Overview of US Food Law and Regulation

FDLI Intro to Food Law

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Topics

• Constitutional and Administrative Law 101
• Evolution of the FFDCA and FDA’s Regulatory Authority
• Additional Key Concepts
• Other Key Federal and State Regulators
Constitutional and Admin Law 101

The 5 Minute JD
• All federal authority must originate in the Constitution
• Congress enacts statutes based on its Constitutional powers
  – 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
  – Legislative history
  – Court and agency interpretations
Civics 101

The Rulemaking Process

- Rule: “the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefore or of valuations, costs, or accounting, or practices bearing on any of the foregoing”

- Rules must derive from statutory rulemaking authority

- Formal rulemaking (evidentiary)

- Informal rulemaking (notice and comment)
Civics 101

- **Notice and Comment Process**
  - Advanced Notice of Proposed Rulemaking – “Thinking about it”
  - Proposed Rule – “Tentative conclusions”
  - Final Rule – “Time to Comply”

- **Administrative Requirements**
  - Executive Orders
  - Office of Management and Budget review
Laws and Regulations

Civics 101

• Administrative Procedure Act (APA)
  – Passed in 1946
  – Reaction to expanded New Deal federal authority
  – Dictates the manner in which 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
    – Process over substance (at times)
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
  – Tied to activities in interstate commerce
  – 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

• Based on “interstate commerce”

• 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

• Key enforcement tools: seizures, injunctions, criminal prosecutions
• 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)**
  - Labels/Labeling
  - False or misleading statements of food label / labeling
  - 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
  – Term of art in Constitutional Law
  – 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

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

2004
Food Allergen Consumer Protection Act (FALCPA)
- Requires “Big 8” allergen labeling
## Expanding the FFDCA

### Key Laws and Amendments

<table>
<thead>
<tr>
<th>Year</th>
<th>Key Laws and Amendments</th>
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<tbody>
<tr>
<td>2007</td>
<td><strong>FDA Act Amendments of 2007</strong></td>
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<tr>
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<td>- Reportable Food Registry</td>
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<td>2011</td>
<td><strong>FDA Food Safety Modernization Act</strong> (FSMA)</td>
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<td></td>
<td>- Preventive Controls and enhanced supply chain oversight</td>
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<td></td>
<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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<td>2021</td>
<td><strong>Food Allergen Safety, Treatment, Education, and Research Act</strong> (FASTER)</td>
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<td>- Adds sesame as the 9th major food allergen that must be declared</td>
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<td>2022</td>
<td><strong>Food and Drug Omnibus Reform Act of 2022</strong> (FDORA)</td>
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<td>- Significant biologic, cosmetic, drug, and device, developments</td>
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<td>- New infant formula requirements and authorities</td>
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<td>- Directs FDA to establish “Office of Critical Foods” to oversee infant formula and medical foods</td>
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<td>- Critical food manufacturers must notify FDA of supply chain disruptions</td>
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<td>- Inspection targets for infant formula facilities</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
Enforcement and Policymaking cont. . .

• Where things stand now
  – Still centers on Adulteration and Misbranding

• Adulteration
  – Harmful substances in the food
  – Manufacturing safety and insanitary conditions
    – Foodborne illness outbreaks
  – Ingredient safety

• Misbranding
  – Product Names and Standards
  – Nutritional Labeling
  – Claims

• Enforcement by Department of Justice Consumer Protection Branch
  – A number of recent high profile criminal food safety matters in the last four years
Additional Key Concepts
Key Definitions

“Food”

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

• Judicial Interpretation
  – 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”

- **Statutory Definition:** Drugs are defined as
  
  - “(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).”
“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
• 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

- “This tablet provides 100% RDI for Vitamin C” → Food/Supplement

- “The vitamin C in this tablet cures flu symptoms” → Drug
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

- 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)
- Dept. Health and Human Services
  - Food and Drug Administration (FDA)
  - Centers for Disease Control and Prevention (CDC)
- 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
  – State laws provide private rights of action for consumers
  – Traditional tort law
  – Products liability laws
  – Consumer deception laws
    – Some make violating the FFDCA a per se deceptive practice
    – Significant class action litigation regarding food labeling (hundreds of cases filed annually)
States and the FDA

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

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

• States at times step into areas where FDA has not taken action
  – California’s Proposition 65, ingredient bans, heavy metal testing requirements for baby food
  – GMO Labeling (now preempted by a federal program to be developed by USDA)
  – Animal husbandry/raising claims requirements
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 Nutrition Labeling
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
  – Difference in approach rooted in *The Jungle* and contemporary reactions
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

• Animal and Plant Health Inspection Service (APHIS)
  – Animal and plant disease control programs
  – Sanitary / Phytosanitary (SPS) requirements for border entry
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
  – MOU
  – FTC advertising guidance incorporates FDA’s standards for claims

• Enforces primarily through litigation

• State attorneys general exercise similar authority
Questions?
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