From Cellular Agriculture to Plant-Based Milks: Hot Issues in the Protein Arena

Protein Trends & Technologies Seminar
Jessica P. O'Connell
May 22, 2019

COVINGTON

BEIJING BRUSSELS DUBAI FRANKFURT JOHANNESBURG LONDON LOS ANGELES
NEW YORK PALO ALTO SAN FRANCISCO SEOUL SHANGHAI WASHINGTON

www.cov.com

Agenda

- Background: food standards and regulatory jurisdiction
- Recent actions: food standards
- Recent actions: cellular agriculture
- What to expect?

Standards of Identity: Background

FDA

- FDCA § 401: FDA may establish a definition and standard of identity for food to "**promote honesty and fair dealing in the interest of consumers**"
- No definition and standard may be established for fresh or dried fruits or vegetables, except for avocados, cantaloupes, citrus fruits, and melons (relating only to maturity and effects of freezing)
- **FDA/CFSAN has established over 280 standards** largely for staple products

USDA

- FMIA & PPIA (§§ 607(c), 457(b)): USDA may establish a definition and standard of identity or composition whenever "**necessary for the protection of the public**"
- Standards may not be "inconsistent with any such standards" established under FDCA
- **USDA must consult with FDA** prior to issuance "to avoid inconsistency in such standards and possible impairment of the coordinated effective administration"
- **USDA/FSIS has established approximately 80 standards** for meat and poultry products

Standards of Identity: Background

FDA

- Standards **establish common or usual name and define nature of the food,** generally in terms of types of ingredients that food must contain (i.e., mandatory ingredients), and those that it may contain (i.e., optional ingredients)
- Standards "also may describe the **manufacturing process when that process has a bearing on the identity of the finished food**"
- If no standard of identity, food must be identified by "common or usual name"

USDA

- Standards vary depending on complexity of food and level of detail necessary to define its characterizing features
- Standards of identity **generally require the presence of certain expected ingredients or mandate how product is to be formulated or prepared**, and sometimes specify how product must be prepared
- Standards of composition specify minimum or maximum amount of ingredients in a product

Gov't Interest in Modernizing Food Standards?

- FDA's 2018 Strategic Policy Roadmap
  - *"**Modernizing certain standards of identity to address current barriers to the development of healthier products while making sure consumers have accurate information about the foods they eat.** Among other steps, **FDA intends to issue a request for information** to identify and help prioritize which potential standards of identity should be modernized based on their public health value."*
- FDA's 2018 Nutrition Innovation Strategy
  - *"FDA can help facilitate innovation while protecting public health through food standards of identity. . . . It's important to take a fresh look at existing standards of identity in light of marketing trends and the latest nutritional science. **The goal is to maintain the basic nature and nutritional integrity of products while allowing industry flexibility for innovation to produce more healthful foods**."*
- Other Statements by former Commissioner Gottlieb
  - *"We'll also look to eliminate standards that may not be necessary. Our priority, again, is public health, and flexibility is key. **We want to maintain the basic nature and nutritional integrity of products while allowing industry flexibility for innovation**. Protection against economic fraud still is critical. But we also see a need for flexibility in standards that allow better public health outcomes by encouraging manufacturers to produce more healthful foods that are still affordable."*

Recent Actions re: Food Standards - Dairy

- FDA standards of identity currently include wide range of dairy standards
- FDA's regulations: Milk is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows
- FDCA 403(g): Food is misbranded if it purports to be or is represented as a food for which a definition and standard of identity has been prescribed
- July 2018, Commissioner Gottlieb: "an almond doesn't lactate"

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION
PART 131 MILK AND CREAM[9]

Subpart A--General Provisions

§ 131.3 - Definitions.
§ 131.25 - Whipped cream products containing flavoring or sweetening.

Subpart B--Requirements for Specific Standardized Milk and Cream

§ 131.110 - Milk.
§ 131.111 - Acidified milk.
§ 131.112 - Cultured milk.
§ 131.115 - Concentrated milk.
§ 131.120 - Sweetened condensed milk.
§ 131.125 - Nonfat dry milk.
§ 131.127 - Nonfat dry milk fortified with vitamins A and D.
§ 131.130 - Evaporated milk.
§ 131.147 - Dry whole milk.
§ 131.149 - Dry cream.
§ 131.150 - Heavy cream.
§ 131.155 - Light cream.
§ 131.157 - Light whipping cream.
§ 131.160 - Sour cream.
§ 131.162 - Acidified sour cream.
§ 131.170 - Eggnog.
§ 131.180 - Half-and-half.
§ 131.200 - Yogurt.
§ 131.203 - Lowfat yogurt.
§ 131.206 - Nonfat yogurt.

Recent Actions re: Food Standards - Dairy

2019 NMPF petition

- Requests that FDA enforce existing "imitation" labeling requirements against non-dairy substitutes for dairy foods
- Codify FDA policies to permit the name of a standardized dairy food to be used in the statement of identity of a non-dairy substitute ***only*** when products are deemed nutritionally equivalent to the dairy products they reference

2018 FDA Request for Comment

- FDA requested comments on the use of dairy terms—such as milk, yogurt, and cheese—in the labeling of plant-based products

2018 FDA PR

- "[S]ome of these products can vary widely in their nutritional content – for instance in relation to inherent protein or in added vitamin content – when compared to traditional milk"
- "We intend to look at these differences in relation to potential public health consequences."

Recent Actions re: Food Standards - Dairy

2017 GFI Petition

- Requests FDA to clarify that new foods may be named by reference to other "traditional" foods in a manner that makes clear to consumers their distinct origins or properties
- Specific focus on soy milk and almond milk

2016 Letter from Congress

- Use of the term "milk" for plant-based products is misleading, harmful to dairy industry
- Violates FDA's standards of identity

1997 petition

- Requests common or usual name regulation defining "soymilk"

Recent Actions: Skim Milk State Litigation

Ocheesee Creamery LLC v. Putnam

- Florida state law standard for "skim milk" requires vitamins lost during skimming to be replaced as food additive
- Milk producer did not want to replace vitamins, but still wanted to call product "skim milk" – with a qualifier
- Florida insisted on name "milk product" rather than "skim milk"
- District Court found Florida requirement allowable under 1st Amendment
- 11th Circuit reversed – March 2017
  - "It is undoubtedly true that a state can propose a definition for a given term. However, it does not follow that once a state has done so, any use of the term inconsistent with the state's preferred definition is inherently misleading."
  - "The State was unable to show that forbidding the Creamery from using the term 'skim milk' was reasonable, and not more extensive than necessary to serve its interest."

** 2018 First Amendment challenge to FDA on same issue: *South Mountain Creamery*

Recent Actions re: Food Standards - Mayonnaise

- FDA 2015 WL: "Just Mayo" products misbranded because they "purport to be the standardized food mayonnaise due to the misleading name and imagery used on the label, but do not" meet the standard for mayonnaise (primarily because of no egg)
- After negotiation: company can keep "Just Mayo" with additional language to indicate "egg free" and clarify that not standardized product

Other Standardized Foods

Yogurt, Ice Cream: tie to ***milk***

Flour: Flour, white flour, wheat flour, plain flour, is the food prepared by grinding and bolting ***cleaned wheat***, other than durum wheat and red durum wheat

Bread: Bread, white bread, and rolls, white rolls, or buns, and white buns are the foods produced by baking mixed yeast-leavened dough prepared from ***flour, bromated flour, phosphated flour***, or a combination of two or more of these

Liquid eggs: Liquid eggs, mixed eggs, liquid whole eggs, mixed whole eggs are eggs of the ***domestic hen*** broken from the shells and with yolks and whites in their natural proportion as so broken

Recent Actions re: Food Standards – Alternatively Sourced Meat Products

- 2018 Petition to FSIS from US Cattlemen's Association
  - Limit the definition of "beef" to product from cattle born, raised, and harvested in the "traditional manner"
  - Prohibit "beef" from coming from alternative sources – animal cells, plants, insects
  - Limit definition of "meat" to tissue or flesh of animals that have been harvested in the "traditional manner"
  - Petition identifies clean/cultured meat and plant based meat as products that should not be eligible to labeled as "beef" or "meat"
  - Comment period ends this month

Jurisdiction: FDA, USDA, Both?

FDA	"Food" and food ingredients under Federal Food, Drug, and Cosmetic Act
	Safety of new food ingredients including in plant-based foods, seafood, and meat and poultry products
	Food products of biotechnology including GE animals
	Safety of animal cloning and labeling
	Safety and labeling of "non-specified" red meats (e.g., bison and venison) and "non-specified" birds (e.g., wild turkey) and products with minimal amounts of meat/poultry
	Live food animals
	Microbial, algal, and fungal cells generated by largescale culture and used as direct food ingredients; animal cell culture technology in therapeutic settings; and processing, manufacture, and packaging of seafood (except catfish)

Jurisdiction: FDA, USDA, Both?

USDA	Regulates “meat and meat food products” and “poultry and poultry products” under Federal Meat Inspection Act and Poultry Products Inspection Act except: – multi-ingredient foods containing < 3% raw meat/poultry or < 2% cooked meat/poultry – non-specified meats or birds
	Regulates establishments that slaughter and/or process meat and poultry products – Processing activities include mixing, grinding, fabrication, preblending, patty formation, stuffing, mechanical tenderization, cooking/smoking, etc.
	Determines safety, wholesomeness, and accuracy of labeling
	Determines suitability of ingredients used in meat and poultry products
	Reviews other new technologies for safety and suitability

Jurisdiction: FDA, USDA, Both?

New ingredients in meat or poultry

- FDA evaluates safety and USDA consults on suitability
- Stems from FDA's "food additive" authority
- For ingredients of biological origin, evaluation is primarily a comparative assessment

Finished meat & poultry product labeling

- Typically regulated by USDA

Other relevant precedents

- FDA evaluated safety and labeling of food from animal clones and progeny; USDA/FSIS deferred to FDA determination and regulates finished products
- Concurrent evaluation of beef, poultry, and pork protein ingredients (e.g., GRN 168, 313, 314) (**More than 25% of GRAS notices filed with FDA have involved substances in products in meat and poultry products, and have undergone concurrent evaluation by USDA/FSIS)
- Congress delegated authority over catfish exclusively

Key FSIS Definitions

Meat: "The part of the muscle **of any cattle, sheep, swine, or goats** that is skeletal or that is found in the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat, and the portions of bone (in bone-in product such as T-bone or porterhouse steak), skin, sinew, nerve, and blood vessels that normally accompany the muscle tissue and that are not separated from it in the process of dressing." 9 CFR § 301.2 (FMIA regulations)

Meat food product: [A]ny product capable of use as human food which is made wholly or in part from **any meat or other portion of the carcass of any cattle, sheep, swine, or goats . . . .**" 21 U.S.C. § 601(j) (FMIA)

What Will Be Regulated & By Whom?

Pre-Market Safety

- Substances used in manufacturing (e.g., animal cells, growth medium)
- Assessment of whether manufacturing changes or affects identity, conditions of use, purity, toxicity, or safety
- Identity, history of safe use, common knowledge of safety, technical effect and intended use, margin of exposure
- Consultation process, food additive / GRAS process, process similar to LACF/AF?

Mfg Process

- Hazard analysis and control measures, GMP
- Preventive controls / HACCP?

Labeling

- Product name (e.g., qualifies as “meat” or “poultry” products?)
- Other mandatory labeling
- USDA or FDA regime?

Facility Inspection

- FDA GMP / FSMA inspection or USDA processing inspection?

Recent Developments in Cellular Agriculture

February 2018: The U.S. Cattlemen's Association petitioned USDA to establish meat labeling requirements excluding products not derived from animals raised and slaughtered

October 2018: USDA and FDA held a joint meeting to solicit stakeholder input on how cellular agriculture should be regulated

November 2018: USDA and FDA issued a statement agreeing on joint oversight

- "American farmers and ranchers feed the world, but as technology advances, we must consider how to inspect and regulate to ensure food safety, regardless of the production method." ~ Secretary Purdue
- "Recent advances in animal cell cultured food products present many important and timely technical and regulatory considerations for the FDA and our partners at USDA." ~ Commissioner Gottlieb

Recent Developments in Cellular Agriculture

March 2019: FDA and USDA released a formal agreement outlining how cellular agriculture will be regulated

- Pre-harvest, FDA is responsible for:
  - Conducting oversight of and providing consultation on tissue collection, cell lines and banks, and the proliferation of cells
  - Ensuring compliance with applicable FDA regulations, including facility registration, CGMPs, and preventive controls
- At harvest, USDA is responsible for:
  - Overseeing facility inspections and compliance with FSIS regulations, including HACCP
  - Approving product labeling according to "joint principles" USDA and FDA will establish

State Impact

Missouri: 2018 law amended the Missouri meat advertising law to prohibit "misrepresenting a product as meat that is not derived from harvested production livestock or poultry."

- State Dept of Ag provided guidance regarding qualifiers

Arkansas: 2019 law states that "meat" does not include synthetic product derived from a plant, insect, or other sources like lab-grown animal cells

- Prohibits, in part, (1) representing the agricultural product as meat or a meat product when the agricultural product is not derived from harvested livestock, poultry, or cervids; (2) representing the agricultural product as rice when the agricultural product is not rice; (3) utilizing a term that is the same as or similar to a term that has been used or defined historically in reference to a specific agricultural product; or (4) affixing a label that uses a variation of rice in the name of the agricultural product when the agricultural product is not rice or derived from rice

20+ laws pending or passed in other states

What to Expect Next

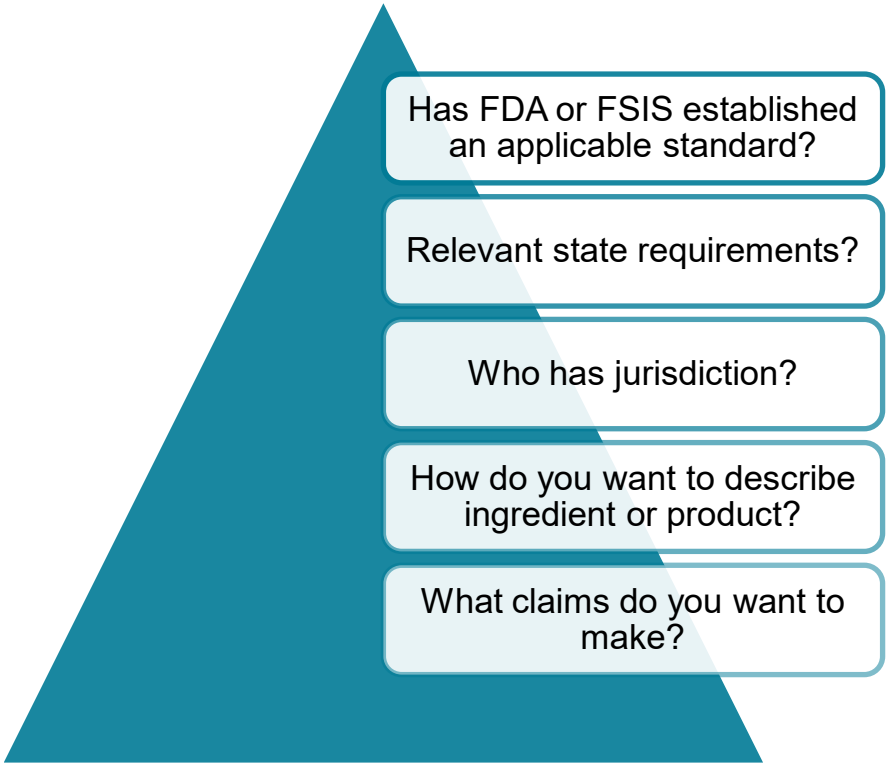
Cell-based meat

- USDA / FSIS decision on U.S. Cattlemen's Petition or naming more generally
- Potential standard of identity specific to these products?
- Case-specific determinations
- Continued political interest and legislation (e.g., Federal Ag Appropriations; Missouri and many other state laws)
- Litigation

Plant-based meat and dairy

- FDA request for comment and issuance of policy statement?
- Continued political interest and legislation (e.g., Missouri law and many other state laws)
- Litigation

Key Questions to Ask



Questions?

Jessica P. O'Connell
jpoconnell@cov.com