
Food Standards of Identity: Enforcement and Compliance Issues

**FDLI Food Enforcement & Compliance Conference
April 12, 2018**

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Agenda

- Standards of Identity: Background
- Prior Efforts to Modernization Food Standards
- Renewed Interest in Modernizing Food Standards?
- Recent Actions re: Food Standards



Standards of Identity: Background

FDA/CFSAN

- 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/FSIS

- 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 (cont'd)

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**”

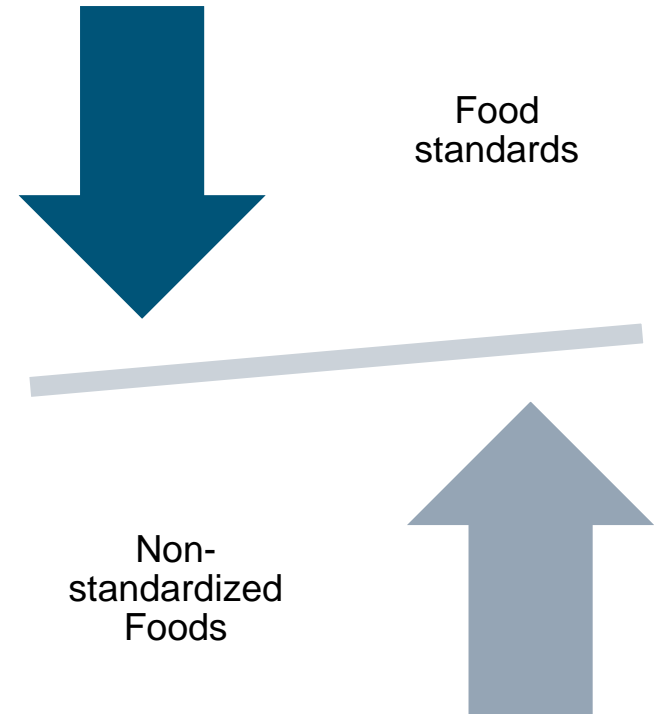


USDA/FSIS

- 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

Decline of Food Standards

- In early '70s, in response to proliferation of new foods that did not conform to standards of identity, FDA adopts a revised policy on food names (based upon Report of the White House Conference)
- Under new policy, FDA:
 - **Adopts fewer new standards**
 - Amends existing standards to permit **wider range of optional ingredients**
 - **Limits scope of “imitation” labeling requirements**
 - **Limits interpretation of when a food “purports to be” a standardized food**
- Results in decline of implementation of food standards and rise of non-standardized foods sold under common or usual name or accurate and descriptive term



Agency Efforts to Modernize Food Standards

- Mar. '95: President Clinton issues “Regulatory Reinvention Initiative” memo directing agencies to make government more effective by revising or eliminating regulations that are outdated or otherwise in need of reform
- Dec. '95: FDA publishes ANRPM:
 - Tentatively concludes that “**several food standards of identity should be revoked** for various reasons including that they are obsolete, or that their provisions are being adequately covered by other regulations”
 - Food standards may “**fail to reflect advances in food science and technology**”
 - Invites comment on whether foods standards are still needed and, if so, whether they should be modified or streamlined
- Sept. '96: FSIS publishes similar ANPRM

67492 Federal Register / Vol. 60, No. 250 / Friday, December 29, 1995 / Proposed Rules

21 CFR Part 170
Administrative practice and procedure. Food additives, Reporting and recordkeeping requirements.

21 CFR Part 171
Administrative practice and procedure. Food additives. Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 171, 170, and 171 be amended as follows:

PART 171—COLOR ADDITIVE PETITIONS

1. The authority citation for 21 CFR part 171 continues to read as follows:
Authority: Secs. 201, 402, 409, 501, 505, 506, 507, 510, 512-516, 518-520, 601, 701, 721, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 351, 355, 356, 357, 360, 360b-360f, 360b-360g, 361, 371, 279e, 381); sec. 215, 353 of the Public Health Service Act (42 U.S.C. 216, 262).

2. Section 171.1 is amended in paragraph (c) in the petition by revising the introductory paragraph preceding paragraph A, and by adding new paragraph (j) to read as follows:

§171.1 Petitions.

(c) * * *

Attached hereto in triplicate (quaduplicate, if intended uses include use in meat, meat food product, or poultry product), and constituting a part of this petition are the following:

(i) If intended uses of the color additive include uses in meat, meat food product, or poultry product subject to regulation by the U.S. Department of Agriculture (USDA) under the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) or Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), FDA shall, upon filing of the petition, forward a copy of the petition or relevant portions thereof to the Food Safety and Inspection Service, USDA, for simultaneous review under the PPPIA and FMIA.

(ii) FDA will ask USDA to advise whether the proposed meat and poultry uses comply with the FMIA and PPPIA, or if not, whether use of the substance would be permitted in products under USDA jurisdiction under specified conditions or restrictions.

§171.20 Publication of regulation.

(a) * * *

Attached hereto, in triplicate (quaduplicate, if intended uses include use in meat, meat food product, or poultry product), and constituting a part of this petition, are the following:

(b) If intended uses of the food additive include uses in meat, meat food product, or poultry product subject to regulation by the U.S. Department of Agriculture (USDA) under the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) or Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*), FDA shall, upon filing of the petition, forward a copy of the petition or relevant portions thereof to the Food Safety and Inspection Service, USDA, for simultaneous review under the PPPIA and FMIA.

(2) FDA will ask USDA to advise whether the proposed meat and poultry uses comply with the FMIA and PPPIA, or if not, whether use of the substance would be permitted in products under USDA jurisdiction under specified conditions or restrictions.

3. Section 171.20 is amended by adding new paragraph (a)(3) to read as follows:

§171.1 Petitions.

(c) * * *

Attached hereto, in triplicate (quaduplicate, if intended uses include use in meat, meat food product, or poultry product), and constituting a part of this petition, are the following:

(b) If intended uses of the food additive include uses in meat, meat food product, or poultry product subject to regulation by the U.S. Department of Agriculture (USDA) under the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) or Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*), FDA shall, upon filing of the petition, forward a copy of the petition or relevant portions thereof to the Food Safety and Inspection Service, USDA, for simultaneous review under the PPPIA and FMIA.

(2) FDA will ask USDA to advise whether the proposed meat and poultry uses comply with the FMIA and PPPIA, or if not, whether use of the substance would be permitted in products under USDA jurisdiction under specified conditions or restrictions.

8. Section 171.100 is amended by redesignating paragraph (b) as paragraph (c) and by adding new paragraph (b) to read as follows:

§171.100 Regulation based on petition.

(b) The regulation shall describe the conditions under which the substance may be safely used in any meat product, meat food product, or poultry product subject to the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) or the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*).

Dated: October 11, 1995.
William B. Schultz,
Deputy Commissioner for Policy.
[FR Doc. 95-31491 Filed 12-29-95; 3:37 pm]
BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

21 CFR Parts 102, 130, 131, 133, 135, 136, 137, 139, 145, 146, 150, 152, 155, 156, 158, 160, 161, 163, 164, 165, 166, 168, and 169

[Docket No. 95N-0294]

Food Standards of Identity, Quality and Fill of Container, Common or Usual Name Regulations; Request for Comments on Existing Regulations

AGENCY: Food and Drug Administration, HHS.
ACTION: Advance notice of proposed rulemaking.

Agency Efforts to Modernize Food Standards (cont'd)

- **Most comments to both ANRPMs strongly support concept of food standards, but ask for increased flexibility and clarity**
 - Comments in support said that food standards ensure level playing field, that products meet consumer expectations, a basis for international harmonization, and national uniformity
- Jan '97: FDA & FSIS form inter-agency Task Force to discuss current and future role of food standards and draft a set of principles for reviewing and revising food standards
- **Task Force considers 5 options**

1) Do not proceed with the review of food standards regulations

2) Remove all food standards and treat all foods as non-standardized

3) Review and revise food standards to make them internally consistent, more flexible, and easier to administer

4) Request external industry groups to review, revise, and administer food standards (private certification)

5) Rely on external groups (e.g., consumer, industry, commodity) to draft recommended revisions, but retain agencies' authority to establish final regulations

2005 Proposed Rule: General Principles & Food Standards Modernization

- May '05: FDA & FSIS jointly publish proposed rule to establish general principles for modernization of food standards
- Agencies tentatively determine that fifth option – i.e., rely on external groups to draft recommended revisions, but retain agencies' authority to establish final regulations – “is the most appropriate course of action”
- Proposal intended to establish **criteria agencies will use in considering petitions to establish, revise, or eliminate a food standard**
- Proposed general principles were the “**first step in instituting a process to modernize their food standards**” and will “**promote honesty and fair dealing . . . protect the public, allow for technological advances in food production, be consistent with international food standards** to the extent feasible, and **be clear, simple, and easy to use**”

DEPARTMENT OF AGRICULTURE
Food Safety and Inspection Service

9 CFR Part 410
[Docket No. 95-051P]
RIN 0583-AC72

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration

21 CFR Part 130
[Docket No. 1995N-0294]
RIN 0910-AC54

**Food Standards; General Principles
and Food Standards Modernization**

AGENCIES: Food Safety and Inspection
Service, USDA; Food and Drug
Administration, HHS.

ACTION: Proposed rule.

2005 Proposed Rule: General Principles and Food Standards Modernization (cont'd)

- Agency will consider a petition proposing to **eliminate a food standard** if it demonstrates that current standard is not consistent with any one of 4 principles:
 - Promotes **honesty** and **fair dealing** in the interest of consumers (FDA) or protects the public (FSIS)
 - Describes **basic nature of the food** to ensure that consumers are not misled by name of food and to meet consumer expectations of product characteristics and uniformity
 - Reflects **essential characteristics** of the food
 - Ensures food **does not appear better** or of **greater value** than is
- A petition proposing to **establish a new or revised food standard** must be consistent with 4 principles along with several other principles including (but not limited to):
 - Contains **clear and easily understood requirements** to facilitate compliance by food manufacturers
 - Permits **maximum flexibility in food technology** used to prepare standardized food, so long as that technology does not alter the basic nature or essential characteristics, or adversely affect the nutritional quality or safety, of the food
 - Should be **harmonized with international standards where feasible**
 - Should be **simple, easy to use, and consistent among all standards** (e.g., should include only those elements necessary to define basic nature and essential characteristics and any unnecessary details should be eliminated)
 - Should allow **variations** in physical attributes of food

2005 Proposed Rule: General Principles and Food Standards Modernization (cont'd)

- In 2006, a dozen major food industry associations submit a citizen petition to FDA & FSIS proposing amendments to food standards via a regulation of general applicability to allow variations “to provide needed flexibility,” including:
 - Addition of ingredients intended solely for technical effects
 - Use of safe and suitable flavors and flavor enhancers
 - Use of advanced technologies and alternative manufacturing processes
 - Changes to product’s basic shape in response to consumer demand
 - Improvements in nutritional properties that do not rise to level of defined nutrient content claim

October 25, 2006

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

FSIS Docket Clerk
Food Safety and Inspection Service
Department of Agriculture
Room 102, Cotton Annex Bldg
300 12th Street, S.W.
Washington, D.C. 20250-3700

**Citizen Petition
to Modernize Food Standards**

On the behalf of the food industry associations listed below, I am submitting this petition to request the Commissioner of Food and Drugs and the Administrator of the Food Safety and Inspection Service (FSIS) to issue, respectively, regulations of general applicability to modernize the food standards. This request is submitted to the Food and Drug Administration (FDA) under section 403 of the Federal Food, Drug, and Cosmetic Act (FDCA), and 21 C.F.R. § 10.30, and to FSIS pursuant to Section 1(n)(7) of the Federal Meat Inspection Act (FMIA) and Section 4(h)(7) of the Poultry Products Inspection Act (PPIA).

The American Frozen Food Institute (AFFI) is the national trade association representing frozen food manufacturers, their marketers and suppliers. AFFI's 482 member companies are responsible for approximately 90 percent of the frozen food processed annually in the United States, valued at more than \$60 billion. AFFI members are located throughout the country and are engaged in the manufacture, processing, transportation, distribution and sale of products nationally and internationally.

The American Meat Institute (AMI) represents the interests of packers and processors of beef, pork, lamb, veal and turkey products and their suppliers throughout North America. Together, AMI's members produce 95 percent of the beef, pork, lamb and veal products and 70 percent of the turkey products in the U.S. Headquartered in Washington, D.C., the Institute provides legislative, regulatory, public relations, technical, scientific and educational services to the industry.

The Chocolate Manufacturers Association (CMA) is the not-for-profit trade association representing the majority of manufacturers and distributors of cocoa and chocolate products in the United States. The association was founded to fund and administer research, promote chocolate to the general public and serve as an advocate of the industry before Congress and government agencies.

2005 Proposed Rule: General Principles and Food Standards Modernization (cont'd)

- Petition draws public outcry – spurred by gourmet chocolate manufacturers – based upon appendix to petition which provided as an example of a permissible variation the replacement of cacao fat with other vegetable fat
- To date, FDA & FSIS still has not acted on petition or 2005 proposal

Los Angeles Times | ARTICLE COLLECTIONS

[← Back to Original Article](#)

The courage of their confections

Two candy makers are asking chocolate lovers to protest plans to allow cheaper ingredients. Vegetable oil, anyone?

April 14, 2007 | Jerry Hirsch | Times Staff Writer

Calling all chocoholics. Put down the truffles and power up the PC. It's time to weigh in on a fundamental question: What is chocolate?

Two of California's oldest confectioners, See's Candies Inc. and Guittard Chocolate Co., are battling an attempt to loosen government rules that dictate what ingredients go into the sweet stuff.



The New York Times

INTERNATIONAL BUSINESS

Battle brewing over the definition of chocolate

By ANDREW BRIDGES AUG. 9, 2007

Chocolate Purists Alarmed by Proposal To Fudge Standards

Lines Drawn Over Cocoa Butter

By Michael S. Rosenwald
Washington Post Staff Writer
Friday, April 27, 2007

Rarely do documents making their way through federal agencies cause chocolate lovers to totally melt down. Then came Appendix C.

Renewed 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 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.**”*

Calls to Update Food Standards

- Several comments request changes to standards of identity as part of Reg Reform
 - Tuna (e.g., change method of fill from pressed cal to drained weight; safe and suitable ingredients)
 - Yogurt (e.g., revoke standards for low-fat and nor fat yogurt per 2009 proposed rule; expand list of allowed dairy ingredients)
 - Frozen cherry pie (e.g., revoke as obsolete)
 - Bakery products (e.g., simplify standards for breads, rolls, and buns)
 - Orange juice (e.g., revise standard for orange juic and orange concentrate to lower minimum Brix level)
 - Fruit jelly (e.g., lower soluble-solids threshold)
 - Peanut butter (e.g., change optional oils to exclude PHOs and include vegetable oils and other ingredients)
 - French dressing (e.g., revoke as obsolete)

Review of Existing Center for Food Safety and Applied Nutrition Regulatory and Information Collection Requirements

A Proposed Rule by the Food and Drug Administration on 09/08/2017

PUBLISHED DOCUMENT

AGENCY:
Food and Drug Administration, HHS.

ACTION:
Request for comments and information.

SUMMARY:
As part of the implementation of [Executive Order 13771](#) entitled, "Reducing Regulation and Controlling Regulatory Costs," and [Executive Order 13777](#) entitled, "Enforcing the Regulatory Reform Agenda," the Food and Drug Administration (FDA, Agency, or we) is seeking comments and information from interested parties to help FDA identify existing regulations and related paperwork requirements that could be modified, repealed, or replaced, consistent with the law, to achieve meaningful burden reduction while allowing us to achieve our public health mission and fulfill statutory obligations. This document relates to the products regulated by the Center for Food Safety and Applied Nutrition (CFSAN).

DATES:

DOCUMENT DETAILS

Printed version:
[PDF](#)

Publication Date:
09/08/2017

Agencies:
[Food and Drug Administration](#)

Dates:
Submit either electronic or written comments on this document by December 7, 2017.

Comments Close:
12/07/2017

Document Type:
Proposed Rule

Document Citation:
82 FR 42503

Page:
42503-42506 (4 pages)

CFR:
21 CFR chapter under

Agency/Docket Number:
Docket No. [FDA-2017-N-5094](#)

Document Number:
2017-19030

Recent Actions re: Food Standards - Honey

- 2006 Petition: Sought US standard for honey based on Codex standard
- 2011 Petition denial: No reasonable grounds for establishing standard; FDA's current enforcement tools sufficient
- 2014 draft/2018 final guidance:
 - “Honey” is the appropriate common or usual name for “a thick, sweet, syrupy substance that bees make as food from the nectar of plants or secretions of living parts of plants and store in honeycombs” – a single ingredient food
 - Additional ingredients should be declared as part of a product's common or usual name
 - Source can be included as part of name

Recent Actions re: Food Standards - Dairy

- FDA standards of identity currently include wide range of dairy standards
- Periodic FDA action:
 - Muscle Milk (2011 WL)
 - Soy Milk (2008/2012 WL)
- Ongoing industry pressure for FDA to take action against products not in compliance with standards

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 CREAM⁹

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

- 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
 - Standards of identity only govern unqualified names?
 - First Amendment argument
- 2009 IDFA/NMPF petition: requests FDA to amend standard for milk and 17 other dairy products to allow any “safe and suitable sweetener,” including non-nutritive sweeteners
- 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 – *Central Hudson* analysis
- 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



Recent Actions re: Food Standards – Tuna

- Temporary Marketing Permits: market test a food product that deviates from the standard of identity for that particular food
- Under 21 CFR 130.17: sole purpose of the tests should be to obtain data necessary for reasonable grounds in support of a petition to amend food standards
- 3 current TMPs for canned tuna – all granted 2014, extended 2016 – major producers
 - Products don't need to bear “Below standard of fill” statement even if they don't meet standard of fill

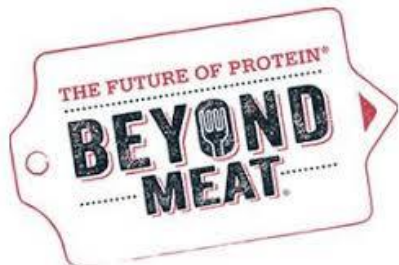


Recent Actions re: Food Standards – White Chocolate

- Petitions from Hershey (1992) and Chocolate Manufacturers Association of America (1993) – requesting that FDA establish a standard of identity for “white chocolate”
- FDA Final Rule 2002
 - “White Chocolate” standard of identity would promote honesty and fair dealing in the interest of consumers by ensuring that products contain cacao-derived ingredients
 - Eliminate need for temporary marketing permits
 - Help avoid consumer confusion re: terms currently on the market
- Future actions on other types of chocolate (e.g., dark chocolate)?

Recent Actions re: Food Standards – Plant-Based 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 be labeled as “beef” or “meat”
 - Comment period ends this month



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Considerations/Questions for the Future

- How likely is FDA or FSIS to undertake rulemaking to update standards? Specific standards or broadly?
- 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.**”*
 - Should primary focus be on nutrition?
 - Can this be done in ways other than rulemaking?
- State involvement where FDA hasn’t acted
- First Amendment impact

Questions?

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