Overview of US Food Law and Regulation

FDLI Intro to Food Law

Veronica Colas, Senior Associate

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Topics

• Constitutional and Administrative Law 101
• Evolution of FFDCA and FDA’s Regulatory Authority
• Additional Key Concepts
• Other Key Federal and State Regulators
Constitutional and Admin Law 101
The 5 Minute JD
Laws and Regulations

Civics 101

• Congress enacts statutes based on its Constitutional powers
  – Laws may be self-implementing or require agency development of rules
  – Delegates execution of the law to the Executive Branch
    – Includes interpretation, implementation, and enforcement
  – “Commerce Clause” of the Constitution is a commonly used source of authority for regulatory programs

• What is the “the law”?
  – Plain language of the statute – if the plain language addresses a situation the analysis should stop there
  – Legislative history (given less weight)
  – Court and agency interpretations
Laws and Regulations

Civics 101

• The Rulemaking Process
  – Rules must derive from statutory rulemaking authority
  – Formal rulemaking (evidentiary)
  – Informal rulemaking (notice and comment)
Laws and Regulations

Civics 101

• Notice and Comment Process
  – Advanced Notice of Proposed Rulemaking – “Thinking about it”
  – Proposed Rule – “Tentative conclusions... speak now, or...”
  – Final Rule – “Comply or Else”
    – Effective date
    – Compliance date

• Administrative Requirements
  – Executive Orders
  – Office of Management and Budget
Laws and Regulations

Civics 101

• Administrative Procedure Act (APA)
  – Dictates how government agencies must conduct business
  – Check on agency power
  – Provides for Judicial Review of agency actions
    – Agencies afforded substantial deference based on expertise
    – “Arbitrary and capricious” standard
    – Difficult to get a court to overturn an agency regulation, although not impossible
History of 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
  – Regulatory authority severely restricted by court decisions
Early Food Law History

Harvey Wiley – First Chief Chemist after 1906 Pure Food & Drug Act
Federal Food, Drug and Cosmetic Act of 1938

- 1938 law established all the major elements of FDA’s food regulation 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)
- Authorized FDA to establish food standards of identity
- Key enforcement tools: seizures, injunctions, criminal prosecutions
- Based on “interstate commerce”
Federal Food, Drug and Cosmetic Act of 1938

• Adulteration (§ 402)
  – Food Safety
  – Poisonous or deleterious substances
  – Contamination or potential contamination with filth
  – Putrid or decomposed substances
  – Unapproved food additives
  – Insanitary conditions
  – Economic adulteration
  – (More in the statute)
Federal Food, Drug and Cosmetic Act of 1938

- **Misbranding (§ 403)**
  - False or misleading statements on food label / labeling
  - Omission of material facts
  - Failing to comply with the numerous other labeling requirements specified by the FFCA
    - Missing mandatory label elements
    - Incorrect nutritional information
    - Unauthorized nutrient content or health claims
    - (Very detailed list in the statute)
Federal Food, Drug and Cosmetic Act of 1938

- Interstate Commerce
  - Law reflects national scope of food production and distribution
  - Has been the subject of expanding Supreme Court interpretations over the years
  - Now broadly interpreted such that virtually all products are within “interstate commerce”
  - FFDCA:
    - “introduction or delivery for introduction into interstate commerce” or
    - “receipt in interstate commerce”
Expanding the FFDCA

Key Laws and Amendments

1958
Food Additive Amendments
- Requires manufacturers to demonstrate safety of ingredients before using them in food
- Gave FDA pre-market authority over ingredients

1976
Vitamin and Mineral Amendments
- Prevented FDA from setting upper limits for vitamins and minerals and treating a product as a drug based solely on potency

1980
Infant Formula Act
- Gave FDA authority to set nutritional standards for infant formula

1990
Nutrition Labeling and Education Act (NLEA)
- Mandatory nutrition labeling
- Nutrient Content Claims
- Health Claims

1994
Dietary Supplement Health and Education Act (DSHEA)
- Dietary supplement labeling
- Dietary supplement Good Manufacturing Practices (GMPs)

1997
FDA Modernization Act of 1997 (FDAMA)
- Authorized expanded health claims

1997
Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act or BT Act)
- Facility registration

2002
Food Allergen Consumer Protection Act (FALCPA)
- Requires “Big 8” allergen labeling
# Expanding the FFDCA

## Key Laws and Amendments

<table>
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<th>2007</th>
<th>2011</th>
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<tr>
<td><strong>FDA Act Amendments of 2007</strong></td>
<td><strong>FDA Food Safety Modernization Act (FSMA)</strong></td>
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<tr>
<td>• Reportable Food Registry</td>
<td>• Preventive Controls and enhanced supply chain oversight</td>
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<td>• Food Defense</td>
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<td>• Facility Suspension</td>
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<td>• Mandatory Recall Authority</td>
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<td>• Enhanced emergency records Access</td>
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Enforcement and Policymaking

• Early enforcement
  – Largely driven by individual civil and criminal prosecutions
  – Focused on “post-market” surveillance
  – Emphasis on food standards and economic adulteration

• 1950s and 1960s
  – Turn toward “pre-market” approvals (ingredients)

• 1970s and 1980s
  – Increased emphasis on rulemaking → regulations and preambles
  – Continued criminal prosecutions

• 1990s and early 2000s
  – Increased emphasis on guidance clarifying and applying regulations
  – Growing use of Warning Letters and public statements to encourage compliance
  – Fewer prosecutions

• Late 2000s – onward
  – Rulemaking and substantial guidance
  – Introduction of high-tech genetic testing and sophisticated foodborne illness tracking
  – Reinvigorated use of criminal prosecutions
Federal Food, Drug and Cosmetic Act

- **Where things stand now**
  - Still centers on Adulteration and Misbranding

- **Adulteration**
  - Harmful substances in the food
  - Manufacturing safety and insanitary conditions
  - Ingredient safety

- **Misbranding**
  - Product Names and Standards
  - Nutritional Labeling
  - Claims
Key Definitions

“Food”

• “Articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such article.”

• In recognition of the circuitous nature of this definition, the courts have further defined foods as “articles used primarily for taste, aroma, or nutritive value.”
Key Definitions

“Drug”

• “(A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

• (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

• (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals;

• and (D) articles intended for use a component of articles in clause (A), (B), (C).”
Key Definitions

“Dietary Supplement”

• A type of “food”

• Product (other than tobacco) that is intended to supplement the diet that contains one or more dietary ingredients

• Dietary ingredient:
  – Vitamin, mineral
  – herb or other botanical
  – amino acid
  – dietary substance for use by man to supplement the diet by increasing total dietary intake or
  – a concentrate, metabolite, constituent, extract, or combination of ingredients described above
Intended Use

• A product’s “intended use” is a key factor in determining how it will be regulated
  – Foods vs. Drugs vs. Devices vs. Tobacco Product vs. Cosmetics

• Foods
  – Conventional Foods
  – Infant Formula
  – Medical Foods
  – Dietary Supplement
Intended Use

• Can the same formulation be regulated as a cosmetic, supplement, food, and drug?
  – Yes, depending on the claims
Science and the Law

- **Scientific analysis is deeply embedded into the FFDCA**
  - Companies, FDA, or both often required to make scientific determinations

- **Examples:**
  - **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)
  - **Misbranding**
    - Nutrient analysis used to verify nutritional information
    - Scientific studies to substantiate claims (especially health claims and structure/function claims)
Who Else is Involved?
Other Key Food Regulators

Federal

- Dept. Health and Human Services
  - Food and Drug Administration (FDA)
  - Center for Disease Control and Prevention (CDC)

- USDA
  - Food Safety and Inspection Service (FSIS)
  - Agriculture Marketing Service (AMS)
  - Animal and Plant Health Inspection Service (APHIS)
  - Agricultural Research Service (ARS)
  - Foreign Agricultural Service (FAS)

- Federal Trade Commission (FTC)
- Environmental Protection Agency (EPA)
- Treasury Department
  - Alcohol and Tobacco Tax and Trade Bureau (TTB)
- Department of Homeland Security
  - U.S. Customs and Board Protection (CBP)
Other Key Food Regulators

State and Local

• State Agriculture and Health Departments
• Attorneys General/NAAG
• Local health departments (County/city)
• Weights and measures
• Environmental

Others

• International Standard-Setting and Policy Setting Bodies
  – Codex Alimentarius
  – World Health Organization
  – World Trade Organization
  – Many others!
Other Statutes

Beyond the 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**
- Humane Methods of Slaughter 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
  – Traditional tort law
  – Product liability laws
  – Consumer deception laws
    – Some make violating the FFDCA a *per se* deceptive practice
  – Significant class action litigation regarding food labeling (thousands of cases filed)
States and the FDA

• “Food Codes”
  – Based on FDA Model Food Code
  – Focused on retail / restaurant sanitation and safety

• Supporting FDA inspections
  – State officials can be deputized to conduct inspection on behalf of FDA

• States/localities can step in in certain areas where FDA has indicated an unwillingness, a lack of resources, or a lack of statutory authority to do so
  – Warnings
    – California’s Proposition 65
    – NYC and Philadelphia sodium warnings
Federal Preemption

When state and federal law conflict

- **Conflict Preemption**
  - If direct conflict between federal and state law, federal law prevails
  - Narrow in practice

- **Implied Preemption**
  - When the federal regulatory program “occupies the field”
  - Extremely limited application

- **Express Preemption**
  - When Congress specifically says a federal law preempts state law
  - E.g., FFDCA provides express preemption for nutrition & menu labeling and other provisions
  - Carve-out from FFDCA preemption for warning requirements
Other Federal Regulators and Their Authorities

USDA’s Food Safety and Inspection Service (FSIS)

• Regulates meat, poultry, and “egg products”
  – Generally, >2% cooked or >3% raw meat or poultry is considered under FSIS jurisdiction
  – Products represented as a meat or poultry product fall under FSIS jurisdiction

• Key statutes:
  – Federal Meat Inspection Act (FMIA)
  – Poultry Products Inspection Act (PPIA)
  – Similar frameworks as FFDCA (adulteration and misbranding)

• More pre-market-oriented than FFDCA:
  – “Continuous Inspection”
  – Label approval
Other Federal Regulators and Their Authorities

USDA – Other Agencies

• Agricultural Marketing Service (AMS)
  – Voluntary grading and quality services (e.g., Prime Beef, Grade AA Eggs, AMS Process Verified No Antibiotics Ever)
  – Administers the National Organic Program and the new Bioengineered Food Disclosure Standard

• Animal and Plant Health Inspection Service (APHIS)
  – Animal and plant disease control programs
  – Sanitary / Phytosanitary (SPS) requirements for border entry
Other Federal Regulators and Their Authorities

Federal Trade Commission

• Regulates advertising under authority of the Federal Trade Commission Act (FTC Act)
  – Section 5 of the FTCA gives the FTC authority to regulate commercial advertising in general and prohibits both "unfair and deceptive acts or practices."
  – Section 12 prohibits false advertisements likely to induce the purchase of food, drugs, or cosmetics. Section 15 defines a false advertisement as one which is "misleading in any material respect."

• Relationship with FDA
  – FTC has primary jurisdiction over advertising; FDA has primary jurisdiction over the label and labeling (both agencies assert jurisdiction over websites and social media)
  – FTC advertising guidance incorporates FDA’s standards for claims

• Enforces primarily through litigation
• State attorneys general exercise similar authority
Federal Food Laws in Nutshell

• Three golden rules of food law:
  1. Intended use matters!
  2. You can’t introduce adulterated food into commerce
  3. You can’t introduce misbranded food into commerce
Questions?
Contact Information

Veronica Colas
Senior Associate, Washington DC
+1 202 637 6937
Veronica.Colas@hoganlovells.com
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