

Federal Regulation of the Food Industry—Part 2: Federal Regulatory Agencies¹

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In general, the federal government is organized into departments, independent establishments, and government corporations. Federal departments are composed of federal agencies that are *each* an authority of the federal government, often in a particular field of expertise (e.g., environmentalism or national defense). Agencies can either be executive agencies, subject to the authority of the president, or legislative agencies under authority of Congress. An independent establishment (or agency) or government corporation is not part of a department, and for the most part, is regarded as independent of the authority of the executive branch, as intended by Congress. Federal agencies can have both quasi-legislative and quasi-judicial power; the capability of passing legally binding regulations, and via its own administrative judicial processes, issue judicial decisions in individual cases.

The following provides a general overview of federal government organizations with emphasis on those agencies involved with the regulation of the food industry.

Federal Departments

The executive branch of the US government oversees the fifteen departments listed in the Appendix. The director of each department (i.e., secretary) is a cabinet-level appointment by the president.

The federal departments and agencies directly or indirectly involved in the regulation of the food industry are discussed below.

Department of Health and Human Services (HHS)

FOOD AND DRUG ADMINISTRATION

The Food and Drug Administration (FDA) is the primary regulatory agency impacting the food industry with regard to food safety, food adulteration, and food labeling or misbranding. The majority of the food-related regulatory activity is within the Human Foods Program (HFP). This program oversees domestic and imported food (including shell eggs, bottled water, and wine beverages with less than 7% alcohol) sold in interstate commerce, except meat, poultry, and processed egg products (which fall under the U.S. Department of Agriculture's [USDA] Food Safety and Inspection Service).

The FDA is the primary enforcement agency for the following federal acts:

- Federal Food, Drug & Cosmetic Act (FDCA);
- Nutritional Labeling & Education Act (NLEA); and
- Dietary Supplement Health & Education Act (DSHEA).

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Under authority of the Federal Food, Drug and Cosmetic Act (FDCA), the FDA has primary jurisdiction for the prevention of *adulteration* and *misbranding* of foods, drugs, and cosmetics sold in interstate commerce.

Under the FDCA, a food is generally considered *adulterated* if it contains a residue of a physical, chemical, or microbial agent at an unsafe level. Thus, the FDA has authority for monitoring the safety of food products through the inspection of food processing and handling facilities, and the examination of food stuffs for the presence of physical, chemical, and microbial contamination. In addition, the agency has authority for regulating, approving, and monitoring the safety of substances directly or indirectly added to foods or animal feeds (e.g., generally recognized as safe [GRAS] substances, food additives, color additives, and animal drugs); the enforcement of pesticide residue tolerances set by the Environmental Protection Agency (EPA); and the enforcement of defect action levels for filth in foods. In addition to the presence of an unsafe level of a substance, a food is also considered adulterated under the FDCA if a food product is deemed to be prepared, packed, or held under unsanitary conditions or has not been manufactured under current Good Manufacturing Practices (cGMPs) (21 C.F.R. § 110). The FDA has further implemented regulations requiring the Hazard Analysis Critical Control Point (HACCP) system for seafood products (HHS FDA 1995) and fruit and vegetable juice products (HHS FDA 2001). Finally, FDA regulations under FDCA protect the consumer from economically adulterated food (e.g., concealed damage, product made to appear of greater value, or an omission or substitution of constituents).

A packaged food product is considered *misbranded* under FDCA if the label or labeling is considered false or misleading, or if it is not labeled in accordance with FDA labeling regulations (21 C.F.R. § 101). Further, packaged food products must have appropriate nutrition information in accordance with the Nutritional Labeling and Education Act (NLEA), and dietary supplements must be appropriately labeled in accordance with the Dietary Supplement Health and Education Act (DSHEA).

The FDA also has enforcement jurisdiction for provisions of the following acts (where applicable to foods, drugs, medical devices, and biological materials):

- Fair Packaging & Labeling Act (FPLA);
- Public Health Service Act (PHSA); and
- Public Health Security and Bioterrorism Preparedness and Response Act.

The Fair Packaging & Labeling Act (FPLA) gives the FDA general authority for developing and implementing food, drug, and cosmetic labeling requirements. Under the Public Health Service Act (PHSA), the agency has additional authority to protect the health of the nation against impure food, drugs, and cosmetics. The FDA has authority to develop model codes and ordinances, guidelines, and interpretations for implementing cooperative state/federal programs for fluid milk and milk products, shellfish, and retail foods. In addition, the FDA administers the Interstate Travel Sanitation (ITS) program in which FDA agents inspect the food service on interstate carriers (e.g., domestic trains, boats, airplanes, and related conveyances that serve meals while traveling interstate).

With passage of the Public Health Security and Bioterrorism Preparedness and Response Act (a.k.a. Bioterrorism Act), the FDA was given increased authority for prevention of food adulteration. Among other things, this act strengthened the FDA's role in the regulation of imported food products and its relationships with state and federal agencies.

NATIONAL INSTITUTES OF HEALTH (NIH)

The National Institutes of Health (NIH) is composed of several highly specialized research- and education-based bodies, termed institutes and centers. These institutes and centers are primarily organized under the authority of the Public Health Service Act plus related acts. The NIH bodies that have the most impact on the food industry and potentially its regulation include National Cancer Institute (NCI); National Heart, Lung, and Blood Institute (NHLBI); National Institute on Alcohol Abuse and Alcoholism (NIAAA); and National Institute of Child Health and Human Development (NICHD).

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

The Centers for Disease Control and Prevention (CDC) is organized into 13 centers, institutes, and offices. Drawing authority from the Public Health Service Act, the CDC works cooperatively with local and state health officials in the investigation and epidemiology of food-borne illness outbreaks, maintains a nationwide system of surveillance and reporting of food-borne illness, and conducts research and education programs in food-borne illness. In addition, under the Vessel Sanitation Program (VSP), the CDC has enforcement authority for the inspection of cruise ships and related vessels that operate in international waters but dock in the United States.

Department of Agriculture (USDA)

The Department of Agriculture (USDA) is an extremely large department with broadly based programs. The numerous USDA agencies provide a diverse array of functions related to marketability, sustainability, quality, and safety of agricultural commodities. The organizational structure of the department includes several agencies that offer a variety of programs, many of which are provided as a service to agricultural industries. Thus, many USDA agencies are not regulatory in nature. While a wide array of federal acts provide the framework for USDA programs, those with the most impact on food regulations and activities include the

- Agricultural Marketing Act;
- Perishable Agricultural Commodities Act;
- Federal Seed Act;
- Federal Meat Inspection Act;
- Poultry Products Inspection Act;
- Humane Slaughter Act; and
- Egg Products Inspection Act.

The USDA, under the direction of the secretary of agriculture, is organized into several federal bodies, including Natural Resources and the Environment; Foreign Agriculture Service Rural Development; Food and Nutrition Service; Food Safety and Inspection Service; Research, Education and Economics; and Marketing and Regulatory Programs. Selected USDA agencies with involvement with the food regulatory system are discussed in the next two sections.

FOOD SAFETY

The Food Safety and Inspection Service (FSIS) is the primary food safety regulatory agency within the USDA and has regulatory authority for all domestic and imported processed egg products, raw meat and poultry, and processed meat and poultry products (e.g., products containing 3% or more of raw meat or poultry, or 2% or more of cooked meat or poultry).

In general, under the Federal Meat Inspection Act (FMIA), the FSIS monitors and regulates the safety and wholesomeness of meat and meat products from slaughtered animals (e.g., cattle, goats, sheep, hogs) in interstate commerce and ensures that imported meat and meat products are regulated under an equivalent inspection program. The FMIA was amended in 1967 (often termed the Wholesome Meat Act) to ensure that meat and meat products in intrastate commerce are regulated under the FSIS inspection program (or equivalent program). The meat inspection program is

very comprehensive in that it includes carcass inspection (post-mortem and anti-mortem) for wholesomeness as well as sanitation requirements for meat slaughtering and processing facilities.

The FSIS poultry and poultry products inspection program under the Poultry Products Inspection Act (PPIA) is similar to that for meat and meat products. The agency monitors and regulates the safety of domestic and imported poultry and poultry products in interstate and intrastate commerce through post-mortem and anti-mortem carcass inspection for wholesomeness and facility sanitation requirements. In addition, the FSIS has implemented extensive *Pathogen Reduction* and *HACCP Regulations* for the meats and poultry industries (USDA FSIS 1996).

Finally, the FSIS has authority to monitor and regulate the safety of egg products under the Egg Product Inspection Act (EPIA). Products covered under this act include processed eggs and egg products (e.g., liquid, dried, frozen), and does not include shell eggs (table eggs), which fall under FDA jurisdiction.

FSIS also enforces labeling requirements and approves labels for meat, poultry, and egg products (9 CFR § 317) to assure that these products are properly marked, labeled, and packaged. In addition, the agency has implemented nutritional labeling regulations for these products.

MARKETING AND REGULATORY PROGRAMS (MRP)

A. Agricultural Marketing Service (AMS)

While more than 30 federal acts empower the Agricultural Marketing Service (AMS) to conduct its programs, most of the food-related activity involves the Agriculture Marketing Act and Perishable Agricultural Commodities Act (PACA). The AMS is generally not considered a regulatory agency, because it provides voluntary standardization, grading, and market news services for specific agricultural commodities. The following program areas are involved: cotton, dairy, poultry, fruit and vegetable, livestock and seed, and tobacco. In addition, the AMS

- oversees marketing agreements and federal pricing orders,
- administers research and promotion programs,
- provides analytical testing and data analyses,
- facilitates import and export certification programs for these selected commodities, and

- is involved in the federal food purchase programs.

The voluntary grading and standardization service may also include plant inspection depending upon the commodity involved. Further, the agency offers enhanced auditing and inspection programs embodying the principles of total quality management and the HACCP system for fruit and vegetable packinghouses, fruit and vegetable processing operations, and dairy product manufacturing operations. More recently, the AMS has started an auditing service for compliance with *Good Agricultural Practices (GAPs)* for fruit and vegetable growers and packinghouses. The AMS has regulatory responsibility for the National Organic Program (NOP) and for the Country of Origin Labeling (COOL) requirement for beef, lamb, pork, fish, perishable agricultural commodities, and peanuts.

B. Animal and Plant Health Inspection Service (APHIS)

Primarily involved in prevention of interstate and import/export transportation of agricultural diseases, the Animal and Plant Health Inspection Service (APHIS) regulations and activities are directed at agricultural production (e.g., farm gate) and transportation. Programs of APHIS include Biotechnology Regulatory Services, Plant Protection and Quarantine, Veterinary Services, Animal Care, International Services, and Wildlife Services.

Department of Commerce (DOC)

The primary role of the Department of Commerce (DOC) is to regulate industrial commerce and to prevent illegal stock market profiteering practices. The DOC agencies that most impact the food industry (directly or indirectly) include the

- **National Institute of Standards and Technology (NIST)** (formerly known as the National Bureau of Standards), which works cooperatively with federal agencies (e.g., FDA; USDA) in regulating standards, weights, and measures as they pertain to food products; and
- **National Oceanic and Atmospheric Administration (NOAA)**, which is primarily involved in conservation and management of marine and coastal resources.

The NOAA agency with the most food industry involvement is the National Marine and Fisheries Service (NMFS). The NMFS administers programs and services to support the domestic and international conservation and management of living marine resources and to support the marine fisheries industries including

- domestic and international fisheries management and development,
- trade and industrial assistance,
- enforcement,
- protected species and habitat conservation, and
- new scientific and technical aspects of marine fisheries programs.

The NMFS collects and analyzes statistical data on commercial and recreational fish catch and a variety of related activities. Under the National Fisheries Inspection Program, the agency provides voluntary inspection/certification of the fisheries industry and administers grades and standards for fish and fish products. Since the National Fisheries Inspection Program was originally in the USDA, it is not a surprise that the program operates in a similar fashion to those under the AMS grading and standardization programs. The fisheries inspection program is a voluntary inspection and certification program in which varied levels of services are offered, ranging from product grading services to inspection services to extended inspection services including HACCP audits.

Department of Defense (DOD)

The Department of Defense (DOD) has a variety of functions and activities that impact the food industry. DOD works cooperatively with the FDA with regard to emergency food supplies and conducts research activities on military food rations. The US Army Veterinary Corps audits, inspects, and approves food and water supplies and manufacturing facilities for military bases and military personnel.

Department of Labor (DOL)

In addition to meeting labor-related regulations under the Department of Labor (DOL), food processing and handling facilities are covered by regulations regarding worker safety administered by the DOL/Occupational Safety & Health Administration (OSHA). OSHA is responsible for enforcement of the Occupational Safety & Health Act (OSHA).

Department of the Treasury (DT)

U.S. CUSTOMS SERVICE

The U.S. Customs Service works cooperatively with other federal regulatory agencies to ensure that importing or exporting foods is done in accordance with US laws and regulations. For imported foods, the U.S. Customs Service regulations require that the country of origin be identified. If the label of an imported article contains any words that

suggest a different country of origin than that from which the article comes, the name of the country of origin must be preceded by *made in* or *product of*.

ALCOHOL TAX AND TRADE BUREAU (TTB)

With passage of the Homeland Security Act (2002) and transfer of the security-related activities of the Bureau of Alcohol, Tobacco and Firearms (ATF) to the Department of Justice, the Alcohol Tax and Trade Bureau (a.k.a. Tax and Trade Bureau or TTB) was established in the Department of the Treasury. The TTB has responsibilities for regulating the manufacture and sale of alcoholic beverages.

Department of Transportation (DOT)

As with any commodity or substance being shipped interstate, the shipping of food products is subject to the appropriate regulations of the Department of Transportation (DOT)/Surface Transportation Board (formerly known as the Interstate Commerce Commission). As needed, in the event of a natural or intentional food contamination the Surface Transportation Board also works cooperatively with the FDA and other agencies in recalls, seizures, and traceback.

Department of Justice (DOJ)

The federal court system is involved in the prosecution of food manufacturers and/or individuals suspected of violating food safety regulations under FDA or FSIS. For example, regulatory seizure of an unsafe food product, when ordered, is conducted by the U.S. Marshals Service.

BUREAU OF ALCOHOL, TOBACCO, FIREARMS AND EXPLOSIVES (ATF)

The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) is involved in criminal investigations regarding purposeful contamination of food and agricultural products. The ATF works cooperatively with the FDA and other agencies in food security-related investigations.

Department of Homeland Security (DHS)

The Department of Homeland Security (DHS) was formed under the Homeland Security Act in 2002 with the mission to “prevent terrorist attacks within the United States, reduce America’s vulnerability to terrorism, and minimize the damage from potential attacks and natural disasters.” In the event of a terrorist attack on the food supply, DHS agencies would work cooperatively with DOJ agencies, as well as FDA, FSIS, and other agencies.

Independent Federal Establishments, Commissions, and Corporations

In addition to federal departments, several independent administrations have been established.

The independent agencies with some food regulatory involvement include the Environmental Protection Agency (EPA), Consumer Product Safety Commission (CPSC), and Federal Trade Commission (FTC).

Environmental Protection Agency (EPA)

Programs of the Environmental Protection Agency (EPA) are primarily involved with protecting human health and safeguarding the natural environment. EPA regulations impact the agricultural and food industries in two general categories: environmental and anti-pollution regulations, and pesticide regulations. The agency, established in 1969 under the National Environmental Policy Act (NEPA), is empowered by a variety of federal acts including the Public Health Service Act, through which the agency is involved in cooperative state/federal programs. The environmental acts that may directly or indirectly impact food regulations or the food industry are the Clean Air Act (CAA), Clean Water Act (CWA), Pollution Prevention Act (PPA), Safe Drinking Water Act (SDWA), and Toxic Substances Control Act (TSCA). Through its enforcement of the Federal Insecticide, Fungicide and Rodenticide Act and the Food Quality Protection Act, the EPA is the primary agency for regulating pesticides and anti-microbial agents. These regulations govern uses, applications, and efficacy, as well as set tolerances for pesticide residues in raw agricultural commodities. The FDA monitors pesticide residues in food products and enforces tolerances. The FSIS does the same for meat and poultry.

Consumer Product Safety Commission (CPSC)

The mission of the Consumer Product Safety Commission (CPSC) is “to protect the public from unreasonable risks of serious injury or death from consumer products.” The primary food-related activity of CPSC is the regulation of the safety of household products and housewares involved in the preparation and transport of foods for home use.

Federal Trade Commission (FTC)

The Federal Trade Commission (FTC) enforces a variety of laws that protect consumers from unfair, deceptive, or fraudulent practices. The agency’s food-related activities are

primarily involved with preventing deceptive and unsubstantiated advertising on food and dietary supplement packages.

Resources

Federal Trade Commission (FTC), <https://www.ftc.gov/>

National Archives, Code of Federal Regulations (eCFR), <https://www.ecfr.gov/>

U.S. Centers for Disease Control and Prevention (CDC), <https://www.cdc.gov/>

U.S. Consumer Product Safety Commission (CPSC), <https://www.cpsc.gov/>

U.S. Customs and Border Protection (CBP), <https://www.cbp.gov/>

U.S. Department of Agriculture (USDA), <https://www.usda.gov/>

U.S. Department of Agriculture, Agricultural Marketing Service (AMS), <https://www.ams.usda.gov/>

U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), <https://www.aphis.usda.gov/>

U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS), <https://www.fsis.usda.gov/>

U.S. Department of Commerce (DOC), <https://www.commerce.gov/>

U.S. Department of Commerce (DOC), National Institute of Standards and Technology (NIST), <https://www.nist.gov/>

U.S. Department of Commerce (DOC), National Oceanic and Atmospheric Administration (NOAA), <https://www.noaa.gov/>

U.S. Department of Commerce (DOC), National Oceanic and Atmospheric Administration (NOAA), National Marine Fisheries Service (NMFS), <https://www.fisheries.noaa.gov/>

U.S. Department of Defense (DOD), U.S. Army Medical Center of Excellence, U.S. Army Veterinary Corps, <https://medcoe.army.mil/amedd-veterinary-corps>

U.S. Department of Health and Human Services (HHS), <https://www.hhs.gov/>

U.S. Department of Health and Human Services, National Institutes of Health (NIH), <https://www.nih.gov/>

U.S. Department of Homeland Security (DHS), <https://www.dhs.gov/>

U.S. Department of Justice (DOJ), <https://www.justice.gov/>

U.S. Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), <https://www.atf.gov/>

U.S. Department of Justice (DOJ), U.S. Marshals Service, <https://www.usmarshals.gov/>

U.S. Department of Labor (DOL), <https://www.dol.gov/>

U.S. Department of Transportation (DOT), <https://www.transportation.gov/>

U.S. Department of the Treasury (DT), <https://home.treasury.gov/>

U.S. Department of the Treasury (DT), Alcohol and Tobacco Tax and Trade Bureau (TTB), <https://www.ttb.gov/>

U.S. Environmental Protection Agency (EPA), <https://www.epa.gov/>

U.S. Food and Drug Administration (FDA), Human Foods Program (HFP), <https://www.fda.gov/about-fda/fda-organization/human-foods-program>

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U.S. Department of Health and Human Services, U.S. Food and Drug Administration. (2001). *Hazard Analysis and Critical Control Point (HAACP); Procedures for the Safe and Sanitary Processing and Importing of Juice: Final Rule*. 66 FR 6138: 6138–6202. <https://www.federalregister.gov/d/01-1291>

Appendix

Federal Departments

- U.S. Department of Agriculture
- U.S. Department of Commerce
- U.S. Department of Defense
- U.S. Department of Education
- U.S. Department of Energy
- U.S. Department of Health and Human Services
- U.S. Department of Homeland Security
- U.S. Department of Housing and Urban Development
- U.S. Department of the Interior
- U.S. Department of Justice
- U.S. Department of Labor
- U.S. Department of State
- U.S. Department of Transportation
- U.S. Department of the Treasury
- U.S. Department of Veterans Affairs

Independent Federal Establishments and Government Corporations

- Central Intelligence Agency
- Chemical Safety and Hazard Investigation Board
- Commodity Futures Trading Commission
- Consumer Product Safety Commission
- Defense Nuclear Facilities Safety Board
- Environmental Protection Agency
- Export–Import Bank of the United States
- Federal Communications Commission
- Federal Deposit Insurance Corporation
- Federal Election Commission
- Federal Emergency Management Agency
- Federal Reserve System
- Federal Maritime Commission
- Federal Trade Commission
- General Services Administration
- Institute of Museum and Library Services
- National Aeronautics and Space Administration
- National Archives and Records Administration
- National Credit Union Administration

- National Endowment for Democracy
- National Foundation on the Arts and the Humanities
- National Labor Relations Board
- National Railroad Passenger Corporation (Amtrak)
- National Science Foundation
- Nuclear Regulatory Commission
- Office of Personnel Management
- Office of Special Counsel
- Peace Corps
- Pension Benefit Guaranty Corporation
- Railroad Retirement Board
- Securities and Exchange Commission
- Selective Service System
- Small Business Administration
- Social Security Administration
- Tennessee Valley Authority
- United States Information Agency
- United States Institute of Peace
- United States International Trade Commission
- United States Postal Service
- United States Trade Representative