys authorized by Congress, consumers noted their expectation of paying a premium for foods labeled as non-GM.
    - Thus, the NBFDL established an obligation for food manufacturers to disclose to consumers whether their food products are scientifically different than GM and are the result of bioengineering.
      - Note: The obligation is only for those products for which –
        - There is detectable genetic material,
        - This material has been modified through in vitro recombinant DNA techniques,
        - This modification could not otherwise be obtained through conventional breeding, and
        - This modification could not be found in nature.
      - It is this detectable material that now becomes a material fact and for which labeling is required in order that the labeling of the product is not misleading.
  - A genetically modified tomato with a purposeful nightshade color of purple was created to contain a higher level of anthocyanins than conventional tomatoes.
    - The tomato variety was developed in the United Kingdom.
    - The genetic material was derived from the snapdragon (to control anthocyanin levels) and Arabidopsis thaliana (as a flavanol activator).
      - Anthocyanins are a group of antioxidants that may prevent inflammation and protect against type-2 diabetes, cancer, and heart diseases.
    - The nutrient content is comparable to traditional tomatoes.

- The product is labeled as BE or the food is labeled as containing a BE ingredient.
    - The specific BE ingredient is not required to be named.

Slide #11D – implied claim…BE labeling exceptions…education campaign...



- Slide #11D – implied claim…BE labeling exceptions...education campaign…
- Week 4 Topic –
  - Within the NBFDL, Congress authorized the Agricultural Biotechnology Education and Outreach Initiative – ABEOI to help increase consumer understanding.
  - Congress provided $7.5 M to fund the ABEOI and the "Feed Your Mind" campaign by the FDA (https://www.fda.gov/food/consumers/agricultural-biotechnology).
    - "Feed Your Mind" is designed to help consumers understand genetically engineered foods, commonly referred to as GM or GMOs (genetically modified organisms).
  - FDA explains that the new terminology for food labeling is "bioengineered" on foods that meet the standard for bioengineered foods (i.e., contain detectable genetic material that has been modified through certain lab techniques and cannot be created through conventional breeding or found in nature).
    - FDA explains that with genetic engineering, a beneficial gene can be transferred into a plant or animal.
      - For example, some GMO plants contain plant-incorporated protectants (PIPs) to make them resistant to insects, reducing the need for pesticides.
  - Regulations implementing the new NBFDL were issued in 2018 and became effective by January 1, 2022.
  - The disclosure location for the bioengineered ingredient/food must be either on the information panel directly adjacent to the statement identifying the name and location of the distributor, or on the principal display panel.
    - Of note, the law required disclosure but not necessarily traditional labeling.
      - A QR code or other text means could be applied to packaging such that the consumer would then need to actively investigate on their own whether the product contains a bioengineered ingredient, or the entire food is a product of bioengineering.
        - However, a Federal court ruled in September 2022 that putting a QR code on a label was not an adequate means to inform consumers that the food has been bioengineered.
        - The lawsuit was brought by the Center for Food Safety and other advocacy groups

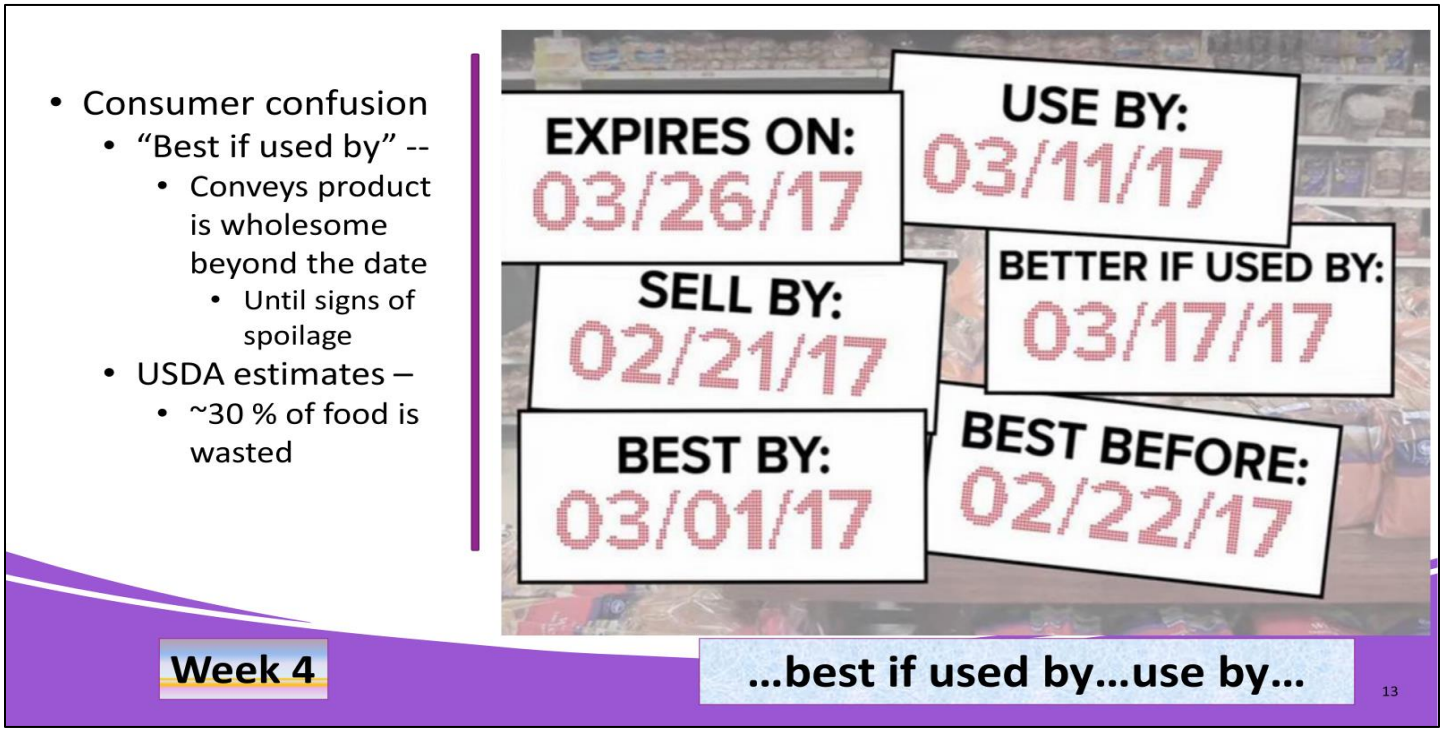
        - Only this part of the regulation was ordered to be changed.
        - According to Andrew Kimbrell, Executive Director of the Center for Food Safety, "these[bioengineered food] regulations are not about informing the public but rather designed to allow corporations to hide their use of genetically engineered ingredients from their customers.
    - Despite criticism, groups such as the American Soybean Association and the National Corn Growers Association praised the new standard when it was announced, saying it would create more transparency in the food industry.
- Manufacturers may use only the term "bioengineered" and are prohibited from using "genetically engineered," "genetically modified," "GM," or "GMO."
- Note that FDA does not have the authority to prohibit use of these terms (e.g., GMO or non-GMO) on foods that do not meet the standard for a bioengineered food.
- Foods containing highly refined ingredients such as soybean oil from genetically modified soybeans or sugar from genetically modified sugar beets do not require disclosure.
- The US Department of Agriculture publishes a list of bioengineered crops and animals that need disclosure.
- The law and implementing regulations do not require disclosure for certain bioengineered foods, including –
    - Restaurant food;
    - Foods produced by "very small manufacturers" defined as having receipts less than $2.5 million;
    - Food made from animals fed bioengineered organisms; and
    - Foods where one or more ingredients have bioengineered content that is inadvertent or technically unavoidable if it is not more than 5 % of any ingredient.
    - Food from animals except bioengineered fish, seafood, and game animals meeting the standard of "detectable engineered DNA."
- The disclosure requirement –
    - Applies to all foods regulated by the Food and Drug Administration but does not apply to certain foods regulated by the Food Safety and Inspection Service.
    - The Food Safety and Inspection Service regulated foods do require disclosure if --
        - The first ingredient is something other than meat, poultry, or egg product, or
        - The first ingredient is water, stock, or broth and the second ingredient is something other than meat, poultry, or egg product.
- The US labeling of bioengineered foods/ingredients is consistent with some countries (e.g., Japan and Australia) but not others (e.g., European Union).
    - In the US, the regulations do not allow for manufacturers to identify the specific bioengineered ingredients in their product, which could cause consumers to make an incorrect assumption about what is bioengineered in the food supply.
        - For example, a pizza labeled as bioengineered may be mistakenly understood to contain a major ingredient being bioengineered rather than a minor ingredient (i.e., the squash instead of the wheat or tomato sauce).
- The European Union requires disclosure by ingredient.
- Confusion likely will result initially because the common term "GMO" no longer can be used for certain foods that meet the standard for a bioengineered food/ingredient and will be replaced with "BE" ("bioengineered").
- The intent for this change may have been to avoid the contentious history of "GM foods" but may end up creating mistrust and seen as a tactic to mask commonly accepted terminology.
- As of 2017, 24 countries have assessed the safety of human and animal foods subjected to genetic engineering.
    - The criteria for approval in each country may vary but the objective of being safe for human and animal health and the environment remains consistent.

        - A GMO is a plant, animal, or microorganisms that has had its genetic material (DNA) changed using technology, referred to by scientists as genetic engineering.
        - Cross-breeding and selective breeding of plants and animals are related processes but not as specific.
            - These breeding schemes generally are managed by lay persons as opposed to laboratory personnel.
- In 2020, GMO plantings in the US made up –
    - 92 % of all corn
    - 96 % of all cotton
    - 94 % of all soybeans
- Most GMO crops are used for food for animals, but they are also used to make ingredients used in food products.
    - GMO crops in the US include –
        - Alfalfa
        - Apples
        - Canola
        - Corn
        - Cotton
        - Papaya
        - Pink Pineapple
        - Potatoes
        - Soybeans
        - Summer squash
        - Sugar beets

- Slide #12D – implied claim…fresh versus frozen…and other meanings...
- Week 4 Topic –
  - Fresh meat and poultry –
    - Antimicrobial treatments –
      - Because antimicrobial substances and irradiation purposefully reduce the level of spoilage and pathogenic microorganisms, which thereby extends the shelf-life of the product, any treated meat or poultry product cannot be described as fresh.
    - Color delay --
      - Because color oftentimes is used to assess product freshness in red meat products, any uncured red meat product treated with a substance that delays discoloration (e.g., ascorbic acid, erythorbic acid, or citric acid), fresh cannot be used to describe the product.
      - Note – the policy is specific to red meat because the color of poultry is not changed when such substances are used.
    - Internal temperature –
      - Since at least the 1930s, frozen turkeys (at or below 1 degree Fahrenheit) were permitted to be labeled and sold as fresh.
      - However, in 1995, USDA determined the practice to be deceptive.
        - USDA changed the policy to require poultry chilled to an internal temperature of below 26 degrees to be labeled as frozen.
        - Note – such poultry likely would be hard to the touch, seemingly frozen solid, at the surface but not at the center.
          - Poultry is commonly distributed in ice-filled boxes to help maintain "freshness" of poultry.
        - The controversy arose when California issued regulations earlier in the 1990s prohibiting poultry from being marketed within the State as fresh if chilled to below 26 degrees Fahrenheit.
          - California issued their policy, in part, to provide incentives for production of in-state poultry rather than supporting poultry processing from out-of-state from large poultry processors.

        - In the State debate on the legislation. it is rumored that a California Representative attempted to roll a “fresh-frozen” poultry carcass with an internal temperature of 1 degree Fahrenheit down the aisle of the Chamber to demonstrate just how “hard to the touch” a poultry carcass was at this low internal temperature.
    - When the USDA proposed a change in policy, the poultry industry strongly objected citing that poultry is shipped at very low temperatures to reduce losses and to prevent harmful bacteria from multiplying.
        - USDA countered with “poultry cannot be defined at one precise and arbitrary temperature and that frozen is not the opposite of fresh.”
        - In keeping with the Nutrition Labeling and Education Act enacted in 1990 that focused on providing informative labeling to consumers, USDA cited a need for clearer labeling of fresh versus frozen poultry.
            - Thus, any raw poultry with an internal temperature of below 26 degrees Fahrenheit cannot be described as fresh.
    - Although there is no regulation specific to the internal temperature of red meat regarding fresh versus frozen, it is accepted practice in the red meat industry to abide by the “26-degree internal temperature” rule for poultry.
- “Never frozen” –
    - This phrase is not permitted to describe –-
        - Poultry where the internal temperature has ever been below 0 degrees;
        - Red meat product that has ever been frozen;
        - Any refrigerated secondary product if the meat or poultry component has ever been frozen.
    - NOTE -- generally, trademarks, company names, and fanciful names containing the word “fresh” are acceptable regardless how the actual product was handled provided the term is used in such a manner that it remains clear to the purchaser that the product is not fresh.
- Preservatives/preserved –
    - The term fresh cannot be used to describe any of the following products or practices –
        - Canned product
        - Chemically preserved product;
        - Cured product (e.g., corned beef, smoked cured turkey, or prosciutto)
        - Dried product
        - Hermetically sealed shelf stable product
- Products in the marketplace may contain a stick-on label that says previously frozen.
    - Although not unsafe, such product should not be refrozen simply because of the consequences of the freezing/thawing cycle –
        - Wall lining of the cellular material becomes disrupted, causing purge and seepage of moisture from the product.
- Be aware of the use-by date on the product as it applies to food establishments –
    - As a management practice (and as defined in the Uniform Food Code), product dating is required in order that product is not maintained in facilities beyond its functional use.
    - Oftentimes, food establishments will freeze product as it nears the end of the use-by date.
    - This is an acceptable practice for preventing the discarding of food that cannot be sold after the use-by date.
    - Such product oftentimes also is donated to community food banks.

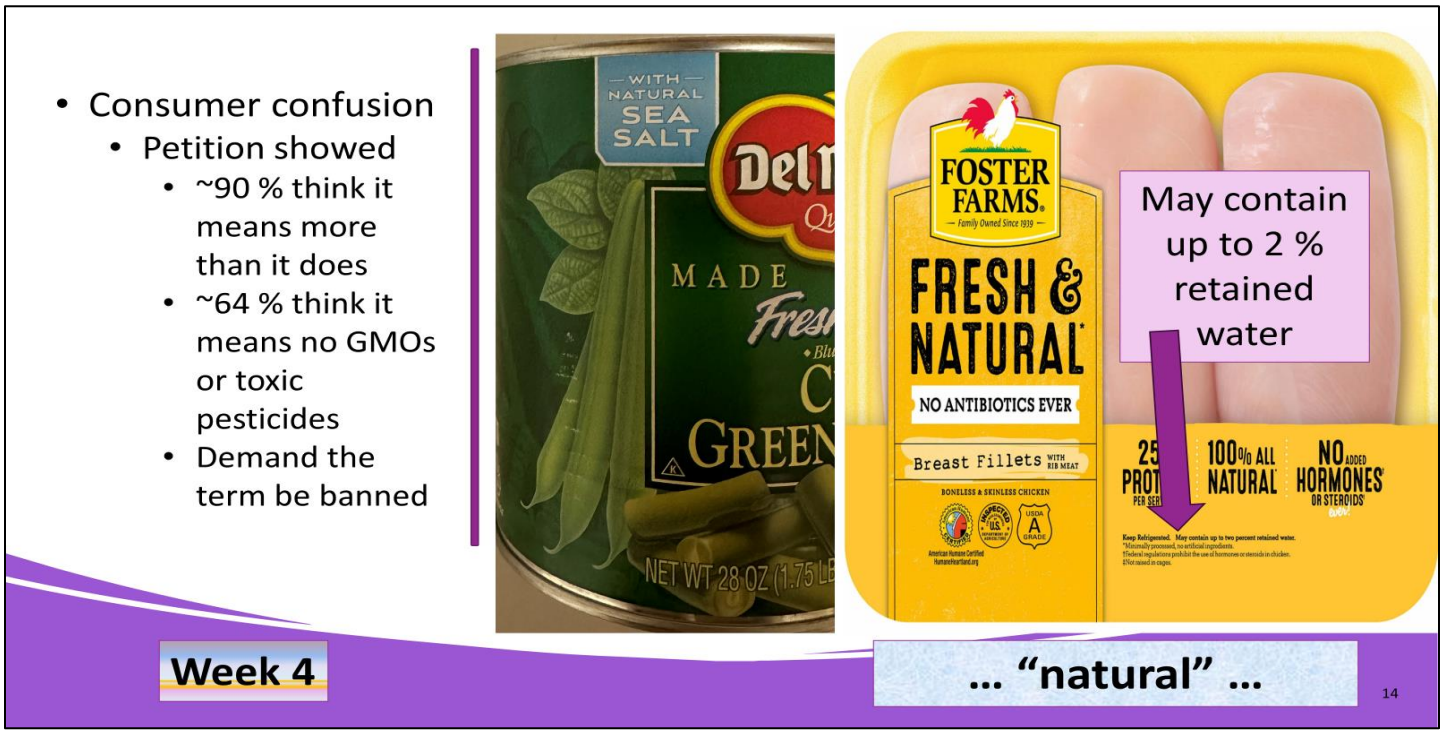
Slide #13D – implied claim…"best if used by"…use by…labeling issues…



- Slide #13D – implied claim…"best if used by"…"use by"…
- Week 4 Topic –
  - USDA estimates that ~30 % of the food supply is wasted at retail and consumer levels due primarily to the "use by" date labeling.
  - Food waste comes from consumers and retailers throwing away wholesome food because of confusion about the meaning of the "use by" dates displayed on food labels.
  - The phrase implies that product is no longer wholesome beyond the stated date.
    - Generally, this is not a true assumption.
  - To reduce consumer confusion and wasted food, USDA and FDA recommend that food manufacturers consistently apply a "best if used by" date rather than a "use by" date.
    - A "best if used by" date conveys to consumers that the product will be of best quality if used by the calendar date shown.
    - Foods not exhibiting signs of spoilage and that were properly handled should be wholesome and may be safely consumed beyond the labeled "best if used by" date.
      - Product should still be safe and wholesome until the time of spoilage is evident.
      - Spoiled foods will develop an off odor, flavor, or texture, and appear to be slimy due to naturally occurring spoilage bacteria.
      - Spoiled foods should not be consumed; they likely won't cause a foodborne infection but likley will cause stomach discomfort.
  - Note that there are other dates appearing on food products.
  - All products are required to have a production date signifying when the product was produced.
    - This date usually is coded to reflect the time of day and production lot.
  - As part of the managerial process contained in the Uniform Food Code for use by food establishments, products produced within the food establishment likely will have a date by which the product must be consumed.
    - Except for foods packaged in a reduced oxygen packaging method, foods held for more than 24 hours must be clearly marked to indicate the date by which the food must be consumed on the premises, sold, or discarded when held at a temperature of 41 degrees Fahrenheit or less for a maximum of 7 days.
      - The day of preparation is counted as Day 1.

        - This managerial process does not apply to consumers or to the products they purchase.
        - This date is not a “best if used by date.”
    - Further, at food establishments selling fresh, pre-packaged products in conformance with the Uniform Food Code cannot be sold beyond the use-by date.
        - Such product, when approaching the expiration date, can be frozen and the product can then be donated to community food banks, generally maintaining optimal quality in the frozen state for up to a year beyond the “best if used by” date.
- Based on a 2019 survey by the Johns Hopkins University Center for a Livable Future (“Widespread confusion about food safety labels leads to food waste, survey finds”) –
    - There is widespread confusion on U.S. consumer attitudes and behaviors related to food date labels.
        - This confusion has led to unnecessary discards, increased waste, and food safety risks.
    - The USDA Economic Research Service (ERS) estimates –
        - ~30 % of food may be wasted at the retail and consumer level even though relatively few food items are likely to become unsafe before becoming unpalatable;
        - 84 % of consumers discarded food shortly before the end of time stated on the “use by” date on the package at least occasionally; and
        - 37 % of consumers reported that they always or usually discarded food near the end of the “use by” package date.
        - Importantly, more than half of the participants incorrectly thought date labeling was federally regulated or reported that they were unsure and thus were more likely to discard food.
- Retailers have cosmetic standards that they enforce (“US Extra Fancy” and “US Fancy”; “US Number 1” or “Utility” not sold despite being edible) –
    - In addition to the waste derived from the managerial process for discarding food nearing the end of the product’s “use by” date, 35 to 103 million tons of food loss annually in USA at $162 billion.
    - The “Food Loss and Waste 2030 Champions” program –
        - USDA and the Environmental Protection Agency (EPA) announced a food loss and waste reduction goal –
            - Began in September 2015;
            - Calling for a 50% reduction by 2030;
            - There is an application process; and
            - Progress reports are on public websites for 30 corporations (e.g., Amazon, Blue Apron, Walmart, Sprouts Farmers Market, The Wendy's Company, YUM Food Brands).
- There is an exception for infant formula, which the “use by” date is based on nutritional bioavailability.
- There are various alternate forms of “use by” date labeling –
    - “Freeze by” – when product should be frozen for maintaining peak quality;
    - “Sell by” – for retail display -- inventory management.

Slide #14D – implied claim…use of “natural” and other issues…



- Slide #14D – implied claim…use of “natural” and other issues...
- Week 4 Topic –
  - Consumers now regard many uses of this term as non-informative.
  - A citizen petition from Consumers Union submitted to FDA requested that the term “natural” be prohibited, asserting –
    - There was a ‘‘drastic’’ difference between the government’s current policy for use of the term ‘‘natural’’ and ‘‘what people think the term should mean.
    - The term “natural” is vague even though both FDA and USDA FSIS define the term through guidance as meaning no artificial flavor or flavoring, coloring ingredient, or chemical preservative, or any other artificial or synthetic ingredient. .
    - There no longer is a common consumer understanding, creating a sense of false and misleading inference.
      - For example, using the labels “natural chili” or “chili – a natural product” --
        - The term “natural” would be unacceptable for a product containing beet powder, which artificially colors the finished product.
        - However, a claim such as “all natural ingredients” might be acceptable if the beet powder was present.
    - The petition relied on Consumer Reports National Research Center survey data to support its position that consumers were misled by the term ‘‘natural.’’
      - According to the petition, the survey suggested that nearly two-thirds of U.S. consumers were currently misled by use of the term ‘‘natural’’ on certain food labels and nearly 90 % expected it to ‘‘mean much more than it does.”
      - For example, according to the petition,
        - 66 % of consumers think “natural processed food products” mean no toxic pesticides were used
        - 66 % think no artificial ingredients or colors were used
        - 65 % think no chemicals were used during processing
        - 64 % think no GMOs were used
    - Also, when consumers were asked what they thought the term natural should mean –
      - 87 % believed no artificial materials or chemicals should be used during processing

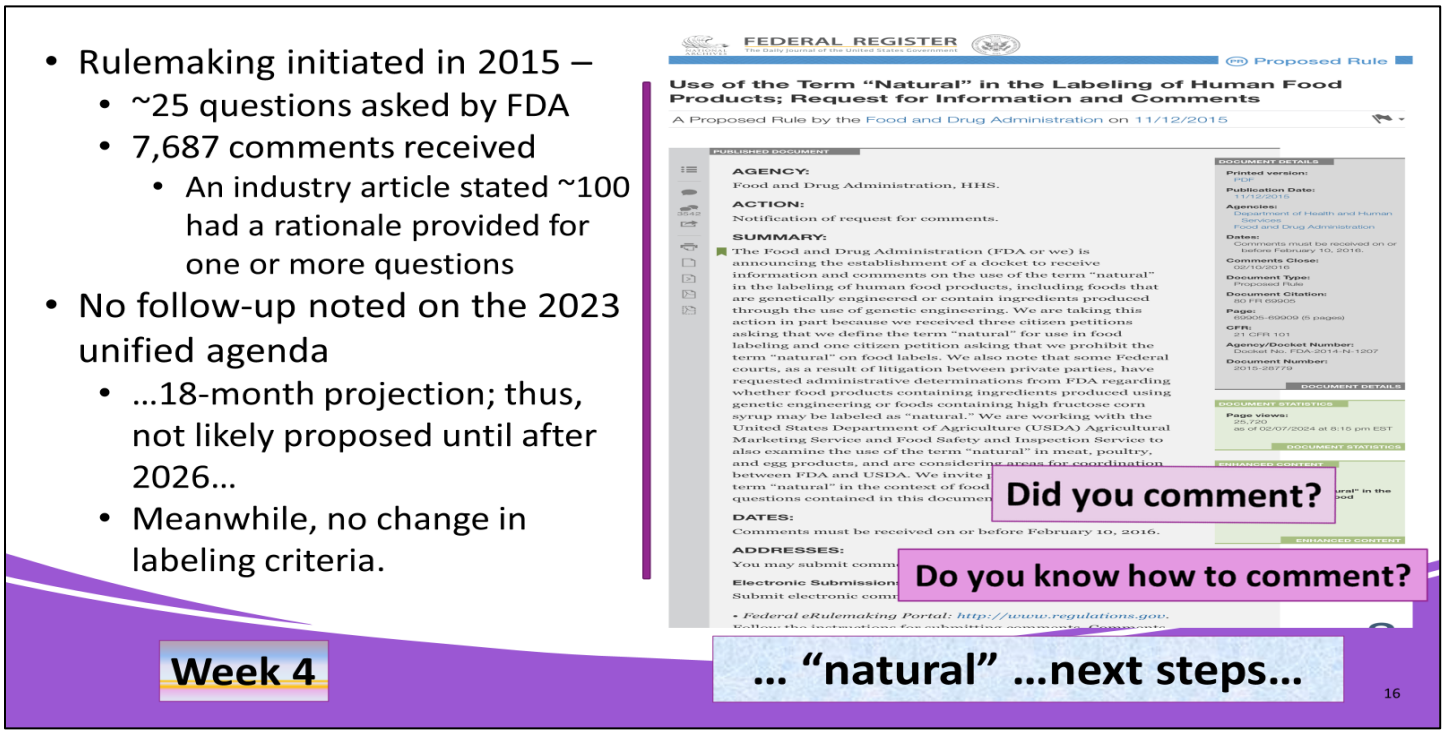
        - 86 % believed no artificial ingredients or colors should be used
        - 86 % believed no toxic pesticides should be used
        - 85 % believed no GMOs should be used
    - Consumers Union asserted that it has observed a push from industry to allow the use of the term ‘‘natural’’ on food labels that do not represent what their survey indicates consumers believe the term natural should mean.
    - Consumers Union further stated that ‘‘consumers demand far more from the “natural” label, in line with what they expect from the “organic” label such that the term ‘‘natural’’ in food labeling ‘‘should be banned altogether.”
- In the picture of the Del Monte cut green beans, natural sea salt is incorporated into the product.
    - Sea salt is unrefined and includes additional minerals than table salt that provide unique flavor.
- In the picture of the Foster Farms “Fresh and Natural” chicken wings –
    - Fresh and Natural is the brand name of the product and does not mean that the product is “fresh” or “natural.”
    - The name of the product is breast fillets with rib meat.
    - Note that the labeling separately asserts that the product is 100 % all natural.
        - Elsewhere on the labeling back panel, there is the following statement –
            - “Fresh and Natural -- the name says it all. For more than 80 years, we’ve stayed true to our family name by offering cage free*, 100 % all-natural** chicken with no added hormones*** or steroids*** ever! Always fresh. Always natural*. We believe good food feeds good times. Enjoy yours.”
                - *not raised in cages.
                - ** minimally processed, no artificial ingredients.
                - *** Federal regulations prohibit the use of hormones or steroids in chicken.
        - Also on the front package label, there is a statement that the product “may contain up to 2 % retained water.
            - During the water chilling process, poultry will absorb some of the water, and this amount must be prominently declared on the label.
            - It is not unusual for poultry to declare 8 to 12 % retained water on the label.
            - In such circumstances, USDA FSIS has clarified that retained water is not permissible unless the Agency is provided data to demonstrate the retained water is an inevitable consequence of the process to meet applicable food safety requirements.
            - The required labeling statement will help consumers to make informed purchasing decisions.

Slide #15D – implied claim…history of "natural" terminology…

- Slide #15D – implied claim…more history of "natural" terminology…
- Week 4 Topic –
  - Originally, the inference of a natural product was that it was somehow more wholesome.
  - Both the FDA and the USDA FSIS limited the use of the term to a product –
    - Containing no artificial (synthetic) ingredient,
    - Containing no added color,
    - Containing no added flavors,
    - Only minimally processed such that the product is not fundamentally altered.
      - In essence, if you could make the product in your home kitchen, using ingredients and appliances found there, the product likely could bear the term "natural" on the label.
      - USDA FSIS provided examples of minimal processing to include –
        - Traditional processes to make food edible, to preserve it, or to make it safe (e.g., smoking, roasting, freezing, drying, and fermenting, or
        - Those physical processes that do not fundamentally alter the raw product or that only separate a whole, intact food into component parts (e.g., grinding, separating eggs, and pressing fruits to produce juice).
        - Severe processes (e.g., solvent extraction, acid hydrolysis, and chemical bleaching) would be more than minimal processing.
  - The FDA and USDA approach hasn't worked well based on receipt of numerous citizen petitions.
  - A series of citizen petitions were submitted to both the FDA and the USDA FSIS regarding the term "natural" and use of the derivative terms "all natural," 100 % natural," "from nature," "naturally grown," and "naturally sourced," as well as use of genetically engineered ingredients in products labeled as "natural."
    - At least one citizen petition requested that the term "natural" be prohibited on food labels (see previous slide discussion).
    - A petition from the Grocery Manufacturers Association (GMA) requested that the FDA issue a regulation authorizing statements such as "natural" on foods that are or contain foods derived from biotechnology."
      - Specifically, GMA requested that the term not be considered false nor misleading solely because the food is or contains a food derived from biotechnology.

- The FDA has received referrals from three Federal District Courts for an administrative determination under 21 CFR 10.25(c) for the question of whether food products containing ingredients produced using bioengineering may be labeled as one of the terms associated with “natural.”
    - The FDA has declined to decide for the Courts regarding whether and under what circumstances food products containing ingredients produced using genetic engineering may or may not be labeled natural.
    - The FDA did inform the Courts that a public process (such as a proposed rulemaking or notification of request for comment) would be pursued along with engagement with the USDA FSIS and the Agricultural Marketing Service (AMS) that have responsibilities for the labeling of meat and poultry products and organic products.

Slide #16D – implied claim…natural…what are the next steps…



- Slide #16D – implied claim… "natural" …next steps...
- Week 4 Topic –
  - In 2015, the FDA issued a notification for request for comment on how it might define "natural" as a truthful term on food labeling --
  - In considering how to more uniformly address the term "natural," the following questions were asked of consumers in the form of a notification of request for comment; consumers were asked to provide a rationale for each of their responses.
    - Should we define, through rulemaking, the term "natural?"
    - Should we prohibit the term ''natural'' in food labeling?
    - If we define the term ''natural,'' what types of food should be allowed to bear the term ''natural?''
    - Should only raw agricultural commodities be able to bear the term?
      - Note that Section 201(r) of the Food Drug and Cosmetic Act (FD&CA) defines the term ''raw agricultural commodity'' as ''any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.''
    - Should only single ingredient foods, e.g., bottled water or bagged spinach, be able to bear the term?
    - If multi-ingredient foods should be able to bear the term, what type(s) of ingredients would disqualify the food from bearing the term?
    - Provide any data or other information to suggest that consumers associate, confuse, or compare the term ''natural'' with ''organic''
      - The U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS) administers the National Organic Program, which enforces laws and regulations regarding certified organic foods.
    - Is the term ''natural'' on food labels perceived by consumers the same way as ''organic?''
    - Is ''natural'' perceived by consumers to be ''better'' (or not as good as) ''organic?''
    - If we were to revise our policy regarding the use of the term ''natural'' or engage in rulemaking to establish a regulatory definition for ''natural,'' should certain production practices used in agriculture, for example, genetic engineering, mutagenesis, hybridization, the use of pesticides, or animal husbandry practices, be a factor in defining ''natural?''
    - Provide any data or other information to suggest that consumers associate, confuse, or compare the term ''natural'' with ''healthy.''

        - We have a regulation that defines the term ‘‘healthy’’ when used as an implied nutrient content claim with specific conditions related to the food’s nutrient profile that must be met in order to use the term on the label or in labeling of a food (see § 101.65(d)).
    - Is the term ‘‘natural’’ on food labels perceived by consumers the same way as ‘‘healthy?’’
    - Is ‘‘natural’’ perceived by consumers to be ‘‘better’’ (or not as good as) ‘‘healthy?’’
    - Do consumers view ‘‘natural’’ and ‘‘healthy’’ as synonymous terms?
    - Should manufacturing processes be considered in determining when a food can bear the term ‘‘natural?’’
        - For example, should food manufacturing processes, such as drying, salting, marinating, curing, freezing, canning, fermenting, pasteurizing, irradiating, or hydrolysis, be a factor in defining ‘‘natural?’’
    - Should the term ‘‘natural’’ only apply to ‘‘unprocessed’’ foods?
        - If so, how should ‘‘unprocessed’’ and ‘‘processed’’ be defined for purposes of bearing the claim?
    - If the term natural should include some processing methods, what should those methods be?
        - In making determinations related to processing, should one look at the process to make a single ingredient of a food, or does one evaluate the process done to the formulated finished food product (or both)?
    - The current policy regarding use of the term ‘‘natural’’ hinges in part on the presence or absence of synthetic ingredients.
        - For example, under the current policy synthetic forms of Vitamin D would not be used in a food claiming to be ‘‘natural,’’ whereas naturally sourced Vitamin D (e.g., from salmon or egg yolks) could be.
    - Should the manner in which an ingredient is produced or sourced affect whether a food containing that ingredient may be labeled as ‘‘natural?’’
    - What can be done to ensure that consumers have a consistent and accurate understanding of the term ‘‘natural’’ in food labeling to ensure that it is not misleading?
    - What are the public health benefits, if any, of defining the term ‘‘natural’’ in food labeling?
    - Should ‘‘natural’’ have some nutritional benefit associated with it?
        - If so, what should be the benefit?
        - What nutrients should be considered?
        - What data are available to support the association between ‘‘natural’’ and a given nutritional benefit, and/or between ‘‘natural’’ and certain nutrients?
        - How might we determine whether foods labeled ‘‘natural’’ comply with any criteria for bearing the claim?
- FDA is still analyzing the ~7,600 comments received on the questions posed about natural.
    - ~100 appeared to be substantive in that the comments provided responses with supporting documentation.
    - More than 50 % of the comments opposed permitting a GMO to qualify a product as natural.
    - More than 80 % of the comments do want a definition for natural.
    - If a proposed rule is the next action by FDA, the likelihood of it publishing within the next two years is remote because no planned action is listed on the latest unified agenda for FDA.
        - The unified agenda annually identifies projected regulatory actions within the next 18 months.
        - See -- https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-unified-agenda-track

FEDERAL REGISTER
The Daily Journal of the United States Government

Proposed Rule

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

A Proposed Rule by the Food and Drug Administration on 11/12/2015

PUBLISHED DOCUMENT

AGENCY:

Food and Drug Administration, HHS.

ACTION:

Notification of request for comments.

SUMMARY:

The Food and Drug Administration (FDA or we) is announcing the establishment of a docket to receive information and comments on the use of the term "natural" in the labeling of human food products, including foods that are genetically engineered or contain ingredients produced through the use of genetic engineering. We are taking this action in part because we received three citizen petitions asking that we define the term "natural" for use in food labeling and one citizen petition asking that we prohibit the term "natural" on food labels. We also note that some Federal courts, as a result of litigation between private parties, have requested administrative determinations from FDA regarding whether food products containing ingredients produced using genetic engineering or foods containing high fructose corn syrup may be labeled as "natural." We are working with the United States Department of Agriculture (USDA) Agricultural Marketing Service and Food Safety and Inspection Service to also examine the use of the term "natural" in meat, poultry, and egg products, and are considering areas for coordination between FDA and USDA. We invite public comment on the term "natural" in the context of food labeling and on specific questions contained in this document.

DATES:

Comments must be received on or before February 10, 2016.

ADDRESSES:

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.*

Follow the instructions for submitting comments. Comments

DOCUMENT DETAILS

Printed version:
PDF

Publication Date:
11/12/2015

Agencies:
Department of Health and Human Services
Food and Drug Administration

Dates:
Comments must be received on or before February 10, 2016.

Comments Close:
02/10/2016

Document Type:
Proposed Rule

Document Citation:
80 FR 69905

Page:
69905-69909 (5 pages)

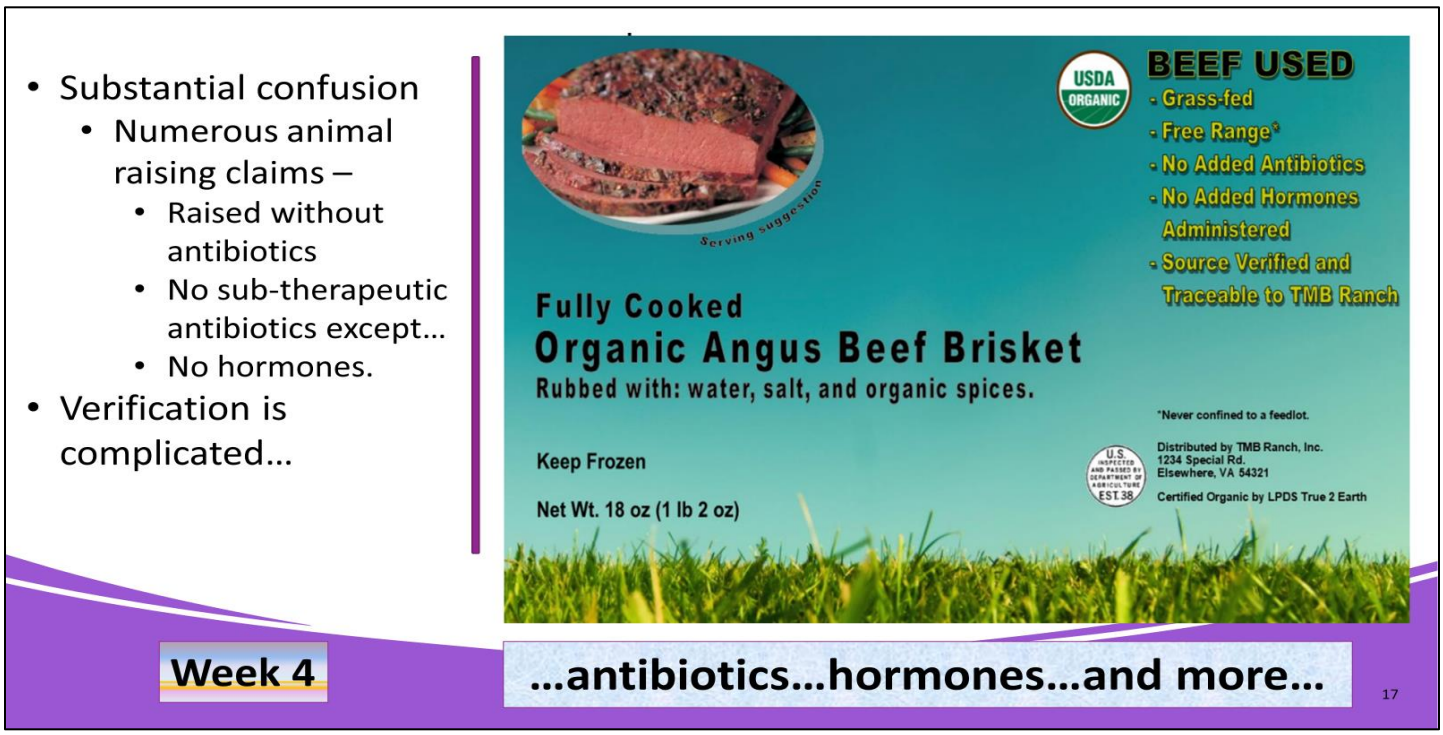
CFR:
21 CFR 101

Agency/Docket Number:
Docket No. FDA-2014-N-1207

Document Number:
2015-28779

DOCUMENT DETAILS

Slide #17D – implied claim…antibiotics…hormones…and more…



- Slide #17D – implied claim…antibiotic…hormones …and more...
- Week 4 Topic –
  - USDA FSIS is the Federal agency responsible for approval labeling claims related to antibiotic and hormone use in livestock, poultry, and egg products.
  - For negative antibiotics use claims in livestock (red meat) products –
    - "Raised without antibiotics" –
      - To use this claim, source animals cannot be administered antibiotics in their feed, water or by injections at any point in the production process.
      - This includes ionophores which are recognized as antibiotics by USDA.
        - Examples of this type of claim include, but are not limited to:
          - Raised Without Antibiotics,
          - No Antibiotics Administered,
          - No Added Antibiotics,
          - No Antibiotics Ever and
          - Raised Antibiotic Free.
    - No Sub-Therapeutic Antibiotics:
      - USDA FSIS will approve a claim that states that animals have not been administered subtherapeutic antibiotics if the claim is part of a complete claim that explain what the term "sub-therapeutic" means,
      - For example –
        - "No sub-therapeutic antibiotics. Animals do not receive antibiotics on a daily basis; animals only receive antibiotics in the case of illness."
      - Other examples of this claim that USDA is likely to find to be truthful and not misleading include:
        - "Beef Raised with No Sub-Therapeutic Antibiotics Ever, animals may be given antibiotics for the treatment of illness" or
        - "Beef Raised with No Sub-Therapeutic Antibiotics, animal do not receive antibiotics on a daily basis only in the case of illness."
  - Negative Hormones Use

- Under Federal law, hormones are only approved for use in beef cattle (e.g., to improve feed efficiency), swine (e.g., for gestation purposes), and lamb production (e.g., to improve feed efficiency).
- There are no hormones approved for use in the production of poultry, goat, veal calves, mature sheep, or exotic, non-amenable species (such as bison, buffalo, elk, and venison).
- Thus, additional terminology is necessary on these labels to convey that Federal law prohibits hormone use in these species.
- USDA FSIS will only approve a negative hormone claim on products made from a kind or species for which Federal law prohibits hormone use when it is accompanied by the qualifying statement:
    - "There are no hormones approved for use in (kind or species [poultry, goat, veal, mature sheep, or exotic, non-amenable]) by Federal Regulations."
    - The qualifying statement must be prominently and conspicuously displayed on the label, e.g., it appears adjacent to the claim or is in type at least one-third the height, in accordance with 9 CFR 317.2(b) for meat products or 9 CFR 381.116(b) for poultry products.
    - As for any labeling claim, USDA FSIS confirms compliance with these regulations during the label approval process.
- Hormone use in meat animals can be detected using quantifiable methodology for verification purposes.

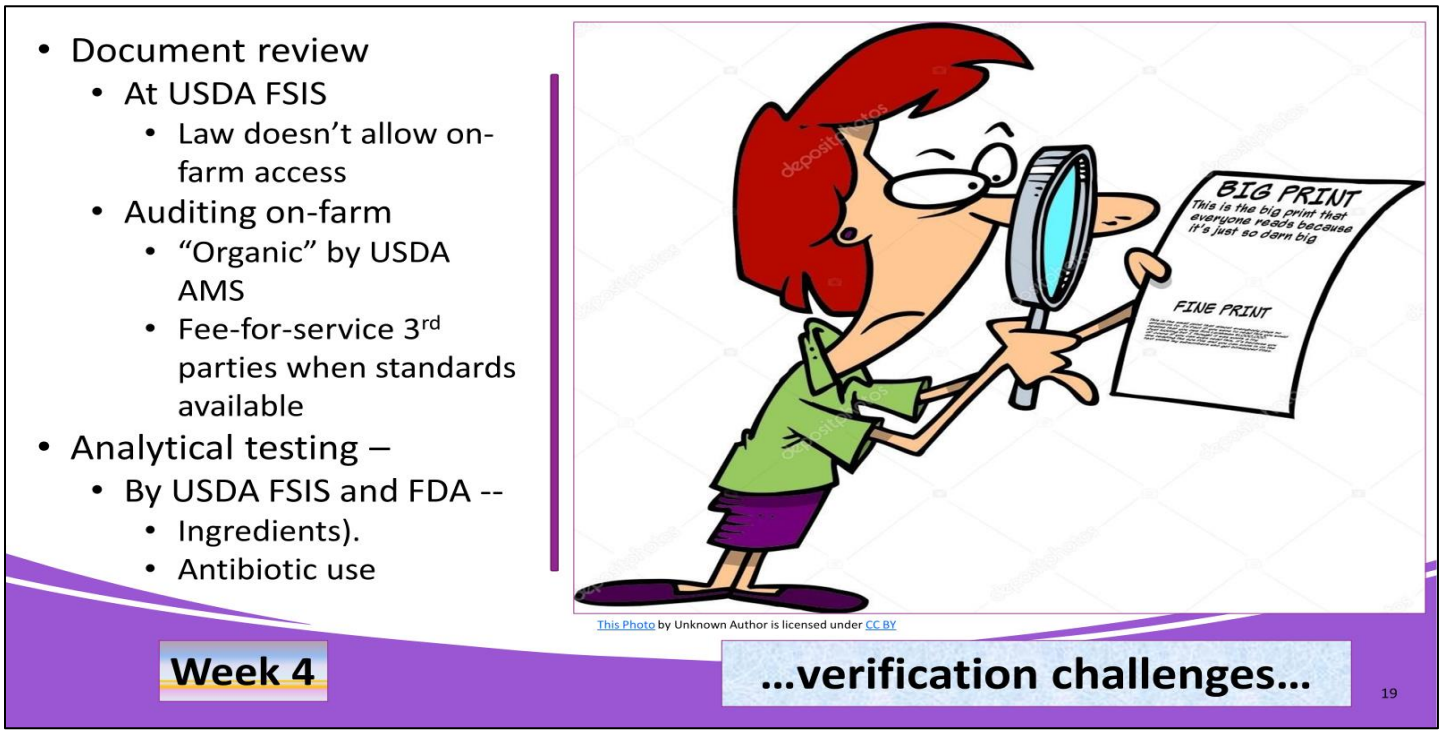
- Food and Drug Administration (FDA) –
    - FDA has approved the used of recombinant bovine growth hormone (rBGH) for use in diary cattle to increase milk production.
    - Although in wide use in the U.S., in the beginning stages of use, there were complications and concerns.
    - In 2010, the Sixth Circuit Court of Appeals, Federal court, struck down an Ohio ban on labeling dairy products as "rbGH free," or "rbST free," or "artificial hormone free" if produced from cows not treated with bovine growth hormone.
        - The Court ruled that an absolute ban on hormone-free claims violated dairy processors' First Amendment rights and was "more extensive than necessary to serve the State's interest in preventing consumer deception."
        - The Court also ruled that rbST-treated milk was compositionally different due to health data of treated cattle.
        - The FDA further clarified that when following the labeled use of the drug, no such compositional differences are detectable.
    - By 2023, manufacturers of dairy products from cattle can still label products as being from cows free of being treated with growth hormone but there is no requirement to label milk from cows treated with the hormone.
        - The World Health Organization was in agreement with the FDA regarding the safety of use of the hormone treatment and that the large protein would be broken down through regularly digestive processes without harm to humans.
        - Regardless, some stores voluntarily choose not to sell milk from cows treated with growth hormones.
        - When approving the use of rbST, FDA also approved the methodology capable of detecting extremely small amounts in milk as a means of verification of proper use.

- Slide #18D – implied claim…free range…pasture-raised…other...
- Week 4 Topic –
  - According to the USDA FSIS, both "free range" and "pasture-raised" require documentation to support that the poultry housing conditions demonstrate continuous, free access to the outside throughout their normal growing cycles.
    - The definitions do not require chickens spend any time on actual pasture other than the outside area is allowed to be a varied environment that might include dirt, shrubs, or trees.
  - A citizen petition was filed by Perdue Farms (LLC) followed by comments from CROPP Cooperative (Organic Valley and Organic Prairie – Farmer Owned) regarding concerns about free range from a poultry industry perspective.
    - Perdue Foods asked that the term "pasture-raised" no longer be considered synonymous with the term "free-range," based on consumer understanding.
      - Perdue commissioned a consumer survey in September 2021 –
      - The survey design was in accordance with the requirements for use in Federal Court litigation (i.e., Manual for Complex Litigation, Fourth, Federal Judicial Center, §11.493; Shari Diamond, Reference Guide on Survey Research, in Reference Manual on Scientific Evidence (Federal Judicial Center, 3d ed. 2011).
      - Survey results –
        - Consumers who purchase and have an opinion about the meaning of "pasture raised" chicken have the following perceptions –
        - 89.8 % of respondents said "pasture-raised" implies that chickens are guaranteed to spend at least some of their lives raised on pasture;
        - 69.4 % of those same respondents said they believe "pasture-raised" chickens are guaranteed to spend the majority of their lives raised on pasture; and
        - 55.9 % of those same respondents said that they understand "pasture" to mean that the ground is covered mostly with grass and other plants.
    - Earlier, in 2020, Perdue Farms conducted a marketing survey similar to the survey from 2021 --
      - 1801 consumers were asked similar questions.

        - 71 % of meat shoppers are at least somewhat confident that they know what the term “pasture raised” means when seen on a package label or in an advertisement for chicken;
        - 60 % of meat shoppers have a different definition for “pasture-raised” than the USDA labeling requirements, or don’t know;
        - 73 % of meat shoppers align around the term “pasture” meaning ground covered with rooted vegetation;
        - 56 % have a literal interpretation that “pasture-raised” means the chicken spend most of their lives on pasture; and
        - 13 % think the definition includes chickens that don’t necessarily spend time outdoors.
    - Thus, consumers would be better served by defining “pasture-raised” and “free-range” differently.
- Perdue identifies as the number one brand of fresh chicken in the U.S.
    - Marketing by Perdue focuses on how chickens are raised, stressing higher value and nutritional benefits of the pasture-raised product.
    - Note – there are no data included with the Perdue assertions about nutritional benefits of pasture-raised poultry.
        - Perdue has its own “PastureBird” standard called the “Perdue Foods, LLC Pasture Raised Process Verified Program” –
        - Product labeled pasture-raised is –
            - Sourced from chickens --
            - Having spent at least 51 % of their life on pasture --
                - The pasture is covered by at least 51 % rooted vegetation of any kind;
                - The pasture is the sole locational option other than temporary perches such as feeders, drinkers, and enrichments; and
                - The chickens are moved to fresh pasture every twenty-four hours.
- CROPP Cooperative then followed up with comments based, in part, on a review of the Perdue publicly filed comments stating --
    - There is an unacceptable level of variation among animal raising claims in food and woefully insufficient mechanisms of enforcement to ensure truth, making truth-in-labeling daunting.
    - Agreement that “pasture-raised” and “free range” do not mean the same thing.
    - Suggesting that terms such as “meadow-raised” and “pasture grown” also are used but less common; still, the terms are problematic especially when poultry is lumped with other livestock.
    - Not agreeing with Perdue’s definition of “pasture-raised” or with the definition of “pasture.”
    - CROPP cited the National Organic Program regulation that defines “pasture” as –
        - “Land used for livestock grazing that is managed to provide feed value and maintain or improve soil, water, and vegetative resources.”
    - CROPP further stated that the statement “majority of their lives physically” for chickens is in some instances unrealistic and cannot be applied to other categories of livestock (e.g., cattle that must be inside shelter in certain regions of the world and climate for health and safety).
    - CROPP asked that the USDA FSIS consider what constitutes the necessary time on pasture by each specie considering –
        - Daily biological sleep cycles,
        - Inclement weather conditions, and
        - Other health and welfare concerns.
    - CROPP offered that “daily grazing throughout the growing season” would suffice.
    - CROPP also suggested that the USDA FSIS should work with the USDA Agricultural Marketing Service to provide for on-farm auditing in cases where animal-raising claim have drawn suspicion and cannot be substantiated based solely on a paper trail.
- In response to a petition filed by the poultry industry, on June 2023, the USDA FSIS issued a press release stating –
    - “USDA Launches Effort to Strengthen Substantiation of Animal-Raising Claims.”

- This announcement was in response to evidence that there appeared to be substantial ambiguity amongst consumers and the industry in their understanding as to what “free range” and associated animal raising claims mean.

Slide #19D – implied claim…verification challenges…



- Slide #19D – implied claim…verification challenges...
- Week 4 Topic –
  - Although the USDA FSIS assigns a government inspector to every slaughter, processing, and egg facility every day, no on-farm verification of labeling claims is authorized by law.
  - For verification of labeling claims, USDA FSIS inspectors do verify that an approved label is on file at the slaughter and/or processing facility for every label applied to product prior to the product entering commerce.
  - Verification of on-farm activities to support a label claim shifts to a records review by staff in Washington, DC.
  - USDA FSIS does not exercise its authority of prior label approval to point of purchase materials (e.g., pamphlets and placards) displayed in conjunction with products sold at retail and bearing animal raising claims.
    - If there is a concern about the truthfulness of these materials, USDA FSIS would work with the Federal Trade Commission on pursuit of action to correct or remove such false advertisement.
    - USDA FSIS does require these materials be neither false or misleading.
  - From USDA FSIS guidance documents, the documentation needed to support claims includes –
    - A detailed written description explaining the controls used for ensuring that the raising claim is valid from birth to harvest, or the period of raising being referenced by the claim.
    - A signed and dated document describing how the animals are raised, which may include feed formulations (e.g., vegetarian fed, raised without antibiotics, grass fed).
    - A written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution.
    - A written description for the identification, control, and segregation of non-conforming animals/product.
    - If a third-party certifies a claim, a current copy of the certificate from the certifying organization.
      - NOTE: If the claim was certified by a third-party certifying organization, USDA FSIS will not approve the label bearing the claim if it does not include the certifying entities name and website address, along with any logo, and an asterisk or other symbol must connect the claim to this information.
      - For organic product, regulation oversight is by the Agricultural Marketing Service (AMS) at USDA, which does have authority for on-farm verification.
        - Thus, USDA FSIS will accept that organic products are appropriately verified for truthfulness.

- In general, if a manufacturer desires to make a secondary product out of an already labeled product bearing a pre-approved animal raising claim, the purchased label may be used to support the secondary claim.
- If a company purchases product bearing animal raising claims and would like to carry forward those claims onto its labeled product, the company needs to provide a copy of the purchased product label and segregation procedures when entering their federal establishment.
- Companies cannot carry forward certified claims, logos and/or websites from purchased products that are certified by a third-party entity unless the companies that are carrying the claim forward are also under that same certification.
- Companies cannot carry forward USDA AMS organic claims, logos and/or websites without being certified organic themselves.

- Types of animal raising claims and more specific documentation needed to substantiate the claims –
  - Animal Welfare and Environmental Stewardship –
    - These claims describe how animals are raised based on the care they receive by the producer or how the producer maintains the land and replenishes the environment.
    - USDA FSIS has not defined these claims in regulations or policy guidelines.
    - For animal welfare claims, such as "Raised with Care," or environmental stewardship claims, such as "Sustainably Raised,"
      - USDA FSIS will only approve a claim if a statement is provided on the label showing the name of the entity that established the standard and includes additional terminology explaining the meaning of the claim for consumers
      - If the entity has a website that describes the standards used to define the claim, the label may provide the website address instead of explaining what the claim means on the product label, e.g., "Raised with Care as defined by TMB Ranch at: [website address]."
      - As an alternative, animal welfare and environmental stewardship claims can be certified by a third-party certifying organization that posts the standards used to define the claim on its website.
        - If the claim is certified by a third-party certifying organization, USDA FSIS will not approve the label bearing the claim if it does not include the certifying entities name, website address, and logo, when the organization has a logo.
      - The claims may appear on any panel of the package.
      - The additional terminology that explains the meaning of the claim may appear with the claim or may be connected to the claim by an asterisk or another symbol and placed elsewhere on the same panel that bears the claim.
      - Examples of these types of claims include, but are not limited to:
        - Humanely Raised*,
        - Sustainably Farmed*, and
        - Raised with Environmental Stewardship*.
  - Breed --
    - These claims refer to the declaration of a specific breed of livestock or poultry.
    - Examples of this type of claim include --
      - Angus,
      - Wagyu (American Kobe),
      - Hereford,
      - Berkshire,
      - Duroc,
      - Muscovy,
      - Silkie, and
      - Heritage poultry, pork or beef breeds.

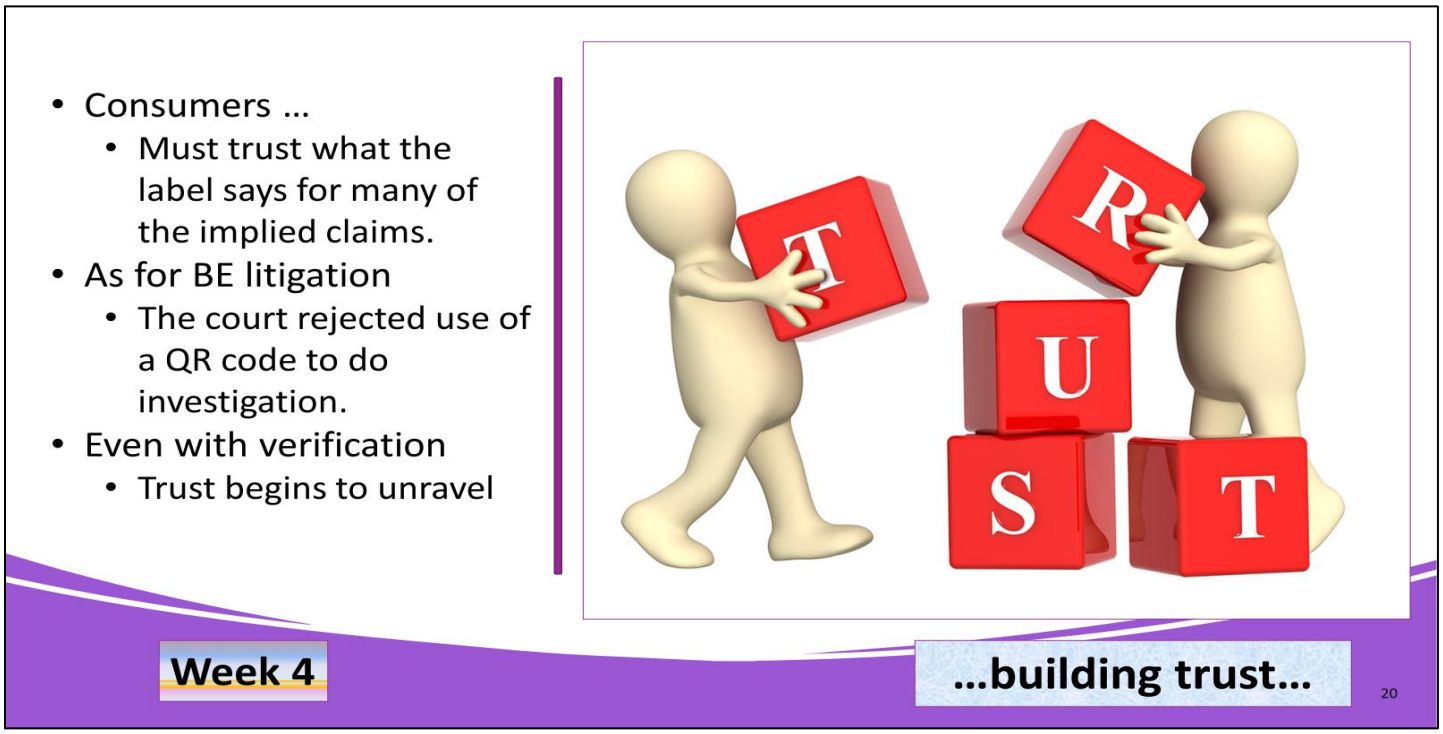
- Additional documentation needed includes a signed and dated document that substantiates the breed claim (e.g., under a USDA AMS Certified Meat and Poultry Program or a certificate from a breed organization).
- Documentation to support the breed by phenotype (e.g., hide color) or genotype (e.g., traceable to one registered parent).
- A written description for the identification, control, and segregation of non-conforming animals/product.

- Diet –
  - These claims refer to what animals are fed prior to harvest and processing.
  - These claims require that the animals only eat the diet claimed for the lifetime of the animal, except for milk consumed prior to weaning.
  - USDA FSIS considers Grassfed, Grass Fed and Grass-Fed synonymous terms.
  - "Grass Fed" or "100% Grass Fed" claims may only be applied to –
    - Meat and meat product labels derived from cattle that were only (100%) fed grass (forage) after being weaned from their mother's milk.
    - The diet must be derived solely from forage, and animals cannot be fed grain or grain by-products and must have continuous access to pasture during the growing season until slaughter (i.e., never confined to a feedlot).
    - Forage consists of grass, forbs, browse, or cereal grain crops in the vegetative state.
    - Hay, haylage, baleage, silage, crop residue without grain, and other roughage sources may also be fed.
    - Routine mineral and vitamin supplementation may be included in the feeding regimen.
    - If incidental supplementation occurs due to inadvertent exposure to non-forage feedstuffs or to ensure that the animal's wellbeing during adverse environmental conditions occurs, the producer must provide a signed and dated document to the establishment attesting the above incident is not a routine occurrence.
    - When animals have less than 100-percent access to grass or forage the partial "grass fed" claim must accurately reflect the circumstances of raising, e.g., "Made from cows fed 85% grass and 15% corn."
    - The claim "Grass Finished" is not the same as "Grass Fed" because animals that are "grass finished" can be fed grain, in which case the claim "Grain Fed, Grass Finished" would be truthful and not misleading.
    - Examples of this type of claim include, but are not limited to:
      - Grass (Forage) Fed,
      - Grain Fed,
      - Vegetarian Feed,
      - Raised Using Vegetarian Feeds [This means all vegetable feeds and no animal products (e.g., whey) are fed to the animal.],
      - Raised Using Vegetarian Feeds (with a disclaimer to clarify animal products are fed to the animal for a certain period of time, e.g., "except for dairy products fed from birth to eight weeks" or "after 8 weeks"), and
      - Fed No Animal By-Products.
    - A producer may use the USDA Process Verified Program (PVP) carried out by USDA AMS to verify their product meets the producer-s grass-fed standard.
      - The USDA PVP is a voluntary, user-fee verification service that offers a unique way to market their products.
      - USDA AMS auditors conduct a comprehensive review of a producer's program, which includes an on-site audit of all facilities and phases of the operation that impact process verified points.
      - Additional information about the USDA PVP service, shield, certificate, and official listing are available at www.ams.usda.gov/services/auditing/process-verified-programs.

- Living/Raising/Raising Conditions –
  - These claims refer to the environment in which the animals or birds were raised during their lifespan.
  - Examples of this type of claim include but are not limited to:
    - Cage or Crate Free,
    - Free Range,
    - Not Confined,
    - Free Roaming,
    - Pasture Fed,
    - Pasture Grown,
    - Meadow Raised, and
    - Pasture Raised.
  - For these claims, additional terminology is necessary on the label to define its meaning on livestock products and to convey that the animals were never confined to a feedlot.
  - Because USDA FSIS has not defined these claims in the regulations or policy guidelines, nearly all living/raising conditions claims need to describe the standards used to define that claim as applied to that particular product, e.g., "Cage free. Chickens were never confined to cages during raising."
- Negative Antibiotics Use – Livestock/Red Meat Raised Without Antibiotics --
  - To use this claim, source animals cannot be administered antibiotics in their feed, water or by injections at any point in the production process.
  - This includes ionophores which are recognized as antibiotics by USDA FSIS.
  - USDA FSIS is working with researchers at USDA Agricultural Research Service (ARS) to develop methodology to conduct analytical tests on meat and poultry at slaughter, processing, and retail to assess for the presence of markers for antibiotic use in live animals; such methodology is currently not reliable.
  - Examples of this type of claim include, but are not limited to:
    - Raised Without Antibiotics,
    - No Antibiotics Administered,
    - No Added Antibiotics,
    - No Antibiotics Ever, and
    - Raised Antibiotic Free.
- No Sub-Therapeutic Antibiotics –
  - USDA FSIS will approve a claim that states that animals have not been administered sub-therapeutic antibiotics if the claim is part of a complete claim that explain what the term "sub-therapeutic" means, e.g., "No sub-therapeutic antibiotics. Animals do not receive antibiotics on a daily basis; animals only receive antibiotics in the case of illness."
  - Other examples of this claim that USDA FSIS is likely to find to be truthful and not misleading include:
    - "Beef raised with no sub-therapeutic antibiotics ever, animals may be given antibiotics for the treatment of illness" or
    - "Beef raised with no sub-therapeutic antibiotics; animal do not receive antibiotics on a daily basis only in the case of illness."
  - Additional documentation needed specific to poultry since treatment may occur *in ovo,* the establishment needs to submit a company letter (signed and on company letterhead) answering the following questions:
    - Do you use antibiotics pre-hatch in any way with respect to the eggs that you hatch for the poultry that will bear the claim? If so, please describe how you use antibiotics?
    - Do you inject any vaccines *in ovo*? If so, please state whether any of the vaccines includes an antibiotic. If any of them does, please state what antibiotics are used, what the antibiotics are used for, and in what amount they are used.

        - Do you inject any antibiotics *in ovo*? If so, please state what antibiotics are used, what the antibiotics are used for, and in what amount they are used. What is the withdrawal time for the antibiotics?
        - Have you verified that the poultry that you use to produce your products was not derived from eggs or poultry that were injected or otherwise treated in any way with antibiotics? If so, how have you verified these conclusions?
    - Negative hormone/steroid use --
        - Under Federal law, hormones are only approved for use in beef cattle, swine (e.g., gestation), and lamb production.
        - There are no hormones approved for use in the production of poultry, goat, veal calves, mature sheep, or exotic, non-amenable species (such as bison, buffalo, elk, and venison); thus, additional terminology is necessary on these labels to convey that Federal law prohibits hormone use in these species.
        - USDA FSIS will only approve a negative hormone claim on products made from a kind or species for which Federal law prohibits hormone use when it is accompanied by the qualifying statement:
            - "There are no hormones approved for use in (kind or species [poultry, goat, veal, mature sheep, or exotic, non-amenable]) by Federal Regulations."
            - The qualifying statement must be prominently and conspicuously displayed on the label, e.g., it appears adjacent to the claim or is in type at least one-third the height, in accordance with 9 CFR 317.2(b) for meat products or 9 CFR 381.116(b) for poultry products.
- USDA FSIS evaluates certifiers' acceptance standards as necessary to assess suitability for animal raising claims on labels.
    - Examples of this type of claim include but are not limited to:
        - USDA Process Verified Production (PVP) administered by USDA AMS),
        - Animal Welfare Approved (AWA), or
        - GAP Step ratings (Global Animal Partnership (GAP)).
        - The USDA organic regulations are administered by USDA AMS National Organic Program(NOP) and described at 7 CFR Part 205.
            - For animal products to be labeled as organic, livestock producers must be certified organic and any operations that subsequently handle the organic product must be certified organic (e.g., slaughter plants, meat packing facilities).
            - Organic operations are inspected annually by USDA-accredited certifying agents.
            - The label bearing the claim needs to include the certifying entity's name, website address, and logo, when the organization has a logo.
- For the FDA, generally there is no pre-market review or approval of most label claims other than those regulated (e.g., "healthy," "low fat," low sodium") for which there are regulatory criteria for manufactures to comply.
    - As can USDA FSIS, FDA also can analyze certain nutrients in food products in commerce for compliance against the label claim.

Slide #20D – implied claim…building trust…



- Slide #20D – implied claims …building trust...
- Week 4 Topic –
  - Regulations implementing the new National Bioengineered Food Disclosure Law (NBFDL) were issued in 2018 and became effective by January 1, 2022.
  - The disclosure location for the bioengineered (BE) ingredient/food had to be either on the information panel directly adjacent to the statement identifying the name and location of the distributor, or on the principal display panel.
  - The original law required disclosure but not necessarily traditional labeling.
    - A QR code or other text means could be applied to packaging such that the consumer would then need to actively investigate on their own whether the product contained BE ingredient, or the entire food was a product of BE.
  - A Federal court ruled in September 2022 that putting a QR code on a label was not an adequate means to inform consumers that the food contained or had been manufactured via BE.
    - The lawsuit was brought by the Center for Food Safety and other advocacy groups
    - Only this part of the regulation was ordered to be changed.
    - According to Andrew Kimbrell, Executive Director of the Center for Food Safety, “these[bioengineered food] regulations are not about informing the public but rather designed to allow corporations to hide their use of genetically engineered ingredients from their customers.
  - Despite criticism, groups such as the American Soybean Association and the National Corn Growers Association praised the new standard when it was announced, saying it would create more transparency in the food industry.

Slide #21D – food recalls…

- Slide #21D – …food recalls...
- Week 4 Topic –
  - Food recalls are a source of concerns with truthful labeling –
  - Recalls and alerts are warnings that specific food shouldn't be consumed.
  - Recalls are issued when specifically produced product is believed to still be available at wholesale and retail markets, as well as in people's freezers, pantries, or refrigerators.
    - From "Food for Thought – Part 2:: An analysis of food recalls for 2022; PIRG 2023 (US Public Interest Research Group)," –
    - In 2022 in the U.S. –
      - Causes included –
        - Undeclared allergens at 42 %.
          - How does this happen?
          - There are numerous contributing causes, including a change in suppliers for a cheaper ingredient but the ingredient list wasn't sufficiently checked .
          - Most allergen-related recalls have severe public health consequences.
          - Most allergen-related recalls are triggered by the consumer (purchaser) finding the problem.
        - Pathogens (15 % for *Listeria monocytogenes* and 13 % for *Salmonella*).
        - Foreign material (e.g., metal and plastic) at 9 %.
        - Lead at 3 % -- unreported in the prior couple of years.
        - Hepatitis A and Viagra at one incident each; neither reported in recent years.
        - Numerous products were affected, including infant formula.
      - The number of public health threats from *Salmonella* nearly doubled in 2002 compared to 2019, causing more than 1 million infections, 26,500 hospitalizations, and 420 deaths a year from all food sources.
      - One in six Americans become ill every year from contaminated food or beverages, amounting to 50 million illnesses, 128,000 hospitalizations, and 3,000 deaths.
  - In 2022, there were a total 289 recalls; up slightly from 2021 with 286 recalls.
    - FDA reported 221 food and beverage recalls,

    - USDA FSIS reported 68 recalls, for a total of 289.
- For a perspective on the amount of product affected, in Calendar Year 2021 –
    - Total number of recalls was forty-seven and number of pounds affected was just over 15.5 million pounds
        - For Class I recalls there were 38 at nearly 14.5 million pounds; Class I means that the affected food will cause illness/death if consumed.
        - For Class II recalls there were 9 recalls at nearly just over 1 million pounds; Class II means that the affected food may cause illness/death if consumed.
        - For Class III recalls there none; Class III means that the affected food is not likely to cause illness or death if consumed.
    - Aside from the pathogen recalls, there were eleven recalls due to allergens and one recall due to an unapproved substance
- Since 2020,
    - At the FDA, the number has remained relatively consistent in four of the last five years.
    - At USDA FSIS, for the past three years, the number of recalls were only half of the average reported for 2017 through 2019.
- Food gets implicated in recalls when the following happens --
    - People get sick and seek medical attention, and then the local public health officials and the Centers for Disease Control and Prevention (CDC) trace an outbreak to a particular food item;
    - Pathogens and allergens are the typical agents causing the illness;
    - Consumers file a complaint with regulators or companies;
    - Food spoilage and foreign materials are typically identified by consumers, but illness is not typically a result;
    - A regulator (e.g., FDA, USDA FSIS, or State and local public health officials,) uncover a problem; or
    - The manufacturer self-reports a problem after testing or other investigation.
- Allergens can be deadly when consumed.
    - About 6 % of the U.S. population suffers from some sort of food allergy (Asthma and Allergy Foundation of America).
    - Sadly, their unidentified presence in food is virtually 100 % avoidable.
    - Careless manufacturers fail to manage this issue for a variety of reasons –
        - Changing ingredient suppliers and not paying attention to the ingredient list;
        - Cross contact or
        - Failing to change the labeling for different product lines.
    - Of the allergen recalls –
        - Peanuts and tree nuts were the most common followed in descending order by –
        - Milk,
        - Egg products,
        - Gluten,
        - Soy,
        - Fish,
        - Anchovies,
        - Sulfites (as a preservative), and
        - Coconuts.
    - A food allergy is different than a food intolerance.
        - An intolerance can cause digestive issues or headache.
        - An allergy causes the body's immune system to react to a food (usually the protein component) and cause serious symptoms (e.g., shortness of breath, rash or hives, chest pain, a swollen airway or difficulty in swallowing).
- The original eight foods identified as major food allergens were:
    - Milk,
    - Eggs,

    - Fish (such as bass, flounder, or cod),
    - Crustacean shellfish (such as crab, lobster, or shrimp),
    - Tree nuts (such as almonds, walnuts, and pecans),
    - Peanuts,
    - Wheat, and
    - Soybeans.
- As of January 2023, there are now nine foods identified as major food allergens –
    - Sesame was added.
- All allergens are required to be labeled as an allergen on packaged foods, including dietary substances.
- The Center for Disease Control and Prevention says many illnesses occur long after recalls have been announced — sometimes weeks or months later.
- For a perspective on how difficult it is to get manufacturers to take recalls seriously –
    - Whole Foods Market Warning Letter –
        - Full name is "The Food and Drug Administration (FDA) In Brief: FDA Issues Warning Letter to Whole Foods Market After Repeated Recalls of Foods Packaged with Incorrect Allergen Labeling; Food and Drug Administration, December 2020
        - Quote from William A. Correll, Jr., Director, Office of Compliance, Center for Food Safety and Applied Nutrition —
            - *"Last week, the FDA warned Whole Foods Market for engaging in a pattern of offering misbranded food for sale — either by receiving finished Whole Foods store brand products from third-party suppliers with misbranded labels or by using misbranded labels when repackaging food — in bakery and deli sections of their stores. The warning letter follows a series of recalls in the past year of more than 30 food products sold under the Whole Foods brand because the food did not declare at least one ingredient that is a major food allergen.*
                - *The FDA is committed to protecting the health of the American people. It's important that food packaging, at all points of the supply chain, appropriately lists the presence of all major food allergens so that individuals with food sensitivities can take appropriate steps to avoid products that may cause them serious and life-threatening harm.*
                - *Undeclared food allergens are the number one leading cause of Class I food recalls for at least the last three years. Consumers deserve to know exactly what they are buying to eat and to trust that the product labels clearly list all major food allergens.*
                - *The entire food supply chain can and must do better to prevent exposing consumers to incorrectly labeled packaged food. To address the problem, the FDA is working to improve industry's compliance with allergen labeling requirements and reduce food recalls due to undeclared allergens.*
                - *Manufacturers should also ensure that they have controls in place to prevent unintentionally adding allergens during their manufacturing processes. Whey they fail to follow the law, we will take the necessary action."*
        - FDA clarified that in some cases, Whole Foods Market would receive finished products for repackaging and label them using misbranded scale labels.
        - This is the first time the FDA warned a retail establishment for engaging in a pattern of offering for sale misbranded store brand labeled food products containing undeclared allergens. Whole Foods was told to respond within fifteen business days of receiving the warning letter to inform of the specific actions the company will take to address this violation.
- From "USA: FDA and USDA Food Recall Incidents; Food Allergy Research and Resource Program (FARP), Institute of Agriculture and Natural Resources, , October 2023" --
    - Reporting on recalls that include food and beverages recalled due to undeclared allergenic foods. For this report, recalls due to colors, sulfites, bacterial contamination, and physical and/or chemical contamination are not included in the report.
    - FARM tabulates FDA recalls to be able to see a general trend in incidents over the year and compare it to other years.

    - FDA also issues firm press releases that list the most significant product action in the last 60 days, based on the extent of distribution and the degree of health risk.
    - In November 2015, the USDA FSIS issues a 26-page set of guidelines to assist meat, poultry, and processed egg product producers in properly managing ingredients in an effort to reduce adverse reactions to food allergens. The guidelines included information on preventive controls measures for allergens, as follows: Ingredients, packaging, labeling, storage, checklists, and allergen training.
- From "Have a food allergy? This industry practice could increase your risk; SSorscher and PLurie, Center for Science in the Public Interest, January 2023" --
    - Americans are sent to the emergency room more than 200,000 times per year for allergic reactions to food.
    - In January 2023, new regulations went into effect implementing the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act. It was this Act and the implementing regulations that added sesame as a major food allergen, increasing the list of major allergens from eight to nine.
    - Shockingly, it was reported that at least five companies publicly admitted to adding sesame in the wake of the new regulation going into effect, as follows: Chick-fil-A, Dave's Killer Bread, Culver's, Olive Garden, and Pan-O-Gold.
    - Consumers may not note the allergen declaration especially if it's a new change to a product the consumer has repeatedly eaten over a span of time.
    - The new Food Safety Modernization Act and associated implementing regulations require companies to institute preventive controls for food safety hazards, included allergens.
    - Alcohol is a new focus for assessing whether labeling should be strengthened for these items not covered by the Food Safety and Modernization Act.
- From "Getting Ready for FSMA's Allergen Guidelines; Food Safety Magazine, 2016" –
    - Expenses associated with a food recall could bankrupt a small business. Costs include notifying consumers, removing food from the supermarket shelves, and paying damage that could potentially result from lawsuits.
    - About 20 % of reactions lead to anaphylaxis — a systemic reaction that can cause breathing passages to swell shut and blood pressure to plummet, resulting in shock and possibly death.
    - A high-profile case is that of Natalie Giorgi, a 13-year-old girl who, in 2013, took a bite of a Rice Krispies square that contained a trace amount of undisclosed peanut butter. Although Natalie knew she was allergic to peanut butter, she was very careful about what she tasted. Since the Rice Krispies square did not indicate the presence of peanut butter, she died. The kitchen staff did not tell the family about the possibility of the peanut butter. Although Natalie's father was a physician, he could not save her. The incident occurred at a family camp run by the city of Sacramento, CA. The family reached a settlement of $15 million with the city.
    - In Great Britain, the owner of an Indian restaurant was sentenced to six years in prison after a customer died from anaphylactic shock. The customer ate curry lace with peanut and was not noted to the customer. The restaurateur had switched almond powder for a cheaper ground-nut mix that contained peanuts.
    - Food can become accidentally contaminated (i.e., cross contamination). That is why preventive controls such as required in Hazard Analysis and Critical Control Points (HACCP) systems and Food Safety Preventive Controls are essential.
- For current recalls –
    - FDA -- https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts
    - USDA FSIS -- https://www.fsis.usda.gov/recalls