



Overview of U.S. Food Law and Regulation

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TOPICS

- The Basics - Definitions
- Sources of Law
- Evolution of FFDCA and FDA's Regulatory Authority
- Science and the Law
- Other Key Federal and State Regulators
- States and FDA
- Food Facility Registration



THE BASICS

Key Definitions

- 21 USC § 321(f): **“Food”**
 - “Articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such article.”
 - Ordinarily used for taste, aroma, or nutritive value

Key Definitions

- 21 USC § 321(ff): **“Dietary supplement”**
 - intended to supplement the diet
 - bears or contains
 - (A) a vitamin;
 - (B) a mineral;
 - (C) an herb or other botanical;
 - (D) an amino acid;
 - (E) a dietary substance to supplement the diet; or
 - (F) a concentrate, metabolite, constituent, extract, or combination of the above
 - intended for ingestion
 - not represented for use as a conventional food
- Type of “food”

Key Definitions

- 21 USC § 321(g): “**Drug**”
 - Intended to treat, cure or prevent disease
 - Intended to affect the structure or function of the body (except food)
- Drugs require either –
 - Premarket approval or
 - Conformance to OTC monograph

Intended Use

- A product's "intended use" is a key factor in determining how it will be regulated
- Foods
 - Conventional Foods
 - Dietary Supplements
 - Infant Formula
 - Medical Foods
- The same formulation may be regulated as a cosmetic, supplement, food, or drug – it depends on the **claims**.

What Is This?



- a) Food
- b) Dietary Supplement
- c) Drug
- d) Other

What Is This?



- a) Food
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- c) Drug
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What Is This?

For treatment of constipation.



- a) Food
- b) Dietary Supplement
- c) Drug
- d) Other

What Is This?



Contains
Melatonin

- a) Food
- b) Dietary Supplement
- c) Drug
- d) Other

“Dietary
Supplement”



SOURCES OF LAW

Sources of Law

- U.S. Constitution
- Statutes
- Regulations
- Case Law

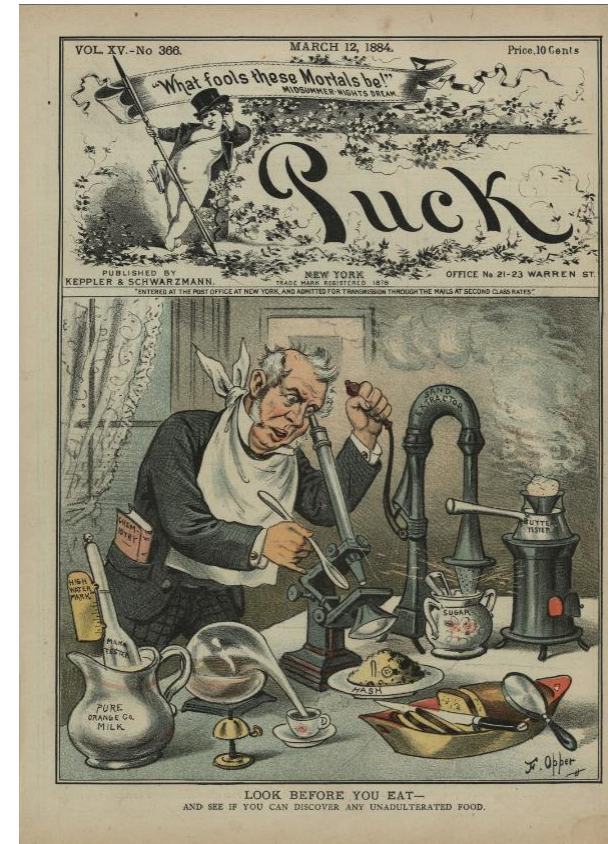


HISTORY OF THE FEDERAL FOOD, DRUG, & COSMETIC ACT

The “FFDCA”

Early Food Law History

- 1785 – Massachusetts enacts first food adulteration law
- 1862 – Bureau of Chemistry (within USDA)
- 1906 – Pure Food and Drug Act
 - Influenced by Upton Sinclair's 1906 novel *The Jungle*
 - Authority to the USDA Bureau of Chemistry
 - Premised on adulteration and misbranding
 - Authorized criminal prosecutions and seizures for violative products
- Continued proliferation of inferior products – Example: “BRED-SPRED”



Federal Food, Drug and Cosmetic Act of 1938

- 1938 law established all the major elements of FDA's food regulations to this day
- Premised on expanded concepts of adulteration and misbranding
 - Prohibits the introduction into commerce of adulterated or misbranded product (or adulterating or misbranding product already in commerce).

Federal Food, Drug and Cosmetic Act of 1938 (cont'd)

- Authorized FDA to establish food standards of identity
- Authorized factory inspections
- Key enforcement tools: seizure, injunctions, criminal prosecutions
- Based on “interstate commerce”

Adulteration (FFDCA § 402)

- Food safety
- Poisonous or deleterious substances (if injurious)
- Contamination or potential contamination with filth
- Putrid or decomposed substances, otherwise unfit for food
- Unapproved food additives
- Insanitary conditions
- Economic adulteration
- (See statute for even more...)

See FFDCA § 402; 21 U.S.C. § 342.

Misbranding (FFDCA § 403)

- False or misleading statements on food label/labeling
- Misrepresentation related to standard of identity and/or “imitation”
- Failing to comply with other labeling requirements specified by the FFDCA
 - Missing mandatory label elements
 - Incorrect nutritional information
 - Unauthorized nutrient content claims or health claims
 - (See detailed list in statute)

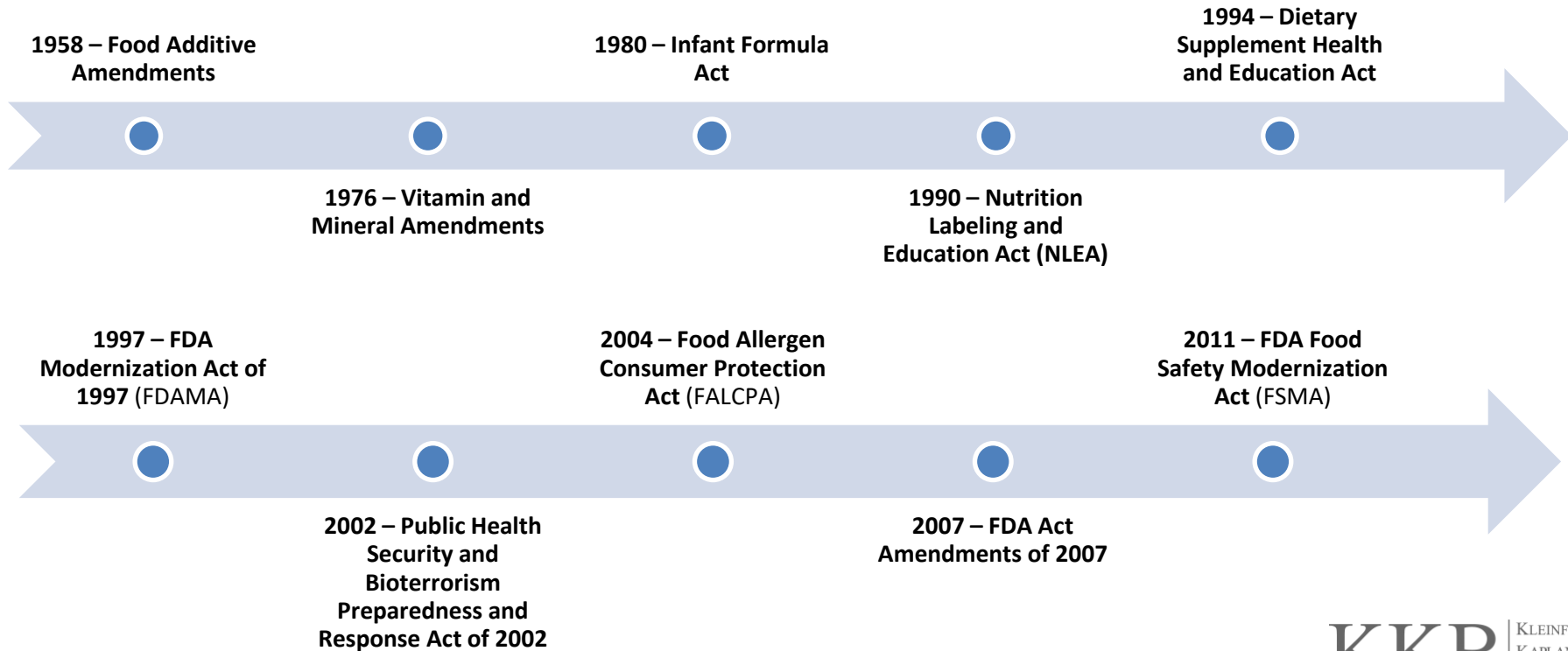
See FFDCA 403; 21 U.S.C. § 343.

Interstate Commerce

- Law reflects national scope of food production and distribution
- Has been subject of expanding Supreme Court interpretations over the years
- Broad interpretation = Virtually all products
- FFDCA:
 - “Introduction or delivery for introduction into interstate commerce,” OR
 - “Receipt in interstate commerce”

See FFDCA 301; 21 U.S.C. § 331.

Expanding the FFDCA





Science and the Law

Science and the Law

- Scientific analysis deeply embedded in FFDCA
 - Companies, FDA, or both often required to make scientific determinations
- Example: Adulteration
 - Microbiological analysis, toxicological studies, contaminant analysis, etc. to demonstrate presence of poisonous or deleterious substance
 - Use of genetic sequencing to identify outbreaks
 - Scientific support for food processing systems (e.g., validating critical limits)

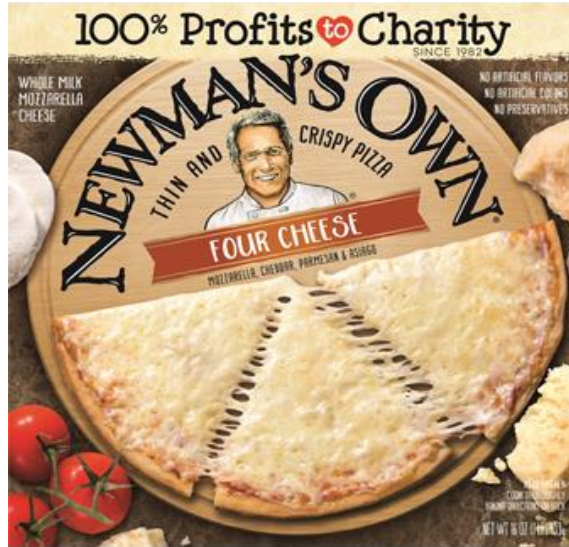
Science and the Law (cont'd)

- Example: Misbranding
 - Nutrient analysis used to verify nutritional information
 - Scientific studies to substantiate claims (especially health claims and structure/function claims)



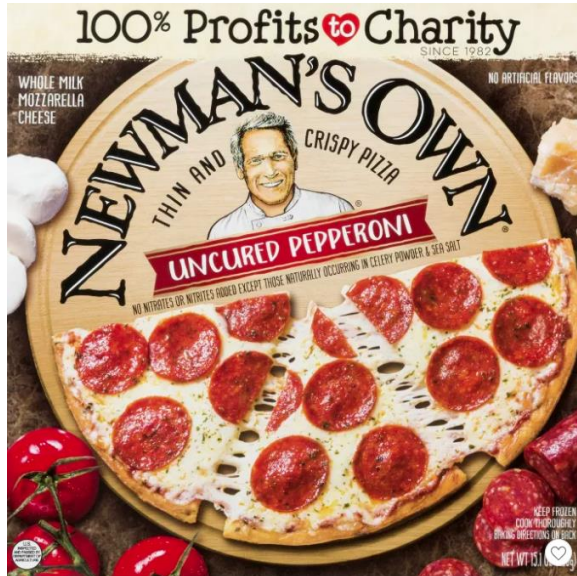
Who Else is Involved?

Who Regulates This?



- a) Food and Drug Administration
- b) US Department of Agriculture
- c) Alcohol and Tobacco Tax and Trade Bureau
- d) Other

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Other Key Food Regulators - USDA

- Food Safety and Inspection Service (FSIS)
 - Key statutes:
 - Federal Meat Inspection Act (FMIA)
 - Poultry Products Inspection Act (PPIA)
 - Similar frameworks as FFDCA (adulteration and misbranding)
 - Regulates meat, poultry, and “egg products”
 - Generally, >2% cooked or >3% raw meat or poultry is considered under FSIS jurisdiction
 - Products represented as meat or poultry product fall under FSIS jurisdiction
 - More premarket-oriented than FFDCA –
 - Continuous inspections
 - Label pre-approval required (for some)

FDA vs. USDA (abridged)

FDA	USDA
Non-specified red meats (bison, rabbits, deer, game animals, zoo animals)	Cattle, sheep, swine, goats, horses, mules, other equines
Non-specified birds (wild turkeys, wild ducks, wild geese)	Ratites, squab, domesticated birds (chickens, ducks, turkeys, guineas)
Products with $\leq 3\%$ raw meat, $< 2\%$ cooked meat, or $< 30\%$ fat, tallow, meat extract	Products with $\geq 3\%$ raw meat, $>2\%$ cooked meat, or $>30\%$ fat, tallow, meat extract
Closed-face sandwiches	Open-face sandwiches
Shell eggs, other egg products	Dried, frozen, liquid eggs

Other Key Food Regulators - USDA

- Agriculture Marketing Service (AMS)
 - Voluntary grading and quality services (e.g., Prime Beef, Grade AA Eggs)
 - Administers the National Organic Program and the new Bioengineered Food Disclosure Standard
- Others
 - Animal and Plant Health Inspection Service (APHIS)
 - Agricultural Research Service (ARS)



Who Regulates This?



- a) Food and Drug Administration
- b) U.S. Department of Agriculture
- c) Alcohol and Tobacco Tax and Trade Bureau
- d) Other

Other Key Food Regulators

- Treasury Department
 - Alcohol and Tobacco Tax and Trade Bureau (TTB)
- Dep't of Health and Human Services
 - Centers for Disease Control and Prevention (CDC)
- Environmental Protection Agency (EPA)
- Department of Homeland Security
 - U.S. Customs and Border Protection (CBP)

Other Key Food Regulators - FTC

- Regulates advertising under authority of the Federal Trade Commission Act (FTC Act)
 - Regulate commercial advertising in general
 - “Unfair and deceptive acts or practices”
 - “False advertisements” = “misleading in any material respect”
- Relationship with FDA
- Enforces primarily through litigation (*consider* National Advertising Division of BBB)
- State attorneys general exercise similar authority

Other Key Food Regulators

- State and Local
 - State Agriculture and Health Departments
 - Attorneys General
 - Local health departments (County/City)
 - Weights and measures
- International Standard-Setting and Policy Setting Bodies
 - Codex Alimentarius, and many others!

Other Statutes – Beyond FFDCA

- **Public Health Service Act**
- Filled Milk Act
- Federal Import Milk Act
- **Fair Packaging and Labeling Act**
- **Federal Trade Commission Act**
- Federal Insecticide, Fungicide, and Rodenticide Act
- Packers and Stockyards Act
- **Egg Products Inspection Act**
- **Federal Meat Inspection Act**
- **Poultry Products Inspection Act**
- Agricultural Marketing Act
- Animal Health Protection Act
- Animal Welfare Act
- Plant Protection Act
- State laws
- And more!

States and the FDA

- “Mini FFDCA” laws
 - Almost all states have laws that resemble the FFDCA and the FTC Act
 - Some expressly incorporate the FFDCA and/or FDA regulations
- State law causes of action – private rights of action for consumers
 - **Significant class action litigations regarding food labeling**

States and the FDA

- **“Food Codes”**
 - Based on FDA Model Food Code
 - Focused on retail/restaurant sanitation and safety
- **Supporting FDA inspections**
- **States/localities step in federal gaps**



Food Facility Registration

Food Facility Registration

- **Who:** Domestic & foreign facilities engaged in manufacturing, processing, packing, or holding food for consumption in the U.S.
- **What:** Register with FDA
- **When:** Before beginning to manufacture/process, pack, or hold food for consumption in the U.S.

See 21 CFR Part 1, Subpart H

Food Facility Registration (cont'd)

- **Why:** Helps FDA determine location and source of potential bioterrorism incident or foodborne illness outbreak and notify facilities that may be affected
- **Excluded:** Food contact substances, pesticides; certain food facilities are exempt (see 21 CFR 1.226)
- **Cost:** Free!
- **What Else?** Submit electronically (unless waiver); Renew every other year between 10/1 and 12/31

Food Facility Registration (cont'd)

- **For up-to-date information, see FDA website and guidances:**

<https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/registration-food-facilities-and-other-submissions>

Three Golden Rules of Food Law

- **Intended use matters!**
- **Do not introduce adulterated food into commerce**
- **Do not introduce misbranded food into commerce**



Thank You! *Questions?*

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