

ISSUE BRIEF



TRUST FOR AMERICA'S HEALTH IS A NON-PROFIT, NON-PARTISAN ORGANIZATION DEDICATED TO SAVING LIVES BY PROTECTING THE HEALTH OF EVERY COMMUNITY AND WORKING TO MAKE DISEASE PREVENTION A NATIONAL PRIORITY.

APRIL 2008

PREVENTING EPIDEMICS.  
PROTECTING PEOPLE.

# Fixing Food Safety:

## PROTECTING AMERICA'S FOOD SUPPLY FROM FARM-TO-FORK

Approximately 76 million Americans -- one in four -- are sickened by foodborne disease each year. Of these, an estimated 325,000 are hospitalized and 5,000 die.<sup>1</sup> Medical costs and lost productivity due to foodborne illnesses are estimated to cost \$44 billion annually.<sup>2, 3</sup> Major outbreaks can also contribute to significant economic losses in the agriculture and food retail industries.

**Experts estimate that most foodborne illnesses could be prevented if the right measures were taken to improve the U.S. food safety system.**

“FOODBORNE ILLNESSES ARE DEFINED AS DISEASES, USUALLY EITHER INFECTIOUS OR TOXIC IN NATURE, CAUSED BY AGENTS THAT ENTER THE BODY THROUGH THE INGESTION OF FOOD. EVERY PERSON IS AT RISK OF FOODBORNE ILLNESS.”<sup>4</sup>

-- World Health Organization

A 2007 public opinion poll conducted by the Trust for America's Health (TFAH) found that 67 percent of Americans are worried about food safety.<sup>5</sup> In fact, concerns about food safety and food contamination rank higher than Americans' concerns about pandemic flu, biological or chemical terror attack, and natural disasters, like Hurricane Katrina.<sup>6</sup>

The recent *E. coli* contamination of spinach and lettuce, concerns about the safety of farm-raised fish from China, and alarming reports of cattle slaughter practices have

heightened anxieties about the vulnerability of the nation's food supply.

Studies from the National Academy of Sciences (NAS), the Institute of Medicine (IOM), the U.S. Government Accountability Office (GAO), and the FDA Science Board, which serves as an advisory committee to the U.S. Food and Drug Administration (FDA), have all raised serious concerns about the system that is responsible for keeping the country's food safe.<sup>7, 8, 9</sup>

The U.S. food safety system has not been fundamentally modernized since its incep-

tion over 100 years ago. Current food safety polices are largely based on early twentieth century laws written to deal with concerns that rarely pose significant threats today because of changes in farming and processing practices and technologies.<sup>10</sup>

These outdated concerns receive the bulk of the national resources devoted to food safety, and emerging threats are often only addressed on a piecemeal basis in the aftermath of a crisis. The result is a fractionalized system focusing on antiquated threats, instead of a strategic approach to protecting the nation's food supply through state-of-the-art technologies, practices, and policies.

Obsolete laws, misallocation of resources, and inconsistencies among major food safety agencies underlie watchdog groups' calls for a "fundamental re-examination of the

federal food safety system."<sup>11</sup> In fact, a 2007 GAO report concluded that the federal oversight of food safety is now one of the government's "high risk" programs.

This report provides an overview of the current problems in U.S. food safety and recommended solutions. Fixing food safety in the U.S. will require a collaborative effort by food producers, processors, distributors, retailers, and consumers, combined with strong leadership from the federal, state, and local government.

Sections of this report include:

- I. Top Concerns with the Government's Food Safety System;**
- II. An Overview of Foodborne Disease Threats; and**
- III. Recommendations**

## I. Top Concerns With the Government's Food Safety System

While most of the food Americans eat each day is safe, according to experts, the chance for getting seriously ill needs to be improved. In fact, one in four Americans will experience food borne illness on an annual basis.

Recent outbreaks combined with vulnerabilities identified by the leading experts, including reports from the GAO, NAS, IOM, and FDA's Science Board serve as a

wake up call for policymakers that problems in the U.S. food safety system must be addressed now before they become worse.

The "food safety system" includes the government and the food industry. The food industry produces, processes, distributes, and sells food, while the government serves a regulatory function.

### THE GOVERNMENT'S GOALS IN THE FOOD SAFETY SYSTEM ARE TO:

- Reduce foodborne disease in the U.S.;
- Maintain public confidence in food safety and the food supply; and
- Exert international leadership on food safety.

Most food producers and food companies take safety issues very seriously. Historically, much of the innovation for improving food safety has come from within the food industry. However, food producers, processors, and retailers operate in markets and allocate their resources in response to market pressures and incentives.

Government regulatory agencies exist to balance the public interest with market forces, taking responsibility for ensuring that safety comes first. The role of government is to set standards on behalf of the public and hold companies accountable for meeting the standards.

Food safety requires strong public-private partnerships. For regulation to be effective, it must realistically address current industry practices and structures. This includes keeping pace with advances and changes in the industry.

Currently, however, there are a number of **obstacles** that impair the ability of the government to carry out these functions effectively. Key problems that experts have identified include:

- **Inadequate Federal Leadership, Coordination, and Resources;**
- **Outdated Laws and Policies; and**
- **Limited Federal, State, and Local Coordination.**

Today's U.S. laws and policies do not meet the need for a food safety system that protects the nation's food supply from farm-to-fork.

A **comprehensive system** would use strategic inspection practices and state-of-the-art surveillance to prevent disease outbreaks and

harmful contaminants in meat, poultry, seafood, produce, and processed foods that could lead to human illness.

A modern, successful food safety strategy must:

- Make prevention of food safety problems the central focus of the system;
- Update priorities so resources are devoted to the areas of highest hazard and risk;
- Develop uniform best practices and standards;
- Invest in research to continually update practices and standards to keep pace with changes in the food supply and the industry; and
- Shift from the current outdated inspection practices that focus on end products and limited inspections at processing plants to instead strategically inspect foods throughout the food production and processing processes via "control points."

## **Inadequate Federal Leadership, Coordination and Resources**

According to the 2007 GAO report, "the federal oversight of food safety is fragmented, with 15 agencies collectively administering at least 30 laws related to food safety."<sup>12</sup>

The 4 agencies with the largest roles include the **U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN), Environmental Protection Agency's (EPA) Office of Prevention, Pesticides and Toxic Substances (OPPTS), and U.S. Centers for Disease Control and Prevention's (CDC) Food Safety Office.**

The other agencies involved include:<sup>13</sup>

- FDA's Center for Veterinary Medicine;
- Department of Commerce's National Marine Fisheries Service (NMFS);
- Department of Treasury's Customs Service;

- National Institutes of Health (NIH);
- USDA's Animal and Plant Health Inspection Service (APHIS);
- USDA's U.S. Codex Office;
- USDA's Agricultural Marketing Service (AMS);
- USDA's Agricultural Research Service (ARS);
- USDA's Cooperative State Research, Education, and Extension Service (CSREES);
- USDA's Economic Research Service (ERS); and
- USDA's Grain Inspection, Packers and Stockyard Administration (GIPSA).

None of the agencies has ultimate authority or responsibility, so accountability for the total system is limited. No one person in the

federal government has the oversight and accountability for carrying out comprehensive, preventive strategies for reducing foodborne illness.

The nation lacks an integrated, holistic approach to ensuring food safety. The government's ability to play an effective role in preventing foodborne illness is severely undermined by this fragmentation of food safety responsibilities among many agencies, each of which operates more or less independently with often differing regulatory

approaches. No agency has statutory authority or a practical mandate to forge an integrated strategy that puts research, regulatory, and educational tools of government to work in a coherent way to minimize risks.

In addition, according to GAO, limited funds restrict the capabilities of food safety agencies. The current funds are often not strategically used to focus on the greatest threats, because they are supporting the outdated legacy systems and practices.<sup>14</sup>

### SEGMENTED RESPONSIBILITIES: LEAD AGENCIES

**FDA's CFSAN:** FDA has responsibility for overseeing the safety of all domestic and imported food with the exceptions of:

- Meat, poultry, and frozen, dried, and liquid eggs, which are under the authority of USDA's FSIS.<sup>15</sup>

**USDA's FSIS:** The mission of FSIS is to serve as "the public health agency in the U.S. Department of Agriculture responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged."<sup>16</sup>

**CDC's Office of Food Safety:** Surveillance and identification of foodborne illness outbreaks are among the Food Safety Office's primary responsibilities. "The role of the Foodborne Disease Outbreak Response and Surveillance Team (ORST) is to conduct national surveillance on foodborne infections and outbreaks of foodborne illness and to assist in the investigation of foodborne disease outbreaks that take place in the United States or affect its population."<sup>17</sup>

**EPA's OPPTS:** The Office of Prevention, Pesticides and Toxic Substances (OPPTS) is charged with protecting public health and the environment from potential risk of pesticides and toxic chemicals. The agency "regulates the use of all pesticides in the United States and establishes maximum levels for pesticide residues in food, thereby safeguarding the nation's food supply."<sup>18</sup>



## Resource Shortages

“THE PRESIDENT’S [FY 2009] BUDGET BARELY GIVES FDA ENOUGH FUNDS TO OPERATE AT LAST YEAR’S LEVEL, AND DOES LITTLE TO MAKE UP FOR THE STEADY LOSS OF STAFFING THAT THE AGENCY HAS ENDURED FOR THE PAST DECADE. INDEED, THIS OVERSTRETCHED AGENCY HAS LOST 1,000 STAFFERS OVER THE PAST 10 YEARS IN THEIR FOOD, DRUG AND MEDICAL DEVICE SAFETY PROGRAMS.”<sup>19</sup>

-- Mark McClellan, former FDA commissioner and administrator of the Centers for Medicare and Medicaid Services

A series of reports have highlighted the problems resulting from chronic underfunding of U.S. food safety efforts, particularly those run by FDA.

A 2008 report by the FDA Science Board’s Subcommittee on Science and Technology found that continual underfunding of FDA has resulted in:

*A plethora of inadequacies that threaten our society – including but not limited to, inadequate inspections of manufacturers, a dearth of scientists who understand emerging new science and technologies, inability to speed the development of new therapies, an import system that is badly broken, a food supply that grows riskier each year, and an information infrastructure that was identified as a source of risk in every FDA Center and function.*<sup>20</sup>

In the past three years alone, CFSAN has lost 20 percent of its science staff and 600 inspectors.

The Subcommittee’s report urged Congress to increase FDA’s food safety base by \$755 million over 5 years, which includes \$350 million to strengthen imports and \$100 million to strengthen FDA oversight of nutritional supplements, animal feed, and cosmetics.

In addition to allocating more federal dollars to food safety, some food safety experts have called on Congress to authorize FDA to collect food manufacturer and producer registration fees and import fees. These fees would provide a steady base of revenue for food safety initiatives.<sup>21</sup>

### Misaligned Priorities and Resources

	FDA’s Food Safety Programs	USDA’s Food & Agriculture Safety Programs
<b>Scope of Responsibility</b>	Experts estimate that 85 percent of known foodborne illness outbreaks are associated with FDA-regulated food products.	Experts estimate less than 15 percent of known foodborne illness outbreaks are associated with USDA-regulated food products
<b>Funding for Food Safety Activities</b>	<ul style="list-style-type: none"> <li>▲ Fiscal year (FY) 2007: \$563 million<sup>22</sup></li> <li>▲ FY 2008: \$619 million</li> <li>▲ Proposed FY 2009: \$661 million</li> </ul>	<ul style="list-style-type: none"> <li>▲ FY 2007: \$1.02 billion<sup>23</sup></li> <li>▲ FY 2008: \$1.07 billion</li> <li>▲ Proposed FY 2009: \$1.09 billion</li> </ul>
<b>Number of Field Staff or Inspectors</b>	1,700	7,600

\*Note: The increases in funding for FDA food safety programs over the past 3 years have barely kept up with inflation, which means that these programs have had no capacity to address the increasing challenges in food safety.

## IMPORTED FOOD

According to USDA's Economic Research Service, approximately 15 percent of the nation's food supply is imported.<sup>24</sup> However, the country relies more heavily on imports for certain types of foods. For instance, 60 percent of the fresh fruits and vegetables consumed in the U.S. are imported, as is 75 percent of the seafood Americans consume.<sup>25</sup>

Currently, FDA and the U.S. Customs Border and Protection enter data on all U.S. food imports into a database system that electronically screens paperwork on shipments to determine whether their contents might pose a risk to the public's health. Imported goods that trigger concern can be physically inspected, but due to limited resources, FDA only inspects approximately one percent of shipments.

In addition, of the thousands of foreign food manufacturing facilities that export food to the U.S., FDA only conducts approximately 100 inspections a year. The current paradigm for protecting foreign foods places the responsibility for catching problems onto FDA through infrequent and inadequate inspections, instead of setting up a more strategic regulatory system where FDA sets standards for food processors that they can then hold industry accountable for meeting those standards.

The majority of U.S. food imports go straight to Americans' plates without any domestic processing and related FDA oversight. Given that FDA "often has very limited information regarding conditions under which most food is produced in foreign countries," this may mean that these foods pose a higher-risk to the consumer.<sup>26</sup>

In light of growing concerns regarding the safety of imported goods, the Bush Administration released its **Import Safety Action Plan** in November 2007. The Plan is integrated with the FDA's **Food Protection Plan**, also released in November. The Food Protection Plan discusses the need to build safety into the entire food supply chain -- including imported foods. The Plan directs FDA to "work with foreign governments, which have a greater ability to oversee manufacturers within their borders to ensure compliance with safety standards."<sup>27</sup>

The Plan, however, fails to call for accountability on the part of the food importers to ensure that preventive action is taking place in the country of origin. According to Michael Taylor, former FDA Deputy Commissioner for Policy, "FDA will never have enough resources to police and ensure the safety of imports without harnessing the expertise and efforts of the private sector and making a U.S.-based entity legally accountable for ensuring prevention is 'built-in' for imports, just as it should be for domestically produced food."<sup>28</sup>

Until food importers are legally accountable for assuring that foreign growers, producers and processors are shipping goods to the U.S. that meet U.S. food safety standards, it is unlikely that the quality and safety of U.S. food imports will improve.

## FOOD DEFENSE

**Agroterrorism** is the “deliberate introduction of an animal or plant disease with the goal of generating fear, causing economic losses, and/or undermining stability.”<sup>29</sup>

The deliberate contamination of our nation’s food supply is a serious threat that could have a quick, widespread impact. In January 2004, the Bush Administration responded to this very real threat with *Homeland Security Presidential Directive/HSPD- 9*, “Defense of United States Agriculture and Food.”<sup>30</sup> This directive calls for a coordinated national approach to countering threats to the food supply. HSPD-9 directed U.S. agencies to protect the food supply by:

- Identifying and prioritizing sector-critical infrastructure and key resources for establishing protection requirements;
- Developing awareness and early warning capabilities to recognize threats;
- Mitigating vulnerabilities at critical production and processing nodes;
- Enhancing screening procedures for domestic and imported products; and
- Enhancing response and recovery procedures.<sup>31</sup>

The directive tasked the U.S. Department of Homeland Security (DHS) with leading national food defense efforts,

while working in coordination with USDA, U.S. Department of Health and Human Services (HHS), and EPA.

Despite increased responsibility and concern, FDA has not received additional funding to support food-related anti-terrorism activities, and USDA has only received an additional \$150 million.

One tool used by FDA and FSIS is *CARVER + Shock*, a computer program that assesses the vulnerabilities within a food supply system and infrastructure to an attack.<sup>32</sup> Interested parties work with food safety officials on a voluntary basis to identify weaknesses in their systems. Once these vulnerabilities are identified, food growers, producers and manufacturers can “focus resources on protecting the most susceptible points in their system.”<sup>33</sup> Food safety officials, however, currently have no means to ensure that farmers and manufacturers implement measures to protect the food supply.

In fact, the November 2007 FDA *Food Protection Plan* stated that additional legislative authority is needed to give FDA the power to “implement measures solely intended to protect against the intentional adulteration of food by terrorists or criminals.”<sup>34</sup>

## RECENT THREATS, EXISTING VULNERABILITIES

### Contaminated Wheat Gluten

Americans witnessed the real danger of deliberate food contamination in early 2007, when thousands of cats and dogs were sickened and died after ingesting pet food that had been contaminated with **melamine**, a nitrogen-rich chemical used to make plastic and sometimes as a fertilizer.<sup>35</sup> Although U.S. officials did not call this contamination malicious or agroterrorist in nature, some experts believe it was done for economic gain by exporters who substituted wheat gluten with melamine.<sup>36</sup> A U.S. federal grand jury recently indicted 2 Chinese businessmen and their firms, along with a U.S. company and its president and chief executive officer, for their roles in a scheme to import products purported to be wheat gluten into the U.S. that were contaminated with melamine.<sup>37</sup>

### Botulism

Botulism is a “paralytic illness caused by a nerve toxin that is produced by the bacterium *Clostridium botulinum*.”<sup>38</sup>

Although botulism is a naturally occurring toxin, there are serious concerns that it could be used as a weapon. A July 2005 issue of the *Proceedings of the National Academy of Sciences* outlined a relatively easy and potentially devastating method using botulism to kill thousands of people and disrupt the U.S. economy. The study, conducted by Stanford Graduate School of Business Professor Lawrence M. Wein, determined that “a mere 4 grams of botulinum toxin dropped into a milk production facility could cause serious illness and even death for 400,000 people in the United States.”<sup>39</sup>

The report recommended that FDA make current volunteer safety guidelines mandatory, “such as requiring that milk tanks and trucks be locked and that 2 people be present when milk is transferred from one stage of the supply chain to the next. Before releasing milk into silos, milk-tank truck drivers should be required to employ a new 15-minute test that can detect the 4 types of toxins associated with human botulism.”<sup>40</sup>

## Outdated Laws and Policies

A number of problems are created by the current food safety laws being out of date. Resources and attention are being spent on food safety issues that are no longer significant threats to our food supply, but these practices are required under current law and

policies. The current statutes require wasting resources on antiquated activities. And, while most food safety resources are going to support outdated problems, new problems are not receiving adequate attention or funds.

### OUTDATED PRACTICES AT FSIS, REQUIRED BY LAW

FSIS spends most of its resources inspecting every beef and pork carcass in ways not too different from practices used 100 years ago, based on the agency's mandate from Congress. Current laws, in effect since 1906, require carcass-by-carcass and daily inspections of meat and poultry to check for animal diseases, although the health of animals coming to slaughter has greatly improved in modern times due to changes in agricultural practices and technologies.

While the agency focuses virtually all of its resources and efforts on slaughter and processing plants, it lacks many modern tools necessary to improve public health protection, such as clear legal authority to set binding standards and practices for reducing pathogen contamination in raw products; it lacks any legal authority to act on the farm, where some of the most significant meat and poultry safety hazards originate; and it is given few resources to oversee what happens to the safety of products after they leave inspected plants, such as during transport, storage and commercial handling at retail.

For example, FSIS spends approximately \$1 billion to regulate meat, poultry, and processed egg products, even though many of these regulation practices are considered obsolete. In fact, about 3,000 of the 7,600 USDA inspectors (and a commensurate share of the \$1 billion spent on USDA inspections) are currently devoted to a poultry slaughter inspection practice that has been considered obsolete for more than 20 years. The practice involves 2 seconds of visual inspection for every one of the 8 billion chickens produced annually in the U.S. Modern agricultural practices make the need for this type of inspection obsolete, while no inspection practice has been developed to address the current health threat from poultry products -- bacteria that cause disease, including Salmonella.

### FDA'S CFSAN NO MATCH FOR MODERN THREATS

Current statutes that provide the foundation for FDA's food safety functions date back to 1906 and 1938. Unlike USDA's inspection mandates, FDA's law sets forth a system that is largely reactive to problems prevalent in an early twentieth century agricultural and food system, such as adulteration and misbranding. It empowers FDA primarily to act only after food safety problems occur, rather than prevent them.

These laws permit FDA to inspect processing plants and warehouses and remove harmful or potentially harmful food from the market through court enforcement action and to block imports if it detects potential problems. FDA's functional powers and effectiveness are limited, however, because:

- Congress has not provided the agency with a modern, public health mandate to prevent foodborne illness;
- Congress has not updated the agency's legal tools to meet the challenges of a high-tech, globalized food supply; and
- Congress has not provided the funding stream FDA needs to carry out research, standard setting, and inspection at a level commensurate with today's food safety challenge.

*"The near unanimity about the agency's weaknesses -- among Congressional Democrats and Republicans, industry and consumer groups, and authoritative independent analysts -- is striking. But hand wringing is not enough. The FDA desperately needs an infusion of money and talent."*<sup>41</sup>

-- New York Times Editorial



## PIECEMEAL MODERNIZATION: THE EXAMPLE OF HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP)

Despite the statutory and resource constraints under which they operate, FSIS and FDA have made efforts to modernize their food safety programs. The most prominent example of this is the institution of Hazard Analysis and Critical Control Points (HACCP) as a regulatory standard for some sectors of the food system.

HACCP is a food industry-developed, science-based approach that focuses on identifying and minimizing hazards throughout the production and processing system, rather than relying solely on the traditional techniques of food inspection, which focus on end-product testing and are largely reactive rather than preventive. HACCP controls are designed, validated and implemented to prevent or minimize potential hazards, and these controls are continuously verified and monitored by the food processor and subject to inspection by regulatory agency.

The HACCP system can be adapted to fit the different production and processing procedures of different types of foods. FDA requires HACCP for seafood (1995) and juice (2001), while FSIS requires it for meat and poultry (1996).<sup>42</sup>

## EXAMPLES OF THE NEED FOR MODERNIZING AND INTEGRATING THE FOOD SAFETY SYSTEM

- *E. coli* O157:H7 originates in the gut of cattle and other mammals but, with manure as its vehicle, spreads throughout the food supply, contaminating meat, fresh produce, juice, and other foods. FSIS is responsible for inspecting meat and poultry plants but is not empowered to deal directly and preventively with the problem on the farm. FDA regulates produce but has ambiguous legal authority and no clear mandate to set safety standards for animal producers and growers of fruits and vegetables. CDC works with state and local health departments to investigate outbreaks but cannot act preventively.
- FDA regulates frozen pizza. However, if the pizza is topped with 2 percent or more of cooked meat or poultry, then FSIS is the regulatory agency. Inspections at pizza production facilities follow 2 sets of guidelines, one issued from FDA and one from USDA.<sup>43</sup> And, FSIS inspects plants making pepperoni pizza every day, after it has already inspected the manufacture of the pepperoni on a daily basis and the slaughter of every animal used to make the pepperoni, while FDA inspects cheese pizza plants on average once every 10 years.<sup>44</sup>
- A decade ago, concerns about produce safety became prominent, as federal, state, and local health officials began seeing more frequent produce-related outbreaks. FDA responded by issuing in collaboration with USDA a guidance document outlining general principles for minimizing microbial food safety hazards in fresh fruits and vegetables.

This included guidance on “good agricultural practices” for managing manure, irrigation water, worker hygiene and other safety-related practices on the farm, as well as sanitation during processing and transportation. Experts considered these recommended principles sound but limited. In many cases, the guidance lacked the specificity required to make them actionable, in part because not enough research has been done to establish credible and effective criteria or performance standards for implementing the broad principles. While many producers and processors likely made good faith efforts to comply with FDA’s guidance, it has failed to drive widespread change.

## HOW IS THE SAFETY OF OUR FOOD MONITORED FOR DISEASE OUTBREAKS?

The systems used to monitor the safety of the nation's food supply is a patchwork of various government agencies at the federal, state, and local level working largely independently, with limited coordination, alongside food safety practitioners from the private sector, public interest groups, and academia -- all of whom collect and use food safety information for a wide variety of purposes.

This group of diverse actors includes, but is not limited to:

- FDA, CDC, USDA, and EPA at the federal level;
- Departments of health, agriculture and the environment and public health laboratories across the 50 states;
- Over 3,000 local health departments and retail inspection agencies;
- Millions of agricultural producers; hundreds of thousands of food processors, retailers and restaurants; and dozens of associations representing various segments of the food and agriculture industry;
- A wide range of government and university-based food safety researchers; and
- An active community of consumer representatives and organized victims of foodborne illness.

The fragmented nature of the current food safety surveillance system complicates efforts by food safety regulators to share data in a timely and efficient manner. These challenges include, but are not limited to:

- The analysis of data on a variety of subjects, ranging from foodborne illness disease rates to the cost of preventive action.
- Data collection that is spread across various disciplines including public health epidemiology, medical research, microbiology, risk analysis, and economics.
- Multiple actors in this complex food safety surveillance system that are only loosely affiliated with one another and are not accountable to any one oversight body or agency.
- A surveillance system that is designed to respond to foodborne illness outbreaks, rather than gather the data that would help government and industry design effective prevention strategies.
- Institutional issues that impede data sharing among government agencies and private sector. For example, government agencies face legal restrictions on data sharing. In the event that legal restrictions do not hinder data sharing, agencies may be reluctant to share data they consider to be their own. For the private sector there are competitive business reasons for firms to withhold food safety information, while university-based researchers may collect a lot of data but only publish bits and pieces of their results.

There are no easy solutions to these barriers. However, initial steps to address these issues include a recognition that a problem exists and buy-in from key leaders at relevant agencies to do something about this problem. Once there is support from the leadership at the government agencies, the next steps include legislative action to: 1) mandate coordinated data collection among government agencies, and 2) improve the collection of and accessibility to data in a timely and efficient manner. At the same time, action should be taken by leading food safety officials to build a network-of-networks among all actors in the food safety system, including private sector and academia.

## Inadequate Federal, State, and Local Collaboration

The current decentralized governmental food safety system means state and local governments have jurisdiction for food safety issues in their communities beyond those that are directly regulated and monitored by federal agencies.

In lieu of official required national standards, 2 voluntary efforts have been developed to try to create more uniform standards and practices as well as enhancing the efficiency and effectiveness of the nation's food safety system: FDA's **Food Code** and a **Voluntary National Retail Food Regulatory Program**.

FDA's Food Code is intended to serve as a model "that assists food control jurisdictions at all levels of government by providing them with a scientifically sound technical and legal basis for regulating the retail and food service segment of the industry (restaurants and grocery stores and institutions such as nursing homes)."<sup>45</sup> The Food Code does not attempt to regulate food processors or growers.

The Food Code is updated periodically to provide the most current food safety provisions to state and local agencies. FDA gets

feedback from many organizations on its code, including the Conference for Food Protection, a group of state and federal officials, industry representatives, consumer groups, and academic officials that meets every 2 years to recommend Code changes. The Conference seeks to balance the interests of industry with those of food safety officials and consumer groups. Despite this, food safety advocates have criticized FDA for relying too heavily on industry at the expense of consumer groups.

Many states revise and update their own codes after FDA publishes a new version of the Food Code, although this is done on a voluntary basis. The most recent version of the Food Code was issued in 2005 and the next version is due out in 2009.

All but four states have adopted codes patterned after the 1993, 1995, 1997, 1999, 2001 or 2005 versions of the Food Code. The four states that have not adopted any version of the Food Code – California, Kentucky, Maryland, and North Carolina – are taking steps towards adopting the voluntary standards.



STATUS OF STATE FOOD CODE ADOPTIONS						
State	2005	2001	1999	1997	1995	1993
Alabama		✓				
Alaska	✓					
Arizona			✓			
Arkansas		✓				
California						
Colorado		✓				
Connecticut			✓	✓		
Delaware			✓			
District of Columbia			✓			
Florida		✓				
Georgia		✓				
Hawaii				✓		
Idaho		✓				
Illinois					✓	
Indiana		✓				
Iowa				✓		
Kansas			✓			
Kentucky						
Louisiana			✓			
Maine			✓			
Maryland						
Massachusetts			✓			
Michigan			✓			
Minnesota					✓	
Mississippi	✓					
Missouri			✓			
Montana			✓			
Nebraska		✓				
Nevada						✓
New Hampshire		✓				
New Jersey		✓				
New Mexico			✓			
New York			✓			
North Carolina						
North Dakota		✓				
Ohio		✓				
Oklahoma		✓				
Oregon			✓			
Pennsylvania		✓				
Rhode Island						✓
South Carolina						✓
South Dakota					✓	
Tennessee			✓			
Texas		✓				
Utah			✓	✓		
Vermont		✓				
Virginia			✓			
Washington		✓				
West Virginia			✓			
Wisconsin	✓	✓				
Wyoming	✓					

Source: FDA's Center for Food Safety and Applied Nutrition<sup>46</sup>

The FDA, in collaboration with federal, state, and local regulatory agencies, industry, trade associations, academic, and consumers, has also established a **Voluntary National Retail Food Regulatory Program**. The program's goal is to reduce or eliminate the occurrence of illnesses and deaths from food produced

or handled at the retail level.<sup>47</sup>

The program seeks to provide state and local food regulatory officials with science-based measures of performance that will lead to more effective and uniform regulation of the food industry.

Participation in the program is voluntary. To be part of the program, the jurisdiction must carry out an initial self-assessment of its retail food safety program within 12 months of

enrollment in the program, conduct self-assessments every 36 months after that, and submit to verification audits by outside parties.

### Status of States Enrolled in Voluntary National Retail Regulatory Program

State	State Agency Enrolled	Self-Assessment Completed	Achieved at least 1 of 9 Standards Based on Self-Assessment	Achievement Verified by External Evaluator
Alabama	✓	✓		
Alaska	✓	✓	✓	✓
Arizona*	✓			
Arkansas	✓	✓	✓	
California	✓	✓	✓	
Colorado	✓	✓		
Connecticut	✓	✓	✓	
Delaware	✓			
District of Columbia	✓			
Florida	✓	✓	✓	✓
Georgia	✓	✓	✓	✓
Hawaii	✓	✓	✓	
Idaho	✓	✓	✓	✓
Illinois	✓	✓	✓	
Indiana				
Iowa	✓	✓	✓	✓
Kansas	✓	✓	✓	✓
Kentucky				
Louisiana				
Maine				
Maryland	✓	✓	✓	
Massachusetts	✓	✓	✓	✓
Michigan	✓	✓	✓	✓
Minnesota	✓	✓	✓	
Mississippi	✓	✓	✓	
Missouri	✓	✓	✓	✓
Montana	✓	✓	✓	
Nebraska	✓	✓	✓	
Nevada	✓	✓	✓	
New Hampshire				
New Jersey	✓			
New Mexico	✓	✓	✓	
New York				
North Carolina	✓	✓	✓	✓
North Dakota				
Ohio	✓	✓	✓	
Oklahoma	✓	✓	✓	
Oregon	✓	✓	✓	✓
Pennsylvania	✓	✓	✓	
Rhode Island	✓	✓	✓	
South Carolina				
South Dakota	✓			
Tennessee	✓			
Texas	✓	✓	✓	✓
Utah	✓			
Vermont				
Virginia	✓			
Washington				
West Virginia	✓			
Wisconsin	✓	✓	✓	
Wyoming	✓	✓	✓	

Source: FDA's Center for Food Safety and Applied Nutrition.<sup>18</sup> Note: \*No state-wide agency is enrolled in the program. However, 11 of 15 counties in Arizona are enrolled. Of the 11 counties, 5 have had their achievements verified by an outside auditor.

## STANDARDS FOR THE VOLUNTARY NATIONAL RETAIL FOOD REGULATORY PROGRAM

1. Regulatory Foundation
2. Trained Regulatory Staff
3. Inspection Program Based on HACCP Principles
4. Uniform Inspection Program
5. Foodborne Illness and Food Security Preparedness and Response
6. Compliance and Enforcement
7. Industry and Community Relations
8. Program Support and Resources
9. Program Assessment

## II. An Overview of Foodborne Disease Threats

### AGRICULTURE INDUSTRY AND FOOD SAFETY

- Agriculture today is primarily based on a large-scale agribusiness model. As consolidation (shifting away from the single-family farm) has taken place, certain livestock or crops are increasingly centralized in specific regions and even certain farms. For example in 1990, 74 percent of all wet corn (a popular livestock feed) was milled by the top 4 processing firms in only 15 facilities.<sup>49</sup> Five million head of cattle were fattened by the top 30 feedlots in 1998.<sup>50</sup> And 83 percent of all beef in the U.S. was processed by the largest 5 beef packers in 32 plants.<sup>51</sup> This centralization can facilitate the spread of disease because there is significant contact between livestock or crops, which can lead to a single infected animal or contaminated product causing widespread damage.
- As specialized centers of activity have developed throughout the nation, livestock rearing has changed from a localized process to a geographically dispersed effort. An animal is most likely born on a breeding farm, at which point it is shuttled to a different farm for fattening, and then transported again for slaughter and processing. The carcass may even be sent to another state for disposal.<sup>52</sup> In addition, animals are frequently shown or displayed at regional shows or auctions. This mingling of animals from various regions of the country, as well as the widespread distribution networks of the industry, can accelerate the spread of disease.
- Many countries have adopted sophisticated systems of animal identification and tracking that are important to identify and isolate sources and spread of diseases in an animal population. However, the U.S. is dramatically behind in this effort, promoting a voluntary system that is decades behind some of our trading partners, and provides inadequate protection to the nation's farmers and consumers.

### FDA'S MAJOR CONCERNS RELATED TO FOOD PROCESSING, PACKAGING, TRANSPORTATION, AND PREPARATION<sup>53</sup>

- Biological pathogens (e.g., bacteria, viruses, parasites)
- Naturally occurring toxins (e.g., mycotoxins, ciguatera toxin, paralytic shellfish poison)
- Dietary supplements (e.g., ephedra)
- Pesticide residues
- Toxic metals (e.g., lead, mercury)
- Decomposition and filth (e.g., insect fragments)
- Food allergens (e.g., eggs, peanuts, wheat, milk)
- Nutrient concerns (e.g., vitamin D overdose, pediatric iron toxicity)
- Dietary components (e.g., fat, cholesterol)
- Radionuclides
- TSE-type diseases (e.g., chronic wasting disease in deer)
- Product tampering

## HIGH MERCURY LEVELS IN SEAFOOD

Although mercury occurs naturally in the environment, it is also released into the air through industrial pollution. The mercury then falls from the air and can accumulate in streams and oceans, becoming methylmercury. Fish absorb the methylmercury as they feed in these waters and over time it builds up in them. Some fish, particularly larger fish such as swordfish and king mackerel, are more susceptible to high levels of methylmercury based on what they eat.<sup>54</sup>

According to EPA it has been demonstrated that high levels of methylmercury in the bloodstream of unborn babies and young children may harm the developing nervous system, making the child less able to think and learn.<sup>55</sup> More recent studies have suggested a link between mercury and poor health outcomes in adults, including increased risk of cardiovascular disease and neurological symptoms.<sup>56</sup>

In 2004, FDA and EPA warned women who might become pregnant and children to limit their consumption of canned and fresh tuna to 6 ounces a week due to high mercury levels. In fact, a recent analysis by *The New York Times* and the Environmental and Occupational Health Sciences Institute in New Jersey found levels of mercury in tuna sushi far higher than the amount typically found in canned tuna.<sup>57</sup>

Although FDA officials have not commented on these findings, the agency has said it is reviewing its seafood mercury warnings.

## EXAMPLES OF POTENTIAL DISEASE THREATS

### *E. coli* 0157:H7

In the late summer and early fall of 2006, nearly 200 people became sick and at least 3 died due to *E. coli* contamination in spinach. It is possible that even more illnesses or deaths were related to the outbreak as “officials believe that for every *E. coli* case reported, 20 go unreported.”<sup>58</sup> Illnesses associated with *E. coli* often also go undiagnosed.<sup>59, 60</sup>

“*Escherichia coli* 0157:H7 (*E. coli*) is a leading cause of foodborne illness.”<sup>61</sup> *E. coli* is most contracted through “eating undercooked, contaminated ground beef... (or) eating contaminated bean sprouts or fresh leafy vegetables such as lettuce and spinach. Person-to-person contact in families and child care centers is also a known mode of transmission.”<sup>62</sup>

The deaths and illnesses from the spinach have led to a renewed call for increased regulation. FDA does not inspect produce on a similar scale as USDA’s inspection of beef, and it has fewer inspectors and more facilities to inspect than it did in 2003.<sup>63</sup> Additionally, “more outbreaks of the disease are now traced to produce than to meat, poultry, fish, eggs, and milk combined.”<sup>64</sup>

In August 2006, just prior to the outbreaks, FDA launched a Lettuce Safety Initiative to respond to recurring outbreaks of *E. coli* in lettuce.<sup>65</sup> The initiative focused first on California regions, where a large portion of past outbreaks have occurred (including the most recent spinach outbreak), and concentrates on the following objectives:

- Assessing industry approaches and actions.
- Early detection and rapid response.
- Observing and identifying practices that might lead to contamination.
- Consideration of regulatory action.<sup>66</sup>

*“In the last 20 years, the incidence of produce-related food-borne illness has increased 2½ to 3 times.”<sup>67</sup>*

— Richard H. Linton, director of the Center for Food Safety Engineering at Purdue University

## Hepatitis A

In January 2008, a produce handler at a grocery store in Buffalo, New York was diagnosed with hepatitis A. As a precaution, county health officials issued a warning to anyone who may have purchased and consumed certain kinds of produce from the store in the prior 3-week period. Health officials set up free clinics to distribute hepatitis A vaccine and immune globulin (IG) shots. More than 8,300 people were vaccinated over a 5-day period at a cost of some \$500,000.

*Hepatitis A is a viral infection that causes inflammation of the liver and can result in short-term illness.<sup>68</sup> Transmission occurs by the fecal-oral route, either by direct contact with an infected person or by ingestion of contaminated food or water. Although foodborne or waterborne hepatitis A outbreaks are relatively uncommon in the United States, food handlers with hepatitis A are frequently identified.<sup>69</sup>*

The majority of foodborne hepatitis A outbreaks are associated with infected food handlers working in grocery stores and restaurants, such as the case in Buffalo. A single infected individual can transmit hepatitis A to dozens, if not hundreds of persons.<sup>70</sup>

Hepatitis A outbreaks have also been associated with fresh produce that was contaminated sometime during growing, harvesting or processing. In 2003, more than 500 individuals in 6 states were infected by eating contaminated green onions. Three individuals died as a result.<sup>71</sup> Hepatitis A contaminated shellfish have also been the source of outbreaks, although the last reported U.S. outbreak occurred in 1988.<sup>72</sup>

Hepatitis A is the only common vaccine-preventable foodborne disease in the U.S., although only children under the age of 2 are routinely vaccinated.<sup>73</sup> Instead of widespread vaccination, scientists believe reducing foodborne transmission of hepatitis A can be achieved by improving sanitary conditions in food production and encouraging routine proper food-handler hygiene.

## Listeria

*Listeria monocytogenes* (LM), a harmful bacterium, causes some 2,500 illnesses and 500 deaths in the U.S. each year.<sup>74</sup> LM, which can be present in soil and water, has been found in a variety of raw foods, such as uncooked meats and vegetables. Processed foods can also become contaminated with LM, particularly deli meats and unpasteurized cheeses.

*Listeriosis is a serious infection caused by eating food contaminated with the bacterium *Listeria monocytogenes*. Symptoms include fever, muscle aches, nausea, and diarrhea. Infected pregnant women can pass the illness on to the fetus which can result in miscarriage or stillbirth, premature delivery or infection of the newborn.<sup>75</sup>*

Voluntary recalls of food products contaminated with LM, or suspected to be contaminated with LM, are frequent. On March 3, 2008 Costco Wholesale recalled 10,000 pounds of frozen chicken entrees produced in Washington State and distributed across the Pacific Northwest.<sup>76</sup> A day earlier, a Michigan firm recalled some 2,000 pounds of frozen chicken entrees that were possibly contaminated with LM, while in November 2007, a Texas producer recalled some 98,000 pounds of frozen sausage roll products thought to be contaminated with LM.<sup>77</sup>

Although healthy people rarely contract listeriosis, pregnant women, newborns, the elderly and persons with compromised immune systems are at highest risk of infection. The medical community recommends that those people at risk avoid high risk foods such as deli meats, pates and other processed meats, and unpasteurized cheese, and practice good hygiene when cooking -- washing hands after handling meat or poultry; keeping raw meat and poultry away from foods that won't be cooked; cleaning all cooking utensils in hot soapy water.



## Salmonella

In February 2007, FDA issued a nationwide advisory warning consumers to avoid certain brands of peanut butter due to risk of contamination with *Salmonella Tennessee*, a subtype of the *Salmonella* bacteria, after 290 people in 39 states were sickened from the contaminated food.<sup>78</sup> Although 46 people were hospitalized as a result, there were no deaths associated with the contamination.

*Salmonella* live in the intestinal tracts of humans and other animals, including birds, and the germ is usually passed to humans by eating foods contaminated with animal feces.<sup>79</sup> Most people infected with *Salmonella* develop diarrhea, fever and stomach cramps 12 to 72 hours after infection.<sup>80</sup>

Each year, some 40,000 cases of *Salmonella* infection are reported in the U.S., although scientists believe the actual number of infections is much higher as mild cases often go unreported. Children, the elderly and the immuno-compromised are the most likely to have severe infections. CDC estimates that some 600 persons die from acute *Salmonella* infection each year.

As with many foodborne illnesses, good hygiene and safe kitchen practices can do a lot to prevent illness. For example, proper cooking of meat, poultry and eggs can significantly reduce the risks associated with those foods.

## Mad Cow Disease

In March 2006, the USDA announced that a cow in Alabama tested positive for bovine spongiform encephalopathy (BSE), better known as mad cow disease. The Alabama cow was the third such case in the U.S., with the first case occurring in Washington state in December 2003.<sup>81, 82</sup>

*Mad cow* is a fatal illness that strikes the central nervous system of cattle. Humans can contract a related illness called variant Creutzfeldt Jakob disease (vCJD) by eating infected beef.

Also in 2003, a single cow in Canada was diagnosed with mad cow disease, leading many nations (including the U.S.) to place a ban on Canadian cattle and beef imports. Economic losses due to the import bans have been massive, with estimates ranging from \$1.6 to \$3.2 billion.<sup>83,84</sup>

If a significant outbreak of mad cow disease occurred in the U.S., the USDA estimates that there would be a loss of \$15 billion, resulting from a 24 percent decline in domestic beef sales and an 80 percent decline in beef and live cattle exports.<sup>85</sup> Slaughter and disposal costs of at-risk cattle could add up to an additional \$12 billion.<sup>86</sup> Experts point out that generally concerns about mad cow are related to animal health rather than human health in the U.S.

## ADULTERATED FOOD

A large number of food advisories and recalls are due to adulterated food, which runs the gamut from food that is improperly inspected to food that is contaminated with a foreign substance.<sup>87,88</sup>

Prevention and stringent controls at the manufacturer level are the keys to reducing the number of incidents of adulteration.

Under FDA's food safety statute, food is considered "adulterated" if:<sup>89,90,91</sup>

- It bears or contains any poisonous or deleterious substance that may render it injurious to health;
- It bears or contains any added poisonous or deleterious substance other than pesticide residue, food additive, color additive, or new animal drug (which are covered by separate provisions) that is unsafe;
- Its container is composed in whole or in part of any poisonous or deleterious substance that may render the contents injurious to health;
- It bears or contains a pesticide chemical residue that is unsafe (EPA establishes tolerance for pesticide residues in food, which is enforced by the FDA).
- It is, or it bears or contains, an unsafe food additive;
- It is, or it bears or contains, an unsafe new animal drug;
- It is, or it bears or contains, an unsafe color additive;
- It consists, in whole or in part, of any filthy, putrid, or decomposed substance or is otherwise unfit for food;
- It has been prepared, packed or held under unsanitary conditions (insect, rodent, or bird infestation) whereby it may have become contaminated with filth or rendered injurious to health;
- It has been irradiated and the irradiation processing was not done in conformity with a regulation permitting irradiation of the food (with exceptions approved by FDA including refrigerated or frozen uncooked meat, fresh or frozen uncooked poultry, and seeds for sprouting);
- It contains a dietary ingredient that presents a significant or unreasonable risk of illness or injury under the conditions of use recommended in labeling;
- A valuable constituent has been omitted in whole or in part or replaced with another substance; damage or inferiority has been concealed in any manner; or a substance has been added to increase the product's bulk or weight, reduce its quality or strength, or make it appear of greater value than it is; or
- It is offered for import into the U.S. and is a food that has previously been refused admission, unless the person reoffering the food establishes that is in compliance with U.S. law.

## CDC'S LIST OF MAJOR CAUSES OF FOODBORNE ILLNESS: BACTERIAL, PARASITIC, VIRAL, AND NON-INFECTIOUS<sup>92</sup>

Amebiasis (*Entamoeba histolytica* Infection) [parasitic]  
Anisakiasis (*Anisakis* Infection) [parasitic]  
Ascariasis (Intestinal Roundworm Infection) [parasitic]  
Botulism (*Clostridium botulinum* toxicity) [bacterial]  
Brainerd Diarrhea [bacterial]  
Brucellosis (*Brucella* Infection) [bacterial]  
Campylobacteriosis (*Campylobacter* Infection) [bacterial]  
Cholera (*Vibrio cholerae* Infection) [bacterial]  
Cryptosporidiosis (*Cryptosporidium* Infection) [parasitic]  
Cyclosporiasis (*Cyclospora* Infection) [parasitic]  
Cysticercosis (Neurocysticercosis) [parasitic]  
Diphyllobothriasis (*Diphyllobothrium* infection) [parasitic]  
Enterohemorrhagic *Escherichia coli* [bacterial]  
Enterotoxigenic *Escherichia coli* (ETEC) [bacterial]  
*Escherichia coli* O157:H7 [bacterial]  
Giardiasis (*Giardia* Infection) [parasitic]  
*Helicobacter pylori* [bacterial]  
Hepatitis A [viral]  
Listeriosis (*Listeria* Infection) [bacterial]  
Marine Toxins [non-infectious]  
Norovirus [viral]  
Rotavirus [viral]  
*Salmonella* Enteritidis [bacterial]  
Salmonellosis (*Salmonella* Infection) [bacterial]  
Shigellosis (*Shigella* Infection) [bacterial]  
Toxoplasmosis (*Toxoplasma* Infection) [parasitic]  
Trichinellosis/Trichinosis (*Trichinella* Infection) [parasitic]  
Typhoid Fever ( *Salmonella* Typhi Infection) [bacterial]  
*Vibrio parahaemolyticus* [bacterial]  
*Vibrio vulnificus* [bacterial]  
Viral Gastroenteritis [viral]  
Yersiniosis (*Yersinia enterocolitica* Infection) [bacterial]

### III. Recommendations

Modernizing the food safety system could significantly decrease the number of foodborne illnesses in the U.S. each year and help restore public confidence in the system and in the safety of food.

Action must be taken to realign U.S. food safety policies with current priorities and threats.

The nation should focus on building a modern food safety system that emphasizes:

#### ■ **Farm-to-Fork Disease Prevention**

**Practices:** Food safety priorities must shift from a system focused on outdated, limited end-product and processing plant inspections to a system where the emphasis is on preventing outbreaks and illnesses throughout the entire food production process and supply chain.

▲ Preventive strategies, such as the Hazard Analysis and Critical Point (HACCP) process, should be at the center of food safety practices. Outdated practices, like those called for in the current the FSIS inspection mandate, should be repealed.

▲ Uniform performance standards and best practices should be defined and adopted, and should be enforceable, including detention and recall authority, records access, establishment registration, and civil penalty authority.

▲ Food safety education programs for commercial food handlers and consumers are essential components of preventing disease.

#### ■ **The Ability to Keep Pace with Modern**

**Threats:** Threats to the food supply change as industry practices and farming and processing technologies change. Government strategies for protecting and inspecting the food supply must be able to adapt quickly to these changes.

▲ Ongoing research is needed to identify emerging threats and up-to-date ways to contain them.

▲ Government food safety officials and food companies must be able to keep track of information about disease outbreaks in humans, plants, and animals and results of food inspections so they can quickly detect and contain problems.

#### ■ **Monitoring Foreign Imports and**

**International Practices:** Food safety agencies must have clear statutory authority and receive resources necessary to educate overseas regulators and food producers about U.S. food safety standards, require that food importers demonstrate these standards are being met, and permit U.S. regulators to inspect foreign establishments as well as food at the port of entry. Food safety agencies should also be given the authority and funding to participate in international negotiations and discussions, such as with the Codex Alimentarius Commission and the World Trade Organization. Trade agencies often take the lead in these discussions, but often lack the food safety mission, expertise, and credibility to effectively represent U.S. interests.

To accomplish these goals:

#### ■ **Start by Strengthening FDA and Aligning Resources with the Highest-Risk Threats:**

Funding for FDA's food program must grow substantially, at least doubling in real terms over the next 5 years, and statutory mandates should be updated to strengthen the agency's abilities to carry out preventive efforts and oversee food imports. FDA is responsible for overseeing the biggest threats to the country's food safety, but the agency lacks the resources and the mandates needed to carry out its programs and adequately protect the nation from foodborne disease threats. Government funding should be realigned so that it can be strategically allocated to food safety research, regulation, and education to maximize reduction in foodborne disease. Resources for inspections should be distributed and used in the manner most likely to contribute to disease reduction.

■ **As a Second Step, Strategically Realign and Elevate Food Safety Functions at HHS:** As immediate measures are taken to strengthen current food safety functions at FDA, steps should also be taken to realign and elevate organizationally all of the food regulatory functions at HHS. Currently, FDA's senior management focus is split between regulating medical products (drugs and devices) and food, with its food functions typically taking the backseat in terms of resources and management attention. FDA's food functions should be brought together under unified leadership, with a single official, reporting to the Secretary, focusing full time on, and being responsible and accountable for, providing food safety leadership nationally and internationally and effectively implementing a modern, prevention-oriented food safety system. Efforts should also be made to better align the surveillance functions at CDC with other federal food safety efforts and with state and local efforts in a way that provides more timely and responsive reporting to allow public health officials throughout the country to better detect and control outbreaks.

■ **Set a Long-Term Goal to Integrate Federal Food Safety Agencies:** While the immediate focus is on fixing FDA, in order to strategically address food safety concerns, make good use of federal resources, and have stronger national and international leadership, the goal over time should be to consolidate and align all federal food safety functions into a single agency to increase effectiveness, responsibility, and accountability. This

agency could then address the food supply as a whole and set priorities accordingly. It should oversee regulation and inspection, but also must also have research and surveillance functions as part of its mandate. It should also be required to report on accomplishments, progress, and problems.

- ▲ The realigned agency should include: FSIS; the food regulatory functions of FDA, including CFSAN, the Center for Veterinary Medicine, and the food portion of FDA's field resource; and the food safety aspects of the EPA's pesticide program.
- ▲ The placement of CDC's foodborne disease surveillance program should be reviewed. It must be able to function in a way that not only monitors foodborne disease outbreaks and helps investigate preventive strategies but also provides accountability to gauge how well U.S. food safety systems are working.

In addition to changes at the federal level, measures must be taken to better integrate and coordinate policies and practices among levels of government, including:

■ **Creating Uniform Standards and Practices Across Federal-State-Local Levels:** While the states play a critical food safety role, particularly at the retail level, the federal-state relationship is not well defined or financed. States should be encouraged and incentivized to adopt and comply with the uniform standards and practices of the FDA's Food Code and the National Retail Food Regulatory Program.

## FDA'S FOOD PROTECTION PLAN<sup>93</sup>

In November 2007, HHS unveiled its plans to strengthen and update the U.S. food safety system. In order to make many of the necessary changes, the plan stresses the need to **realign roles and responsibilities** within the agency and for **legislative action**.

- For instance, FDA is seeking legislative changes that will allow the agency to require food facilities to renew their FDA registrations every 2 years, which the agency argues will allow for superior prevention.
- Also, among other recommended changes, FDA is urging Congress to empower the agency to issue mandatory recalls of contaminated products when voluntary recalls fall short.

The Food Protection Plan was developed in conjunction with the broader U.S. Import Safety Action Plan that focuses on how the U.S. can improve the safety of all imported products.

The Food Protection Plan focuses FDA's efforts on 3 critical areas: prevention; intervention; and response. According to FDA Commissioner Andrew von Eschenbach, while the FDA will maintain and improve its response capacity, "the primary goal is to prevent contaminated food from ever reaching the consumer."<sup>94</sup>

### Prevention

FDA will boost efforts to prevent food from becoming contaminated via a 3-pronged approach of: 1) promoting increased corporate responsibility to prevent foodborne illnesses; 2) identifying food vulnerabilities and assessing risks; and 3) expanding the understanding and use of proven mitigation strategies.

### Intervention

FDA will intervene at critical points in the food supply chain from production to consumption. Inspections will be based on risk assessments and enhanced risk-based surveillance.

### Response

FDA intends to improve both the agency's immediate response to a foodborne illness outbreak, and its risk communication with the U.S. public, industry and other interested parties.



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