

## Securing U.S. Agriculture and Food: New Obligations, New Opportunities

The U.S. enjoys the world's safest and most bountiful food supply. Securing our food and agriculture against intentional misdeeds is critical to our safety and economy and is becoming a key focus of the nation's homeland security efforts. This Bulletin briefly summarizes U.S. food safety law and reviews recent developments in food safety that affect growers, processors, distributors, importers and consumers of food products.

### Introduction

Agriculture contributes \$1 trillion annually to our gross domestic product; 22 percent of all jobs in this country are food-based. The U.S. food production industry exceeds \$200 billion; every year we export over \$55 billion worth of food products. Crops, livestock and food originate from 500,000 farms; it is processed by 57,000 food processors and 6,000 meat, poultry, and egg product processors. Because a complex food supply chain stretches from farm to table, assuring its safety is not a simple task.

Our nation's food safety laws traditionally have focused on protecting the nation's food supply from natural and accidental animal, plant and food pathogens. Since the events of September 2001, concern has arisen that pathogens or chemicals could be intentionally introduced and spread rapidly and easily through the food chain. Recent incidences of bovine spongiform encephalopathy ("BSE" or "Mad Cow") in a dairy cow in Washington State (from a farm in Canada) identified in a USDA surveillance program and the H7 strain of avian flu on two Delaware poultry farms have reminded us of the interdependence of our food sectors.

In his October 2001 executive order establishing the Office of Homeland Security, the President added agriculture and food industries to the list of critical infrastructure sectors needing protection. The Homeland Security Act of 2002 requires federal agencies to take steps to assure the continued safety of food and agriculture. Most recently, on January 30, 2004, the President issued Homeland Security Directive No. 9: Defense of United States Agriculture and Food. The President's directive "establishes a national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies."

After briefly summarizing U.S. food safety laws, this Bulletin will review the November 2003 food security assessment of the Government Accounting Office ("GAO"), the food security initiatives of the Food and Drug Administration and the Department of Agriculture, as well as Presidential Directive No. 9. The Bulletin

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concludes by noting potential applications of the SAFETY Act in the food industry. The objective of food security is simple: the best detection is early detection.

## Federal Agencies Regulating Food Safety

Domestic and imported foods must meet the same standards: food must be pure, wholesome, safe, produced under sanitary conditions and properly labeled. The Food and Drug Administration enforces the provisions of the Food, Drug and Cosmetic Act which prohibits the sale of adulterated food. FDA is responsible for ensuring the safety and security of 80% of the U.S. food supply. Through its Center for Food Safety and Applied Nutrition (CFSAN) and the Office of Regulatory Affairs (ORA), the FDA regulates both domestic and imported foods, except meat and poultry and processed eggs, and has primary responsibility for enforcing food safety laws including food import and export regulations. FDA inspects food production establishments and food warehouses and collects and analyzes samples for chemical and microbial contaminants. FDA samples and inspects imported foods.

Several agencies of the U.S. Department of Agriculture (USDA) play an important role in assuring food safety. The Food Safety and Inspection Service (FSIS) regulates meat, poultry and egg products and maintains a comprehensive system of domestic and import inspection and controls. These products account for more than \$120 billion in sales, or one-third of all U.S. consumer spending on food. FSIS officials each year inspect 39 million cattle and calves, 97 million hogs, 3.5 million sheep and lambs, eight billion poultry and fowl and 3.2 billion pounds of liquid egg products. In addition, FSIS inspects 3.8 billion pounds of imported meat, poultry and processed egg products from countries which have inspection systems equivalent to our own.

USDA's Animal and Plant Health Inspection Service (APHIS) inspects imported agricultural products for disease and pests which might infect plants and animals. Through monitoring activities at airport terminals, seaports, and border stations, it guards U.S. borders against the entry of foreign agricultural pests and diseases. FSIS has more than 7,600 inspectors in slaughter and processing plants and at import facilities nationwide.

## GAO on Food Security

On November 19, 2003, Lawrence Dyckman, a Director of GAO's Natural Resources and Environment team, issued a Statement for the Record before the Senate Governmental Affairs Committee, U.S. Senate entitled: "Bioterrorism: A Threat to Agriculture and the Food Supply." GAO reported that if they wanted to cause economic dislocation terrorists would target crops and livestock; and if they wanted to cause human injury they would target finished food products.

GAO's Statement summarized four of its recent reports that recommended that FDA and USDA strengthen import and border food and agriculture inspection programs. GAO concluded that "[t]he U.S. agriculture and food sectors have features that make them vulnerable to bioterrorism attacks." GAO reports observed that U.S. Customs, USDA and FDA border and import inspection programs faced challenges in detecting

### Related Websites

Following is a brief listing of government websites related to food security:

[www.FoodSafety.gov](http://www.FoodSafety.gov)

[USDA Food Safety & Inspection Service](#)

[FDA Counterterrorism Site](#)

[EPA Food Security Site](#)

[Presidential Directive 9](#)

foot-and-mouth disease and BSE, given the volume of imported food and agriculture products. The U.S. imported about 125 million pounds of beef (0.35 percent of total imported) and about 1,000 cattle (0.003 percent of total imported) from countries that later discovered BSE, during the period when BSE would have been incubating. GAO documented security lapses at USDA's Plum Island Animal Disease Center, which studies serious animal diseases, including some that can cause illness and death in humans. Land, buildings and other facilities of the Plum Island Animal Disease Center were transferred to the Department of Homeland Security in June 2003.

GAO reported that the U.S. agriculture and food industries have largely been free of deliberate acts of contamination. In 1975, 750 people became ill when a group poisoned salad bars at several Oregon restaurants with Salmonella bacteria. In January 2003, 92 persons became ill after purchasing ground beef from a Michigan supermarket that was intentionally contaminated with nicotine.

A recent outbreak of foot-and-mouth disease caused the United Kingdom economy \$10 billion; a similar outbreak in the U.S. might cost the U.S. economy \$24 billion, spreading to one-third of the nation's cattle herds. GAO's report noted that both FDA and USDA had issued recommendations for securing food processing plants but that both agencies lack statutory authority to mandate security measures.

## **FDA'S Implementation of the Bioterrorism Act**

On June 12, 2002, President Bush signed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act"). Four provisions in Title III, Subtitle A, of the Act require the Secretary of Health and Human Services, through FDA, to propose and issue final food regulations: Section 303: administrative detention; Section 305: the registration of food and animal feed facilities; Section 306: the establishment and maintenance of records; and Section 307: prior notice of imported food shipments.

### **▶ Registration of Food Facilities**

On October 8, 2003, FDA announced the implementation of regulations requiring the registration of food facilities. Domestic and foreign food facilities that manufacture, process, pack or hold food for human or animal consumption in the United States were required to register with FDA by December 12, 2003. FDA will have for the first time an official roster of foreign and domestic food facilities, allowing timely notification and response in the event of a food safety threat. Exempt from notification are farms, private residences, transport vehicles, restaurants, retail food establishments, nonprofit food establishments, fishing vessels, and establishments that are entirely regulated by USDA. If an unregistered foreign facility attempts to import food into the United States, the food will be held at the port of entry unless FDA or U.S. Customs directs otherwise. Foreign food establishments must identify a U.S. agent.

### **▶ Notice of Import**

FDA's import notice regulations require food importers to provide the FDA with advance notice of human and animal food shipments imported or offered for import on or after December 12, 2003. This allows FDA to know, in advance, when specific food shipments will arrive at U.S. ports and what the shipments will contain. This advance information will allow the FDA, working with U.S. Customs and Border

Protection, to more effectively target inspections and ensure the safety of imported foods. The FDA expects to receive about 25,000 notifications about incoming shipments each day.

#### ▶ **Detention**

On May 9, 2003, FDA also proposed regulations implementing the provisions in the Bioterrorism Act that gave FDA the authority to detain any article of food for which there is credible evidence or information that the article poses a threat of serious adverse health consequences or death to humans or animals. The administrative detention authority granted to FDA under the Bioterrorism Act is self-executing and currently in effect.

#### ▶ **Record Keeping**

FDA also published on May 9, 2003, a proposed regulation implementing the provisions in the Bioterrorism Act that would require manufacturers, processors, packers, transporters, distributors, receivers, holders, and importers of food to keep records identifying the immediate previous source from which they receive food, as well as the immediate subsequent recipient to whom they sent food.

### **Other FDA Food Security Initiatives**

#### ▶ **Increased Food Import Inspections**

Since 2001, FDA has quintupled the number of food import examinations. By 2002, FDA had more than doubled its presence to 90 ports of entry, and by July 2003, FDA had conducted over 62,000 food exams. The Technical Support Working Group (TSWG) of the Department of Defense and FDA are working with Sensor Research and Development to develop a prototype of a food pathogen detector. FDA is collaborating with the TSWG on a project at the John A. Volpe National Transportation Systems Center on a project related to the security of domestic and overseas transport of food.

#### ▶ **FDA Food Security Preventive Measures Guidance**

On March 21, 2003, FDA published two food security guidance documents. The first was designed to assist operators of food establishments and is entitled "Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance." The second was designed to assist importers: "Importers and Filers: Food Security Preventive Measures Guidance." Other guidance documents include "Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance," "Cosmetic Processors and Transporters: Cosmetic Security Preventive Measures Guidance," and "Guidance for Industry: Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations and Fluid Milk Processors; Food Security Preventive Measures Guidance."

#### ▶ **FDA Vulnerability and Risk/Threat Assessments**

FDA, together with the Institute of Food Technologists (IFT) and Battelle Memorial Institute, has assessed the vulnerability of FDA-regulated foods to intentional contamination with biological, chemical and radiological agents. These assessments, in the main, use a methodology called Operational Risk Management (ORM) and identified food/agent combinations that FDA is seeking to protect by implementing

shields for protecting these foods.

### ▶ **Operation Liberty Shield**

In March 2003, the U.S. government launched Operation Liberty Shield to increase security and readiness at a time of elevated risk. During this operation, FDA increased surveillance of domestic and imported food, including conducting 844 inspections of domestic firms based on risk/threat assessments of specific commodities. These inspections focused on food security with the benefit of the guidance documents referenced above. As well, FDA collected and analyzed 387 import samples for chemical and microbiological contaminants. USDA also increased food security for its regulated industries including meat, poultry and processed egg products.

### ▶ **Emergency Preparedness**

FDA has established an Office of Crisis Management (OCM) to coordinate the emergency response activities of the five FDA Centers. In May 2003, FDA participated in the TOPOFF 2 terrorism exercise that simulated two separate terrorist acts including the possibility of food contamination by radiation. FDA has entered into an Inter Agency Agreement (IAG) with the U.S. Army to design and develop two mobile laboratories to be deployed at borders, ports, or other locations, to analyze import samples.

### ▶ **Analysis of Food Samples**

FDA is seeking to develop analytical methods for detecting priority biological and chemical agents in food, with emphasis on methods that permit rapid analysis and practical sensitivity. Under contract, Midwest Research Institute is validating methods for the detection of microbiological agents in foods. The New Mexico State University Physical Science Laboratory is evaluating rapid test methods for microbiological analyses of produce samples.

FDA, CDC, USDA, EPA, DOE and the States have developed a nationwide Food Emergency Response Network (FERN), a network of state and federal laboratories that is committed to analyzing food samples in the event of a biological, chemical, or radiological event. As of June 2003, 63 laboratories participated in the FERN network, representing 27 states and 5 federal agencies.

### ▶ **Research**

FDA food security research will focus on three areas:

1. Development of prevention and mitigation technologies,
2. Elucidation of agent characteristics needed to develop prevention technologies, and
3. Development of means for continuously assessing foods for contamination with chemical, microbiological, and radiological agents. FDA's research infrastructure includes intramural research capabilities, collaborative Centers of Excellence (e.g., National Center for Food Safety and Technology, Joint Institute for Food Safety and Applied Nutrition, National Center for Natural Products Research) and extramural research including research contracts and grants.

On June 25, 2003, FDA published in the Federal Register a Request for Applications (RFA) entitled "Food Safety, Nutrition, Bioterrorism, Agricultural Research, Medical, Analytical Methods and Risk Assessment." The RFA requested applications to support research in four project areas:

1. Development and rapid analytical screening methods for the detection of pathogens that are not usually associated with food and foodborne illness at a contamination level of 100 to 10,000 microbial pathogens/gram of food without pre-growth or selective enrichment;
2. Development of PCR-based methods for rapid confirmatory identification of pathogens that are not usually associated food and foodborne illness;
3. Development of rapid screening methods capable of detecting a broad range of non-traditional chemical and toxin adulterants; and
4. Development of improved equipment, software, procedures, and/or methods for determining radionuclide contamination in foods.

## **U.S. Department of Agriculture**

Shortly after September 11, USDA formed a Homeland Security Council to coordinate the Department's efforts to secure the nation's agriculture against intentional acts. The mission of the Department's Food Animal and Plant Health Inspection Service (APHIS) is to protect plant and animal health to ensure a safe food supply. In 2003, APHIS border functions were transferred to the new Department of Homeland Security and approximately 2,600 members of the Department's border inspection service were transferred to DHS.

USDA has initiated numerous programs to guard against the accidental and intentional introduction of foreign animal diseases and plant pathogens. The Department provided \$43 million to states, universities and tribal lands to increase homeland security prevention, detection and response efforts. As well, the Department is spending \$18 million to develop rapid tests for agents that pose the most serious threat to agriculture, including foot and mouth disease, rinderpest and wheat rust. The Department established an Office of Food Security and Emergency Preparedness.

## **The President's FY 2005 Food Safety Budget**

President Bush's proposed budget for FY 2005 underscores the importance of food and agriculture safety. The proposed FDA budget of \$470 million is dedicated to protecting the food supply from intentional and accidental risks. One-hundred and eighty-one million dollars is specifically set aside for protecting food from deliberate contamination, a \$65 million increase from the 2004 budget. Similarly, the proposed FY 2005 budget for the Department of Agriculture includes \$381 million for its Food and Agriculture Defense Initiative. These funds are earmarked for pest and disease monitoring, a tracking system for disease agents, and research on emerging animal diseases. The USDA budget proposes \$952 million for the Food Safety and Inspection Service.

## **Presidential Directive 9: Defending U.S. Food and Agriculture**

On January 30, 2004, President Bush released Homeland Security Presidential Directive 9, which establishes a national policy to defend the agriculture and food systems against attacks, major disasters, and other emergencies. Directive priorities

include increased monitoring and surveillance of food and agriculture, expanded vulnerability assessments of the food and agriculture sectors, the development of mitigation strategies to protect vulnerable food and agriculture sectors, as well as response planning and recovery and the expansion of food and agricultural security programs in the university community. Several executive agencies must quickly develop responsive programs. The Directive requires the Secretary of Agriculture within 120 days to make recommendations to the Homeland Security Council on financial risk management tools to encourage self-protection for food and agriculture enterprises vulnerable to losses due to terrorism. The food and agriculture industries may wish to consider the adoption of programs modeled on the SAFETY Act, as outlined below.

The Directive requires the Secretary of Agriculture to develop a National Veterinary Stockpile (“NVS”) with sufficient animal vaccine, antiviral, or therapeutic products to respond to “the most damaging animal diseases affecting human health and the economy and capable of deployment with 24 hours of an outbreak. The Directive also requires USDA to develop a National Plant Disease Recovery System (“NPDRS”) capable of responding to high-consequence plant diseases, such as wheat smut or soybean rust.

## **DHS Grants**

The Department of Homeland Security’s Office of University Programs is reaching out to academia to assist in the creation of learning and research environments critical to homeland security through its Homeland Security Centers of Excellence Program. Under that program, the Office of University Programs is encouraging universities to become centers of multi-disciplinary research where these important areas of inquiry can be analyzed, debated and shared. Seventy million dollars in fiscal year 2004 has been dedicated to this program. Similar programs are being offered or contemplated by Federal agencies such as the USDA. As efforts mount to assure the continued safety of our food supply, so too will the funds available to entities involved in the agricultural industry.

In December 2003, the Science and Technology division of DHS called for proposals focusing on research efforts to combat intentional acts designed to compromise the safety of our food and agriculture. The notice invited colleges and universities to submit letters of intent by January 5, 2004, followed by full proposals, due on February 9, 2004. The Department anticipates establishing two Centers by April 2004; one will focus on combating animal-related security and the other will focus on post-harvest food security.

## **SAFETY Act Certification**

The SAFETY Act (“Support Anti-Terrorism by Fostering Effective Technology”) may serve as a safe harbor for food and agricultural companies to insulate themselves from the liability that might arise out of a malicious act designed to compromise our food supply. Passed as part of the Homeland Security Act of 2002, this piece of tort legislation offers a variety of legal protections to qualified sellers, vendors, subcontractors and buyers of protective technology products and services. The key element of the SAFETY Act is that it provides protection for not only the manufacturers, suppliers and providers of security products and services, but also for possible targets that will need to employ such products and services.

Under the SAFETY Act, if a certified product or service fails, all vendors and buyers of

the product or service are immune from liability. Only the manufacturer can be held liable; however, the manufacturer of a certified product is entitled to a presumption of dismissal. Food-related companies may benefit from the SAFETY Act and failing to take advantage of the Act's safeguards could have material adverse consequences, whether that means seeking to certify eligible products or services or seeking to purchase products or services that have been approved under the SAFETY Act by the Department of Homeland Security.

## Conclusion

Assuring the continued safety of imported and domestic food and agriculture is a Herculean task because of the complexity and geographic reach of our foreign and domestic food chain and the many federal and state agencies that regulate agriculture and food. Securing the safety of our food and agriculture against intentional misdeeds presents both obligations and opportunities. Should you have questions or concerns about these issues, please contact John Clerici at 202-496-7574, John Conner at 202-496-7649, Brian Finch at 202-496-7241 or Bob Stewart at 202-223-4392.

### ■ About Us

**McKenna Long & Aldridge LLP** (MLA) and its consulting affiliate, **Technology Sciences Group Inc. (TSG)**, provide comprehensive regulatory and technical expertise necessary to ensure compliance and identify opportunities in the area of food safety. MLA and TSG assist in the registration of food facilities, obtaining regulatory approvals for new antimicrobial products or animal drugs. MLA assists entities in obtaining certifications under the SAFETY Act and in legal matters relating to food safety. MLA attorneys and TSG scientists work regularly with the agencies that regulate food safety, including the FDA, EPA, USDA and DHS.

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