



In Light of Changing Preferences: FDA Modernization of Standards of Identity and Labeling Claims

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Where are We and How We Got Here?

John Johnson III

Benjamin L. England & Associates, LLC



MIXED NUTS

LESS THAN 50% PEANUTS

PEANUTS - ALMONDS - CASHEWS - HAZELNUTS - PECANS



FARFALLE



"AL DENTE" PERFECTION IN 11-12 MINUTES



ITALY'S #1 BRAND OF PASTA

ENRICHED MACARONI PRODUCT

NET WT. 1 LB. (454 g)

SWEET PEAS



TOLL HOUSE

ESTD. 1939

80 CALORIES 3 SAT FAT 0g SODIUM 5g FIBER PER SERVING

62% CACAO BITTERSWEET CHOCOLATE MORSELS 100% REAL CHOCOLATE



2lb

Great Value

Breaded Butterfly Shrimp



Mrs. Smith's

SINCE 1919

ORIGINAL FLAKY CRUST MADE WITH REAL BUTTER

Cherry Pie



Del Monte

Quality

100% JUICE

Fruit Cocktail

IN 100% FRUIT JUICE



NET WT 16 OZ

McCormick

ALL NATURAL

PURE Vanilla

EXTRACT

MADE WITH MADAGASCAR VANILLA BEANS

NET 2 FL. OZ. (59 ml)

100% NATURAL SPRING WATER

Poland Spring

BRAND

Proudly From MAINE



MAD for the NORTH

2 .5L



24-16.9 FL. OZ. (1 PT., 0.9 (500 mL) PLASTIC BOTTLE

Jif

CREAMY PEANUT BUTTER

CHOICE OF #1 CHOOSY MOMS

NET WT 16 OZ (1 LB) 454g

How We Got Here...

Need to protect: “the time-honored standards employed by housewives and reputable manufacturers.”



Just a Teaspoonful

Will make a great difference in your dessert



MAPLEINE
Makes the daintiest dainties

In Whipped Cream, Puddings, Sauces, Cakes, Candies, Ice Cream, Blanc Mange, Jellies and Custards

It is Delicious

Our Cook Book—Mapleine Dainties—tells how to use it in fifty different ways. Grocers sell Mapleine—35c for a 2-oz. bottle (in Canada 50c).



Crescent Mfg. Co.
Dept. E 2 Seattle, Wn.



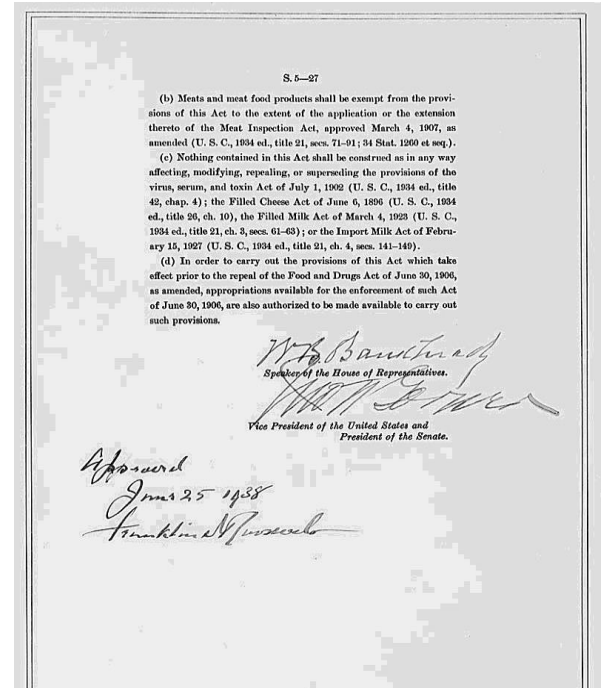
The Law

“promote[s] honesty and fair dealing in the interest of consumers.”

Section 401

“Misbranding was one of the chief evils Congress sought to stop.”

62 Cases of Jam at 596 (1951)



Challenges

- Peanut butter battles



Challenges, cont.

“A large supermarket was found to be increasing the sales appeal of swiss cheese by punching artificial ‘eyes’ in portions where they had not formed naturally. Some 12,000 lbs. were seized. The charge was concealment of inferiority and non-compliance with the cheese standards.”

FDA, Annual Report 1967

“Inspection and Laboratory manpower allocated for ‘economic’ violations such as short weight and misleading labeling continued at greatly reduced levels because of the urgency action to deal with health hazards. Health protection, however, also protects the consumer’s pocketbook...”

FDA, Annual Report 1970

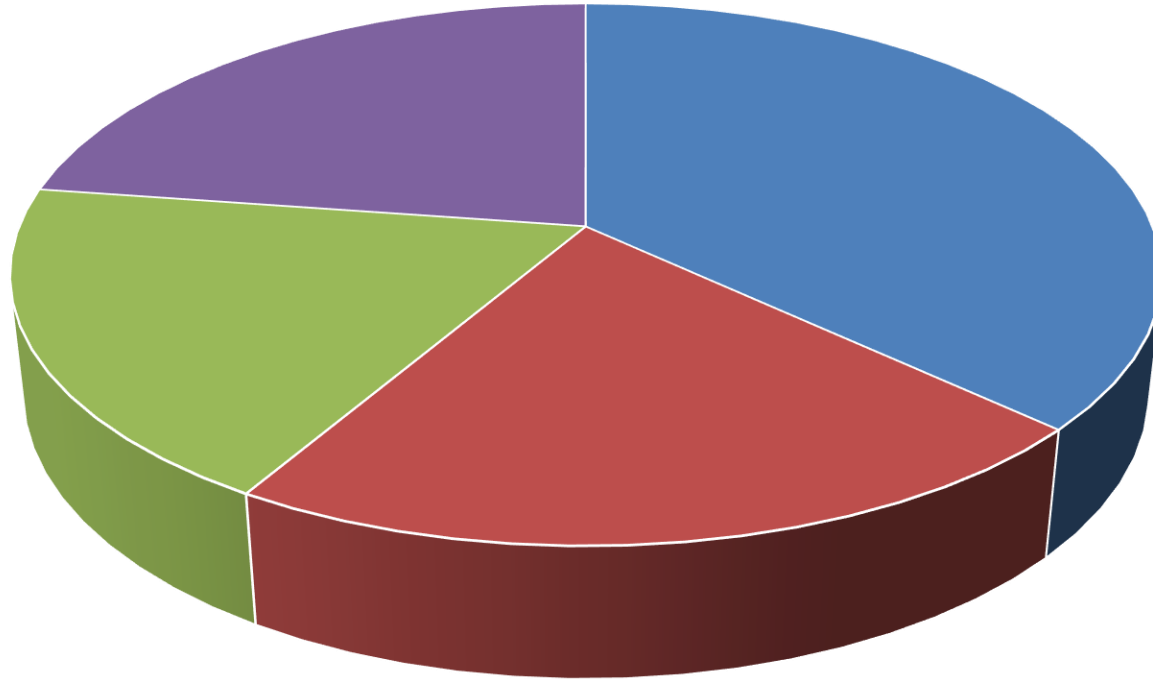


Change

“we conclude that regulation should shift away from controlling food composition and focus on providing consumers with more complete information about foods.”

*White House Conference on Food, Nutrition, and Health
(1969)*

Where we are Today



■ Dairy (96) ■ Fruits & Vegetables (56) ■ Grain & Bakery (49) ■ Others (59)

Select the Food Standard



Possible Disconnect?

- Italian Ice is “Water Ice”
- Pasta is “Macaroni Product”

FDA Warnings ...

19 Letters since 2005

- Plant-based ingredient (“Parmesan cheeze,” Just Mayo)
- Formulation issues (colorants added, types of flour, etc.)
- “Technicalities” (source of bottle water)



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Twitter: FDAStorytime

Standards of Identity: Public Health Considerations



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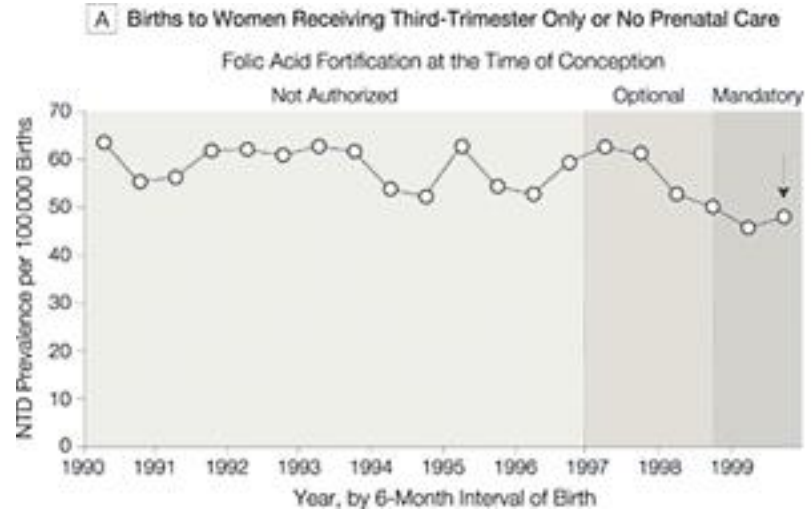
@CSPI; @SarahSorscherDC

www.cspinet.org

Benefits of Standards

- Inform of the nature of the product
- Ensure that product meets expectations
- Ensure good manufacturing practices
- Control the safety of new additives





Folic Acid and Enriched Flour

Broad Statutory Authority



Misbranding/consumer deception required under Pure Food and Drug Act of 1906

United States v. Ten Cases Bred Spred, 49 F.2d 87 (8th Cir. 1931).

Misbranding/consumer deception *not* required under Federal Food, Drug, and Cosmetic Act of 1938:

Federal Security Administrator v. Quaker Oats Co, 318 U.S. 218, 232 (1943); *but see 62 Cases of Jam v U.S.* 340 U.S. 593 (1951) (permitting “imitation” products under statutory exception)

Deregulatory Approach (1970s – 1980s)

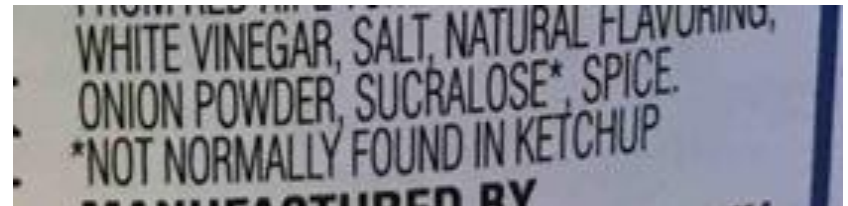
Beginning in the 1970s, FDA has shifted towards reduced reliance on standards:

- Fewer new standards adopted
- Existing standards amended for greater flexibility
- Allowance for common or usual names under 21 C.F.R. § 101.3
 - Must be non-misleading
 - “Imitation” used for “nutritionally inferior” foods



Nutrition Labeling and Education Act of 1990 (NLEA) and 21 CFR § 130.10

- Authorized Nutrient Content Claims (e.g. “Low Fat,” “No Sugar Added”) added to standardized name
- Deviations from the standard permitted to achieve the claim *if*:
 - New ingredients are safe and suitable
 - Product is not nutritionally inferior
 - No changes to mandatory or prohibited ingredients
 - Label declaration required



Is the Current System Adequate?

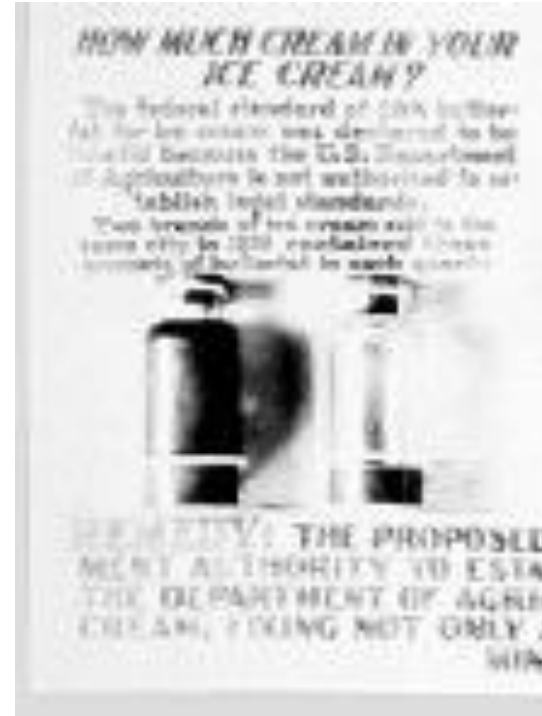


INGREDIENTS: ENRICHED FLOUR [UNBLEACHED WHEAT FLOUR, MALTED BARLEY FLOUR, REDUCED IRON, THIAMINE MONONITRATE (VITAMIN B1), RIBOFLAVIN (VITAMIN B2), NIACIN (VITAMIN B3), FOLIC ACID], WATER, YEAST, SUGAR, SOYBEAN OIL, SALT, WHEAT GLUTEN, MONOGLYCERIDES, DEXTROSE, MODIFIED WHEY, CALCIUM PROPIONATE (A PRESERVATIVE), VINEGAR, SORBIC ACID, SOYBEAN OIL (HYDROGENATED), CALCIUM SULFATE, ARTIFICIAL FLAVOR, CITRIC ACID, ASCORBIC ACID, SOY LECITHIN. CONTAINS WHEAT, MILK AND SOY INGREDIENTS.

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Ongoing Limitations of Standards

- **Milkfat/fat Minimums:**
 - Cheeses
 - Ice cream, frozen custard
 - Buttermilk/milk chocolate
- **Sugar Minimums**
 - Brix levels in juice set a minimum level for “soluble solids”
- **Limits on Substitution (Absent a Nutrient Content Claim):**
 - Cheeses with a federal standard of identity precluded from using a salt substitute like potassium chloride



“Horizontal” versus “Vertical” Approaches

- 2005 Proposed Rule: General Principles and Food Standards Modernization
 - provides for case-by-case petition process, reviewed for consistency with specific principles
- 2006 GMA petition requests that 21 CFR part 130 be amended to create “horizontal” changes “placing standardized foods on equal footing with non-standardized foods.”
- 2019 FDA proposes meeting on “Horizontal Approaches to Food Standards”

Public Health Considerations

- Benefits of case-by-case review through notice-and-comment rulemaking
- Review of regulations prioritized according to public health benefit
- FDA should decide which nutritional changes are beneficial
- Nutritional changes may have unintended consequences
- Standards may interact with other labeling requirements
- Can we trust “safe and suitable” ingredients?



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**Standards of Identity:
Modernization Efforts
and International
Standards**

Seth A. Mailhot, Partner
Leader, FDA Group

September 18, 2019

Overview



- FDA's Modernizing Standards of Identity
- Geographical Indications and International Standards

Modernizing Standards of Identity

- From FDA's Meeting Announcement on Modernizing Standards of Identity (SOI):
 - FDA is interested in modernizing the SOI program in a manner that will achieve three primary goals:
 - 1) protecting consumers against economic adulteration;
 - 2) maintaining the basic nature, essential characteristics, and nutritional integrity of food; and
 - 3) promoting industry innovation and providing flexibility to encourage manufacturers to produce more healthful foods.

Discussion Questions

1. Can the SOI regulations be used to encourage production of more healthful foods, and if so, what changes can be made to accomplish this? How can the SOI regulations act as a barrier to development of healthier foods?
2. What has changed – for example, in manufacturing, food technology, nutritional science, or marketing trends – that FDA should be aware of when reviewing SOI regulations?
3. Other than maintaining the basic nature, essential characteristics, and nutritional integrity of food, what factors might be included in SOI to promote honesty and fair dealing in the interest of consumers?
4. When an existing SOI is under review, how should the agency assess whether the SOI reflects consumer expectations about that food?

Discussion Questions (cont.)

5. In 2005, a proposed rule was issued as a first step in instituting a process to modernize SOI. This rule proposed a set of 13 general principles to consider when establishing, revising, or eliminating a SOI. (70 FR 29214 at 29234-35).
 - Should previously proposed principles be updated to better promote innovation and encourage production of more healthful foods?
 - Are there other principles FDA should consider?
6. Other than the approach proposed in question five, how else could FDA modernize its SOI program, including revising its SOI regulations? How do proposed approaches satisfy FDA's three SOI modernization goals?

SOI General Principles

1. Promotes honesty and fair dealing in the interest of consumers.
2. Describes the basic nature of the food to ensure that consumers are not misled by the name of the food and to meet consumers' expectations of product characteristics and uniformity.
3. Reflects the essential characteristics of the food – or those that define or distinguish a food or describe the distinctive properties of a food and that may contribute to achieving the food's basic nature or may reflect relevant consumer expectations of a food product.
4. Ensures food does not appear to be better or of a greater value than it is. May be used as a vehicle to improve the overall nutritional quality of the food supply.
5. Contains clear and easily understood requirements to facilitate compliance by food manufacturers.

SOI General Principles (cont.)

6. Permits maximum flexibility in the technology used to prepare the food provided the technology does not alter the basic nature or essential characteristics, or adversely affect the nutritional quality or safety, of the food. Provides for any suitable, alternative manufacturing process that accomplishes the desired effect, and describes ingredients as broadly and generically as feasible.
7. Harmonizes with international food standards to the extent feasible.
8. Is simple, easy to use, and consistent among all food standards. Includes only those elements that are necessary to define the basic nature and essential characteristics of a particular food, without unnecessary details.
9. Allows for variations in the physical attributes of the food. Where necessary to provide for specific variations in the physical attributes of a food within the standard, variations are consolidated into a single food standard.

SOI General Principles (cont.)

10. Incorporates general requirements that pertain to multiple food standards of a commodity group into general regulatory provisions that address the commodity group whenever possible.
11. Considers other relevant regulations. Any specific requirements for foods intended for further manufacturing are incorporated within the reference standard rather than provided as a separate standard.
12. Provides terms that can be used to name a food and allows terms to be used in any order that is not misleading to consumers.
13. Names of ingredients and functional use categories in a food standard should be consistent with other food standards and relevant regulations in this chapter, and, when appropriate, incorporate current scientific nomenclature.

Geographical Indications

- Geographical indication (GI): sign used on products that have a specific geographical origin and possess qualities or a reputation that are due to that origin
- In order to appropriately function as a GI, the qualities, characteristics or reputation of the product should be essentially due to the place of origin
- Examples:
 - Roquefort cheese
 - Georgian wine
 - Pinggu Peaches

International Standards of Identity

- Codex Alimentarius: collection of internationally adopted food standards and related texts presented in a uniform manner to:
 - protect consumer health and
 - ensure fair practices in the food trade.
- Publication of the Codex is intended to harmonize definitions and requirements for foods and facilitate international trade
- Codex includes standards for all the principal foods, whether processed, semi-processed or raw
- “All food standards adopted by the Codex Alimentarius Commission will be reviewed by the Food and Drug Administration and will be accepted without change, accepted with change, or not accepted.” 21 C.F.R. 130.6(a)

QUESTIONS?



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Seth's practice includes representation of the medical device, pharmaceutical, dietary supplement, tobacco and food industries, and covers both premarket and post-market issues. His practice is focused on development of premarket submission strategies, and FDA enforcement of good manufacturing practices, both domestically and abroad.

Admissions

- California
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- New England School of Law, J.D., Valedictorian, *summa cum laude*
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