Chapter 9 – Public Health Collaboration

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9.1 – Public Health Collaboration

9.1.1 – Purpose of Collaboration

To fulfill its mission to monitor and ensure the safety of the supply chain for human and animal food, medical products, cosmetics, and tobacco products that are domestically produced or enter the United States from other parts of the world, the FDA engages in collaboration with state, local, territorial, and tribal (SLTT) regulatory agencies, foreign governments, regulatory coalitions, development organizations, and academic institutions, among others. Furthermore, the Food Safety Modernization Act (FSMA) directs, and a safe U.S. food supply depends upon, integration efforts with other domestic and international food safety systems. To support these efforts, the FDA conducts field inspection audits and completes Quality Factor Checklists (QFCs) to provide oversight and ensure the quality of contractually purchased domestic inspections in specifically targeted facilities under FDA's workplan.

9.1.2 – Policy on Partnerships and Collaboration

Consumer protection is enhanced by establishing, facilitating, maintaining, and leading partnerships with federal and SLTT agencies, and through international cooperation.

As such, it's important that we follow current procedures that help us establish clear and mutual understanding of the communication roles, responsibilities and expectations to be shared with our consumer protection partners.

You are encouraged to collaborate with federal and SLTT partners whenever possible. That's why the agency issues the IOM and other FDA manuals to international regulators and conformity assessment bodies, and to SLTT inspectors. We foster and promote collaboration and partnerships through several means: our correspondence, FDA testimony, agency press releases, reprints from the Federal Register, and distribution of all pertinent FDA-issued policy and regulations that have significance in other regulatory jurisdictions. In the best interest of public health, the agency may also share FDA's non-public information, if the sharing complies with our confidentiality laws and procedures. You may wish to consult SOP-001659 for more on correspondence with our state, local tribal and territorial partners.

To avoid duplicative and overlapping public health expenditures of resources--OII divisions, headquarters' offices, and, in particular, resident post personnel, must maintain, liaise, foster and promote partnerships with federal and SLTT officials.

Be sure to follow division or program policy regarding your outreach and communications with appropriate federal and SLTT and international officials in your efforts to share information, coordinate operations, and arrange joint inspections. If an assignment calls for joint work with SLTT inspectors, make every effort to accomplish this collaborative work. (See IOM 9.3.1.)

9.1.2 – State Laws, Codes, Agencies

Many states have enacted the basic Uniform Food, Drug, and Cosmetic Bill, while others have adopted at least a part of the Uniform Bill. The provisions of these laws are very similar to the 1938 provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act). A few states have also enacted the Pesticide Food and Color Additives, or Kefauver-Harris type amendments. (See IOM 9.3.3.)

Most states without the Uniform FD&C Act have laws based on the 1906 Food and Drug Act. Most larger cities have their own ordinances and regulations too. Additionally, a portion of the U.S. food supply is consumed within the state in which it is produced, and therefore, is not directly under the jurisdiction of

the FD&C Act as amended. Thus, the various state and local agencies are solely responsible for regulating these products.

Many states have adopted, by reference into their state laws and/or codes, some of the FSMA rules. Several states have also adopted, by reference, the final version of the Preventive Controls for Human Foods. These adoptions by reference allow state partners to conduct state or contract inspections under their own state authority.

The departments of the executive branch of the federal government operate under the laws and regulations for which they are specifically responsible. Since responsibilities may overlap and be duplicative, operating agreements and liaisons between agencies are essential for smooth and efficient governmental operations. Section 702(c) of the FD&C Act [21 U.S.C. 372(c)] recognizes this by providing that the records of any department in the executive branch shall be open to inspection by authorized HHS personnel.

Division or program management is responsible for maintaining official liaisons between the FDA and other federal and state agencies. However, for day-to-day operations, interpersonal contact between various operating federal, territorial, tribal, and state investigators, inspectors, and agents is desirable and encouraged.

9.1.2.1 - Agreements and Memoranda of Understanding (MOU)

It is FDA policy to enter into MOUs with other entities in situations in which there is a need to define lines of authority, or responsibility, or to clarify cooperative procedures (see SMG 2820.1). The FDA and various agencies often enter into formal or informal agreements to improve consumer protections through more effective use of collective resources and/or to eliminate duplication of activities. These agreements specify areas of primary responsibility, document each party's intentions, and outline the terms of the collaboration without creating a legally binding commitment. The key components of an MOU include purpose, scope of work, roles and responsibilities, communication and decision-making, resources, confidentiality, duration, and termination. With regards to information sharing, do not disclose FDA's non-public information unless, the agreement and MOU contain confidentiality provisions that comply with FDA's information disclosure laws and procedures (for instance, sharing with the public (FOI), federal government officials (21 CFR 20.85), state/local officials (21 CFR 20.88), foreign entities (21 CFR 20.89)). The Division of Information Disclosure reviews all MOUs that include information sharing to ensure the information-sharing intent complies with federal laws, regulations, and policy, and that the disclosure language is correct and that any appropriate supporting documents have been developed. Questions regarding information disclosure should be addressed to Division of Information Disclosure at FDAInfoShare@fda.hhs.gov. When establishing new human food-related MOUs or reviewing/renewing existing food-related MOUs, contact the Human Foods Program/Office of Integrated Food Safety System Partnerships/Office of Domestic Partnerships at ODP.Feedback@fda.hhs.gov. For assistance on information disclosure issues related to existing MOUs, contact the OC/OO/OMES/DID at FDAInfoShare@fda.hhs.gov. Contact the Office Food Safety System Partnerships at OP.Feedback@fda.hhs.gov when encountering an MOU for the first time, drafting an MOU, or for clarification of disclosure. Your state liaison may also be of assistance understanding MOUs with SLTTs.

A complete listing of domestic, academia, and non-profit entities with which we share MOUs is publicly available on the FDA MOUs page.

9.1.2.1.1 – Information Sharing with Other Agencies

The Division of Information Disclosure Policy (DIDP) is responsible for the following: advancing public health through information sharing, ensuring that the FDA is sharing critical information to the fullest permissible extent, and preventing protected information from being inadvertently disclosed. DIDP reviews proposed guidance documents, regulations, final regulations, proposed legislation, and other agency documents, relative to the practice and policies of sharing information. DIDP also reviews, establishes, coordinates, and collaborates with other offices, centers, and agency stakeholders on interagency sharing agreements, including agreements with other federal agencies, state and local agencies, and international organizations. DIDP also provides training on information sharing agreements to stakeholders.

Regulations provide the FDA with the discretion to share certain records with federal agencies and state or local government officials who perform counterpart functions to the FDA as part of cooperative law enforcement or regulatory efforts (21 CFR 20.85 and 20.88) regarding all commodities. Any disclosure under 20.85 or 20.88 requires a written agreement certifying that 1) the agency has legal authority to protect non-public information (NPI) received from the FDA from public disclosure and 2) that shared records are not to be further disclosed unless permission is provided by the FDA.

NPI includes but is not limited to: (1) confidential commercial information, such as information that would be protected from public disclosure pursuant to Exemption 4 of the Freedom of Information Act (FOIA); (2) personal privacy information, such as the information that would be protected from public disclosure pursuant to Exemption 6 or 7(c) of the FOIA; or (3) information that is otherwise protected from public disclosure by federal statutes and their implementing regulations. This includes the Trade Secrets Act (18 U.S.C. 1905)), Privacy Act (5 U.S.C. 552a), other FOIA exemptions not mentioned above (5 U.S.C. 552), the FD&C Act (21 U.S.C. 301 et seq.), and the Health Insurance Portability and Accountability Act (HIPAA), Pub. L. 104-191 See also HHS Health Information Privacy website).

Note: The FDA cannot disclose Trade Secret Information (TSI) to *any* outside agency without express written authorization from the owner or submitter.

DIDP processes requests from outside agencies only after considering the FDA's concerns for confidentiality, the requester's need for the information, and the benefit to the public health.

9.1.3 – Other Government Inspections

General procedures regarding cooperation with other federal, state, and local officials are furnished below.

During establishment inspections, you should determine the specific type of inspection service and inspecting units, such as the name of the federal, state, county, or city health agency or department. Obtain the name and title of the inspectional official, and general method of operation. IOM 5.8.9.1 discusses coverage of Grade A dairy plants.

9.2 – Roles and Responsibilities of Other Federal Agencies

This subchapter deals with the roles and responsibilities of other agencies that share an agreement or MOU with the FDA. Information regarding each agency's mission and responsibilities should be described in the MOU as appropriate. Information about the complete MOU or agreement can be found on the FDA Memoranda of Understanding page.

Prior to the inspection of any firm that has the potential to be covered by another federal agency, you should first check to see if an agreement or MOU exists between FDA and the likely or suspected agency involved to determine the obligations of both agencies. If you're not sure if another entity might be involved, consult with your state liaison who can assist you in finding this information. You should also inquire about this, or the involvement of any other inspecting entity/outside inspecting unit, while at the firm for the establishment inspection. If you determine that other entities are, in fact, involved, note the name of this other federal, state, county, or city health agency or department. You should also obtain the name and title of any other inspectional official if present or onsite during your inspection and their general method of operation. Introduce yourself to the other agency personnel if present and allow them to accompany the inspection if requested. (IOM 5.8.9.1) discusses coverage of Grade A dairy plants.)

Prior to inspection of any firm that has the potential to be covered by Department of Defense (DOD) and/or is potentially located on a military facility, check to see if an agreement or MOU exists between FDA and the DOD to notify the appropriate MOU liaisons and to determine the obligations of both agencies.

Resources for federal and SLTT officials are publicly available online.

9.2.1 - U. S. Department of Agriculture (USDA)

The U.S. Department of Agriculture (USDA) is made up of 29 agencies and offices with nearly 100,000 employees at more than 4,500 locations across the country and abroad. The USDA provides leadership on food, agriculture, natural resources, rural development, nutrition, and related issues based on public policy, the best available science, and effective management.

9.2.1.1 - USDA Acts

Note the following USDA Acts, under which the FDA has been delegated detention authorities for products subject to USDA inspection:

- Federal Meat Inspection Act (FMIA) (See IOM 2.5.11.2.1)
- Poultry Products Inspection Act PPIA (See IOM 2.5.11.2.2)
- Egg Products Inspection Act (EPIA) (See IOM 2.5.11.2.3)

(See IOM 2.5.11.2 for additional information and IOM Exhibit 9-1 for a chart depicting jurisdictional lines for products regulated by the FDA and USDA.)

9.2.1.2 - FDA-USDA Alerts

A notification process exists that allows us to report pertinent food safety observations to the appropriate agency and allows those observations to be tracked by all relevant parties. This Interagency Referral Report was designed to give the FDA, Food Safety Inspection Service (FSIS), and Agricultural Marketing Service (AMS) personnel a mechanism to report relevant information about an observed food safety condition in dual jurisdiction facilities.

9.2.1.3 - Agricultural Marketing Service (AMS)

The Agricultural Marketing Service (AMS) administers programs that create domestic and international marketing opportunities for U.S. producers of food, fiber, and specialty crops. It also provides the agriculture industry with services to ensure the quality and availability of wholesome food for consumers across the country. Much of the agency's support for agriculture is provided through commodity-specific efforts, which are bulleted below. AMS also oversees the National Organic Program, Science and Technology Program, and Transportation and Marketing Program. It also provides regulatory oversight for over 20 research and promotion programs, and enforces other federal regulations such as the Perishable Agricultural Commodities Act (PACA) and the Seed Act.

Programs under AMS include:

- Dairy Program
- Specialty Crops Program (Note: Farm Bill legislation defines specialty crops as fruits and vegetables, tree nuts, dried fruits, horticulture, and nursery crops, including floriculture.)
- Fair trade Practices
- National Organic Program
- Cotton and Tobacco
- Federal Grain Inspection Service (FGIS)
- Livestock and Poultry
- Transportation and Marketing
- Science and Technology
- Commodity Procurement

9.2.1.3.1 - Federal Grain Inspection Service (FGIS)

The Federal Grain Inspection Service (FGIS) facilitates the marketing of U.S. grain and related products by establishing standards for quality assessments, regulating handling practices, and managing a network of federal, state, and private laboratories that provide impartial official inspection and weighing services. FGIS establishes and maintains official standards for barley, canola, corn, flaxseed, oats, rye, sorghum, soybeans, sunflower seed, triticale, wheat, mixed grain, rice, and pulses. Its Field Management Division, with associated Field Offices Directory found here, provides and supervises inspection and weighing services for grain and related products for domestic and export trade, and develops and revises directives, handbooks, and other instructional documents.

9.2.1.3.2 – Livestock and Poultry Program (L&P)

USDA shell egg grading is a voluntary service paid for by shell egg producers. As an independent third party, USDA is recognized for assuring that eggs meet the U.S. grade standards for quality and sanitary processing. Only shell eggs officially graded by USDA are eligible to bear the USDA grademark/shield. All egg labels bearing the USDA shield require pre-approval by AMS to ensure truth in labeling prior to their use. Additionally, only product that is both officially graded and certified by USDA as sourced from cage-free flocks are eligible to use the "Certified Cage Free" design. AMS maintains a list of facilities that are part of the voluntary inspections service.

9.2.1.3.3 – Food and Nutrition Service (FNS)

USDA's Food and Nutrition Service administers 16 nutrition assistance programs to ensure children, income eligible individuals, and families have equitable access to healthy, safe, and

affordable foods that promote optimal health and well-being. FNS accomplishes this by partnering with over 175 states, U.S. territories, and tribal organizations that operate federal nutrition programs--collectively serving 1 in 4 Americans over the course of a year.

FNS's mission is to increase food security and reduce hunger in partnership with cooperating organizations by providing children and low-income people access to food, a healthy diet, and nutrition education in a manner that supports American agriculture and inspires public confidence. According to its website, FNS's commitment to nutrition security applies a health equity lens to the way it operates its programs. FNS recognizes that long standing disparities in diet-related diseases are rooted in structural racism and require equities beyond those available in FNS. Therefore, the agency works with federal partners and stakeholders across the country to meet the goals of the White House Conference on Hunger, Nutrition, and Health to promote and elevate nutrition security.

FNS also administers the National School Lunch Program (or NSLP), a federally assisted meal program operating since 1946 in public and nonprofit private schools and residential childcare institutions, providing nutritionally balanced, low-cost or free lunches to children each school day.

9.2.1.4 - Animal Plant Health Inspection Service (APHIS)

APHIS' work centers around animal and plant health, but its programs also address animal welfare, biotechnology, wildlife damage management, and global trade. APHIS protects the health of U.S. agriculture and natural resources against invasive pests and diseases, regulates genetically engineered crops, administers the Animal Welfare Act, and helps people and wildlife coexist. APHIS also certifies the health of U.S. agricultural exports and resolves phytosanitary and sanitary issues to open, expand, and maintain markets for U.S plant and animal products.

9.2.1.5 - Food Safety and Inspection Service (FSIS)

FSIS protects public health by preventing illness from meat, poultry and egg products by ensuring these products are safe, wholesome, and properly labeled.

FSIS is part of a science-based national system to ensure food safety and food defense. It ensures food safety through the authorities of the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, as well as upholding humane animal handling standards through the Humane Methods of Slaughter Act.

Meat and meat products are regulated by both the FDA and the USDA. The USDA's FSIS has primary responsibility for regulating meat from the species of animals listed in the Federal Meat Inspection Act and the Poultry Products Inspection Act. These animals are considered "amenable species" and include cattle, sheep, swine, goats, domestic poultry (chickens, turkeys, ducks, geese, and guinea), ratites (ostriches, emus), and squab (young pigeons).

The FDA regulates game meats and game meat products, referred to as "non-amenable" meats, including: antelope, bison, deer, elk, reindeer, muskrat, non-aquatic reptiles, opossum, rabbit, raccoon, squirrel, water buffalo, grouse, pheasant, quail, wild turkey, wild geese, and wild ducks.

Non-amenable meats and meat products are from animals and birds that are reared, slaughtered, and commercially sold for food. The 2022 Food Code (3-201.17) generally provides for food establishments to use game meat that is processed under a voluntary inspection program or

through a regular inspection program, as allowed by law. All non-amenable meat and meat products must meet the FDA's requirements, including the FDA's labeling requirements for packaged foods.

FSIS can perform voluntary inspections (on a fee for service basis) for certain non-amenable species, under the Agricultural Marketing Act of 1946. More information can be found at Voluntary and Other Reimbursable Inspection Services. FDA-regulated, or non-amenable, meats that are slaughtered under voluntary inspection of FSIS may receive a USDA FSIS voluntary mark of inspection.

9.2.2 - U.S. Department of Commerce (DOC)

The Department of Commerce (DOC) mission is to create conditions for economic growth and opportunity for all communities across the country. Through its 13 bureaus, the DOC works to drive U.S. economic competitiveness, strengthen domestic industry, and spur the growth of quality jobs in all communities across the country.

Its scientists research emerging technologies, such as quantum computing and artificial intelligence (AI), while its United States Patent and Trademark Office's intellectual property (or IP) protections ensure American innovators profit from their work.

9.2.2.1 National Institute of Standards and Technology (NIST)

NIST, one of the nation's oldest physical science laboratories, founded in 1901, is part of the DOC. Congress established the agency to remove a major challenge to U.S. industrial competitiveness historically— our country's second-rate measurement infrastructure that at the time lagged behind the capabilities of the United Kingdom, Germany, and other economic rivals.

NIST provides technology, measurement science, and standards that propel development of innumerable products and services, ranging from the smart electric power grid and electronic health records to atomic clocks, advanced nanomaterials and computer chips.

As its website states, NIST measurements support the smallest of technologies to the largest and most complex of human-made creations — "from nanoscale devices so tiny that tens of thousands can fit on the end of a single human hair up to earthquake-resistant skyscrapers and global communication networks." The agency promotes U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve quality of life. *It's important to note for our FDA purposes that pharmaceutical and related healthcare product companies use NIST laboratories to conduct research and development (R&D).

9.2.2.2 - National Oceanic and Atmospheric Administration (NOAA)

NOAA's mission is to understand and predict changes in climate, weather, ocean, and coasts; to share that knowledge and information with others; and to conserve and manage coastal and marine ecosystems and resources. NOAA's products and services include daily weather forecasts, severe storm warnings, climate monitoring, fisheries management, coastal restoration, and supporting marine commerce. Its scientists use cutting-edge research and high-tech instrumentation to provide citizens, planners, emergency managers, and other decision makers with reliable information. The agency holds key leadership roles in shaping international ocean, fisheries, climate, space, and weather policies, and its many assets include research programs, vessels, satellites, science centers, laboratories and its scientists and experts.

9.2.2.2.1 National Marine Fisheries Service (NMFS)

NMFS, also known as NOAA Fisheries, is an office of NOAA that operates under the authority of the Agriculture Marketing Act and the Fish and Wildlife Act and is responsible for the development and advancement of commercial grade standards for fishery products and better health and sanitation standards in the industry and for furnishing inspection, analytical, and grading services to interested parties. The NMFS conducts inspections for federal waters harvest and licenses harvesters for federal waters bivalve molluscan shellfish that is landed in the United States. Its major purpose is to encourage and assist industry in improving the quality and safety of its products. The NMFS Liaison Office is located in the DOC/NOAA Seafood Inspection Program.

The Lacey Act, as amended in 1981 and 2008, prohibits the importation, exportation, transportation, sale, receipt, acquisition, or purchase of any fish or wildlife or plant taken, possessed, transported, or sold in violation of any law, treaty, or regulation of the United States or any Indian tribal law, or foreign law. The law also requires that all containers used to ship wildlife be properly marked and prohibits false labeling. Additionally, portions of the Lacey Act provide that the Secretary of Interior designate injurious wildlife and ensure the humane treatment of wildlife shipped to the United States.

9.2.3 - U.S. Patent and Trademark Office (USPTO)

The United States Patent and Trademark Office (USPTO) is the federal agency for granting U.S. patents and registering trademarks. Its mandate is found in Article I, Section 8, Clause 8, of the Constitution, wherein the legislative branch is empowered to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." The USPTO registers trademarks based on the commerce clause of the Constitution (Article I, Section 8, Clause 3). Under this system of protection, as the USPTO website states, American industry has flourished. New products have been invented, new uses for old ones discovered, and employment opportunities created for millions of Americans. The strength and vitality of the U.S. economy depends directly on effective mechanisms that protect new ideas and investments in innovation and creativity. The continued demand for patents and trademarks underscores the ingenuity of American inventors and entrepreneurs. The USPTO is at the cutting edge of the nation's technological progress and achievement.

The USPTO advises the president of the United States, the secretary of commerce, and U.S. government agencies on intellectual property (IP) policy, protection, and enforcement; and promotes the stronger and more effective IP protection around the world. It also furthers effective IP protection for U.S. innovators and entrepreneurs worldwide by working with other agencies to secure strong IP provisions in free trade and other international agreements. The agency also provides training, education, and capacity-building programs designed to foster respect for IP and encourage the development of strong IP enforcement regimes by U.S. trading partners.

9.2.4 – Department of Defense (DOD)

The DOD is America's largest government agency with a mission to provide the military forces needed to deter war and ensure our nation’s security. The Army, Marine Corps, Navy, Air Force, Space Force, and Coast Guard are the uniformed armed forces of the United States. The Army National Guard and the Air National Guard are reserve components of their services and operate in part under state authority. The

Defense Department has 11 combatant commands, each with a geographic or functional mission that provides command and control of military forces in peace and war.

Note that the DOD has many components aside from the uniformed service branches. As it pertains to food safety/protection, one of these components is the Defense Logistics Agency (DLA), which houses: DLA Troop Support, the Subsistence supply chain (food support for U.S. military around the world), and, ultimately, the Food Safety Office. The Food Safety Office is responsible for food safety issues and technical and quality assurance policies for food intended for service members and their families worldwide. In partnership with the U.S. Army Veterinary Services, the Subsistence Food Quality team proactively responds by auditing and monitoring military food supplies, like operational rations and commercial products. The U.S. Army Veterinary Services routinely performs food safety operations and inspections to ensure deployed forces receive the safest food and water available. They also care for military working animals and provide public health services during humanitarian assistance missions.

9.2.5 – Department of Health and Human Services (HHS)

The mission of the U.S. Department of Health and Human Services (HHS) is to enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

9.2.5.1 - Centers for Disease Control and Prevention (CDC)

The CDC works to protect America from health, safety, and security threats, both foreign and in the United States. As its website states, CDC fights disease and supports communities and citizens to do the same.

As the nation's health protection agency, CDC saves lives and protects people from health threats. It conducts critical science and provides health information that protects our nation against expensive and dangerous health threats and responds when these arise.

The FDA and CDC maintain a close working relationship to assure the prompt exchange of information, especially when it relates to suspected foodborne outbreaks. Determining who the "lead" agency is for an outbreak investigation depends on agreements made between the agencies, as described below:

- Outbreaks Involving Interstate Conveyances - Reports of illness attributed to travel on an interstate conveyance (plane, bus, train, or vessel) are the responsibility of the FDA.
- Outbreaks on Foreign Flag Vessels - If an outbreak involving a foreign flag vessel or a U.S. Flag vessel with an international itinerary comes to your attention, immediately report it to your supervisor. This situation falls under the jurisdiction of the CDC's Vessel Sanitation Program in Atlanta, GA.
- Botulism Antitoxin Shipments – The CDC is responsible for maintaining and shipping necessary supplies of botulinum antitoxin. When it makes a shipment of botulinum antitoxin, the CDC will immediately notify FDA.

9.2.5.1.1 - National Center for Health Statistics (NCHS)

NCHS collects, analyzes, and disseminates timely, relevant, and accurate health data and statistics. Its products and services inform the public and guide program and policy decisions to improve the nation's health.

9.2.5.1.1 - Agency for Toxic Substances and Disease Registry (ATSDR)

The ATSDR (formerly CDC Superfund) has been designated as the lead agency for the DHHS response to chemical emergencies. The CDC ATSDR Public Health Advisors are located at EPA Regional Offices. These advisors would not only alert your office of chemical emergencies but would also be invaluable in answering questions concerning the severity of the problem and discussing protective measures.



Note: Under no circumstances should you or any FDA employee enter areas designated as "hazardous."

ATSDR Emergency Response Teams are available 24 hours a day, and are comprised of toxicologists, physicians, and other scientists available to assist during an emergency involving hazardous substances in the environment.

Emergency Response (24 Hours) at ATSDR: (770) 488-7100

The following are possible situations and circumstances in which ATSDR guidance is indicated:

With regards to wrecks, like those, for instance, involving trains and trucks carrying FDA products, the physical impact usually causes the most damage. Rupture of toxic items carried in the same load, although illegal, may worsen the contamination. In train wrecks, other railcars loaded with chemicals, oils, and/or other contaminating materials may rupture and contaminate food and drug products contained within otherwise undamaged cars. Removal of the wreckage may cause further physical damage or chemical contamination. Exposure to weather may also adversely affect the products.

Furthermore, the runoff of toxic chemicals from wrecked and ruptured cars may contaminate adjacent or nearby streams supplying water to downstream firms that fall under FDA jurisdiction.

Hazardous waste sites also pose a hazard to the immediate environment, as well as offsite, if runoff contaminates nearby surface waters, or if leachate contaminates ground water supplies.

In summary, remember that hazardous waste sites, as well as chemical spills that occur on land or water, can pose a serious threat to the environment, and contaminate FDA-regulated products, both directly and indirectly.

9.2.5.2 - Centers for Medicare and Medicaid Services (CMS)

CMS is the federal agency that provides health coverage to more than 160 million Americans through Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace. CMS works in partnership with the entire health care community to improve quality, equity, and outcomes in the health care system.

9.2.5.3 – Health Resources and Services Administration (HRSA)

The Health Resources and Services Administration (HRSA) provides equitable health care to the nation's highest-need communities. Its programs support people with low incomes, people with HIV, pregnant people, children, parents, rural communities, transplant patients, and the health workforce.

9.2.5.4 - National Institutes of Health (NIH)

NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

9.2.5.4.1 - National Institute on Drug Abuse (NIH/NIDA)

NIDA's mission is to advance science on drug use and addiction and to apply that knowledge to improve individual and public health.

9.2.6 – Department of Homeland Security (DHS)

DHS has multiple missions that make up its strategic plan, including countering terrorism and homeland security threats, securing U.S. borders and approaches, securing cyberspace and critical infrastructure, and strengthening preparedness and resilience.

9.2.6.1 - U.S. Customs and Border Protection (CBP)

CBP's mission is to protect the American people, safeguard the nation's borders, and enhance U.S. economic prosperity.

9.2.6.2 - United States Secret Service (USSS)

The United States Secret Service (USSS or Secret Service) is a federal law enforcement agency under the Department of Homeland Security charged with safeguarding America's financial and payment systems from criminal exploitation and ensuring the security of protectees (for example, U.S. political leaders, their families, and visiting heads of state or government), key locations, and events of national significance. The Secret Service is the lead agency in charge of the planning, coordination, and implementation of security operations for events designated as National Special Security Events (NSSE).

The Secret Service may request FDA assistance on matters and events involving special security. Authority for Secret Service to request FDA assistance, and for the FDA to respond, is derived from the "Presidential Protection Assistance Act of 1976," P.L. 94-524 (90 Stat. 2475-7), Sections 1-10. Section 6, in part, states: "Executive Departments and Executive Agencies shall assist the Secret Service in the performance of its duties by providing services, equipment, and facilities on a temporary and reimbursable basis when requested by the Director and on a permanent and reimbursable basis upon advance written request of the Director; except that the DOD and the Coast Guard shall provide such assistance on a temporary basis without reimbursement when assisting the Secret Service in its duties directly related to the protection of the President or the Vice President or other officer immediately next in order of succession to the office of the President."

The FDA's primary purpose in support of the Secret Service is to minimize the possibility of foodborne illness or injury. Assistance provided by the FDA encompasses food defense-related FDA field activities designed as a proactive effort to prepare for the protection of food during special security events. FDA's authority for entry and inspection is derived from Secret Service authority and its request for FDA assistance. When called upon by the Secret Service to assist with an NSSE, FDA's response and role is that of an advisor. Authority for decisions regarding food and beverages to be consumed by protectees is retained by the Secret Service.

The Secret Service may request the FDA to provide food safety and food defense monitoring at NSSEs, which include presidential inaugurations, national political conventions, and political summits. Since the venues for NSSEs are large-scale retail food establishments, the ACOHAFO has designated the Office of State Cooperative Programs' Division of Retail Food Protection (OSCP-DRFP) and the OII Emergency Response Coordinators as the lead FDA personnel to work collaboratively with the Secret Service and the state or local entity with retail food safety jurisdiction to address food safety and food defense issues before and during NSSEs. More specific information regarding

procedures and roles and responsibilities during NSSEs, is provided in the Special Event Planning Guidance (SEPG). If you are contacted by the Secret Service related to an NSSE, immediately contact your supervisor, who in turn will contact the OSCP Director.

Note: If you are assigned and working in support of an NSSE, do not issue a Notice of Inspection - FDA 482 unless the investigation evolves into the collection of a sample for the enforcement of the FD&C Act. You are in the firm under the Secret Service authority.

The FDA may initiate action against products encountered which are suspected of being in violation of the FD&C Act or the FPLA.

Criteria for Secret Service Request for FDA Assistance

The decision to request FDA assistance is made by Secret Service Office of Protective Operations (Headquarters). The FDA has provided certain criteria to aid Secret Service in determining how it might derive maximum benefit from our agency. However, regardless of what criteria are used, the FDA should always respond to Secret Service requests for assistance. Note too that Secret Service considers factors other than the FDA-supplied criteria in making its judgments regarding requests for assistance.

9.2.7 – U.S. Department of Justice (DOJ)

The mission of the Department of Justice is to uphold the rule of law, keep our country safe, and protect civil rights.

9.2.7.1 – Offices of the United States Attorneys (USAO)

Charged with ensuring “that the laws be faithfully executed,” the 93 United States Attorneys work to enforce federal laws throughout the country. The President appoints a United States Attorney to each of the 94 federal districts (Guam and the Northern Mariana Islands are separate districts but share a United States Attorney). The United States Attorney is the chief federal law enforcement officer in their district and is also involved in civil litigation where the United States is a party.

You may be contacted by the U.S. Attorney's office to discuss possible or pending cases or other matters pertinent to the FDA. Notify your supervisor of these contacts. You may be accompanied by your supervisor or a compliance officer in your communications with the U.S. Attorney, or their office. If you are contacted by the U.S. Attorney's Office regarding any criminal issues, this is to be referred immediately to the appropriate Office of Criminal Investigations (OCI) contact.

Special Note: During any discussion with the U.S. Attorney, you may inform them that you are qualified to report the facts of the case or item being discussed, but you should also relay that you are a fact witness only and not qualified as an "expert."

9.2.7.2 - Drug Enforcement Administration (DEA)

The DEA enforces the controlled substances laws and regulations of the United States.

9.2.7.3 - Federal Bureau of Investigation (FBI)

The FBI’s mission is to protect the American people and uphold the U.S. Constitution via protection against terrorism, counterintelligence, cybercrime, corruption, and organized/white-collar/violent crime.

The FBI, USDA, and FDA are authorized to investigate reported tampering of FDA-regulated consumer products under the Federal Anti-Tampering Act (FATA), Title 18, USC, Section 1365. In most cases, FDA's authority for such investigations is also found in the FD&C Act.

The USDA and the FBI share enforcement of the FATA with FDA as described below:

- FBI Responsibility: The FBI's primary response in FATA matters is to investigate particularly those cases that involve a serious threat to human life or if a death has occurred. The FBI will also investigate FATA matters involving threatened tampering, and actual or threatened tampering coupled with an extortion demand.
- The FBI will rely on the FDA to determine if tampering with FDA products has occurred.
- USDA Responsibility - The USDA will investigate and interact with the FBI on tampering with products regulated by USDA.

All reports of tampering or tampering threats must also be immediately reported to OCI. For complete information regarding FBI/FDA actions under FATA. (See IOM 8.1.5.9.3.)

9.2.7.4 - U.S. Marshals Service (USMS)

The U.S. Marshals Service (USMS) is the enforcement arm of the federal court. The USMS is primarily responsible for the service of civil process. In other words, when the FDA takes an action, such as seizure, the U.S. Marshal serves the complaint for forfeiture and "arrests" the goods. FDA employees typically accompany the U.S. Marshal to assist in identifying the goods that are to be seized. The USMS is also responsible for ensuring the safe conduct of judicial proceedings and protecting federal judges, jurors, and other members of the federal judiciary. Special Note: Division Offices may find it useful to contact the local U.S. Marshals when preparing a situation plan to deal with issues of personal safety while conducting inspections or other operations. (See IOM 5.3.1.1.1).

9.2.8 – Department of Labor: Occupational Safety and Health Administration (OSHA)

OSHA's mission is to assure America's workers have safe and healthful working conditions free from unlawful retaliation. OSHA carries out its mission by setting and enforcing standards; enforcing anti-retaliation provisions of the OSH Act and other federal whistleblower laws; providing and supporting training, outreach, education, and compliance assistance; and ensuring state OSHA programs are at least as effective as federal OSHA, furthering a national system of worker safety and health protections. The OSH Act covers most private sector employers and their workers, in addition to some public sector employers and workers in the 50 states and certain territories and jurisdictions under federal authority. Those jurisdictions include the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, Northern Mariana Islands, Wake Island, Johnston Island, and the Outer Continental Shelf Lands as defined in the Outer Continental Shelf Lands Act.

OSHA and FDA maintain a memorandum of understanding (MOU) to coordinate regulatory oversight in facilities where both agencies have authority. This MOU promotes information sharing related to worker safety and health and the safety and quality of regulated products while clarifying jurisdictional boundaries between both agencies. OSHA is also charged with the enforcement of the Food Safety Modernization Act (FSMA) whistleblower protection provision, which protects employees from discharge or other retaliation by their employers for making complaints about food safety concerns or other violations of the FFDCA or engaging in other protected activities. More information on the MOU and whistle blower referral process can be found in section 10.7.3.1.

9.2.9 – U.S. Department of the Treasury (USDT)

The U.S. Department of the Treasury's mission is to maintain a strong economy and create economic and job opportunities by promoting the conditions that enable economic growth and stability at home and abroad, strengthen national security by combating threats and protecting the integrity of the financial system, and manage the U.S. government's finances and resources effectively. Many different agencies operate under the direction of this department, including the Internal Revenue Service, and the Alcohol and Tobacco Tax and Trade Bureau.

9.2.9.1 - The Alcohol and Tobacco Tax and Trade Bureau (TTB)

The TTB protects the public by enforcing the provisions of the Federal Alcohol Administration Act (FAA Act) to ensure that only qualified persons engage in the alcohol beverage industry. It is responsible for enforcing the laws regulating alcohol production, importation, and wholesale businesses; tobacco manufacturing and importing businesses; and alcohol labeling and advertising.

Visit the TTB website for more information about our mission and functions.

9.2.9.2 - Internal Revenue Service (IRS)

The IRS mission is to provide America's taxpayers top quality service by helping them understand and meet their tax responsibilities and to enforce the law with integrity and fairness to all.

9.2.10 – U.S. Department of Veteran's Affairs (VA)

The Veterans Health Administration (VHA) is the component of the United States Department of Veterans Affairs (VA) led by the Under Secretary of Veterans Affairs for Health that implements the healthcare program of the VA through a nationalized healthcare service in the United States, providing healthcare and healthcare-adjacent services to veterans. The VA is not a part of the U.S. Department of Defense Military Health System.

9.2.11 – Consumer Product Safety Commission (CPSC)

CPSC works to save lives and keep families safe by reducing the unreasonable risk of injuries and deaths associated with consumer products and fulfilling its vision to be the recognized global leader in consumer product safety.

9.2.12 – Environmental Protection Agency (EPA)

The EPA administers many acts including the National Environmental Protection Act (NEPA). Importantly, the FDA must be guided by this act when assisting in voluntary destructions, disposal of laboratory wastes, etc.

In keeping with the act, you should be aware of questionable disposal practices. Also be aware that certain products should not be disposed of in a conventional manner (for example, in the case of sanitary landfills, or flushing down the drain, etc.). Certain products (chloroform, methapyrilene, hexachlorophene, PCB, among others), are classified by EPA as "hazardous and toxic" substances and may require a special method of disposal by a licensed hazardous disposal facility. Any possible hazardous or toxic substance (carcinogen, mutagen, etc.) should not be disposed of without prior consultation by the firm with the EPA and/or the regulating state authority. Refer to 21 CFR 25 and the NEPA for guidance regarding the environmental impact of voluntary destructions.

Important note: Though EPA controls drinking water, the FDA has responsibility for water, and substances in water, used in food and for food processing and bottled drinking water and assumes appropriate regulatory actions for those products.

9.2.13 – Federal Trade Commission (FTC)

FTC's mission is protecting the public from deceptive or unfair business practices and from unfair methods of competition through law enforcement, advocacy, research, and education. FTC also protects the public from unfair or deceptive acts or practices in the marketplace and from unfair methods of competition in the marketplace to promote fair competition.

9.2.14 - U.S. Nuclear Regulatory Commission (NRC)

The U.S. Nuclear Regulatory Commission (NRC) was created as an independent agency by Congress in 1974 to ensure the safe use of radioactive materials for beneficial civilian purposes while protecting people and the environment. The NRC regulates commercial nuclear power plants and other uses of nuclear materials, such as in nuclear medicine, through licensing, inspection and enforcement of its requirements.

9.2.15 - U.S. Postal Service (USPS)

The Postal Service's mission is to provide the nation with reliable, affordable, universal mail service. By law, its basic function is "…. to bind the Nation together through the personal, educational, literary, and business correspondence of the people. It [the Postal Service] shall provide prompt, reliable, and efficient services to patrons in all areas and shall render postal services to all communities."

The FDA cooperates with postal authorities in areas of mutual concern. If contacted by postal authorities, extend courtesy and cooperation. In any doubtful situation or incidents involving excessive expenditure of time and/or resources, consult with your supervisor.

The following authorities are of particular relevance to FDA investigators:

The authority for providing forwarding address information to government agencies is defined in 39 CFR 265.14(d)(5)(i) which states as follows:
(5) Exceptions. Except as otherwise provided in these regulations, names, or addresses of postal customers will be furnished only as follows:

(i)To a federal, state, or local government agency upon prior written certification that the information is required for the performance of its duties.

Additionally, 39 CFR 265.14(d)(7) may apply: Address verification. The address of a postal customer will be verified at the request of a federal, state, or local government agency upon written certification that the information is required for the performance of the agency's duties.

9.2.15.1 - Request for USPS Information

During your field activities, it may be necessary for you to visit local post offices to obtain new or forwarding addresses, and/or obtain the name and address of the holder of a postal box (P.O. Box). Consider the following steps to assist you:

- Introduce yourself and display credentials to the local P.O. clerk or official.
- State the information you need in support of your official work/duties.
- Present the clerk or official with this statement in writing (on FDA letterhead using the wording from IOM Exhibit 9-2) which may be reproduced or typed on division letterhead.

Note: Currently there is no charge for providing this information to a federal agency. The regulation promulgating a fee has been stayed.

Additionally, if you are refused the information or are delayed in any manner, contact the nearest U.S. Postal Inspector to handle the matter.

9.3 – State Local, Tribal and Territorial (SLTT) Interactions

In most cases, your supervisor, State Liaison, or State Cooperative Programs Specialist (See IOM 9.3.2.1 for Milk, Shellfish, Retail Food) is your first contact regarding interactions with SLTT officials. Your State Cooperative Programs Specialist or State Liaison will know the contacts at the SLTT agencies with whom you will be interacting. Please note that you should normally not reach out directly to an SLTT official without supervisory approval or the knowledge of the State Cooperative Programs Specialist, or State Liaison.

9.3.1 - SLTT OPERATIONAL AUTHORITY

All states and local governments have established jurisdiction over many establishments that manufacture, process, pack, hold or sell FDA-regulated products. The authority extends to establishments, located within their state or local boundaries, regardless of the interstate movement or origin of the products involved. Some states divide the responsibility for food, drugs, etc., among the various agencies within the state. See IOM 3.3.31. Laws and regulations and products covered vary from state to state as well as across localities and even tribal and territorial authorities. However, some states have adoption of CFRs into their state laws / codes or have equivalent in-effect state laws / codes to the applicable CFRs.

The rest of this section provides general information about and guidance relating to certain SLTT authorities. These authorities may have different rules and applications within various SLTTs. Details about specific authorities within the SLTT should be answered by your management, state liaison, or cooperative program specialist.

Specific authorities commonly shared by SLTTs include, but are not limited to:

- Inspection
- Sample Collection
- Embargo/Detention
- Seizure
- Destruction
- Initiation of recalls
- Licensing
- Issuance of a Fine or Ticket

Inspection and sample collection authorities are similar to FDA authorities (see IOM Chapter 2 for FDA authorities to inspect and collect samples.)

Most SLTTs have embargo and/or detention authorities. Generally, an embargo means that a product cannot be moved from its current location.

Some SLTTs empower inspectors to place an immediate embargo on products that are, or are suspected to be, adulterated or misbranded or otherwise in violation of its laws or regulations. As a cooperative measure, most state, and some local agencies will have their inspectors embargo products at the

request of an FDA representative. Note, though, that any requests for embargo or detention should be made by division management, in coordination with the state liaison.

In all instances, exercise care in requesting embargoes. The appropriate state agency should be notified of pending or recommended compliance actions as soon as practical, but no later than five working days. When an SLTT institutes an embargo at the FDA's request, the division must assure that cooperating officials are kept informed of the status of the resulting administrative or legal action. The division must promptly notify SLTT officials when the resulting action is final so that the SLTT can update records and release the lot. This helps prevent inordinately long holding times.

Embargoes should not be considered a mere convenience to the FDA—they are an important and effective cooperative measure to be applied only when circumstances indicate.

SLTTs issue licenses or permits to many FDA-regulated firms. The main advantage of licensing is that, in the case of significant problems, a license can be suspended or revoked by the SLTT through an administrative procedure, and the firm cannot operate without its license.

Many state and local health jurisdictions can issue administrative citations and monetary penalties to establishments that violate statutes, ordinances, and rules. These measures are used to promote compliance and deter repeated or ongoing violations, especially when there is a clear risk to public health.

9.3.1.1 – FDA Personnel with State Authority

Certain states have designated selected FDA employees as special representatives, or agents of the particular state agency. In these cases, they have furnished the FDA individuals with official state credentials. The FDA representatives given this authority will receive instructions and training, by their division, in the proper exercise of the powers conferred on them and must operate within the guidelines established by their division to monitor this authority. This is particularly important whenever state embargo powers may be used.

Following major disasters, FDA program directors and division directors may arrange for close cooperation with SLTT food and drug officials, health departments, the Public Health Service, and other agencies engaged in comparable work. When requested to do so, FDA Division personnel will assist SLTT officials during such emergencies. At such times, FDA personnel may be temporarily commissioned by local or state authorities and provided the authority to place embargoes (See IOM 8.1.5.8.6).

9.3.1.2 - Joint Inspections

Joint inspections with SLTT inspectors are arranged by the division supervisory personnel in coordination with the state liaison. Joint inspections are conducted in the same manner as inspections by the FDA alone, and findings are discussed with the accompanying inspector. The SLTT inspector may wish to take action against merchandise, or the responsible firm, under pertinent local or state laws.

9.3.1.3 – FDA-Commissioned State Personnel

Qualified state regulatory officials may be commissioned under section 702(a)(1)(A) of the FD&C Act to conduct examinations and investigations, which can include conducting inspections, collecting samples, copying, verifying records, and carrying out an administrative detention order (following approval by the FDA Division Director).

There are two types of commissions granted by the agency:

- Certificate of Commissions, for the purposes of sharing information at high levels of a state program and for situational awareness only, and
- Credentialling Commissions, reserved for state employees conducting contract inspections using FDA authority.

In both instances, the state employee is acting as an FDA employee, and all information collected or received can only be used for FDA action-- not for state action.

9.3.1.4 – State Contract Inspections

The FDA contracts with state regulatory partners to provide enhanced regulatory oversight of its regulated firms. The agency's contract programs include: Human Food, Animal Food, Shell Eggs, Medical Device, and Mammography Quality Standards Act (MQSA). Contract inspections may be conducted under FDA or state laws, regulations, and/or authorities. If conducted under state laws and regulations, the state regulatory partner must have equivalent regulations. If contract inspections are conducted under FDA laws and regulations, the state must have adoption of the applicable FDA laws and regulations, or the state official conducting the inspection must carry FDA commission credentials. Field Management Directive 76 (FMD-76) governs the oversight of the contract audit program for all contract programs except MQSA.

All certified MQSA Inspectors are required to receive a satisfactory audit from a certified MQSA auditor during each federal fiscal year. State MQSA inspectors are issued a Certified MQSA Inspector ID card in accordance with the MQSA Act. Details concerning the MQSA inspection program and contract inspections are available on the program website.

9.3.2 – SLTT Memoranda of Understanding

The FDA has entered into agreements with various state and local agencies covering a variety of issues and work sharing agreements. Presently, not all states have entered into agreements with the FDA. A listing of current MOUs for states, the District of Columbia, and the Commonwealth of Puerto Rico is found on FDA's MOU page.

9.3.2.1 - Cooperative Programs

The FDA has three cooperative programs with other regulatory authorities: the Grade A Milk program, the National Shellfish Sanitation Program, and the Retail Food Protection program. The cooperative programs leverage state resources (inspectors, laboratories, etc.) to enforce food safety requirements on specific industries. In general, the FDA does not fund these programs, but provides technical, training, and other support to the states. The states provide uniform regulatory requirements over these industries and take actions to ensure that industry complies with national requirements. The requirements are set by the states at national biennial conferences, with concurrence by the FDA. The FDA evaluates all the state programs (except retail) to ensure each state is enforcing the national requirements.

In both the milk and shellfish programs, firms receive certification or permits to ship their product in interstate commerce, or to other facilities in the program to be shipped in interstate commerce. The Interstate Milk Shippers List provides a complete listing of all producers and processors that can ship products under the milk program. The Interstate Certified Shellfish Shippers List provides a complete

list of shellfish firms that can ship in interstate commerce. The Retail Food Protection Program does not have a certification or permitting system specifically for interstate sales.

9.3.2.1.1 - Grade A Milk Program

The FDA has responsibility, under the Public Health Service Act, to assist states in assuring the public that the nation's milk supply is uniformly safe and wholesome.
The National Conference on Interstate Milk Shipments (NCIMS) is the federal/state cooperative program recognized by the FDA as being responsible for ensuring the sanitary quality of milk and milk products shipped interstate.

All 50 states, plus Puerto Rico, are participants in the NCIMS program. Details about the program can be found on the FDA's website at Milk Guidance Documents & Regulatory Information, including information regarding currently listed Grade "A" milk plants and their associated approved products, bulk tank units, single service manufacturers, state regulatory/rating agencies, and federal contacts for the program.

The FDA Milk Specialist for each state is listed on the Milk Safety Programs: FDA Personnel webpage.

9.3.2.1.2 – National Shellfish Sanitation Program

The National Shellfish Sanitation Program (NSSP) is the federal/state cooperative program recognized by the FDA and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of bivalve molluscan shellfish produced and sold for human consumption. The purpose of the NSSP is to promote and improve the sanitation of shellfish moving in interstate commerce through federal/state cooperation and uniformity of state shellfish programs. Bivalve molluscan shellfish covered under the NSSP are defined as follows:

- Bivalve mollusks (including oysters, clams, mussels, cockles) whether they are:
  - Shucked or in the shell,
  - Raw (including post-harvest processed),
  - Frozen or unfrozen,
  - Whole or in part,

  AND
- Scallops in any form (except when the final product form is the adductor muscle only).

The NSSP Guide for the Control of Molluscan Shellfish consists of a Model Ordinance (MO) that is intended to cover molluscan shellfish that are raw (live, fresh, or fresh frozen) and molluscan shellfish subjected to post-harvest processing (PHP) as defined in the guide. Cooked shellfish, shellfish subject to 21 CFR part 113 or 114, and raw shellfish packaged with the explicit intent that they will be cooked by the end consumer (such as breaded or marinated) are generally recognized as products that are beyond the scope of the NSSP and are subject to the Seafood HACCP regulations (21 CFR 123). However, such shellfish products intended for interstate commerce are still subject to the appropriate harvest and/or approved source controls outlined in the guide when they are necessary to control a food safety hazard.

Participants in the NSSP include agencies from shellfish-producing and non-producing states, as well as the FDA, CDC, EPA, NOAA, and the shellfish industry. Under international agreements with the FDA, foreign governments also participate in the NSSP. Other components of the NSSP include program guidelines, state growing area classification and dealer certification programs,

and FDA evaluation of State program elements. See this FDA webpage for more details about the program.

The FDA Shellfish Specialist for each state is listed on the Interstate Certified Shellfish Shippers List.

9.3.2.1.3 – Office of Retail Food Protection

The Office of Retail Food Protection supports the decentralized regulatory system overseeing retail food safety in the United States. This system includes over 2,500 state, local, and tribal agencies responsible for regulating more than one million food establishments, such as restaurants, grocery stores, vending machines, and cafeterias. The division collaborates with regulatory partners, associations, and industry stakeholders to leverage their unique strengths and constituencies.

The Office of Retail Food Protection formulates and executes strategies to strengthen the food safety and defense capabilities of state, local, and tribal regulatory programs. It also works to build cooperative relationships with the foodservice and retail food industries, advocating for the adoption of effective food safety management systems.

The FDA Office of Retail Food Protection assists regulatory agencies and industries through a range of initiatives. These include offering a model Food Code, providing scientifically based guidance, delivering training, ensuring standardization, developing program standards, and offering technical assistance--all of which are focused on promoting the use of science-based food safety principles.

The FDA Retail Food Specialist for each state is listed on the Directory of FDA Retail Food Specialists.

9.3.3 – State Authorities and Phone Contact Numbers

This section contains information regarding various state enforcement authorities. Some states operate under state laws patterned after the FD&C Act of 1906 or the current FD&C Act. However, most of the states operate under a "Uniform FD&C Act" which was developed by the Association of Food and Drug Officials (AFDO).

States that have adopted the Uniform FD&C Act as their legal guideline have in most cases adopted the entire act. The food authority in most cases includes, among other things, the adoption of the food and color additive provisions, pesticide residue amendments, enrichment guidance, etc. The Uniform FD&C Act also includes a provision for automatic adoption of changes in the FD&C Act. Some state legislatures have also included this provision in their laws. Some other provisions of the Uniform Act adopted by states include the new drug provisions, medical device laws, and cosmetic requirements.

Some states have also adopted the Association of American Feed Control Officials (AAFCO) Model Bill as their legal guideline for feed inspections. Individual state information and contacts can be found at the AAFCO website.

In most cases, the contact for "Consumer Protection Issues" is located in the Office of the State Attorney General and usually covers consumer fraud and other consumer protection issues. The State Attorney General's staff usually has mechanisms to deal with health fraud issues not efficiently dealt with by traditional FDA approaches. Contact your Division Health Fraud Monitor for guidance in cooperative efforts with the State Attorney General's staff.

A complete listing of the personnel and programs at the state and local level may be found in the FDA Internet Directory of State and Local Officials prepared by the Office of Domestic Partnerships.

If you need to contact a state official concerning the cooperative programs, you should contact your state cooperative program specialist.

9.4 – International Arrangements

9.4.1 – International Arrangements

Over the years, the agency has entered into agreements with foreign governments regarding the safety and quality of foods, drugs, and other products exported to the United States. Refer to FDA's website on International Programs for additional information. With respect to FDA's international arrangements and related Confidentiality Commitments (CCs) with foreign governments to support sharing various types of non-public information, refer to the FDA website link for the CCs associated with various countries and their specific regulatory authorities.

9.4.2 – Mutual Recognition Agreements

9.4.2.1 - International Community

Changes in the Food and Drug Administration Modernization Act (FDAMA) have required that the FDA begin the process of acceptance of mutual recognition agreements, or MRAs, relating to the regulation of FDA-regulated commodities as well as facilitate commerce between the United States and foreign countries and other activities to reduce the burden of regulation and to harmonize regulatory requirements. (For more on this, see Section 410 of FDAMA and the FDA's MRA webpage.)

9.4.2.2 - Food Products

In July 1999, the United States and the European Community (EC) signed the "Agreement on Sanitary Measures in Trade in Live Animals and Animal Products (99-801)". This agreement is very much like an MRA and is based on the equivalence process. It covers a very wide range of human food products--all of animal origin--such as milk and dairy products, seafood, honey, wild game, snails, frog legs, and canned pet food. For purposes of this agreement, the EC is considered one "party". Activities to begin assessing equivalence are underway.

9.5 – Non-Government Agreements

The agency has entered agreements with various non-governmental groups to formulate various programs and guidance. See FDA's Cooperative Agreements page for more.

9.6 – Tribal Affairs

The federal government has obligations to federally recognized Indian tribes. The agency understands the importance of government-to-government relations, collaboration and consultation, as appropriate, with federally recognized tribal governments of the United States, per U.S. Constitution Article VI treaty clause, related Acts of Congress (P.L 93-638) , Executive Orders such as 13175, and Policy. The FDA respects tribal sovereignty and honors the government-to-government relationship and trust responsibilities we have with federally recognized American Indian and Alaska Native Tribes (hereafter referred to as Tribes).

Refer to this FDA website for additional information, including related links confirming FDA jurisdiction on Tribal lands.

9.6.1 – Interacting with Tribes and Tribal Public Health Authorities

Tobacco inspections are particularly relevant in our collaborations with Tribes as the American Indian and Alaska Native population has the highest prevalence of cigarette smoking of any population group in the United States. If you are engaging with tribal nations as it pertains to tobacco inspections, consult this webpage regarding CTP and federally recognized Tribes.

Note that the agency interacts with each Tribe individually, so the way in which you conduct field work on tribal lands may vary. Before conducting a non-tobacco inspection, investigation or other field work on tribal land, or at a firm that is owned or operated by a Tribe, consult with your state liaison and supervisor to ensure that you are following appropriate procedures. This includes updating District Use Codes (DUCs) in FMS when you determine a firm is located on Tribal Land (DUC = TL) and/or tribal owned (DUC = TO) In addition, as clarified in the IGA-OII MOU regarding roles and responsibilities, when Tribal-elected officials intend to be contacted, Office of the Commissioner/Office of Policy, Legislation and International Affairs/Intergovernmental Affairs (IGA) will be engaged to initiate the communications in collaboration with OII. While the FDA has regulatory jurisdiction on tribal lands in the United States, it is, nevertheless, in the spirit of partnership building and respectful collaboration across SLTT jurisdictions, that we extend advance inspection notification to Tribes whenever possible. In such cases, for example, a Dear Tribal Leader Letter (DTLL) transmitted to the Tribal Elected Officials by the Office of the Commissioner, Intergovernmental Affairs (IGA) may be advisable to support and facilitate ORA's field work. A DTLL will also help in case you may need to meet with tribal officials before entering tribal lands to conduct field operations. A DTLL may also clarify if the Tribe is interested in observing the inspection. If you are unsure how to proceed, contact your supervisor, state liaison, and OP, who, in turn, can reach out to IGA before you initiate contact with any tribal elected leaders.

At the beginning of each year, the U.S Department of the Interior updates in the Federal Register the list of federally recognized Indian Tribes (There are 574 tribal entities as of 1/08/2024.). It also maintains a tribal leader directory on its website.

To help you identify and locate tribal land locations with respect to FDA-regulated facilities scheduled for inspection, visit the OII Applications page, which includes Work Planning Tracking Tools (WPTT) for all program areas. In the WPTT, within the "Layer List," there is an interactive GIS map of Tribal Land areas associated with workplan FDA-regulated firm locations.

9-1 FDA/ USDA Jurisdiction

This table summarizes information concerning jurisdiction overlap for human food products regulated by either or both FDA and USDA. It does not cover products made for on-site consumption such as pizza parlors, delicatessens, fast food sites, etc.

This table does not apply to meat and meat products intended for use in animal food.

FDA JURISDICTION	USDA JURISDICTION		
21 USC 392(b) Meats and meat food products capable of use as human food shall be exempt from the provisions of this Act to the extent of the application or the extension thereto of the Meat Inspection Act. FDA is responsible for all non-specified red meats (bison, rabbits, game animals, zoo animals and all members of the deer family including elk (wapiti) and moose)). FDA is responsible for all non-specified birds including wild turkeys, wild ducks, and wild geese. For products not intended to use for human food this exemption does not apply. Any ingredient, including meat and meat food products, used in animal food is regulated by FDA.	The Federal Meat Inspection Act regulates the inspection of the following amenable species capable of use as human food: cattle, sheep, swine, goats, horses, mules, or other equines, including their carcasses and parts. It also covers any additional species of livestock that the Secretary of Agriculture considers appropriate. Mandatory Inspection of Ratites and Squab (including emu) announced by USDA/FSIS April 2001	The Poultry Products Inspection Act (PPIA) defines the term poultry as any domesticated bird. USDA has interpreted this to include domestic chickens, turkeys, ducks, geese, and guineas. The Poultry Products Inspection Act states poultry and poultry products shall be exempt from the provisions of the FD&C Act to the extent they are covered by the PPIA. Mandatory Inspection of Ratites and Squab announced by USDA/FSIS April 2001	The Egg Products Inspection Act defines egg to mean the shell egg of domesticated chicken, turkey, duck, goose, or guinea. Voluntary grading of shell eggs is done under USDA supervision. (FDA enforces labels/labeling of shell eggs.)
Products with 3% or less raw meat; less than 2% cooked meat or other portions of the carcass; or 30% or less fat, tallow, or meat extract, alone or in combination. Products containing less than 2% cooked poultry meat; less than 10% cooked poultry skins, giblets, fat, and poultry meat (limited to less than 2%) in any combination. * Closed-face sandwiches. Any meat or meat food product used in or for animal food is regulated by FDA, regardless of %	Products containing greater than 3% raw meat; 2% or more cooked meat or other portions of the carcass; or greater than 30% fat, tallow, or meat extract, alone or in combination. * Open-face sandwiches.	Products containing 2% or more cooked poultry; 10% or more cooked poultry skins, giblets, fat, and poultry meat in any combination. *	Egg products processing plants (egg breaking and pasteurizing operations) are under USDA jurisdiction.
FDA is responsible for shell eggs and egg containing products that do not meet USDA's definition of "egg product." FDA also has jurisdiction in establishments not covered by USDA, e.g., restaurants, bakeries, cake mix plants, etc.			Products that meet USDA's definition of "egg product" are under USDA jurisdiction. The definition includes dried, frozen, or liquid eggs, with or without added ingredients, but

Egg processing plants (egg washing, sorting, packing) are under FDA jurisdiction.			mentions many exceptions. The following products, among others, are exempted as not being egg products: imitation egg products, dietary foods, dried no-bake custard mixes, eggnog mixes, acidic dressings, noodles, milk and egg dip, cake mixes, French toast, sandwiches containing eggs or egg products, and balut and other similar ethnic delicacies. Products that do not fall under the definition, such as cooked products, are under FDA jurisdiction.
Cheese pizza, onion and mushroom pizza, meat flavored spaghetti sauce (less than 3% red meat), meat flavored spaghetti sauce with mushrooms, (2% meat), pork and beans, sliced egg sandwich (closed-face), frozen fish dinner, rabbit stew, shrimp-flavored instant noodles, venison jerky, buffalo burgers, alligator nuggets, noodle soup chicken flavor	Pepperoni pizza, meat-lovers stuffed crust pizza, meat sauces (3% red meat or more), spaghetti sauce with meat balls, open-faced roast beef sandwich, hot dogs, corn dogs, beef/vegetable pot pie.	Chicken sandwich (open face), chicken noodle soup	Homogeneous cheese and meat products, e.g., cheese balls with pepperoni, must contain more than 50 percent meat to be amenable to USDA inspection. Cheese products that contain 50 percent or less meat are considered products of the dairy food industry and, thus, are exempt from USDA inspection. When cheese and meat are separate components in a package, the packaged product is amenable, provided, it contains 2 percent cooked meat.

Jurisdiction for products produced under the School Lunch Program, for military use, etc. is determined via the same algorithm although the purchases are made under strict specifications so that the burden of compliance falls on the contractor. Compliance Policy Guide 565.100, 567.200 and 567.300 provide additional examples of jurisdiction. IOM 9.2.1 and 2.6.1 provide more information on our interactions with USDA and Detention Authority.

* These percentages are based on the amount of meat or poultry product used in the product at formulation.

9-2 – Address Information Request



To: Postmaster

Agency Control Number:
Date:

ADDRESS INFORMATION REQUEST

Please furnish this agency with the new address, if available, for the following individual or verify whether or not the address given below is one at which mail for this individual is currently being delivered. If the following address is a post office box, please furnish the street address as recorded on the boxholder's application form.

Name:
Last Known Address:

I certify that the address information for this individual is required for the performance of this agency's official duties.

(Signature of Agency Official)

(Title)

FOR POST OFFICE USE ONLY

[ ] MAIL IS DELIVERED TO ADDRESS GIVEN
[ ] NOT KNOWN AT ADDRESS GIVEN
[ ] MOVED, LEFT NO FORWARDING ADDRESS
[ ] NO SUCH ADDRESS
[ ] OTHER (SPECIFY):

NEW ADDRESS

BOXHOLDER'S STREET ADDRESS

Agency return address

Postmark/Date Stamp

Under the authority of 39 CFR 265.6(d)(5)(i) and (d)(7)

265.6 Availability of records.

(d) Disclosure of names and addresses of customers. Upon request, the names, and addresses of specifically identified Postal Service customers will be made available only as follows:(5) Exceptions. Except as otherwise provided in these regulations, names, or addresses of Postal Service customers will be furnished only as follows: (i) To a federal, state or local government agency upon prior written certification that the information is required for the performance of its duties. The Postal Service requires government agencies to use the format appearing at the end of this section when requesting the verification of a customer's current address or a customer's new mailing address. If the request lacks any of the required information or a proper signature, the postmaster will return the request to the agency, specifying the deficiency in the space marked 'OTHER'. A copy of PS Form 1093 may be provided.

(7) Address verification. The address of a postal customer will be verified at the request of a Federal, State, or local government agency upon written certification that the information is required for the performance of the agency's duties. "Verification" means advising such an agency whether or not its address for a postal customer is one at which mail for that customer is currently being delivered. "Verification" neither means nor implies knowledge on the part of the Postal Service as to the actual residence of the customer or as to the actual receipt by the customer of mail delivered to that address. The Postal Service requires government agencies to use the format appearing at the end of this section when requesting the verification of a customer's current address or a customer's new mailing address. If the request lacks any of the required information or a proper signature, the postmaster will return the request to the agency, specifying the deficiency in the space marked "OTHER".

U.S. Food and Drug Administration
www.fda.gov

INSTRUCTIONS FOR COMPLETING IOM EXHIBIT 9-2

If you have already attempted to locate the individual or firm by sending mail marked on the outside of the envelope "DO NOT FORWARD. ADDRESS CORRECTION REQUESTED", without results, then proceed with this form according to the instructions below.

INSTRUCTIONS

1. Address the request to the Postmaster at the post office of the last known address.
2. Insert FEI # if known; or assignment or sample number for Agency Control number.
3. On the lines provided, give the name and last known address, including zip code, of the individual or firm. Do not include any other identifying information such as race, date of birth, social security number, etc.
4. The Postal Service provides the service of address verification to Government agencies only. For this reason, the Postal Service requires the signature and title of an agency official to certify that the address information requested is required in the performance of the agency's official duties. The agency official should be if possible, the chief of the office requesting the information. In the interests of efficiency, the signature may be preprinted or rubber-stamped.
5. Type or stamp the agency's return mailing address in the space provided at the bottom of the request. Include your full name and title or the appropriate person’s full name and title to whom the form should be returned to. Mail or deliver the request to the Postmaster at the post office of the last known address.

You are not required to submit this request in duplicate or to furnish a return envelope.