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# Current Developments in U.S. Food Regulation

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The issue of food regulation, while not novel, has received increasing media and legislative attention. In 2013, an entire issue of *Natural Resources & Environment* will be devoted to the topic of food law and regulation. In light of this increased attention, this article generally discusses the history of food regulations in the United States with a review of relevant recent legislative developments and existing funding challenges.

The origins of U.S. food regulation date back more than 100 years to the Food and Drugs Act of 1906. Ironically, 1906 also was the year that Upton Sinclair wrote *The Jungle*, which helped focus the public's attention on the nation's food safety via Sinclair's exposition of the plight of employees in the meat-packing industry during the early twentieth century. More than one hundred years later, significant issues remain with the safety of food in the United States. In fact, in 2011, the Centers for Disease Control and Prevention reported that annually more than forty-eight million Americans become sick from contaminated food every year, one hundred thousand people require hospitalization due to food contamination and three thousand die from food contamination. Recent food-borne illness outbreaks include a *listeriosis* outbreak from cantaloupes grown in Colorado, *listeria* in bags of salad, and *salmonella* associated with tomatoes, papaya, eggs, and peanut butter. In 2012 alone, *Consumer Reports* published two separate reports on the presence of arsenic in juice and food.

Much of today's current food regulatory scheme emanates from the Food Quality Protection Act of 1996 (FQPA). In enacting the FQPA, Congress presented the U.S. Environmental Protection Agency (EPA) with the enormous challenge of implementing the most comprehensive and historic overhaul of the nation's pesticide and food safety laws in decades. The FQPA amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food Drug, and Cosmetic Act (FFDCA) by fundamentally changing the way EPA regulates pesticides. Some of the law's major requirements include stricter safety standards, especially for infants and children, and a complete reassessment of all existing pesticide tolerances.

Today, EPA regulates pesticides primarily pursuant to two federal laws—FIFRA and the FFDCA. Under FIFRA, EPA registers pesticides for use in the United States and mandates labeling and other requirements designed to protect human health and the environment. Under the FFDCA, EPA establishes tolerances for pesticide residues in food. These tolerances are enforced by the U.S. Department of Health and Human Services—Food and Drug Administration and the U.S. Department of Agriculture—Food Safety and Inspection Services, as well as the Office of Pest Management Policy. The 1996 FQPA represented substantial progress in resolving inconsistencies between FIFRA and the FFDCA. More particularly, it mandates a single health-based standard for all pesticides in food, provides special protections for infants and children, and expedites approval of safer pesticides. Additionally, it creates incentives for the development and maintenance of effective crop protection and requires periodic reevaluation of pesticide

registrations and tolerances in order to ensure that the scientific data supporting these registrations is current.

Section 408 of the FFDCA authorizes EPA to set tolerances, or maximum residue limits, for pesticide residues on foods. In the absence of a tolerance being set for a pesticide residue, a food containing such a residue is subject to seizure by the government. Once a tolerance is established, the residue level in the tolerance is the trigger for enforcement actions. That is, if residues are found above that level, the food source will be subject to seizure.

In setting tolerances, EPA is required to make a finding that the tolerance is "safe." Safe is defined as meaning there is a "reasonable certainty that no harm will result from aggregate exposure to the pesticide residue." To make this determination, EPA must consider the toxicity of the pesticide and its breakdown products, aggregate exposure to the pesticide in foods and from other sources of exposure, and any special risks posed to infants and children. Some pesticides are exempted from the tolerance requirement. EPA may grant exemptions in cases where the pesticide residues do not pose a dietary risk under reasonably foreseeable circumstances.

In the United States, food safety is a joint responsibility with several departments of the federal government sharing jurisdiction over the safety of the nation's food supply. The Food and Drug Administration (FDA) is charged with protecting consumers against food that is impure, unsafe, produced under unsanitary conditions, or fraudulently labeled. 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, poultry, and processed eggs—and has primary responsibility for enforcing food safety laws including food import and export regulations.

The U.S. Department of Agriculture has several agencies that carry out a wide range of programs that may play a role in assuring food safety by establishing the safety of imported fruits and vegetables. The Centers for Disease Control and Prevention (CDC) work closely with state and local public health epidemiologists and laboratories to identify illnesses and clusters of foodborne illnesses. The U.S. Customs Service serves as the point of entry for products imported into the United States. Working with the FDA, the Customs Service participates in the effort to assure food safety.

President Obama signed the FDA Food Safety Modernization Act (FSMA) into law on January 4, 2011, providing the FDA for the first time with a legislative mandate to require comprehensive, prevention-based controls across the nation's food supply. The legislation is intended to alter FDA's food safety approach from being primarily reactive to being more proactive. It does so by requiring food facilities to evaluate the hazards in their operations, implement and monitor effective measures to prevent contamination, and develop corrective action plans. It also requires FDA to establish science-based standards for the safe production and harvesting of fruits and vegetables to minimize the risk of serious illnesses or death. This new ability to hold food companies accountable for preventing contamination is considered a significant milestone in the efforts to modernize the food safety system.

Additionally, the FSMA enhances inspections and compliance by permitting the FDA to apply its inspection resources in a risk-based manner and to develop more efficient and effective inspection approaches. The legislation provides significant enhancements to FDA's ability to achieve greater oversight of

the millions of food products coming into the United States from other countries each year. An estimated 15 percent of the U.S. food supply is imported, including 60 percent of fresh fruits and vegetables and 80 percent of seafood.

More specifically, the amended law

- requires importers to perform supplier verification activities to ensure the safety of imported food;
- authorizes FDA to refuse admission to imported food if the foreign facility or country refuses to allow an FDA inspection;
- authorizes FDA to require certification, based on risk criteria, that the imported food is in compliance with food safety requirements; and
- provides an incentive for importers to take additional food safety measures by directing FDA to establish a voluntary program through which imports may receive expedited review of their shipments if the importer has taken certain measures to assure food safety.

Significantly, for the first time, FDA also will enjoy mandatory recall authority for all food products. Given the food industry's general compliance with FDA's requests for voluntary recalls, FDA anticipates that it will invoke this authority infrequently. Nonetheless, this new authority is considered a critical improvement in FDA's ability to protect the public health.

The amended law also recognizes the importance of strengthening existing collaboration among all food safety agencies—federal, state, local, territorial, tribal, and foreign—to achieve the nation's public health goals and to protect the safety of the country's food sources. It also recognizes the importance of building the capacity of state, local, territorial and tribal food safety programs. Among other provisions, it directs the FDA secretary to improve training of state, local, territorial and tribal food safety officials and authorizes grants for training, conducting inspections, building capacity of labs and food safety programs, and other food safety activities.

In January 2013—two years after enacting the FSMA—FDA released two important draft rules implementing this legislation. If finalized, the new rules will require food producers to develop formal plans to identify and prevent foodborne illnesses, establish corrective measures in the event an issue arises, and comply with food monitoring recordkeeping requirements. Further, the rules would set new standards for the growth, harvest, and packaging of food and vegetables on domestic and foreign farms.

Against this seemingly solid legislative and regulatory backdrop, it would seem the U.S. food supply is indeed carefully guarded. Yet, foodborne illness and death continues. How can that be? Despite the wonderful powers bestowed upon the numerous responsible agencies, funding required to actually carry out the mandates prescribed by these laws is lacking. The regulatory reality is that much of the 2011 FSMA remains in limbo pending funding from the White House Office of Management and Budget. In fact, arguably due to budget shortfalls, it has taken two years for FDA to finally release draft rules that implement the FSMA. Implementation and enforcement of these new rules will certainly require further funding.

For its part, FDA has attempted to bridge its funding gap through increased fees. FDA also hopes to transfer some enforcement responsibilities to state regulators. However, a large funding gap still exists. A divided Congress and the current economic challenges will continue to present challenges to full implementation of the FSMA and improved food safety

in the United States.

Thus, despite the impact of recent legislative changes, the federal agencies charged with implementing them are insufficiently funded to achieve the intended goals. In the future, Congress must do more than issue mandates in furtherance of human health and safety, but also support those mandates with the funding required to achieve them. The continued safety of the country's food supply should demand nothing less.

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