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# Role of Regulation in Minimizing Terrorist Threats Against the Food Supply: Information, Incentives and Penalties

by

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# **Role of Regulation in Minimizing Terrorist Threats Against the Food Supply: Information, Incentives, and Penalties**

## Michael T. Roberts\*

### I. INTRODUCTION

Ringing alarm bells as he announced his resignation as Secretary of the Department of Health and Human Services, Tommy Thompson posited: "I, for the life of me, cannot understand why the terrorists have not . . . attacked our food supply because it is so easy to do."<sup>1</sup> The seeming ease of a terrorist attack on the United States food supply evokes the obvious question of what steps should be taken to minimize the threat. Determining what steps should be taken and implementing those steps naturally turns our attention to the government's important role in protecting the safety of the nation's food supply from terrorist attacks.

The government's role in protecting the safety of the nation's food supply has historically depended on two factors: first, incremental legislation and regulation in response to specific problems, and second, effective coordination and cooperation among regulatory authorities and other public and private stakeholders. These factors remain the same even when the government is responding to terrorist threats against the food supply. While the government has passed legislation and has taken specific steps to minimize the threat of food terrorism, it also relies upon a food regulatory system

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<sup>1.</sup> Mike Allen, *Rumsfeld to Remain at Pentagon; Thompson Quits HHS, Warns of Vulnerabilities*, WASH. POST, Dec. 4, 2004, at A1.

dependent upon effective cooperation and coordination among public and private stakeholders. $^2$ 

Measuring the effectiveness of the government's response to the threat of food terrorism is not easy. Much has been written about the role of government regulation in reducing health risks.<sup>3</sup> Rather than devise a regulatory construct specifically to address the threat of food terrorism, this article evaluates the government's efforts, within the existing regulatory construct, to minimize the risk of food terrorism by focusing on the effectiveness of the government's use of three regulatory tools: information, incentives, and penalties. This article concludes that there are inherent limitations and weaknesses of the food regulatory system.

### II. SETTING THE TABLE

It has long been recognized that the government is responsible for ensuring the safety of the food supply.<sup>4</sup> This responsibility stems from the government's overall role in protecting the public health.<sup>5</sup> This role is buttressed by rulings from the Supreme Court pronouncing that the preservation of public health is the most important duty of the state as a sovereign power.<sup>6</sup> Since September 11, 2001, this role has focused more sharply on abating the threat of terrorist activity against the nation's food supply.<sup>7</sup>

<sup>2.</sup> See Press Release, Dep't of Homeland Security, Fact Sheet: Strengthening the Security of Our Nation's Food Supply (July 6, 2004), *available at* http://www.dhs.gov/xnews/releases/press\_release\_0453.shtm.

<sup>3.</sup> See, e.g., STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION (1993) (exploring the difficulties that plague the efforts of government regulation to reduce health risk and proposing a new, centralized agency); CASS R. SUNSTEIN, RISK AND REASON: SAFETY, LAW, AND THE ENVIRONMENT (2002) (employing cost-benefit analysis to addressing government regulation to protect safety and the environment).

<sup>4.</sup> PETER BARTON HUTT & RICHARD A. MERRILL, FOOD & DRUG LAW 1 (1991).

<sup>5.</sup> See generally Richard A. Epstein, In Defense of the "Old" Public Health: The Legal Framework for the Regulation of Public Health 1-4 (John M. Olin Law & Economics, Working Paper No. 170, 2002), available at http://www.law.uchicago.edu/Lawecon/WkngPprs\_151-175/170-rae.old-public-health.pdf (describing governmental public health approaches).

<sup>6.</sup> See Jacobson v. Mass., 197 U.S. 11 (1905).

<sup>7.</sup> JIM MONKE, AGROTERRORISM: THREATS AND PREPAREDNESS CRS-1 (Cong. Research Serv., CRS Report for Congress Order Code RL32521, Aug. 13, 2004), *available at* http://www.fas.org/irp/crs/RL32521.pdf.

#### A. DEFINING FOOD TERRORISM

"Food terrorism" is defined, by a World Health Organization (WHO) report, as "an act or threat of deliberate contamination of food for human consumption with chemical, biological or radionuclear agents for the purpose of causing injury or death to civilian populations and/or disrupting social, economic, or political stability."<sup>8</sup> In a similar vein, a Congressional Research Service report to Congress defines "agroterrorism" as "the deliberate introduction of an animal or plant disease with the goal of generating fear, causing economic losses, and/or undermining stability."<sup>9</sup>

Historically, food terrorism includes the deliberate sabotage of military and civilian food supplies, primarily during military campaigns, via the intentional contamination of food by chemical, biological, or radionuclear agents.<sup>10</sup> More recent non-military examples include the Rajneeshee cult, which contaminated Oregon salad bars with *Salmonella typhimurium* in an attempt to influence a local election in 1984.<sup>11</sup> In 1996 a disgruntled laboratory worker infected food with *Shigella dysenteria* type two.<sup>12</sup> Attacks against agriculture also have a long history, with many countries developing agricultural bioweapons programs during the twentieth century.<sup>13</sup>

The WHO report demonstrates the potential impact of food terrorism on human health by extrapolating from numerous documented examples of unintentional outbreaks of food borne disease.<sup>14</sup> In the United States, these include a 1985 outbreak of *Salmonella typhimurium* infection that affected 170,000 people, caused by contamination of pasteurized milk from a dairy plant and a 1994 outbreak of *Salmonella enteritidis* infection that affected 224,000 people in forty-one states, caused by contaminated pasteurized liquid ice cream. The ice

- 13. MONKE, *supra* note 7, at CRS-5.
- 14. FOOD SAFETY DEP'T, supra note 8, at 5.

<sup>8.</sup> FOOD SAFETY DEP'T, WORLD HEALTH ORGANIZATION, TERRORIST THREATS TO FOOD: GUIDANCE FOR ESTABLISHING AND STRENGTHENING PREVENTION AND RESPONSE SYSTEMS 4 (2002), *available at* http://www.who.int/foodsafety/publications/general/en/terrorist.pdf.

<sup>9.</sup> MONKE, supra note 7, at CRS-1.

<sup>10.</sup> See FOOD SAFETY DEP'T, supra note 8.

<sup>11.</sup> PETER CHALK, HITTING AMERICA'S SOFT UNDERBELLY: THE POTENTIAL THREAT OF DELIBERATE BIOLOGICAL ATTACKS AGAINST THE U.S. AGRICULTURAL AND FOOD INDUSTRY 29 (2004). See also FOOD SAFETY DEP'T., supra note 8, at 5.

<sup>12.</sup> See CHALK, supra note 11, at 29.

cream was contaminated via the inadvertent contamination of the pre-mix in tanker trucks.<sup>15</sup> Aside from the human health toll, the potential impact of food terrorism on the social, economic, and political stability of the United States is enormous.<sup>16</sup>

### B. UNDERSTANDING THE FOOD SUPPLY SYSTEM

Two aspects of the U.S. food supply system make it difficult to minimize acts or threats of deliberate contamination. First, the food supply system encompasses a multi-faceted production and delivery system of food products, commonly referred to as a "farm-to-table" or "farm-to-plate" system.<sup>17</sup> Essential system components include the production, processing, preparing, packaging, labeling, distribution, and, of course, consumption of food.<sup>18</sup> At each of these stages, food products may be exposed to various levels of risk.<sup>19</sup> Food can be contaminated deliberately by chemical, biological, or radionuclear agents at any stage of the food supply system.<sup>20</sup> The complexity of this system renders it difficult for a regulatory system to address the numerous risk points.<sup>21</sup>

Second, the food supply system is increasingly global.<sup>22</sup> Food is the subject of an international distribution chain that involves a wide variety of entities from small local companies to multinational companies, from exporters to retailers.<sup>23</sup> Much of this international development is driven by consumers who increasingly demand various types of food year-round.<sup>24</sup> A

<sup>15.</sup> *Id*.

<sup>16.</sup> CHALK, *supra* note 11, at 4, 19-26.

<sup>17.</sup> See Robert V. Tauxe, *Linking Illnesses to Foods: A Conceptual Framework, in* TOWARD SAFER FOOD: PERSPECTIVES ON RISK AND PRIORITY SETTING 47 (Sandra A. Hoffman & Michael R. Taylor, eds., 2005).

<sup>18.</sup> See INST. OF MEDICINE & NAT'L RESEARCH COUNCIL, ENSURING SAFE FOOD FROM PRODUCTION TO CONSUMPTION 25 (1998).

<sup>19.</sup> See Tauxe, supra note 17, at 47 ("[t]he issue is complex: there are many chemical and biological hazards, many foods, and many points from farm to table at which microbes or other hazards can enter foods, and where microbes can multiply or be eliminated.").

<sup>20.</sup> FOOD SAFETY DEP'T, *supra* note 8, at 11.

<sup>21.</sup> See generally INST. OF MEDICINE & NAT'L RESEARCH COUNCIL, supra note 18, at 25-49 (overview of the complex, current U.S. food safety system).

<sup>22.</sup> See Anita Regmi & Mark Gehlhar, Processed Food Trade Pressured by Evolving Global Supply Chains, AMBER WAVES (Feb. 2005).

<sup>23.</sup> See id.

<sup>24.</sup> See Michael R. Taylor, Lead or React? A Game Plan for Modernizing

global food supply system renders governance difficult where national regulatory regimes approach regulation differently and where these regimes are limited in ensuring the safety of food produced and processed beyond national borders.<sup>25</sup>

Considering the complexities and broad scope of the food supply system, the role of protecting food from acts or threats of deliberate contamination is daunting. For example, the contamination of food in one country can directly affect health in other parts of the world.<sup>26</sup> In 1989, staphylococcal food poisoning in the United States was caused by mushrooms canned in China.<sup>27</sup> In 1996 and 1997, cyclosporiasis outbreaks in the United States were linked to consumption of Guatemalan raspberries.<sup>28</sup> A more recent example is the 2003 outbreak of hepatitis in Pennsylvania, North Carolina, Tennessee, and Georgia caused by green onions imported from Mexico.<sup>29</sup>

# III. RESPONSE OF U.S. FOOD REGULATORY SYSTEM TO TERRORISM

## A. FOOD SAFETY REGULATORY SYSTEM

The existing United States food regulatory system has developed piecemeal over the last century, generating new rules and regulations in response to emerging food problems.<sup>30</sup> As a result, the regulatory system is complicated and plagued by gaps, overlaps, and inconsistencies.<sup>31</sup> Its fragmented legal and organizational structure allocates to various government agencies differing responsibilities for specific food

the Food Safety System in the United States, 59 FOOD & DRUG L.J. 399, 400 (2004).

<sup>25.</sup> See Caroline Smith DeWaal, Rising Imports, Bioterrorism, and the Food Supply, 59 FOOD & DRUG L.J. 433, 438-39 (2004).

<sup>26.</sup> FOOD SAFETY DEP'T, *supra* note 8, at 5.

<sup>27.</sup> Id.

<sup>28.</sup> Id. at 5-6.

<sup>29.</sup> See LINDA CALVIN ET AL., ECONOMIC RESEARCH SERVICE, U. S. DEP'T OF AGRIC., THE ECONOMICS OF FOOD SAFETY: THE CASE OF GREEN ONIONS AND HEPATITIS A OUTBREAK, (Dec. 2004), available at http://www.ers.usda.gov/publications/vgs/nov04/VGS30501/VGS30501.pdf.

<sup>30.</sup> Timothy M. Hammonds, It Is Time to Designate a Single Food Safety Agency?, 59 FOOD & DRUG L.J. 427, 427 (2004).

<sup>31.</sup> See U.S. GEN. ACCOUNTING OFFICE (GAO), GAO-04-588T, FEDERAL FOOD SAFETY AND SECURITY SYSTEM: FUNDAMENTAL RESTRUCTURING IS NEEDED TO ADDRESS FRAGMENTATION AND OVERLAP 2-3 (March 2004), available at www.gao.gov/new.items/d04588t.pdf.

commodities.<sup>32</sup> The numbers tell the story. The safety and quality of the food supply is governed by thirty principal laws administered by fifteen agencies,<sup>33</sup> twenty-eight House and Senate subcommittees that oversee food safety,<sup>34</sup> and more than eighty-five state and 3,000 local regulatory agencies that license and inspect retail food establishments under various state laws and regulations.<sup>35</sup>

Within this system the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) have most of the regulatory responsibilities.<sup>36</sup> The FDA has jurisdiction over all "food" under the Federal Food, Drug, and Cosmetic Act.<sup>37</sup> The USDA, through its Food Safety and Inspection Service (FSIS) agency, has jurisdiction over products containing more than "small amounts" of meat, poultry, and processed egg products under the Federal Meat Inspection Act and Poultry Products Inspection Act.<sup>38</sup> The USDA, through its other agencies, also has jurisdiction over the primary agriculture production.

The legal standards promulgated under this federal system include two basic standards: food must not be adulterated or misbranded.<sup>39</sup> This means that food products must be safe and the labeling of food products must not be false or misleading.

The regulatory driver for food safety standards for both FDA and USDA has been a collective group of regulations called "good manufacturing practices" (GMPs). GMPs are standards that were adopted as regulations for food processing and handling following consultations with industry, experts, the public, and other interested parties and after rigorous notice and comment periods.<sup>40</sup> In the 1990s, the FDA and the USDA also adopted a preventive approach to ensure the safety

<sup>32.</sup> See id.

<sup>33.</sup> See id. at 2.

<sup>34.</sup> INST. OF MEDICINE & NAT'L RESEARCH COUNCIL, supra note 18, at 26.

<sup>35.</sup> DONNA U. VOGT, FOOD SAFETY ISSUES IN THE 109<sup>TH</sup> CONGRESS CRS-11 (Cong. Research Serv., CRS Report for Congress Order Code RL31853, Feb. 4, 2005), *available at* http://kuhl.house.gov/UploadedFiles/foodsafety.pdf.

<sup>36.</sup> GAO FEDERAL FOOD SAFETY, supra note 31, at 3.

<sup>37.</sup> See id.

<sup>38.</sup> See id.

<sup>39.</sup> See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(b) (2000); Federal Meat Inspection Act, 21 U.S.C. § 602 (2000); Poultry Products Inspection Act, 21 U.S.C. § 452; Egg Products Inspection Act, 21 U.S.C. § 1032 (2000).

<sup>40.</sup> VOGT, *supra* note 35, at 7.

of food called the "Hazard Analysis and Critical Control Point" (HACCP) system.<sup>41</sup> As a uniform science-based approach to food safety, HACCP is predicated upon seven basic principles and applies a technical analysis of the food production process carried out by the food plant itself.<sup>42</sup>

Despite the seeming simplicity of the legal standards governing the food supply, the respective regulatory approaches of the USDA and the FDA are markedly divergent.<sup>43</sup> The USDA's regulatory approach is predicated upon continuous inspection and prior approval.<sup>44</sup> The FDA's regulatory approach is predicated upon random inspection and enforcement in the marketplace.45 Also, the USDA traditionally has had more enforcement authority and resources than the FDA.<sup>46</sup> Much has also been made of the different food safety philosophies of the FDA and the USDA.<sup>47</sup> In their frequent plant inspections, USDA inspectors use sight, smell, and touch to detect food safety problems.<sup>48</sup> In contrast, FDA inspectors rarely inspect food facilities and focus more on evaluating the entire food production process within an establishment.<sup>49</sup> There is also the problem of demarcating the regulatory authority of these two agencies for food facilities and food products that fall under the jurisdiction of both agencies. Famous examples include pizza and soup products, both of which contain ingredients that may fall under the jurisdiction of either the FDA or multiple USDA agencies.<sup>50</sup> Another classic example is the deli whose closed-face and open-face sandwiches may be regulated by the FDA and the USDA, respectively.51

Key to effective regulation within this complex and fragmented food regulatory system is interagency cooperation and cooperation between these agencies and public and private

<sup>41.</sup> *Id*.

<sup>42.</sup> *Id*.

<sup>43.</sup> See GAO FEDERAL FOOD SAFETY, supra note 31, at 3.

<sup>44.</sup> *Id*.

<sup>45.</sup> Id.

<sup>46.</sup> Id.

<sup>47.</sup> See Robin J. Strongin, How Vulnerable Is the Nation's Food Supply? Linking Food Safety and Food Security, NAT'L HEALTH POL'Y FORUM, MAY 17, 2002, at 5, available at http://www.nhpf.org/pdfs\_ib/IB773\_FoodSafety\_5-17-02.pdf.

<sup>48.</sup> Id.

<sup>49.</sup> *Id*.

<sup>50.</sup> See GAO FEDERAL FOOD SAFETY, supra note 31, at 5.

<sup>51.</sup> Id. at 7-8.

stakeholders. Evidence of interagency cooperation is provided by the more than fifty interagency agreements entered into by the federal agencies to govern their combined food safety oversight responsibilities.<sup>52</sup> The FDA and the USDA have signed several Memoranda of Understanding (MOU) that encompass dual jurisdiction establishments, food additive petitions, and others.<sup>53</sup> For years, federal and state agencies have also coordinated in an effort to protect the food supply.<sup>54</sup> This coordination extends to industry, where trade associations composed of food producers, processors, ingredient suppliers, retailers, and service establishments form model policies and support programs to help members enhance food safety and meet regulatory requirements.<sup>55</sup> Other groups, such as consumer organizations, professional organizations, and academic organizations play important roles in promoting food safety, researching food safety technology, and in training and education.56

### **B.** INTERNATIONAL CONSIDERATIONS

The emergence of the global food system makes the regulation of food produced, processed, and handled beyond U.S. boundaries critical.<sup>57</sup> Three important international considerations stand out: inspecting importation of food products into the United States, regulating food safety in other countries, and setting international food safety standards.

The increasing levels of imported foods have severely taxed the ability of federal agencies to ensure safety.<sup>58</sup> In a March 2004 hearing of the House Appropriation Committee's Subcommittee on Agriculture, acting FDA Deputy Commissioner Lester Crawford acknowledged that "[t]he FDA is overwhelmed by imports, which have increased five-fold

<sup>52.</sup> Id. at 2.

<sup>53.</sup> Hearing before the Subcomm. on Civil Serv. and Agency Org. of the H. Comm. on Gov't Reform, 108th Cong. (2004) (Statement of Robert E. Brackett, Ph.D., Dir. of the Center for Food Safety and Applied Nutrition), available at http://www.fda.gov/ola/2004/foodsafety0330.html.

<sup>54.</sup> See Stuart M. Pape et al., Food Security Would Be Compromised by Combining the Food and Drug Administration and the U.S. Department of Agriculture Into a Single Food Agency, 59 FOOD & DRUG L.J. 405, 414 (2004).

<sup>55.</sup> INST. OF MEDICINE & NAT'L RESEARCH COUNCIL, supra note 18, at 31.

<sup>56.</sup> Id. at 32.

<sup>57.</sup> See generally id. at 46.

<sup>58.</sup> See DeWaal, supra note 25, at 436.

since 1994."<sup>59</sup> The interdependence of the FDA, the USDA, and the United States Customs Service created communication problems and has historically challenged federal efforts to guard the safety of imported food.<sup>60</sup> For example, food refused entry by the FDA reportedly may have been allowed into commerce by the Customs Service.<sup>61</sup>

Absent the ability to inspect every single imported food product, protecting the United States food supply depends on the safety efforts of other countries. Other countries, including Canada, Australia, New Zealand, and the United Kingdom, have made efforts to reform decentralized and fragmented food safety systems.<sup>62</sup>

In addition to national food safety regimes, various international bodies set international standards for food safety. These international organizations include the WHO, which is actively engaged in numerous food safety initiatives;<sup>63</sup> the Food and Agriculture Organization of the United Nations (FAO), which serves as a useful gateway to feed and food safety information;<sup>64</sup> and the Codex Alimentarius Commission, which as a subsidiary body of the WHO and FAO, develops standards, codes of practice, and guidelines for food commodities.<sup>65</sup> The World Trade Organization (WTO), based on the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), resolves trade disputes that involve food safety issues, such as the regulation of hormone use in cattle.<sup>66</sup>

<sup>59.</sup> See DeWaal, supra note 25, at 436 (quoting Hearing Before the Subcomm. on Agriculture of the H. Comm. On Appropriations, 108th Cong. (2004) (Statement of Lester M. Crawford, D.V.M., Ph.D., Deputy Commissioner for the Food and Drug Administration)).

<sup>60.</sup> See U.S. GEN. ACCOUNTING OFFICE (GAO), GAO/T-RCED-98-271, FOOD SAFETY—WEAK AND INCONSISTENTLY APPLIED CONTROLS ALLOW UNSAFE IMPORTED FOOD TO ENTER U.S. COMMERCE 7-8 (Sept. 10, 1998), available at http://www.gao/gov/archive/1998/rc9827t.pdf.

<sup>61.</sup> See id.

<sup>62.</sup> See U.S. GOV'T. ACCOUNTABILITY OFFICE (GAO), GAO-05-212, FOOD SAFETY: EXPERIENCES OF SEVEN COUNTRIES IN CONSOLIDATING THEIR FOOD SAFETY SYSTEMS (Feb. 2005), available at http://www.gao.gov/new.items/d05212.pdf.

<sup>63.</sup> See World Health Organization, Food Safety, http://www.who.int/topics/food\_safety/en/ (last visited Oct. 9, 2006).

<sup>64.</sup> See Food and Agriculture Organization, Feed and Food Safety Gateway, http://www.fao.org/ag/aga/agap/frg/Feedsafety/feedsafety.htm (last visited Oct. 9, 2006).

<sup>65.</sup> See Codex Alimentarius, http://www.codexalimentarius.net/web/index\_en.jsp (last visited Oct. 9 2006).

<sup>66.</sup> See World Trade Organization, http://www.wto.org/ (last visited Oct. 9,

# C. RECENT REGULATION IN RESPONSE TO FOOD TERRORIST THREATS

Consistent with historical patterns of response to food crises, the federal government has responded to threats of food terrorism by enacting new food law to be applied and enforced within the established food regulatory system. Recent regulation has, to a limited extent, altered the United States food regulatory system by shifting some power from the states to the federal government, granting additional authority to federal agencies, particularly to the FDA, and realigning and reassigning regulatory authority, particularly from the USDA to the new Department of Homeland Security (DHS). Despite these changes, however, interagency cooperation and collaboration among stakeholders remains central to the regulatory role in minimizing the threat of terrorist activity against the food supply.

1. Bioterrorism Act

The emerging regulation is largely encompassed in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act).<sup>67</sup> The Bioterrorism Act has four major provisions related to food. The first is the food facility registration requirement, which requires domestic and foreign facilities that manufacture, process, produce, pack, or hold food for human or animal consumption in the United States to register with the FDA.<sup>68</sup> Registering elicits information about the food products (brand names and general food categories), facility addresses, and contact information.<sup>69</sup>

The second major provision is the establishment and maintenance of records, which requires firms to keep records of all foods they receive and release.<sup>70</sup> These records include

<sup>2006).</sup> 

<sup>67.</sup> *See* Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188 (codified in scattered sections of 42 U.S.C.).

<sup>68.</sup> See Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,894 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1, 20).

<sup>69.</sup> See id.

<sup>70.</sup> See Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. 71,561-62 (Dec. 9, 2004) (to be codified at 21 C.F.R. pt. 1, 11) (hereinafter Establishment and Maintenance of Records). See also Michael T.

information regarding the identity of the food, the immediate supplier of the food, and the immediate consumer of the food.<sup>71</sup> While federal statutes have allowed FSIS to inspect slaughter and processing plant records, FDA has never before had the authority to require food processors to keep records or the ability to inspect them.<sup>72</sup> In the event there is a suspected food safety problem, the Bioterrorism Act gives FDA access to records including the name and address of facilities' immediate supplier and customer.

The third major provision of the Bioterrorism Act is the prior notice requirement for imported food shipments, which requires that entities provide prior notice of all foods for human or animal consumption before they enter the United States.<sup>73</sup> Prior notice helps FDA assess whether a shipment will trigger an inspection.<sup>74</sup>

The fourth major provision is administrative detention, which provides procedures for the seizure of foods meant for animal or human consumption. $^{75}$ 

These provisions were created largely in response to the limited scope of FDA's authority and are geared toward food processors and importers.<sup>76</sup>

## 2. Homeland Security Act

Another important law is the Homeland Security Act.<sup>77</sup> This Act created the Department of Homeland Security (DHS) and transferred parts of many agencies to the new DHS.<sup>78</sup> For

74. See Press Release, U.S. Dep't of Health and Human Servs., HHS Issues New Rules to Enhance Security of the U.S. Food Supply (Oct. 9, 2003), *available at* http://www.hhs.gov/news/press/2003pres/20031009.html.

75. Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. 31,660 (June 4, 2004) (to be codified at 21 C.F.R. pt. 1, 10, 16).

76. Joseph A. Levitt, CFSAN's Program Priorities: From Food Safety to Food Security, 58 FOOD AND DRUG L.J. 19, 24 (2003).

77. Homeland Security Act of 2002, Pub. L. No. 107-296, §§ 101(a)-101(b), 116 Stat. 2135, 2142 (2002).

78. See H.R. REP. NO. 107-609, at 63-64 (2002) (combining twenty-two agencies into a single Department of Homeland Security).

Roberts & Margie Alsbrook, *United States Food Law Update*, 1 J. FOOD L. & POLY 187, 199-201 (2005) (generally describing the record-keeping rule).

<sup>71.</sup> See Establishment and Maintenance of Records, supra note 70.

<sup>72.</sup> Vogt, *supra* note 35, at CRS-16.

<sup>73.</sup> See Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,974 (Oct. 10, 2002) (to be codified at 21 C.F.R. pt. 1).

example, agriculture border inspections were transferred from the USDA's Animal and Plant Health Inspection Service (APHIS) agency to DHS.<sup>79</sup> Section 421 of the Homeland Security Act authorized the transfer of up to 3,200 APHIS border inspection personnel to DHS.<sup>80</sup> As of March 1, 2003, approximately 2,680 APHIS inspectors became employees of DHS in the Bureau of Customs and Border Protection (CBP). The USDA retained a significant presence in border inspection and management of data collected during the inspection process because of its scientific expertise.<sup>81</sup> APHIS also conducts off-shore, pre-clearance inspections at the port of origin.<sup>82</sup>

## 3. Presidential Directives

Following the creation of DHS, President Bush issued a series of directives known as "Homeland Security Presidential Directives" (HSPD).<sup>83</sup> The first of these directives, HSPD-5, directs DHS to coordinate development of the new National Response Plan that incorporates national prevention, preparedness, response, and recovery plans into a single, allhazard plan.84 "HSPD-7 defines USDA and HHS as 'sectorspecific agencies' with responsibilities for securing the agriculture and food sectors."85 HSPD-8 sets out a national preparedness goal for all hazards, including agriculture.<sup>86</sup> The most important directive, HSPD-9, instructs the heads of DHS, USDA, HHS, the Environmental Protection Agency (EPA), the Justice Department, and the Central Intelligence Agency (CIA) to coordinate their efforts to prepare for, protect against, respond to, and recover from an agro-terrorist attack.<sup>87</sup> The features of HSPD-9 include an integrated diagnostic system,

<sup>79.</sup> See Homeland Security Act of 2002, supra note 77, § 421.

<sup>80.</sup> Id.

<sup>81.</sup> Monke, *supra* note 7, at CRS-12.

<sup>82.</sup> Id.

<sup>83.</sup> See U.S. GOV'T ACCOUNTABILITY OFFICE (GAO), GAO-05-214, HOMELAND SECURITY—MUCH IS BEING DONE TO PROTECT AGRICULTURE FROM A TERRORIST ATTACK, BUT IMPORTANT CHALLENGES REMAIN 13 (Mar. 2005).

<sup>84.</sup> Id. at 19-20.

<sup>85.</sup> Id. at 20.

<sup>86.</sup> Id.

<sup>87.</sup> See Press Release, Homeland Security Presidential Directive/HSPD-9 (Jan. 30, 2004), available at http://www.whitehouse.gov/news/releases/2004/02/20040203-2.html.

animal and commodity tracking systems, vulnerability assessments, and coordination with academic communities at federal, state, and local levels for capacity-building grants.<sup>88</sup> It is important to note that HSPD-9 did not create enforceable laws.<sup>89</sup> Moreover, the viability of HSPD-9 is dependent on federal appropriations.<sup>90</sup>

### 4. Additional Regulation

Additional regulation germane to minimizing the threat of food terrorism includes a final rule by APHIS, effective March 18, 2005, that places additional requirements on laboratory facilities that possess, use, transfer, or receive select agents capable of causing substantial harm to human, plant, or animal health.<sup>91</sup>

Similarly, the FDA enacted a feed ban to ensure protection against bovine spongiform encephalopathy (BSE). In October 2005, the FDA published a proposed feed-ban rule to amend the agency's regulations to prohibit the use of cattle origin materials in the food or feed of <u>all</u> animals.<sup>92</sup> BSE is transmitted to cattle when cattle eat BSE-infected tissue. The proposed rule is intended to shore up the FDA regulatory protection by keeping the BSE-causing agent out of the animal food and feed supply.<sup>93</sup>

Additionally, the Terrorism Risk Insurance Act (TRIA)<sup>94</sup> acts as a federal "backstop" for certain acts of terrorism via a federal program that distributes the risk of loss from foreign terrorist attacks between the federal government and the insurance industry.<sup>95</sup> For the Terrorism Risk Insurance to apply, terrorist events must meet certain criteria.<sup>96</sup>

92. Substances Prohibited From Use in Animal Food or Feed, 70 Fed. Reg. 58,570 (proposed Oct. 6, 2005) (to be codified at 21 C.F.R. pt. 589).

93. See id. at 58,579-80; see also Press Release, FDA, FDA News: FDA Proposes Additional "Mad Cow" Safeguards (Oct. 4, 2005), available at http://www.fda.gov/bbs/topics/news/2005/new01240.html.

94. See Terrorism Risk Insurance Act of 2002, Pub. L. No. 107-297, § 108(a), 116 Stat. 2322 (2002).

95. Nat'l Assoc. of Mfrs, Terrorism Risk Insurance, available at http://www.nam.org/s\_nam/sec.asp?CID=202306&DID=234654.

96. Mass. Office of Consumer Affairs and Business Regulation, Terrorism

<sup>88.</sup> Id.

<sup>89.</sup> Id.

<sup>90.</sup> *Id*.

<sup>91.</sup> See Agricultural Bioterrorism Protection Act of 2002: Possession, Use, and Transfer of Biological Agents and Toxins, 70 Fed. Reg. 13,242 (March 18, 2005) (to be codified at 7 C.F.R. pt. 331 and 9 C.F.R. pt. 121).

#### 5. Agency Action

These laws, regulations, and executive actions are significant and contribute to efforts to abate the concern of food terrorism. There is also an impressive "cooperative" regulatory food-safety system that has evolved over time. Hence, it is no surprise that the federal regulatory agencies, state agencies, the private sector, and the academic community have joined together in a collaborative effort on various fronts to reduce the threat of food terrorism.<sup>97</sup>

Federal food agencies participate with other agencies and coordinate activities through the HHS Secretary's Command Center.<sup>98</sup> Interagency efforts at this level include agencies such as the DHS, the USDA, the FDA, the CIA, the Federal Bureau of Investigations (FBI), and others.<sup>99</sup> Interagency conference calls and meetings help facilitate communication and collaboration.<sup>100</sup>

Coordination has resulted in a number of new organizations geared toward addressing the threat of food terrorism. A sampling of these organizations includes:

• The USDA Office of Food Security and Emergency Preparedness Response, which coordinates the development of infrastructure and capacity for the department to prevent, prepare for, and respond to food terrorist attacks.<sup>101</sup>

• The FDA's Center for Food Safety and Applied

Risk Insurance Act of 2002 FAQs, http://www.mass.gov/?pageID=ocaterminal&&L=5&L0=Home&L1=Business& L2=Insurance&L3=Commercial+Buyers&L4=Terrorism+Coverage&sid=Eoca &b=terminalcontent&f=\_doi\_Commercial\_Comm\_Terr\_RiskIns&csid=Eoca (last visited Jan. 23, 2007).

<sup>97.</sup> See Press Release, Dep't of Homeland Security, Fact Sheet: Strengthening the Security of our Nation's Food Supply, available at http://www.dhs.gov/xnews/releases/press\_release\_0453.shtm.

<sup>98.</sup> See Hearing before the Subcomm. on Civil Serv. and Agency Org. of the H. Comm. on Gov't Reform, 108th Cong. (2004) (Statement of Robert E. Brackett, Ph.D., Dir. of the Center for Food Safety and Applied Nutrition), available at http://www.fda.gov/ola/2004/foodsafety0330.html.

<sup>99.</sup> See Hearing before the Subcomm. on Research, Nutrition, and Gen. Legislation of the S. Comm. on Agric., Nutrition, and Forestry, 109th Cong. (2006) (Statement of Alex M. Azar, J.D., Deputy Secretary, U.S. Dep't of Health and Human Servs.), available at http://www.hhs.gov/asl/testify/t060109.html.

<sup>100.</sup> See id.

<sup>101.</sup> See Press Release, Homeland Security, supra note 97.

Nutrition's (CFSAN) Office of Food Safety, Defense, and Outreach (OFSDO), which disseminates food safety and food defense information to federal partners, state and local governments, industry, and consumers.<sup>102</sup>

• The USDA steering committee, which develops a National Veterinary Stockpile.<sup>103</sup>

• The Food Emergency Response Network (FERN) established by the FDA and the FSIS.<sup>104</sup> It integrates state and federal laboratories to analyze food samples implicated in threats, terrorist events, or contamination.<sup>105</sup>

• The FDA Office of Crisis Management (OCM), which coordinates preparedness and emergency response activities within the FDA and with federal, state, and local counterparts.<sup>106</sup>

Coordination has also led to initiatives involving federal agencies and private stakeholders, including the following:

• An FDA and USDA initiative called the Strategic Partnership Program Agroterrorism (SPPA), designed to conduct vulnerability assessments in the private sector with the CARVER + Shock tool.<sup>107</sup> These assessments are used to develop strategies and countermeasures to reduce potential threats along the farm-to-table continuum.<sup>108</sup>

• Food Security Councils, which represent key components of the agriculture and food chain, coordinate food defense efforts.<sup>109</sup>

• HHS, USDA and joint laboratory networks, which work to enhance diagnostic and monitoring capabilities.<sup>110</sup>

106. *Id*.

<sup>102.</sup> See Interview by Alice Sharp with David Acheson, Director, Office of Food Safety, Defense and Outreach, *Getting It Out There*, FOOD SAFETY, *available at* http://www.gdspublishing.com/ic\_pdf/usfs/ofsdo.pdf (last visited Mar. 7, 2007).

<sup>103.</sup> See GAO HOMELAND SECURITY, supra note 83, at 5.

<sup>104.</sup> U.S. Dep't of Agric., Food Emergency Response Network – FERN (Fiscal Year 2005), *available at* http://www.fsis.usda.gov/About\_FSIS/Cooperative\_Agreements\_FERN\_2005/in dex.asp.

<sup>105.</sup> Vogt, *supra* note 35, at CRS-17.

<sup>107.</sup> U.S. Food and Drug Admin., Strategic Partnership Program Agroterrorism (SPPA) Initiative, (Aug. 2005), http://www.cfsan.fda.gov/~dms/agroterr.html.

<sup>108.</sup> See Center for Food Safety and Applied Nutrition, SPPA Questions and Answers (Sept. 23, 2005), http://www.cfsan.fda.gov/~dms/agroter4.html.

<sup>109.</sup> Press Release, Homeland Security, *supra* note 97.

<sup>110.</sup> See GAO HOMELAND SECURITY, supra note 83, at 5.

• Agency-created working groups that fund research to address a range of issues.<sup>111</sup>

• FDA and USDA guidance documents issued to producers, processors, transporters, distributors, and consumers to minimize the risk of food terrorism.  $^{112}$ 

Partnerships by government agencies have also been entered into with academic institutions for food safety centers addressing food terrorist threats, including the following:<sup>113</sup>

• The University of Minnesota led Homeland Security National Center for Food Protection and Defense, which works with academia, industry, and government to address food defense issues.<sup>114</sup>

• Texas A&M University Homeland Security National Center for Foreign Animal and Zoonotic Disease Defense, which works with academia, industry, and government to address potential threats to animal agriculture.<sup>115</sup>

Coordination has involved federal agencies with states at various levels, including the following.

• A DHS award was given to Iowa to establish a multistate partnership in the development of food security planning initiatives and security strategies to be used as guidelines and models for state and local governments.<sup>116</sup>

• The USDA created sixteen Area and Regional Emergency Coordinator Positions to help states develop emergency response plans and serve as a technical resource for states and industry.<sup>117</sup>

• The Government Coordinating Council, a federally led joint federal-state food and agriculture sector team acts as a counterpart to the industry Sector Coordinating Council to improve communications and coordination.<sup>118</sup>

• Efforts by USDA and state departments of agriculture have expedited the planning for a National Animal Identification System.<sup>119</sup>

<sup>111.</sup> *Id*.

<sup>112.</sup> See Press Release, Homeland Security, supra note 97.

<sup>113.</sup> See id.

<sup>114.</sup> See id.

<sup>115.</sup> See id.

<sup>116.</sup> See id.

<sup>117.</sup> See id.

<sup>118.</sup> See id.

<sup>119.</sup> See id.

• The USDA National Surveillance Unit within APHIS's Veterinary Services program serves as a focal point for the collection, processing, and delivery of surveillance information.<sup>120</sup>

### IV. EVALUATION OF GOVERNMENT RESPONSE TO FOOD TERRORISM

One way of evaluating the effectiveness of this hodgepodge of new legislation, executive action, and agency coordination is to assess its delivery of information, incentives, and penalties. This evaluative approach provides an analytical framework from which to gauge the government's response. This evaluation is squared with issues concerning the structure of the food regulatory system; a critical inquiry then arises as to whether the structure is sufficient to minimize the threat of food terrorism.

## A. INFORMATION

Information is necessary to assess risk, identify problems, facilitate coordination, and incorporate traceability capability in the multifaceted global food supply and distribution chain. Conveying information concerning food terrorism is also essential to building and maintaining public trust with government. A fragmented food regulatory system renders the gathering and application of information especially challenging.

Measuring the use of information as a tool raises several issues. What types of information are needed? How much information is needed? Who has access to the information? What is the information used for? What is the cost of gathering the information? These questions are particularly important because irrelevant or inadequate information may generate inadequate or even excessive demands for regulation.

The specific food-defense information tools used by government agencies include the essential prongs of the Bioterrorism Act: registration, recordkeeping, import notice and inspection. These tools enable government agencies to obtain information concerning the supply chain. Collaborative efforts by agencies are also designed to obtain and share information. The gathering of this information has helped build a more accurate inventory of food distribution and enhanced capability to identify and trace food problems. This

<sup>120.</sup> See id.

is especially important given the complex nature of the food production and delivery system.

There are, however, limits to the Bioterrorism Act's ability to gather information. The Act limits access regarding trade secrets and confidential business information.<sup>121</sup> Also, registration information and information collected under the Bioterrorism Act regarding the location of food supplies to prevent intentional or unintentional contamination is protected from public disclosure by the Freedom of Information Act (FOIA).<sup>122</sup>

Other information-gathering limitations may not make as much sense. For example, several entities are exempt from the registration requirements, namely certain retail stores, nonprofit food and feeding establishments, fishing vessels, trucks, and other motor carriers.<sup>123</sup> Do these exemptions make sense? A farm may pack or hold food without losing its exemption, so long as the food is grown, raised, or consumed on that farm or another under the same ownership.<sup>124</sup> However, if a farm packs or holds a neighboring farm's products, then the farm facility must register.<sup>125</sup> Does it make sense for registration requirements for farms to be predicated upon ownership? Are not non-profit food establishments less of a target for terrorists?

Also of concern are gaps in security at food-processing facilities, as reported by a General Accounting Office (GAO) report.<sup>126</sup> The report finds that "federal food safety statutes provide FDA and USDA with broad authority to regulate the safety of the United States food supply but do not specifically

<sup>121. 5</sup> U.S.C. § 552(b)(4) (2002).

<sup>122.</sup> Michael T. Roberts & Doug O'Brien, Animal Identification: Confidentiality of Information (Fall 2004), http://lmic.info/memberspublic/animalID/fs05.pdf.

<sup>123.</sup> See Vogt, supra note 35, at CRS-14.

<sup>124.</sup> Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,894, 58,905 (Oct. 10, 2003) (to be codified at 21 C.F.R. pt. 1, 20) (supplementary information).

<sup>125.</sup> See *id.* at 58,905-06 (explaining that a packing shed that packs food grown or raised on several farms under different ownership is not covered by the "farm" definition; thus, such a shed must register) (supplementary information).

<sup>126.</sup> See U.S. GEN. ACCOUNTING OFFICE (GAO), GAO-03-342, FOOD-PROCESSING SECURITY: VOLUNTARY EFFORTS ARE UNDER WAY, BUT FEDERAL AGENCIES CANNOT FULLY ASSESS THEIR IMPLEMENTATION (Feb. 2003).

authorize them to impose security requirements at foodprocessing facilities."<sup>127</sup> The report notes that oversight of these facilities is governed by voluntary guidelines.<sup>128</sup> As stated by the report, the government instructs inspectors not to enforce implementation of security measures or document any observations because of the possible release of information under FOIA and potential misuse of the information.<sup>129</sup> If security gaps at food-processing facilities were made public, terrorists could use them as a road map for terrorist activity.<sup>130</sup> The extent of the adoption of voluntary guidelines is unknown.<sup>131</sup> The report acknowledges that according to trade association officials, food processors are voluntarily taking steps, including many of the measures suggested by the FDA and the FSIS, such as installing fences, requiring that employees wear identification, and restricting access to certain plant areas.<sup>132</sup>

Another GAO report noted problems with coordination and communication. The report points to the DHS's lack of coordination of federal working groups and research efforts.<sup>133</sup> The same report notes the lack of integration of agencies' diagnostic laboratory networks. This could lead to the HHS not receiving timely information from the USDA on agricultural diseases that could spread to humans.<sup>134</sup> Communication problems cited in the report include the limited flow of critical information among key stakeholders, such as between the DHS and key agriculture states and industry representatives, leading to unclear expectations, a lack of clear understanding of initiatives in place, and a duplication of efforts.<sup>135</sup>

Finally, there is also the consideration of alignment. It does not necessarily follow that creating a record-keeping burden leads to facilities being better prepared to respond to a terrorist activity. The information certainly is beneficial to managing the food system as a whole, but focusing on gathering information at the expense of implementing safety measures is shortsighted.

<sup>127.</sup> *Id.* at 3.

<sup>128.</sup> Id.

<sup>129.</sup> Id.

<sup>130.</sup> Id. at 4.

<sup>131.</sup> Id. at 15.

<sup>132.</sup> *Id*.

<sup>133.</sup> See GAO HOMELAND SECURITY, supra note 83, at 8.

<sup>134.</sup> *Id.* at 9.

<sup>135.</sup> *Id.* at 7-8.

### **B.** INCENTIVES

In addition to information, incentives are necessary to help motivate the food industry to adopt and employ security measures to reduce risk of harm from terrorist attacks and to encourage cooperation among stakeholders. Measuring the effectiveness of incentives raises several questions. What are the best types of incentives? How effective are the incentives? Are there enough incentives? Is there too much reliance on incentives? Are the incentives aligned with the goal of minimizing terrorist threats? What are the costs of incentives?

Although the Bioterrorism Act does include a series of grants and incentives to help develop vaccines and antidotes to protect food supply, livestock, and crops, the focus of the Act, and the existing food regulatory system, is not on the development of incentives. A dearth of regulator-sponsored incentives, however, does not mean that the incentives for abating food terrorism are lacking. Indeed, the fragmented regulatory approach to food safety constitutes the overarching incentive for action. Government agencies and public and private stakeholders work together because there is no other option short of restructuring the regulatory agencies if the goal is to minimize the threat of terrorist activity against the food supply. Moreover, the self-interest of the food industry drives it to cooperate with government agencies in order to protect brand image, limit liability, and avoid penalties. It stands to reason, therefore, that the Bioterrorism Act's record keeping requirements can be good for business because it can lead to smaller food recalls, which limits liability exposure.

Should good governance rely on the good will of regulators to shore up the regulatory gaps and on the self-interest of industry? Answering this question requires consideration of the moral hazard problem.<sup>136</sup> The primary concern is that "[b]usinesses would be inclined to spend less on security than might be appropriate for the nation as a whole if they faced losses from an attack that would be less than the overall losses for society."<sup>137</sup> If this is the case, then the gap between private and public costs of a terrorism event can lead to incomplete information about the vulnerabilities of the food system and

<sup>136.</sup> See CONG. BUDGET OFFICE, CONG. OF THE U.S., HOMELAND SECURITY AND THE PRIVATE SECTOR 18 (Dec. 2004) available at http://www.cbo.gov/ftpdocs/60xx/doc6042/12-20-HomelandSecurity.pdf.

<sup>137.</sup> Id. at 2.

under-spending on security, especially when there is unequal access to the same information.<sup>138</sup> Government can help close the gap by internalizing the cost of security through new regulations that affect the behavior of the food industry, new taxes, or penalties.<sup>139</sup> The gap could be further closed by regulations which finance the food industry's efforts to provide better information for making security decisions. These efforts could ramp up current efforts to involve the food industry in information collection and dissemination, research and development, and the provision of additional information on the risks of attacks and opportunities to reduce risks to the food system.<sup>140</sup>

Enthusiasm for developing incentives to generate and share additional information should be tempered, however, by recognizing the risk of giving terrorists access to information. Plus, not all communication provides a social benefit, as there may be competitive and even anti-trust concerns in the sharing of information across the food industry.

In addition to the value of information gathering, the threat of terrorist activity has underscored the importance of developing incentives for the food industry to adopt HACCP programs. <sup>141</sup> The food safety system has not provided sufficient incentives for food industry to embrace HACCP.<sup>142</sup> Not only does HACCP need to be adopted and utilized more fully, but HACCP now needs to be adapted to food terrorism programs especially including those involving the surveillance of imported foodstuffs.<sup>143</sup> Application will help stakeholders focus on the most likely agents and modalities for accomplishing terrorism through the use of the food supply.<sup>144</sup> Implementing and applying HACCP in this manner will require extensive cooperation between all relevant food industry stakeholders and regulators, including other countries

<sup>138.</sup> *Id.* at 3.

<sup>139.</sup> *Id*.

<sup>140.</sup> *Id.* at 6.

<sup>141.</sup> Lester Crawford, Deputy Commissioner, U.S. Food and Drug Admin., A Conversation on Food Safety and Global Security, Remarks to the Open Forum, U.S. Dep't of State, (Sept. 6, 2002), *available at* http://www.state.gov/s/p/of/proc/tr/13454.htm.

<sup>142.</sup> See generally Neal D. Fortin, The Hang-Up With HACCP: The Resistance to Translating Science Into Food Safety Law, 58 FOOD & DRUG L.J. 565 (2003).

<sup>143.</sup> Crawford, supra note 141.

<sup>144.</sup> *Id*.

and international organizations.145

Without unduly burdening the private sector, the government could develop incentives that either require or motivate food processors to take safety measures, beginning with basic physical security steps such as installing fences, alarms, or outside lighting to improve security.

### C. PENALTIES

Penalties are designed to reduce the risk of terrorist attacks on the food supply by deterring behavior which increases the risk of terrorist attacks. As with information and incentives, the use of penalties generates several important questions. Are the penalties effective? Do the penalties deter bad behavior? To whom are the penalties geared?

Together, the food regulatory system and new food laws enacted in response to the threat of food terrorism present a wide array of enforcement tools for regulatory authorities. There are several penal tools that are available to the FSIS and the FDA in varying degree and scope: warning letters, adverse publicity, injunction, retention, seizure, and criminal prosecution.<sup>146</sup> "These sanctions are not mutually exclusive and may build upon one another."147 Because the FSIS's jurisdiction over meat facilities is built around continuous inspection, the agency's summary powers to withdraw inspection services, condemn foods, and obtain plant records are as intrusive as those of any government agency over a private industry sector. The FSIS may also detain product in the plant, which involves instituting a seizure action requesting a federal district court to direct a United States Marshal to take custody of the product.<sup>148</sup> The FDA's authority under the Bioterrorism Act to detain food under certain conditions, namely credible evidence that a shipment presents a serious threat, is a first for the agency with respect to food.<sup>149</sup>

<sup>145.</sup> Id.

<sup>146.</sup> Michael T. Roberts, Mandatory Recall Authority: A Sensible and Minimalist Approach to Improving Food Safety, 59 FOOD & DRUG L.J. 563, 567 (2004).

<sup>147.</sup> *Id.* at 567-68.

<sup>148.</sup> Id. at 567 n.46.

<sup>149.</sup> See Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. 31,660 (June 4, 2004) (to be codified at 21 C.F.R. pt. 1, 10, 16).

Notwithstanding the broadening of scope of the FDA's enforcement authority under the Bioterrorism Act, important differences between the USDA and the FDA inspection and enforcement authorities remain. For example, the USDA corrects problems quickly, whereas the FDA may take longer to implement change across all regulated facilities.<sup>150</sup> There is also a discrepancy with respect to imported foods. The USDA is legally required to inspect certifications from other countries while the FDA is not.<sup>151</sup>

A recurring and divisive debate over food safety is whether there should be mandatory food recall authority to recall unsafe food from commerce. Currently, the federal government does not have the authority to recall unsafe food. Recalls of unsafe food are conducted voluntarily by food companies and are monitored by either the FSIS with meat products or the FDA for other food products.<sup>152</sup> Defenders of this voluntary system contend that the federal government has sufficient enforcement authority and that enacting a mandatory recall authority would undermine the cooperative arrangement that exists between government and private industry. The current "authority" of the government to compel a recall is due to the implicit threat of adverse publicity.<sup>153</sup> Is this arrangement enough in light of food terrorism? Should there be a provision for immediate notice and recall if terrorism is suspected to have rendered a food product unsafe? If a mandatory food recall was instituted, appropriate safeguards could be implemented to prevent regulatory overreach.<sup>154</sup>

Other improvements are necessary. As recommended by the Government Accountability Office (GAO) report, the FDA needs to implement enforcement action for non-compliant firms under the feed ban rules.<sup>155</sup> It is also important to remember that penalties do not work without funding, which is needed for increased resources, inspections, and staffing.

<sup>150.</sup> See generally id.

<sup>151.</sup> See GAO FEDERAL FOOD SAFETY, supra note 31, at 7.

<sup>152.</sup> Roberts, *supra* note 146, at 568.

<sup>153.</sup> See id.

<sup>154.</sup> See id. at 577-82.

<sup>155.</sup> See generally U.S. GEN. ACCOUNTING OFFICE (GAO), GAO-02-183, MAD COW DISEASE: IMPROVEMENTS IN THE ANIMAL FEED BAN AND OTHER REGULATORY AREAS WOULD STRENGTHEN U.S. PREVENTION EFFORTS (Jan. 2002), available at http://www.gao.gov/new.items/d02183.pdf.

## V. STRUCTURAL CONSIDERATIONS

An evaluation of the regulatory role of the United States federal government in minimizing the threat of terrorist attacks against the food supply also requires an appraisal of the food regulatory system structure. This appraisal invariably leads to a debate over whether a single food safety entity should be created. Proponents of a single food safety agency argue that the existing system is fragmented and ill-equipped for meeting the challenges of food safety, including potential terrorist attacks on the food supply.<sup>156</sup> They assert that a single agency would be more focused, and that efficiency in delivering information, incentives, and penalties would be improved.<sup>157</sup>

Opponents of a single food agency believe that the cooperative system has historically worked well and that moving from a long, settled system to a new entity would generate confusion and pose a security threat that would outweigh any supposed benefits that would accrue with a single agency.<sup>158</sup> Despite legislative attempts to establish a single federal food safety agency, it is doubtful that proposed legislation will gain traction in the near future.<sup>159</sup>

If the current fragmented system remains in place, it will be imperative that interagency cooperation and collaboration with the various private stakeholders occur at optimal levels. Otherwise, the problems associated with information gathering, devising incentives for private industry, and appropriating meaningful penalties will fail to minimize the threat of food terrorism. Regulators especially should continue to work with industry to incorporate considerations of food terrorism into food safety management programs. Policy makers should also avoid viewing the Bioterrorism Act as the regulatory hammer. While the act gathers useful information and allows the government to rapidly track food products implicated in a food-borne outbreak, it will not, nor is it designed to, deter the intentional contamination of food.

It will also be imperative for regulators to look for ways to

<sup>156.</sup> See Hammonds, supra note 30, at 427.

<sup>157.</sup> See id.

<sup>158.</sup> See Pape et al., supra note 54, at 405.

<sup>159.</sup> See GAO FEDERAL FOOD SAFETY, *supra* note 31, at 17-18 (setting forth the Bush Administration position in 2002 towards the issue of consolidating food safety agencies).

improve their preparation and response initiatives to food product in a global context. The WHO should be encouraged to continue its helpful role in disseminating information worldwide to help countries adopt effective domestic regulation and to cooperate with each other. As a global problem, terrorism demands global solutions.

### VI. CONCLUSION

Examining the regulatory role is critical in responding to Tommy Thompson's charge that the food system is easy prey for a terrorist attack. To be fair, the regulatory response to threat of food terrorism has been impressive and deserves recognition. A realistic appraisal of the three regulatory tools information, incentives, and penalties—requires, however, an honest appraisal of the inherent limitations and weaknesses of the food regulatory system and its dependence on the cooperation and coordination of all stakeholders.

An honest and useful appraisal of the essential regulatory tools first raises the question as to the specific purposes for information, incentives, and penalties. Measuring the effectiveness of these tools to their specific purposes then helps identify weaknesses and concerns about not just whether the tool is effective, but what steps the government could take to reduce further the threat of terrorism against the food system.

Because these regulatory tools via the Bioterrorism Act and other government activity are applied and enforced within a long-established food regulatory system, appraisal of this system is invariable. This appraisal hinges on whether the cooperation and collaboration by public agencies and the food industry that underpins the food regulatory system works. Some argue that a single food safety agency would be better equipped to meet the challenges of food terrorism threats. While minimizing terrorist threats is only part of a larger debate about the efficacy of a single food agency, the debate at least helps clarify the reasons for the shortcomings of the government's response to terrorist threats against the food supply.