Traditional Meat and Dairy Food and Innovative Substitutes: Key Regulatory and Enforcement Issues

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LATHAM & WATKINS LLP

Labeling of Meat and Dairy Substitutes: Current Legal and Regulatory Framework

Eitan Bernstein Latham & Watkins LLP

March 21, 2019

Regulatory Authorities

FDA

- Oversees most of the U.S. food supply
- Oversight includes dairy products

USDA

- Oversees meat, poultry and egg products
- Complex division between FDA and USDA jurisdiction

FTC

- Regulates false and misleading advertising of foods
- States

Misbranding

Under the Federal Food, Drug, and Cosmetic Act (21 USC § 343):

A food shall be deemed to be misbranded-

- (a) False or misleading label. If (1) its labeling is false or misleading in any particular....
- (b) Offer for sale under another name. If it is offered for sale under the name of another food.
- (c) Imitation of another food. If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated....
- (g) Representation as to definition and standard of identity. If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 341 of this title, unless (1) it conforms to such definition and standard....
- The Federal Meat Inspection Act and the Poultry Products Inspection Act contain nearly identical language (21 USC §§ 453(h), 601(n)).

Imitation of Another Food

- Per FDA regulations, a food that is "a substitute for and resembles another food" will <u>not</u> be subject to the "imitation of another food" labeling requirements if:
 - It is not "nutritionally inferior" to that food, and
 - It is labeled with a common or usual name that is not false or misleading, and that complies with FDA requirements for common and usual names (e.g., it is not "confusingly similar to the name of any other food that is not reasonably encompassed within the same name"), or in the absence of such a name, it is labeled with an "appropriately descriptive term" that is not false or misleading (21 CFR § 101.3(e)).
- USDA policy likewise applies the "imitation of another food" labeling requirement when the product is nutritionally inferior.

Standards of Identity

Dairy

- Congress directed FDA to establish "a reasonable definition and standard of identity" for any food (with certain exceptions) when in FDA's judgment "such action will promote honesty and fair dealing in the interest of consumers" (21 USC § 341).
- FDA has issued regulations establishing standards of identity for milk, yogurt, cheeses and ice cream, as well as related items (e.g., heavy cream, sour cream, evaporated milk).
- A definition for butter is provided by statute (21 USC § 321a).
- Each of these standards of identity requires that the product contain or be prepared from certain dairy ingredients.

Standards of Identity

Meat & Poultry

- USDA may prescribe "definitions and standards of identity or composition" for articles subject to the FMIA or PPIA when USDA determines that "such action is necessary for the protection of the public" (21 USC §§ 457(b), 607(c)).
- USDA has established such standards of identity by regulation as well as through policy memoranda and in its Food Standards and Labeling Policy Book.
- These include standards of identity for a variety of meat food products and poultry products, including hamburger, ground beef, sausage, meat loaf, meat pies and other items.
- The FMIA and PPIA define the terms "meat food product," "poultry" and "poultry product," and USDA regulations further define the terms "meat," "beef" and "beef products" (21 USC §§ 453(e)-(f), 601(j); 9 CFR § 301.2; 7 CFR §§ 1260.119-120).

Recent Developments

Dairy

- July 2018: FDA Commissioner announces that FDA will undertake to review and modernize
 its standards of identity for dairy products.
- September 2018: FDA issues request for information regarding the use of dairy food names in the labeling of plant-based products.
- January 2019: Comment period closes on the request for information.
- **February 2019:** Citizen petition requests that FDA enforce existing imitation labeling requirements for non-dairy substitute products and amend regulations with specific language regarding non-dairy foods that substitute for standardized dairy foods.
- March 2019: DAIRY PRIDE Act reintroduced in Congress.

Recent Developments

Meat & Poultry

- February 2018: Citizen petition requests that USDA establish certain requirements for products labeled as "beef" or "meat."
- July 2018: FDA holds public meeting on foods produced using animal cell culture technology.
- August 2018: Missouri passes law prohibiting the misrepresentation of products as meat that are not derived from harvested production livestock or poultry; challenged in court.
- March 2019: FDA and USDA enter agreement regarding oversight of human food produced using animal cell culture technology derived from cell lines of USDA-amenable species.

Leveling the Playing Field for Innovative Milks and Meats

"Traditional Meat and Dairy Foods and Innovative Substitutes:

Key Regulatory and Enforcement Issues"

Food and Drug Law Institute's
Food Enforcement and Compliance Conference
March 21, 2019

Elan Abrell Senior Regulatory Specialist





On the menu today

- The Good Food Institute
- GFI's rulemaking petition to FDA
- Federal regulation of cell-based meat
- State label censorship
- 2018 Missouri statute
- Pending 2019 state bills





Creating a more healthy, humane, and sustainable food supply by...

- Fostering Innovation
- Supporting Innovation
- Corporate Engagement
- Institutional Engagement

GFI is a non-profit organization. We're 100% supported by gifts and grants.

"Without severe cuts in consumption, agricultural emissions will take up the entire world's carbon budget by 2050...

Shifting global demand for meat and dairy products is central to achieving climate goals."

—Royal Institute of International Affairs (Chatham House)



Rob Bailey, Antony Froggatt and Laura Wellesley Energy, Environment and Resources | December 2014

Livestock – Climate Change's Forgotten Sector Global Public Opinion on Meat and Dairy Consumption





Plant-Based Milks





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Supporting Documents View All (2)

Attachment A Soyfoods Association of North America, Summary of Consumer Research re Citizen Petition...



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Comments Received

113







*This count refers to the total comment/submissions received on this docket, as of 11:59 PM yesterday. Note: Agencies review all submissions, however some agencies may choose to redact, or withhold, certain submissions (or portions thereof) such as those containing private or proprietary information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. This can result in discrepancies between this count and those displayed when conducting searches on the Public Submission document type. For specific information about an agency's public submission policy, refer to its website or the Federal Register document.

GFI's regulatory petition

- Purpose: Clarity on terms like "soy milk"
- Proposal: Amend 21 C.F.R. § 102.5 to explicitly allow compound names



Treeline nut cheese



GFI's regulatory petition

Rationale:

- These are the terms that consumers use.
- The proposed approach is consistent with the FDCA and FDA practice.
- Restricting producers from using compound names would violate the First Amendment.



Cell-Based Meat – animal meat *without* the animal





FEDERAL REGULATION

FDA-USDA Shared Jurisdiction

- November 16, 2018: USDA and FDA announce agreement to create a "joint regulatory framework"
 - Will leverage FDA's experience regulating cell-culture technology and living biosystems, and USDA's expertise in regulating livestock and poultry products for human consumption
- March 7, 2019: Agencies release Formal Agreement
- FDA will oversee cell collection, cell banks, and cell growth and differentiation
- Transition to USDA oversight during cell harvest stage
- USDA will oversee production and labeling of food products derived from the cells of livestock and poultry, including premarket approval and inspection of labels



MISSOURI'S 2018 LABEL CENSORSHIP STATUTE

Missouri Passes a Law

- Mo. Rev. Stat. § 265.494(7), as amended by 2018 Senate
 Bills 627 and 925
- Rationale: "to protect our cattlemen in Missouri and protect our beef brand"
- Makes it unlawful to "misrepresent a product as meat" if it is not from "harvested production livestock or poultry"





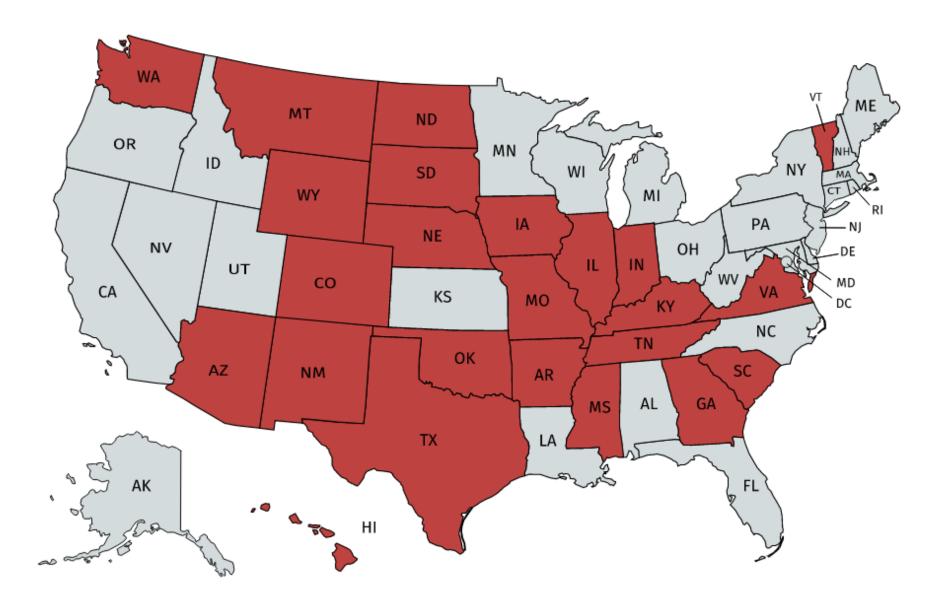
GFI's Response

- Joined Tofurky to sue Missouri's prosecuting attorneys
- Co-counsel: ACLU-Missouri and the Animal Legal Defense Fund
- Violates the First Amendment and two other constitutional provisions



THE STATES: 2019 LABEL CENSORSHIP BILLS

So Many Missouris





Word Bans and Compelled Speech

- 17 states have introduced bills similar to the Missouri law, seeking to block the use of meat terms on labels for plant-based or cell-based meat, or both;
 - Arkansas, Arizona, Georgia, Hawaii, Illinois, Iowa, Kentucky, Mississippi, Montana, Nebraska, New Mexico, Oklahoma, South Dakota, South Carolina, Tennessee, Texas, Vermont
- 5 states would mandate specific language on labels for plantbased or cell-based meat, or both;
 - Colorado, Indiana, North Dakota, Virginia, Wyoming
- 1 state would have banned the sale of cell-based meat and the use of state funds for R&D.
 - Washington



Status as of March 15

- 6 states have passed a bill in both chambers;
- 3 states have passed a bill in one chamber;
- 8 states have at least one active bill in committee; and
- 6 states have bills that are now effectively dead.



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Senior Vice President, Environmental and Regulatory Affairs & Staff Counsel, National Milk Federation



Outline

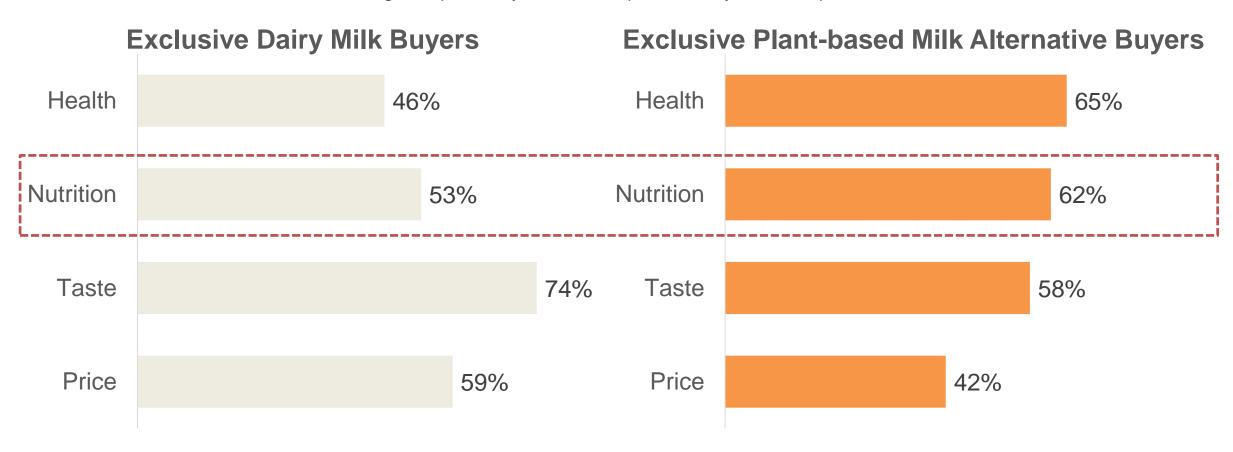
- Nutrition Perceptions*
- Nutrition Reality
- Global Labeling
- NMPF Citizen Petition

alternative buyers (n=789); exclusive plant-based milk buyers (n=110).

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?

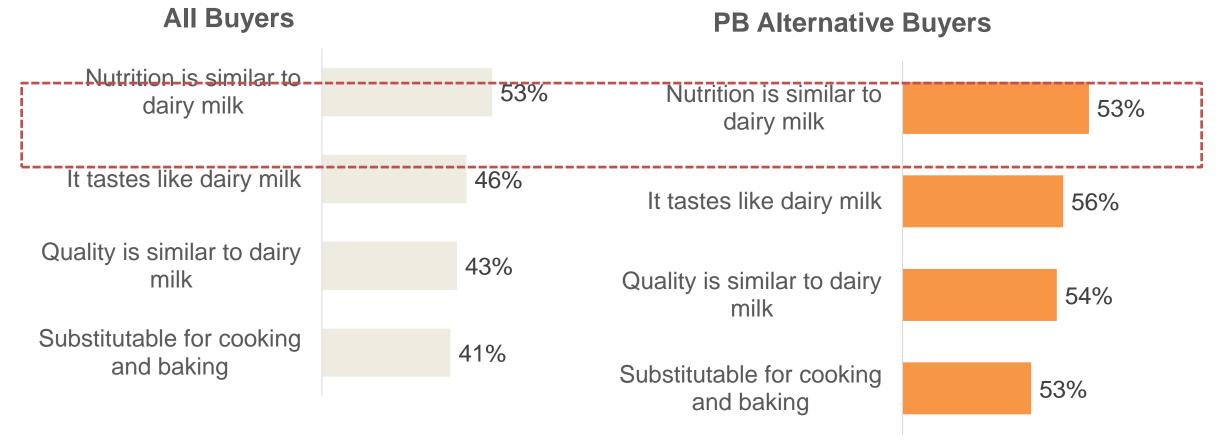


The #1 Reason Consumers Believe Non-dairy Products are Labeled "Milk" is Because Products are Comparable to Dairy Milk on Nutrition

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"



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	S	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
All	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

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

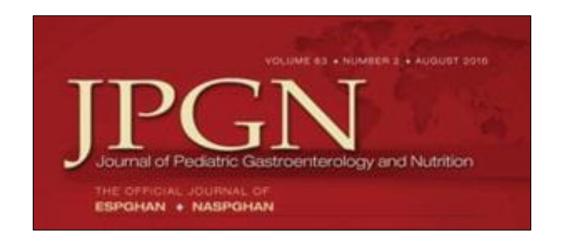
Public Health Consequences

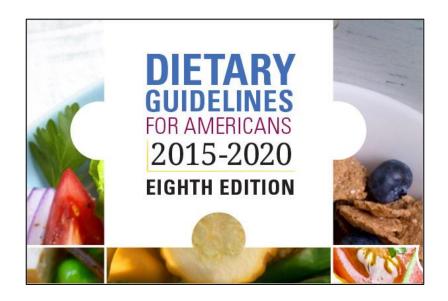
"...case reports show that <u>feeding rice-based beverages to young children resulted in a disease called kwashiorkor, a form of severe protein malnutrition</u>. There has also been a case report of a toddler being diagnosed with <u>rickets</u>, a <u>disease caused by vitamin D deficiency</u>, after 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

"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)

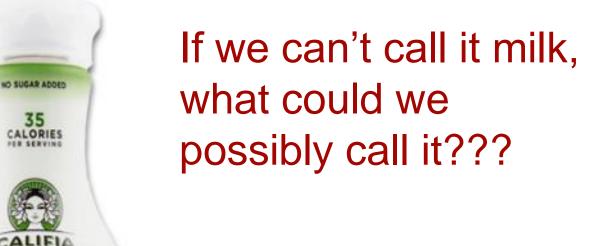


SWEETEN

CARRAGEENAN FREE

50% MORE CALCIUM

ARFL OZ (LAL)



U.S.





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."



Oat-ly "Oat <u>Drink</u>" 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











2018 Strong Commercial Dairy Sales



Total Dairy Sales % Change vs. Year Ago

	2017	2018 (thru Nov)
Domestic + Exports	+0.7%	+2.2%
Domestic	+0.1%	+0.4%
Exports	+4.7%	+13.0%

Total Dairy Sales

Products That Do Not Violate the Rules







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

- 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 CRF 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.

- 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.

- 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.

- Options for Labeling of <u>Nutritionally Inferior</u> Foods
 - **■**"Almond Beverage"
 - "Almond Milk Imitation Milk"
 - "Almond Milk Milk Substitute Nutritionally Inferior [and any other material distinctions]"



- Options for Labeling of <u>Not-Nutritionally Inferior</u>* 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 <u>all</u> 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).