



# Rapid Public Health Policy Response Project

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## Protecting the Nation's Fruits and Vegetables: How Should the System Be Strengthened?

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## Protecting the Nation's Fruits and Vegetables: How Should the System Be Strengthened?

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### **About this Paper**

Reports of illness linked to a Salmonella outbreak continue to grow, with 943 cases in 40 states and the District of Columbia identified from mid-April to July 4, 2008. Raw tomatoes remain the prime suspect but the investigation has been broadened to other produce as well. This is only the latest in a recent series of widespread, pathogen-linked outbreaks associated with fruits or vegetables along the “farm-to-fork” continuum that encompasses harvesting, packing, processing, transporting, distribution, and preparation.

The statutes that govern the activities of the FDA, which is responsible for produce safety, are generally focused on the agency's response after food safety challenges occur. Most proposals for reform, by contrast, promote a public health approach that emphasizes the risk-based science of prevention. Recommendations to strengthen the nation's food safety system include establishing and enforcing science-based standards for produce safety; making it easier to trace contaminated fruits and vegetables back to their source; emphasizing industry accountability; increasing domestic and foreign inspections; monitoring imports more closely; increasing FDA's resources; and updating the statutes governing its authority

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### **About the Rapid Public Health Policy Response Project**

The Rapid Health Policy Response Project of the School of Public Health and Health Services at The George Washington University presents data and other background information on breaking public health stories. The goal is to educate the public, policymakers, legislators, health care providers, the media and others in order to promote informed decisionmaking.

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More than 943 people in 40 states and the District of Columbia were sickened by the same genetic strain of Salmonella from mid-April to July 4, and the Centers for Disease Control and Prevention notes that many more illnesses from the same source, or sources, have probably gone unreported.<sup>1</sup> Raw tomatoes remain the prime suspect in the contamination, but in late June, the investigation was broadened to include other produce typically consumed with tomatoes.<sup>2,3</sup>

This is only the latest in a recent series of widespread, pathogen-linked outbreaks of illness associated with fruits or vegetables. At least 713 such outbreaks have occurred from 1990 through 2005, according to a Center for Science in the Public Interest survey.<sup>4</sup> And tomatoes have been the culprit in the past – more than 3,000 Americans have become ill from 24 known tomato outbreaks since 1990.<sup>5</sup> A few other facts highlight the concerns:

- ▶ Leafy greens, including bagged spinach and lettuce, are by far the most common source of outbreaks, with bacterial and viral contaminants, including *Salmonella*, *E. coli*, and the norovirus, implicated in hundreds of outbreaks sickening thousands of people in dozens of states.<sup>4</sup>
- ▶ Imports—including green onions, strawberries, cantaloupe, and raspberries—have caused sizeable and sometimes lethal disease outbreaks. For example, thousands of Americans became ill after eating raspberries grown in Guatemala that were contaminated by the *Cyclospora* parasite. And three people died in Pennsylvania following an outbreak of hepatitis A linked to contaminated green onions from Mexico.<sup>6</sup>
- ▶ More illness results from each produce outbreak (an average of 48 cases) than from the average outbreak associated with poultry (30 cases), beef (27 cases), or seafood (10 cases).<sup>4</sup>
- ▶ Foodborne illness is costly. On November 14, 2003, the day before the FDA announced that Mexican green onions had caused an outbreak of hepatitis A in three southern states, the product was selling for \$18.30 per box. Faced with a steady drumbeat of bad news, prices dropped steadily, reaching \$5.73 per box on December 10th, a 72 percent decrease.<sup>7</sup> Huge losses were likewise reported by the spinach industry after the 2006 *E. coli* outbreak in California.<sup>8</sup>

Calls to improve the nation's food safety system in general, and its approach to fruits and vegetables in particular, have grown louder. How can the American consumer be protected?

## Agriculture on an Industrial Scale

The scale and complexity of the American food supply is vast. As an Institute of Medicine workshop summary described it: “Thousands of different food items – many of them produced in other countries – pass quickly through an elaborate system of processors, distribu-

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tors, and purveyors to a public with increasingly broad tastes and immense purchasing power. This “farm-to-fork” continuum is an extraordinarily complicated industrial infrastructure.”<sup>9</sup>

As Americans eat a more varied array of fruits and vegetables in greater quantities, and expect them to be available year-round, safety has come into sharper focus. Per capita produce consumption jumped by 36 percent from 1981 to 2000 and a typical grocery store, which carried 173 different kinds of fresh fruits and vegetable in 1987, now carries 558.<sup>10</sup>

Much of what is available has been imported from around the world. Sixty percent of all fresh fruits and vegetables consumed in the United States are grown elsewhere, and the U.S. Food and Drug Administration acknowledges that it “often has very limited information regarding conditions under which most food is produced in foreign countries.”<sup>10</sup>

Contamination of fruits and vegetables can occur at any point as produce is harvested, packed, processed, transported, distributed and prepared. On the farm, irrigation systems, inadequately treated manure, animals in the fields or packing areas, the equipment used to handle produce, and the refrigeration for storage are all potential gateways for pathogens. A worker’s careless habits of hygiene at any handling step can also be a culprit.<sup>11</sup>

“Fresh-cut” produce, the fastest growing segment of the industry, poses a special risk. The slicing, dicing, and shredding involved in preparing salad mixes, peeled baby carrots, broccoli and cauliflower florets, and other chopped vegetables provide an entry point for pathogens that may have been present on the surface. As the plant’s cellular structure breaks down, those contaminants proliferate in the high-moisture environment that results. Fresh-cut produce also creates a scenario in which a disease agent on a single food item can contaminate multiple packages.<sup>12</sup>

The fact that produce is consumed raw heightens the challenge. Many sources of contamination in meat and other foods can be eliminated by a “kill step,” such as high heat. There is no similar intervention for fresh fruits and vegetables.

### **A Fragmented Regulatory System**

The regulatory system in place to safeguard food in the United States is deeply fragmented, with some 15 federal agencies charged with administering at least 30 laws related to food safety.<sup>13</sup> The Food and Drug Administration has by far the broadest responsibilities, overseeing 80% of the food supply, including produce. Meat, poultry, and egg products fall under the jurisdiction of the U.S. Department of Agriculture.

The U.S. General Accountability Office (GAO) has designated federal oversight of food safety a “high-risk area,” a status intended to increase the priority and visibility of government programs in need of “broad-based transformation”:

Specifically, the patchwork nature of the federal food oversight system calls into question whether the government can plan more strategically to inspect food production processes, identify and react more quickly to outbreaks of contaminated food, and focus on promoting the safety and the integrity of the nation’s food supply... The system has caused inconsistent oversight, ineffective coordination, and inefficient use of resources.<sup>13</sup>

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The differing statutes that govern the FDA and the USDA promote sharply divergent approaches. Because products regulated by USDA must be approved before they are sold, thousands of USDA inspectors maintain a daily presence in U.S. meat and poultry processing plants, and in slaughterhouses, where they inspect every animal carcass.<sup>14</sup> The FDA has no comparable requirement for approving food before it is sold, and no mandate governing the frequency of its inspections at any point in the production process. FDA inspectors virtually never appear on farms, except after a disease outbreak, and their visits to domestic food plants may occur as seldom as once every ten years.<sup>15</sup>

Likewise, the USDA has a much more elaborate process for monitoring the imported food under its jurisdiction. Before a foreign country is allowed to sell meat to the United States, the USDA evaluates the legal framework governing its food system and conducts an extensive in-country assessment. Once granted, importation status is subject to annual review, and is not a *carte blanche* for food to enter the country. Every shipment of meat and poultry is, at a minimum, visually inspected at the American border and in FY 2006, the USDA physically examined or sampled about 15% of would-be imports.<sup>6</sup>

Almost none of that happens under the FDA's watch. There are no procedures for reviewing the food safety programs of foreign countries and almost no resources for monitoring foreign agricultural or food processing practices. The GAO estimates that the agency conducted on-site inspections of just 100 out of the 190,000 foreign food firms registered to export to the U.S. in 2007.<sup>16</sup> And the FDA visually inspected only 115,000 of the 8.9 million shipments of food that arrived on American shores in 2006 (about 1.3% of the total), and sent samples from an additional 20,662 shipments (0.2%) for laboratory analysis.<sup>17</sup>

The approaches taken by the two agencies are driven not only by statute but also by resources. Although the FDA is responsible for a much greater volume of food, the USDA spent far more on inspection and enforcement activities, dedicating about \$1.02 billion to food safety in FY 2008, compared with \$620 million for the FDA. More generous funding allowed USDA to place 7,600 inspectors and other staff in the field, compared to 1,700 at the FDA.<sup>18</sup>

Resource shortfalls at the FDA have been extensively documented.<sup>19</sup> Nominal increases in the budget of the Center for Food Safety and Applied Nutrition (CFSAN), where the bulk of food-related activities occur (\$407 million in 2004, compared to \$467 million in 2008), are not commensurate with its growing responsibilities or rising personnel costs. One result is that FTEs at the CFSAN have fallen from 3,082 to an estimated 2,700 during the same time period.<sup>20</sup>

In 2007, the FDA Science Board's Subcommittee on Science and Technology, an advisory body to the Commissioner comprised of experts from industry, academia, and government, assessed the consequences of all this. Noting that CFSAN had reduced its inspections of the food supply by 78 percent over the past 35 years, the subcommittee's report, *FDA Science and Mission at Risk*, bluntly stated:

FDA does not have the capacity to ensure the safety of food for the nation... The FDA's ability to provide its basic food system inspection, enforcement and rulemaking

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functions is severely eroded, as is its ability to respond to outbreaks in a timely manner and to develop and keep pace with the new regulatory science... The FDA cannot sufficiently monitor either the tremendous volume of products manufactured domestically or the exponential growth of imported products.<sup>21</sup>

### Setting Safety Standards for Produce

The statutes that govern FDA activities, developed in the early 20th century for a world of very different agricultural and food distribution practices, focus on the agency’s response *after* food safety challenges occur. Most proposals for reform promote a public health approach that instead targets prevention. That shifts the emphasis towards risk-based strategies designed to identify likely vulnerabilities in the supply chain *before* food reaches the consumer.

The FDA has begun moving in this direction for produce, with non-binding industry guidance designed to promote good agricultural practices. Documents developed for fresh fruits and vegetables in 1998, and for fresh-cut produce in 2008, provide broad recommendations for on-farm safety.<sup>22,12</sup>

But the guidance is at a “very high level of generality,” according to Michael Taylor, Research Professor at The George Washington University’s School of Public Health and Health Services. “The documents say things like ‘minimize the potential of microbial contamination from water used with fresh fruits and vegetables.’ But we need specific standards – what is an acceptable level of contamination? An FDA that is playing a leadership role would drive the science and the research needed to set more specific standards.”<sup>23</sup>

Two key trade associations – the United Fresh Produce Association and the Produce Marketing Association – are on record as supporting federally mandated standards for produce.<sup>24</sup> In calling for a commodity-specific, risk-based regulatory framework for produce safety, the industry groups cite the Leafy Greens Products Handler Marketing Agreement, developed in California, as a model.<sup>25</sup> That agreement commits companies to following specific practices, as spelled out by a collaborative board of scientists, food safety experts, farmers, shippers, and processors, and mandates government inspections to ensure compliance.

The Center for Science in the Public Interest has also called for action to enhance on-farm safety, urging Congress to mandate that the FDA:

- “Require all growers and processors to keep a written food safety plan based on the principles of preventive process control...
- “Develop specific, standardized and enforceable criteria” on such issues as water quality, the use of manure, and worker sanitation.
- Insist on package marking that will allow contaminated fruits and vegetables to be traced back to their source.
- Audit written plans at least once per growing season.<sup>26</sup>

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The Department of Health and Human Services has been less receptive to these kinds of regulations, according to an investigation by *The Wall Street Journal*.<sup>27</sup> The newspaper reported that FDA officials proposed stringent, industry-backed new rules for growers and processors at a February 2007 meeting that followed on the heels of an *E. coli* outbreak on spinach the previous fall. “The plan went nowhere after it got a cold reception from FDA’s parent agency,” wrote the *Journal*.

## Strengthening the Food Safety Infrastructure

Beyond on-farm measures to improve the safety of fruits and vegetables, the GAO, the National Academy of Sciences, federal legislators, advocacy groups, and the FDA itself have advanced broader strategies to shore up food safety.

**The FDA’s Food Protection Plan.** The FDA has announced plans to implement a Food Protection Plan intended to safeguard domestic and imported products with an integrated strategy built around three components:<sup>28</sup>

- ▶ Preventing foodborne contamination by promoting corporate responsibility; identifying food vulnerabilities and assessing risks; and expanding the use of effective mitigation.
- ▶ Intervening at critical points in the food supply chain with focused inspections; enhanced risk-based surveillances; and improved detection of signals that food may be contaminated.
- ▶ Responding swiftly when contamination does occur, including improving communication to the public and the industry.

While praising the “farm-to-fork” principles around which the Food Protection Plan is built, advocates say much more is needed, including more legal authority and resources for the FDA, and greater industry accountability.<sup>26, 29</sup>

**Overhauling prevention practices.** Hazard Analysis and Critical Control Points (HACCP) systems require companies to anticipate risks at critical junctures, and to develop specific strategies for controlling them. The FDA currently requires companies to develop HACCP systems for seafood and juice, and the USDA requires them for all meat and poultry products. The Center for Science in the Public Interest has called for HACCP mandates on other food producers as well.<sup>26</sup>

**Increasing FDA resources.** In June, 2008, just a few days after the FDA warned consumers not to eat certain types of tomatoes, the President amended his FY 2009 budget request to seek an additional \$275 million for the FDA, including \$125 million specifically dedicated to food safety.<sup>30</sup> Among many others calling for new funding, the FDA Science Board recommends steadily increasing the FDA’s budget for food-related activities so that it more than doubles to \$1.4 billion by 2013.<sup>31</sup>

**Updating FDA’s statutory authority.** New laws could codify the duty to prevent problems throughout the food system; strengthen FDA’s inspection mandate and authority;



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require the development of science-based standards for safe food; impose new requirements on foreign food producers and U.S.-based importers to implement preventive controls that meet U.S. standards; and provide more enforcement tools to the FDA, including mandatory recall and “traceback” systems that allow contamination sources to be identified more quickly.<sup>18,26,29</sup>

**Creating a new food safety agency.** Many proposals for a federal umbrella agency with overarching authority for food safety have been floated over the years. The GAO has urged that a blue-ribbon panel, perhaps under the auspices of the National Academy of Sciences, be convened to “conduct a detailed analysis of alternative organizational food safety structures.”<sup>32</sup> Bills to create a Food Safety Administration have been introduced in both houses of Congress, although they have not moved out of the committees that are considering them.<sup>33</sup>

Most of these proposals will take time to be debated and implemented. As members of the FDA Science Board’s Subcommittee on Science and Technology point out, “the years of neglect cannot be wiped away instantly.”<sup>34</sup> Nonetheless, there is a consensus that steps must be taken to ensure that when American consumers sit down to eat a salad, they can feel confident about its safety.

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