

**2019 Eastern Milk Seminar
October 28-30, 2019
Madison, WI**

Status of Labeling for Non-Dairy “Milk”

**Clay Detlefsen, Esq.
National Milk Producers Federation**

Outline

- Nutrition Perceptions*
- Nutrition Reality
- Global Labeling
- NMPF Citizen Petition
- Next Steps

* <https://www.usdairy.com/trends-and-initiatives/community-focus#{67494D6B-7720-437D-998B-0B5F59B38D89}>

Base: Total general population age 18+ (n=2010); exclusive dairy milk buyers (n=914); dual dairy milk + plant-based milk alternative buyers (n=789); exclusive plant-based milk buyers (n=110).

Public Health Consequences

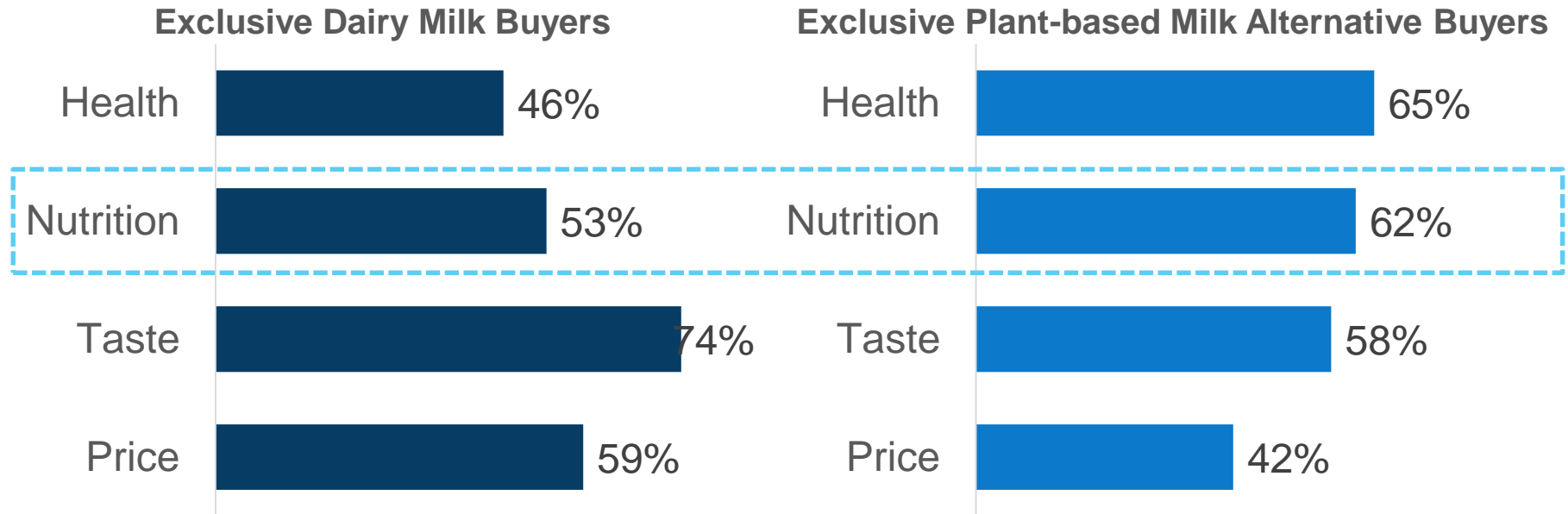
“...case reports show that feeding rice-based beverages to young children resulted in a disease called kwashiorkor, a form of severe protein malnutrition. There has also been a case report of a toddler being diagnosed with rickets, a disease caused by vitamin D deficiency, after parents used a soy-based alternative to cow’s milk. Because these dairy alternative products are often popularly referred to as “milk,” we intend to look at whether parents may erroneously assume that plant-based beverages’ nutritional contents are similar to those of cow’s milk, despite the fact that some of these products contain only a fraction of the protein or other nutrients found in cow’s milk.”

FDA Commissioner Scott Gottlieb, M.D. July 26, 2018

Nutrition is a Purchase Driver for Both Dairy Milk and Plant-based Milk Alternatives and has Higher Importance to Plant-based Milk Alternative Buyers

Top Purchase Decision Factors

Q. Which of the following are important in your decision to purchase dairy milk and/or plant-based milk alternatives?



The #1 Reason Consumers Believe Non-dairy Products are Labeled “Milk” is Because Products are Comparable to Dairy Milk on Nutrition

Beliefs are Stronger Among Plant-based Milk Alternative Buyers

Why Would a Manufacturer Label a Product Milk if it Does not Contain Milk?

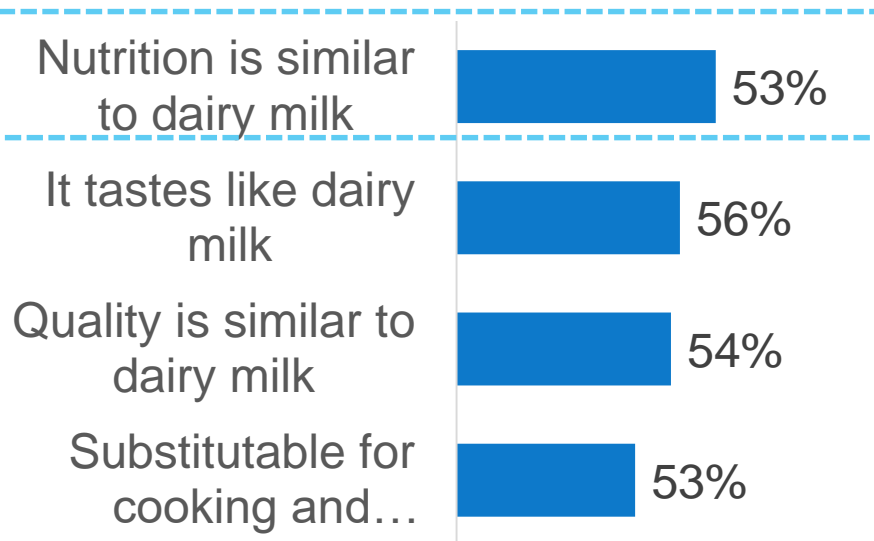
Q. Below are some reasons why a manufacturer would label a product “milk” even though the product may not contain dairy milk.

Please select the reasons why you believe a manufacturer would label a product “milk”

All Buyers



PB Alternative Buyers



Two-thirds of Plant-based Milk Alternative Buyers Believe Plant-based Milk Alternatives Contain the Same Nutritional Content as Dairy Milk

Only 17% of Plant-based Milk Alternative Buyers Disagree

Nutritional Content is the Same as Dairy Milk

Q. How much do you agree or disagree that plant-based milk alternatives have the same nutritional content as dairy milk products?

	Dairy Milk Buyers	Plant-based Milk Alternative Buyers
Strongly/Somewhat Agree (net)	24%	68%
Strongly Agree	4%	32%
Somewhat Agree	20%	37%
Neither Agree or Disagree	42%	17%
Strongly/Somewhat Disagree (net)	34%	15%
Somewhat Disagree	19%	5%
Strongly Disagree	15%	10%

Eight in 10 Consumers View Almond Milk Alternative as Having the Same or More Protein and Vitamins Compared to Dairy Milk

Plant-based Milk Alternative Buyers are More Likely to View the Nutritional Content of Almond More Positively

Nutrition Perceptions of Almond Milk Alternatives

Q. Thinking about Almond Milk Alternatives, would you say that almond milk alternatives contain... (Select one)

	All Buyers				Plant-based Milk Alternative Buyers			
	The Same or More than Dairy Milk	More than Dairy Milk	Same as Dairy Milk	Less than Dairy Milk	The Same or More than Dairy Milk	More than Dairy Milk	Same as Dairy Milk	Less than Dairy Milk
Protein	77%	30%	48%	23%	79%	44%	35%	21%
Vitamins	78%	22%	56%	22%	86%	38%	48%	13%
Key Nutrients (e.g., Calcium, Potassium)	68%	17%	52%	32%	74%	74%	41%	26%

More than 70% Consumers View Soy Milk Alternative as Having the Same or More Protein and Vitamins Compared to Dairy Milk

Nutrition Perceptions of Soy Milk Alternatives

Q. Thinking about Soy Milk Alternatives, would you say that soy milk alternatives contain... (Select one)

	All Buyers				Plant-based Milk Alternative Buyers			
	The Same or More than Dairy Milk	More than Dairy Milk	Same as Dairy Milk	Less than Dairy Milk	The Same or More than Dairy Milk	More than Dairy Milk	Same as Dairy Milk	Less than Dairy Milk
Protein	75%	24%	50%	25%	77%	44%	33%	23%
Vitamins	73%	16%	57%	27%	82%	29%	53%	18%
Key Nutrients (e.g., Calcium, Potassium)	66%	14%	52%	34%	76%	28%	48%	29%

More than 60% Consumers View Coconut Milk Alternative as Having the Same or More Protein & Vitamins Compared to Dairy Milk

Nutrition Perceptions of Coconut Milk Alternatives

Q. Thinking about Coconut Milk Alternatives, would you say that coconut milk alternatives contain... (Select one)

	All Buyers				Plant-based Milk Alternative Buyers			
	The Same or More than Dairy Milk	More than Dairy Milk	Same as Dairy Milk	Less than Dairy Milk	The Same or More than Dairy Milk	More than Dairy Milk	Same as Dairy Milk	Less than Dairy Milk
Protein	62%	16%	46%	38%	66%	27%	40%	33%
Vitamins	71%	16%	55%	29%	80%	35%	46%	20%
Key Nutrients (e.g., Calcium, Potassium)	66%	15%	51%	34%	82%	29%	52%	19%

Over 40% of Plant-based Milk Alternative Buyers Believe that Plant-based Milk Alternatives Contain the Same or More Essential Nutrients and Vitamins as Dairy Milk

Plant-based Milk Alternatives Essential Nutrient and Vitamin Content

Q. Dairy milk contains 9 essential nutrients and vitamins. Would you say that plant-based milk alternatives contain...?

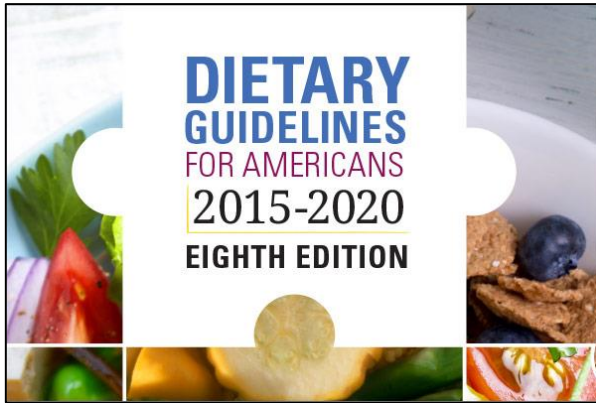
	Dairy Milk Buyers	Plant-based Milk Alternative Buyers
Same/more essential nutrients than dairy milk	17%	44%
More	5%	22%
Same	12%	22%
About 6 essential nutrients	4%	7%
About 3 essential nutrients	4%	5%
It depends on the source of plant-based milk	26%	20%
It depends on the brand of plant-based milk	6%	3%

Nutritional Comparison & Variability

Product	Milk (1%)	Almond	Cashew	Coconut	Rice	Soy
# of Ingredients	3	3-15	3-15	9-15	8-12	2-18
Calories	102	25-270	40-360	45-80	120-130	70-140
Total Fat (g)	2.4	2-14	3-25	4-5	2.5	0-6
Total Carbs (g)	12	1-32	2-24	1-10	23-26	3-17
Protein (g)	8	1-8	1-11	0-1	1	6-12
Sodium (mg)	107	100-260	105-470	0-180	65-105	5-160
Potassium (mg)	366	0-190	20	40-72	20-70	30-460
Vitamin A (%)	5	0-10	0-10	10	10	0-15
Calcium (%)	28	2-50	2-30	4-45	30-45	0-45
Vitamin D (%)	24	0-25	25-30	0-30	25	25-30
Riboflavin (%)	26	2-30	ns	ns	0	6-30
Phosphorus (%)	22	2-4	ns	ns	6-15	8-25
Magnesium (%)	6	4	10	8-10	8	6-15
Vitamin B12 (%)	18	0-25	50	25-50	0-25	20-50
Niacin (eq) (%)	10	ns	ns	ns	ns	4

“Non-dairy milk beverages vary in their nutritional profiles. These should not be considered a nutritional substitute for cow’s milk until nutrient quality and bioavailability is established.”

“A Comparison of the Nutritional Value of Cow’s Milk and Non-dairy Beverages” Journal of Pediatric Gastroenterology and Nutrition, Singhal, S.; Baker, R.; Baker, S. - August 2016



“Other products sold as ‘milks’ but made from plants (e.g., almond, rice, coconut, and hemp ‘milks’) may contain calcium and be consumed as a source of calcium, but they are not included as part of the dairy group because their overall nutritional content is not similar to dairy milk and fortified soy beverages (soymilk)...”

2015-2020 Dietary Guidelines for Americans



“Never before have we seen an increase like this in alternative milks,” said Kim Larson, a spokeswoman for the Academy of Nutrition and Dietetics.

‘The nutritional profile of these will vary, especially in the protein area, but also in terms of vitamins in (sic) minerals. Often consumers mistakenly believe (plant-based milks) are healthier,’ Larson said, ***‘which is not true. This ‘health halo’ has blurred the lines so much that other plant based milks jumped on the wave and are enjoying the ride.’*** (USA Today)

“On one hand I can agree with the gripe of the dairy industry that these alternative milks that don’t have nutrition are harvesting unfairly the health halo of milk,’ Lowry said. ***Although many almond milk producers have varieties containing extra protein,*** Lowry said ***he doesn’t believe many almond milk drinkers are aware of the lack of protein.”***

Ripple co-founder, Adam Lowry (Bevnet.com)



American Academy of Pediatrics



DEDICATED TO THE HEALTH OF ALL CHILDREN®

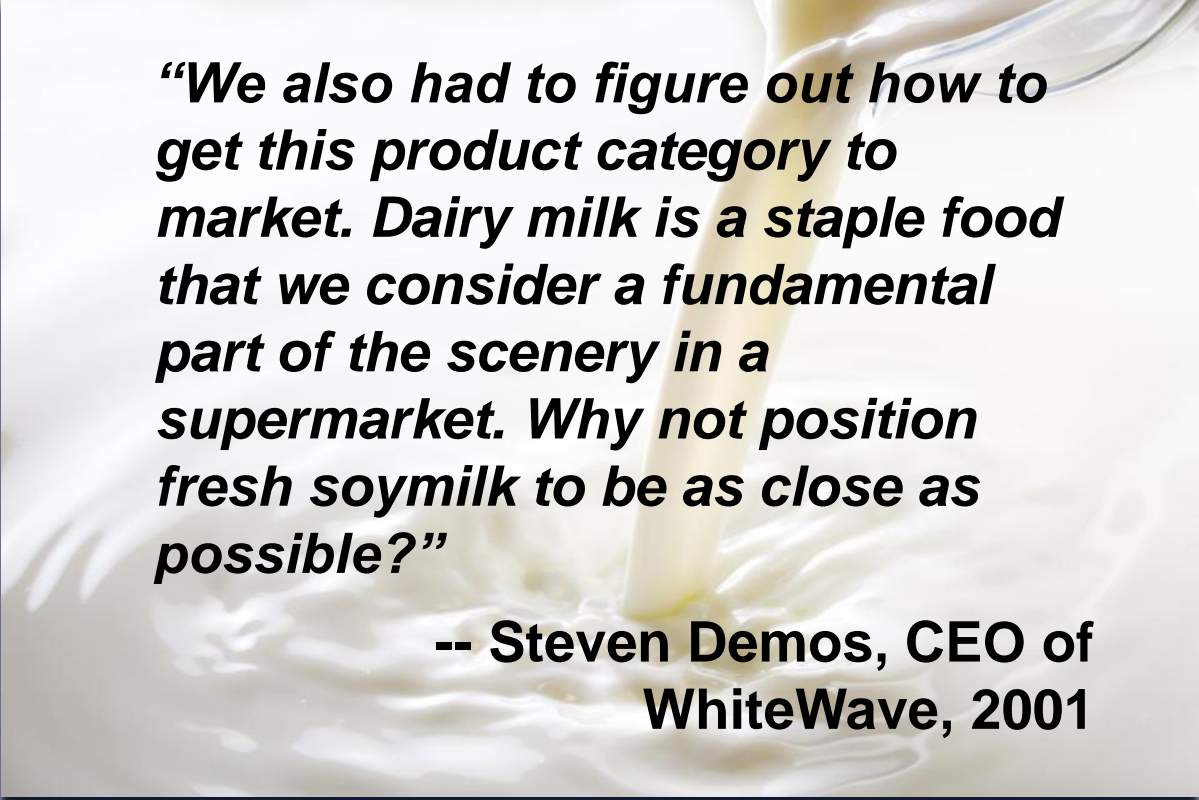
“Given the importance of dairy products in the diet of children and the confusion that parents exhibit with regards to the nutrients contained in plant-based alternative products, the AAP recommends that FDA reserve the label of “milk” solely for traditional dairy products to ensure that children receive the optimal nutrition they need to thrive.”

-Submitted to Docket No. FDA-2018-N-3522 Use of the Names of Dairy Foods in the Labeling of Plant-Based Products, January 23, 2019



- As Commissioner Gottlieb indicated-professional medical associations are seeing an increase of malnutrition cases.
- NASPGHAN cited numerous published clinical cases of nutritional problems associated with dairy alternatives consumed by infants and toddlers including:
 - Soy (3): Rickets and Failure to Thrive
 - Rice (17): Kwashiorkor and Failure to Thrive
 - Almond (10): Rickets, Metabolic Alkalosis, Failure to Thrive & Others

Why call it Milk???



“We also had to figure out how to get this product category to market. Dairy milk is a staple food that we consider a fundamental part of the scenery in a supermarket. Why not position fresh soymilk to be as close as possible?”

**-- Steven Demos, CEO of
WhiteWave, 2001**

If we can't call it
milk, what could
we possibly call
it???





Canadians and Britons are not confused!

Regulations in Canada and the United Kingdom don't allow the use of "milk" as a name for Almond Breeze, the same brand sold in the United States as "almondmilk."

**Same product.
Two different labels.**



**Oat-ly “Oat Drink”
has been sold since
1990, no consumer
confusion in Sweden
and elsewhere!**

Margarine Sales are Weak, Let's Call it Butter

- Margarine sales are down, butter is up!
- These are likely “margarine” products or spreads
- Calling margarine or spreads “butter” is false and misleading
- False and misleading = Misbranded



Margarine Sales are Weak, Let's Call it Butter

- Now Even Country Crock Has Renamed Itself



Products That Do Not Violate the Rules



These products do not act as a substitute or resemble a standardized dairy food

Enforcement Discretion Has Limits: AAP v. FDA

Case # PWG 18-883

- “... if the agency’s decision [**enforcement discretion**] is tantamount to amending or revoking a rule, then it amounts to substantive rulemaking subject to the APA’s constraints and generally reviewable by the courts.”
- “Thus when the FDA takes action to the contrary of the FDCA, through the ultra vires action, the FDA exceeds the authority granted by Congress and its action cannot stand.”

The Butter Act - March 4, 1923

- *“That for the purposes of the Food and Drug Act of June 30, 1906 (Thirty-Fourth Statutes at Large, page 768), “butter” shall be understood to mean the food product usually known as butter, and which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for.”*

Is non-enforcement of the butter standard “tantamount to amending or revoking a rule”?



FDA Does Enforce Standards of Identity Against Milk Companies:

South Mountain Creamery v. FDA

Case # 1:18-cv-00738

- **FDA told SMC that it:**
 - “does not object to the distribution of non-fat, or skim, milk without added vitamins A or D based on the absence of those vitamins if the product is prominently labeled to notify consumers that the product does not contain vitamins A and D in one of the following ways: (a) ‘Non-fortified skim milk, 0% DV vitamins A&D’; (b) ‘Non-fortified non-fat milk, 0% DV vitamins A&D’; (c) ‘Skim milk, 0% DV vitamins A&D’; or (d) ‘Non-fat milk, 0% DV vitamins A&D.’”
- **We agree with the options provided and the enforcement of the standards of identity**



FDA Does Enforce Standards of Identity Against Foreign Companies

GLORIA S.A.

Import Alert Date Published : 07/09/2019

- Desc: Evaporated Milk
- Notes: The article appears to be misbranded within the meaning of the following section of the FD&C Act: 403(g) in that the article appears to be represented as a food for which a definition and standard of identity have been prescribed by regulations as provided by section 401 and the food does not appear to conform to such definition and standard in accordance with 21 CFR 131.130 which defines "Evaporated Milk" as "the liquid food obtained by partial removal of water only from milk" 09 C - - 09 Milk, Plain
- Districts may detain without physical examination the food products from the firms identified on the Red List for this alert
- We agree with this decision to enforce the standards of identity



NMPF Citizen Petition

- Filed February 21, 2019
- Calls for FDA to 1) take enforcement action against misbranded non-dairy foods that substitute for and resemble reference standardized dairy food(s) but are nutritionally inferior to the reference food and include the name of the reference food in the statement of identity; and (2) amend 21 CFR section 101.3(e), Food Labeling – General Provisions, of FDA regulations to codify policies that permit use of standardized dairy terms for non-dairy substitutes that resemble and substitute for the same reference dairy food only under limited and defined conditions.
- The petition applies only to “non-dairy foods that substitute for and resemble standardized dairy foods” and contains an extensive 1st Amendment analysis.

NMPF Citizen Petition

- For *nutritionally inferior non-dairy substitute foods*, the statement of identity could identify a referenced standardized dairy food, provided that either: (1) the name of the food were qualified through use of the legally defined term, “imitation”; *or* (2) the name of the food were qualified through use of the term “substitute” or “alternative” *and* material differences including nutritional inferiority and performance limitations were disclosed.
- For *nutritionally equivalent non-dairy substitute foods*, the statement of identity could identify a reference standardized dairy food, provided that the name of the food were qualified through use of the term “substitute” or “alternative” and material differences, including performance limitations, were disclosed.

NMPF Citizen Petition

- Nutritionally inferior substitute non-dairy foods would not be required to bear “imitation” labeling if either:
 - (1) the foods were not represented as forms of “milk” or other standardized dairy foods (e.g., “oat beverage,” “almond drink”): or
 - (2) If represented as a form of milk or other standardized dairy food, the product name is qualified through the use of “substitute” or “alternative” and labeling adequately discloses other material facts concerning the differences between the reference standardized food and the substitute food.

NMPF Citizen Petition

- Options for Labeling of Nutritionally Inferior Foods
 - “Almond Beverage”
 - “Almond Milk - Imitation Milk”
 - “Almond Milk – Milk Substitute – Nutritionally Inferior [and any other material distinctions]”



NMPF Citizen Petition

- Options for Labeling of Not-Nutritionally Inferior* Foods
 - “Almond Beverage”
 - “Almond Milk - Milk Substitute [and any other material distinctions]”
 - “Almond Milk - Milk Alternative[and any other material distinctions]”



*Hypothetical Example – Product will need to meet parameters for all essential nutrients in the standardized food, including protein quality and disclose performance limitations

First Amendment Justification

- Key Cases Supporting Proposed Actions Requested
 - *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980)
 - 4-part test that must be satisfied for the government to justify a restriction on commercial speech
 - *Zauderer v. Office of Disc. Counsel*, 471 U.S. 626 (1985)
 - Applied First Amendment to compelled commercial speech (Regulator argued that advertisement was misleading in the absence of the required disclosure requirement)
 - *American Meat Institute v. USDA* (D.C. Cir. *en banc*) – upheld USDA regulations mandating highly detailed country-of-origin labeling requirements based on *Zauderer*. Concurring opinion by Judge Kavanaugh explains that *Zauderer* aligns with *Central Hudson* (not a relaxed test).

Nutrition Facts	
4 servings per container	
Serving size 1 1/2 cup (208g)	
Amount per serving	
Calories	240
% Daily Value*	
Total Fat 4g	5%
Saturated Fat 1.5g	8%
Trans Fat 0g	
Cholesterol 5mg	2%
Sodium 430mg	19%
Total Carbohydrate 46g	17%
Dietary Fiber 7g	25%
Total Sugars 4g	
Includes 2g Added Sugars	4%
Protein 11g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 6mg	35%
Potassium 240mg	6%

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

There are baby steps being made...



- While this still doesn't follow the rules set by FDA, it is a step in the right direction

Next Steps

- Anticipate that FDA will take action in mid-to-late 2020
 - Guidance or regulation???
- Anticipate FDA will focus on nutrition
- Anticipate that the plant based food makers will continue to scoff at FDA and do whatever they feel like
- Suggest FDA enforce the Butter Act – it cannot re-write what Congress has penned
- Sit back and enjoy watching folks engage in a discussion about the misleading nutritional inferiority of these products and bogus fictitious 1st Amendment assertions