Kentucky Law Journal

Volume 96 | Issue 4 Article 8

2008

Let Us Eat Lettuce (and Spinach): Is the Bioterrorism Preparedness Act Enough or is an Independent Food Safety Agency Required?

Robert M. Yoke
University of Kentucky

Let Us Eat Lettuce (and Spinach): Is the Bioterrorism Preparedness Act Enough or is an Independent Food Safety Agency Required?

Robert M. Yoke[1]

INTRODUCTION

ON September 14, 2006, federal officials warned consumers that an outbreak of an E. coli strain called 0157:H7 might be linked to fresh bagged spinach and recommended that consumers avoid eating such spinach until more information was known.[2] However, the first case of E. coli was reported on August 23rd, and it was not known until about three weeks later that there was even an outbreak at all.[3] As the amount of information grew, it became clear that the contamination was an accident, but "'[t]here is always a question in the back of our mind whether it may have been a deliberate attack on the food supply.'"[4] What if this had been a deliberate bioterror attack on the food supply? Would the regulatory response system currently in place detect it in time? How widespread could the problem become?

This outbreak was discovered slowly and seemingly by coincidence. The initial breakthrough indicating that there was something wrong came from a state public health laboratory in Wisconsin.[5] Officials at the lab noticed that eight patients in the state had all contracted the same genetic strain of E. coli at almost the exact same time.[6] Recognizing the potential danger to the public at large, they placed a message on a national data network operated by the Centers for Disease Control (the "CDC").[7] Unfortunately the message was posted on a Friday and it was not until the

---

1 B.A. Education, 2003, Purdue University; J.D. expected 2008 University of Kentucky College of Law. The Author would like to thank his wife and family for their support, and for putting up with him during law school.

2 Gardiner Harris, *U.S. Warns of Outbreak and of Eating Bag Spinach*, N.Y. TIMES, Sept. 15, 2006, at A14.

3 *Id.*

4 *Pattern of E. Coli Outbreaks is Seen*, N.Y. TIMES, Sept. 19, 2006, at A21 (quoting Dr. David Acheson of the Center for Food Safety and Applied Nutrition).

5 Maria L. La Ganga, *A Mom Suspected Spinach; As Public Health Officials Looked for the Source of Lethal E. Coli, the Mother of Two Sick Children Began to Focus on their Salad*, L.A. TIMES, Oct. 9, 2006, at A1.

6 *Id.*

7 *Id.*

following Monday that officials at the CDC discovered that this strain of E. coli matched posts from several other states which had been reported in recent weeks.[8] This contact, however, allowed local officials in the affected states to begin investigating the foods consumed by those suffering from E. coli.[9] Within a couple of days the FDA had issued its warning about bagged spinach, and a few days later officials in New Mexico had confirmed that the strain of E. coli did, in fact, come from that bagged spinach.[10] Once the bagged spinach was identified, it took less than twenty-four hours for investigators to identify the producer and narrow down their search to nine farms in California.[11] Eventually investigators found the same strain of E. coli in cattle feces near a Salinas Valley farm that produced the bagged spinach.[12] And while E. coli outbreaks are certainly not unusual, even in leafy vegetables as opposed to beef, this was the first time an outbreak had been traced to a specific farm where it was grown.[13]

While the E. coli outbreaks in bagged spinach and loose leaf lettuce have been proven not to be the result of any terror attacks, it remains that the increased authority granted under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act") was designed to bring more food establishments in line with regulations in the event that there is such an attack. The response of the government to these recent threats can provide us with some indication of the likelihood that an actual bioterror attack could be identified and contained quickly. And if the current increased regulatory authority would not allow for such a quick and efficient government response, would the proposed Food Safety Administration allow for such a response?

The purpose of this Note is to examine the procedures that were established under the Bioterrorism Preparedness and Response Act of 2002 and compare the provisions which increased the regulatory authority of the FDA with the provisions of the bill that would create a new, independent Food Safety Administration. The main thrust will be whether the existing system is working and then whether the new agency would likely create a better system that would substantially increase the protection of the food supply. Part I will examine the existing authority of the FDA as defined in title III of the Bioterror Act. Part II will describe some critiques

8 *Id.*

9 *Id.*

10 *Id.*

11 Annys Shin, *At E. Coli Hunt's End, a Safety Standards Gap*, WASH. POST, Sept. 22, 2006, at D1.

12 Annys Shin, *E. Coli Detected Near Spinach; Cattle Manure Within a Mile of California Fields*, WASH. POST, Oct. 13, 2006, at D1.

13 *Id.* ("Though last month's E. Coli outbreak was the 20th in 10 years linked to leafy greens and the ninth traced to the Salinas Valley, investigators have never found a specific source of contamination, which made [these] findings unusual").

of the current agency system and the proposal for a unified Food Safety Administration. Part III compares the relevant portions of both the current and proposed systems to explore whether the relevant changes in the proposed system would have a real effect. The Note concludes that the procedures in title III of the Bioterrorism Act are working as designed and that from this narrow perspective a change to a unified agency would be little more than a reorganization.

I. THE CURRENT LEVEL OF AUTHORITY GRANTED TO THE FDA UNDER TITLE III OF THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002

A. The FDA's Report to Congress on the E. Coli Outbreak in Bagged Spinach

On November 15, 2006, Robert Brackett, the director of the FDA Center for Food Safety and Applied Nutrition, testified before Congress regarding the recent E. coli outbreak in bagged spinach. His testimony began by explaining why ready-to-eat vegetables might be harmful to unsuspecting consumers.[14] The great potential for contamination comes from the combination of growing these products in fields and the fact that they "are often consumed without cooking or other treatments that could eliminate pathogens if present.".[15] In order to detect an outbreak like the spinach outbreak, the CDC actively searches for evidence of outbreaks and provides this information to the FDA or USDA to evaluate and notify the public.[16] In this case, once the outbreak located in the spinach was detected and evaluated, the FDA began on-site inspections of farms in the Salinas Valley to investigate the source of the E. coli and the extent of the contaminated products.[17] To further refine their investigation to determine the precise source of the contamination, the investigators took samples of facilities, water, the surrounding environment, and reviewed nearby animal management practices.[18] In conducting this investigation, and similar investigations following other food contamination outbreaks, the FDA began issuing various documents to producers which provide information on appropriate practices for handling and growing produce.[19] In this way, the FDA encourages producers to engage in practices that minimize the

14 *Food Safety: Hearing Before the S. Comm. on Health, Education, Labor and Pensions*, 109th Cong. (2006), *available at* http://www.fda.gov/ola/2006/foodsafety1115.html (statement of Robert E. Brackett, Ph.D., Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration).

15 *Id.*

16 *Id.*

17 *Id.*

18 *Id.*

19 *Id.*

potential for outbreaks. Additionally, the FDA is conducting research on better detection methods and the potential of treating the products before they are shipped to prevent disease from spreading.[20]

But is the combination of continued research and voluntary standards enough to protect against a potential bioterror attack on the food supply? It certainly seems that research on treating products before they are shipped for food-borne diseases is potentially an effective way to ensure against attacks. Is the fact that this is the first time that an E. coli outbreak caused by leafy vegetables was traced to a particular farm in a known problem area a sign of improvement or merely a chance happening? In essence, did we get lucky in finding the true source or are the increased regulations of the FDA and other agencies progressing to a level that create a safe food supply? If the increased regulations are not working, is there a need for a single food safety agency? Since this outbreak occurred after the final rules of the FDA were promulgated according to the Bioterrorism Act, we can have some idea of how well the paper trail actually worked.

B. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002

With the increased focus on protecting the United States from terrorist attacks, Congress recognized that there is a serious potential threat to our nation's food supply. The increased nationalization of the food market has evolved into a system where large quantities of food are produced and processed in only a few places. From these huge facilities food is then shipped all over the country to retail establishments such as restaurants and supermarkets. Congress saw the need for expanded power and funding for both the FDA and the Department of Agriculture to raise awareness and standards across the county. The Bioterrorism Act[21] was enacted "[t]o improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies."[22] In order to meet this objective the President's Council on Food Safety was charged with meeting and coordinating with the various government agencies to address threats concerning food processing and manufacturing facilities and public communication in a crisis situation.[23]

1. *Current Agency Models and Jurisdictions Remain Intact.*—Under title III of the Bioterrorism Act, both the current agency structure and jurisdiction are

20 *Id.*

21 Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (codified in scattered sections of 7, 18, 21, 29, 38, 42, and 47 U.S.C.).

22 *Id.*

23 *Id.* § 301(a) (codified in a note in 21 U.S.C. § 341 (2006)).

preserved. Various agencies are given directives for their particular areas of food safety and preparation with regard to concerns for bioterror attacks on the food supply. Under section 302 the FDA is required to set up and improve communication with other agencies to protect against adulterated food.[24] This section gives the FDA the authority to carry out this congressional mandate but requires it to be responsive and to make reports to certain other agencies and committees of Congress. An advantage of the reporting requirement is that the FDA is now more accountable to Congress should there be some lapse or a failure in the system. The FDA gains more regulatory authority but is also more responsible for properly utilizing that authority. When enacting the statute, Congress specifically proscribed in several places that the authority granted by title III to the FDA is not to be construed in a way that will alter the jurisdiction between the FDA and the Department of Agriculture.[25] This served to answer concerns that the new powers granted to the FDA would usurp any authority of the USDA.

2. *Appropriations for Agencies to Comply with the Act.*—To accomplish its goal of better protecting the food supply, Congress initially appropriated roughly $545,250,000 to the various agencies affected by title III of the Bioterrorism Act.[26] The President's Council on Food Safety received $750,000 to implement its strategy for crisis communication and public education in regard to threats on the food supply from bioterrorism for the fiscal year 2002 and such sums as necessary for subsequent years.[27] To protect against the intentional adulteration of food, Congress appropriated $100,000,000 to the FDA for the fiscal year 2002 and continuing appropriations as necessary through the fiscal year 2006.[28] Congress also granted $10,000,000 to the states for the fiscal year 2002 and such sums necessary through 2006 to conduct inspections[29] and another $19,500,000 under the same terms for surveillance,[30] all of which is disbursed by the FDA. The Department of Agriculture was appropriated $30,000,000 for the fiscal year 2002 and further appropriations for subsequent years to upgrade and expand the capacity of the Animal and Plant Health Inspection Service[31] and $15,000,000 under

24 *Id.* § 302 (codified in 21 U.S.C. § 381 (2006)).

25 *Id.* § 308(c) (codified in a note in 21 U.S.C. § 381 (2006)); *id.* § 310(b) (codified in 21 U.S.C. § 398 (2006)); *id.* § 315 (codified in a note in 21 U.S.C. § 331 (2006)).

26 *Id.* § 301(b) (codified in a note in 21 U.S.C. § 341 (2006)); *id.* § 302(f); *id.* § 311 (codified in 21 U.S.C. § 399 (2006)); *id.* § 312 (codified in 42 U.S.C. § 247b-20 (2006)); *id.* § 331(c) (codified in 7 U.S.C. § 8320 (2006)); *id.* § 332(b) (codified in 21 U.S.C. § 679c (2006)); *id.* § 333; *id.* § 335(b) (codified in 7 U.S.C. § 3354(b) (2006)) (totaling all individual appropriations in title III to reach the sum).

27 *Id.* § 301(b) (codified in a note in 21 U.S.C. § 341 (2006)).

28 *Id.* § 302(f).

29 *Id.* § 311 (codified in 21 U.S.C. § 399 (2006)).

30 *Id.* § 312 (codified in 42 U.S.C. § 247b-20 (2006)).

31 *Id.* § 331(c) (codified in 7 U.S.C. § 8320 (2006)).

the same terms to upgrade and expand the food safety inspection service.[32] Congress appropriated an additional $180,000,000 for the fiscal year 2002 and funding through 2006 for the purpose of upgrading and modernizing biosecurity at certain Department of Agriculture facilities.[33] The Department of Agriculture also received $190,000,000 for the fiscal year 2002 with necessary sums in subsequent years in order to conduct research and development on agricultural bioterrorism.[34] The initial appropriation to enhance the current regulatory authority is actually more than merely what is explicitly indicated in the statute. There is also a provision allowing for one-time grants of $50,000 to qualifying universities or colleges and one-time grants of $100,000 to individual food producing associations to improve biosecurity.[35]

There are also increased administrative costs associated with increased administrative authority. Title III expands the administrative detention authority of the FDA[36] which leads to the increased cost of all facets of detention, including appeals and potential court costs, through the simple act of enabling detention in more situations. More administrative detentions mean that there must be more money spent on the detentions. The FDA is also given greater debarment authority for food import violations.[37] Given the severe nature of a debarment action, it is likely that this will generate appeals within the agency and potentially court costs, thus increasing the amount of money that the FDA must spend to carry out its new mandates. There are increased registration requirements for "any facility that is engaged in manufacturing, processing, packing, or holding food for consumption."[38] In order to fulfill this congressional mandate, the FDA was required to engage in the expensive process of rulemaking.[39] In conjunction with the new registration requirements there are also, not surprisingly, new recordkeeping requirements,[40] which also require rulemaking by the FDA in order to be properly effected.[41] Additionally, the FDA must also promulgate rules that require all importers of food into the United States to provide notice that the food is foreign.[42] And to

32 *Id.* § 332(b) (codified in 21 U.S.C. § 679c (2006)).

33 *Id.* § 333.

34 *Id.* § 335(b) (codified in 7 U.S.C. § 3354(b) (2006)).

35 *Id.* § 334 (codified in 7 U.S.C. § 3353 (2006)).

36 *Id.* § 303(a) (codified in 21 U.S.C. § 334 (2006)).

37 *Id.* § 304(e) (codified in 21 U.S.C. § 381(k) (2006)). Debarment involves the ability of the FDA to prevent a regulated party from further importing food into the United States.

38 *Id.* § 305(a) (codified in 21 U.S.C. § 350d (2006)).

39 *Id.* § 305(e) (codified in a note in 21 U.S.C. § 350(d) (2006)).

40 *Id.* § 306(a) (codified in 21 U.S.C. § 350c (2006)).

41 *Id.* § 306(d) (codified in a note in 21 U.S.C. § 350c (2006)).

42 *Id.* § 307(a) (codified in 21 U.S.C. § 381(m) (2006)); *id.* § 307(c) (codified in a note in 21 U.S.C. § 381 (2006)).

go along with the various increases in agency authority and ability, there is necessarily a need for increased manpower to enact and maintain the various registration, tracking, and enforcement mechanisms. Congress saw the need for this increase and allowed the agencies to commission other federal officials to conduct inspections so long as there is an agreement between the agencies.[43] Title III of the Act also allows the agencies to create electronic monitoring and registration systems to ease the burden of the new requirements and potentially lower the cost of utilizing other agencies and adding new personnel.[44]

3. *FDA Authority Under Title III of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.*—Title III of the Act directs the FDA to increase its protection against adulterated food entering the food supply.[45] Additionally, the FDA is directed to promulgate new rules regarding registration of food products.[46] The goal is to permit the FDA to track suspicious food quickly to its point of origin in the food supply. Once an outbreak is detected the new registration requirements will allow the FDA to trace the food from the consumers that are sick back through grocery stores and shippers to the point where the contaminated items entered the food supply.

Title III gives the FDA new authority to detain articles of food for which there is credible evidence or information indicating that it presents a threat to the health of people or animals.[47] Detention effectively prevents the food from reaching consumers until the threat can be ascertained by FDA officials. Under section 303 of the Act, the FDA has the authority to detain all food which it already had existing jurisdiction over,[48] and may detain food with the approval of the District Director of the district where the detained food is located or her supervisor.[49] Once food is detained, it must be removed to a secure facility under the conditions specified in the order and may be held for thirty days, with an exception for perishable items, and may not be released without FDA permission.[50]

The FDA accordingly established new administrative procedures for appealing a detention order that allows anyone who may claim ownership of the detained food to appeal. For non-perishable food, a notice of intent to appeal and request for a hearing must be filed within four days from

43 *Id.* § 314 (codified in 21 U.S.C. § 372 (2006)).

44 *Id.* § 305(d) (codified in a note in 21 U.S.C. § 350d (2006)).

45 *Id.* § 302(a) (codified in 21 U.S.C. § 381 (2006)).

46 *Id.* § 305(a) (codified in 21 U.S.C. § 350d (2006)).

47 *Id.* § 303(a) (codified in 21 U.S.C. § 334 (2006)).

48 *Id.*; Federal Food, Drug, and Cosmetic Act § 201(f), 21 U.S.C. § 321(f) (2006).

49 21 C.F.R. § 1.391 (2008).

50 *Id.* § 1.379. Under 21 C.F.R. § 1.383, perishable items will be dispensed within four days, rather than the normal thirty. *Id.* § 1.383.

receipt of the detention order.[51] The FDA must then conduct an informal adjudication to determine whether the food may still be detained.[52]

Title III also provides new registration requirements for food facilities.[53] The registration requirements apply to all foreign and domestic facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States.[54] The definition of food is again consistent with the Federal Food, Drug, and Cosmetic Act and therefore applies to the same facilities that were subject to FDA jurisdiction prior to the passage of the Act. Additionally, there are many facilities that do handle food, but are not subject to registration. Common entities that do not have to register are private individuals, transport vehicles that operate only as carriers, farms, restaurants, retail food establishments, fishing vessels, and facilities regulated by the USDA.[55] Facilities subject to registration must provide general information such as the name, address, and phone number for the facilities and the names of people in charge at those facilities.[56] The information that the FDA requires for registration is not available to the public and information that would reveal individual persons is not even available under the Freedom of Information Act.[57] Failure to register a facility that is covered by the Act constitutes a prohibited act and the FDA may file for civil or criminal sanctions against the party that fails to register.[58] Thus if there is some act of bioterrorism or adulteration of the food produced at an unregistered facility, the FDA can impose penalties for failing to register and hindering the ability to track the source of the initial contamination.

Title III also requires those facilities that are required to register with the FDA to maintain records for a period of no more than two years depending on the type of food at that facility.[59] The records that are required to be kept are those that identify the immediate previous source and immediate subsequent recipient of the food produced by the facility.[60] This effectively creates an easy to follow paper trail that allows the FDA to quickly and efficiently trace any potentially contaminated food item through the production chain to the original source of contamination. The requirement to maintain such records extends further than the requirement to register

51 *Id.* § 1.402.

52 *Id.* § 1.403.

53 Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, § 305(a), 116 Stat. 594, 667-68 (codified in 21 U.S.C. § 350d (2006)).

54 21 C.F.R. § 1.225.

55 *Id.* § 1.226.

56 *Id.* § 1.232.

57 *Id.* § 1.243.

58 *Id.* § 1.241; 21 U.S.C. § 331(dd) (2006).

59 21 C.F.R. § 1.360.

60 *Id.* §§ 1.337, 1.345, 1.352.

the facility with the FDA. Some additional facilities that must maintain records of the food sources are retail establishments. These entities are exempt from the requirement of keeping record of the recipient of the food,[61] for the obvious reason that this would require keeping track of individual consumers.

Additionally, the rule requires that different records be maintained by those defined as transporters than those defined as non-transporters. Non-transporters of food, such as those who merely hold the food or those who actually process and pack food, must identify both the immediate non-transporter previous source of the food and the immediate non-transporter subsequent recipient of the food.[62] These entities are essentially the facilities that handle the food. Transporters of food must also keep track of the facility that the food was shipped from and that which it was shipped to.[63] Transporters must also maintain records of the specific route of movement that the food followed and any transfer points that the food passed through.[64]

The records themselves must be maintained "at a reasonably accessible location" and preferably on–site.[65] Should the FDA require access to the records, they must be produced within twenty-four hours from the time of receipt of the official request.[66] Ideally, the information would be produced almost immediately in the case of a potential bioterror attack. Additionally, the failure to maintain these records qualifies as a prohibited act according to FDA guidelines and this allows the FDA to seek judicial remedies if an entity is found to be failing in maintaining the appropriate records.[67]

Because these registration requirements are new to foods under FDA authority, there were many concerns voiced during the notice and comment phase of the rulemaking process. One important concern that the FDA addressed was the potential benefit of the new record establishment and maintenance system.[68] While the FDA cautions that its estimates of benefits are only fully realized in the context of an outbreak of a foodborne pathogen due to the unknown probability of a bioterror attack, it emphasizes that the increased traceback ability will help in the event of

61 *Id.* § 1.327.

62 *Id.* §§ 1.337, 1.345.

63 *Id.* § 1.352.

64 *Id.*

65 *Id.* § 1.360.

66 *Id.* § 1.361.

67 *Id.* § 1.363.

68 Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. 71,562, 71,614-15 (Dec. 9, 2004) (addressing comments raised in industry regarding various aspects of the record maintenance and retention requirements of the Act).

an attack.[69] Among the most important benefits of the recordkeeping rule is that it enhances food safety and security.[70] The agency will be able to ascertain and investigate outbreaks much more quickly now that it will not be hampered by incomplete or nonexistent records at food facilities.[71] This is especially important because there are so many potential places where an outbreak or bioterror attack could enter the food supply, such as on the farm, during distribution, during processing, and even at the retail level.[72] The records allow the FDA to fully complete more investigations and to perform the investigations faster, which will lead to the ability to shore up any weaknesses in the recordkeeping system and potentially identify other possible sources of contamination.[73]

The two major advantages of the recordkeeping system with regard to bioterror attacks are the ability to mitigate an ongoing attack and to identify a hoax.[74] With regard to mitigation of a bioterror attack, the FDA will be able to quickly identify the chain in which the contaminated food traveled.[75] Once the food is identified, the thoroughness and easy availability of the records will allow the FDA to quickly determine the scope of the contamination and thus reduce the risk to the health of the public.[76] Because there will be more records available at the time of crisis, the FDA can also determine if a bioterror attack is small or even a hoax. The FDA presents the scenario of a small contamination that is boasted by a terrorist to affect the entire nation.[77] With the ability to quickly and accurately traceback a product through the entire supply chain, the FDA can identify a false claim swiftly.[78] This will prevent the loss of large amounts of perfectly good food and allow consumers to have confidence in both the food supply and the government's ability to regulate it.[79]

69 *Id.* at 71,614.
70 *Id.*
71 *Id.*
72 *Id.*
73 *Id.*
74 *Id.*
75 *Id.*
76 *Id.*
77 *Id.*
78 *Id.* at 71,615.
79 *Id.*

II. CRITICS OF THE CURRENT SYSTEM

A. Issues and Problems That Remain Unresolved

While the FDA has recently taken steps to try to ascertain the extent and nature of the problem of E. coli contamination, there is some question as to just how much the FDA can do. Shortly before the FDA reported that there was an outbreak of E. coli in the spinach and warned consumers not to eat it, the agency had launched a broad investigation into the repeated outbreaks of E. coli that were linked to the Salinas Valley.[80] Part of the problem is the length of time it takes to recognize that there has actually been an outbreak, and often, once an initial point of origin has been established, the field has already been plowed to make it ready for the next crop.[81] Plowing hinders investigative efforts because researchers are left to speculate on the actual causes of the outbreaks due to simple lack of evidence. Thus, there are many theories as to the source of E. coli bacteria ranging from soil contamination to birds and wildlife feeding on cow manure and spreading the bacteria to other fields.[82] These difficulties force the FDA and other agencies into a responsive role rather than a proactive one. Because there is not yet any clear determination of the extent of the problem, there is little that the agency could do in enforcing new mandatory rules simply because there is no way of telling whether they will be effective. Occasionally, the FDA has found it necessary to seek out criminal sanctions against producers, and an investigation exploring that option is underway in the current E. coli outbreak.[83] However, considering that the voluntary practices require farmers to "maximize their efforts to minimize contamination,"[84] it seems extremely difficult to impose serious criminal sanctions, and the most likely result would be some sort of fine if there was a violation.

Critics of the current system point to many problems in the wake of the recent E. coli outbreak. One common concern is the lack of a singular regulatory voice in the area of food safety. The Department of Agriculture generally oversees the production of meat and poultry while the Department of Health and Human Services, through the FDA, oversees what is essentially the remainder of the food supply.[85] This gives rise to a situation where both jurisdiction and funding are decidedly different within what would

80 Rong-Gong Lin II, *E. Coli Spurs Review of Lettuce Farms; Salinas Valley Growers' Practices are being Evaluated by State and Federal Health Officials After Products' Link to Repeated Outbreaks*, L.A. TIMES, Sept. 11, 2006, at B1.

81 *Id.*

82 *Id.*

83 Gardiner Harris & Libby Sander, *U.S. Opens Criminal Inquiry on Health Measures Taken by Spinach Growers*, N.Y. TIMES, Oct. 5, 2006, at A20.

84 *Id.*

85 Shin, *At E. Coli Hunt's End, a Safety Standards Gap*, *supra* note 11.

seemingly be the same task of ensuring food safety. Ideally, this division of labor would work smoothly with both agencies receiving comparable manpower and financing, but in reality the FDA lags far behind in both aspects. The Department of Agriculture oversees roughly 6,000 meat and poultry facilities nationwide with over 7,000 inspectors[86] and performs daily inspections on the production floor.[87] The FDA lags far behind with less than 2,000 inspectors responsible for more than 120,000 production facilities nationwide.[88] Adding to the problems for the FDA is the fact that many cows graze close to produce fields in California.[89] Because the FDA has no authority over the cattle industry, it can do nothing to regulate the proximity of cattle to green leafy vegetables and thus a substantial cause of contamination remains simply because of the difference in jurisdiction between the agencies. Another problem cited is the lack of recall power of the FDA.[90] This problem was evident in the recent E. coli outbreak as the FDA could merely caution people not to eat the spinach and relied on a voluntary recall from Natural Selection Foods.[91]

There have also been repeated calls to modernize the current system. One of the problems continually focused upon is the extreme lack of centralization. While the FDA and Department of Agriculture regulate the majority of the food in the country, it is the EPA that is responsible for determining how much pesticide may be used, the CDC covers food-borne illness, and the Fisheries Service in the Department of Commerce oversees some seafood inspections.[92] Even with the new provisions and programs in the Act, the duplicity of regulation and jurisdiction that remains in the current system is unlikely to change unless there is some defining national problem that substantially alters the food supply in a way similar to the mad cow scare that caused the United Kingdom to unify its food safety departments.[93] And even with the United Kingdom in the middle of a food crisis, it still took roughly three years for the new independent food safety agency to become fully functional.[94]

---

86 Marian Burros, *Tainted Spinach Brings Demands for New Rules*, N.Y. TIMES, Sept. 27, 2006, at F5.

87 Shin, *At E. Coli Hunt's End, a Safety Standards Gap*, *supra* note 11.

88 Burros, *supra* note 86.

89 *Id.*

90 Shin, *At E. Coli Hunt's End, a Safety Standards Gap*, *supra* note 11.

91 Julia Preston & Monica Davey, *Possible Source of Bad Spinach is Named as Outbreak Widens*, N.Y. TIMES, Sept. 16, 2006, at A1.

92 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, 400 (2004).

93 *Id.* at 401.

94 John Krebs, *Establishing a Single, Independent Food Standards Agency: The United Kingdom's Experience*, 59 FOOD & DRUG L.J. 387, 388 (2004).

Some groups simply wish for an increase in funding for the FDA. They point to the decrease in funding and staff between 2003 and 2006 and the increasing risk of contamination as clear evidence of a need for change.[95] The funding that has been available to the FDA following the initial increases in 2003 has not been increased or even kept at pace with inflation.[96] Thus, the increased burden placed upon the agency by the Act has not been adequately funded by Congress. The simple lack of funding and decreased staffing leads directly to the current situation where some facilities can literally go years without an inspection by the FDA.[97]

Additionally, both the FDA and USDA lack statutory authority to conduct a mandatory recall of food.[98] The voluntary recalls issued by the FDA and USDA really only work on the implicit threat that an agency will take some regulatory action against the private actor if the actor fails to voluntarily recall its product from the market.[99] Unfortunately, the threats that the agency can make do not necessarily cause a speedy recall because many of the serious sanctions, such as an injunction or criminal court proceeding, require the assistance of a court.[100] One of the main obstacles in the face of mandatory recall authority has been Congress's failure to allow the agencies to issue such recalls.[101] A mandatory system would likely help the situation, but there remains the problem of funding. Making rules mandatory instead of voluntary works no real change unless the FDA has more funding and officials to ensure that the mandatory rules are followed.

Additionally, if a mandatory recall were issued, some sort of agency hearing would have to occur. In one model, the agency would issue its mandatory recall and then the affected company could request an informal hearing, at which time the agency would then only be allowed to stop further distribution pending the hearing.[102] The problem with this solution is that the recall does not really occur because the products in the market simply stay there. The mandatory recall would amount to a mere hold on dispersing the products with no effect on those products already in the market. Thus, it seems likely that mandatory recall authority will require Congress to solve both the process problem and the finance problem associated with granting the agencies mandatory recall authority. While

95 Burros, *supra* note 86.

96 Ricardo Alonso-Zaldivar, *Spinach Scare's Larger Warning; Tight FDA Budgets have Cut Produce Inspection. Compliance with Safety Rules is Voluntary.* L.A. TIMES, Sept. 22, 2006, at A1.

97 *Id.*

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

99 *Id.* at 567-68.

100 *Id.* at 568.

101 *Id.* at 576.

102 Roberts, *supra* note 98, at 579.

other agencies receive plenty of support from Congress in the issuance of recalls, it seems that the food industry still is not on the congressional radar for granting such authority.[103]

The many problems faced by the food industry over the years and the increased concern over a possible attack upon the food supply have brought an increasingly vigorous call for reform. As reports of food contamination outbreaks increase, that call will likely get stronger. The question remaining is whether the public or the administration will find a way to convince Congress to unify food safety. However, there are many competing interests that would likely wish for the current system to remain in place. Both the FDA and Department of Agriculture have an interest in keeping their systems and personnel in place and, logically, regulated parties also share that interest. Agencies generally develop a working relationship with the parties that they regulate and these parties are often interested in maintaining a regulatory status quo so they do not have to change their operations. Creating a new food safety agency and removing this power from the existing agencies would likely meet great resistance from both the current agencies and regulated parties. Consequently there has not been a great deal of movement in Congress pushing toward a unified food safety system, but there has been one Senator who has repeatedly tried to convince the rest of the legislature of the need for a single food safety agency.

B. The Current Proposal for an Independent Federal Food Safety Agency

One prominent proponent of a unified food safety agency has been Senator Richard Durbin who has sought to create a single, independent agency since 1996.[104] Senator Durbin proposes to create a brand new, full and independent regulatory agency complete with head administrators appointed by the President and confirmed by the Senate.[105] This agency would be separate from both the FDA and the USDA with the goal of "streamlin[ing] policy in ways that more effectively address food safety hazards without feeling tied to the past policies of [either agency]."[106] Senator Durbin recognizes that the current agencies are often stuck with rules once they are promulgated and a change in regulatory course requiring at least informal rulemaking may be too costly a process for the agency to endeavor. The main thrust of Senator Durbin's argument is that the new agency, once created, will save time and money by eliminating the redundancies that exist in the

103 *Id.* at 577-78.

104 Richard J. Durbin, *Food Safety Oversight for the 21st Century: The Creation of a Single, Independent Federal Food Safety Agency*, 59 FOOD & DRUG L.J. 383, 383 (2004).

105 *Id.* at 384.

106 *Id.*

current food regulation system.[107] The Government Accountability Office agrees with his position to the extent that it sees redundancy in the current system and seeks to fix such problems.[108]

The Food Marketing Institute (FMI), a nonprofit association of food retailers, wholesalers, and distributors, agrees with Senator Durbin's position.[109] One concern of this interest group is the ability to disseminate information to the public, arguing that a lack of a single agency creates a situation where there is no single spokesperson or agency who can quickly ascertain a problem and reassure the public regarding that problem.[110] Additionally, the FMI sees the current system of multiple agencies, departments within those agencies, and the further regulation of state governments as creating a counterproductive competition for regulatory power.[111] Because each agency must fight for its own current budget and has specific congressionally mandated areas of regulation, there is little incentive for the current agencies to reduce the redundancy.[112]

Senator Durbin currently sponsors a bill in the Senate that would establish a single food safety agency that combines all of the food safety power currently granted to various agencies, including the FDA and USDA, and establish a "Food Safety Administration to protect the public health by preventing food-borne illness, ensuring the safety of food, improving research on contaminants leading to food-borne illness, and improving security of food from intentional contamination, and for other purposes."[113] The bill also foresees the potential cost problem of creating a new agency from scratch. While the bill authorizes appropriation of sums as necessary,[114] it specifically limits the amount appropriated to the aggregated budget of the constituent parts that would become the new agency.[115] This provision makes this new agency almost a pure reorganization of the existing structure, and this would likely appeal to those who do not wish to simply increase funding for the food safety portion of the government in order to achieve

---

107 *Id.*

108 *Federal Food Safety and Security System: Fundamental Restructuring is Needed to Address Fragmentation and Overlap: Hearing Before the Subcomm. on Civil Serv. and Agency Organization of the H. Comm. on Government Reform*, 108th Cong. 17-18 (2004), *available at* http://www.gao.gov/new.items/d04588t.pdf (statement of Lawrence J Dyckman, Director, Natural Resources and Environment, Government Accountability Office).

109 Timothy M. Hammonds, *It is Time to Designate a Single Food Safety Agency*, 59 FOOD & DRUG L.J. 427, 427 (2004) ("FMI has proposed the creation of a single food safety agency because we believe new challenges have arisen that, taken together, threaten to overwhelm the ability of the current regulatory system to respond effectively").

110 *Id.* at 428.

111 *Id.* at 430.

112 *Id.*

113 Safe Food Act of 2007, S. 654, 110th Cong. (2007).

114 *Id.* § 508.

115 *Id.* § 509.

positive results. While it may cost several billion dollars to change over and run the new agency in the first year, this appropriation will theoretically be money that is already being spent and thus will not be a new cost for the government.

One of the major changes that this agency will oversee is the vast transfer of power from other agencies to the new Food Safety Administration (FSA). The administration would be in charge of the transfer of power of several divisions of other agencies to the new agency.[116] Presumably the existing facilities will remain intact but simply answer to a different agency authority. Additionally, there will be new performance standards established by agency rulemaking for the levels of contaminants in food[117] and new inspection power to ensure that the standards are followed.[118] It appears that the goal of these sections is to increase the visibility and frequency of inspections to promote a safer food supply at the processing and retail level. Another interesting requirement of the new bill is that it establishes a statutorily mandated traceback requirement to trace food "from point of origin to retail sale."[119] While this section of the bill is sparse and would require potentially significant rulemaking, it is a step in the right direction toward the goal of being able to quickly and efficiently find the source of any breakouts of contamination in the food supply. A potential change that this section might enact would be to require prior and subsequent food facilities or transporters to be listed physically on the package rather than merely in a record at each facility. While this is certainly feasible for bulk items and might aid identification at the retail level, it does not seem plausible for a pack of gum.

Some of the elements of the new agency will remain the same and potentially there will not be a great deal of change needed. One such element is registration requirements. Under the new program food establishments will be required to register with the agency,[120] but much of the information that is required is substantially the same as that already required under the Bioterrorism Act. What is unclear is whether this information will be able to be transferred easily to the new agency, or if there will be a need for a

116 *Id.* § 102 (including the Food Safety and Inspection Service of the USDA, the Center for Food Safety and Applied Nutrition of the FDA, egg surveillance services under the Egg Products Inspection Act, the Office of Regulatory Affairs of the FDA that administer inspections, the Center for Veterinary Medicine of the FDA, the facilities of the EPA that regulate pesticide residues in food, the part of the Research, Education, and Economics mission area of the USDA related to food safety and animal feed research, the part of the National Marine Fisheries Service of the NOAA that administers seafood inspection, the Animal and Plant Inspection Health Service of the USDA, and other agencies designated by Executive Order to carry out the Act).

117 *Id.* § 204.

118 *Id.* § 205.

119 *Id.* § 210.

120 *Id.* § 202.

new, costly rulemaking procedure to enact the registration requirements under the new system. There will also continue to be public education functions[121] and funding for research projects.[122] Again it seems likely that the existing infrastructure will be utilized, but the agency would likely have to create some new regulations.

One of the major changes in the proposed Food Safety Administration is that it will have mandatory recall authority, unlike the current situation in the FDA and USDA. The FSA will not be allowed to issue a mandatory recall until a voluntary recall has been attempted,[123] but the ability to conduct a mandatory recall would be a huge increase in the authority of the agency. Without this ability to exercise greater control over potentially contaminated sources of food, the new agency would be little more than a reorganization of the existing agencies. In addition to mandatory recall authority, the FSA would also oversee regular, unannounced inspections of food establishments[124] that will better enable the agency to "enforce the adoption of process controls in food establishments . . . ."[125]

The FSA would also oversee and enforce new preventative process controls and performance standards for food facilities as developed through agency regulations.[126] The purpose of adding new process controls is to ensure that the food is produced and handled in a sanitary manner to reduce food contamination and adulteration. This will allow for the FSA to promulgate regulations that require food establishments to adopt the controls[127] and to ensure that they maintain records of compliance.[128] With the authority to conduct inspections, the FSA will also ensure that the records are readily accessible[129] and will be able to test and sample the products in order to ensure that the process controls are effective and in compliance at the facility.[130]

In accordance with new process controls, the FSA will establish performance standards to objectively determine if the new regulations are being complied with by food establishments. These standards will operate with regard to the level of protection from food-borne contaminants.[131] The standards will include the level of a contaminant "that can safely and

121 *Id.* § 302.
122 *Id.* § 303.
123 *Id.* § 403(b)(2).
124 *Id.* § 201(c)(1).
125 *Id.* § 201(c)(2).
126 *Id.* §§ 203, 204.
127 *Id.* § 203(b)(1).
128 *Id.* § 203(b)(4).
129 *Id.* § 203(b)(6).
130 *Id.* § 203(b)(5).
131 *Id.* § 204(b)(2).

lawfully be present in food,"[132] and process standards for processed food.[133] An addition to this section is the ability of the FSA to enforce its standards.[134] If the agency determines that the standards were not met or remedied upon an inspection, then the agency has several sanction measures at its disposal.[135] The FSA will have the ability to "detain, seize, or condemn food" that fails to meet the standards,[136] order a mandatory recall of food from the facility,[137] increase the frequency of inspections,[138] "withdraw the mark of inspection" that shows that the food is approved by the agency,[139] and even to withdrawal registration of the facility effectively shutting it down.[140] These controls and abilities will help the FSA to ensure that there is a higher quality standard and that food facilities operate at a higher level of compliance with the regulations.

III. Is the Current System Working or is a New Agency Necessary?

Judging from the example of the recent outbreaks of E. coli in spinach and lettuce we can examine how the requirements of title III of the Bioterrorism Act have functioned. Once the FDA was able to ascertain that there was an outbreak and the product that the outbreak was linked to, it only took a few days to perform the traceback function and for the FDA to find out exactly where the contamination entered the food supply.[141] While the search did take several days, it is important to note that the FDA was able to isolate the exact product, its origin, and where it had been distributed throughout the country.[142] This is exactly the type of ability that was contemplated when the registration and document maintenance portions of the Act were passed. Had this been a deliberate contamination of the food supply, the process would have worked.

The main difficulty in isolating the source of contamination is no longer the traceback function, but it is the determination that there is, in fact, an outbreak. It took over a week for the various cases across the country to be linked through the data systems maintained to monitor diseases throughout the country.[143] This portion of finding an outbreak still relies

132 *Id.* § 204(c)(1)(A).
133 *Id.* § 204(c)(1)(C).
134 *Id.* § 204(d)(1).
135 *Id.* § 204(d)(2).
136 *Id.* § 204(d)(2)(A).
137 *Id.* § 204(d)(2)(B).
138 *Id.* § 204(d)(2)(C).
139 *Id.* § 204(d)(2)(D).
140 *Id.* § 204(d)(2)(E).
141 *See* La Ganga, *supra* note 5.
142 *Id.*
143 *Id.*

upon individuals in state and local agencies across the country to place information online so others can search for a pattern. Thus, the real difficulty in detecting an outbreak is still a major issue to deal with.

Although the registration requirements led to a swift determination of the source of the contamination once an outbreak was discovered, the FDA was unable to do anything but issue a press release suggesting a recall. If the FDA had mandatory recall authority it might have been able to act more quickly and recall the affected food, thus preventing some people from becoming ill. Although the FDA now has broader authority to detain food, it is limited to detention only when an FDA official issues a detention order "during an inspection, examination, or investigation."[144] If the FDA had the ability to temporarily detain food for 24-48 hours without an inspection in situations of an outbreak or bioterror attack to perform the traceback function, it might be able to prevent further spread of the contamination without unduly affecting food that is not contaminated.

Both mandatory recall authority and temporary detention are powers present in the proposal for a new Food Safety Administration. In addition to the added authority, the FSA would also centralize all of the various agencies into one. This would have the effect of creating a single, powerful agency that would no longer have to struggle for authority and financial support at the expense of other agencies performing the same functions. The major drawback for private parties is that they already are familiar with the regulations and polices of the FDA, USDA, and other agencies. There would likely be a difficult transition phase during which various industries would become accustomed to the new policies developed under the FSA.

While the reorganization of the various government agencies into one central agency would certainly simplify the process of determining which agency's regulations to comply with, it is not clear that the agency would perform the functions designed to prevent a bioterror attack with any more efficiency than they are already performed. Since the major difficulty in containing outbreaks and bioterror attacks is the actual identification of contaminated food, it does not appear that any of the broader powers of the FSA would substantially benefit this ability. Certainly the FDA would greatly benefit from mandatory recall authority and greater detention power and these provisions should have been included in the Act when Congress granted the FDA additional power. Additionally, the great lack of funding of the FDA severely limits its ability to perform its duties. Thus there is not so much a need for a new agency that centralizes all food safety, as there is a need for Congress to grant the current agencies the power and appropriate the finances necessary to properly perform their existing functions. The records system is working as it is designed and will certainly help save lives

144 Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, § 303(a), 116 Stat. 594, 663 (codified in 21 U.S.C. § 334(h) (2006)).

in the event of a bioterror attack, and it can only work better if Congress grants the FDA the ability to fulfill its duty.

CONCLUSION

The additional power granted to the FDA under title III of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 has produced a regulatory system that works as designed to trace contaminated food to the original source of contamination quickly and efficiently. In terms of the structure set up under title III, any reorganization into a new Food Safety Administration would be little more than a reorganization of the existing structures that are functioning as designed. However, the lack of FDA power to issue a mandatory recall of contaminated food is a serious drawback. While the existing requirements allow food to be traced better than ever, without the addition of mandatory recall authority the FDA is limited in the action it can take to stop contaminated food from moving further along the food supply chain. Whether it be a unified Food Safety Administration with mandatory recall power or an additional grant of power to the FDA, the utility of the enhanced tracing powers will continue to be limited without mandatory recall authority.