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## REFORMING THE FOOD SAFETY SYSTEM: WHAT IF CONSOLIDATION ISN'T ENOUGH?

### I. INTRODUCTION

In the fall of 2006, animal waste contaminated crop fields and infected ready-to-eat spinach with *E. coli* bacteria, resulting in three deaths and more than 200 illnesses.<sup>1</sup> Not long afterward, a salmonella outbreak in lettuce and tomatoes sickened 171 people in nearly twenty states.<sup>2</sup> That a virtuous food could bring about disease seems paradoxical: “Here you think you’re feeding your child a great, healthy meal,” said Dennis Krause, father of a young boy infected with *E. coli*. “But here I was, poisoning him.”<sup>3</sup> According to Carol Tucker Foreman, director of the Food Policy Institute at the Consumer Federation of America, “[f]armers can do pretty much as they please . . . as long as they don’t make anyone sick.”<sup>4</sup>

Though the contamination of fresh vegetables was a surprise to many, it was only one of the latest of several problems facing the United States’s food supply. Another *E. coli* contamination hit fast food restaurants in New York and New Jersey in late 2006,<sup>5</sup> and a *Consumer Reports* study found that eighty-three percent of fresh chickens tested were infected with campylobacter or salmonella bacteria.<sup>6</sup> Indeed, the General Accounting Office (GAO) estimates that foodborne diseases account for up to 33 million bouts of illness and up to 9000 deaths every year.<sup>7</sup>

In examining these dangers, government officials and commentators have singled out the current “balkanized structure” of the national food safety system — composed of fifteen federal agencies that work

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<sup>1</sup> Mike King, *Seal Cracks in Food Safety System*, ATLANTA J.-CONST., Nov. 7, 2006, at A14; Libby Sander, *Source of Deadly E. Coli Is Found at California Ranch*, N.Y. TIMES, Oct. 13, 2006, at A20.

<sup>2</sup> King, *supra* note 1.

<sup>3</sup> Monica Davey, *As Children Suffer, Parents Agonize over Spinach*, N.Y. TIMES, Sept. 24, 2006, § 1, at 1 (internal quotation marks omitted).

<sup>4</sup> Michael Pollan, *The Vegetable-Industrial Complex*, N.Y. TIMES, Oct. 15, 2006, § 6 (Magazine), at 17 (internal quotation marks omitted).

<sup>5</sup> Alex Koppelman, *What’s Wrong with Our Food?*, SALON, Dec. 7, 2006, [http://www.salon.com/news/feature/2006/12/07/pollan\\_bad\\_food/](http://www.salon.com/news/feature/2006/12/07/pollan_bad_food/).

<sup>6</sup> *Dirty Birds*, CONSUMER REPORTS, Jan. 2007, [http://www.consumerreports.org/cro/food/chicken-safety-1-07/overview/0107\\_chick\\_ov.htm](http://www.consumerreports.org/cro/food/chicken-safety-1-07/overview/0107_chick_ov.htm).

<sup>7</sup> U.S. GEN. ACCOUNTING OFFICE, GAO/T-RCED-99-256, *FOOD SAFETY: U.S. NEEDS A SINGLE AGENCY TO ADMINISTER A UNIFIED, RISK-BASED INSPECTION SYSTEM* 2 (1999) [hereinafter GAO REPORT, U.S. NEEDS A SINGLE AGENCY].

under thirty foundational statutes — as a main cause.<sup>8</sup> Many of these officials and commentators have recommended consolidation of federal agencies into a single food safety agency; they recommended it almost as soon as the Food and Drug Administration (FDA) and United States Department of Agriculture (USDA) were separated and have regularly recommended it ever since.<sup>9</sup> A recent *New York Times* editorial stated that “the idea of merging [food inspection agencies] into a single food safety administration” is a good one and “has gained some momentum thanks to the recent E. coli outbreak caused by contaminated spinach.”<sup>10</sup> Others have used more severe words: “The food safety process is collapsing,” asserted Representative Rosa DeLauro, who has repeatedly called for a unification of the FDA and the USDA.<sup>11</sup> Another commentator opined:

The public is never in more need of assurance than when a food safety crisis arises. It is precisely at those times that the current regulatory structure prevents effective action. Because it is rare that a single agency has complete jurisdiction over the entire scope of a major food safety prob-

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<sup>8</sup> INST. OF MED., NAT’L RESEARCH COUNCIL, ENSURING SAFE FOOD: FROM PRODUCTION TO CONSUMPTION 85 (1998) [hereinafter ENSURING SAFE FOOD], available at [http://books.nap.edu/openbook.php?record\\_id=6163&page=R1](http://books.nap.edu/openbook.php?record_id=6163&page=R1); U.S. GEN. ACCOUNTING OFFICE, GAO-05-549T, OVERSEEING THE U.S. FOOD SUPPLY: STEPS SHOULD BE TAKEN TO REDUCE OVERLAPPING INSPECTIONS AND RELATED ACTIVITIES 1 (2005) [hereinafter GAO REPORT, STEPS SHOULD BE TAKEN]; see also U.S. GEN. ACCOUNTING OFFICE, GAO-04-588T, FEDERAL FOOD SAFETY AND SECURITY SYSTEM: FUNDAMENTAL RESTRUCTURING IS NEEDED TO ADDRESS FRAGMENTATION AND OVERLAP 18 (2004) [hereinafter GAO REPORT, FUNDAMENTAL RESTRUCTURING IS NEEDED] (noting that several former high-ranking food safety officials support the consolidation of food safety activities).

<sup>9</sup> DONNA U. VOGT, FOOD SAFETY: RECOMMENDATIONS FOR CHANGES IN THE ORGANIZATION OF FEDERAL FOOD SAFETY RESPONSIBILITIES, 1949-1997 (1998), reprinted in ENSURING SAFE FOOD, *supra* note 8, app. B at 115; see also 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, 405 (2004) (“There is a recurring debate in Washington, D.C., regarding the necessity of combining the food regulatory functions of the Food and Drug Administration . . . and the meat and poultry regulatory functions of the U.S. Department of Agriculture . . . into a single food agency. As with the Brood-X cicadas that visit the Washington, D.C. metropolitan area every seventeen years, FDA practitioners have long viewed this debate as never-ending and virtually immune to outside forces and the vagaries of the political process.”); Press Release, Center for Science in the Public Interest, Too Many Chefs in the Food-Safety Kitchen? (Oct. 7, 2004), <http://www.cspinet.org/new/200410071.html> (discussing legislation that would have combined the USDA and the FDA).

<sup>10</sup> Editorial, *Consolidating Food Safety*, N.Y. TIMES, Oct. 20, 2006, at A22. Professor Michael Pollan has noted an increase in calls for consolidation after September 11. See Koppelman, *supra* note 5 (“There was talk after 9/11 that we needed to rationalize the food-safety regime in this country, we needed to take all these different food safety bits and pieces of the government and put it under one agency, streamline it and rationalize it, because the standards are different for meat than they are for vegetables. I think that’s something we need to look at.”) (interview with Professor Michael Pollan).

<sup>11</sup> Andrew Martin, *Stronger Rules and More Oversight for Produce Likely After Outbreaks of E.Coli*, N.Y. TIMES, Dec. 11, 2006, at A20 (internal quotation marks omitted).

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lem . . . [often] the public is faced with a lengthy delay while overlapping bureaucracies creak into some attempt at a coordinated response.<sup>12</sup>

Critics of the current system point to wasted resources, enforcement duties that slip through the jurisdictional cracks, and a lack of agency accountability as just a few of its faults.

In light of ever-increasing threats to our food supply,<sup>13</sup> news reports of contamination, and the recent consolidation of food safety agencies in several other countries,<sup>14</sup> the calls for agency unification have become more urgent. But the multiplicity of agencies is too often treated as the whole problem, and consolidation of agencies as the entire cure; the larger problems stem from food safety agencies' inadequate funding and insufficient powers. This Note discusses several of these oft-noted food safety problems, suggesting solutions that lie not in agency consolidation, but in increased statutory power and greater funding commitments. It argues that although the food safety system evinces both agency overlap and disjointedness that at times seem striking, most dangers to the food supply are resolvable not through mere consolidation, but rather through increased funding or additional authority. Moreover, the unification of the fifteen federal agencies presently responsible for the U.S. food supply is likely to come at an enormous cost, in terms of both money and other institutional resources. Though the current structure of the federal food safety system is far from ideal, calls for consolidation — rather than coordination or a simple infusion of resources into the agencies — may be more a reaction to the arbitrariness of the jurisdictional lines drawn between the agencies than a valid concern that those divisions themselves give rise to food safety problems. And though a small number of problems are in fact exacerbated by the fragmented food safety system, equally effective and less costly solutions to these problems might be possible.

## II. HISTORY OF AGENCY CONTROL OF FOOD SAFETY

The structure of the federal food safety network began as and has remained an essentially bifurcated one. The federal government took its first meaningful steps to protect the nation's food supply with the

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<sup>12</sup> Timothy M. Hammonds, *It Is Time To Designate a Single Food Safety Agency*, 59 FOOD & DRUG L.J. 427, 428 (2004).

<sup>13</sup> In addition to the age-old concerns of microbial contamination, more recent threats to the nation's food supply include the emergence of bioterrorism, *see infra* section IV.D, pp. 1361–63, and the discovery of bovine spongiform encephalopathy, or “mad cow disease,” *see, e.g.*, U.S. GEN. ACCOUNTING OFFICE, GAO-05-212, FOOD SAFETY: EXPERIENCES OF SEVEN COUNTRIES IN CONSOLIDATING THEIR FOOD SAFETY SYSTEMS 13 (2005) [hereinafter GAO REPORT, FOOD SAFETY SYSTEMS].

<sup>14</sup> *See* GAO REPORT, FOOD SAFETY SYSTEMS, *supra* note 13, at 13.

passage of the Pure Food and Drugs Act<sup>15</sup> in 1906 and the Federal Meat Inspection Act<sup>16</sup> in 1907.<sup>17</sup> The two statutes were administered by the Bureau of Chemistry and the Bureau of Animal Industry, respectively.<sup>18</sup> Because the Bureau of Chemistry was an agency within the Department of Agriculture — “a department whose primary mission at the time was to assist American food producers”<sup>19</sup> — tensions developed between Bureau officials and the Agriculture Secretaries supervising them.<sup>20</sup> Though the Department Secretaries felt less concerned about food safety,<sup>21</sup> Bureau of Chemistry head Harvey Washington Wiley, whose work ignited the public’s concern over misbranded and adulterated foodstuffs in the 1880s and 90s,<sup>22</sup> favored extensive regulation; indeed, the Pure Food and Drugs Act was commonly referred to as the Wiley Act at the time of its passage.<sup>23</sup> The Bureau of Chemistry became the Food, Drug, and Insecticide Administration and in 1930 was renamed the Food and Drug Administration.<sup>24</sup>

Concerned that the Department of Agriculture’s promotional goals were at odds with the FDA’s goal of enforcement, President Roosevelt transferred the FDA from the USDA to the relatively new Federal Security Agency in 1940.<sup>25</sup> In 1953, the FDA was moved again to the Department of Health, Education, and Welfare (HEW).<sup>26</sup> In 1980, HEW was altered to create the Department of Health and Human Services (HHS); the FDA remains a part of HHS today.<sup>27</sup>

Other agencies became involved with food regulation at various times. With the advent of the Environmental Protection Agency (EPA) in 1970, the duties of pesticide regulation and setting pesticide tolerance levels were transferred from the USDA and the FDA to the EPA.<sup>28</sup> In contrast, the Department of the Treasury has retained rela-

<sup>15</sup> Pub. L. No. 59-384, 34 Stat. 768 (1906) (repealed 1938).

<sup>16</sup> Pub. L. No. 59-242, 34 Stat. 1260 (1907) (codified at 21 U.S.C. §§ 601-695 (2000)).

<sup>17</sup> Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61, 79 (2000).

<sup>18</sup> *Id.* at 78-79.

<sup>19</sup> *Id.* at 79.

<sup>20</sup> *See id.* at 78-81.

<sup>21</sup> *See id.*

<sup>22</sup> John P. Swann, *History of the FDA — Introduction*, <http://www.fda.gov/oc/history/historyoffda/default.htm> (last visited Feb. 10, 2007).

<sup>23</sup> John P. Swann, *History of the FDA — The 1906 Food and Drugs Act and Its Enforcement*, <http://www.fda.gov/oc/history/historyoffda/section1.html> (last visited Feb. 10, 2007).

<sup>24</sup> Peter Barton Hutt, *Symposium on the History of Fifty Years of Food Regulation Under the Federal Food, Drug, and Cosmetic Act: A Historical Introduction*, 45 FOOD DRUG COSM. L.J. 17, 18 (1990).

<sup>25</sup> Merrill & Francer, *supra* note 17, at 82-84.

<sup>26</sup> Swann, *supra* note 22.

<sup>27</sup> *Id.*

<sup>28</sup> Merrill & Francer, *supra* note 17, at 85.

tively consistent control over alcohol labeling for decades,<sup>29</sup> despite the FDA's efforts to gain more authority over the liquor industry.<sup>30</sup>

From these hundred-plus years of historical accident the current patchwork of federal food safety agencies has emerged, involving fifteen agencies with regulatory responsibilities<sup>31</sup> and thirty main statutes.<sup>32</sup> USDA duties include ensuring the quality of meat and poultry through the inspection of carcasses and processing plants, as well as through the grading of eggs, dairy, meat, and poultry products.<sup>33</sup> The FDA, an agency in the U.S. Department of Health and Human Services, inspects and ensures the quality of all foodstuffs, as well as animal drugs and animal feed.<sup>34</sup> Also in the Department of Health and Human Services is the Centers for Disease Control and Prevention, which investigates foodborne illnesses.<sup>35</sup> In addition, the food supply is regulated by the Department of Commerce's National Marine Fish-

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<sup>29</sup> In 1862, Congress created the Office of Internal Revenue, responsible for the "collection, among others, of taxes on distilled spirits and tobacco products," as an agency within the Treasury Department. ATF Online — Bureau of Alcohol, Tobacco, and Firearms, History [hereinafter History of ATF], <http://www.atf.treas.gov/about/atfhistory.htm> (last visited Feb. 10, 2007); see also Act of July 1, 1862, ch. 119, 12 Stat. 432 (creating the Office of Internal Revenue). Except for a twenty-month period directly following Prohibition, the Treasury has retained jurisdiction over alcohol. See History of ATF, *supra*.

<sup>30</sup> See *Brown-Forman Distillers Corp. v. Mathews*, 435 F. Supp. 5, 12 (W.D. Ky. 1976) (holding that the FDA had no authority to regulate the labeling of alcoholic beverages under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. §§ 301–397 (West 1999 & Supp. 2006)).

<sup>31</sup> GAO REPORT, FOOD SAFETY SYSTEMS, *supra* note 13, at 6. This does not even include the multitude of local agencies, which also coordinate with federal officials and have an impact on the safety of the U.S. food supply. "Often, federal agencies such as FDA will train and contract with state enforcement officials to conduct food plant inspections. FDA also developed a model ordinance for milk sanitation and a 'Food Code' for retail food store and restaurant sanitation to be adopted by state legislatures." VOGT, *supra* note 9, at 129.

<sup>32</sup> GAO REPORT, STEPS SHOULD BE TAKEN, *supra* note 8, at 1.

<sup>33</sup> See U.S. GEN. ACCOUNTING OFFICE, GAO/RCED-91-1B, FOOD SAFETY AND QUALITY: WHO DOES WHAT IN THE FEDERAL GOVERNMENT 4 (1990) [hereinafter GAO REPORT, WHO DOES WHAT]. The USDA operates the Food Safety and Inspection Service (which supervises all domestic and imported meat, poultry, and processed egg products); the Animal and Plant Health Inspection Service (which oversees health of agricultural sources); the Grain Inspection, Packers and Stockyards Administration (which establishes inspection and quality guidelines for grain); the Agricultural Marketing Service (which creates condition standards for dairy, fruit, vegetable, livestock, meat, poultry, and egg products); the Agricultural Research Service (which conducts food safety research); the Economic Research Service (which analyzes the economic issues affecting food safety); the National Agricultural Statistics Service (which provides statistical data on food safety); and the Cooperative State Research, Education, and Extension Service (which responsible for "[s]upporting food safety research, education, and extension programs in the land-grant university system and other partner organizations"). GAO REPORT, STEPS SHOULD BE TAKEN, *supra* note 8, at 21.

<sup>34</sup> See GAO REPORT, WHO DOES WHAT, *supra* note 33, at 4. Technically, the FDA is responsible for inspecting all foods. See 21 U.S.C. § 374 (2000). Other agencies share authority with the FDA for certain foods.

<sup>35</sup> GAO REPORT, FOOD SAFETY SYSTEMS, *supra* note 13, at 7.

eries Service (which regulates seafood);<sup>36</sup> the EPA (which regulates pesticides and establishes pesticide residue tolerance levels for food and animal feed);<sup>37</sup> the Alcohol and Tobacco Tax and Trade Bureau (which regulates alcoholic beverages,<sup>38</sup> except wines containing less than seven percent alcohol<sup>39</sup>); the Department of Homeland Security (which coordinates agency action to prevent deliberate contamination);<sup>40</sup> and the Federal Trade Commission (which regulates false advertising of food products).<sup>41</sup> Over 3000 state and local agencies also oversee the food supply, with jurisdiction over retail food establishments such as supermarkets and restaurants.<sup>42</sup>

Agency jurisdiction is, therefore, most often divided by food category. Yet the jurisdictional lines outlined by governing statutes and agreed upon by agencies are often arbitrary, producing memorable examples of distinctions that do not seem to make a difference. These demarcations, and their practical consequences, have led to peculiar and well-documented results. For example, pizza “is regulated by FDA unless topped with 2 percent or more of cooked meat or poultry, in which case it is USDA-regulated. This means that inspection at pizza production facilities must be conducted simultaneously under two sets of guidelines by two different inspectors from separate agencies.”<sup>43</sup> While the USDA regulates the meats in the Federal Meat Inspection Act<sup>44</sup> and the Poultry Products Inspection Act,<sup>45</sup> the FDA regulates the rest; beef and chicken are thus under USDA regulation while the FDA oversees venison, quail, and pheasant.<sup>46</sup> This arrangement seems even more inexplicable because it is one of happenstance rather than clearheaded organization. As one politician put it:

[I]f Congress were to set up an organizational structure today, I hardly believe that we would have the USDA inspect manufacturers of spaghetti with meat sauce, pepperoni pizza, open face meat and poultry sandwiches, corn dogs and beef broth daily and require the FDA to inspect manufacturers of spaghetti without [meat] sauce, cheese pizzas, close faced . . . sandwiches, bagel dogs and chicken broth once every 5 years.

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<sup>36</sup> *Id.*

<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

<sup>39</sup> Wines containing less than seven percent alcohol are controlled exclusively by the FDA.

See ENSURING SAFE FOOD, *supra* note 8, at 28.

<sup>40</sup> GAO REPORT, FOOD SAFETY SYSTEMS, *supra* note 13, at 7.

<sup>41</sup> See ENSURING SAFE FOOD, *supra* note 8, at 28.

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

<sup>43</sup> *Id.* at 27 (citations omitted).

<sup>44</sup> 21 U.S.C. §§ 601–695 (2000).

<sup>45</sup> *Id.* §§ 451–471 (2000).

<sup>46</sup> U.S. GEN. ACCOUNTING OFFICE, GAO/RCED-00-195, FOOD SAFETY: ACTIONS NEEDED BY USDA AND FDA TO ENSURE THAT COMPANIES PROMPTLY CARRY OUT RECALLS 6 n.1 (2000).

We also would not require school lunches to be inspected twice, once by the USDA and once by the FDA.<sup>47</sup>

### III. CONSOLIDATION'S COST

“If granted the opportunity to create a new regulatory scheme from scratch, one may indeed opt to create a single food agency” instead of the current U.S. system, a product of more than a century of various historical events.<sup>48</sup> But undoing this history has a price: costs associated with consolidation, though hard to estimate, are likely to be considerable. Putting aside the possibility of new jurisdictional battles stemming from the separation of food safety from drug safety within the FDA,<sup>49</sup> the food agency unification process would be “massive, time-consuming, and costly.”<sup>50</sup> Even a former FDA official in support of consolidation conceded that the “transition to a new statutory and organizational structure is an enormous management task” and would be “inherently costly and disruptive.”<sup>51</sup> Although the GAO’s recent study of food agency consolidation in foreign countries indicated that unification may be beneficial,<sup>52</sup> costs associated with consolidation in these countries were considerable;<sup>53</sup> in Denmark, the costs constituted up to twenty-one percent of the agencies’ yearly budgets.<sup>54</sup> In addition, the size of the United States’s regulatory regime, combined with the study’s inconclusive findings, make clear analogies to a complete consolidation in the American system impossible.<sup>55</sup> Completely merging U.S. food supply responsibilities into one federal body would be a larger undertaking than any realized by the other Western countries

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<sup>47</sup> *Question: What Is More Scrambled than an Egg? Answer: The Federal Food Inspection System: Hearing Before the Subcomm. on the Fed. Workforce and Agency Organization of the H. Comm. on Government Reform, 109th Cong. 2 (2005)* (statement of Rep. Jon C. Porter) [hereinafter *Hearing*]; see also VOGT, *supra* note 9, at 129 (“Critics . . . claim that too many agencies are responsible for food safety activities. Foods posing similar health risks may be inspected by different agencies at different frequencies.”).

<sup>48</sup> Pape et al., *supra* note 9, at 406.

<sup>49</sup> If food agencies were not consolidated within the FDA, and instead a unitary food agency were created, a new set of jurisdictional conflicts might follow since it is not always clear whether something is a “food” or a “drug.” See, e.g., *Nutrilab, Inc. v. Schweiker*, 713 F.2d 335, 335 (7th Cir. 1983) (deciding whether a starch blocker is a food or a drug under the Federal Food, Drug, and Cosmetic Act). The result could be two separate agencies executing the same statute.

<sup>50</sup> Pape et al., *supra* note 9, at 406; see also *id.* (describing consolidation as requiring a “multi-year implementation period”).

<sup>51</sup> Michael R. Taylor, *Lead or React? A Game Plan for Modernizing the Food Safety System in the United States*, 59 *FOOD & DRUG L.J.* 399, 403 (2004).

<sup>52</sup> GAO REPORT, *FOOD SAFETY SYSTEMS*, *supra* note 13, at 5.

<sup>53</sup> See *id.* at 17–24.

<sup>54</sup> *Id.* at 19.

<sup>55</sup> The GAO’s rationale for selecting the countries evaluated was that, although they are smaller, they are “similar to the United States in that they are high-income countries where consumers have high expectations for food safety.” *Id.* at 25.

the GAO examined. In the United States, consolidation would entail combining fifteen federal departments, not including state and local organizations, into a single agency protecting more than 300 million people. The consolidation of all FDA activities into one central location was estimated in 1989 to cost between \$447 and \$477 million<sup>56</sup> — several times more than the consolidation of other nations' food agencies. In comparison, the most populous country the GAO examined was Germany, with just over 82.4 million people,<sup>57</sup> and the only complete or near-complete consolidations occurred in countries that originally had only two or three safety agencies to begin with.<sup>58</sup>

Moreover, the costs of consolidation in different countries reported by the GAO are misleadingly low because they capture only administrative expenses such as moving and temporary staff fees.<sup>59</sup> Loss of productivity and institutional experience, though noted by governments as start-up expenses, are not examined in the GAO report;<sup>60</sup> because there are so many more separate agencies in the United States than in other comparable nations, these costs may be much more significant for a U.S. consolidation than the GAO report would seem to indicate. In addition, a temporary drop in regulatory effectiveness could be devastating if a bioterrorist attack were to occur during this time. One former FDA official interprets this risk as effectively foreclosing the argument for consolidation:

Post-September 11th, with increased terrorism and bioterrorism concerns, the debate [about consolidation] should now be closed. Due to the time required to merge such large, multifaceted regulatory agencies, and the jurisdictional confusion and regulatory gaps that would necessarily arise during the implementation period, we believe food security would be compromised by combining [agencies].<sup>61</sup>

Because many of the perceived benefits of consolidation, such as increased regulatory effectiveness, flow from additional funding for re-

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<sup>56</sup> U.S. GEN. ACCOUNTING OFFICE, GAO/HRD-89-142, FDA RESOURCES: COMPREHENSIVE ASSESSMENT OF STAFFING, FACILITIES, AND EQUIPMENT NEEDED 5 (1989).

<sup>57</sup> GAO REPORT, FOOD SAFETY SYSTEMS, *supra* note 13, at 10.

<sup>58</sup> According to the study, the only complete or near-complete consolidations examined took place in Canada (which consolidated three agencies into two), Denmark (which combined three agencies into one, with a few exceptions), the Netherlands (which combined two agencies into one), and New Zealand (which merged two ministries to create a semi-autonomous agency with total responsibility for the food supply). *See id.* at 17-24. The study also examined the coordination of food safety systems in nations like Ireland, which created a Food Safety Authority to better harmonize its several federal, regional, and local authorities. *See id.* at 41-44. Nevertheless, these figures shed little light on what coordination would cost the federal government, as the number of coordinated authorities in such countries is far fewer than the 3000-plus local authorities in the United States. *See ENSURING SAFE FOOD, supra* note 8, at 28.

<sup>59</sup> *See, e.g.,* GAO REPORT, FOOD SAFETY SYSTEMS, *supra* note 13, at 21.

<sup>60</sup> For example, Canada noted declines in productivity and workers' level of experience, but no definite cost was attached to these declines. *See id.* at 17.

<sup>61</sup> Pape et al., *supra* note 9, at 405.

search and inspections, as well as from increased jurisdiction and enforcement powers, the bare cost of physically and administratively combining agencies does not reflect the true cost of creating an effective farm-to-table food safety organization. Even proponents of consolidation would concede that a unified agency would still require far more funding for inspections and enforcement than is currently offered to protect the public.<sup>62</sup> To have a consolidated agency adequately funded to undertake these changes would cost far more than would a mere unification of agencies, but such an agency would be needed to fully address the safety issues most troubling to commentators.

#### IV. POTENTIAL JURISDICTIONAL PROBLEMS — AND CONSOLIDATION AS A POTENTIAL SOLUTION

Commentators and politicians have posited that a unified agency would enjoy advantages in the policing of both natural and manmade threats to food safety. They have highlighted weak agency accountability, inefficiency, and inconsistency among agencies, microbial contamination, bioterrorism, and the rising popularity of foreign food-stuffs as challenges that cannot be confronted adequately by the current jurisdictional system. As one GAO report stressed: “A federal food safety system with diffused and overlapping lines of authority and responsibility cannot effectively and efficiently accomplish its mission and meet new food safety challenges. These challenges are more pressing today as we face emerging threats . . . .”<sup>63</sup>

An analysis of these issues shows that combining food safety agencies, without much more in the way of increased funding and/or statutory authority, would provide little benefit. Although some of the issues described by consolidation proponents — weakened accountability, inspection inefficiencies, and duplicated research — could be ameliorated through consolidation, many of the others — responses toward pathogens, bioterrorism, and inconsistencies — could not. Moreover, this latter set of challenges includes what are arguably more urgent problems than those in the former, and a moderate amount of inter-agency coordination could be sufficient to remedy those problems addressable by consolidation.

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<sup>62</sup> See, e.g., GAO REPORT, U.S. NEEDS A SINGLE AGENCY, *supra* note 7, at 7 (arguing for consolidation but stressing that “[r]egardless of where a single agency is housed, what is most important are certain principles, including a clear commitment by the federal government to consumer protection, a system that is founded on uniform laws that are risk-based, adequate resources devoted to that purpose, and competent and aggressive administration of the laws by the responsible agency”).

<sup>63</sup> GAO REPORT, FUNDAMENTAL RESTRUCTURING IS NEEDED, *supra* note 8, at preface; see also Taylor, *supra* note 51, at 400–01 (naming imported food, bioterrorism, and mad cow disease as challenges to the food safety system that would be better handled by a unified agency).

*A. Overlap and Inefficiency*

Perhaps the most glaring shortcoming in the current food safety system is its arbitrary jurisdictional lines. These lines may cause inefficiencies, as there is potential for overlap in both inspection and research responsibilities, and they flout the recent recommendation by Paul Volcker, Chairman of the National Commission on the Public Service, that agencies with similar objectives be combined into large departments.<sup>64</sup> Instances of seemingly duplicative work are numerous: Food processing plants produce food products regulated by more than one agency, in which case multiple government representatives, each with varying guidelines, have to undertake multiple inspections of the same plant.<sup>65</sup> Fee-for-service inspections<sup>66</sup> and inspections of overseas factories<sup>67</sup> often involve multiple agencies. In the area of research, agencies conduct millions of dollars of food safety research each year, but the research is split among several largely uncoordinated agencies, increasing the risk of duplicative efforts.<sup>68</sup>

Proponents of consolidation have made much of these inefficiencies and jurisdictional overlaps, most notably those between the USDA and the FDA, and have pointed out the current system's confusion and arbitrariness. For example, the GAO published a chart outlining the various agencies involved in regulating a pepperoni pizza at various stages of production; the result was a baffling bureaucratic maze.<sup>69</sup> And in instances in which the two agencies' work is truly duplicative, there is no question regarding the system's inefficiency.<sup>70</sup> The benefit of double-checked inspections notwithstanding, with funding dollars stretched so thin, any inefficiencies obviously ought to be reduced.

But it is also important to note that some of these overlaps are relatively minor. For example, dual-jurisdiction facilities — plants that process some foods regulated by FDA and others regulated by the USDA, such as cheese pizza and meat pizza — are relatively rare,

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<sup>64</sup> GAO REPORT, FOOD SAFETY SYSTEMS, *supra* note 13, at 8; GAO REPORT, FUNDAMENTAL RESTRUCTURING IS NEEDED, *supra* note 8, at 1.

<sup>65</sup> GAO REPORT, FUNDAMENTAL RESTRUCTURING IS NEEDED, *supra* note 8, at 5–6.

<sup>66</sup> *See id.* at 6.

<sup>67</sup> *See Hearing, supra* note 47, at 5.

<sup>68</sup> ENSURING SAFE FOOD, *supra* note 8, at 80.

<sup>69</sup> *See* GAO REPORT, FUNDAMENTAL RESTRUCTURING IS NEEDED, *supra* note 8, at 5.

<sup>70</sup> In response to the question of whether USDA inspectors could handle the tasks of FDA workers at sites that both agencies currently regulate, the FDA responded:

FDA and USDA inspectors have different educational backgrounds, have received different training, and have responsibility for different food products and industries. These differences are due to the different legal authorities and the different scientific knowledge necessary to understand and regulate different food products and different processing techniques. The core qualifications for the agencies' inspection personnel are different.

*Hearing, supra* note 47, at 110.

numbering about 1450, or around two percent of all food processing facilities in the country.<sup>71</sup> It therefore does not seem likely that eliminating the costs associated with duplicative enforcement would come close to ameliorating the agencies' present funding shortages.<sup>72</sup> Relevant differences among foods require the imposition of varied safety plans with some duplicative regulation, whether by one agency or by several.<sup>73</sup> Additionally, and most importantly, the overlaps do not seem to constitute a great danger to the food supply. Many of these dual-jurisdiction establishments are low-risk locations, such as warehouses, that do not require adherence to complicated safety plans,<sup>74</sup> and consolidation proponents such as the GAO have not suggested that, as a result of agency overlap, one or more organizations have neglected their responsibilities in reliance on other agencies. Though jurisdictional overlap may lead to inefficient, duplicative work on the part of the FDA and USDA, such duplication is relatively uncommon and does not significantly hamper food safety.

### B. Inconsistency Among Agencies

1. *Overview.* — In addition to overlap, the odd jurisdictional lines drawn by history have led to food safety agencies' adherence to inconsistent inspection procedures and enforcement measures, sometimes for similar foods.<sup>75</sup> Take, for example, the FDA's and USDA's approaches to the inspection of meat pizza and cheese pizza in light of the agencies' related enforcement powers. Because their protocols differ, the FDA (responsible for cheese pizza) visits each pizza factory it regulates once every five years, while the USDA (responsible for meat pizza) inspects every day.<sup>76</sup> The inconsistencies are also evident with respect to enforcement powers. If the FDA notices noncompliance in a factory, the most it can do is temporarily detain the food at issue, whereas when the Food Safety and Inspection Service (FSIS), an agency within the USDA, finds substantial noncompliance with one of its regulations, it has the authority to effectively shut down a food processing estab-

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<sup>71</sup> *Id.* at 37, 94.

<sup>72</sup> It might, however, be the case that Congress would be less willing to fund fully an inefficient agency if instances of duplicative work were especially high or costly.

<sup>73</sup> It could be, for instance, that a high-risk food and a low-risk food are prepared in the same plant; in this case, it would not necessarily be inefficient for two sets of inspectors to look over each food with differing standards, because the inspections might require two altogether different sets of quality criteria. See Pape et al., *supra* note 9, at 414 (finding consolidation a misguided answer to the problems of inconsistent standards and duplicative responsibilities because "[t]he agencies have trained personnel to address issues specific to the products they inspect under their existing regulatory regimes").

<sup>74</sup> *Hearing, supra* note 47, at 37.

<sup>75</sup> GAO REPORT, FUNDAMENTAL RESTRUCTURING IS NEEDED, *supra* note 8, at 6–7.

<sup>76</sup> See *id.* at 7–8.

ishment.<sup>77</sup> The agencies' safety plans are also inconsistent: the FDA, which examines seafood, has a different plan for ensuring meat safety than does the USDA, which examines chicken.<sup>78</sup> This discrepancy means that establishments processing different types of meat, such as a plant processing both chicken and seafood, must adhere to different safety plans for those different meats, causing confusion.

Like the issue of overlap, much has been made of these inconsistencies, especially in light of the fine jurisdictional distinctions that have developed.<sup>79</sup> One report showed the inconsistencies as follows:

TABLE 1<sup>80</sup>

Manufacturer Inspected by FSIS Daily	Manufacturer Inspected by FDA on Average Once Every 5 Years
Open-face meat and poultry sandwiches	Closed-face (traditional) meat and poultry sandwiches
Hot dog in pastry dough	Hot dog in a roll
Corn dog	Bagel dog
Dehydrated chicken soup	Dehydrated beef soup
Beef broth	Chicken broth
Spaghetti sauce with meat stock	Spaghetti sauce without meat stock
Pizza with meat topping	Pizza without meat topping
Soups with more than two percent meat or poultry	Soups with less than two percent meat or poultry

As in the case of jurisdictional overlaps, jurisdictional inconsistencies are less troubling than some examples suggest. As an initial matter, inconsistencies are not per se detrimental to the nation's food supply. Indeed, rational inconsistencies — inspection and enforcement differences grounded in sound risk-based assessments of food safety — are efficient and sensible, and are recommended by the GAO as such.<sup>81</sup> Even without such inconsistencies, many safety systems would utilize different regulations for foods of differing risk levels, so any factory

<sup>77</sup> *Id.* at 6–7.

<sup>78</sup> *Id.* at 6.

<sup>79</sup> The USDA and FDA, aware of these well-known inconsistencies, have taken steps to resolve them. See Meeting To Discuss Possible Changes to the Regulatory Jurisdiction of Certain Food Products Containing Meat and Poultry, 70 Fed. Reg. 67,490 (Nov. 7, 2005).

<sup>80</sup> GAO REPORT, FUNDAMENTAL RESTRUCTURING IS NEEDED, *supra* note 8, app. 2 at 22.

<sup>81</sup> *Id.* at 18 (urging any food safety system to be “risk based”).

producing multiple food items would often still be forced to employ different safety protocols for its various products. And although certain jurisdictional distinctions between the USDA and FDA seem curious in light of the agencies' differing approaches to enforcement and inspection, the distinctions are at least theoretically risk based; they are therefore sensible to the extent that they are grounded in real differences in the regulatory goals of the various agencies. The USDA, with its focus on meat, eggs, and other extremely perishable products, has greater enforcement authority and more regularly conducts inspections than the FDA,<sup>82</sup> presumably because the government selected those foods for a higher level of regulation. So while it may seem strange that, for instance, a cheese pizza factory is examined only once every half-decade while a meat pizza factory is tightly regulated on a daily basis, the discrepancy may stem from legislators' belief that meat, in general, needs much stricter oversight than cheese, tomatoes, or wheat. And although the fact that cheese pizza is under FDA jurisdiction until it is covered with enough pepperoni seems patently absurd, such outcomes are inevitable in any system based on bright-line rules.

2. *Eggs: A Special Case.* — Nonetheless, interagency inconsistencies concerning the same dangerous food could pose, and have posed, problems. Specifically, inconsistencies among agencies have affected the safety of eggs because the inconsistencies affect consumer behavior. Eggs, which are overseen by several agencies within the USDA and the FDA, as well as by state governments,<sup>83</sup> are responsible for seventy-five percent of all salmonella outbreaks.<sup>84</sup> Despite the food's significant potential to cause illness, different agencies maintain different labeling and packaging requirements that tend to confuse consumers. For example, the USDA, whose Agricultural Marketing Service runs a voluntary grading program for eggs, banned the repackaging and redating of eggs under its watch out of a concern that the procedure was misleading to consumers. In contrast, the FDA, which is responsible for all in-shell eggs, does not prohibit the practice.<sup>85</sup> The result is that the one-third of American eggs graded by

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<sup>82</sup> According to the GAO, "[u]nder current law, USDA inspectors maintain continuous inspection at slaughter facilities and examine each slaughtered meat and poultry carcass. They also visit each processing plant at least once during each operating day. For foods under FDA jurisdiction, however, federal law does not mandate the frequency of inspections." *Id.* at 7. According to one report, FDA factory inspections happen, on average, about once every ten years. See FDA ET AL., FOOD SAFETY FROM FARM TO TABLE: A NATIONAL FOOD SAFETY INITIATIVE: REPORT TO THE PRESIDENT (1997), available at <http://www.cfsan.fda.gov/~dms/fsreport.html>.

<sup>83</sup> U.S. GEN. ACCOUNTING OFFICE, GAO/T-RCED-99-232, FOOD SAFETY: U.S. NEEDS A CONSISTENT FARM-TO-TABLE APPROACH TO EGG SAFETY 3-4 (1999) [hereinafter GAO REPORT, EGG SAFETY].

<sup>84</sup> *Id.* at 1.

<sup>85</sup> *Id.* at 9.

the USDA cannot be redated while non-USDA-graded eggs can, and both sit side-by-side in the average supermarket case.<sup>86</sup> Similarly, USDA-graded eggs often carry an expiration date of thirty days after the date of packaging, while other eggs might display an expiration date of either thirty or forty-five days after packaging:

[A] consumer may be more likely to select the eggs not graded by USDA because a later date on the carton seems to imply that those eggs will be fresher for a longer period of time. But the eggs with the later date may actually be older than the USDA-graded eggs in the cooler.<sup>87</sup>

Assuming that fresher eggs are safer eggs, and considering that fifty percent of consumers eat undercooked eggs,<sup>88</sup> customers seeking newer, possibly safer eggs might be misled into selecting a more dangerous product because of agency discrepancies.

Yet inconsistency with regard to egg safety seems to be unique. In no other case do the FDA and USDA have essentially the same authority to date and label an easily contaminated product with differing standards.<sup>89</sup> Even for eggs, consolidation would be only part of the solution. At least as vital would be the creation of additional safety regulations. Thus far, changes like the establishment of the hazard analysis and critical control point (HACCP) safety approach on farms or the requirement that eggs be maintained at a temperature below forty-five degrees have been slow in coming.<sup>90</sup> And, as in other areas, insufficient FDA funding and authority is a cause for concern. The FDA does not have the personnel and resources to inspect egg farms even though they are a potential source of disease. The FDA's Food Code, which recommends but cannot require the substitution of pasteurized eggs for raw eggs when serving populations with compromised immune systems, has not been uniformly adopted by the states.<sup>91</sup> However worrisome inconsistent labeling may be, ensuring

<sup>86</sup> *Id.* at 10.

<sup>87</sup> *Id.*

<sup>88</sup> FDA ET AL., *supra* note 82.

<sup>89</sup> Eggs are a rare case because both agencies have authority over the same practice — egg-carton dating — and because eggs are particularly prone to contamination. Other foods do not pose similar problems. Butter, cheese, and fresh produce are primarily under the FDA's jurisdiction but can be voluntarily inspected by the Agricultural Marketing Service. See AMS at USDA, Dairy Programs — Grading, <http://www.ams.usda.gov/dairy/grade.htm> (last visited Feb. 10, 2007); AMS at USDA, Fresh Product Grading and Quality Certification, Program Overview and Inspection Fees, <http://www.ams.usda.gov/fv/fpboverview.htm> [hereinafter Fresh Product Grading] (last visited Feb. 10, 2007). However, the Service's fresh produce inspection is intended for quality control at the wholesale, rather than retail, level. See Fresh Product Grading, *supra* (“Shippers of fresh produce can have their commodities graded for quality and condition . . . to establish the quality of the product. Receivers use the grading services to determine whether a shipment meets contract terms . . . . Institutional buyers and government agencies use services to ensure deliveries meet required specifications.”).

<sup>90</sup> GAO REPORT, EGG SAFETY, *supra* note 83, at 6, 8.

<sup>91</sup> *Id.* at 9.

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egg safety could be better achieved by increasing FDA authority and funding.

3. *Insufficiencies, Not Inconsistencies.* — If differences in food safety practices created to deal with different sorts of foods are not by themselves problematic except in rare cases, interagency inconsistencies are harmful only if one or more of the inconsistent approaches or enforcement procedures at issue are themselves insufficient. To continue with the frozen pizza example: the fact that meat pizza and cheese pizza are regulated so differently may be inefficient, even strange; yet the far more important question is whether the safety standard for either food is deficient. If so, the obvious solution is not to consolidate, but to modify procedures. If factory inspections once every five years do not adequately protect the public, that inadequacy itself, and not the fact that some factories are inspected more often, is the problem. In the case of frozen pizza, the regulation of cheese pizza is not necessarily inadequate, but only inconsistent with that of similar foods; its potential for harm could therefore be low despite the disparity.<sup>92</sup> Though the inconsistency may be senseless, it is not necessarily dangerous, and if inspections are so infrequent as to constitute a health threat, the simpler solution would be to make them more frequent.

This point seems to be lost on some critics, who point to safety problems “falling through the cracks,” though these “cracks” are not necessarily jurisdictional ones. One commentator argues that “[u]nder the current structure, food-safety problems fall through the cracks of agency jurisdiction” because “[l]ettuce and other fresh vegetables and fruits are essentially unregulated for safety” and because FDA guidelines for farmers “are entirely unenforceable.”<sup>93</sup> Though it may be true that these little-regulated foods receive meager attention, they fall well within FDA jurisdictional boundaries.<sup>94</sup> So while these foods may fall through a number of cracks — in priorities, bureaucracies, or budgets — jurisdictional cracks are not among them.

This is not to say that the jurisdictional lines are drawn properly. Resources are almost certainly improperly distributed among the federal food safety organizations. In light of recent research, proponents of consolidation note that the lines chosen by lawmakers, as well as the allocation of resources and authority to the FDA and USDA, might not

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<sup>92</sup> The Congressional Report did not, for example, criticize the existence of dual-jurisdiction establishments on the grounds that they were unsafe; it attacked only their inefficiency and obvious irrationality at the margins. See *Hearing*, *supra* note 47, at 95.

<sup>93</sup> See *Overlap and Duplication in the Federal Food Safety System: Hearing Before the Oversight of Government Management, Restructuring and the District of Columbia Subcomm. of the S. Comm. on Governmental Affairs*, 106th Cong. 103 (1999) (statement of Caroline Smith DeWaal, Director, Food Safety Programs, Center for Science in the Public Interest).

<sup>94</sup> See *supra* note 34 and accompanying text.

be well grounded in science. According to a GAO official, the government has learned “that the food safety threats are seafood first, fruits and vegetables second, eggs third, and meat and poultry fourth,” but “[t]he resources by statute are heavily directed toward the fourth priority and not priorities one through three.”<sup>95</sup> In other words, the riskiest foods are under FDA jurisdiction while most of the money and inspectors belong to the USDA. Considering the numbers, resources appear to be misdirected: foods under the FDA’s oversight account for about two-thirds of reported foodborne illnesses, yet the USDA spends nearly fifty percent more on food safety than the FDA.<sup>96</sup>

But the solution to this misallocation, which, it is worth emphasizing, is not an inconsistency as much as a simple lack of FDA funding, is not necessarily consolidation. Instead, Congress should reorder funding priorities and grant food agencies more authority. Though it might be easier for one all-powerful agency to respond to new research by rejiggering funding commitments without legislative approval, a large degree of funding flexibility is unnecessary because food risks will probably remain relatively static; unless food risks fluctuate wildly from year to year, all that is needed is a one-time reallocation. Congress could therefore solve the current misallocation problem by giving the FDA more resources to address properly the riskiest foods under its watch. Ultimately, it is irrelevant whether one agency or several rearrange their priorities to tackle adequately and efficiently these larger food safety threats; the problem is that, currently, no agency has adequate authority and resources to properly address them. As one GAO official explained: “That is not something that the agencies can do a heck of a lot about. They are directed by statutes to do certain things the way they are doing them now.”<sup>97</sup>

### *C. Fragmentation of Information and Responsibility*

In a food safety crisis, the fragmentation of the regulatory system and the multiplicity of safety agencies may bring about an attendant fragmentation of information or authority. A recent instance of fragmented information arose when the carcinogen dioxin contaminated animal feed in the 1990s. The FDA, which regulated the contaminated feed, discussed problems concerning animal feed with meat producers but did not advise them about the health of the animals that had eaten the feed. The USDA, on the other hand, is responsible only for the livestock themselves; as a result, that agency ignored the issues

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<sup>95</sup> *Hearing, supra* note 47, at 98 (statement of Robert A. Robinson, Managing Director, Natural Resources and Environment, U.S. GAO).

<sup>96</sup> GAO REPORT, FUNDAMENTAL RESTRUCTURING IS NEEDED, *supra* note 8, at 9.

<sup>97</sup> *Hearing, supra* note 47, at 98 (statement of Robert A. Robinson).

concerning animal feed and instead discussed only livestock health.<sup>98</sup> In the case of Bovine Spongiform Encephalopathy (BSE), or “mad cow disease,” fragmentation of responsibility has resulted in the USDA inspecting the cattle for disease and the FDA inspecting the safety of the cattle feed known to spread the disease.<sup>99</sup> According to one report, if BSE-infected cattle were found, rather than instituting one expansive recall, each agency would need to recall separately the foods under its watch.<sup>100</sup>

As with interagency inconsistencies, the fact that separate agencies notified different corners of the meat industry about a possible carcinogen danger or wished to institute separate BSE recalls is not inherently problematic unless some information or recall authority falls through the cracks. Though the dissemination of information about dioxin occurred in a piecemeal manner and may have been more efficiently undertaken by a single organization, the GAO does not cite evidence that any industry members were not informed of the contamination.<sup>101</sup> In the case of BSE, the larger problem regarding recalls seems to be that “[n]either FDA nor USDA has authority under existing food safety laws to require a company to recall food products.”<sup>102</sup> In this case, consolidation, without more, would lead to a single agency calling for recalls with a single voice — and having that voice summarily disregarded by food producers. The insufficiency of the agencies’ authority, rather than its fragmentation, may be the biggest obstacle to keeping the United States’s food supply safe; jurisdictional fragmentation, meanwhile, only adds to the current system’s inefficiency.

#### D. Bioterrorism

Still more recent is the risk of bioterrorism in the form of intentional interference with the U.S. food supply. Many experts believe that food could be used as a conduit for chemical or biological agents, resulting in “severe disruption” of the U.S. economy.<sup>103</sup> What is more, because “the vast majority of foodborne outbreaks are never traced to a specific food source,”<sup>104</sup> bioterrorism can currently be carried out effectively and anonymously, making it difficult for authorities to identify responsible parties or even whether an outbreak was caused by a malicious act at all. Because of the nebulous jurisdictional issues sur-

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<sup>98</sup> GAO REPORT, U.S. NEEDS A SINGLE AGENCY, *supra* note 7, at 5.

<sup>99</sup> GAO REPORT, FUNDAMENTAL RESTRUCTURING IS NEEDED, *supra* note 8, at 14.

<sup>100</sup> *Id.* at 15.

<sup>101</sup> *Id.*

<sup>102</sup> *Id.*

<sup>103</sup> U.S. GEN. ACCOUNTING OFFICE, GAO-04-259T, BIOTERRORISM: A THREAT TO AGRICULTURE AND THE FOOD SUPPLY 3 (2003) [hereinafter GAO REPORT, BIOTERRORISM].

<sup>104</sup> *Id.* at 6.

rounding bioterrorism, the low cost to bioterrorists of infecting the food supply, and the great potential for economic and physical harm,<sup>105</sup> observers worry that the unconsolidated food oversight system is unequipped to take on such novel threats.<sup>106</sup> Neither the FDA nor the USDA “feels that it has authority to require [food] processors to adopt physical facility security measures such as installing fences, alarms, or outside lighting,”<sup>107</sup> or to mandate background checks for employees of food processing facilities.<sup>108</sup> Both agencies issued only nonbinding guidelines to mitigate bioterrorism risks.<sup>109</sup> And because neither agency required food processors to report back on safety measures that they had adopted, it is unclear if food processing facilities are complying with either set of the agencies’ recommendations.<sup>110</sup>

Although GAO reports identify consolidation as a possible means of better protecting the U.S. food supply,<sup>111</sup> an examination of the possible dangers indicates that more straightforward solutions such as increasing the funding and authority of the USDA and the FDA would be effective. For example, several GAO reports highlight that neither the FDA nor the USDA believes that its enabling statute “provide[s] [it] with clear authority to regulate all aspects of security at food-processing facilities.”<sup>112</sup> The simplest answer would be to give one or both agencies this authority, preferably through a statute promoting regulatory flexibility as the particular threats to the food supply change over time. Although the latest report advocated consolidation,<sup>113</sup> an earlier report recommended increased authority:

This report recommends that the Secretary of the Department of Health and Human Services and the Secretary of Agriculture study what additional authorities their agencies may need relating to security measures at food-processing facilities to reduce the risk of deliberate contamination of

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<sup>105</sup> One possible form of bioterrorism is the infection of a plant or animal with a highly contagious disease to decimate that food source. Another possibility is the introduction of an animal disease that would be passed on to humans; some deadly animal viruses are transmissible to humans through direct contact. “It takes relatively few dollars and little imagination to introduce these deadly pathogens.” Richard Gilmore, *US Food Safety Under Siege?*, 22 *NATURE BIOTECHNOLOGY* 1503, 1504 (2004).

<sup>106</sup> See, e.g., GAO REPORT, FUNDAMENTAL RESTRUCTURING IS NEEDED, *supra* note 8, at 16.

<sup>107</sup> *Id.*

<sup>108</sup> GAO REPORT, BIOTERRORISM, *supra* note 103, at 13.

<sup>109</sup> *Id.*

<sup>110</sup> *Id.*

<sup>111</sup> GAO REPORT, FUNDAMENTAL RESTRUCTURING IS NEEDED, *supra* note 8, at 16.

<sup>112</sup> *Id.*; see also U.S. GEN. ACCOUNTING OFFICE, GAO-03-847, COMBATING BIOTERRORISM: ACTIONS NEEDED TO IMPROVE SECURITY AT PLUM ISLAND ANIMAL DISEASE CENTER 4 (2003) (noting that “the guard force on Plum Island,” a facility devoted to research on highly contagious foreign animal pathogens, “has been operating without authority from USDA to carry firearms or to make arrests”).

<sup>113</sup> GAO REPORT, FUNDAMENTAL RESTRUCTURING IS NEEDED, *supra* note 8, at 17–19.

the food supply. On the basis of the results of these studies, the agencies should seek additional authority from the Congress, as needed.<sup>114</sup>

Indeed, unless a new consolidated food safety agency had a sweeping mandate from Congress, it is hard to see how it could find the statutory authority to, for example, require security measures as extensive as background checks on food-factory employees.

The GAO also identified several other weaknesses in the federal food safety system as potentially problematic in the area of bioterrorism;<sup>115</sup> for none of them did consolidation emerge as a solution. Foot and mouth disease, for instance, is particularly dangerous because it is highly contagious and potentially economically devastating.<sup>116</sup> However, the general lack of communication between the USDA and U.S. Customs is one of the primary sources of this danger, and solving this problem should be given priority over any consolidation efforts. In addition, “because of the sheer magnitude of international passengers and cargo that enter this country on a daily basis, completely preventing the entry of foot-and-mouth disease may be infeasible.”<sup>117</sup>

Another weakness in the federal food safety system is the security at the Plum Island Animal Disease Center.<sup>118</sup> The GAO found that “Plum Island officials had not adequately controlled access to the pathogens” and that foreign scientists and students with incomplete or nonexistent background checks were given access to the biocontainment area.<sup>119</sup> Resolving such problems, rather than pushing for consolidation, should be a priority in tackling the threat of bioterrorism.

### *E. Imported Foods*

The United States’s consumption of imported foods has risen in recent years, increasing the likelihood that contaminated food from other countries, such as the imported raspberries infected with *Cyclospora* that sickened 2500 people in 1996 and 1997, will cross American borders.<sup>120</sup> The GAO has remarked that the FDA and USDA, both of which inspect imported foodstuffs, waste resources by failing to coor-

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<sup>114</sup> U.S. GEN. ACCOUNTING OFFICE, GAO-03-342, FOOD PROCESSING SECURITY: VOLUNTARY EFFORTS ARE UNDER WAY, BUT FEDERAL AGENCIES CANNOT FULLY ASSESS THEIR IMPLEMENTATION 4 (2003).

<sup>115</sup> See GAO REPORT, BIOTERRORISM, *supra* note 103, at 4.

<sup>116</sup> See *id.* at 9 (“[E]ven a single case of the disease would cause our trading partners to prohibit U.S. exports of live animals and animal products and could result in losses of between \$6 billion and \$10 billion a year while the country eradicated the disease and until it regained disease-free status.”).

<sup>117</sup> *Id.*

<sup>118</sup> See *id.* at 14.

<sup>119</sup> *Id.* at 15.

<sup>120</sup> U.S. GEN. ACCOUNTING OFFICE, GAO/RCED-00-65, FOOD SAFETY: FDA’S USE OF FASTER TESTS TO ASSESS THE SAFETY OF IMPORTED FOODS 3 (2000).

dinate their activities at the ports of entry at which most foreign foods arrive.<sup>121</sup> In addition, the agencies use different standards.<sup>122</sup>

Although imported food may pose health risks preventable by proper oversight, it is not clear that this oversight would be best enhanced by consolidation. As in other areas, the most significant shortcomings are minimal funding and authority:

FDA lacks the authority to require that imported foods be produced under a system equivalent to the one that it administers domestically; instead, FDA relies primarily on sampling at ports-of-entry to determine whether food imports meet domestic requirements. Even if FDA's criteria for sampling and testing were systematically risk-based and its resources were adequate to keep up with a growing demand, sample analysis is not capable of detecting many of the most serious risks to consumer health . . . . The General Accounting Office has reported that FDA lacks the necessary controls over detained and suspect shipments. Unscrupulous importers are able to circumvent the system, and are seldom punished in proportion to the seriousness of their violations.<sup>123</sup>

Although there is a lack of interagency communication regarding imported foods, the breakdown is between the FDA and Customs, rather than another food-centric agency, and could be resolved through increased enforcement power for the FDA or coordination between the FDA and Customs. The FDA has the authority to refuse dangerous shipments, but Customs has the authority to make foreign producers remove their wares from the country by sending "redelivery notices" that order the importer to return the food to Customs for reinspection, reexport, or destruction.<sup>124</sup> At some ports, however, Customs had no knowledge of up to sixty-eight percent of the FDA's refusal notices.<sup>125</sup> Refused imports that are not handled properly by Customs are likely to make it to the marketplace, and imports that slip through the cracks may cause grave illness; in one report, more than one-third of the shipments refused by the FDA at the Los Angeles port of entry were refused because of salmonella.<sup>126</sup> But better communication between the FDA and Customs is possible. Indeed, the two agencies coordinate with no outward signs of problems at most ports at which they coop-

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<sup>121</sup> U.S. GOV'T ACCOUNTABILITY OFFICE, GAO/RCED-05-213, OVERSIGHT OF FOOD SAFETY ACTIVITIES: FEDERAL AGENCIES SHOULD PURSUE OPPORTUNITIES TO REDUCE OVERLAP AND BETTER LEVERAGE RESOURCES 19 (2005).

<sup>122</sup> ENSURING SAFE FOOD, *supra* note 8, at 89.

<sup>123</sup> *Id.* (citations omitted).

<sup>124</sup> U.S. GEN. ACCOUNTING OFFICE, GAO/T-RCED-98-271, FOOD SAFETY: WEAK AND INCONSISTENTLY APPLIED CONTROLS ALLOW UNSAFE IMPORTED FOOD TO ENTER U.S. COMMERCE 4 (1998).

<sup>125</sup> *Id.* at 7.

<sup>126</sup> *Id.* at 8.

erate.<sup>127</sup> In addition, increasing FDA authority (or, in other words, a “consolidating” Customs’s authority over food imports into the FDA) would as easily resolve this issue as would mass consolidation.

#### F. Accountability

Diffuse responsibility for food safety may lead to weakened accountability and inconsistent goals among the agencies.<sup>128</sup> Numerous federal officials oversee agencies that are organizationally and financially separate from similar government units; some agencies generally take on different duties but jockey for resources when their jurisdictions overlap.<sup>129</sup> Add to this a “lack of a unified mission among the various agencies with regard to food safety,”<sup>130</sup> and the potential for insufficient regulatory response increases. In a food safety crisis, this disjointed structure may mean that no agency is fully accountable; the public may lose faith in government regulation and distrust the safety of its food. As one journalist lamented, “[s]crub the cutting board, we are warned, don’t nibble the cookie dough, don’t eat burgers rare. In other words, handle meat like a biohazard — and then eat it.”<sup>131</sup>

Unlike many safety issues raised by consolidation proponents, the problem of diffuse accountability, which arguably affects all the safety issues described above, could be significantly improved by consolidation. However, a small steering committee, responsible for creating an organizational mission for food safety agencies and responsive to the public during an outbreak of disease, might serve the same purpose at a lower cost. In Germany, for example, the establishment of a coordinating body “did not require significant start-up spending.”<sup>132</sup>

### V. CONCLUSION

Perhaps because inconsistent safety regulations imply agency confusion, or because the jurisdictional lines seem so nonsensical, many of the food safety system’s shortcomings are thought to be inextricably

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<sup>127</sup> In a study of agency cooperation at U.S. ports, the GAO found that FDA-Customs coordination creates definite problems at two of the eight ports it examined, although it found some degree of coordination at five of the ports. *See id.* at 7.

<sup>128</sup> *See* Merrill & Francer, *supra* note 17, at 127; Taylor, *supra* note 51, at 400, 401 (arguing that “the [food safety] system lacks a focal point for food safety leadership, responsibility, and accountability” and that “a single official and agency with both a clearly-defined food safety mission and accountability for success is needed”).

<sup>129</sup> ENSURING SAFE FOOD, *supra* note 8, at 85.

<sup>130</sup> *Id.* While all of the agencies discussed herein share the goal of ensuring food safety, the individual participants in that regulatory endeavor may adopt differing means to achieve that end. In other words, the agencies “lack a unified mission” even as they pursue the same objective, defined at a high level of generality.

<sup>131</sup> Denise Grady, *When Bad Things Come From ‘Good’ Food*, N.Y. TIMES, Jan. 2, 2007, at D1.

<sup>132</sup> GAO REPORT, FOOD SAFETY SYSTEMS, *supra* note 13, at 20.

connected to the system's unconsolidated nature. This is simply not the case. While consolidation could increase accountability and allow regulatory flexibility in the long run, most of the benefits of consolidation would not come primarily from the unification of agency responsibilities itself. Rather, consolidation would only be beneficial if the entire system were transformed by a legislature with a renewed regulatory spirit and a willingness to give additional funding and authority. Indeed, many of the benefits that are portrayed as likely to result from consolidation would probably only occur if consolidation were accompanied by an overall legislative fervor to resolve the system's inadequacies through such improvements. In contrast, a simple combination of agencies without these improvements would only serve as a short-term drain on resources for a system that can hardly afford it.

Given that most of the real problems with the food system are better solved through increases in regulatory authority and spending, and that consolidation would be costly and could lead to a dangerous drop in efficiency, consolidation is an especially unconvincing answer to the problem. Instead, the government should focus on creating mandatory safety guidelines, allowing more agency authority, and increasing enforcement personnel. These changes would best ensure the safety of imported foods and protect the food supply from accidental or malicious contamination. For those problems best solved by consolidation (lack of coordination, efficiency, accountability), the possibility of a small control body might serve many or all of these purposes. As the GAO has asserted, "[f]or the nation's food safety system to be successful, it will also be necessary to reform the current patchwork of food safety legislation to make it uniform, consistent, and risk-based."<sup>133</sup> Removing a few bureaucratic walls alone will not accomplish this feat.

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<sup>133</sup> GAO REPORT, FUNDAMENTAL RESTRUCTURING IS NEEDED, *supra* note 8, at 18.