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FOOD VIGILANCE SYSTEM IN UNITED STATES

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ABSTRACT

Food is essential to life, hence food safety is a basic human right. Historically, documented human tragedies and economic disasters due to consuming contaminated food occurred as a result of intentional or unintentional personal conduct and governmental failure to safeguard food quality and safety. Maintaining the safety of food requires constant vigilance by government, industry and consumers. In the US, four agencies play major roles in carrying out food safety regulatory activities: the Food and Drug Administration (FDA), which is part of the Department of Health and Human Services (DHHS); the Food Safety and Inspection Service (FSIS) of the US Department of Agriculture (USDA); the Environmental Protection Agency (EPA); and the National Marine Fisheries Service (NMFS) of the Department of Commerce. The Food Safety Modernization Act, passed in the United States in 2011, was a major reform of previous US food safety laws. It involved a shift in focus from food contamination events to prevention-based controls for food manufacture, harvesting, processing, packing, and storage.

INTRODUCTION

Ensuring food is safe requires constant vigilance and a pro-active approach to control known and emerging health risks. Known food hazards can be monitored to ensure controls are in place and are effective. Emerging food-related public health and safety risks are less well characterized and therefore difficult to monitor. While not all risks can be identified before they occur, ongoing research and development in the food industry and elsewhere, as well as surveillance of foods and investigation of foodborne disease outbreaks, can help identify some of the potential emerging risks.[1] To provide safer food and make use of precious water and nutrient resources, communities increasingly value sustainable food production. However, this should be done safely to maximize public health gains and environmental benefits. Food safety is being challenged nowadays by the global dimensions of food supply chains, the need for reduction of food waste and efficient use of natural resources such as clean water. Food safety deals with safeguarding the own national food supply chain from the introduction, growth or survival of hazardous microbial and chemical agents. But within a larger international context, borders are fading

and surely this is the case for foodstuffs which are an important globally traded commodity. There is great divergence in the degree of organization, infrastructure, teaching capacity across countries and food protection (food quality, food preservation, food safety) needs to be tackled globally. This special issue assembled topics in food safety, with case studies of food safety concerns from various parts of the world, research on risk factors in agricultural production of fresh produce, use of water and water treatment technologies in food production, and outlooks on food safety for vulnerable persons. The main conclusion throughout all papers is that ensuring food safety of the food supply chain is a continuous challenge and needs our attention.[2]

History of U.S Food Vigilance System

The first food safety regulations appeared in the mid-1800s as the government began to regulate pharmaceuticals. They first introduced the U.S. Pharmacopeia, the first compendium of standard drugs for the United States in 1820, and followed it with the Drug Importation Act in 1848, which placed restrictions on foreign drugs that often had adulterants. By the end of the 19th century, laws such as the Tea Importation Act were passed to begin inspecting goods coming into the United States, and in 1898 the Committee on Food Standards was created.

The 1900s saw many advances to food safety regulations, including the Biologics Control Act, and studies of chemical preservatives and colors to determine their effects on human health (the Certified Color Regulations were introduced in 1907). 1906 was an important year for food safety. When Upton Sinclair wrote *The Jungle*, he originally meant to call attention to the plight of workers. Instead, he created a huge outcry about the practices of the meat packing industry. That same year, President Theodore Roosevelt introduced the Food and Drugs Act and the Meat Inspection Act as a response to public concerns about adulterants in food. When a toothache syrup created for teething children was found to contain unlabeled morphine that killed many infants in 1913, the Gould amendment regulated that ingredients be "plainly and conspicuously marked on the outside of the package in terms of weight, measure, or numerical count." The Food and Drug (and Insecticide) Administration became a separate entity from the Bureau of Chemistry in 1927, and was shortened to the FDA in 1930. In 1938, the Federal Food, Drug, and Cosmetic (FDC) Act was passed. This regulation included requirements such as showing drugs to be safe, tightening regulation on mislabeling or misleading ingredients, set safe tolerances for dangerous substances, set standards for identity, quality, and container fill for foods, and authorized inspections and court injunctions. In 1944, congress passed the Public Health Service Act, which regulated biological products and control of communicable diseases. By 1953, the Factory Inspection Amendment required the FDA to give manufacturers written reports of conditions observed during inspections and analyses of factory samples. 1958 was also an important year, as the Food Additive Amendment passed, which prohibits the approval of any food additive shown to induce cancer in humans or animals. Also in this year the FDA published the first list of substances generally recognized as safe (GRAS). In 1962, the Thalomide crisis prompted stronger support for regulation on drugs, and the Consumer Bill of Rights was passed, mandating that consumers have more information to make their choices. By 1969, the White House Conference on Food, Nutrition, and Health was recommending systematic review of GRAS substances. Saccharine was removed from the GRAS list in 1971. 1982, saw the introduction of the Tamper-Resistant Packaging Regulations, which still affect many in the food manufacturing

industry today. The FDA officially became an agency of the Department of Health and Human Services in 1988. In 1990, they introduced the Nutrition Labeling and Education Act, which required all packaged foods to bear nutrition labeling. The food ingredient panel, serving sizes, and terms such as “low fat” and “light” were standardized under this act. The “Nutrition Facts” were mandated on packaging in 1992. In 1997, the FDA 21 CFR Part 11 regulations were introduced to require the keeping of electronic records on food manufacturing. Food safety shifted in the early 2000’s to reflect bioterrorism threats, and also developed a focus on obesity and heart health. In 2003, food labels had a requirement to include trans fats. A year later, the Food Allergy Labeling and Consumer Protection Act required food labeling for food that might contain proteins derived from the most common allergens: peanuts, soybeans, cow’s milk, eggs, fish, crustacean shellfish, tree nuts, and wheat. The Food Safety and Modernization Act of 2011 allowed the FDA to hold imported foods to the same standards as domestic ones.[3]

DISCUSSION

Every organization and every person involved with the food chain from farm and sea to table shares responsibility for the safety of food. Food safety system includes producers, processors, shippers, retailers, food preparers, and, ultimately, consumers. The government plays an important role by establishing standards and overseeing their enforcement. Supporting roles are played by trade and consumer organizations that inform policy and by professional organizations and academic institutions that engage in research and education. Great responsibility lies with consumers who must be cognizant of the level of safety associated with the foods they purchase and who must handle these foods accordingly. The food safety system in USA is complex and multilevel. It is also essentially uncoordinated. As a consequence, the government's role is also complex, fragmented, and in many ways uncoordinated.[4] FDA has jurisdiction over domestic and imported foods that are marketed in interstate commerce, except for meat and poultry products. FDA's Center for Food Safety and Applied Nutrition (CFSAN) seeks to ensure that these foods are safe, sanitary, nutritious, wholesome, and honestly and adequately labelled. CFSAN exercises jurisdiction over food processing plants and has responsibility for approval and surveillance of food-animal drugs, feed additives and of all food additives (including colouring agents, preservatives, food packaging, sanitizers, and boiler water additives) that can become part of food. CFSAN enforces tolerances for pesticide residues that are set by Environmental Protection Agency (EPA) and shares with Food Safety and Inspection Service (FSIS) responsibilities for egg products. The FDA's statutes give CFSAN jurisdiction over restaurants, but it has always ceded this responsibility to states and localities. The agency provides leadership for state regulation of retail and institutional food service through the development of a model Food Code, which it recommends be adopted by states and localities.

Food Safety Modernization Act (FSMA)
Enacted in 2011 and set to be implemented through seven major substantive rules - FSMA introduces a new era in food safety by focusing on preventing food safety risks rather than on responding to crises after they happen. As it enters the enforcement stage for the new rules, it considers the practical challenges of each rule and identify areas where enforcement may provide clarity, including in relation to one of the most difficult aspects of the final rules: regulation of supply chain. Each of the seven foundational rules plays a distinct role in the new integrated

national food safety system, and together, they reflect the USFDA mandate to comprehensively regulate and modernize virtually all aspects of the food industry. Under this framework, FDA requires preventive controls for food facilities and mandatory produce safety standards for a broad range of farming activities. Importers must verify that food produced on foreign farms and facilities is produced under standards at least as rigorous as those that apply to domestic food, and an accreditation program will regulate certain audits of foreign foods and foreign facilities. Regulations to minimize food safety risks during transport will apply to persons involved in the transportation of food by motor or rail carrier, including shippers, carriers, receivers, loaders and even brokers. And larger facilities will be required to protect against intentional adulteration intended to cause wide-scale public harm.[4] FSMA provides the agency with expanded enforcement authority to compel compliance with the new rules and to respond to and contain problems when they occur. Under FSMA, FDA now has mandatory recall authority, more flexible authority to administratively detain or to deny entry to food that poses potential safety risks, the ability to suspend facility registrations and the authority to require expanded record-keeping. The enforcement penalties for non-compliance are severe. Failure to comply with the rules may result in significant civil and strict-liability criminal penalties, which means that responsible persons can be guilty of a crime without negligence or knowledge of a violation. In some of the most challenging provisions of the rules, FDA imposes obligations on covered parties to verify and to provide or receive documentation regarding food safety risks to other parties in their food supply and distribution chains. In some instances, these requirements even require covered entities, such as importers, to obtain verifications from entities multiple steps back in the supply chain. Given the complexity of many modern supply chains, complying with these provisions will prove challenging in practice, and the industry will be watching to determine how FDA enforces these particular regulations. As with all the regulations, questions remain about FDA's expectations for certain aspects of the FSMA rules, as well as how those uncertainities may impact business operations. As these deadlines approach, it is important to examine particular challenges with each of the rules and understand key considerations regarding likely implementation challenges and potential enforcement risks. [9] In the US, four agencies play major roles in carrying out food safety regulatory activities: the Food and Drug Administration (FDA), which is part of the Department of Health and Human Services (DHHS); the Food Safety and Inspection Service (FSIS) of the US Department of Agriculture (USDA); the Environmental Protection Agency (EPA); and the National Marine Fisheries Service (NMFS) of the Department of Commerce.[4]

Food Safety and Inspection Service (FSIS) FSIS seeks to ensure that meat and poultry products for human consumption are safe, wholesome, and correctly marked, labeled, and packaged if they move into interstate or international commerce. By the mid-1990s, roughly 7,400 FSIS inspectors were responsible for inspecting 6,200 meat and poultry slaughtering and processing plants by continuous carcass-by-carcass inspection during slaughter as well as by full daily inspection during processing. FSIS shares responsibility with FDA for the safety of intact-shell eggs and processed egg products. Because of the statutorily mandated continuous inspection requirements, FSIS's inspection budget is about four times that of FDA. Food scientists believe that inspection of each animal carcass is no longer the best or most cost-effective means of preventing

foodborne diseases, but this effort is required by statute and so is fully funded. The sensory evaluation inspection methods used in FSIS inspections were appropriate when adopted 70 years ago, when major concerns included gross contamination, evidence of animal disease, and other problems that are no longer acute concerns. Those methods are not appropriate or adequate to detect the major microbial and chemical hazards of current concern. The FSIS is responsible for monitoring meat, poultry, and eggs for pesticides, animal drugs, and environmental contaminants. The Agricultural Marketing Service (AMS) has responsibility to maintain standards for shell egg surveillance and to ensure the proper disposal of restricted eggs, which are shell eggs that may be dirty, cracked, leaking, or otherwise unsuitable for consumer purchase. The GIPSA's Federal Grain Inspection Service provides federal quality and safety standards and a system for applying them to US grain for both domestic consumption and export. The National Agricultural Statistics Service (NASS), in conjunction with AMS, monitors chemical residues in foods via the Pesticide Data Program. The AMS collects data on pesticide levels as measured in fruits and vegetables, whereas NASS collects data from farmers about pesticide use on fruits, vegetables, nuts, and field crops.[4]

Food and Drug Administration (FDA)

Because of the FDA-USDA jurisdictional split along commodity lines, some food products that might be perceived by consumers as similar are regulated differently, depending on content. The most cited example is pizza, which is regulated by FDA unless topped with 2 percent or more of cooked meat or poultry, in which case it is USDA-regulated. This means that inspection at pizza production facilities must be conducted simultaneously under two sets of guidelines by two different inspectors from separate agencies.

Environmental Protection Agency (EPA) EPA licenses all pesticide products distributed in the United States and establishes tolerances for pesticide residues in or on food commodities and animal feed. EPA is responsible for the safe use of pesticides, as well as food plant detergents and sanitizers, to protect people who work with and around them and to protect the general public from exposure through air, water, and home and garden applications, as well as food uses. EPA is also responsible for protecting against other environmental chemical and microbial contaminants in air and water that might threaten the safety of the food supply. In both programs, EPA works with state and local officials. EPA registers pesticides and pesticide excipients for use in the United States and establishes tolerances for food and feeds. Enforcement of tolerances is the responsibility of other agencies (FDA or FSIS). Therefore, EPA monitoring of pesticides and industrial chemicals in food is a limited part of its monitoring of these contaminants in the environment. EPA is responsible for establishing criteria to be used by the states to develop water quality standards. Under the Clean Water Act, EPA has the authority to set standards to restore or maintain the integrity of the nation's waters, which directly affect the safety of fish, shellfish, and wildlife (as well as water for human consumption). EPA is also responsible for enforcing standards for drinking water set under the Safe Drinking Water Act. Water for food processing must be safe and potable as defined by these standards.[4]

National Marine Fisheries Service (NMFS) NMFS conducts a voluntary seafood inspection and grading program which is primarily a food quality activity. Seafood is the only major food source that is both "caught in the wild" and raised domestically. Seafood is an international commodity for which quality and safety standards vary widely from country to

country. Inspection of processing is a challenge because much of it takes place at sea. Mandatory regulation of seafood processing is under FDA, and applies to all seafood related entities in FDA's establishment inventory, including exporters, all foreign processors that export to the United States, and importers. However, fishing vessels, common carriers, and retail establishments are excluded. NMFS conducts a voluntary inspection of seafood processing plants, fishing vessels, and seafood products. FDA has regulatory responsibility for ensuring seafood safety, and NMFS coordinates its inspection efforts with FDA's Office of Seafood Safety. FDA, working with the seafood industry, adopted a mandatory HACCP program for seafood in late 1995.[4]

HACCP Systems

Many parts of the current food safety assurance system are in the early stages of transition to Hazard Analysis Critical Control Point (HACCP) programs. The leadership of FSIS, FDA, and industry in making this fundamental change to a hazard prevention system is commendable. It is widely accepted by the scientific community that use of HACCP systems in food production, processing, distribution, and preparation is the best known approach to enhancing the safety of foods. If HACCP programs are fully implemented, they will substantially increase the effectiveness of the system. HACCP programs use a systematic approach to identify microbiological, chemical, and physical hazards in the food supply, and establish critical control points that eliminate or control such hazards. The control must effectively address the identified hazard and the effectiveness of the control point must be validated. This approach appears to be much more effective in ensuring the safety of foods than traditional visual inspection practices. The HACCP system institutes methods to control food safety hazards, whereas traditional inspection and testing procedures are not designed to detect and control contaminants that are sporadically distributed throughout foods and are not visible. In 1995, the FDA issued its final rule on HACCP for seafood, requiring all seafood processors to conduct a hazard analysis to determine whether food safety hazards are reasonably likely to occur. If no hazards are identified, no HACCP plan is needed, but reassessments are required whenever procedures are changed significantly. Written HACCP plans for seafood must be specific to each location and type of seafood product. In response to the need to train members of the seafood industry in HACCP techniques, the National Seafood HACCP Alliance for Training and Education was created. This organization provides information on HACCP training courses, as well as sample HACCP models for various seafood products. The Pathogen Reduction and HACCP system regulation of USDA establishes requirements in an effort to reduce the occurrence and numbers of pathogens on meat and poultry products and reduce the incidence of foodborne illness associated with consuming these products. Regulatory performance standards for pathogen reduction and end-product testing to determine whether the HACCP system meets those standards are basic to the USDA's approach to HACCP. During the first three months of implementation of HACCP based inspection by large meat and poultry processors, enforcement actions against 13 plants were taken by FSIS to address system failures and improper implementation or misunderstanding of HACCP procedures by processors or inspectors. In response to the need to train members of the meat and poultry industry, the international meat and poultry HACCP alliance was formed at Texas A&M University. The alliance is composed of industry associations and is affiliated with federal agencies, universities, and professional organizations.

Implementation of HACCP is the responsibility of food producers, processors, distributors, and consumers. The role of government is to ensure that HACCP programs are properly implemented throughout the food supply continuum by evaluation of HACCP plans and inspection of records indicating monitoring of critical control points. Implementation of this innovative approach requires a major educational effort and cultural change among federal inspectors. Adequate resources have not been provided to enable the implementation of HACCP-based inspection effectively, efficiently, and without disruption. Food safety laws were adopted very early as a way to protect trade with Europe and promote interstate commerce. There were also elements of consumer protection in the earliest laws, such as proper weights and measures, purity of ingredients, and fair pricing. By the early 1900s, states had adopted a patchwork of laws and there was a determined movement for national legislation. Comprehensive legislation was added in 1906, when Congress adopted two laws that covered meat products and non-meat products separately. That framework remains in place today, but it is being modernized to bring greater alignment to the different programs. Recent changes to the laws focus on adopting legal approaches that can more readily apply modern scientific approaches to food safety.[5] The FDA Food Safety Modernization Act (FSMA), signed into law by President Obama on Jan. 4 2011, enables FDA to better protect public health by strengthening the food safety system. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur. The law also gives FDA new tools to hold imported foods to the same standards as domestic foods and directs FDA to build an integrated national food safety system in partnership with state and local authorities.[6] It is transforming the nation's food safety system by shifting the focus from responding to foodborne illness to preventing it. Congress enacted FSMA in response to dramatic changes in the global food system and in our understanding of foodborne illness and its consequences, including the realization that preventable foodborne illness is both a significant public health problem and a threat to the economic well-being of the food system.[7] The FDCA served as the principal food safety law for FDA-regulated foods in the USA through 2011, but unlike the Meat Inspection Act, the law's reactive approach provided inadequate protection to both consumers and the food industry. The introduction of process control food safety systems like HACCP in the late 1990s, combined with international shifts toward preventive food safety systems as a prerequisite to trade, led to efforts to reform the law. The effort was jump-started in 2002 with Congress's adoption of the Bioterrorism Act. Food was recognized as a potential target, and Congress adopted several provisions ensuring that food facilities, both domestic and foreign, were registered and that importers provided the FDA with notice of food shipments. The 2000s were also marked by a period of major outbreaks linked to FDA regulated foods, including such diverse products as spinach, peanut butter, and eggs. Like the 1890s Popular Treatise on the Extent and Character of Food Adulterations and the 1930s American Chamber of Horrors, these outbreaks provided clear evidence that the FDA's program was failing. They also triggered a public outcry for Congress to take action to improve the law. Consumer organizations worked alongside the processed food industry and actual victims to educate members of Congress on the

need for comprehensive legislation encompassing the HACCP model for the processed food industry, production guidelines for farmers, and more stringent control of imported foods. The FSMA introduced many new concepts into the US food law, several of which had already been adopted in other countries and regions such as the European Union. The new law implements significant changes to inspections of domestic food firms and applies new approaches to imports, including requiring more inspections of foreign firms that import into the USA. Unlike the older law where inspections were discretionary and hampered by restrictions on the inspector's authority to review records, the new law mandates inspection schedules and makes access to a firm's food safety plans, associated records, and testing results part of the inspection routine. The law implements process control systems throughout the food industry and allows the agency to set performance standards for the most significant foodborne contaminants, to provide a benchmark for measuring firms for compliance. Regulatory testing is done through accredited laboratories, and certain test results are reported directly to the FDA. Imported products are subject to a number of new mandatory and voluntary requirements. Importers must operate through the Foreign Supplier Verification Program which requires an import agent to verify that firms are in compliance with the process control requirements of the Act. A variety of third parties, including foreign national governments, foreign cooperatives, and other recognized third-party auditors can certify that food is in compliance with the law. Private auditors must report public health risks they discover in the course of certifying the safety of a foreign firm. Certification can be either mandatory for high-risk products, or voluntary under the Voluntary Qualified Importer Program. The FSMA added important enforcement authorities as well, providing the agency with the power to suspend registrations, administratively detain food where it presents a threat to public health, and levy civil penalties when firms refuse recall orders. These new powers are viewed as transformative of the FDA's authority. Whereas the FDA's enforcement historically has been limited to conditions inspectors observed during infrequent visits to food processing plants or in post-outbreak investigations, the new authority provides knowledge about operations over time, and focuses on prevention.[5] The FDA published seven major rules under FSMA, each of which created new requirements that put more responsibility on industry to prevent contamination of the U.S. food supply rather than reacting to it.

Preventive Controls Rules for Human and Animal Food

The FDA's Preventive Controls Rules apply to all facilities required to register with the FDA as a food facility, unless covered by an exemption. A covered facility must implement a written Food Safety Plan that identifies known or reasonably foreseeable biological, chemical, and physical hazards related to foods in the facility. For each identified hazard, the Food Safety Plan must determine whether the hazard requires preventive controls and, if so, outline preventive controls to minimize or prevent that hazard. While similar to other food safety programs, such as HACCP, ISO 22000, or British Retail Consortium (BRC), these plans do not satisfy the requirement of having an FDA Food Safety Plan. A Preventive Controls Qualified Individual (QI) must create or oversee the development of a facility's Food Safety Plan. The Preventive Controls QI may or may not be an employee of the facility. The Preventive Controls Rules also require covered facilities to approve their raw material and ingredient suppliers when the receiving facility has identified a hazard requiring a preventive control. In approving suppliers, facilities must consider multiple factors,

including the supplier's performance (i.e., compliance with FDA regulations, including FDA warning letters, Import Alerts, etc). Facilities can use the FDA's public databases or a third party tool to monitor a supplier's status.

Produce Safety Rule

The FDA's Produce Safety Rule establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of produce. The rule puts more responsibility on farms to protect their crops from contamination by creating requirements for water quality testing, raw manure application, examining grazing areas, employee health and hygiene training, and more. The rule gives special attention to sprouts due to their frequent association with foodborne illness outbreaks.

Foreign Supplier Verification Program (FSVP) Rule The FSVP rule requires importers to verify their foreign suppliers are producing food in compliance with applicable FDA regulatory requirements. To approve a supplier, an importer must evaluate the risks posed by foods it supplies by determining potential hazards associated with each food, as well as by evaluating the supplier's performance (i.e., FDA compliance history). Importers must then implement an FSVP for each approved supplier and each food imported from that supplier. The rule gives importers the flexibility to choose appropriate verification activities for each food and supplier. Examples of potential verification activities include annual onsite audits of a supplier's facility, sampling and testing a supplier's products, or reviewing a supplier's food safety records.

The FDA defines an importer as "the U.S. owner or consignee of a food offered for import into the United States" for purposes of this rule. If there is no U.S. owner or consignee, the FDA considers the U.S. agency or representative of the foreign owner of consignee at the time of entry to be the importer.

Accredited Third-Party Certification

The Third-Party Certification rule established a voluntary program for the accreditation of third-party certification bodies to conduct food safety audits and issue certifications of foreign facilities and the foods they produce. Under the program, the FDA recognizes accreditation bodies, which then may accredit third-party certification bodies.

Accredited third-party certification bodies can perform two types of audits: consultative and regulatory. A consultative audit is conducted in preparation for a regulatory audit, while a regulatory audit is the basis for certification. Foreign facilities can use certification from a Third-Party Certification Body for two purposes: participation in the FDA's Voluntary Qualified Importer Program (VQIP) or to satisfy a request by the FDA that a food exported to the U.S. be accompanied by this certification (a request that may be made if the FDA suspects a food has the potential to be harmful to U.S. consumers). When a certification body conducts a regulatory audit, it must provide the FDA with a full report on the results of its inspection. The results of a consultative audit may remain private, but a certification body is required to report to the FDA if a consultative audit reveals issues that may pose a serious risk to consumer health.

Sanitary Transportation Rule

The Sanitary Transportation rule created new requirements for shippers, receivers, loaders, and carriers that transport food in the U.S. by motor or rail vehicle to ensure food is protected during transportation, via both the design and maintenance of transportation vehicles and equipment and by taking appropriate measures to ensure food safety by maintaining proper

temperature controls and protecting food from contamination. Shippers, loaders, carriers, and receivers must develop written procedures detailing how they will ensure the safe transportation of food according to their specific requirements under the rule. The Sanitary Transportation rule applies whether or not the food is offered for or enters interstate commerce.

Intentional Adulteration Rule

As with the FDA's Preventive Controls Rules, the Intentional Adulteration Rule applies to all facilities required to register with the FDA as a food facility, unless covered by an exemption. The rule requires facilities to develop and implement a written Food Defense Plan that assesses vulnerabilities within the facility, identifies a mitigation strategy for each vulnerability, and identifies monitoring procedures to ensure effectiveness of the mitigation strategies. A QI must prepare a facility's Food Defense Plan.

Complying with FSMA

FSMA focused on FDA-regulated foods and amended FDA's existing structure and authorities, in particular the Federal Food, Drug, and Cosmetic. Among its many provisions, FSMA expanded FDA's authority to conduct a mandatory recall of contaminated food products; enhanced surveillance systems to investigate foodborne illness outbreaks; established new preventive controls and food safety plans at some food processing facilities and farms; enhanced FDA's traceability capacity within the nation's food distribution channels; increased inspection frequencies of high-risk food facilities (both domestic and foreign facilities); and expanded FDA's authority and oversight capabilities regarding foreign companies that supply food imports to the United States. FSMA does not directly address meat and poultry products under the jurisdiction of USDA.

When the law was enacted, FDA has identified five key elements of FSMA:

Preventive controls—FSMA provides FDA with a legislative mandate to require comprehensive, prevention-based controls across the food supply. As examples, the act requires mandatory preventive controls for food facilities and mandatory produce safety standards, and also gives FDA the authority to prevent intentional contamination.

Inspection and Compliance—FSMA provides FDA with the ability to conduct oversight and ensure compliance with new requirements and to respond when problems emerge. Examples include establishing a mandated inspection frequency (based on risk); giving FDA access to industry records and food safety plans; and requiring certain testing to be conducted by accredited labs.

Response—FSMA provides FDA with the ability to respond to problems when they emerge. Examples include giving FDA mandatory recall authority for all food products; expanding FDA's authority to administratively detain products that are in violation of the law; giving FDA the authority to suspend a facility's registration, effectively prohibiting the company from selling any products within the United States; establishing pilot projects so FDA can enhance its product tracing capabilities; and requiring additional recordkeeping by facilities that "manufacture, process, pack or hold" foods designated as "high-risk."

Imported Food Safety—FSMA provides FDA with the ability to help ensure that food imports meet U.S. food safety standards. Examples include requiring importers to verify that their foreign suppliers have adequate preventive controls; establishing a third-party verification system; requiring certification by a credible third party for high-risk foods as a condition for entry into the

United States; establishing a voluntary qualified importer program for expedited review and entry from participating importers; and giving FDA the right to refuse entry into the United States of food from a foreign facility if FDA is denied access to the facility or the country where the facility is located.

Enhanced Partnerships—FSMA provides FDA with the authority to improve training of state, local, territorial, and tribal food safety officials. Examples include requiring FDA to develop and implement strategies to enhance the food safety capacities of state and local agencies through multi-year grants, as well as strategies to enhance the capacities of foreign governments and their industries; and giving FDA the authority to rely on inspections of other federal, state, and local agencies in meeting its increased inspection mandate for domestic facilities.[8]

How to Report a Problem with Food

A consumer, health professional, or member of the food industry willing to voluntarily report a complaint or adverse event (illness or serious allergic reaction) related to a food product, can be done by use of either of 3 options:

- ✓ Call an FDA Consumer Complaint Coordinator to speak directly to a person about the problem.
- ✓ Complete an electronic Voluntary Med Watch form online.
- ✓ Complete a paper Voluntary Med Watch form that can be mailed to FDA.

Members of the food industry who needs to submit a Reportable Food Registry report when there is a reasonable probability that an article of food will cause serious adverse health consequences or death to humans or animals, should go through the Reportable Food Registry page.[9]

The CFSAN's Adverse Event Reporting System (CAERS)[10]

The CFSAN launched CAERS in 2003 to centrally help track and monitor adverse events. The CFSAN's scientists have developed rapid methods to detect microbial and viral food contaminants, and the FDA works with public and private sector partners to complete and operate two nationwide high-tech systems for rapid identification and control of outbreaks of foodborne disease.

Surveillance [4]: Surveillance for human foodborne diseases is primarily the responsibility of state and local health departments, which are required or authorized to collect and investigate reports of communicable diseases. Although specific reporting requirements vary by state, such common and serious bacterial foodborne pathogens as *Salmonella, Shigella, Campylobacter, and E. coli* 0157:H7 are reportable in most states. In addition, recognized outbreaks of foodborne disease are reportable in most states regardless of cause. Investigations are conducted to identify cases of illness, determine their sources, and control outbreaks. Responsibility for the primary investigation of individual cases or outbreaks may lie with local and state health departments. This system results in regional disparities in the probability of detecting outbreaks and may affect the thoroughness of an investigation. On a national level, the CDC collects data from the states on the occurrence of specific pathogens such as *Salmonella, Shigella, Campylobacter,* and *E. coli,* and collects summary data on foodborne disease outbreaks investigated by local and state health departments. CDC conducts field investigations of foodborne diseases only at the request of state health departments. CDC also plays a role in coordinating investigations of multistate or international outbreaks. The FDA and FSIS are called into investigations when the safety of a food in their jurisdictions is questioned.

The FDA and FSIS are charged with ensuring that foods implicated in a foodborne illness outbreak and traveling in interstate commerce are removed from the market. Most recalls of food products regulated by FDA and FSIS, whether requested by the agency or initiated by the private entity, are carried out voluntarily by the businesses that manufacture, distribute, or sell these products. By statute they must use different methods to achieve that charge; FSIS uses its recall authority and FDA requests voluntary recalls of hazardous food by industry.

SUMMARY AND CONCLUSION

Food Safety was launched because of an increasing awareness of food safety within a sustainable global food supply. Implementation of food safety management systems alongside the supply chain in different regions needs knowledge from food safety research but also understanding of local practices, context and environmental conditions. In times of increasing concern on food and nutrition security, a debate on stringency of food safety regulation is expected, as strict food safety legislation is sometimes blamed as one of the causes contributing to food waste. This debate is part of the interface of risks assessment, risk management and risk communication. Food safety research will continue to provide insights and is needed to help out in tackling current and emerging food safety challenges in a changing world. In U.S the food processing sector is extensively regulated by the FDA or USDA FSIS, depending on the food product. Each of the regulated topics is based on the goal of wanting to prevent adulterated or misbranded food from reaching the consumer. It is the food business' burden to establish that the food is not adulterated or misbranded. Until that burden is met, a reasonable belief that the food is adulterated or misbranded authorizes the FDA or FSIS to take appropriate enforcement actions.

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