

**THE FOOD MODERNIZATION ACT WHAT
EVERY TEXAS LAWYER SHOULD KNOW**

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OVERVIEW

Mike is a partner in the Dallas office of Strasburger & Price. Mike leads the firm's Food and Drug Law industry team. He is also the Chair of the Drug Device and Biotechnology section of the FDCC. He was licensed to practice in Texas in 1994 and New York in 1986. He devotes most of his practice to counselling clients in FDA regulated industry on issues related to transportation, labeling and compliance, and defending complex litigation matters. He has served as national coordinating counsel, regional trial counsel and as Texas counsel in a wide variety of complex litigation matters including environmental water contamination, and claims and regulatory compliance involving FDA regulated businesses, such as food manufacturers, processors, suppliers, importers, packaging manufacturers, retailers, and transportation and distribution.

Mike has lectured and written extensively on issues involving FDA regulated industry and is the author of a law book entitled *The Supply and Distribution of FDA-Regulated Products*, and a number of book chapters on FDA law. He is also the founder of the Food Law Forum an annual legal symposium based in Texas, hosted by Southern Methodist University and sponsored by SMU and Michigan State University.

Mike began his career in NYC but was required to move to Texas when he read the fine print in his prenuptial agreement which states "when you marry a woman from Lubbock, Texas you move to Texas."

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THE FOOD MODERNIZATION ACT WHAT EVERY TEXAS LAWYER SHOULD KNOW

I. THE GLOBAL SUPPLY CHAIN – FOOD IN THE 21ST CENTURY

Introduction

On September 11, 2001 the world changed. Congress and government regulators recognized that the laws and rules were well designed to respond to widespread unintended adverse outcomes from medical products and outbreaks of food borne illness but were inadequate to prevent intentional and criminally negligent outcomes and outbreaks. Congress has acted by enacting aggressive new legislation that revolutionizes the supply and distribution of food and drugs in the United States. In response to the new legislation, FDA is implementing a massive restructuring of how it oversees the transport of regulated products throughout the United States. The sea-change in the oversight of the transportation of regulated products has created new opportunities, challenges and risks for suppliers, manufacturers, distributors, marketers and sellers of FDA regulated products.

The first step towards the regulation of the food and drug industry was the formation of the U.S. Pharmacopeia, the first compendium of standard drugs for the United States. Eleven physicians meet in Washington D.C. in 1820 to establish this list.¹ The FDA was initially named the Division of Chemistry in the late 19th century, later changed to the Bureau of Chemistry, then the Food, Drug and Insecticide Administration, and is today known as the Food and Drug Administration.

In 1862, President Lincoln appointed a chemist named Charles M. Wetherill who set up a laboratory and began analyzing samples of food, soils, fertilizers, and other agricultural substances. Dr. Harvey W. Wiley became the Bureau of Chemistry's chief chemist in 1883 and started the campaign for federal legislation governing food adulteration, a grass roots movement that created political support for legislation governing food and drugs was known as the Pure Food Movement.

The Food and Drug Act was signed into law by President Roosevelt on June 30, 1906. At its inception the Food and Drug Act was commonly known as the Wiley Act because Wiley was a driving force behind the legislation.² With the passage of the Federal Food and Drugs Act in 1906 the modern era of the FDA began but it was a far cry from what we know today and the compounds available to the consuming public without prescription or physician make today's regulation look paternalistic. Another reported driving force behind the Food and Drug Act was the novel, *The Jungle*, by Upton Sinclair which described of the condition of the meat-

packing industry. The book chronicled the plight of the worker from a socialist's perspective but the author's principle political point was obscured and outrage ran to the handling of food. The focus of the Food and Drug Act was on the product labeling rather than the pre-market approval of products placed on store shelves. The notion of letting the consumer know what was in a product was more important than requiring proof of safety before marketing and Americans were decades from any requirement of evidence of efficacy for regulated products. The sentiment may best be demonstrated by a contemporaneous quote in the Journal of the America Medical Association:

“Life is a dangerous thing at best and very few of us get out of it alive,” while those of us who spend all our energies trying to elude its incidental risks might almost as well never have lived at all. Health is largely a matter of a proper balance of opposing forces; and that balance can be preserved, in part, by cultivating a due measure of indifference to inevitable dangers.³

Despite great strides over the past 100 years, the early days were much like today as laws and regulations are largely reactive to product outcomes. Adverse outcomes, whether real or perceived have historically motivated consumers and law makers to require more from manufacturers and less from consumers. Elixir sulfanilamide was a drug therapeutic claims touted the compound as a “wonder drug.” The drug had been in a pill form which was large and difficult to ingest in sufficient quantities for much therapeutic benefit until mixed with diethylene glycol, antifreeze like substance, for oral administration. Tragically use of the drug resulted in many deaths including many children.⁴ In response in 1938, the Food and Drug Act was replaced with the Food, Drug and Cosmetic Act with a new emphasis on safety. This Act mandated pre-market approval of all new drugs and required that drugs be labeled with directions for safe use. Several amendments to this Act were later passed in response to drug experience and world events such as the sedative Thalidomide, which produced thousands of grossly deformed newborns in many countries creating the impetus for the Kefauver-Harris Amendment.

It wasn't until 1962 that the law required proof of efficacy; that is to say, that the product does what the manufacturer says it does. The changes in food and drug laws over the past century suggest that the focus of these regulations shifted from protecting consumers by educating and informing consumers and implementing pre-market controls.⁵

1. White House Global Strategy
 i. **National Strategy for Global Supply Chain Security**

On January 23, 2012 the White House issued its *National Strategy for Global Supply Chain Security*.⁶ The White House strategy includes two goals:

The first goal of the White House strategy is to “Promote the Efficient and Secure Movement of Goods.” The first goal concerns protecting and securing the timely, efficient flow of legitimate commerce by:

- a. Resolving threats early by integrating security processes into supply chain operations;
- b. Increasing verification and detection by identifying goods that are not what they are represented to be, are contaminated, are not declared, or are otherwise adulated or misbranded;
- c. Enhancing security
- d. Modernizing supply chain infrastructure and processes; create new for low risk cargo; simplifying trade compliance processes; and create incentives for stakeholder collaboration

The second goal is to “Foster a Resilient Supply Chain.” The second goal contemplates shifting focus from responding to threats and hazards after they arise to anticipating them and creating an approach to withstand and recover rapidly from disruptions by establishing:

- a. Risk management principles to identify and protect key assets, infrastructure, and support systems; and implement sustainable operational processes and redundancy; and
- b. Trade resumption policies and practices establishing “national and global guidelines, standards, policies, and programs.”⁷

The administration’s approach considers enhanced collaboration at the federal and state level as well as with stakeholders under a proposed “all-of-nation approach to leverage the critical roles played by state, local, tribal and territorial governments, and private sector partners.”⁸ On a global scale the Administration’s plan recognizes that the “global supply chain transcends national borders and Federal jurisdiction” and seeks to “implement global standards, strengthen detection, interdiction, and information sharing capabilities, and promote end-to-end supply chain security efforts with the international community.”

To implement the strategy, the White House set a number of focus areas:

- a. Align Federal activities across the entire Government;

- b. Refine and reassess the threats and risks associated with the global supply chain;
- c. More use of advanced technology to oversee cargo in air, land, and sea environments;
- d. Identify infrastructure projects to serve as models for the development of critical infrastructure resiliency best practice;
- e. Incorporate global supply chain “resiliency” goals and objectives into the Federal infrastructure investment programs and project assessment process;
- f. Promote legislation that supports implementation of the strategy by Federal departments and agencies;
- g. Work with industry and foreign governments to speed the flow of low-risk commerce in specific supply chains that meet designated criteria; and
- h. Align trusted trader program requirements across Federal agencies. Standardize application procedures, enhance information-sharing agreements, and security audits conducted by joint or cross-designated Federal teams.

ii. **“Harmonizing” the global regulatory market**

Globalization has come to mean that FDA now exerts far more oversight overseas, as opposed to at the border, than in the past: we had to change our operating model in important ways. In FDA’s view to enforce the new law it had to develop a meaningful presence overseas and create a new directorate within FDA that would be responsible for both international operations and our field investigators who inspect facilities in the U.S. and overseas.⁹ Speech by Margaret A. Hamburg, MD.¹⁰

As Globalization marches forward the emergence of the concept of “harmonization” has come to the forefront. Harmonization is a catch phrase for negotiating with international bodies to create a seamless scheme of regulation and enforcement of the laws of different nations. As this concept evolves, we may see not so much harmonization as counterpoint as the harmonies clash between nations and the liberties granted their citizens do not meld. For the student of global harmonization, the following organizations are focusing on developing the standards and procedures in this evolving marketplace:

- International Conference on Harmonisation (ICH),
- Pharmaceutical Inspection Cooperation Scheme (PIC/S),
- International Pharmaceutical Regulators Forum (IPRF), and

Asia Pacific Economic Cooperation’s (APEC) Pharmaceutical Product Supply Chain,

While the regulators focus on establishing a system of oversight, not all products or facilities can be inspected and tested and “companies must feel responsible and accountable, always. Quality must be built into products from start to finish and must be a focus of all activities.”¹¹

At the bottom of the massive increase in regulation and oversight are very real concerns for example:

another concern that I want to mention. This is the growing opportunities for intentionally adulterated, counterfeited or otherwise falsified medical products to infiltrate the legitimate medical products supply, which signal an alarming trend. Recent incidents of this kind have caused serious threats to health, with tragic consequences around the world. I’m sure that you are aware of some of these episodes--from contaminated heparin (the blood-thinning drug), to counterfeit Avastin (a cancer treatment), to children’s cough syrup containing ethylene glycol, a well-known poison. Such adulterated medical products may contain too much, too little, or the wrong active ingredient, and could contain toxic ingredients. They prevent patients from getting the real medical products that they need and for antibiotics, they can also increase the likelihood of drug resistance, which is a serious and growing concern for us all.¹²

iii. Critical Infrastructure Partnership Advisory Council

The Department of Homeland Security has established the (CIPAC)¹³ which is a Federal Advisory Committee Act-exempt body established by the Secretary of Homeland Security, as authorized in Section 871(a) of the Homeland Security Act [6 U S C §451(a)], to implement the National Infrastructure Plan (NIPP) Framework.¹⁴ The NIPP Framework is a partnership between government and critical infrastructure and key resources owners and operators, and provides a forum in which they can engage in a broad spectrum of activities to support and coordinate critical infrastructure protections.

2. FDA and Global Engagement

i. Commissioner statement

In discussing the greatest impact on public health FDA Commissioner stated:

The rise of global markets and supply. Many regulators around the globe face additional

concerns, as their systems are skeletal at best. Change has been rapid and profound. Emerging markets and developing economies are gaining new prominence, and the increased flows of people, capital, information and goods across borders have realigned many roles, relationships and risks.

At every step in global supply chain networks -- from raw materials and other ingredients, to manufacture, storage, sale, and distribution -- there are opportunities for a product to be improperly formulated or packaged, contaminated, diverted, counterfeited, or adulterated. For so many countries, including my own, import volumes have increased exponentially and inspecting products at ports of entry is no longer adequate to ensure that our consumers have safe products. Rather, prevention of problems before they reach our borders requires strengthening quality and safety oversight in countries from which we import products, with benefits for consumers everywhere. It also means strengthening the integrity of supply chains as products move through the system.¹⁵

Highlighting the burden on the US manufacturer the Commissioner observed:

“[m]any regulators around the globe face additional concerns, as their systems are skeletal at best. Nearly 40 percent of finished drugs Americans consume today are made elsewhere, as are about 50 percent of all medical devices. Approximately 80 percent of the manufacturers of active pharmaceutical ingredients used in the United States are located outside our borders.

China already has the largest number of foreign, FDA-registered, drug manufacturing establishments, followed by India. And China has the fourth highest volume of exports to the U.S. of medical equipment and is the leading supplier of sutures, sterile, surgical, and dental goods. In addition to the growth in sheer volume of imports and foreign facilities, today’s complicated supply chain involves a web of sources and shippers, as well as repackagers and redistributors. Innovations in transportation, refrigeration, and communication have made it increasingly easy to ship drugs, medical devices, and biologics over long distances.¹⁶

As significant advances in global product sourcing creates greater opportunities, “[t]oday’s global supply chain poses greater risks to consumers because there are so many additional steps, potential vulnerabilities and questions to be asked including: Who has handled the product? How was it manufactured, packed, distributed, and stored? And who supplied the ingredients?”¹⁷

ii. Global Engagement Report

FDA views its success in protecting the U.S. public as depending increasingly on its ability to reach beyond U.S. borders and engage with regulatory counterparts in other nations, as well as industry and regional and international organizations.

Through effective global engagement, FDA is working with its many international partners to weave a global safety net that benefits public health in the United States and around the world.

FDA’s Office of International Programs issued its November 21, 2013 report entitled “Global Engagement”¹⁸ identifying the FDA’s efforts concerning all FDA regulated products. FDA identifies its efforts as a “paradigm shift” recognizing that it will move from being an observer of the global market to an active participant. FDA recognizes that inspection at the U.S. borders or ports-of-entry is no longer sufficient to ensure the safety of the ever increasing tide of imports to the United States.¹⁹

Since 2002, for example, imports of pharmaceutical products and biologics have more than doubled, and medical device imports have quadrupled. Foreign sourced pharmaceuticals now account for some percent of the drugs consumed in the United States, and an astonishing 80 percent of the active ingredients in U.S.-consumed drugs are sourced from abroad.¹³ With respect to medical devices, imports now represent more than 35 percent of the U.S. medical equipment market.²⁰

iii. Pathway to Global Product Supply

As described in more detail in FDA’s 2011 Special Report, *Pathway to Global Product Safety and Quality*,²¹ “the Agency is working to transform itself over the next ten years from a domestic agency operating in a globalized economy to a truly global agency fully prepared for the regulatory pressures of globalization.”²²

How will it be done and when?

By “including a global data information system they can use to proactively share real-time information and resources across markets. To achieve a true and lasting

paradigm shift, FDA will be engaging stakeholders in a process that will unfold over the next several years.”²³

As of 2011 the FDA had offices in the following foreign countries:

China with posts in Beijing, Shanghai, and Guangzhou.

India with posts in New Delhi and Mumbai.
Latin America with posts in San Jose, Costa Rica; Santiago, Chile; and Mexico City, Mexico.

Europe with posts in Brussels, Belgium; London, United Kingdom; and Parma, Italy.
Asia-Pacific, located at FDA headquarters.
Sub-Saharan, located in Pretoria, South Africa.

Middle East and North Africa, located in Amman, Jordan.²⁴

The FDA is a founding member of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH),²⁵ which seeks to harmonize regulatory standards, processes, and procedures for the pharmaceutical industry. Established in 1990, ICH brings together drug regulatory authorities and pharmaceutical industry experts of the United States, European Union, and Japan. Additional participants, as observers, include WHO, Canada, and Australia.

Global pathway FDA’s July, 7, 2011 revised report, *Pathway to Global Products and Safety*,²⁶ lays out FDA’s ten year “vision” for transforming the global supply chain for FDA regulated products. As FDA puts it “Ten Years From Now, the World Will Be Very Different Than it is Today.” Historically, FDA’s primary tool for product safety and quality was inspections at production facilities and ports of entry.²⁷ In the decade ahead

“the world economy will be shaped by several distinct forces: the rise of emerging markets, the scarcity of natural resources, and the increased flow of capital, information, and goods across borders. The cumulative effect of these trends means not only phenomenal growth in the import sector but increasing complexity for regulators, as the distinction between foreign and domestic products continues to blur.”²⁸

Because of these forces, a shift in global product flows will make it difficult to identify the “source” of a product and to ensure that all players along the supply chain meet their safety and quality responsibilities.²⁹ To address this changed world, FDA’s Global Pathway builds on four (4) core concepts:

- a. Global coalitions of regulators;
- b. Develop a real time global data information network.
- c. Expand intelligence gathering and modernized analytics and
- d. Risk based resource allocation.

The 10 Year Plan:

- a. ***The great rebalancing.*** FDA sees globalization in trade as “likely leave traditional Western economies with a lower share of GDP in 2050 than they had in 1700.” Western economies with aging population and emerging populations increasing with urban expansion.
- b. ***The productivity imperative.*** FDA sees “Rich nations” experiencing “the natural progress of opulence.”
- c. ***The global grid.*** Cross-border capital flows have expanded at three times the rate of GDP growth. These days, a typical manufacturing company relies on more than 35 different contract manufacturers around the world. Id at 7
- d. ***Government and the marketplace.*** FDA foresees an enhanced role for regulators. Citing three reasons (i) negative impact of globalization on local economy; (ii) government stimulus; and (iii) more dispersed economic power and regulation requiring manufacturers to adapt.

Greater governmental involvement in the medical and healthcare marketplace.

Estimates predict that by the end of 2010, more than 40% of the final assembly in the consumer goods and life sciences industries will be performed by foreign producers, due largely to the lower cost of production.³⁰

While imports in and of themselves are not problematic, what does present a problem for regulators is reflected in the World Health Organization estimate that between 5% and 8% of all of pharmaceuticals worldwide were counterfeit in 2003.³¹ Moreover, increasing cases of adulterated, misbranded and improperly transported and unapproved products and products distributed by unregistered manufacturers through both traditional and online distribution sources has increased the burden for the FDA products

With this backdrop, there is a call for a transformation of the FDAs operating model for supply and distribution. In furtherance of the shifting manufacturing market and increased risk for adulterated and misbranded products a number of initiatives have been instituted. For example, FDA moved to PREDICT (Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting)³² Focusing on cargo that presents the highest risk: focusing on product codes, manufacturer’s history, country of origin, recall security risks. PREDICT is the FDA’s electronic screening tool for import operations that replaces the legacy screening tool in OASIS (Operational and Administrative System for Import Support). It works behind the scenes to screen all lines of imported product electronically submitted to the FDA via the US Customs and Border Protection interface. MARCS (Mission Accomplishment and Regulatory Compliance Services) Imports Entry Review is FDA’s new application used to make initial admissibility decisions, assign field work, and display the results of the PREDICT risk-based screening and database lookups. National rollout of PREDICT began in September of 2009 to all 16 import Districts and was completed in December 2011. PREDICT is designed to calculate a customized risk score for every line in an entry.

In 2008 the General Accounting Office³³ recommended that FDA increase inspections of foreign drug establishments and improve information it receives to manage overseas inspections.³⁴ But at current rates, it would take an estimated nine years for FDA to inspect every high priority pharmaceutical facility just once.³⁵

FDA’s successes in engaging foreign partners have not helped the agency substantially increase the coverage of its safety and quality assurance activities.³⁶

3. Good Importer Practices - Guidance for Industry³⁷

In January 2009 FDA issued its draft Guidance on “Good Importer Practices” setting forth four Guiding principles. In general, FDA recommends importers know the foreign firms and any other firms with which they do business and through which such products pass (e.g., consolidators, trading companies, distributors). In addition, FDA recommends understanding the products that they import and the vulnerabilities associated with these products and the hazards that may arise during the product life cycle, including all stages of production, ensuring proper control and monitoring of these hazards.

Guiding Principle I Establishing a Product Safety Management Program

FDA suggests importers establish a product safety management program that includes the following:

Establish a management structure for product safety.

Assign responsibility for compliance to specific individuals

Ensure assigned individuals have training, knowledge, experience, skills, and competence to perform compliance.

Maintain documented policies, specifications, and procedures

Establish a process to analyze and evaluate risks in the product life cycle

Develop and maintain a system for communication

Establish a formal quality-assurance program

Guiding Principle II Knowing the Product and Applicable U.S. Requirements

To ensure imported products are in compliance with all applicable U.S. statutes and regulations, importers should have a good understanding of the products they are importing, the applicable regulatory requirements, and the compliance history of the products and the firms involved in the products' design, production and handling. The importer should have sufficient knowledge of the product, its intended use, its inherent vulnerabilities and risks, and the methods by which it is grown, harvested, manufactured, processed, packed, received, transported, stored, imported, and distributed. The importer should know the regulatory framework that governs the products in the country of production; the compliance status of the products it imports; the foreign firms that manufacture those products; and other firms with which it conducts business involved in the product's life cycle.

Guiding Principle III Verifying Product and Firm Compliance with U.S. Requirements throughout the Supply Chain and Product Life Cycle

Have knowledge of the firms/persons in the foreign supply chain (e.g., name, address, type of business, etc.), to the extent feasible, from the production or growing of raw materials to manufacturing/processing, packaging, storage, and transportation of products destined for import into the United States:

- Know what preventive controls, if any, firms must institute at each critical point in the product's life cycle, and the steps firms need to take to ensure that those controls are being appropriately applied.
- Prior to doing business with a supplier, perform an assessment of the supplier to determine whether it

has implemented an effective product safety program to help ensure you receive a product that meets applicable U.S. requirements.

- Resolve any potentially significant or questionable information gaps about the firms involved.
- Obtain a written guarantee of product compliance from company representatives, Insist on compliance with U.S. requirements in the purchasing contract.
- Deal directly with the supplier, or its authorized agent, to avoid fraudulent schemes.
- Require all those in the supply chain to have evidence of compliance with applicable U.S. requirements.
- Require foreign firms to train their employees on U.S. requirements.
- Establish mechanisms to verify compliance with U.S. requirements.
- Inspect the foreign firm either through periodic visits or by placing personnel in critical, foreign production facilities. Alternatively, the importer could hire qualified third parties to perform inspections.
- Consider purchasing from certified firms.
- Determine if the source country has laws that regulate the product, if the foreign regulatory scheme applies to exports and covers U.S. requirements, if there is a competent regulatory authority that regularly inspects the facility for compliance with the source country's requirements, and whether the source country's oversight includes any sampling and analysis.
- Conduct paper audits.
- Periodically reassess monitoring mechanisms.
- Be alert to evidence that casts suspicion on the product.
- Obtain guarantees or certifications subject to substantiation, if appropriate, that products vulnerable to moisture, contaminants, temperature, or other environmental conditions have been maintained under acceptable conditions during transit.

During Entry: Control, Monitor, and Verify Product Compliance

The guidance recommends conducting a risk-based monitoring program of incoming products including:

- Examination of shipping records - certifications, certificates of analysis, letters of guarantee, etc.;
- Physical examination of packaging and labeling;
- Risk-based product sampling and testing to ensure the product is authentic, and meets company specifications and U.S. requirements.

- Consider using a licensed customhouse broker. Know the correct harmonized tariff schedule number, as well as the correct commodity and product codes, and provide them to the broker/filer.
- Avoid any broker/filer that repeatedly provides incorrect information to the U.S. Government.

In Distribution. - Control, Monitor, and Verify Product Compliance. Stablish procedures to:

- review and handling of safety complaints from consumers and customers
- identify non-compliant products, and for communicating information within the organization and to third parties, including Federal, State, and local authorities.
- identify the source and destination of a potentially violative product
- isolate and hold the product until all applicable agencies have issued the relevant releases.
- recall products from distribution channels in the United States.
- notify distributors, retailers, consumers and other end users.

II. THE FOOD SUPPLY CHAIN- MASSIVE RESTRUCTURING AND INFLUX OF REGULATIONS

Introduction:

The United States’ food supply is a modern day miracle. If you calculate the number of meals, the number of producers, the number of ingredients that each consumer encounters in the course of a year, it is truly a miracle that the marketplace has performed so well for so long without the current influx of new laws and regulations. Relying on references to a CDC statement that itself relies on data that arguably does not support the conclusion, FDA states that “one of every six Americans will get ill each year.” The CDC data relied on by FDA includes all level of illness and does not exclude consumer handling as the contributing cause.

Because of consumer concerns over food handling practices, Congress established the FDA more than 100 years ago. Over time and in reaction to a serious health impacts from adulterated and misbranded products, the scope of how the FDA goes about fulfilling its mission has expanded. In setting FDA’s mission,³⁸ Congress provided that the (Food and Drug) Administration shall—

- (1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;

- (2) with respect to such products, protect the public health by ensuring that—
 - (a) foods are safe, wholesome, sanitary, and properly labeled;
 - (b) human and veterinary drugs are safe and effective;
 - (c) there is reasonable assurance of the safety and effectiveness of devices intended for human use;
 - (d) cosmetics are safe and properly labeled; and
 - (e) public health and safety are protected from electronic product radiation;
- (3) participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements; and
- (4) as determined to be appropriate by the [FDA], carry out paragraphs (1) through (3) in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.

Over most of the past 100 years the FDA’s role was to respond to incidents and outbreaks, remove offending products and punish offenders. With the passage of new laws, most notably the Food Drug Administration Safety Innovation Act (FDASIA) and Food Safety Modernization Act (FSMA), the emphasis is now on prevention. That is, to establish rules and guidelines that give the FDA significantly greater oversight through facility registration, inspections, record production requirements and greatly enhanced enforcement powers. The scope of the oversight for FDA does not stop at the border either, and the law grants oversight and inspection power of facilities abroad. The new “normal” for the food industry is robust compliance programs and employees who enforce them. Simply relying on supplier indemnification is no longer enough.

Beginning in 1906, when faced with information concerning widespread unsanitary food handling, Congress established the Food and Drug Administration and set its mission to promote the public health and to ensure that “foods are safe, wholesome, sanitary and properly labeled.”³⁹ Since that time, outbreaks of foodborne illness have resulted in Congress increasing the grant of federal oversight of the food industry providing the FDA more and greater powers to regulate and punish food manufacturers for violations of the Food Drug and Cosmetic Act (FDCA) and FDA’s

Regulations. Most recently and perhaps most profoundly, the Food Safety Modernization Act of 2010 (FSMA) signed into law on January 4, 2011 gave the FDA significant new muscle and, since its enactment, FDA has flexed its substantial new regulatory might through fines, product detention, suspension of registration and criminal prosecution of executives and employees.

The Company: Peanut Corporation of America (PCA). The Crime: not complying with good manufacturing practices resulting in a potentially deadly outbreak of food borne illness. The Punishment: PCA is out of business, and on February 20, 2013 the Department of Justice unsealed a 76 count criminal indictment of former executives and employees.⁴⁰

The indictment relates to a national outbreak of salmonella in 2008 and 2009 that was traced to PCA “as a likely source for that outbreak.”

As charged in the indictment, PCA produced peanuts ... under insanitary conditions, which included PCA’s failure to follow appropriate practices to ensure its plants were sanitary, its failure to prevent cross-contamination between raw and cooked product, and its failure to take adequate steps to keep rodents and insects out of the plant.⁴¹

The Indictment charges that the employees committed fraud and conspiracy by falsifying data concerning the “quality and purity of the peanut products and specifically misled PCA customers about the existence of foodborne pathogens...” The indictment charges that test results were ignored and the company falsified documents that attested to quality “stating that shipments of peanut products were free of pathogens when, in fact, there had been no tests on the products at all or when the laboratory results showed that a sample tested positive for salmonella.”

Compounding the criminal problems, once the investigation began “[defendants] gave untrue or misleading answers to questions” concerning “the plant, its operations, and its history.” The charges range from conspiracy to introduce adulterated food into interstate commerce and misbranding with the intent to defraud, to wire fraud and obstruction of justice. One of the defendants has already pled guilty.

Announcing the indictment, the Deputy Assistant Attorney stated that:

Under the FDCA, it is illegal to introduce into our markets a food or drug that is adulterated – which, for foods, generally can mean either that the product is tainted or that it was produced or handled in insanitary conditions. As a result, the FDCA is a powerful tool for

protecting the health and safety of all Americans. Using the FDCA, the Department has worked to prevent adulterated products from reaching consumers by securing injunctions that ban companies from distributing food or drugs until they have cleaned up their facilities. And, when adulterated products do reach the market and pose a significant danger to the public, we will not hesitate to bring criminal cases that seek to hold wrongdoers accountable and deter other would-be violators.⁴²

As the FDCA becomes more expansive and compliance more complex, a number of industry groups are producing free practice guides to help navigate the new rules and regulations. For example, the Grocery Manufacturers Association (GMA) has created a Supply Chain Handbook⁴³ which provides and outline of how to conduct an assessment to ensure programs exist to ensure safety and compliance. The GMA Handbook recommends (i) having knowledge of your supplier’s safety programs, (ii) conduct supplier inspection surveys, facility audits, product testing and evaluation, and (iii) review product specification compliance.

1. The Food Safety Modernization Act (FSMA)

FSMA is an impressive restructuring and enhancement in governmental oversight of the food industry which imposes an enormous workload on the FDA including 50 new rules, guidance documents, reports within 3 years and tight deadlines. Under the Obama Administration, the FDA was charged with building a new system which is a long-range process and will require significant new resources.

Under FSMA, the term “facility” includes any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food. The term facility does not include farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels.⁴⁴

Retail Food Establishments are redefined and the FDA was directed to amend the definition of the term to clarify that, in determining the primary function of an establishment, the sale of food products directly to consumers by such establishment, including roadside stands or farmers’ market where such stand or market, a “community supported agriculture program” and “any other such direct sales platform as determined by the Secretary.”⁴⁵

FDA’s new power to obtain records “applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person

in any format (including paper and electronic formats) and at any location.”⁴⁶

Title I of FSMA provides the framework for “Improving Capacity to Prevent Food safety problems” in a number of significant ways, including expanding FDA’s ability to obtain records.⁴⁷ Under prior law, FDA could obtain only limited records and for the product under suspicion. The new law expands on that power allowing the agency to declare products “adulterated” where “Secretary has a reasonable belief” the product will cause serious adverse health consequences as follows:

USE OF OR EXPOSURE TO FOOD OF CONCERN.—If the Secretary believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals, each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article and to any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, that are needed to assist the Secretary in determining whether there is a reasonable probability that the use of or exposure to the food will cause serious adverse health consequences or death to humans or animals.⁴⁸

Accordingly, having a person in charge and trained on the requirements and limitations when the investigator or inspector arrives is a critical first step. What you say in response to an investigator’s inquiry can result in problems far more serious than whatever the underlying cause for the investigation of inspection and knowledge, preparation and awareness of the obligations and limits must be a first priority].

With this expanded power to obtain records, it is incumbent on both the manufacturer and the FDA to ensure that proprietary and commercially sensitive information not becomes publically available. Section 350c(c) provides for the protection of such information and requires the FDA “shall take appropriate measures to ensure that there are in effect effective procedures to

prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary pursuant to this section.”

The Hazard Analysis and Risk-Based Preventive Controls⁴⁹ charges the “owner, operator, or agent in charge” of a facility to evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated⁵⁰ or misbranded,⁵¹ monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice.

There are a number of steps to take to ensure compliance:

1. Hazard analysis
2. Preventive controls
3. Monitoring of effectiveness
4. Corrective actions
5. Verification of Effectiveness
6. Recordkeeping
7. Written plan documentation
8. Reanalyze requirement

“Preventive controls” are defined as “risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis” that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis. Those procedures, practices, and processes may include sanitation procedures, hygiene training, environmental monitoring program to verify the effectiveness of pathogen controls, allergen control, a recall plan, Current Good Manufacturing Practices (cGMPs) and supplier verification.

The Act further addresses establishing protections against intentional adulteration⁵² and authorizes FDA to issue regulations to establish measures to protect against intentional adulteration and to employ science-based mitigation strategies or measures to prepare and protect the food supply chain at specific vulnerable points. The focus of the Act is food for which there is “a high risk of intentional contamination” that could cause serious adverse health consequences or death.”⁵³

In addressing the issue of building domestic capacity, Congress required FDA to prepare an initial report “that identifies programs and practices that are intended to Promote the safety and supply chain security of food and to prevent outbreaks of foodborne illness and other food-related hazards that can be addressed through preventive activities.”⁵⁴

Among the tools available under FSMA is authority for requiring unique identification numbers.⁵⁵ FSMA seeks to improve the reportable food registry and FDA is given authority to require UPC, SKU, or lot or batch numbers sufficient for the consumer to identify the article of food, and manufacturer contact information for reportable foods. According to the FDA “[T]he core authority for these proposed regulations is to be found in the SFTA. You are not going to find any provisions in the FSMA proper specifically addressing transportation, except one key provision in Section 111(a) which directs FDA to complete the implementation of the 2005 SFTA, essentially on the same schedule that the FSMA laid out for the preventive controls rule.”⁵⁶ The FDA’s authority under FSMA for the provisions in the Sanitary Transportation Rule is set forth in the Sanitary Transportation Practices provision of the FDCA.¹

Sanitary transportation practices⁵⁷ overseen by FDA DOT DOA EPA⁵⁸ provide for the issuance of regulations for the sanitary transport of food requiring “shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices prescribed by the Secretary to ensure that food is not transported under conditions that may render the food adulterated.”⁵⁹ “According to the FDA under these proposed regulations, food shippers, receivers, and carriers by motor vehicle and rail would, for the first time -- and I emphasize this is a first -- be required to use sanitary transportation practices as specified in”⁶⁰ “FDA looks to the key provisions of the 2005 SFTA which requires FDA to promulgate regulations establishing sanitary transportation practices. Once these regulations become effective, food that is transported under conditions not in compliance with the regulations is deemed adulterated. And as we have said, transportation, as defined in the law proper, only encompasses the movement of food in the U.S. by motor vehicle or rail”⁶¹

FSMA defines “Responsible Persons”⁶² broadly and the term “transportation” means any movement in commerce by motor vehicle or rail vehicle and “bulk vehicle” includes a tank truck, hopper truck, rail tank car, hopper car, cargo tank, portable tank, freight container, or hopper bin, and any other vehicle in which food is shipped in bulk, with the food coming into direct contact with the vehicle.

While the scope of the law is limited, FDA considered whether it should be expanded stating “the law does provide authority to apply its requirements to other persons engaged in the transportation of food, but we have not proposed to do so. We have requested comment on whether persons other than shippers,

receivers, and carriers by motor vehicle and rail should be subject to these proposed regulations.”⁶³

Subsection (c) authorized FDA to issue regulations concerning sanitation, packing, limitations on vehicles, information that must be disclosed to a “carrier” a manufacturer that arranges for transport or furnishes the vehicle and recordkeeping.

In practice, vendor and services agreements need to address the rollout of the compliance requirements and responsibility to provide accurate records]

The FSMA provides for the preemption of state laws or regulations that make compliance with the federal law impossible or when the state action creates an obstacle to enforcing federal regulations.

Title II of FSMA addresses improving Capacity to Detect and Respond to Food Safety Problems and targets inspection resources for domestic facilities, foreign facilities, and ports of entry.⁶⁴ FSMA sets the “Inspection Frequency” and a heightened frequency for “high risk facilities” which will be inspected once every 3 years. High Risk is based on:

- (a) known safety risks of the food manufactured, processed, packed, or held at the facility.
- (b) compliance history, including recalls, outbreaks, and violations of food safety standards.
- (c) The “rigor and effectiveness” of the facility’s hazard analysis and risk-based preventive controls.
- (d) Whether the food manufactured, processed, packed, or held at the facility meets the criteria for priority under section 801(h)(1).
- (e) Whether the food or the facility that manufactured, processed, packed, or held such food has received a certification as described in section 801(q) or 806, as appropriate.
- (f) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources

Non High Risk facilities will be inspected within 7 years of enactment and then every 5 years thereafter.

Foreign Facilities: FDA will inspect 600 foreign facilities and “may rely on inspections conducted by other Federal, State, or local agencies under interagency agreement, contract, memoranda of understanding, or other obligation.

Identification and Inspection at Ports of Entry: The FDA will allocate resources to inspect any article of food imported into the United States based known safety risks of the article of food, based on the following factors:

¹ 21 USC §350e

- (1) The known safety risks of the food imported.
- (2) The known safety risks of the countries or regions of origin and countries through which such article of food is transported.
- (3) The compliance history of the importer, including recalls, outbreaks of foodborne illness, and violations of food safety standards.
- (4) The rigor and effectiveness of the activities conducted by the importer of such article of food to satisfy the requirements of the foreign supplier verification program.
- (5) Whether the food importer participates in the voluntary qualified importer program.
- (6) Whether the food meets the criteria for priority under section 801(h)(1).
- (7) Whether the food or the facility that manufactured, processed, packed, or held such food received a certification as described in section 801(q) or 806.
- (8) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

Enhanced Track and Trace:⁶⁵ Enhancing tracking and tracing of food and recordkeeping to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated FDA will establish a product tracing system to receive information that improves the capacity of the FDA to effectively and rapidly track and trace food that is in the United States or offered for import into the United States. Prior to the establishment of such product tracing system, the Secretary shall examine the results of applicable pilot projects and shall ensure that the activities of such system are adequately supported by the results of such pilot projects.

Additional Requirements for High-Risk Facilities: FDA is required to identify high risk foods and specify the heightened recordkeeping requirements.

Enforcement. “Prohibited Acts”⁶⁶ are amended to include “the violation of any recordkeeping requirement of the FDA Food Safety Modernization Act.”⁶⁷ Failure to comply with “the recordkeeping requirements under section 204 of the FDA Food Safety Modernization Act (other than the requirements under subsection (f)) [will result in the food being] refused admission.”⁶⁸

The standard for “Administrative Detention” of food is changed from ““credible evidence or information indicating” to reason to believe” and modifies “presents a threat of serious adverse health consequences or death to humans or animals” to ‘is adulterated or misbranded’.”⁶⁹

2. FDA’s Operational Strategy for Implementing FSMA

In May, 2014 the FDA issued its Operational Strategy for Implementing FSMA⁷⁰ which gave FDA a new public health mandate.⁷¹ FSMA gave FDA “farm to table”⁷² oversight to establish standards for “modern food safety prevention practices” and encompasses those who grow, process, transport, and store food. Through “FSMA implementation teams” FDA is guiding FSMA implementation.

FDA identifies the central “driver” in its change as “the dramatic expansion in the global scale and complexity of the food system.”

Hundreds of thousands of growers and processors worldwide are producing food for the U.S. market, using increasingly diverse and complicated processes, managing complex and extended supply chains, and making millions of decisions every day that affect food safety. The burgeoning scale and complexity of the food system make it impossible for FDA on its own, employing our historic approaches, to provide the elevated assurances of food safety envisioned by FSMA and needed to maintain a high level of consumer confidence in the safety of the food supply.

FDA views food safety as depending a top-level management commitment working in a continuous improvement mode, to: (1) implement science- and risk-based preventive measures at all appropriate points across the farm-to-table spectrum, and (2) manage their operations and supply chains in a manner that provides documented assurances that appropriate preventive measures are being implemented as a matter of routine practice every day.

FDA’s operational strategy for implementation of FSMA includes:

Advancing the Public Health

- Primary focus on improved public health outcomes, reducing the risk of foodborne illness through preventive practices;
- FDA serving as the central public health leadership catalyst for innovation and repository of the science and expertise needed to understand and prevent food safety problems.
- Oversight of systems that protect food safety, within their operations and through their supply chains. Oversight will include judicial enforcement, “but FDA will focus primarily on assessing whether systems are working effectively to prevent problems and on taking immediate

action to protect public health through voluntary corrective action or a range of administrative remedies.”

Working to create an integrated global food safety network that includes federal, state, local, tribal, territorial, and foreign agencies, international organizations, the food industry, growers, academic experts, and consumers.

FDA’s Risk-Based Oversight will include commodity and sector-specific guidance, education and outreach, technical assistance, incentives for compliance, such as less frequent or intense inspection for good performers, reliable third-party audits to verify compliance, public education, transparency, and publicity to promote compliance and prevention; and modernized approaches to inspection and enforcement based on the prevention framework and the enhanced inspection and enforcement tools provided by FSMA.

FDA will significantly expand its inspection and surveillance tools to include a wider range of inspection, sampling, testing, and other data collection activities conducted through its own field force and through collaboration with partner agencies and the food industry.

Enforcement includes judicial actions when necessary to complement non-judicial compliance actions and address matters for which there is no adequate administrative remedy, such as:

- Seizure actions that are needed to back up administrative detentions or for other reasons
- Injunction actions when other measures are inadequate to prevent future non-compliance
- Criminal prosecution in appropriate cases

Guiding Principles for Implementation of FSMA’s Import System⁷³: Rather than relying primarily on FDA detecting and stopping food safety problems at the border, under FSMA importers provide assurances that their foreign suppliers have taken proper steps to prevent problems. To complement FDA’s oversight of importers, FSMA directs FDA to strengthen private audit systems, increase its overseas presence, and work in partnership with foreign governments to strengthen and capitalize on their capacity to help ensure the safety of food destined for the United States, all in keeping with the collaboration and leveraging elements of our operational strategy for FSMA implementation. Key features of FDA’s import implementation effort will include:

- audit foreign supplier verification programs and hold importers accountable for effectively managing their supply chains in accordance with FSMA

- Reconfiguring current import screening and field exam activities to complement oversight of FSMA’s foreign supplier verification requirement
- Implementing the voluntary qualified importer program to expedite entries for good performers and allow more resources to be directed toward high-risk imports
- Audit accrediting bodies and accredited third-party certifiers
- Assessments of foreign government regulatory systems
- Data integration and analysis systems

3. FSMA Registration Guidance:

FDA’s oversight begins with registration requirements which provides for the registration of food facilities.⁷⁴ FSMA requires FDA to issue regulations requiring registration for any “facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States.” Both domestic and foreign facilities must be registered by “the owner, operator, or agent in charge” of the food facility. Foreign facilities are also required to include with the registration the name of the United States agent for the facility. FSMA provides for email contact for the “contact person” or US agent for foreign facilities and for “even year” renewal registration. The registration provides an “assurance” to permit inspection of the facility. In December 2012 FDA issued is Registration Guidance (5th Edition).⁷⁵

Suspension of Registration: FSMA grants FDA with significant power to suspend the registration of a facility. If the registration of a facility is suspended under this subsection, no person shall import or export food into the United States from such facility, offer to import or export food into the United States from such facility, or otherwise introduce food from such facility into interstate or intrastate commerce in the United States. A facility registration can be suspended where, in its judgment, there is a “reasonable probability of causing serious adverse health consequences or death” where the facility “(A) created, caused, or was otherwise responsible for such reasonable probability; or “(B)(i) that knew of, or had reason to know of, such reasonable probability; and “(ii) packed, received, or held such food. In the event the FDA issues an order suspending a registration there are options to vacate the order. FSMA provides for an “opportunity” for an informal hearing in 2 days and places the burden of proof on the facility to show “adequate grounds do not exist to continue the suspension of the registration.” Vacating a suspension order will require a “Corrective Action Plan.”

4. Sanitary Transportation:

Before enactment, the Transportation Sanitary Rule⁷⁶ began tepidly stating “[w]e lack sufficient data to quantify the potential benefits of the proposed rule.” Notwithstanding this disclaimer, Congress charged FDA to implement the new law.

III. SANITARY TRANSPORTATION OF FOOD: CONTRACTS AND THE NEW RULES

New terms and shifting responsibilities require attention by all supply chain members

Pursuant to the Sanitary Food Transportation Act of 2005 and the Food Safety Modernization Act (FSMA), the U.S. Food and Drug Administration (FDA) published the final rule entitled “Sanitary Transportation of Human and Animal Food” (SFT Rule) on April 6, 2016. The SFT Rule is effective June 6, 2016, with compliance beginning April 6, 2017, for small businesses, which have until April 6, 2018, to comply. The SFT Rule establishes the requirements for sanitary transportation practices applying to shippers, loaders, carriers and receivers engaged in the transportation of food to ensure the safety of the food they transport. This article will provide an overview of the scope and coverage of the SFT Rule.

Key Definitions

Shippers are persons who arrange for the transportation of food in the United States by a carrier or multiple carriers sequentially. Importantly, this definition includes a freight broker. The definition also includes imported food. For example, where a freight broker has arranged the U.S. land-based transportation leg of the foreign shipment, the broker is deemed the “shipper.”

Carriers are persons who physically move food by rail or motor vehicle in commerce within the United States, regardless of ownership of the vehicles. The term does not include any person who transports food while operating as a parcel delivery service.

Loaders are a new category defined by the SFT Rule and are defined as persons who load food onto a motor or rail vehicle during transportation operations.

Receivers are defined as persons who receive food at a point in the United States after transportation, regardless of whether that person is at the food’s ultimate destination. The term does not include consumers.

Transportation is defined as any movement of food by motor vehicle or rail vehicle in commerce within the United States.

Transportation equipment is the equipment used in food transportation operations, for example, bulk and nonbulk containers, bins, totes, pallets, pumps, fittings, hoses, gaskets, loading systems and unloading systems. Transportation equipment also includes a railcar not

attached to a locomotive or a trailer not attached to a tractor.

“Transportation equipment is the equipment used in food transportation operations...”

Transportation operations are all activities associated with food transportation, including food requiring temperature control, which may affect the sanitary condition of food including cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. The SFT Rule excludes food in enclosed containers.

Vehicles are motorized land conveyances (i.e., motor vehicles) or those that move on rails (i.e., railcars), which are used in transportation operations.

1. Coverage

With some exceptions, the SFT Rule applies to shippers, loaders, receivers and carriers involved in transportation operations for the transportation of human and animal food by rail or motor vehicle in commerce within the United States, whether or not the food is being offered for or enters interstate commerce. Applicability of the SFT Rule depends on the type of food being transported, the means of transportation, the intended destination of the food and the person(s) involved in the transportation operations. The definition of a “shipper” now includes one that “arranges for the transportation,” which now includes a transportation broker. Further, the SFT Rule applies even where the different transportation operations are conducted under the ownership or operational control of a single corporate/legal entity, that is, food shipments involving shippers, loaders, carriers and/or receivers that are corporate subsidiaries or affiliates of a common corporate parent company/legal entity.

Failure to comply with the SFT Rule requirements that causes the food to be “actually unsafe” renders the food adulterated and is a prohibited act under the Federal Food, Drug, and Cosmetic Act of 1938. An “inconsequential failure” by a carrier to meet the shipper’s temperature-control specifications, or from a broken seal or other evidence of tampering, will not create a “per se presumption of adulteration.” But if a covered person “becomes aware” or there is evidence of possibly “material” deviation from the specifications, a “qualified individual” must determine that the food is not unsafe. Failure to take such action may render the food adulterated.

The SFT Rule does not solve or purport to solve any clearly identified problem but is part of FSMA’s overall “paradigm shift” from response to outbreaks to preventing them in the first place. Prevention is accomplished through a set of seven new rules and accompanying agency guidances that implement

FSMA. Currently, it is common for manufacturing and distribution agreements to address regulatory requirements the old-fashioned way by simply stating: “XYZ Corp. will comply with all laws and regulations.” This simple provision served industry well for generations when the focus was on response, but today prevention places the obligation on all participants in the supply chain to ensure upstream and downstream compliance.

2. Exclusions

The SFT Rule contains several exclusions for certain types of food and businesses. Additionally, the SFT Rule does not apply to issues not pertaining to the establishment of sanitary transportation practices, such as cargo security and food quality or appearance. Cargo security will be addressed in the up-coming Intentional Contamination Rule.

3. Responsibilities under the SFT Rule

The SFT Rule sets out equipment, operational, training and records requirements for those who serve as shippers, receivers, loaders and carriers engaged in transportation operations. The same person may act and be responsible in more than one of the above four capacities on a given shipment, and it is now necessary to ensure that the roles are specified in writing and that all participants in the supply chain have written procedures in place to ensure compliance. The responsibilities should be assigned among the parties in a written contract maintained in accordance with record-keeping requirements set forth in the SFT Rule. It is important for those involved in the transportation of food to specify in their contracts precisely who is responsible for ensuring compliance.

This section will discuss the new equipment, operations, training and records requirements for shippers, carriers, loaders and receivers engaged in transportation operations under the SFT Rule. Special attention is required to the new obligations the SFT Rule imposes on loaders and carriers.

i. Vehicles and Transportation Equipment

The SFT Rule imposes requirements for the design, maintenance and storage of vehicles and transportation equipment (V&TE) used in transportation operations. Specifically, V&TE must be designed and of such material and workmanship as to be suitable and adequately cleanable for their intended use to prevent the food they transport from becoming unsafe, that is, for it to be unadulterated, during transportation operations. Thus, the “intended use” of the vehicle will determine the material and workmanship necessary for it to be “suitable.” V&TE must then be maintained and stored to prevent them from becoming unsafe. While the SFT Rule does not specify which party is responsible for

the V&TE requirements and, by default, responsibility would fall to the shipper, each participant in the supply chain is responsible and must have procedures in place to ensure compliance and must know who is responsible for the V&TE and if those duties are assigned by contract.

ii. Transportation Operations

Operational responsibilities under the SFT Rule include responsibilities for the measures taken during transportation to ensure food safety, such as adequate temperature controls, preventing contamination of ready-to-eat food from touching raw food, protection of food from contamination by nonfood items in the same load or previous load and protection of food from cross-contact, that is, the unintentional incorporation of a food allergen. While the operational responsibilities apply to all shippers, carriers, loaders and receivers engaged in transportation operations, shippers have primary responsibility for determining appropriate V&TE for transportation operations absent a contractual agreement to assign some of these responsibilities to other parties. While the default responsibility falls to the shipper unless otherwise agreed by contract, but all parties should make sure their procedures and contracts clearly delineate who has responsibility. All parties should also ensure that their procedures address documentation and records necessary to support their compliance and a mechanism for ensuring others in the supply chain are compliant.

a. *Shippers*

Shippers are required to develop and implement written procedures to ensure that vehicles and equipment used in their transportation operations are in appropriate sanitary condition, that is, the V&TE will prevent the food from becoming adulterated, and, where applicable, to ensure that adequate temperature control is provided during the transportation of food that requires temperature control for safety under the required conditions of shipment. Measures to implement these procedures may be accomplished through a carrier or other party covered by the SFT Rule under a written agreement in compliance with the SFT Rule, but the shipper must furnish also have a procedure to request information from a carrier regarding prior cargo and most recent cleaning in the event that a bulk vehicle is used for food transportation.

“...the SFT Rule applies to shippers, loaders, receivers and carriers involved in transportation operations for the transportation of human and animal food...”

b. *Carriers*

Where the carrier and shipper have a written agreement that the carrier is responsible, in whole or in

part, for sanitary conditions during the transportation operations, the contract must include the following six requirements: written specifications for the other party detailing the required sanitary specifications, including design and cleaning and, where applicable, operating temperature. The shipper should

- (1) The V&TE must be appropriate and meet the shipper's specifications.
- (2) Must assign duty of providing the temperature information (if required) and demonstrating temperature compliance to the receiver. Recorded temperatures can be appropriate means to demonstrate compliance. Thus, carriers will need to have written procedures for documenting temperature before during and at delivery.
- (3) Precooling must be addressed.
- (4) Bulk carriers should have documentation regarding prior cargo.
- (5) Procedures must be in place to document most recent cleaning.
- (6) Must have written procedures for cleaning, sanitizing and inspecting V&TE.

c. Loaders

Loaders have responsibility for vehicle inspection. Before loading food not completely enclosed by a container, a loader must determine whether the V&TE are in appropriate sanitary condition and, where applicable, verify that each mechanically refrigerated cold storage compartment or container is adequately prepared for the transportation of such food. The loader may make its determination of whether the V&TE are in appropriate sanitary condition using industry standards. Perhaps recognizing that the SFT Rule is a solution in search of problem, the FDA made a significant concession to industry in allowing industry standards to apply to assess appropriate sanitary conditions for V&TE.

The loader also must have written procedures in place to determine specifications and to determine if the V&TE are in appropriate sanitary condition. The SFT Rule requires a written policy and creation of documentation verifying the specifications and determining the V&TE are adequately prepared.

d. Receivers

Upon receipt of temperature-controlled food, "the receiver must take steps to adequately assess that the food was not subjected to significant temperature abuse, such as determining the food's temperature, the ambient temperature of the vehicle and its temperature setting, and conducting a sensory inspection, for example, for off-odors." This will require the receiver to know what it is receiving and to have procedures in place to assess

and document the lack of problems. Thus, the receiver needs a policy to request operating temperature specifications provided by the shipper and to ensure that compliance with those specifications has been accomplished.

iii. Training

When the carrier agrees in writing to be responsible for sanitary conditions during transport, the carrier must provide training to its personnel on food safety and basic sanitary food transportation practices. Training is to be done at hiring and as needed thereafter. Further, the carrier must establish and maintain records documenting the training, including the date of the training, the type of training and the person(s) trained.

"When the carrier agrees in writing to be responsible for sanitary conditions during transport, the carrier must provide training . . . on food safety and basic sanitary food transportation practices."

i. Records

The SFT Rule requires shippers, carriers, loaders and receivers engaged in transportation operations to maintain records of all written procedures, agreements and training (required of carriers) necessitated by the SFT Rule. The required retention time for these records depends upon the type of record and when the covered activity occurred but does not exceed 12 months. Specifically, shippers must maintain records demonstrating they provide specifications and operating temperatures to carriers as a regular part of their transportation operations for 12 months after termination of an agreement with a carrier. Shippers must also retain records of written agreements and procedures required by the SFT Rule for "12 months beyond when the agreement and procedures are in use." For carriers, records of written procedures required by the SFT Rule must be kept for 12 months beyond when the agreements are in use in their transportation operations, and training records must be kept for 12 months after the person stops performing the duties. Any agreement assigning responsibilities under the SFT Rule must be kept for 1 year beyond its termination.

Records required to be maintained under the SFT Rule must be kept as originals, including true copies and electronic copies, and must be available "promptly" or within 24 hours if kept off-site. However, records of procedures that are in effect at a particular facility must be kept on-site.

Allocation of Responsibilities; Role of Written Contracts

Duties assigned by the SFT Rule to a shipper, loader, carrier or receiver may be reassigned by written

contract and maintained in accordance with record-keeping requirements of the SFT Rule. Absent any contract reassigning responsibilities created by the SFT Rule, duty assignments appear to apply by default. Responsibility for ensuring that transportation operations are carried out in compliance with the SFT Rule must be assigned to “competent supervisory personnel.” The SFT Rule does not specifically address the issue of personal liability for responsible individuals, but it should be expected that FDA will apply its ordinary rules in this regard that impose liability on individuals in position of responsibility for compliance.

While the SFT Rule excludes certain small entities, FDA commented clearly that those entities, noncovered shippers, loaders and receivers, will remain subject to the current Good Manufacturing Practices provisions in Section 117.93 of the Preventive Controls Rule that goes into effect in September 2016, as well as the rules prohibiting introducing adulterated food into commerce.

FDA intends to further promote the application of sanitary transportation practices through guidance for transportation activities performed by noncovered businesses.

Waivers

Shippers, receivers, loaders and carriers subject to the SFT Rule may petition for a waiver of any requirement with respect to any class of persons, vehicles, food or nonfood products. FDA may grant the petition on its own initiative. The petition must describe with particularity the waiver requested, including the persons, vehicles, food or nonfood product(s) to which the waiver would apply and the SFT Rule requirement(s) to which the waiver would apply. The petition must also present information demonstrating that the waiver will not result in the transportation of food under conditions that would be unsafe for human or animal health and will not be contrary to the public interest. Failure to include the required information in a petition is grounds for denial of that petition. The petition may also be denied if it is determined that either the waiver could result in the transportation of food under conditions that would be unsafe for human or animal health or that it could be contrary to the public interest. When a waiver is granted, a notice will be published in the Federal Register setting forth the waiver and the reasons for such waiver. This notice should assist in understanding the SFT Rule’s application after the effective date.

Conclusion

Under the SFT Rule, when any covered person or company at any point in the transportation supply chain becomes aware of a possible failure of temperature control or any other condition that may render a food

unsanitary or adulterated, that food must not be sold or distributed until a determination of safety is made.

When the shipper has determined that temperature control is necessary, FDA requires the shipper and the carrier to agree upon how that is going to be done, how it is going to be monitored and how that is going to be recorded. FDA wants this agreement in writing because it will want to review the processes being used.

FDA has revised the final rule to place primary responsibility for determinations about appropriate transportation operations on the shipper. Each participant in the supply chain needs to have procedures in place to ensure it knows who is responsible for the V&TE. The default responsibility falls to the shipper unless otherwise agreed by contract, but all parties should make sure their procedures and contracts clearly delineate who has responsibility and who is to maintain documentation to support compliance.

The time-tested provision that the parties “will comply with all laws and regulations” has served industry well for generations and so too have general indemnification provisions. For those in the food industry today, however, the stakes are higher and the regulatory responsibility is increasing and can be assigned by contract. The stakes are higher for a number of reasons: First, FSMA’s paradigm shift from response to prevention requires a fresh look at policies and procedures and contracts to ensure compliance. Second, the U.S. Centers for Disease Control and Prevention, FDA and state health authorities are becoming more sophisticated in identifying the source of contamination and prosecuting those who fail to comply. Third, terrorists and other bad actors are increasingly looking for ways to exploit our open food supply chain and disrupt commerce to frighten, injure or kill the public. The issue of intentional contamination will be the focus of the final rule to be issued under FSMA. Finally, governmental enforcement, including recent U. S. Department of Justice pronouncements, is increasing the focus on senior management and executives in civil and criminal enforcement actions.

Exporters and Foreign Transportation:

The rule sets forth sanitary transportation practices for shippers, carriers, and receivers who transport food that will be consumed or distributed in the United States and brings the provisions of the FDA’s cGMP and the Food Code to bear on the transportation industry.

The rule’s compliance and recordkeeping requirements extend to a “person outside of the United States, such as an exporter, who ships food to the United States in an international freight container by oceangoing vessel or in an air freight container, and arranges for the transfer of the intact container in the United States... if that food will be consumed or distributed in the United States.” When the FDA

determines that shipper failed to comply with the requirements of this rule, food may be considered adulterated under the FDA and refused admission into the United States.

Additional Requirements for High-Risk Foods:

FSMA further requires that the FDA designate a class of foods as high-risk for which additional record keeping requirements will be appropriate, including retaining records for a longer time period. On February 4, 2014, the FDA published notice seeking comments and scientific data concerning the Designation of High-Risk Foods for Tracing.

4. Prior Notice of Imported Food:

FDA published its final rule⁷⁷ adopting its May 5, 2011 interim final rule entitled “Information Required in Prior Notice of Imported Food.”⁷⁸ The final rule adopts the requirement of additional information required in a prior notice of imported food, specifically that a person submitting prior notice of imported food, including food for animals, must report the name of any country to which the article has been refused entry.

Often cited but never definitively proven CDC conclusion that “[e]ach year about 48 million people (1 in 6 Americans) get sick; 128,000 are hospitalized; and 3,000 die from food borne diseases, according to 2011 data from the Centers for Disease Control and Prevention.”⁷⁹ This is a significant public health burden that is largely preventable.” This CDC supports virtually all recent food law and regulatory efforts. Despite to practically incomprehensible complexity of the US food supply it nothing short of a miracle that even the often cited CDC data is so low. Nonetheless, the FDA Food Safety Modernization Act (FSMA) was signed into law by President Obama on January 4, 2011, granting FDA expansive new power “to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur.” The real muscle in the new law is that it grants FDA with enforcement power for compliance and enforcement of “risk-based food safety standards.”

Prior Notice Requirement⁸⁰ requires additional information to be provided in a notice of imported food submitted to FDA. This change requires information identifying “any country to which the [food] article has been refused entry.” As this final rule imposes no new regulatory requirements, a delayed effective date is unnecessary.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act)⁸¹ was signed into law on June 12, 2002, and among other things, it created the requirement that FDA receive certain information about imported foods before arrival in the United States.⁸² It also provided that an article of food imported or offered for

import is subject to refusal of admission into the United States if adequate prior notice has not been provided to FDA. The FDA was directed to issue implementing regulations requiring prior notice of imported food.

In calendar year 2011, 10,537,372 prior notices were submitted, 9,054,230 of which were submitted through the CBP system with the remaining 1,483,142 being submitted through the FDA system.

FSMA defines “importer” as (A) the US owner or consignee of the article of food at the time of entry of such article into the US; or (B) if there is no US owner or consignee, the US agent or representative of the foreign owner or consignee of the article of food.⁸³ The foreign supplier verification program provides that each importer shall perform risk-based foreign supplier verification activities for the purpose of verifying that the food imported by the importer or agent of an importer is— (A) produced in compliance with the requirements of section 301 or section 303, as appropriate; and (B) is not adulterated under section 402⁸⁴ or misbranded under section 403(w).⁸⁵

New regulations are required to ensure foreign suppliers comply with processes and procedures, including reasonably appropriate risk-based preventive controls, to ensure the same level of public health protection consistent with those under section 418⁸⁶ or section 419⁸⁷ and such other requirements as necessary to verify that food imported into the United States is as safe as food produced and sold within the United States.

The foreign supplier verification program may include monitoring records for shipments, lot-by-lot certification of compliance, annual on-site inspections, checking the hazard analysis and risk-based preventive control plan of the foreign supplier, and periodically testing and sampling shipments.⁸⁸

“Prohibited Act” include importation or offering for importation of a food if the importer⁸⁹ does not have in place a foreign supplier verification program in compliance with such section 805.”⁹⁰

FDA also has authority to require certifications regarding imported high risk foods, or foods from what is termed “high risk countries. “Certification or assurances may be provided in the form of shipment-specific certificates, a listing of certified facilities that manufacture, process, pack, or hold such food, or in such other form as the Secretary may specify.”⁹¹

FDA is granted extensive oversight power and does not limit the authority of the FDA to conduct inspections of imported food or to take such other steps as the FDA deems appropriate to determine the admissibility of imported food. FSMA contemplates audits of foreign suppliers and defines both accredited third-party auditors and consultative audits. The Act does permit auditors to serve both roles but does not allow them to be owned or controlled by an eligible entity.⁹²

Final Rule: Prior Notice of Imported Food Shipments: In its Final Rule Published for Food Imports: FDA focuses on Food Safety for its “Prior Notice” Rule and takes a common sense approach for Imported Foods requiring notice of another country’s refusal to allow entry to be reported if the refusal relates to food safety concerns. In calendar year 2011 more than 10.5 million prior notices were submitted, 9 million were submitted through the Customs and Border Patrol system with the remaining 1.5 million submitted through the FDA system. Even though FDA estimates that its final rule entitled “Information Required in Prior Notice of Imported Food”⁹³ only adds about 1 minute to each import entry it reviews, FDA was unable to quantify or otherwise demonstrate benefits from the rule. FDA did conclude that “potential benefits can result from FDA’s ability to use the additional information to better identify imported food shipments that may pose a safety or security risk to U.S. consumers.” The final rule was published on May 30, 2013.

Citing CDC data, FDA concludes there is a “largely preventable” public health burden stating “[e]ach year about 48 million people (1 in 6 Americans) get sick; 128,000 are hospitalized; and 3,000 die from food borne diseases.”⁹⁴ Despite these generalized estimates concerning all aspects of the food supply, including consumer handling, no data is provided concerning imports.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002⁹⁵ requires that FDA obtain information about imported foods before arrival in the United States. It also provided that an article of food imported or offered for import is subject to refusal of admission into the United States unless adequate prior notice has been provided to FDA. Section 304 of the Food Safety Modernization Act (FSMA), signed into law by President Obama on January 4, 2011, further amended the FDCA requiring prior notice identifying “any country to which the [food] article has been refused entry.”

In its Notice⁹⁶ FDA clarified that the phrase “refused entry” only includes refusals related to “food safety.” FDA stated that it “considers ‘refused entry’ to mean a refusal of entry or admission of human or animal food based on food safety reasons, such as intentional or unintentional contamination of an article of food.” While the Act and the Final Rule do not specify refusals based on food safety concerns, FDA “agreed” that only refusals for food safety reasons should be reported.

FDA further clarified that the phrase “article of food” refers only to the specific food item for which the Prior Notice is being submitted. FDA stated that it will not consider the phrase an “‘article of food’ to refer to food from the same batch or lot that is not being imported or offered for import into the United States and

for which Prior Notice will not be submitted, or to refer to food of a similar type that was previously refused entry by a country.” FDA provides an illustration where “Country A refuses entry, this fact is not submitted as part of prior notice for the portion that had been shipped to the United States.”

In determining whether there has been a violation of the prior notice regulations, FDA will look at the “totality of the circumstances” and will follow its compliance policy guide entitled “Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.”⁹⁷ Among the considerations in enforcing a violation, FDA will “take into account the severity of the violations, whether they are flagrant, and whether the person has had previous violations, particularly if they were similar types of violations.”

The prior notice regulations⁹⁸ describe the information that must be submitted in a prior notice. The 2011 Interim Rule required that the prior notice include the identity of any country to which an article of food has been refused entry and the final rule adopts those changes. FDA received 15 comments in response to the Interim Rule and did not make any changes to the regulatory language.

One comment requested that FDA clarify the scope of the term “refused entry” to include only refusals related to “food safety.” In addressing this concern FDA stated that it “considers ‘refused entry’ to mean a refusal of entry or admission of human or animal food based on food safety reasons, such as intentional or unintentional contamination of an article of food. FDA agrees that only refusals for food safety reasons should be reported.”

FDA further clarified that “the term ‘article of food’ to refer only to the specific food item for which prior notice is being submitted. As such, FDA does not consider ‘article of food’ to refer to food from the same batch or lot that is not being imported or offered for import into the United States and for which prior notice will not be submitted, or to refer to food of a similar type that was previously refused entry by a country.” FDA provides an illustration that where “Country A refuses entry, this fact is not submitted as part of prior notice for the portion that had been shipped to the United States.”

In determining whether there has been a violation of the prior notice regulations, FDA will look at the “totality of the circumstances” and will follow its compliance policy guide entitled “Sec. 110.310 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.”⁹⁹ Among the considerations in enforcing a violation FDA will “take into account the severity of the violations, whether they are flagrant, and whether the person has had previous violations, particularly if they were similar types of violations.”

According to the FDA, the new rule adds “58 seconds (on average) per entry” unless of course you have a violation. The 2011 analysis did not quantify potential benefits from the new rule but FDA believes “potential benefits can result from FDA’s ability to use the additional information to better identify imported food shipments that may pose a safety or security risk to U.S. consumers.”

5. Foreign Supplier Verification Programs (FSVPs)

On November 27, 2015 FDA published its final rule on Foreign Supplier Verification Programs (FSVPs) for Importers of Food for Humans and Animals, FDA’s rule.¹⁰⁰ In fiscal year 2011, nearly 10.5 million product lines of food (representing unique food products) were imported into the United States and approximately 15 percent of all food consumed in the US is imported, including approximately 50 percent of fresh fruit and 20 percent of fresh vegetables. There are more foreign firms registered with FDA than domestic firms (even though fewer kinds of foreign firms are required to register). In addition, FDA is able to physically examine only a small fraction of the food that is offered for import into this country. At the time FSMA was enacted there were more than 250,000 foreign food facilities registered to export food to the United States (in contrast to approximately 167,000 domestic food facilities) even completing 19,200 foreign inspections in 2016 would translate to a statutory inspection rate of less than once every 10 years.¹⁰¹

FSMA takes the concept of “harmonization” into account in section 404 providing “that the provisions of the act and any amendments to the FDCA may not be construed in a way that is inconsistent with the agreement establishing the World Trade Organization (WTO)¹⁰² or any other treaty or international agreement to which the United States is a party.”¹⁰³ The FSVP regulations recognize Codex Alimentarius in establishing international food safety standards, guidelines, and recommendations.¹⁰⁴ Codex was formed in 1963 by the Food and Agriculture Organization and the World Health Organization to develop food standards, guidelines, and related texts such as codes of practice, and is recognized as the international standards organization for food safety. In describing the general characteristics of food import control systems, the Guidelines for Food Import Control Systems¹⁰⁵ developed by the Codex Committee on Food Import and Export Inspection and Certification Systems recognize a number of related concepts, including countries can set their own appropriate levels of protection based on risk that are applied equally to imported and domestic food. The Guidelines recognize that there is a potential need for different approaches to compliance monitoring of domestic and imported food to ensure consistent levels

of protection and that there is utility in conducting audits, in addition to assessing importer controls to ensure that imported foods are safe, including importers’ use of supplier verification systems.

Under FSMA, FDA is required to establish rules requiring importers to ensure that food imported into the US is produced in compliance with processes and procedures, including reasonably appropriate risk-based preventive controls, that provide the same level of public health protection as those required under the hazard analysis and risk-based preventive controls and standards for produce safety sections of the FDCA. The Foreign Supplier Verification Program rule requires importers to create and follow programs to help ensure the safety of imported food. The regulations vary based on the type of food product (such as processed foods, produce, and dietary supplements) and category of importer.¹⁰⁶

The hazard assessment under the rule assumes well accepted and understood standards throughout the international food safety community (i.e. hazard analysis and critical control point (HACCP) and preventive controls programs) and proposes a flexible, risk-based approach to foreign supplier verification. The regulations focus on foreseeable food safety risks identified through a hazard assessment process, but there are exemptions.¹⁰⁷

The rule further recognizes that FSMA further requires persons who import food into the United States to perform risk-based foreign supplier verification activities for the purpose of verifying the food is produced in compliance with hazard analysis and risk-based preventive controls or standards for the safe production and harvesting of certain fruits and vegetables.¹⁰⁸ FSMA further requires verifying that the food is not adulterated¹⁰⁹ or misbranded.¹¹⁰ Section 805(c) of the FDCA directs FDA to issue regulations on the content of FSVPs.¹¹¹

The FSVP regulations require importers to:

- (1) Review the compliance status of the food and the foreign supplier, including issuance of FDA warning letters, import alerts, or certification requirements.
- (2) Conduct their own analysis or review and evaluate the hazard analysis conducted by the food’s foreign supplier.
- (3) Establish written verification procedures. Verify that reasonably likely hazards are adequately controlled and to document such control or conduct an on-site audit.
- (4) Review complaints, investigate adulteration or misbranding (with respect to allergen labeling), and take corrective actions in the case of supplier noncompliance.

- (5) Reassess the effectiveness of its FSVP when it becomes aware of a new hazard or every 3 years.
- (6) Ensure that the importer's name and Dun and Bradstreet Data Universal Numbering System (DUNS) number is provided for each line of entry of food.
- (7) Maintain records of their FSVP activities.

Modified Provisions for Certain Types of Importers

Dietary supplement compliance supplier verification activities would focus on verifying that the supplier is in compliance with the dietary supplement CGMP regulations.

Very small food importers and importers of food from very small foreign suppliers (i.e., entities with annual food sales of no more than \$500,000) the importer would not be required to conduct hazard analyses and would be able to verify their foreign suppliers by obtaining written assurance that describes the processes and procedures the suppliers use to ensure the safety of the food.

For imports from countries that are comparable or equivalent to the US, currently including New Zealand, Australia and Canada. For suppliers in these countries, the rule is relaxed, provided the supplier is in compliance in that country. FDA does emphasize that "importers have always had the responsibility to offer for entry into the United States products that are not adulterated."¹¹²

In adopting the regulations, the FDA recognized that it did not propose specific regulations on supplier verification in the Preventive Controls Proposed Rule, but requested comment on when and how approval and verification of suppliers of raw materials and ingredients are an appropriate part of preventive controls.¹¹³

Definitions: The Rule defines a number of terms, including:

Audit: Onsite auditing is required of foreign suppliers in certain circumstances as a mechanism for supplier verification. Section § 1.500 define audit as the systematic, independent, and documented examination (through observation, investigation, discussions with employees of the audited entity, records review, and, as appropriate, sampling and laboratory analysis) to assess an audited entity's food safety processes and procedures.¹¹⁴

Food: has the meaning given in the FDCA.¹¹⁵ FDA concluded that pesticides were not intended to be considered "food" for purposes of section 805 of the FDCA and the FSVP regulations and had requested comment on this exclusion.

Foreign Supplier: is an establishment that manufactures/processes the food, raises the animal, or harvests the food that is exported to the United States without further manufacturing/processing by another

establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a *de minimis* nature. The definition of foreign supplier does not include firms that only pack or hold food even if they are required to register with FDA. FDA concluded that "Congress intended the importer to verify a single foreign supplier for a particular shipment of a food and, when several entities are required to register as foreign facilities with respect to that food, excluding a subsequent (and registered) packer or holder would be consistent with this intent."

Hazard and Hazard Reasonably Likely to Occur: A hazard is any biological, chemical, physical, or radiological agent that is reasonably likely to cause illness or injury in the absence of its control.

Importer: is (A) the US owner or consignee of the article of food at the time of entry of such article into the US; or (B) the US agent or representative of a foreign owner or consignee. Under the definition, the importer of an article of food might be the importer of record of the article (i.e., the individual or firm responsible for making entry and payment of import duties). Where food has not been sold or consigned to a person in the US at the time of entry, the foreign owner or consignee would need to have a U.S. agent or representative who would be responsible for meeting the FSVP requirements.

Qualified Individual: Is a person with the "necessary education, training, and experience" to perform the activities needed to meet the requirements of this the law. The person may be, but is not required to be, an employee of the importer. Among the activities the Qualified Individual must be able to perform are a food hazard analysis and verification of foreign supplier processes and procedures to ensure that hazards are adequately controlled. A qualified individual must have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience to develop and implement a food safety system. The qualified individual includes a third-party or an employee of a foreign government.

Raw Agricultural Commodity (RAC): Includes fruits or vegetables as defined in section 201(r) of the FDCA.¹¹⁶

Exemptions (§ 1.501)

1. Exemption for Food from Juice and Seafood HACCP Facilities Section 805(e) states that the foreign supplier verification requirements "shall not apply to a facility if the owner, operator, or agent in charge of such facility is

required to comply with, and is in compliance with,” the HACCP regulations for seafood or juice. FDA concluded that it was Congress’s intent that section 805(e) apply to food being imported from foreign suppliers that are facilities subject to and in compliance with FDA requirements for juice or seafood HACCP. The importer would still be required to verify a foreign supplier’s compliance with the juice or seafood HACCP provisions, but would do so under the regulations that are specific to those foods.

2. Food Imported for Research or Evaluation or for Personal Consumption: FDA excludes small quantities for research and evaluation purposes or for personal consumption, provided that such foods are not intended for retail sale and are not sold or distributed to the public. Food imported for research must be labeled as such.

3. Alcoholic Beverages.

Scope of FSVP (§ 1.502): Importers would be required to develop procedures for the operation of their FSVPs, such as procedures for the following:

- Review of the compliance status of foods and foreign suppliers
- Analysis of hazards reasonably likely to occur with foods
- Determination and performance of appropriate foreign supplier verification activities for foods
- Review of complaints, investigation of adulteration or misbranding, and taking of corrective actions
- Reassessment of the FSVP
- Ensuring that required information is submitted at entry
- Maintenance of records¹¹⁷

To help ensure that importers are obtaining food only from appropriate foreign suppliers, § 1.506(a) requires each importer to follow written procedures to ensure that they import foods only from foreign suppliers that are approved based on the required evaluation conducted under §1.505.¹¹⁸

Severe Adverse Consequences or Death to Humans or Animals (SAHCODHA): In certain situations, conducting onsite auditing alone may not be sufficient to ensure that the hazard is adequately controlled. When onsite auditing alone cannot provide adequate assurances that such a hazard is adequately controlled,

the importer must conduct one or more additional verification activities to provide such assurances.¹¹⁹ Foreign supplier verification activities that importers may choose to conduct, if they are appropriate for the hazard, are as follows:

- Periodic onsite auditing.
- Periodic or lot-by-lot sampling and testing of the food.
- Periodic review of the foreign supplier’s food safety records.
- Any other procedure established to be appropriate.

In lieu of an audit FDA provides that importers are required to use the risk evaluation they conduct to determine which verification activity or activities are appropriate and the frequency with which those activities must be conducted. However, with respect to foods with a SAHCODHA hazard that would be controlled by the foreign supplier, the importer would be required to conduct or obtain documentation of an onsite audit of the foreign supplier before initially importing the food and at least annually thereafter, unless the importer documented a determination, based on the risk evaluation, that instead of initial and annual onsite supplier auditing, some other supplier verification activities and/or less frequent onsite auditing would be appropriate to provide adequate assurances of safety.²

Records: § 1.510(b) requires importers to maintain records required under the FSVP regulations in English and make these records available promptly to an authorized FDA representative, upon request, for inspection and copying. Section 805(d) of the FDCA states that records related to a foreign supplier verification program “shall be made available promptly to a duly authorized representative [of FDA] upon request.” The rule states that an importer must maintain records at its place of business or at a reasonably accessible location; records would be considered to be at a reasonably accessible location if they could be immediately retrieved from another location by computer or other electronic means.¹²⁰ If records are requested in writing by FDA, an importer must send records to the Agency electronically rather than making the records available for Agency review at the importer’s place of business¹²¹ and importers are required to maintain records for a period of at least 2 years.¹²²

6. Protecting Against Intentional Contamination

On May 27, 2016 FDA issued its final rule entitled “Mitigation Strategies to Protect Food against Intentional Adulteration.”¹²³ The rule requires facilities

² See final rule comment 177.

that are required to register (both domestic and foreign) “to identify and implement focused mitigation strategies to significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation.” FDA will begin enforcing the rule in July 2018.¹²⁴

The rule is designed for acts of intentional contamination and provides exemptions for qualified facilities. FSMA directed FDA to issue regulations facilities that manufacture, process, pack or hold food and requires facilities to consider hazards that may be intentionally introduced, including by acts of terrorism¹²⁵, food for which there is a high risk of intentional contamination and for which such intentional contamination could cause serious adverse health consequences or death to humans or animals,¹²⁶ and setting forth science-based minimum standards for the safe production and harvesting of produce, and requires that the rulemaking consider hazards that may be intentionally introduced, including by acts of terrorism.¹²⁷

Intelligence gathered since the attacks on the United States on September 11, 2001, indicated that terrorist organizations have discussed contamination of the food supply as a means to harm U.S. citizens and disrupt the global economy and much of the defensive apparatus in the federal government has mobilized to anticipate the threat. FDA, USDA, DHS, State and local governments and the food industry collaborated to conduct vulnerability assessments of a variety of products and processes within the food and agriculture sector.¹²⁸

For the student or even the casual observer of the acronym riddled FDA might believe FDA’s acronym is itself an acronym for Finding Descriptive Acronyms. In the food area, federal acronym creation professionals are working overtime. In addition to a number of guidance documents to assist the food industry, FDA made the following resources available:

- The “ALERT” program,
- The “Employees FIRST” training tool,
- The “CARVER+Shock Vulnerability Assessment” software tool,
- The “Mitigations Strategies Database,”
- The “Food Defense Plan Builder” software tool,
- The Food Related Emergency Exercise Bundle, and
- The “Food Defense 101” training courses.

FDA and USDA’s Food Safety and Inspection Service (FSIS) adapted a military targeting tool known as CARVER to assess vulnerabilities of the food and agriculture sector. CARVER is an acronym for the following six attributes used to evaluate the attractiveness of a target for attack:

- Criticality-- public health and economic impact of an attack;
- Accessibility--ability to physically access and egress from target;
- Recuperability--ability to recover from an attack;
- Vulnerability--ease of accomplishing an attack;
- Effect--amount of direct loss from an attack as measured by loss in production; and
- Recognizability--ease of identifying a target.

A seventh attribute, “Shock”, was added to the original six attributes to assess the combined health, economic, and psychological impacts of an attack on the food industry.¹²⁹

The ALERT program was instituted in 2006 and is an acronym for five elements for use by the food industry:

- A--ASSURE that the supplies and ingredients you use are from safe and secure sources?
- L--LOOK after the security of the products and ingredients in your facility?
- E--EMPLOYEES and people coming in and out of your facility?
- R--REPORTS about the security of your products while under your control?
- T--THREAT or issue at your facility, including suspicious behavior

The FIRST tool was instituted in 2008 is a food defense awareness training program for front-line food industry workers about the risk of intentional adulteration. This tool identifies the following five key elements:

- F--Follow a food defense plan and procedures;
- I--Inspect your work area and surrounding areas;
- R--Recognize anything out of the ordinary;
- S--Secure all ingredients, supplies, and finished product; and
- T--Tell management if you notice anything unusual or suspicious.

In 2008, WHO issued its “Terrorist Threats to Food--Guidelines for Establishing and Strengthening Prevention and Response Systems”¹³⁰ to provide policy guidance to its Member States for integrating consideration of deliberate acts of sabotage of food into existing prevention and response programs.

FSMA requires that the owner, operator, or agent in charge of a facility shall identify and evaluate hazards that may be intentionally introduced, including by acts of terrorism.¹³¹ In addition, the owner, operator, or agent in charge of a facility must identify and implement preventive controls to provide assurances that any hazards that relate to intentional adulteration will be

significantly minimized or prevented and addressed.¹³² FDA states that the provisions in the rule are applicable to activities that are intrastate in character, not merely activities interstate and facilities are required to register with the FDA even where the food remains intrastate and does not enter interstate commerce.¹³³

Scope of Intentional Adulteration Covered by this Rule

Acts of intentional adulteration may take several forms, including acts of terrorism, acts of disgruntled employees, consumers, or competitors, or economically motivated adulteration. Vulnerability assessments performed by FDA, USDA, DHS, FBI and state and local law enforcement view an intentional attack as a low probability with a potentially exceedingly high consequence. FDA identifies four (4) Key Activity Types: bulk liquid receiving and loading; liquid storage and handling; secondary ingredient handling; and mixing and similar activities.¹³⁴ FDA is looking to industry to establish mitigation strategies that may include sealing or locking outbound conveyances of bulk liquid, or requiring that inbound conveyances be sealed or locked as a condition of receipt of the bulk liquid.¹³⁵

Definitions:

Actionable Process Step

Is a “point, step, or procedure in a food process at which food defense measures can be applied and are essential to prevent or eliminate a significant vulnerability or reduce.”¹³⁶

Contaminant

Is defined as “any biological, chemical, physical or radiological agent that may be intentionally added to food and that may cause illness, injury or death.”¹³⁷

Facility

Is defined to mean a domestic facility or a foreign facility that is required to register under the FDCA.¹³⁸

Focused Mitigation Strategies

Is analogous to the term “preventive controls” in a HACCP-type framework for food safety.¹³⁹

Food Defense

Refers to the sum of actions and activities (including identification of actionable process steps; implementation of focused mitigation strategies; monitoring, corrective actions, verification, and training activities) taken to protect food from intentional acts of adulteration related to terrorism.¹⁴⁰

Manufacturing/Processing

Means “making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients.”¹⁴¹

Mixed-Type Facility

Is “an establishment that engages in both activities that are exempt from registration under section 415 of the FDCA and activities that require the establishment to be registered.”¹⁴²

Monitor

Means to “conduct a planned sequence of observations or measurements to assess whether focused mitigation strategies are consistently applied and to produce an accurate record for use in verification.”¹⁴³

Qualified End-User

With respect to a food is the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment¹⁴⁴ that is located in the same State and within 275 miles, and is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.¹⁴⁵

Qualified Facility

Is a facility that is either a “very small business” or a facility to which both of the following apply: (i) during the 3-year period preceding the applicable calendar year, the average annual monetary value of the food sold directly to qualified end-users exceeded the average annual monetary value to all other purchasers; and (ii) the average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000.¹⁴⁶

Significant Vulnerability

Is analogous to the term “hazard that is reasonably likely to occur” in a HACCP-type framework for food safety. A “significant vulnerability” is defined as a vulnerability that, if exploited, could reasonably be expected to cause wide scale public health harm. A significant vulnerability is identified by a vulnerability assessment conducted by a qualified individual, that includes consideration of the following: (1) Potential public health impact (e.g., severity and scale) if a contaminant were added, (2) degree of physical access to the product, and (3) ability of an attacker to successfully contaminate the product. The assessment must consider the possibility of an inside attacker.¹⁴⁷

Significantly Minimize

Means to reduce to an acceptable level, including to eliminate and is used in FSMA consistent with the

outcome of a “control measure” as described in the HACCP regulations.¹⁴⁸

Small Business

Means a business employing fewer than 500 persons.¹⁴⁹

Very Small Business

Means a business that has less than \$10,000,000 in total annual sales of food per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale.¹⁵⁰

Vulnerability

Is used in the term "vulnerability assessment"¹⁵¹ and is defined as the susceptibility of a point, step, or procedure in a facility's food process to intentional adulteration and may best be described in the food defense context as analogous to the term “hazard” in a HACCP-type framework for food safety.¹⁵²

Among the exemptions from the requirements is the holding of food, except the holding of food in liquid storage tanks.¹⁵³ Also exempt will be the packing, re-packing, labeling, or re-labeling of food where the container that directly contacts the food remains intact¹⁵⁴, produce farms and alcohol.

Food Defense Plan:

¹⁵⁵ Section § 121.126(a)--Requirement for a Food Defense Plan requires that the owner, operator, or agent in charge of a facility prepare, or have prepared, and implement a written food defense plan. The contents of a Food Defense Plan requires written identification of actionable process steps¹⁵⁶, focused mitigation strategies¹⁵⁷, procedures for monitoring¹⁵⁸, other procedures in § 121.145(a)(1),and verification procedures.¹⁵⁹

Identification of Actionable Process Steps

- a. Vulnerability assessments and FDA-identified key activity types.
- b. Written identification of actionable process¹⁶⁰
- c. Identification of four (4) actionable process steps using FDA identified key activity types¹⁶¹ i.e. bulk liquid receiving and loading, liquid storage and handling, secondary ingredient handling, and mixing and similar activities.
- d. Conducting a vulnerability assessment.¹⁶²
Elements of a Facility-Specific Vulnerability Assessment:

- Planning --collect and evaluate appropriate background information on biological, chemical, physical, and radiological agents of concern, such as those found in the CDC’s Select Agents and Toxins List¹⁶³;
- Assemble a vulnerability assessment team--security, food safety/quality assurance or control, human resources, operations, maintenance, and other individuals deemed necessary to facilitate the formation of a vulnerability assessment;
- Develop a process flow diagram
- Identify significant vulnerabilities—prioritize vulnerabilities and identify significant vulnerabilities. Consider (1) The potential public health impact if a contaminant were added; (2) whether downstream processing steps would eliminate or remove agents of concern; (3) the degree of physical access to product; (4) the ability of an aggressor to successfully contaminate the product; and (5) the volume of product impacted. This evaluation should also include the rationale or justification for which process steps were and were not identified as significant vulnerabilities; and
- Identify actionable process steps for identified significant vulnerabilities

Focused Mitigation Strategies

Sections 418 and 420 of the FDCA require the owner, operator, or agent in charge of a facility to identify and implement preventive controls to provide assurances that hazards identified in the hazard analysis conducted under section 418(b)(2) of the FDCA will be significantly minimized or prevented and addressed. There are two types of mitigation strategies, broad mitigation strategies are general facility-level measures whereas “focused mitigation strategies” are specific to an actionable process step in a food operation where a significant vulnerability is identified. FDA gives a number of specific examples of focused mitigation strategies in the rule.¹⁶⁴

§ 121.135(a) requires that the owner, operator, or agent in charge of a facility identify and implement focused mitigation strategies at each actionable process step to provide assurances that the significant vulnerability at each step will be significantly minimized or prevented. The rule requires the focused mitigation strategies be written.¹⁶⁵

Training: Personnel and supervisors assigned to actionable process steps must receive “appropriate training” in food defense awareness and their respective responsibilities in implementing focused mitigation strategies.¹⁶⁶

Records:

§ 121.305(a) requires that the records be kept as original records, true copies (such as photocopies,

pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records. Section 121.305(b) require that records contain the actual values and observations obtained during monitoring. Records must be accurate, indelible, legible¹⁶⁷, created concurrently with performance of the activity documented,¹⁶⁸ and as detailed as necessary to provide a history of work performed.¹⁶⁹

The failure to comply with the foregoing requirements will constitute a prohibited act under 21 USC 331.

7. Third-Party Auditors

Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications¹⁷⁰

On November 27, 2015 FDA issued its final rule on Third-Party Auditors. Congress directed FDA¹⁷¹ to establish a new program for accreditation of third-party auditors conducting food safety audits and issuing food and facility certifications to eligible foreign entities (including registered foreign food facilities) that meet FDA requirements.

This rule ensures competent and independent third-party auditors/certification bodies conduct foreign food safety audits. These certifications will include food certifications required by FDA as a condition of granting admission to a food determined to pose a safety risk. The Rule adds a number of new terms:

Accreditation

Means a determination by a recognized accreditation body that a third-party auditor/certification body meets the applicable requirements including the model accreditation standards.

Accreditation body

Means an authority that performs accreditation of third-party auditors/certification bodies.

Accredited auditor/certification body

Means a third-party auditor/certification body that a recognized accreditation body has determined meets the applicable requirements to issue food or facility certifications to eligible entities.

Audit

Means: (1) by FDA to assess the accreditation body's authority, qualifications, and resources; its procedures for quality assurance, conflicts of interest, and records; its performance in accreditation activities; and its capability to meet the applicable requirements; (2) by a recognized accreditation body to assess the

third-party auditor's/certification body's authority, qualifications, and resources; its procedures for quality assurance, conflicts of interest, and records ;its performance in auditing and certification activities; and its capability to meet the applicable requirements; and (3) by an accredited auditor/certification body to assess the entity, its facility, system(s), and food using audit criteria for consultative or regulatory audits, including compliance with any applicable requirements for preventative controls, sanitation, monitoring, verification, corrective actions, and recalls, and, for consultative audits, also includes an assessment of compliance with applicable industry standards and practices.

Audit agent

Means an individual who is an employee or other agent of an accredited auditor/certification body who, although not individually accredited, is qualified to conduct food safety audits on behalf of an accredited auditor/certification body.

Certification body

Means a foreign government, agency of a foreign government, foreign cooperative, or any other third party that is eligible to be considered for accreditation to conduct food safety audits and to certify that eligible entities meet applicable requirements of the FDCA.

Consultative audit

Means an audit of an eligible entity: (1) To determine whether such entity is in compliance with applicable requirements of the FDCA and industry standards and practices; and (2) which are for internal purposes only and cannot be used to determine eligibility for a food or facility certification issued under this subpart or in meeting the requirements for an onsite audit of a foreign supplier.

Direct accreditation

Means accreditation of a third-party auditor/certification body by FDA.

Eligible entity

Means a foreign entity that chooses to be subject to a food safety audit by an accredited auditor/certification body.

Facility

Means any structure, or structures of an eligible entity under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers.

Facility Certification

Means an attestation to establish that a facility meets the applicable requirements of the FDCA.

Food Certification

Means an attestation that a food meets the applicable requirements of the FDCA.

Food Safety Audit

Means a regulatory audit or a consultative audit.

Foreign cooperative

Means an entity that aggregates food from growers or processors that is intended for export to the United States.

Recognized Accreditation Body

Means an accreditation body is authorized to accredit third-party auditors/certification bodies.

Regulatory audit

Means an audit of an eligible entity to determine whether such entity is in compliance with the FDCA and the results are used to determine eligibility for food certification. The Regulatory Audit may be used by an importer in meeting the requirements for an onsite audit of a foreign supplier.

Relinquishment

Means: (1) With respect to an accreditation body, a decision to cede voluntarily its authority to accredit third-party auditors/certification bodies as a recognized accreditation body; and (2) With respect to a third-party auditor/certification body, a decision to cede voluntarily its authority to conduct food safety audits and to issue food and facility certifications to eligible entities.

Self-assessment

Means a systematic assessment conducted by an accreditation body or by a third-party auditor/certification body to determine whether it meets the applicable requirements.

Third-party auditor

Means a foreign government, agency of a foreign government, foreign cooperative, or any other third party that is eligible to be considered for accreditation to conduct food safety audits and to certify that eligible entities meet the applicable requirements of the FDCA.

8. Traceback Procedures:

On August 13, 2014 the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) posted notice¹⁷² that it will implement new "traceback" procedures on October 14, 2014. The "FSIS estimates that dozens more recalls may occur

once these new protections are in place." The new traceback procedures trace contaminated ground beef back to its source more quickly, remove it from the market, and determine the "root cause." Under the new traceback procedures, FSIS conducts immediate investigations at businesses where tests return "presumptively positive" for E. coli O157:H7 during initial testing and at suppliers that provided the tested materials.

Under the traceback procedure investigators will gather relevant information about the production of the product, including use of antimicrobials and prevention of cross-contamination, sanitary conditions, and relevant purchase specifications. Investigators will review test results to determine whether an establishment has experienced a high event period (HEP). The new procedures impose no new requirements related to HEPs but are "intended to improve and expedite FSIS traceback procedures." FSIS will request that supplier establishments recall product if:

- (1) additional positive results are found;
- (2) introduction or cross contamination was unlikely to have occurred;
- (3) the establishment did not combine material from multiple source lots to create the lot of product that tested positive;
- (4) after traceback identifies the supplier of the source material, FSIS determines that the supplier or downstream users split the implicated lot before sending it to the establishment where the positive sample was taken; and
- (5) the split lot was sent into commerce for further processing into product that does not receive a full lethality treatment to eliminate E. coli

If all of the foregoing occurs, FSIS will request the establishment to initiate a recall.

FSIS further recommends that establishments identify HEP criteria so they can determine whether they need to withhold product from commerce when a HEP has occurred.

9. "Track and Trace" Pilot Project

Food Track and Trace: Pilot Projects for Improving Product Tracing along the Food Supply System Final Report

On March 4, 2013 FDA released a report on two product tracing pilot projects conducted by the Institute of Food Technologists (IFT).¹⁷³ The pilots were required under section 204 of the FDA Food Safety Modernization Act, which required FDA to establish recordkeeping requirements for high-risk foods to help in tracing products. The pilot projects looked at methods

for quick and effective tracking and tracing of food, including types of data that are useful for tracing, ways to connect the various points in the supply chain and how quickly data can be made available to FDA.

FDA is required to designate high-risk foods for which additional recordkeeping requirements are appropriate and necessary¹⁷⁴ in order to rapidly and effectively track and trace such foods during a foodborne illness outbreak or other event. This is the first step towards meeting that requirement.¹⁷⁵

The product tracing system involves documenting the production and distribution chain of products so that in the case of an outbreak or evidence of contaminated food, a product can be traced back to a common source or forward through distribution channels. Product tracing systems enable government agencies and those who produce and sell food to take action more quickly when an outbreak of foodborne illness occurs or contaminated product is identified, thus preventing illnesses. Actions include removing a product from the marketplace and alerting the public if a product has already been distributed.

IFT's 10 Recommendations:

- (1) From an overarching perspective, IFT recommends that FDA establish a uniform set of recordkeeping requirements for all FDA-regulated foods and not permit exemptions to recordkeeping requirements based on risk classification.
- (2) FDA should require firms that manufacture, process, pack, transport, distribute, receive, hold, or import food to identify and maintain records of Critical Tracking Events (CTEs) and Key Data Elements (KDEs) as determined by FDA.
- (3) Each member of the food supply chain should be required to develop, document, and exercise a product tracing plan.
- (4) FDA should encourage current industry-led initiatives and issue an Advance Notice of Proposed Rulemaking or use other similar mechanisms to seek stakeholder input.
- (5) FDA should clearly and more consistently articulate and communicate to industry the information it needs to conduct product tracing investigations.
- (6) FDA should develop standardized electronic mechanisms for the reporting and acquiring of CTEs and KDEs during product tracing investigations.
- (7) FDA should accept summarized CTEs and KDEs data that are submitted through standardized reporting mechanisms and initiate investigations based on such data.
- (8) If available, FDA should request more than one level of tracing data.
- (9) FDA should consider adopting a technology platform that would allow efficient aggregation and analysis of data submitted in response to a request from regulatory officials. The technology platform should be accessible to other regulatory entities.
- (10) FDA should coordinate traceback investigations and develop response protocols between state and local health and regulatory agencies, using existing commissioning and credentialing processes. In addition, FDA should formalize the use of industry subject matter experts in product tracing investigations.
- (11) For more details on IFT's recommendations and their report, please go to Pilot Projects for Improving Product Tracing along the Food Supply System – Final Report (PDF: 5.6MB).

IV. OTHER CONSIDERATIONS:

1. Enhancing Food Safety:

Integrated Food Safety Centers of Excellence: Colorado Florida Minnesota Oregon Tennessee have been established under Sec. 210 to identify and evaluate best practices for foodborne disease surveillance and outbreak investigation, and then share the knowledge. Integrated Food Safety Centers of Excellence will provide assistance to other regional, State, and local departments of health through activities that include—

- (1) providing resources, including timely information concerning symptoms and tests, for frontline health professionals interviewing individuals as part of routine surveillance and outbreak investigations;
- (2) providing analysis of the timeliness and effectiveness of foodborne disease surveillance and outbreak response activities;
- (3) providing training for epidemiological and environmental investigation of foodborne illness, including suggestions for streamlining and standardizing the investigation process;
- (4) establishing fellowships, stipends, and scholarships to train future epidemiological and food-safety leaders and to address critical workforce shortages;
- (5) training and coordinating State and local personnel;
- (6) strengthening capacity to participate in existing or new foodborne illness surveillance and environmental assessment information systems; and
- (7) conducting research and outreach activities focused on increasing prevention,

communication, and education regarding food safety.

2. The Park Doctrine – No Fault Criminal Liability for the Acts of Others

According to the Food and Drug Administration (FDA) the no fault criminal provisions under the Food Drug and Cosmetic Act (FDCA) apply to “anyone who has a responsible share in the furtherance of the transaction.”

The FDA has powerful and persuasive leverage before an enforcement proceeding gets anywhere near a courtroom to influence the behavior of regulated industry and it is increasingly wielding that power. In a series of Warning Letters issued by the FDA in 2013 to manufacturers of dietary supplements throughout the United States, the FDA has preemptively threatened criminal prosecutions for failing to establish and follow procedures “to ensure the quality of the [products] you receive from your contract manufacturers” and citing the Park Doctrine as follows:

United States v. Dotterweich, 320 U.S. 277, 284 (1943) (explaining that an offense can be committed under the Act by anyone who has “a responsible share in the furtherance of the transaction which the statute outlaws”); *United States v. Park*, 421 U.S. 658, 672 (1975) (holding that criminal liability under the Act does not turn on awareness of wrongdoing, and that “agents vested with the responsibility, and power commensurate with that responsibility, to devise whatever measures are necessary to ensure compliance with the Act” can be held accountable for violations of the Act).

The FDA has put regulated industry on notice that it will apply the Park Doctrine, threatening criminal prosecution for marketing adulterated and misbranded products based upon formerly routine violations such as:

Contract Manufacturing: Although your firm may contract out certain ... manufacturing operations, it cannot, by the same token, contract out its ultimate responsibility to ensure that the [Product] it places into commerce (or causes to be placed into commerce) is not adulterated for failure to comply with ... CGMP requirements

Current Good Manufacturing Practices (cGMP) Violations: For failure to have and follow and ensuring that your contract manufacturer has followed acceptable written procedures. “The Act prohibits a person from

introducing or delivering for introduction, or causing the delivery or introduction, into interstate commerce [a Product] that is adulterated for failure to comply with ... CGMP requirements.

New Dietary Ingredients: For using ingredients where “to the best of FDA’s knowledge, [the substance] itself is not commonly used as a food or drink by humans.”

Generally Recognized as Safe (GRAS): For foods the FDA deems “additives” where the FDA declares a substance is not generally recognized as safe (GRAS) by qualified experts for its intended use in food and does not qualify for any of the other exemptions from the food additive definition, it is a food additive.

Website Content: – Where the FDA reviews website content and determines “Your labeling - including the websites at which you take orders for [the products] - promotes your ...products for conditions that cause them to be drugs”

Testimonials: Where the FDA reviews product testimonials and decides that the “claims observed on your website ... provide evidence that your products are intended for use as drugs”

Adverse Event Reporting: failing to report a customer complaint deemed related and serious by the FDA.

Having procedures is not enough, when the FDA inspector comes around, your employees must know the procedures and follow them:

Your firm failed to follow written procedures for holding and distributing operations....In fact, your warehouse manager, who is responsible for warehouse procedures and responsibilities, stated that she was not aware of the procedures.”

Since 1906 when Congress established the Food and Drug Administration (FDA) and set its mission to promote the public health and to ensure that “foods are safe, wholesome, sanitary and properly labeled”¹⁷⁶ Congress has steadily increased federal oversight of the food industry providing the FDA more and greater

powers to regulate and punish food manufacturers for violations of the FDCA and the FDA's Regulations.

New Powers

Most recently the Food Safety Modernization Act of 2010 (FSMA) gave the FDA significant new muscle to detain products, suspend the registration of facilities and criminal prosecution of executives and employees. In Title II FSMA grants the FDA "expanded authority" to recall, detain and seize any regulated food determined to be unsafe, adulterated or misbranded, "or otherwise failing to meet the requirements of the food safety law."¹⁷⁷ The new power granted to the FDA under FSMA has resulted in a demonstrable willingness to use the new authority granted under FSMA without waiting for an adverse health outcome.

The Criminally Responsible Agent Prosecution Doctrine

The "Park Doctrine" is also known by the misnomer the "Responsible Corporate Officer Doctrine" ("RCO") has been hotly debated and questioned since its inception in 1943. And for good reason, the doctrine permits criminal prosecutions where the individual may not have had any involvement in the events leading to the offense. The Doctrine has generally been applied and approved by the courts to convict upper level executives in situations involving repeated violations and small penalties. But the FDA has been clear in stating that "anyone who has 'a responsible share in the furtherance of the transaction'" is potentially criminally liable. What is new is the scope of the use of this doctrine and the severity of the statutory penalties. This doctrine has been seriously questioned as having dubious constitutional validity, and a challenge to the Doctrine will be taken up by the Supreme Court in 2017 in *DeCoster v US*, 16-877.³

Where Did This Doctrine Come From?

"Individuals are the Corporation": The seminal case in what has become known as "Park Doctrine" prosecutions involved misdemeanor violations of the FDCA. In *United States v. Dotterweich*,¹⁷⁸ recognizing that what at issue was a misdemeanor charge against an individual who had no awareness of the alleged wrongful conduct, the Court stated: "[h]ardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be total wanting." The Court was confident that "[i]n such matters, the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries must be trusted." The decision was not without

controversy and the four (4) member dissent was less confident in governmental discretion stating:

The legislative power to restrain the liberty and to imperil the good reputation of citizens not to rest upon the variable attitudes and opinions of those charged with the duties of interpreting and enforcing the mandates of the law.

According to the dissent, "it is inconsistent with established canons of criminal law to rest liability on an act in which the accused did not participate and of which he had no personal knowledge."¹⁷⁹ In *United States v. Park*¹⁸⁰, a case involving a food manufacturer alleging violations of good manufacturing practices, by a food manufacturer, the Court stated:

The requirements of foresight and vigilance imposed on responsible corporate agents are...demanding, and perhaps onerous, but...no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in...enterprises whose services and products affect the health and well-being of the public..."¹⁸¹

In *Park* the four (4) member dissent likened the application of the doctrine to "trial by ordeal" stating "[t]he instructions given by the trial court in this case, it must be emphasized, were a virtual nullity, a mere authorization to convict if the jury thought it appropriate." The dissent further observed:

"the standardless conviction approved today can serve in another case tomorrow to support a felony conviction and substantial prison sentence. "However highly the Court may regard the social objectives of the Food, Drug, and Cosmetic Act, that regard cannot serve to justify a criminal conviction so wholly alien to fundamental principles of our law."¹⁸²

Strict Liability "Defenses":

A manufacturer charged with misbranding a FDA regulated product can assert a defense that he or she was "powerless" to prevent the violation.¹⁸³ Yet in practice, courts are reluctant to permit the defense.¹⁸⁴ Accordingly, absent a showing of impossibility violations of the FDCA are, effectively, strict liability crimes

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<https://www.supremecourt.gov/search.aspx?filename=/docketfiles/16-877.htm>

FDA's Park Doctrine Guidelines:

In January 2011, the FDA published its new "Special Procedures and Considerations for Park Doctrine Prosecutions,"¹⁸⁵ describing the factors the agency considers in deciding to apply the Park Doctrine for FDCA violations. Under the Agency's "Guidelines" the FDA has a two pronged approach. First it will look to whether there was:

- (1) actual or potential harm to the public;
- (2) an obvious violation;
- (3) a pattern of illegal behavior or failure to heed prior warnings;
- (4) a widespread violation; and
- (5) a violation serious.

Second, if the FDA finds some unspecified combination of these factors present it will determine if:

1. there is legal and factual support for the proposed prosecution; and
2. the proposed prosecution a prudent use of agency resources.

One hundred years ago none more exalted than Supreme Court Justice, Oliver Wendell Holmes, Jr. in his dissent in Northern Securities Co. v. United States,¹⁸⁶ reminded us that

Great cases like hard cases make bad law. For great cases are called great, not by reason of their importance... but because of some accident of immediate overwhelming interest which appeals to the feelings and distorts the judgment.

While the so-called Park Doctrine is of highly suspect constitutional validity, until or unless the Court significantly restrict its applicability, "anyone who has a responsible share in the furtherance of the transaction" resulting in a violation of the FDCA runs the risk of criminal prosecution and ensuring compliance of yourself, your coworkers and all of your suppliers can no longer wait until an inspector knocks at the door.

V. CONCLUSION

Congress reacted to the events of September 11, 2001 and to the rapid change in the global sourcing and

delivery of regulated products. The interests of industry and regulators align on many issues but government plays a unique role is creating a uniform system where problems are responded to, anticipated and prevented altogether. As the implementation of the regulations evolves, we are facing a forward looking system for the supply and distribution of food that dove-tails with systems of sister nations, what is envisioned to emerge is a robust global marketplace that can both prevent and respond to and emerging threats.

To their credit, Congress and government regulators recognized that laws and rules designed to respond to widespread adverse outcomes, whether intended and unintended, from medical products and outbreaks of food borne illness but were inadequate to prevent intentional and criminally negligent conduct. Congress has acted by enacting aggressive new legislation that revolutionizes the supply and distribution of food and drugs in the United States while allowing for the US system to "harmonize" with those of sister nations. How and whether a robust global system will succeed is secondary to the urgency of taking bold steps today to thwart, capture and prevent the catastrophic health outcomes of tomorrow.

As FDA restructures of how it oversees the transport of regulated products throughout the United States and from foreign suppliers, the sea-change in the oversight of the supply and distribution of FDA regulated products is creating new opportunities, challenges and risks for suppliers, manufacturers, distributors, marketers and sellers of FDA regulated products. Some of the changes that are underway were anticipated by industry and many industry participants view the new rules as merely codifying what they have been doing all along. Others, particularly those who have grown from smaller operations over the past decade maybe either scrambling to keep up with the changes or not aware of them at all. How industry responds to ensure robust competition and compliance will be a legacy for generations to come.

Make no mistake, every participant in the supply chain has the responsibility to ensure that its supplier is in compliance. No longer can we simply rely on the language in our indemnification agreements. Now, each is its supplier's insurer.

¹ See U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/opacom/backgrounders/miles.html> (last visited August 19, 2014).

² See U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/oc/history/historyoffda/fulltext.html> (last visited August 18, 2014).

³ *Germophobia*, 54(2) JAMA. 135,135-136 (1910).

⁴ U.S. FOOD & DRUG ADMIN., www.fda.gov/oc/history/historyoffda/section2.html (last visited August 18, 2014).

⁵ See U.S. FOOD & DRUG ADMIN., <http://www.cfsan.fda.gov/~lrd/histor1b.html> (last visited January 26, 2006).

⁶ National Strategy for Global Supply Chain Security (2012) available at

http://www.whitehouse.gov/sites/default/files/national_strategy_for_global_supply_chain_security.pdf

⁷ Id. at 2.

⁸ Id.

⁹ Margaret A. Hamburg, MD, *New Realities of Globalization -- Implications for Health, Medicine and the Role of the Regulator* (March 6, 2014) available at <http://www.fda.gov/NewsEvents/Speeches/ucm388388.htm>.

¹⁰ Id.

¹¹ Id. at 5.

¹² Id.

¹³ DEPT. OF HOMELAND SECURITY, <http://www.dhs.gov/critical-infrastructure-partnership-advisory-council> (last visited Aug. 28, 2014).

¹⁴ Id.

¹⁵ Id. Note 7. *New Realities of Globalization -- Implications for Health, Medicine and the Role of the Regulator*” Speech by Margaret A. Hamburg, MD, Commissioner of Food and Drugs Medicines and Healthcare Products Regulatory Agency (MHRA) Annual Lecture 2014, London, England March 6, 2014

¹⁶ Id.

¹⁷ Id.

¹⁸ [FDA, http://www.fda.gov/aboutfda/reportsmanualsforms/reports/ucm298576.htm](http://www.fda.gov/aboutfda/reportsmanualsforms/reports/ucm298576.htm) (last visited Aug. 28, 2014).

¹⁹ Id. at 3

²⁰ Id. at 6

²¹ FDA, *Pathway to Global Product Safety and Quality* (July 7, 2011) available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OC/GlobalProductPathway/UCM262528.pdf> (hereinafter *Pathway to Global Product Safety and Quality*).

²² Id. at 9.

²³ Id. at 9.

²⁴ Id. at 10.

²⁵ INT’L CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE, *Draft ICH Consensus Principle - Principles for Clinical Evaluation of New Antihypertensive Drugs* (Mar. 2, 2000) available at <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073147.pdf>

²⁶ *Pathway to Global Product Safety and Quality*, *supra* note 21.

²⁷ Id. at 2.

²⁸ Id.

²⁹ Id.

³⁰ Id. at 10 (citing *Global Supply Chain Trends 2008 – 2010: Driving Global Supply Chain Flexibility through Innovation*, PRTM Management Consultants).

³¹ Id. at 16 (citing WHO estimate; IMS: global drug market size, ex-manufacturer prices)

³² FDA, *Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT)*, (Feb. 2014) available at <http://www.fda.gov/downloads/ForIndustry/ImportProgram/UCM310772.pdf>.

³³ U.S. GOV’T ACCOUNTABILITY OFFICE, GAO – 10-961, *DRUG SAFETY – FDA HAS CONDUCTED MORE FOREIGN INSPECTIONS AND BEGUN TO IMPROVE ITS INFORMATION ON*

FOREIGN ESTABLISHMENTS, BUT MORE PROGRESS IS NEEDED (2010).

³⁴ *Id.*

³⁵ *Pathway to Global Products and Safety*, *supra* note 21 at 4

³⁶ Id. at 19.

³⁷ U.S. FOOD & DRUG ADMIN., *GOOD IMPORTER PRACTICES (DRAFT GUIDANCE)* (2009) available at <http://www.fda.gov/regulatoryinformation/guidances/ucm125805.htm>

³⁸ 21 USC § 393

³⁹ 21 U.S.C. § 393.

⁴⁰ See *Indictment*, available at <http://www.justice.gov/iso/opa/resources/61201322111426350488.pdf>

⁴¹ See the Department of Justice Press release, Feb. 21, 2013, available at <http://www.justice.gov/iso/opa/resources/22820132211141246302.pdf>.

⁴² See Statement of Principal Deputy Assistant Attorney General Stuart F. Delery, February 21, 2013, available at <http://www.justice.gov/iso/opa/civil/speeches/2013/civ-speech-130221.html>.

⁴³ http://www.gmaonline.org/downloads/technical-guidance-and-tools/GMA_SupplyChain2.pdf

⁴⁴ 21 U.S.C. § 350d(c) excludes such vessels engaged in processing as defined in 21 CFR 123.3(k).

⁴⁵ 21 C.F.R. § 1.227(b)(11).

⁴⁶ 21 U.S.C. § 350c(a)(3).

⁴⁷ Id. § 101 ((21 U.S.C. § 350c(a))

⁴⁸ Id. § 350c(a)(2).

⁴⁹ Id. § 103 (21 U.S.C. § 350g)

⁵⁰ Id. § 402 (21 USC § 342).

⁵¹ Id. § 403(w).

⁵² Id. § 106 21 USC 350i. See also *infra* III of *Protecting Against Intentional Contamination*

⁵³ See *infra* III. 7

⁵⁴ §. 110. 21 U.S.C. § 2204

⁵⁵ §. 211. (21 U.S.C. § 350f)

⁵⁶ MICHAEL KASHTOCK, CONSUMER SAFETY OFFICER AND SENIOR ADVISOR, AT FDA’S CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN), 16, *FSMA PROPOSED RULE ON SANITARY TRANSPORTATION OF HUMAN AND ANIMAL FOOD – PUBLIC MEETING* (Mar. 20, 2014) available at <http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM395355.pdf>

⁵⁷ 21 U.S. Code § 350e.

⁵⁸ See *infra* at III. 4.

⁵⁹ Sec. 111. (21 U.S.C. § 350e).

⁶⁰ M. KASHTOCK, *supra*, note 117, at 16

⁶¹ Id. at 19.

⁶² § 350

⁶³ M. KASHTOCK, *supra* note 117, at 19.

⁶⁴ § 201 (21 U.S.C. 350j).

⁶⁵ Id. § 204

⁶⁶ Id. § 301(e) (21 U.S.C. § 331(e)).

⁶⁷ Id. § 204

⁶⁸ Amending Section 801(a) (21 U.S.C. § 381(a)).

⁶⁹ Id. § 207 (21 USC § 334(h)).

⁷⁰ U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/food/guidanceregulation/fsma/ucm395105.htm> (last visited Aug. 29, 2014).

⁷¹ U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm395105.htm> (last visited Aug. 29, 2014).

⁷² This is a misnomer since FDA does not have legal authority to enforce food handling regulations once a citizen acquires title and possession of an article of food for personal use.

⁷³ Operational Strategy for Implementing FSMA, *supra* Appendix.

⁷⁴ FSMA § 102 (21 U.S.C. § 350d).

⁷⁵ U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM332460.pdf> (last visited Aug. 29, 2014); U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm331957.htm> (last visited Aug. 29, 2014).

⁷⁶ <http://www.fda.gov/food/guidanceregulation/fsma/ucm383763.htm>

⁷⁷ <https://www.federalregister.gov/articles/2013/05/30/2013-12833/information-required-in-prior-notice-of-imported-food?source=govdelivery>

⁷⁸ 76 FR 25542; May 5, 2011

⁷⁹ CENTER FOR DISEASE CONTROL, <http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html> (last visited Aug. 29, 2014).

⁸⁰ § 304 of (21 U.S.C. § 381(m)).

⁸¹ U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/regulatoryinformation/legislation/ucm148797.htm> (last visited Aug. 29, 2014).

⁸² Adding Section 801(m).

⁸³ Title III, Sec. 301. 21 USC § 384a.

⁸⁴ 21 USC § 342

⁸⁵ 21 USC § 343(w)

⁸⁶ 21 USC § 350g

⁸⁷ 21 USC § 350h

⁸⁸ Under 21 USC § 384a(c)(4).

⁸⁹ As defined in Section 805.

⁹⁰ 21 U.S.C. § 331(zz).

⁹¹ 21 U.S.C. § 381(q).

⁹² 21 U.S.C. § 381(d).

⁹³ 21 C.F.R. Pt. 1, *available at* <http://www.gpo.gov/fdsys/pkg/FR-2011-05-05/pdf/2011-10955.pdf>.

⁹⁴ CENTER FOR DISEASE CONTROL, <http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html> (last visited Aug. 29, 2014).

⁹⁵ FDCA, § 801(m).

⁹⁶ 78 F.R. 32359 (2013) *available at* <https://www.federalregister.gov/articles/2013/05/30/2013-12833/information-required-in-prior-notice-of-imported-food?source=govdelivery>.

⁹⁷ U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm153055.htm> (last visited Aug. 29, 2014).

⁹⁸ See 21 CFR §§ 1.276 to 1.285.

⁹⁹ U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm153055.htm> (last visited Aug. 29, 2014).

¹⁰⁰ 21 CFR §1.500 et seq. see FDA-2011-N-0143 <http://www.regulations.gov#!docketDetail;D=FDA-2011-N-0143> FDA's docket.

¹⁰¹ See id. at 26.

¹⁰² Notice of FSMA was provided to the WTO on February 14, 2011(G/SPS/N/USA/2156).

¹⁰³ Id. at 27.

¹⁰⁴ FDA is in a leadership position with the Codex Commission and its objective is to develop science-based international food safety, labeling, and other standards to provide consumer protection, labeling information, and prevention of economic fraud and deception that is consistent with corresponding U.S. regulations and laws.

¹⁰⁵ Codex Alimentarius Commission, CAC/GL 47-2003 http://www.codexalimentarius.net/input/download/standards/10075/CXG_047e.pdf

¹⁰⁶ FSMA Section 301, Sec. 805 of the FDCA (21 U.S.C. 384a).

¹⁰⁷ The rule provides exemptions for certain foods that are already subject to verification under FDA's HACCP regulations. Exemptions also exist for food for personal consumption, alcoholic beverages, food that is transshipped, food that is imported for re-export, and food for research or evaluation.

¹⁰⁸ 21 U.S.C. §§ 350g and 350h.

¹⁰⁹ 21 U.S.C. § 342.

¹¹⁰ 21 U.S.C. § 343(w)(concerning food allergen labeling).

¹¹¹ Section 301 of FSMA adding Section 805 to the FDCA (21 U.S.C. 384a)

¹¹² 60 F.R. 65096 at 65153.

¹¹³ 78 F.R. 3646 at 3665 to 3667.

¹¹⁴ 21 CFR §1.500.

¹¹⁵ Section 201(f) (21 U.S.C. 321(f)

¹¹⁶ 21 U.S.C. § 321(r).

¹¹⁷ 21 CFR §1.510

¹¹⁸ 21 CFR §1.506(a)

¹¹⁹ Id. at 78

¹²⁰ § 1.510(b)

¹²¹ 1.510(b)

¹²² § 1.510(d)

¹²³ See FDA Docket No. FDA-2013-N-1425

¹²⁴ § 419 of the FDCA (21 U.S.C. § 350d,g h).

¹²⁵ § 103.

¹²⁶ § 106.

¹²⁷ § 105.

¹²⁸ Id. at 18.

¹²⁹ Id. at 19.

¹³⁰ WORLD HEALTH ORGANIZATION, <http://www.who.int/foodsafety/publications/general/en/terrorist.pdf>.

¹³¹ § 418(b)(2).

¹³² § 418(c)(2).

¹³³ § 1.225(b)

¹³⁴ Id. at 31.

¹³⁵ Id. at 39.

¹³⁶ Id. at 54.

¹³⁷ Id.

¹³⁸ Id. at 55.

¹³⁹ Id. at 56.

¹⁴⁰ Id. at 57.

¹⁴¹ Id.

¹⁴² Id. at 58.

¹⁴³ Id.

¹⁴⁴ As defined at 21 CFR § 1.227.

¹⁴⁵ Id. at 59.

¹⁴⁶ Id.

¹⁴⁷ 21 CFR § 121.3

¹⁴⁸ Id. .

¹⁴⁹ Id.

¹⁵⁰ Id.

¹⁵¹ In section 420 of the FDCA.

¹⁵² Id.

¹⁵³ 21 CFR § 121.5(b).

¹⁵⁴ 21 CFR § 121.5(c).

¹⁵⁵ FDA provides a tool for creating a defense plan at <http://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm349888.htm>.

¹⁵⁶ § 121.130.

¹⁵⁷ § 121.135(b).

¹⁵⁸ § 121.140(a).

¹⁵⁹ § 121.150(e).

¹⁶⁰ 21 CFR § 121.130.

¹⁶¹ 21 CFR § 121.130(a).

¹⁶² 21 CFR § 121.130(b).

¹⁶³

http://www.selectagents.gov/resources/List_of_Select_Agents_and_Toxins_2013-09-10.pdf

¹⁶⁴ See pages 103-117.

¹⁶⁵ 21 CFR § 121.135(b).

¹⁶⁶ § 121.160.

¹⁶⁷ 21 CFR § 121.305(c), (d) and (e).

¹⁶⁸ 21 CFR § 121.305(d).

¹⁶⁹ § 121.305(e).

¹⁷⁰ PROPOSED RULE ON THE ACCREDITATION OF THIRD-PARTY AUDITORS/CERTIFICATION BODIES TO CONDUCT FOOD SAFETY AUDITS AND TO ISSUE CERTIFICATIONS (posted

Nov. 20, 2013)

<http://www.regulations.gov#!documentDetail;D=FDA-2011-N-0146-0039>.

¹⁷¹ FSMA added section 808 to the FDCA (21 U.S.C. 384d).

¹⁷² 79 FR 47417 available at

<http://www.fsis.usda.gov/wps/wcm/connect/a054fc30-2af6-4ea5-a9e9-468c2df788e8/2011-0009.pdf?MOD=AJPERES>

¹⁷³ U.S. FOOD & DRUG ADMIN.,

<http://www.fda.gov/food/guidanceregulation/fsma/ucm270851.htm> (last visited Aug. 29, 2014).

¹⁷⁴ § 204(d)(2) of FSMA.

¹⁷⁵ FDA's Draft Approach for Designating High-Risk Foods as Required by Section 204 of FSMA. U.S. FOOD & DRUG ADMIN.,

<http://www.fda.gov/food/newsevents/constituentupdates/ucm383648.htm> (last visited Aug. 29, 2014).

¹⁷⁶ 21 U.S.C. § 393.

¹⁷⁷ §§ 206 and 207 of FSMA

¹⁷⁸ 320 U.S. 277 (1943)

¹⁷⁹ Id. at 319

¹⁸⁰ 421 U.S. 658 (1975)

¹⁸¹ Park, 421 U.S. at 672

¹⁸² Id. at 683

¹⁸³ See Park, 421 U.S. at 673.

¹⁸⁴ See, United States v. New Eng. Grocers Supply Co., 488 F. Supp. 230, 234 (D. Mass. 1980) (“[A]lthough an impossibility defense may be available if an executive can show he exercised extraordinary care but nevertheless was powerless to stop the violation, this standard is difficult to meet”).

¹⁸⁵ Special Procedures and Considerations for Park Doctrine Prosecutions (2011) available at <http://www.fda.gov/downloads/iceci/compliancemanuals/regulatoryproceduresmanual/ucm074317.pdf>

¹⁸⁶ 193 U.S. 197 (1904).

