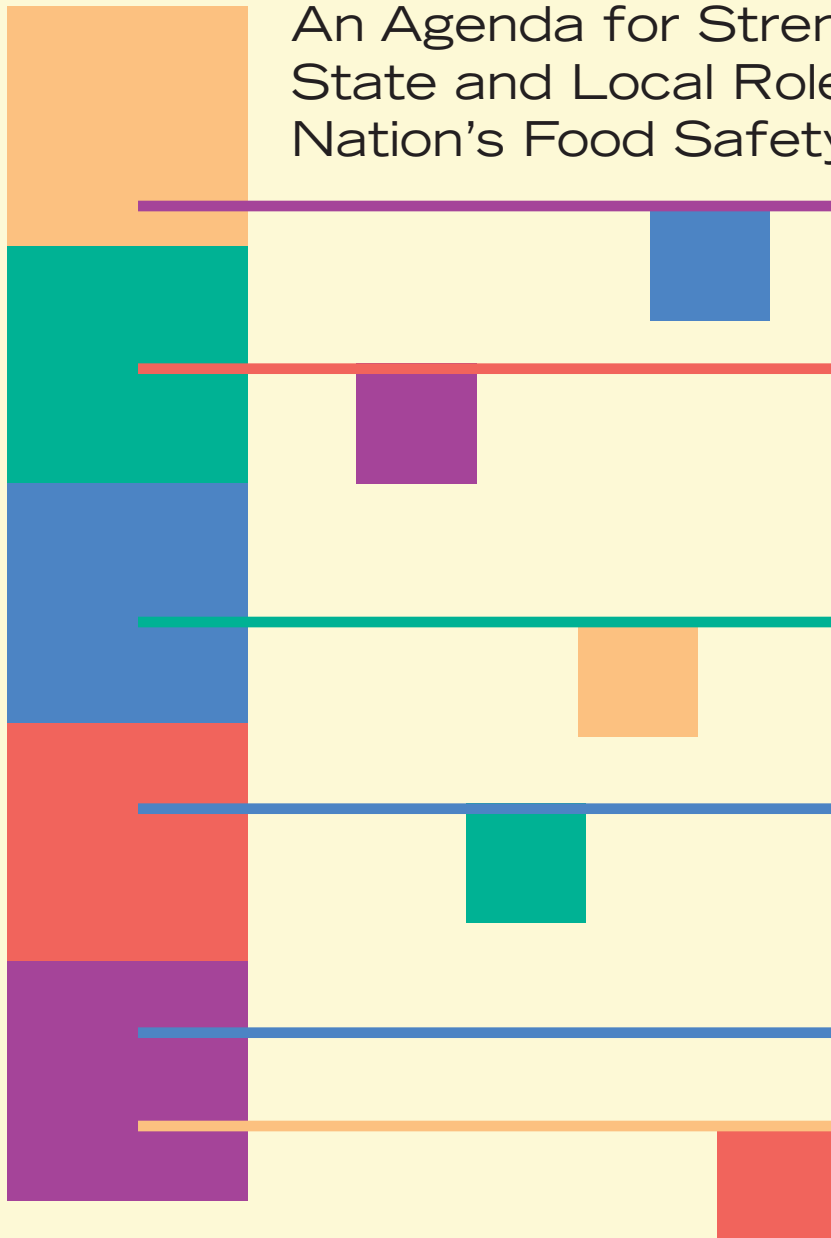


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Stronger Partnerships for Safer Food

An Agenda for Strengthening
State and Local Roles in the
Nation's Food Safety System



Final Report

A project of
Department of Health Policy
School of Public Health and Health Services
The George Washington University

In collaboration with
Association of Food and Drug Officials
Association of State and Territorial Health Officials
National Association of County and City Health Officials

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the Robert Wood Johnson Foundation*

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ABBREVIATIONS and ACRONYMS

AFDO	Association of Food and Drug Officials
APHL	Association of Public Health Laboratories
ASTHO	Association of State and Territorial Health Officials
CDC	Centers for Disease Control and Prevention
CFSAN	Center for Food Safety and Applied Nutrition (FDA)
CIFOR	Council for the Improvement of Foodborne Outbreak Response
CSTE	Council of State and Territorial Epidemiologists
CVM	Center for Veterinary Medicine (FDA)
DHS	U.S. Department of Homeland Security
eFORS	Electronic Foodborne Outbreak Reporting System
EHS-Net	Environmental Health Specialists Network
eLEXNET	Electronic Laboratory Exchange Network
EMAC	Emergency Management Assistance Compact
EPA	Environmental Protection Agency
Epi-X	Epidemic Information Exchange
FDA	Food and Drug Administration
FDCA	U.S. Food, Drug and Cosmetic Act
FERN	Food Emergency Response Network
FMIA	Federal Meat Inspection Act
FOIA	Freedom of Information Act
FoodNet	Foodborne Disease Active Surveillance Network
FORCG	Foodborne Outbreak Response Coordinating Group
FSIS	Food Safety Inspection Service (USDA)
GAO	U.S. Government Accountability Office
HACCP	Hazard Analysis and Critical Control Points
HHS	U.S. Department of Health and Human Services
IOM	Institute of Medicine
NACCHO	National Association of County and City Health Officials
NAS	National Academy of Sciences
NCEH	National Center for Environmental Health (CDC)
NASDA	National Association of State Departments of Agriculture
NCIMS	National Conference of Interstate Milk Shipments
NEHA	National Environmental Health Association
NFSS	National Food Safety System Project
NORS	National Outbreak Reporting System
ORA	Office of Regulatory Affairs (FDA)

OutbreakNet	Outbreak Network for Foodborne Diseases Surveillance and Response (CDC)
PFGE	Pulsed-Field Gel Electrophoresis
PMO	Grade A Pasteurized Milk Ordinance
PPIA	Poultry Products Inspection Act
PulseNet	National Molecular Subtyping Network for Foodborne Disease Surveillance (CDC)
USDA	U.S. Department of Agriculture

EXECUTIVE SUMMARY

THE NEED FOR SYSTEM-WIDE FOOD SAFETY REFORM

Food safety reform is on the front burner in Washington, against the backdrop of numerous large-scale illness outbreaks and sustained criticism of obsolete federal statutes, inadequate resources, and fragmented organizations, all of which cripple the government's response to outbreaks, *and* its ability to prevent problems in the first place.

National policymakers naturally have focused their reform efforts on the key federal food safety agencies, including the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), and Department of Agriculture (USDA); and reform in the federal food safety program is long overdue. These federal agencies are just the tip, however, of a much larger pyramid of state and local agencies working on food safety.

State and local health and agriculture departments have long been the foundation of the nation's food safety system, with primary responsibility for illness surveillance, response to outbreaks, and regulation of food safety in over one million restaurants and grocery stores. State and local agencies collectively conduct many more inspections, test many more food samples for harmful contamination, and bring many more food safety enforcement actions than the federal food safety agencies.

Food safety reform will not be complete—or successful—unless the efforts of these agencies are strengthened and integrated more fully into the national food safety system.

THE VISION FOR REFORM

Since the 1990's, federal, state, and local agencies have expanded their collaboration in some areas—such as illness surveillance and inspection—and there exists today among food safety officials at all levels a ***widely shared vision of an integrated national food safety system that operates as a full partnership among federal, state, and local agencies.***

Such a system would place first priority on preventing foodborne illness, address food safety risks all across the farm-to-table spectrum, and make efficient, science-driven use of all government food safety resources. Achieving this vision of an integrated national food safety system requires building on past collaborations, but also real change in how federal, state, and local agencies understand their roles and relationships, how state and local agencies acquire the capacities to perform their roles, and how agencies at all levels can better interact as parts of an integrated food safety system.

This report recommends a series of actions to strengthen state and local roles in food safety and fulfill the vision of an integrated national food safety system. It is the product of a project, funded by

the Robert Wood Johnson Foundation, which brought together state and local officials, their federal counterparts, members of the food industry, and consumer groups to develop a reform agenda.

CURRENT ROLES, RESPONSIBILITIES, AND COLLABORATION

The report summarizes the current roles and responsibilities of federal, state, and local food safety agencies in the areas of surveillance, outbreak response, inspection, and regulation; and it describes the many ways in which the three levels of government interact and are mutually dependent. Numerous examples of collaboration among federal, state, and local government—some longstanding and many more recent—demonstrate the potential of such collaboration to improve food safety, and the willingness of officials at all levels to form partnerships.

KEY FINDINGS

The report makes 29 findings concerning the strengths and weaknesses of state and local food safety programs and how they interact with the federal government. While there are many positives in the current situation, the report finds that state and local agencies are hampered by chronic underfunding, wide disparities in capacity and practice in all areas of food safety, and substantial legal, resource, and institutional barriers to collaboration.

RECOMMENDATIONS

The report makes 19 specific recommendations for strengthening state and local roles and building an integrated national food safety system that works effectively to prevent foodborne illness. The recommendations address the following issues:

Strengthening Federal, State, and Local Leadership

- Congress should give the Secretary of The Department of Health and Human Services (HHS) a legislative mandate to lead the development of an integrated, national food safety system and direct HHS to create an organizational focal point within the Department for improving food safety and for building an integrated national food safety system.
- Congress should establish and fund an intergovernmental Food Safety Leadership Council (FSLC) through which the federal government would collaborate with state and local governments to design and implement an integrated national food safety system, including the development of a five-year integration and capacity building plan to meet high priority state and local capacity needs.
- Congress should declare that the federal government has a shared responsibility with the states to adequately fund the national food safety system and authorize FDA to provide federal funding and establish a matching grant program to support the capacity building required to enhance the role of state and local agencies in the national system.
- State and local governments should maintain adequate and stable funding streams to play their proper role in funding food safety programs, and should improve their own structures for food

safety oversight, including better integrated surveillance, outbreak response, and food safety regulatory and inspection activities, and a focal point for better linking and integrating the state's food safety activities with the national system.

- State and local governments should collaborate on the development and widespread adoption of a model state and local food safety law to parallel pending reforms at the federal level, clarify the roles of state and local agencies in a more integrated system, and legally empower state and local agencies to work more collaboratively among themselves and with the federal government.
- HHS, in collaboration with the Food Safety Leadership Council, should establish a Food Safety Leadership and Training Institute focused on building among food safety professionals at all levels a common vision for the nation's food safety system and the leadership skills, network of relationships, and trust needed for an integrated system to succeed.

Strengthening Surveillance and Outbreak Response

- Congress should direct the Secretary of HHS to create, in collaboration with the states, a National Foodborne Illness Data Program that better integrates the efforts of FDA, CDC, states, and localities to generate and analyze the data needed to understand and prevent foodborne illness.
- Working through CDC and FDA and in collaboration with states and localities, HHS should establish a network of regional, federally-funded foodborne outbreak response centers to:
(1) support state and local agencies in their day-to-day foodborne surveillance and response activities; (2) improve the thoroughness and timeliness of outbreak detection, response, and follow-up investigation; and (3) establish the relationships, expertise, continuity, and surge capacity needed to ensure well-coordinated and effective response to major outbreaks and follow up investigations.
- Working with states and localities, HHS should foster implementation of best practices for foodborne outbreak response based on the guidelines of the inter-governmental Council to Improve Foodborne Outbreak Response and should establish protocols for managing multi-state outbreaks, including clear definition of federal, state, and local roles.
- Congress should establish traceability requirements that permit federal, state, and local officials to rapidly obtain from food companies reliable information on the source of commodities, ingredients, and finished products.

Strengthening Regulation and Inspection

- HHS and the states should declare that the establishment and enforcement of nationally uniform food safety standards is a common goal and joint responsibility of federal, state, and local governments, with the federal government bearing primary responsibility for establishing science-based standards for preventing foodborne illness and states and localities preserving full legal power to adopt and directly enforce federal standards and to establish their own.
- Working in collaboration with state and local agencies, HHS should develop and implement a plan for integrating federal and state food manufacturing regulatory programs.
- HHS/FDA should make full implementation of FDA's Retail Food Regulatory Program Standards and Manufactured Food Regulatory Program Standards a central component of its plan for building an integrated national food safety system and inspection program and should provide needed resources and incentives for state and local governments to participate.

CONCLUSION

There are no shortcuts to an integrated national food safety system. It requires commitment, resources, and sustained effort, but the potential benefits are great. In fact, food safety reform at the federal level will remain an incomplete solution to today's food safety challenges unless state and local roles are strengthened and better integrated into the national food safety system.

The findings and recommendations outlined here address many of the system changes needed to fulfill the vision of an integrated national food safety system. We hope the report will help stimulate policymakers to act.

I. INTRODUCTION

THE CALL FOR REFORM

In the late spring and summer of 2008, American consumers experienced the worst outbreak of foodborne illness in at least a decade, with over 1400 people across 43 states being sickened by consumption of food contaminated with *Salmonella* Saintpaul.^{1, 2} This outbreak brought the need for food safety reform sharply to the public's attention. Delay in identifying the food culprit and other perceived failings of the system sparked headlines and Congressional hearings. Government officials, consumer advocates, and industry representatives all cited significant problems in how the system responded to the outbreak—including fragmented roles and insufficient communication among the many federal, state, and local government agencies investigating it—and they called for reform.³

As the *Salmonella* Saintpaul outbreak receded from the headlines, the nation was shocked again by another widespread outbreak of illness involving hundreds of hospitalizations and nine deaths, this time associated with *Salmonella*-contaminated peanut butter and other peanut products.⁴ These products were reportedly produced under disturbing insanitary conditions and shipped by a major peanut processing company despite positive tests for *Salmonella* Typhimurium. While the *Salmonella* Saintpaul episode put the spotlight on shortcomings in government's response to large-scale outbreaks, the peanut butter case revealed major breakdowns in prevention, first on the part of the company and its commercial customers, but also including the failure of federal and state food safety agencies to act forcefully to stop the disturbing practices in the peanut plant. Members of Congress and stakeholders alike again called for reforms.

The problems brought to light by these two recent *Salmonella* outbreaks—and the calls for reform—are far from new. For over a decade, authoritative bodies and experts have documented serious constraints on the effectiveness of the government food safety system. These include obsolete statutes, inadequate levels and poor use of resources, organizational fragmentation—at the federal level and in interactions among federal, state, and local agencies—and too little focus on preventing problems rather than just reacting after the fact.

In 1998, the National Academy of Sciences (NAS), in its seminal report, *Ensuring Safe Food—From Production to Consumption*,⁵ addressed these systemic problems: it called for modernization of the federal food safety laws, unification of the federal food safety programs, a more integrated collaboration with state and local agencies, and a farm-to-table systems approach to food safety. A particular emphasis of the NAS report was the need for a more science- and risk-based allocation and use of resources and more effective prevention of food safety problems.

The Government Accountability Office (GAO) has published numerous reports calling for these and other food safety reforms.⁶ Most recently, GAO identified food safety as one of the thirteen

most urgent issues needing attention by the Obama administration and Congress.⁷ Legislative reform of the food safety system is now embraced by industry^{8,9} and consumer groups alike.¹⁰ In the 110th Congress, significant bills, some with bipartisan support, were introduced in the House and Senate—bills that would overhaul the food safety laws under which the Food and Drug Administration (FDA) operates.¹¹ Some have already been reintroduced in the 111th Congress and more are expected.¹²

The country thus finally seems poised for significant food safety reform. Past reform discussions in Washington have focused too narrowly, however, on the key federal agencies: FDA and the Centers for Disease Control and Prevention (CDC) in the U.S. Department of Health and Human Services (HHS) and the Food Safety and Inspection Service (FSIS) in the U.S. Department of Agriculture (USDA). Federal-level reform is essential, but policymakers are now realizing that the federal agencies sit at the top of a much larger pyramid of state and local agencies working on food safety, all of which play important roles in the system and must be considered in any reform effort.

At the local level alone there are approximately 3,000 public health agencies involved in food safety, plus state-level departments of health and agriculture and public health laboratories spread across the 50 states, the District of Columbia, and the U.S. territories and tribal nations. These state and local agencies have long been on the frontline in preventing and responding to foodborne illness. They investigate and contain illness outbreaks; conduct illness surveillance and monitor the food supply for contamination; inspect restaurants, grocery stores, and food processing plants; provide food worker and consumer education; and take regulatory action to remove unsafe or unsanitary products from the market.

These agencies and the roles they play are absolutely essential to the future success of the food safety system. Put simply, it is not possible to have a farm-to-table food safety system that makes good use of resources to prevent illness without taking full advantage of what state and local agencies do—and have the potential to do.

Like their federal counterparts, however, state and local agencies face substantial challenges both in meeting their immediate food safety responsibilities and fulfilling their potential as integral parts of the national food safety system. They work through diverse and often fragmented organizational structures and under an assortment of laws, which, like the federal law, need modernization in key respects. Most state and local food safety agencies are chronically underfunded, and the level of resources available to them varies widely across the country, resulting in great diversity and too many gaps in inspection, laboratory, and technical capacities and practices.

For all these reasons, food safety reform must extend beyond the federal role to include strengthening state and local roles in an integrated national food safety system—a system that is integrated not on the basis of federal control of all food safety efforts but rather on real partnership among agencies at all levels of government.

Growing recognition of the need to address state and local roles is one of the most positive recent developments in the food safety debate, and the need to strengthen those roles has only been underscored by recent events. The food safety bills now pending in Congress contain proposals to build capacity among state and local agencies and improve their interaction with the federal agencies on surveillance, outbreak response, inspection, and regulation. Importantly, then-Senator Barack Obama introduced his own bill, *The Improving Food-Borne Illness Surveillance and Response Act of 2008*, which focused on these very topics.¹³

FDA's November 2007 Food Protection Plan also included better integration of federal, state, and local efforts as a major theme. And, as discussed below, CDC and its state and local counterparts embraced the need for greater collaboration when they founded the inter-agency Council to Improve Foodborne Outbreak Response (CIFOR) in 2006.¹⁴

These events and policy developments set the stage for this report, which spells out in greater detail than has been done before a comprehensive agenda of actions to strengthen state and local roles in the nation's food safety system. Other major legislative, regulatory policy, and structural reforms are certainly needed, but strengthening state and local roles will be essential for long-term success on food safety.

OVERVIEW OF THE PROJECT AND REPORT

The Robert Wood Johnson Foundation (RWJF) has long had an interest in and sought to bolster the central role of state and local health departments, laboratories, and inspection agencies in the nation's public health system. RWJF funded the project on which this report is based in an effort to bring together state and local food safety officials, their federal counterparts, the food industry, and consumer groups to develop an agenda for enhancing state and local food safety roles in the national food safety system. The project is based at The George Washington University School of Public Health and Health Services and is being conducted in collaboration with the Association of Food and Drug Officials (AFDO), the Association of State and Territorial Health Officials (ASTHO), and the National Association of County and City Health Officials (NACCHO). An expert from the University of Florida Emerging Pathogens Institute also participated in the project.

The broad goal of the project is to ensure that the essential role of state and local agencies in the nation's food safety system is fully understood and considered by federal policymakers in both the legislative and executive branches as food safety reform unfolds. More specifically, by recommending a comprehensive agenda of system-level reforms, the project aims to ensure that the food safety reform debate moves beyond generalities about partnership and collaboration and addresses the specific changes that are needed to strengthen state and local roles in an integrated, prevention-oriented, and truly national food safety system.

To frame the agenda, the project team conducted a national kick-off symposium in June 2008, followed by two workshops that examined issues related to illness surveillance and outbreak response (convened jointly by ASTHO and NACCHO) and inspection and regulatory issues (convened by AFDO). These workshops included food safety officials and stakeholders from federal, state, and local government; members of associations such as the National Environmental Health Association (NEHA), the Council of State and Territorial Epidemiologists (CSTE), and the Association of Public Health Laboratories (APHL), food industry representatives, and the consumer and academic communities. Participants were able to analyze current issues, including obstacles to a more integrated and effective food safety system, and make recommendations for enhancing state and local roles in that system. The team members and meeting participants are listed in Appendix A, and the workshop reports are reproduced at Appendices B and C.

The agenda outlined in this report is a synthesis that draws on the discussions that took place at those meetings, past efforts to improve state and local roles in food safety, and the perspectives and analysis of the project team. We do not claim unanimity among all participants on all points in the report or on all recommendations. We believe, however, that the report reflects a broad consensus

among diverse stakeholders on the need to move toward a more integrated food safety system and wide agreement that food safety reform at the national level must include concrete steps to both strengthen state and local efforts—on surveillance, outbreak response, inspection, and regulation—and better integrate them with the federal program.

The remainder of this Introduction will briefly describe previous efforts to enhance state and local roles in food safety and the vision for the nation's food safety system that has emerged from those and other reform efforts. Section II of the report briefly reviews current state and local roles in food safety and the nature of the federal-state-local interaction to illustrate that building an integrated national food safety system does not require starting from scratch.

Section III contains a series of findings regarding strengths and weaknesses of the current system. Section IV contains the report's recommendations.

PREVIOUS EFFORTS TO ENHANCE STATE AND LOCAL ROLES IN FOOD SAFETY

In 1998, sparked by the call for a more integrated food safety system in the National Academy of Sciences' *Ensuring Safe Food* report, government officials at all levels began an effort to improve the federal-state-local partnership. AFDO, as the representative of state and local food regulatory and inspection officials, proposed a vision for a vertically integrated national food safety system; and, in September 1998, FDA hosted a meeting of food safety officials from CDC, USDA, and all 50 states to examine that idea.¹⁵

The "50-State meeting" produced a broad consensus among officials on the need to meet challenges together by better integrating food safety activities at all levels of government. As a result of this meeting, the FDA and its state and local partners, including AFDO, launched the National Food Safety System (NFSS) Project to strengthen partnerships among federal, state, and local agencies to better ensure safe food for consumers and enhance the response when food emergencies or outbreaks of foodborne illness occur.¹⁶

During the period 1999-2002, the NFSS Project made important strides in advancing collaboration among federal, state, and local agencies based on a common vision of an integrated food safety system having the following properties: nationally uniform standards; uniform inspections and enforcement; uniform laboratory practices; adequate training; enhanced communications; and federal oversight. Some of the concrete initiatives resulting from this work are noted in Section II of this report.

The NFSS Project was put on hold in 2002 due to a lack of funding. In August 2008, however, FDA sponsored a second 50-State Meeting as part of the effort to implement its new Food Protection Plan. As in 1998, the 2008 meeting included participants from CDC, USDA, and all 50 states, as well as from the U.S. territories and tribal nations. The participants expressed broad agreement that, despite progress on some specific topics, many of the same problems and obstacles to integration that existed a decade ago persist today. They also expressed broad support for a more integrated food safety system, with enhanced coordination and collaboration among federal, state, and local agencies.¹⁷

While the NFSS Project and FDA's recent 50-State Meeting focused largely on regulatory and inspection issues, government officials are also collaborating to improve how they work together

when illnesses occur, including the work of the aforementioned Council to Improve Foodborne Outbreak Response, which is a multidisciplinary working group of government and national association officials.¹⁸ In June 2008, CIFOR issued draft “Guidelines for Foodborne Disease Outbreak Response,”¹⁹ which are intended to improve how government agencies respond to both local and multi-jurisdictional outbreaks. The draft guidelines include detailed recommendations and suggested procedures for responding to outbreaks; provide descriptions of the suggested roles and responsibilities of federal, state, and local agencies; and emphasize effective coordination and collaboration among government food safety agencies at all levels. Final guidelines are expected in the spring of 2009.

The USDA has also recognized the need for improved collaboration in responding to foodborne outbreaks, and in May 2008 held a stakeholder workshop entitled “Better Communications, Better Public Health Outcomes: Strategies for Improved Coordination During Foodborne Outbreaks.”²⁰ This workshop brought together food safety officials from federal, state, and local agencies, as well as representatives from the industry and consumer groups. As with the FDA’s 50-state meeting, stakeholders from all sides of the food safety spectrum voiced the need for increased collaboration and coordination in managing multi-jurisdictional outbreaks.

These activities illustrate the commitment of state and local officials to building a more integrated and effective food safety system, and they have generated analysis and recommendations on which we have drawn in this report.

THE VISION OF AN INTEGRATED NATIONAL FOOD SAFETY SYSTEM

An important result of all the work that has gone before—by the NAS, GAO, the NFSS Project, CIFOR, and food safety officials at all levels—is a vision for an integrated national food safety system that operates as a full partnership among federal, state, and local agencies. The functional attributes of such a system include:

- Placing first priority on protecting public health and preventing foodborne illness in the United States;
- Addressing food safety risks all across the farm-to-table spectrum of food production, processing, distribution, retailing, and home preparation;
- Making efficient use of all available public resources by closely coordinating federal, state, and local efforts and targeting those efforts on the basis of risk and opportunities to reduce risk across the system;
- Implementing as much as possible nationally uniform food safety standards and mounting an integrated, federal-state-local effort to enforce standards, with respect to both domestic and imported foods, through coordinated inspection programs and compliance strategies;
- Working effectively to detect and contain outbreaks of foodborne illness through robust federal-state-local systems of illness surveillance and outbreak response; and,
- Systematically collecting and disseminating the information that government officials and the private sector need to manage an integrated, science-based food safety system and prevent foodborne illness.

The foundation exists for fulfilling this vision of an integrated national food safety system. The vision is widely embraced by federal, state, and local officials, and many efforts are already under way to build collaboration. Yet, much work and much system change are still required. The recommendations in Section IV take this vision of an integrated national food safety system as their starting point and address some of the major system changes and capacity building efforts that are needed to fulfill it.

The next section provides background for the findings and recommendations later in the report by describing current government food safety roles.

II. CURRENT FOOD SAFETY ROLES, RESPONSIBILITIES, AND COLLABORATION

This section briefly describes the current roles of federal, state, and local agencies in the nation's food safety system and some of the ways in which they currently interact. This section is intended to illustrate both the institutional diversity and complexity of the food safety system and the fact that existing collaboration among agencies provides a solid foundation for building an integrated national system. As the findings in Section III will also make clear, there are important gaps and deficiencies in current interactions arising from resource and capacity limitations, obstacles to the flow of information among agencies, and the inherent difficulty of operating across literally thousands of bureaucratic boundaries.

Institutional fragmentation and barriers are also a factor in the sometimes less-than-optimal collaboration across professional lines, with epidemiologists, environmental health professionals, laboratory scientists, and regulators not always working as closely together as they should. The food safety vision underlying this report depends on forging an integrated effort among all of these disciplines, as well as the organizations in which they work.

PRIMARY FEDERAL ROLES IN FOOD SAFETY

Legislative authority and responsibility for national leadership on food safety is currently divided among five primary federal agencies: FDA, USDA, CDC, the Environmental Protection Agency (EPA), and the Department of Homeland Security (DHS).²¹

Food and Drug Administration (FDA)

FDA, an agency within the Department of Health and Human Services (HHS), has wide-ranging regulatory responsibilities, including oversight of drugs, medical devices, vaccines, the blood supply, and cosmetics, as well as most of the food supply. FDA regulates both food labeling and food safety, with its food safety regulatory authority and responsibility extending from farm-to-table and including all foods except meat and poultry products, catfish, and some processed eggs. FDA is responsible for overseeing most imported food, including the large volume of imported seafood, produce, and food ingredients on which Americans rely. FDA performs its oversight of 80% of the U.S. food supply with a budget of about \$660 million for FY 2009.^{22, 23, 24}

FDA's primary food safety role is to set and enforce standards that ensure the safety of food. These standards can address the conditions under which food is produced, such as basic good manufacturing practices and HACCP (Hazard Analysis and Critical Control Points), or the safety of potentially hazardous chemicals or microorganisms in the food. FDA also provides pre-market oversight of most substances that are intentionally or knowingly added to food—such as food and color additives, preservatives, nutrient formulations in infant formula, and animal drug residues.

For products that violate these standards, FDA can pursue product seizures and other judicial remedies and request recalls. FDA also plays a critical role in responding to foodborne disease outbreaks related to foods under its jurisdiction, including the conduct of regulatory traceback investigations and overseeing voluntary company recalls or other actions to contain the outbreak.

The **Center for Food Safety and Applied Nutrition** (CFSAN) is the unit of FDA that is typically considered to have the lead in food safety for FDA. CFSAN is responsible for FDA initiatives to reduce the risk of foodborne illness, including standard setting and compliance strategies for domestically produced and imported products, and it provides technical guidance to states and localities through such vehicles as FDA's model Food Code for retail food safety.

FDA's **Office of Regulatory Affairs** (ORA) manages the agency's network of field offices and functions primarily as the inspection and enforcement arm of FDA. In this capacity, ORA contracts with states to conduct inspections and works in conjunction with CFSAN and with state and local agencies on implementation of the Food Code and other cooperative programs.

Other FDA components involved in food safety include the **Center for Veterinary Medicine** (CVM), which regulates pet food and pet food ingredients, as well as animal feed, animal feed additives, and animal drugs, all of which can affect the safety of meat, milk, and eggs; and the **National Center for Toxicological Research**, which supports the FDA food safety mission by conducting animal toxicity studies and developing new methods for detecting and assessing the risks of foodborne hazards.

Development of agency-wide food safety strategy and coordination of efforts to implement FDA's new Food Protection Plan are lodged with the **Associate Commissioner for Foods in the Office of the FDA Commissioner**, though line authority for policy, programs, and budget run through the separate operating components to the FDA Commissioner.

U.S. Department of Agriculture (USDA)

The USDA houses the nation's second major food safety regulatory agency, the **Food Safety and Inspection Service** (FSIS), as well as at least seven other USDA agencies with food safety-related responsibilities.²⁵

FSIS has a budget of about \$1 billion to oversee the 20% of the food supply that is comprised of meat and poultry products and some processed egg products. FSIS has the very specific, statutorily-defined mission to provide inspection and regulatory oversight within the nation's more than 6,000 meat and poultry slaughter and processing establishments. FSIS is mandated to visually examine every carcass passing through slaughter plants—including over 8 billion chickens and 125 million head of livestock—and to inspect the several thousand processing plants daily. FSIS collaborates with state inspection agencies that conduct meat and poultry inspection in certain plants.

Unlike FDA, FSIS does not have jurisdiction on farms and generally defers to FDA and the states and localities to oversee food safety at retail.

Centers for Disease Control and Prevention (CDC)

CDC is responsible for national leadership and coordination in the critical field of food safety epidemiology, which generates data of importance to all participants in the food safety system. While state and local health officials are the primary collectors of data on human illnesses associated with foodborne pathogens and other hazards, CDC compiles and analyzes the information and

manages at least 20 national or regional surveillance systems that target one or more foodborne pathogens.²⁶ CDC also works with state and local health officers and food safety regulatory agencies on multi-state outbreak investigations.

The potential contribution of human illness data to ensuring food safety has been greatly enhanced in recent years by three new initiatives in which CDC plays a critical role, working through its coordinating **Office of Food Safety** and other CDC units: the Foodborne Disease Active Surveillance Network (FoodNet), PulseNet, and OutbreakNet. All of these efforts involve collaboration with state and local agencies, as discussed further below.

In addition to its role in food safety epidemiology, CDC works through its **National Center for Environmental Health** (NCEH) to support both state and local environmental health professionals and Public Health Service environmental health officials who work on retail food safety.²⁷ NCEH also participates in EHS-Net, a collaborative program with the FDA that funds nine states for research into environmental factors that cause foodborne illness and provides training opportunities for the state and local environmental health professionals who work on food safety's frontline.²⁸

Environmental Protection Agency (EPA)

EPA implements the nation's pesticide law, under which it establishes the lawful uses and use conditions for pesticides, including those used in food production. EPA is also responsible for setting the tolerances that define the limit on the amount of an agricultural pesticide that can legally remain in food. Pesticide use restrictions are enforced by state agencies under contract to EPA, while FDA enforces pesticide tolerances.

Because EPA makes far more regulatory decisions about the safety of chemicals in food than FDA or any other agency, it plays an important scientific role in establishing practices for chemical risk assessment.

Department of Homeland Security (DHS)

Operating under presidential directives relating to food defense, DHS has the lead in integrating and coordinating efforts among federal, state, and local agencies, as well as the private sector, to protect critical infrastructure and key resources from intentional attack, including in the food and agriculture sectors.²⁹ DHS works closely with the USDA, FDA, and other federal, state, and local agencies to secure the nation's food supply through programs aimed at education and prevention, surveillance, threat detection, and rapid response.

In carrying out these directives, DHS, in conjunction with FDA and USDA, created two bodies in March 2004, one for government officials (the Government Coordinating Council) and one for private industry (the Food and Agriculture Sector Coordinating Council), to work together on food security initiatives.³⁰ The Government Coordinating Council is comprised of federal, state, tribal, and local governmental agencies responsible for a variety of activities including agricultural, food, veterinary, public health, laboratory, and law enforcement programs.³¹ The Food and Agriculture Sector Coordinating Council is comprised of private companies and associations representing key components of the food system.³²

STATE AND LOCAL ROLES IN FOOD SAFETY

Although federal agencies are centrally involved in the nation's food safety work on many levels, the great majority of government food safety activities are performed by state and local agencies, including state and local health departments, public health laboratories, departments of agriculture, and possibly other business regulatory bodies. These agencies carry out a wide range of food safety functions, addressing both prevention and response to food safety problems. The division of labor among state agencies and between state and local agencies varies widely, depending on each state's governmental structure, but the food safety roles played by state and local governments generally include the ones outlined briefly below.

State Roles and Responsibilities

Most state governments have at least some involvement in the full range of food safety prevention and response functions, working typically through both their health departments and agriculture departments (or other agencies that play food safety regulatory roles in some states). States are the primary link between federal agencies and on-the-ground efforts to respond to illness outbreaks, and they are playing an increasingly large role in inspections of food manufacturing facilities.

Surveillance: States have key responsibilities for ongoing foodborne illness surveillance, working both independently and in collaboration with CDC and local agencies. These include implementing state reportable disease requirements and other state and local surveillance activities and participating in FoodNet, PulseNet, OutbreakNet, and other national foodborne illness surveillance initiatives, as discussed further below.

Outbreak Response and Recalls: States typically have lead responsibility, in collaboration with local health departments, on large-scale outbreak investigations. States also oversee many industry recalls of food products, often in collaboration with federal and local regulatory agencies.

Laboratory Testing: State laboratories conduct the majority of all government, food-safety-related laboratory testing, including for pathogens in clinical specimens and chemical and microbial contaminants in food samples.

Retail and Food Service Inspection: While food safety oversight in retail and food service establishments is largely conducted by local agencies, state agencies in some states are involved in retail food safety standard setting and inspection of retail and food service establishments.

Food Manufacturing Inspections: States conduct more than 80 percent of all non-retail food establishment inspections (not including USDA-inspected meat and poultry establishments), including the majority of "FDA inspections" in food manufacturing and processing facilities, which state agencies conduct under contract with FDA.

Farm Inspections: States conduct on-farm inspections for animal health and other conditions related to food safety, and they have primary jurisdiction for enforcement of federal pesticide use restrictions, which relate directly to the possibility of violative and potentially unsafe residues in food. On-farm activities include Good Agricultural Practice assessments of produce growers and partnership programs with shell egg producers to reduce the incidence of *Salmonella enteritidis* contamination.

Technical and Training Assistance: States provide extensive technical and training assistance to staff employed by their state agencies, local health department staff, and to many grocery, restaurant, and other retail food service workers.

Education: States provide food safety education for local health department staff, food workers, and other commercial participants in the food safety system, as well as education for consumers and the medical community.

Local Roles and Responsibilities

The thousands of local health departments and food inspection agencies across the country are at the very frontline of food safety protection, with key roles in both prevention and response. This includes having the primary regulatory responsibility in most jurisdictions for setting and/or enforcing food safety standards in the million or so restaurants and grocery stores in the United States and being the first place most consumers call when they think they have a food safety problem.

There is enormous diversity in the size and capacity of local agencies working on food safety across the country and in how they relate to food safety agencies at the state level. Some have significant specialized food safety expertise, while some have more limited capacity. Some operate independently of their state governments, while others do not. This makes difficult any generalizations about local food safety agencies. They employ, however, the great majority of environmental health professionals working on the critical prevention side of food safety in the United States. Together, local agencies comprise the very broad base of the nation's food safety pyramid.

Surveillance: Local agencies have frontline responsibility for reporting foodborne diseases and other local activities essential to on-going foodborne illness surveillance, including collecting and responding to food-safety-related consumer complaints within their jurisdictions.

Outbreak Response and Recalls: Local agencies are the first responders and lead investigators on local outbreaks and are actively involved with state and federal agencies on larger, multi-jurisdictional outbreaks, implementing recalls, and communicating with the public and food establishments.

Laboratory Testing: Local agencies carry out food safety laboratory functions in some jurisdictions.

Retail and Food Service Licensing and Inspections: Local agencies set retail food safety standards, license retail establishments, and play an extensive role in food safety inspections of grocery stores and restaurants to ensure that good sanitation and other food safety standards are observed.³³

Technical and Training Assistance: Local agencies provide technical and training assistance to their staffs and to many grocery, restaurant, and other retail food service workers.

Education: Local agencies are the frontline source of food safety information and education for consumers and retailers, with 75 percent of local health departments having food safety education programs.³⁴

FEDERAL, STATE, AND LOCAL COLLABORATION ON FOOD SAFETY

There is a long history of federal collaboration with state and local food safety agencies, with the result that federal, state, and local programs are today intertwined and interdependent in many ways. This interdependency and collaboration penetrates through all aspects of the nation's food safety system, including surveillance, outbreak investigation and response, and regulatory and inspection activities. There is room for improvement in how every one of these collaborations operates in practice, as spelled out in Section III's findings. Nevertheless, the range and growing sophistication of the collaborations is an important sign of progress and potential.

Foodborne Illness Surveillance

FoodNet (Foodborne Diseases Active Surveillance Network): FoodNet is a major collaborative effort among CDC, FDA, USDA, and the ten states participating in CDC's Emerging Infections Program. Its goal is to provide more accurate estimates of foodborne illness associated with foodborne pathogens, which it does by conducting active, population-based surveillance in ten sites for laboratory-confirmed cases of infection caused by nine pathogens (*Campylobacter*, *Cryptosporidium*, *Cyclospora*, *Listeria*, *Salmonella*, Shiga toxin-producing *Escherichia coli* O157, *Shigella*, *Vibrio*, and *Yersinia*).³⁵ FoodNet has contributed to the standardization of methods among laboratories and performs targeted case-control studies to identify risk factors for pathogen-specific illnesses.

PulseNet (National Molecular Sub-typing Network for Foodborne Disease Surveillance): PulseNet was established by the CDC in collaboration with state public health laboratories. It is an early warning system for outbreaks of foodborne disease consisting of a national network of public health laboratories that perform DNA fingerprinting on bacteria that may be foodborne, such as *Escherichia coli* O157:H7, *Salmonella*, *Shigella*, *Listeria*, *Campylobacter*, and *Yersinia*.³⁶ The network identifies and labels each disease-causing organism by its DNA fingerprint pattern and rapidly compares new patterns to those existing in the electronic database at CDC to identify related strains, thereby permitting analysts to connect cases to a common source.³⁷

FERN (Food Emergency Response Network): FERN integrates the nation's food-testing laboratories at the local, state, and federal levels into a network that is able to respond to emergencies involving biological, chemical, or radiological contamination of food.³⁸ FDA, USDA, CDC, and EPA all participate in FERN. The FERN structure is organized to ensure federal and state inter-agency participation and cooperation in the formation, development, and operation of the network.³⁹ FERN plays a number of critical roles related to food security and food defense by providing a national surveillance program that will offer early means of detecting threat agents in the American food supply; preparing the nation's laboratories to be able to respond to food-related emergencies; and offering surge capacity for responding to widespread complex food contamination emergencies, whether intentional or inadvertent in origin.⁴⁰

eLEXNET (Electronic Laboratory Exchange Network): eLEXNET is a web-based information network, coordinated by FDA, which allows federal, state, and local food safety officials to compare, share, and coordinate laboratory analysis findings.⁴¹ It is also the data capture and communication system for FERN.⁴² eLEXNET provides the necessary infrastructure for an early warning system that identifies potentially hazardous foods and enables health officials to assess risks and analyze trends.⁴³

Epi-X (Epidemic Information Exchange): Run by the CDC, *Epi-X* is a web-based surveillance communication tool for public health professionals.⁴⁴ Through *Epi-X*, CDC officials, state and local health departments, poison control centers, and other public health professionals are able to access and share preliminary health surveillance information, and are rapidly notified of breaking health events as they occur.⁴⁵ Key features of *Epi-X* include scientific and editorial support, controlled user access, digital credentials and authentication, rapid outbreak reporting, and multi-jurisdictional peer-to-peer consultation.⁴⁶

Outbreak Response

OutbreakNet/NORS: OutbreakNet is a national CDC-coordinated network of public health officials in local and state health departments and federal agencies who investigate outbreaks of enteric disease, including foodborne outbreaks.⁴⁷ In addition to collaborating on foodborne outbreak investigations, state OutbreakNet members report findings of their foodborne outbreak investigations to CDC through the National Outbreak Reporting System (NORS), a national web-based reporting system that tracks foodborne, person-to-person, animal contact, waterborne, and Norovirus outbreaks.⁴⁸ Prior to NORS, which came into effect for foodborne illness reporting on January 1, 2009, states reported foodborne outbreaks through the Electronic Foodborne Outbreak Reporting System (eFORS), a web-based program similar to NORS but which was more limited in scope.⁴⁹

CIFOR: As described in Section I, the Council to Improve Foodborne Outbreak Response is a multidisciplinary working group that seeks to improve performance and coordination among federal, state, and local agencies with respect to routine surveillance of foodborne illness, foodborne outbreak detection and response, laboratory methods for foodborne pathogens, and foodborne disease prevention, communication, and education at the state and local levels.⁵⁰ The Council includes CDC, FDA, USDA, AFDO, APHL, ASTHO, CSTE, NACCHO, NEHA, and NASDA.⁵¹ CIFOR also includes an industry workgroup composed of 16 industry leaders from food production, restaurant, and retail companies.⁵²

Epi-Ready: Epi-Ready is a nationwide team-training initiative, led by the CDC and NEHA, which provides up-to-date foodborne disease outbreak investigation and surveillance training to public and private sector environmental health professionals as well as other professionals who collaborate in conducting foodborne disease outbreak investigations.⁵³

FoodSHIELD: FoodSHIELD is a web-based platform designed to create community and share information about capacity, training, and other matters among laboratories and regulatory agencies at all levels of the food safety system, with a focus on information related to bioterrorism and other intentional contamination.⁵⁴ FoodSHIELD's mission is to support federal, state, and local governmental regulatory agencies and laboratories through web-based tools that enhance threat prevention and response, risk management, communication, and asset coordination, as well as public education.⁵⁵

Prevention, Inspection and Regulatory Activities

EHS-Net (Environmental Health Specialists Network): EHS-Net is a CDC-coordinated collaborative forum of environmental health specialists who work with epidemiologists and

laboratorians to identify and prevent environmental factors that contribute to foodborne illness and other disease outbreaks. It includes environmental health professionals from CDC, FDA and nine states. The EHS-Net goals include translating investigatory findings into improved food safety prevention efforts using a systems-based approach and strengthening relations among epidemiology, laboratory, and environmental health programs.⁵⁶

FDA's Food Code: FDA publishes the Food Code, a model ordinance that FDA develops in collaboration with state and local food safety agencies and that provides a sound technical and legal basis for regulating the retail and food service segment of the industry (e.g., restaurants, grocery stores, and institutions such as nursing homes).⁵⁷ Local, state, territorial, tribal, and federal regulators use the FDA Food Code as a model to develop or update their own food safety rules and to be consistent with national food regulatory policy and emphasize prevention.⁵⁸ AFDO reported in June 2005 that 48 of 56 states and territories have adopted food codes patterned after one of the five versions of the Food Code, beginning with the 1993 edition.⁵⁹

FDA Voluntary National Retail Food Regulatory Program: This cooperative program provides recommended standards and assessment procedures for the regulatory programs through which state, local, territorial, and tribal regulatory agencies implement the Food Code. Its goal is to ensure that these agencies have the capacities and procedures in place to achieve widespread compliance with the Food Code's food safety provisions and thereby more effectively prevent foodborne illness.⁶⁰ This program provides the foundation and framework for future federal-state-local collaboration to improve food safety practices at the retail level.

FDA-State Contract Inspection Agreements: State employees carry out over half of all FDA inspections at domestic food processing plants under contract to FDA.⁶¹ Inspections are performed under the States' laws and authorities, the provisions of the U.S. Food, Drug and Cosmetic Act (FDCA), or both.⁶²

FDA Manufactured Food Regulatory Program Standards: This relatively new FDA-sponsored program is similar to the Voluntary National Retail Food Regulatory Program, except that it focuses on state programs for the regulation of food processing plants.⁶³ Compliance with the program's standards and assessment procedures will likely become a pre-requisite for states conducting inspections under contract to FDA, thus helping to ensure that state-conducted FDA inspections are performed at a uniformly high level of quality nationwide.

Grade A Pasteurized Milk Ordinance (PMO) and the National Conference of Interstate Milk Shipments (NCIMS): The PMO and NCIMS are cooperative programs through which FDA and USDA collaborate with state authorities and the milk industry to ensure the safety of milk shipped in interstate commerce.⁶⁴ The PMO is a model ordinance, developed in collaboration with the FDA and the NCIMS, which is generally recognized as a national standard for milk sanitation and safety and has been adopted by all 50 states.⁶⁵ It is used as the basis for certification of interstate milk shippers through a federal-state cooperative program in which the states carry out much of the monitoring and enforcement to oversee the safety and wholesomeness of fresh milk and cream.⁶⁶

National Shellfish Sanitation Program: The National Shellfish Sanitation Program is the federal-state cooperative program through which FDA and the Interstate Shellfish Sanitation Conference ensure the sanitary control of shellfish.⁶⁷ It is another program in which FDA provides leadership in setting uniform, science-based standards and states play a lead role in implementation and enforcement.

Talmadge-Akin Federal-State Cooperative Inspection of Meat and Poultry Plants: The Federal State Cooperative Act (Talmadge-Akin) authorizes FSIS to enter into cooperative agreements with state agencies to inspect meat and poultry plants on behalf of the federal government and in accordance with federal requirements.⁶⁸ At least nine states carry out federal inspections in about 300 plants under this program.⁶⁹ The meat and poultry inspection laws (Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA), respectively) also authorize state agencies to inspect plants under state inspection laws, provided the state requirements are “at least equal to” the federal inspection requirements, but products from these plants may be sold only within the state where they were processed and inspected.⁷⁰ During fiscal year 2007, 27 States were cooperating under the FMIA and 25 States were cooperating under the PPIA.⁷¹

STATE AND LOCAL FOOD SAFETY RESOURCES

Detailed, up-to-date information on the food safety budgets and levels of activity of state and local agencies is not readily available. In fact, the most current, comprehensive surveys of state and local resources devoted to food safety were reported in 2001 by GAO,⁷² and in 2002 by AFDO⁷³ and CSTE.⁷⁴ The GAO report covered 1998 and 1999 federal and state-level food safety expenditures and activities, but not local food safety efforts. The AFDO report covered 2001 state and local activity and staffing levels, but not expenditures. And the CSTE report focused on epidemiology capacity in state-level food safety programs as of 2001, including such matters as staffing levels, infrastructure, and training, but not expenditures.

It would be important for future planning purposes to have more current and comprehensive resource information. Taken together, however, the available information provides a fair picture of the scope and scale of food safety activity at the state and local level, which, on a countrywide basis, has not changed significantly since the GAO, AFDO, and CSTE reports were issued.

Level of State Resources

According to the GAO, state health and agriculture departments devoted about \$301 million and 5,717 staff years to food safety oversight in 1999, about half of which (\$144 million and 3,039 staff years) was devoted to licensing and inspection activities.⁷⁵ While these resources are significant, the states (and to varying degrees their local subdivisions) were responsible for inspecting over one million establishments in their jurisdictions, including 379,000 restaurants, 307,000 groceries and other retail establishments, and 88,000 dairies—facilities over which state and local agencies have primary inspection responsibility.⁷⁶ The states reported conducting about two million inspections annually.⁷⁷

Other major categories and levels of state expenditure reported by GAO for 1999 included laboratory analyses (\$34 million and 467 staff years), administration and support (\$33 million and 681 staff years), and response to problems such as investigation of outbreaks, recall activities, natural disasters, and regulatory enforcement activities (\$16 million and 343 staff years).⁷⁸

Nationwide, state-level food safety expenditures averaged about \$1.07 per capita.⁷⁹ Many individual states invested in food safety at about the \$1 per capita level but there were also some wide disparities on a per capita basis. For example, based on the AFDO expenditure data, expenditures by Connecticut and California were 25 cents and 50 cents per capita, respectively, while Louisiana and

Alaska spent \$3 and \$7 per capita, respectively.⁸⁰ It is important to note, of course, that the optimal level of expenditure for food safety would be determined on the basis of factors in addition to population size, such as the number and nature of the facilities in a state and the nature of the food safety problems they encounter. The wide range in per capita expenditures reflects among other things, however, the simple reality that each state makes its own decision about how much to invest in food safety.

The CSTE report provides insight into the level and variability of food safety epidemiology capacity, which is a critical component of food safety surveillance and outbreak response at all levels of government. With 47 states and one territory responding to its survey, CSTE found that only 23 states employed at least one dedicated foodborne disease epidemiologist.⁸¹ Based on CDC's population-based epidemiological capacity recommendations⁸² and 2000 U.S. Census data,⁸³ all but 7 states should have at least one dedicated foodborne disease epidemiologist at the masters-level or above;⁸⁴ yet the CSTE survey showed that such personnel were lacking in 28 states.⁸⁵ Similarly, 20 states should have at least one doctoral-level foodborne epidemiologist,⁸⁶ but CSTE's survey showed that only 6 states met this capacity standard.⁸⁷ Such shortages in state and local epidemiological capacity can have significant consequences for the nation's ability to protect consumers from foodborne illness. Indeed, in the CSTE study, a majority of states cited limited staff as a major factor limiting their ability to conduct more active case surveillance and investigate foodborne outbreaks.⁸⁸

Level of State and Local Activity

The AFDO report provided fairly detailed information on the level of food safety activities carried out by state and local agencies collectively in 2001. For example, AFDO reports a total of about 2.5 million inspections, including almost 1.2 million in retail food service establishments; and over 500,000 in retail food stores.⁸⁹ These inspections and other investigations generated over 128,000 enforcement actions, including over 36,000 warning letters; 31,500 stop sale orders; almost 14,000 embargo/seizure actions; almost 10,000 monetary penalties, and about 2,900 license/permit revocations.⁹⁰ State and local laboratories analyzed over 328,000 samples, including over 252,000 for microbiological contamination.⁹¹

State and Local Funding Sources

The majority of the resources expended on food safety by state and local agencies are generated by the state and local governments in the form of general revenue and licensing fees. The balance comes from the federal government.

General revenue funds, which most state food safety programs rely upon to some extent, are derived principally from state taxes, which of course fund a wide range of programs within the state beyond food safety. Because general revenues are not dedicated food safety funds, the level of such funding varies annually based on state and local priorities and available resources.

Most states and localities also rely on fees generated through the licensing of restaurants and other food establishments. In some states, all or a portion of fees generated from issuing licenses are considered "dedicated" funds and are used solely for maintaining state and local food safety programs. In other states, licensing fees revert back to the general fund and may be used to fund any program within the state. Even when fees are dedicated to food safety, however, they are not completely off limits for other purposes, as states sometimes reclaim a portion of these funds when

faced with budget shortages in other program areas. Moreover, even license fees that are dedicated to state and local food safety programs are subject to the appropriations process each budget cycle.

While the majority of state and local food safety funds are derived from state and local sources, federal contracts and grants also provide some level of funding in many states. The primary agencies that provide food safety funding to state and local agencies are FDA, CDC, and USDA.

FDA

The FDA provides limited funding to state agencies to assist with their food safety work (although FDA does provide some funding to local, territorial, and tribal agencies, the vast majority of funds are awarded to states). FDA funding to states varies from year to year, as FDA does not have a dedicated line item in its annual budget for state, local, territorial, or tribal food safety assistance. Rather, funds are awarded based on availability through state contracts, grants, and cooperative agreements.

For the past 36 years, a number of states have received a portion of their food inspection funding from the FDA through state contract inspection agreements. Forty-two states currently participate in the FDA's Food Inspection Contract Program, in which states contract with the FDA to perform inspections in selected food manufacturing and processing plants to determine compliance with federal regulations, state regulations, or both (see Federal, State, and Local Collaboration on Food Safety, above).⁹² These inspections constitute only a small fraction of the total inspections that states conduct each year.⁹³ In FY 2008, states conducted about 10,500 FDA food contract inspections for which FDA contributed approximately \$8 million.⁹⁴

FDA also provides funding to state and local agencies through various grant programs and cooperative agreements. Unlike its contract programs, grants and cooperative agreements are not for inspectional work; rather, they provide state and local agencies with funds to pursue other types of activities, such as food defense, laboratory improvements, and training opportunities for state and local food safety agencies. In FY 2008, FDA provided states with approximately \$11.4 million in grants and cooperative agreements.⁹⁵

CDC

CDC's Food Safety Program supports critical activities in state health departments in all 50 states, as well as activities at the CDC. Funds to state and large city health departments are distributed through CDC's Emerging Infections Program and the Epidemiology and Laboratory Capacity Building Program cooperative agreements, and include programs aimed at improving surveillance and outbreak response, such as PulseNet and FoodNet (see Federal, State, and Local Collaboration on Food Safety, above). All 50 states, several large city health departments, and two territories receive PulseNet funding, while ten states receive funding to participate in FoodNet.⁹⁶

CDC's food safety budget request for 2009 totaled approximately \$22.4 million, a significant portion of which is used to fund state participation in programs such as PulseNet and FoodNet.⁹⁷ This funding level has declined from \$22.9 million in 2007.

USDA

States receive funding from the USDA to conduct meat and poultry inspections under the Federal Meat Inspection Act, Poultry Products Inspection Act, and the Federal State Cooperate Act

(Talmadge-Akin). The FMIA and PPIA provide for FSIS to contribute up to 50 percent of the cost of state inspections conducted under these agreements.⁹⁸ In FY 2007, 27 states participated in the FMIA program and 25 states participated in the PPIA program, with funding for both programs estimated at \$46.5 million;⁹⁹ similarly, Talmadge-Akin funding provides approximately 50 percent of inspection costs to the nine states that participate in that program (though the Talmadge-Akin Act permits FSIS to contribute up to 100 percent of the costs of these inspections).¹⁰⁰

LEGAL FRAMEWORK AND ISSUES AFFECTING COLLABORATION

Current Framework for Collaboration

Food safety agencies at all levels of government work within the legal framework that is created by their respective legislative bodies, interpreted by the courts, and underpinned by the federal and state constitutions. Under our federal system of government, food safety agencies work today within a legal framework that is generally conducive to federal-state-local collaboration. The current legal framework has its origins in the original adoption of the U.S. Constitution and thus pre-dates by over two centuries today's vision of an integrated national food safety system, but, fortunately, it provides the basis for the full partnership required to make that vision work.

The starting point and most fundamental principle is that food safety falls squarely within the traditional and broad “police powers” to protect public health that are reserved to the states by the Constitution. There is thus no question that states, and in turn their local governments, are empowered and expected to protect the safety of the food supply within their boundaries. This includes the power to set and enforce their own food safety standards, even, as a general rule, if the standard is different from and more stringent than an applicable federal standard.¹⁰¹

At the same time, the federal government has broad power under the Constitution to protect the “general welfare” and to regulate interstate commerce and activities that affect commerce, including food safety. Congress has exercised that power in a long series of enactments establishing the food safety programs of FDA, CDC, USDA, EPA and other agencies.

Our federal system carefully balances these federal and state powers. While state and local powers are broad, limits can arise under the Supremacy Clause, if Congress expressly or by clear implication preempts a state enactment, or under the Commerce Clause, if a state law or regulation unduly burdens or discriminates against interstate commerce—legal determinations that are made on a case-by-case basis. As a general rule, however, courts recognize and respect the food safety regulatory and response roles of state and local governments. It is essential to the success of the national food safety system to preserve the legal power of the states to set and enforce standards and otherwise oversee food safety.

An important element of the practical accommodation between federal and state powers is that states generally embrace the goal of uniformity between state and federal food safety laws and regulations, and most states have adopted statutes that are modeled on and consistent with the federal food safety laws. In fact, uniformity is one of the founding principles of the Association of Food and Drug Officials, which represents state and local food safety regulators. The fulfillment of this goal can be seen not only in state laws but in such model ordinances as the Food Code, which

fosters adoption of science-based retail food safety standards that are uniform not only between federal and state governments but among the states as well.

Thus, the combination of well-respected state and local police powers and the shared goal of maximizing uniformity provide a fundamentally sound legal framework for building the federal-state-local partnership.

One of the issues that arose during the course of the project reflects this careful and practical balance between federal-state powers and roles. As a matter of longstanding policy, CDC enters investigations of foodborne illness outbreaks only at the invitation of the state or states within which an outbreak is occurring. This policy reflects the primary, frontline role of state and local agencies in conducting illness outbreaks and is so well entrenched that many participants in the food safety system perceive CDC to be legally precluded from joining or conducting investigations without the state's invitation. In fact, Congress has given CDC broad powers in the Public Health Service Act to conduct "research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man."¹⁰² CDC's policy is thus grounded in prudent forbearance, not a lack of legal authority.

Legal Limitations on Collaboration

Within this fundamentally sound legal framework, however, are some limitations that affect collaboration and the prospects for full partnership.

The central limitation is that there is no statutory mandate at the federal or state level to build an integrated, national food safety system and operate in full partnership. This does not by itself preclude collaboration, as evidenced by the extensive collaboration that already exists, but it means that, in the end, officials are not fully empowered and accountable for integrating their food safety efforts. In July 2008, then-Senator Barack Obama proposed to change this by introducing a bill directing the Secretary of HHS "to leverage and enhance the food safety capacity and roles of State and local agencies and integrate State and local agencies as fully as possible into national food safety efforts" for the purpose of achieving specified improvements in the performance of the food safety system.¹⁰³ If enacted, such legislation would provide a new mandate and accountability at the federal level for building a full food safety partnership.

In addition to the lack of an affirmative mandate for collaboration, there are some specific legal obstacles to full partnership on food safety, including constraints on mutual reliance among agencies in inspection and enforcement situations and on the sharing of information and resources.

Mutual Reliance in Enforcement Cases

Historically, lawyers at the federal level have been unwilling to rely in federal enforcement proceedings on analytical results and other evidence generated by state and local agencies, based on concerns about admissibility and credibility. This undercuts the ability of federal agencies to leverage state and local resources, and reduces the incentive for state and local agencies to collaborate on inspection and enforcement matters. There is no legal prohibition on the reliance in federal court on evidence generated by state and local agencies, but a collaborative effort is required to establish procedures that alleviate any legal limitations on the value of such evidence.

Information Sharing

The free flow of information is essential to any partnership and vital to any integrated, system-wide effort to improve food safety. This topic has been analyzed extensively in a separate report, which documents many ways in which vital information sharing among federal, state, and local agencies faces policy and bureaucratic obstacles, as well as legal ones.¹⁰⁴ The current project has highlighted the extent to which laws created for worthy, non-food safety purposes can create problems for state and local agencies seeking food safety-related information from federal agencies and other states; and local agencies have cited the difficulty of obtaining data from their state agencies.¹⁰⁵

For example, in both active surveillance programs and outbreak investigations, privacy laws aimed at protecting the identities of foodborne illness patients can slow or even block the flow of epidemiological information (that might provide clues to a patient's identity) among CDC and its state and local counterparts, as well as the sharing of such information with regulatory agencies. This can reduce the value of surveillance data for parties working to prevent foodborne illness and make it more difficult for outbreak investigations to proceed quickly and efficiently.

In recall situations, FDA cites the Freedom of Information Act (FOIA) as the basis for not routinely sharing industry distribution lists with state and local agencies on the ground that they constitute commercially valuable business information that is protected from disclosure under FOIA.¹⁰⁶

On occasions when states are able to obtain such information, typically through execution of a Memorandum of Understanding, they are usually prohibited from sharing this information with their local counterparts or the public.¹⁰⁷ This legal barrier to information sharing can hamper prompt action by state and local agencies to remove tainted foods from the shelves.

FOIA-based concerns about protecting confidential business information is also an obstacle to federal agencies sharing full establishment inspection reports, promptly or at all, with states and localities, even though such reports might assist state and local agencies in identifying or understanding problems with products or facilities in their jurisdictions.

Resource Sharing

Large outbreaks commonly cross state lines and can place such heavy demands on a state's investigatory and response resources that they may not be able to meet the challenge alone. CDC provides back up resources when requested, but neighboring states may also have personnel or laboratory resources that could be applied to the benefit of all. The sharing of resources in such cases may be impeded, however, by issues such as:

- Reimbursement—whether, when, and to what extent a state may receive reimbursement for resources and services provided to another state;
- Liability—which state will bear responsibility for any liability for harm arising from the sharing of resources or donation of services;
- Workmen's compensation—who pays for injuries suffered by employees involved in activities conducted outside the state that employs them; and,
- Licensure Requirements—whether the professional licenses and other credentials of employees, such as physicians and other health professionals, loaned from one state to another, will be respected in the recipient state.

These types of legal constraints arise any time states need outside assistance in responding to emergencies. States have addressed them in major emergency situations, such as tornados, hurricanes, and toxic spills, through their participation in the Emergency Management Assistance Compact (EMAC), which is a binding contract among states that spells out how such legal issues are to be resolved when one state agrees to share resources with another.¹⁰⁸ EMAC has not been applied to food safety emergencies, but it provides a model that could be adapted for that purpose.

III. KEY FINDINGS ON STATE AND LOCAL FOOD SAFETY ROLES AND OPPORTUNITIES FOR ENHANCEMENT

This section contains findings on the role state and local agencies currently play in the nation's food safety system, areas in need of improvement, and some of the major opportunities for enhancing state and local roles. These findings are based on input from many experts and participants in the food safety system, including during the two project workshops (see workshop summaries at Appendices B and C), as well as the project team's analysis. These findings form the basis for the recommendations in the section that follows.

GENERAL FINDINGS

Finding 1: Essential Role of State and Local Agencies

The dispersal of many food safety functions and much capacity across thousands of state and local agencies is a valuable feature of the food safety system.

Comment: The wide dispersal of functions and capacity across the *food safety system* parallels the complex and widely dispersed *food system*, which includes millions of local farmers, grocery stores and restaurants, as well as national and international food companies that produce, process, transport, and market food. While this report makes recommendations to address some of the challenges that flow from having so many state and local agencies involved in food safety, it is important to appreciate how the decentralization of food safety functions contributes to the success of the system.

Most fundamentally, the decentralized structure of the food safety system capitalizes on the interest and commitment of state and local governments to help ensure food safety, in fulfillment of their primary role in the U.S. federal system as protectors of public health. State and local agencies also have the advantage of bringing government food safety efforts to the ground level, where problems occur and can be detected, corrected, and prevented, and this proximity to their communities equips state and local agencies with unique knowledge of local conditions, companies, and needs. The on-the-ground capacity and presence of state and local agencies, especially in surveillance and outbreak investigations and on farms and in retail establishments, could never be duplicated at the federal level.

Finding 2: Large and Growing Role in the National Food Safety System

As food safety problems increasingly cut across jurisdictional lines and have national consequences, the role of state and local agencies in the national food safety system is becoming even more important.

Comment: The recent *Salmonella* Saintpaul and *Salmonella* Typhimurium outbreaks demonstrate how rapidly, in today's national and international food system, food safety problems can cross political boundaries. Their detection, containment, and prevention increasingly require nationwide efforts at all levels of government.

State and local agencies have long contributed to national food safety efforts in many ways and their role will only grow more important, as they are:

- the primary sources of the illness surveillance information used by federal and state authorities to detect and contain outbreaks and plan future preventive measures;
- the frontline responders to outbreaks, whether local or national in scope;
- the operators of the majority of the laboratory capacity on which the nation relies for testing food and clinical specimens;
- the principal regulators and inspectors of the retail and food service establishments where Americans consume one out of every four meals;¹⁰⁹
- major contributors to inspection and other oversight of food manufacturers and wholesale distributors; and,
- the most direct communicators with the public on food safety issues, including education on safe food handling and preparation at home.

Looking ahead, the nation's food safety system can be effective in detecting, managing, and preventing food safety problems only with the sustained and enhanced involvement of state and local agencies.

Finding 3: Challenges of a Decentralized System

While decentralization of the food safety system is a strength, its challenging consequences include:

- *Organizational fragmentation that complicates communication, coordination, and collaboration among government agencies and can impede effective response to food safety problems that cut across jurisdictional lines;*
- *Wide disparity in standards and practices among state and local agencies in such critical areas as illness surveillance, laboratory methods, inspection, and retail regulation; and,*
- *Wide disparity in state and local government investments in food safety and thus in their capacities to detect and address food safety problems.*

Comment: The challenges posed by having many agencies working on a common problem are not unique to food safety, and, in fact, the challenges posed by the decentralization of the food safety system are typical of those faced by the nation's public health system as a whole.

Every food safety agency, whether federal, state, or local, operates within its own mandate, accountability, and constraints. They thus have a natural tendency to work independently and take ownership of their particular piece of the food safety enterprise. They are under greater pressure to satisfy their core mandate and responsibility within their own jurisdictions than to focus on interagency coordination, sharing of information, and active collaboration to solve food safety problems that may have originated in another jurisdiction. The stove-piping that often results from this reality can be compounded by the fact that staff working in health and agriculture departments often come from diverse professional backgrounds and may not speak the same professional language.

Significant disparities in standards and practices are also a natural consequence of having a decentralized food safety system and are common across state and local agencies. Such disparities can affect their capacity to collaborate effectively as part of the national food safety system, such as when states adopt different versions of the Food Code, laboratories use differing methodologies that make sharing and aggregation of data difficult, or inspection agencies take different approaches to conducting and reporting on food safety inspections. These disparities can get in the way of spotting trends and patterns that could be used to plan prevention strategies.

Disparity in the resources available to state and local food safety agencies also affects their ability to function effectively as part of the national food safety system. This is seen most acutely in the differences across jurisdictions in epidemiological capacity, with some having fulltime experts able to promptly follow up on reported illnesses while others rely on staff that may have multiple duties besides food safety and lack specialized training to investigate foodborne illnesses. Such differences can mean that the ability to detect and contain illness outbreaks and develop the knowledge needed to prevent them in the future can depend on the happenstance of where the illness occurs.

Finding 4: Obstacles to Achieving the Shared Vision

Many federal, state, and local officials and agencies share the vision of an integrated national food safety system, but there are significant practical obstacles to real federal-state-local partnership, in addition to the natural organizational barriers; these obstacles include obsolete food safety laws and other legal constraints, coupled with scarce resources and the lack of positive incentives to collaborate across organizational lines.

Comment: In its November 2007 Food Protection Plan, FDA embraced the vision of an integrated national food safety system and has engaged state and local officials in a dialogue about how to build on existing collaborations. In workshops held in conjunction with this project and in an August 2008 FDA meeting with food safety officials from the 50 states, territories, and tribal nations, state and local officials supported much closer collaboration and a more integrated approach to food safety among all government agencies. These sentiments were echoed in USDA's May 2008 national food safety stakeholder workshop on improving federal, state, local, and industry collaboration during foodborne outbreaks.

Today's food safety laws at all levels of government were written, however, before the vision of an integrated national system emerged, which means that agencies have no mandate to operate as part of a national system. Moreover, agencies operate under legal rules that can make it difficult to share information, staff, and other resources; and they typically lack funds to invest in information sharing systems, joint training, travel, and other elements of real partnership among agencies. While federal, state, and local agencies work together in outbreak situations and in some specific program areas, such as retail sanitation, they have very few positive incentives for broader, on-going collaboration to better prevent foodborne illness.

Finding 5: Chronic Underfunding of State and Local Agencies

As a general matter, state and local food safety programs are significantly understaffed and underfunded in relation to the magnitude and difficulty of the food safety problem and the importance of their contribution to the national food safety effort.

Comment: Like our nation’s entire public health infrastructure, state and local food safety programs struggle to achieve adequate funding and chronically fall short. Some state agencies are relatively well funded to perform specific functions, while many others operate with very limited and often unstable funding that not only keeps staffing levels low but precludes the investment in training, equipment, and other physical infrastructure required for a modern, science-based food safety program. As at the federal level, food safety funding at state and local levels has not kept up with rapid change in the food system and the growing complexity of food safety problems.

Local health departments are under particular pressure as tight budgets are putting some localities under pressure to consolidate their health departments with neighboring localities or dissolve them altogether. This threatens the critical base of the food safety pyramid with respect to both outbreak response and retail inspection at a time when the national interest calls for a more robust local effort.

Finding 6: Information Sharing

Federal, state, and local health, regulatory, and inspection agencies collect large volumes of data and information that could be mutually beneficial, but such information tends to be stove-piped within and among agencies, with its sharing and use constrained by inconsistent methods of data collection; legal, policy, and bureaucratic obstacles to data sharing; and lack of investment in information technology and systems to support data sharing.

Comment: These problems in the nation’s “food safety information infrastructure” have been documented elsewhere.¹¹⁰ Many persist due simply to a lack of adequate priority and commitment to solving them, such as inadequate investment in compatible information systems and other mechanisms to foster information sharing, while others are the product of policies and legal barriers that impede the flow and optimal use of available resources. The latter include barriers to sharing epidemiology data arising from privacy laws, tendencies of data generators to feel ownership of their data and resist sharing, the policies of FDA not to share and FSIS to limit sharing of distribution lists with state and localities in recall situations, and the practice of federal agency lawyers not relying on state-generated laboratory results and other evidence in enforcement cases. Full partnership on food safety among federal, state, and local agencies depends on reducing the barriers to information flow among them.

Finding 7: Need for Action to Achieve Shared Vision

Achieving the vision of a more effective and integrated national food safety system depends on reducing the disparities in practice and capacity, legal and resource constraints, and other obstacles to full partnership among federal, state, and local agencies.

Comment: Shared vision and goodwill among agencies and individuals will not be sufficient to achieve the vision of an integrated national food safety system. Concerted action is required to reduce or eliminate disparities and other obstacles to partnership and provide positive incentives for collaboration.

Finding 8: Need for Federal Leadership

Food safety success in the United States requires the federal government to play a leadership role, in collaboration with state and local agencies, to remove obstacles to partnership, ensure adequate funding and capacity, and make optimal use of all resources across the national food safety system.

Comment: Federal leadership is needed to build an integrated national food safety system. Leadership from and collaboration with states and localities are also essential, but only the federal government can lead the creation of a national vision and policy framework for food safety, marshal the resources to build the food safety capacity needed at all levels to address national food safety issues, and integrate the activities of agencies at all levels.

Finding 9: Federal Leadership Hampered by Fragmented Structure

The capacity of the federal government to lead development of an integrated, national food safety system is impaired by the fragmentation in food safety organizational structures at the federal level, resulting in the lack of a clear focal point for interaction on many food safety matters between state and local agencies and the federal government.

Comment: At least four major federal agencies—FDA, CDC, USDA, and EPA—have significant operational responsibilities for food safety that involve interaction with the state and local agencies. On surveillance and outbreak response, CDC and the federal regulatory agencies interact and share responsibilities among themselves and with the many state and local agencies, with coordination often being difficult and the focal point for federal leadership unclear. On regulatory matters, the USDA relationship with state meat and poultry inspection programs is well-defined, but FDA's relationships with the states are more diverse and much more challenging to coordinate. This challenge is made more difficult by the fact that, within FDA, there is fragmentation of responsibility for food safety, especially between CFSAN and ORA, and in working relationships with states and localities. This fragmentation at the federal level, and especially within FDA and HHS, complicates day-to-day interactions with state and local agencies and contributes to a leadership void at the federal level for purposes of creating a unifying vision for food safety and driving the development of an integrated national system.

Finding 10: Need to Build on the Current Collaboration

The history of interaction among federal, state, and local food safety agencies provides a strong foundation on which to build, but much work remains at all levels to institutionalize an integrated national food safety system that operates on the basis of seamless collaboration and mutual advantage, dependence, and trust.

Comment: Federal, state, and local agencies and officials have a long history of working together and a resulting appreciation among many of how working together can improve food safety. In considering actions to build an integrated national system, however, it is important to recognize that the obstacles to full partnership noted earlier are significant, and the natural tendency of organizations to protect their turf, prerogatives, and autonomy is a persistent reflection of how people and organizations behave. Any realistic strategy to build a more integrated food safety system must take account of these realities and address them by ensuring that change brings mutual advantage and builds trust throughout the system.

Finding 11: National Interest in Strengthening State and Local Roles

The significant national interest in food safety justifies a stronger federal effort, in collaboration with state and local food safety agencies, to ensure that state and local agencies function effectively as integral components of the national food safety system.

Comment: Food safety problems have national consequences for public health, the economy, and trade. Because success in detecting, containing, and preventing food safety problems depends on the integrated and effective effort of federal, state, and local agencies, there is a compelling national interest in helping build the capacity of state and local agencies, breaking down barriers to partnership, and providing incentives for active collaboration to improve food safety. This national interest justifies investing federal resources in the capacity of state and local agencies—as key elements of an integrated national food safety system—to detect, contain, and prevent outbreaks of foodborne illness. Investment in surveillance, laboratories, and other local capacity related to food safety can also have spillover benefits for the public health infrastructure in general, as some of the needed capacity can be applied to multiple local health concerns.

FINDINGS ON SURVEILLANCE AND OUTBREAK RESPONSE

Finding 12: Importance of State and Local Roles in Surveillance and Outbreak Investigations

The success of the food safety system in preventing and reducing foodborne illness is heavily dependent on the quality, timeliness, and ready availability of the food safety information generated by state and local agencies through illness surveillance and outbreak response investigations.

Comment: State and local agencies play a primary role in collecting the raw data on foodborne illness on which the food safety system depends to understand the incidence and causes of illness, contain outbreaks, and plan future preventive efforts. The reforms currently underway at the federal level to build a more science- and risk-based, prevention-oriented food safety system cannot succeed without this information, which needs to be of high scientific quality and transparently available to decision-makers in real time to make its full contribution to food safety.

Finding 13: CIFOR Guidelines

The Council to Improve Foodborne Outbreak Response is an important collaboration among federal, state, and local officials to improve their consistency, collaboration, and effectiveness in responding to outbreaks, and CIFOR's June 2008 draft Guidelines for Foodborne Outbreak Response provide a valuable template for such improvement.

Comment: CIFOR is a promising example of how officials at all levels—including epidemiologists, regulators, and laboratory-based scientists—can collaborate to improve their collective food safety efforts. It also includes an industry workgroup, which recognizes that the food industry has its own needs for timely and high quality information on the incidence and causes of foodborne illness. The CIFOR draft guidelines document shortcomings in the current system for outbreak response and recommend solutions aimed at achieving more timely and thorough reporting of illnesses and outbreaks, improved standardization of data collection in the field and in labs, and deeper analysis of outbreak data to discover root causes and help devise preventive measures. CIFOR's overall approach and many of its specific recommendations are embraced in this report. As a collaborative body, CIFOR makes recommendations to federal, state, and local agencies but does not have the authority to impose requirements.

Finding 14: Lack of Consistent Testing and Reporting

There is no national requirement for laboratory testing of clinical specimens and reporting of foodborne illness by health care providers or through public health agencies to the federal government; the resulting gaps in illness surveillance are obstacles to detecting outbreaks and understanding the full dimension of foodborne illness in the United States.

Comment: CDC coordinates a number of foodborne illness-related surveillance systems that can be used to detect outbreaks, most notably PulseNet, and compiles data that can be useful in understanding illness patterns and trends for purposes of planning prevention efforts. In keeping with the long tradition of local autonomy in public health, however, state and local reporting of infectious diseases to CDC is voluntary, and state reporting requirements vary from state to state. Given competing pressures and the general scarcity of resources in the public health system, including laboratory capacity, the voluntary approach to testing and federal reporting assures that many illnesses go unreported. Moreover, the diversity of resources and practices across the country results in a geographically unbalanced picture of foodborne illness in the United States. For example, states that invest the most in surveillance, testing, and reporting of illness may appear to have greater numbers of outbreaks and cases of illness, when the opposite may be true.

Finding 15: Lack of Standardized Protocols

There are no standardized protocols for epidemiological data collection that state and local officials are obligated to follow consistently; the result is disparate approaches to data collection among states that make it difficult to compare and aggregate data collected in different locations.

Comment: The lack of standardized protocols for data collection is another manifestation of the traditional deference to states and localities in public health. The differing practices in some cases may reflect differing local circumstances, but in other cases may simply be a function of local custom or the preferences of individual investigators. Differing approaches to collecting data can affect the quality and comparability of essential epidemiology results in both surveillance and outbreak situations. This issue is addressed thoroughly in the CIFOR draft Guidelines for Foodborne Outbreak Response.

Finding 16: Lack of Uniform Laboratory Methods

Federal, state, and local clinical and public health laboratories do not consistently use nationally uniform methods for testing clinical specimens, which inhibits meaningful data sharing and aggregation of data for purposes of understanding foodborne illness on a nationwide basis.

Comment: CIFOR also raises the need for consistency in clinical laboratory test methodologies in its draft guidelines because of the importance of such consistency in building nationally useful databases for understanding and investigating foodborne illness.

Finding 17: The Power and Potential of PulseNet

PulseNet has greatly improved the ability of public health officials to detect outbreaks by compiling and analyzing data linking cases of illness to a common pathogenic agent, but the voluntary nature of PulseNet reporting means the database is inevitably incomplete, and many clusters of illness revealed through PulseNet go uninvestigated; the result is that detection and containment of ongoing outbreaks

is not what it could be, and opportunities to better understand foodborne illness incidence and patterns are lost.

Comment: PulseNet is a prime example of how technology—in this case molecular fingerprinting of pathogens through the use of pulsed-field gel electrophoresis (PFGE), the internet, and large computer databases—provides powerful tools for integrating the efforts of federal, state, and local agencies, enabling them to make a contribution to food safety that is much greater than the sum of its parts.

Finding 18: The Power and Potential of FoodNet

FoodNet has greatly improved estimates of the national burden of foodborne illness and has great potential to provide decision-makers with insights on the incidence and patterns of foodborne illness for purposes of planning prevention. But, FoodNet lacks sufficient resources for conducting special studies and analyzing existing data, as well as mechanisms for sharing FoodNet data with non-FoodNet states and localities on a detailed and timely basis. FoodNet is thus not fulfilling its potential as a source of data that federal, state, and local agencies can use to prevent foodborne illness.

Comment: FoodNet is well-designed as a sentinel site system that permits the collection of in-depth data on foodborne illness within a defined population and on a basis that permits extrapolation to the nation as whole. The question is how to take full advantage of the FoodNet infrastructure and the data it currently generates to inform prevention. FoodNet suffers from the general underinvestment in food safety epidemiology, which inhibits the conduct by FoodNet sites of case control studies or other special studies that would, for example, help attribute reported illnesses to particular foods. Moreover, the utility of the large volumes of data generated by each FoodNet site is limited by the fact that the data are regarded as “owned” by that site, despite FoodNet being coordinated and partially funded through CDC. Neither government regulatory agencies nor food companies are able to access and analyze detailed FoodNet data to inform their food safety work.

Finding 19: Lack of State and Local Capacity for Food Safety Epidemiology

Many state and local agencies responsible for foodborne illness surveillance and outbreak response lack access to an epidemiologist who specializes in food safety epidemiology, and, with few exceptions, state and local agencies lack the full scientific capacity, laboratories, and specialized staffing needed to fully manage day-to-day food safety issues, much less the surge capacity to follow up on PFGE-identified illness clusters and respond effectively to outbreaks.

Comment: The shortage of food safety epidemiologists and laboratory capacity is partly a function of the general underfunding of state and local food safety efforts and overall public health programs. It also reflects the fact that many local health departments are too small to justify spending scarce public health resources on a fulltime food safety epidemiologist or adequate lab capacity. The consequences include the inability to follow up on all reported cases or even clusters of foodborne illness in many jurisdictions and the likelihood that limited capacity at the local level will be the rate limiting factor in investigating large scale, multi-state outbreaks.

Finding 20: Lack of Credentialing and Training Standards

There are no national standards for the credentialing or training of state and local staff involved in surveillance and outbreak response, which can jeopardize the scientific quality of data collection and investigations.

Comment: CDC and the CSTE have developed a set of recommended “applied epidemiology competencies” as a benchmark for training and staffing of public health departments, but the lack of mandatory national standards and federal funding incentives for elevating the qualifications of food safety epidemiologists contribute to the disparity and weakness of capacity across state and local agencies.

Similarly, NEHA has developed credentialing standards for food safety regulatory professionals. Even though many environmental health professionals have acquired these credentials, many states do not require them to practice in the field of environmental health as it relates to food safety. Currently, there are no mandatory national standards or federal funding incentives for credentialing environmental health professionals or other professionals working on food safety, such as nurses and health educators. The Public Health Accreditation Board is working on a program to accredit state and local health departments, which could provide a framework for elevating and recognizing the credentials of food safety professionals.

Finding 21: Lack of Established Mechanisms for Multi-State Outbreak Response

There is no established organizational mechanism and no standard protocol for ensuring effective coordination and collaboration among federal, state, and local agencies in responding to multi-state outbreaks of foodborne illness.

Comment: CDC and the federal food safety regulatory agencies share responsibility for national-level coordination of multi-state outbreaks, with CDC being in the lead to identify a food vehicle and FDA and USDA leading efforts to identify the origin of the problem and the responsible parties for purposes of containment and future prevention. These agencies interact on a largely ad hoc basis during outbreaks, with the state and local agencies that are on the frontline of data collection and outbreak response not always having clarity about who is in charge at the federal level. As the CIFOR draft guidelines note, some states also lack mechanisms for coordinating responses to multi-jurisdictional outbreaks within their borders.

In December 2000, as an outgrowth of President Clinton’s Food Safety Initiative, top officials of HHS, USDA, and EPA entered into a memorandum of understanding to establish an inter-agency body called the Foodborne Outbreak Response Coordinating Group (FORCG). This group, to be co-chaired by the Assistant Secretary of Health at HHS and USDA’s Under Secretary for Food Safety and to include representatives of state and local agencies, was intended to address the need for a high-level federal focal point for managing multi-state outbreaks, defining roles and responsibilities among federal, state, and local agencies, and fostering better communication among agencies and with the public. FORCG was not implemented following a change in administration.

Federal, state, and local officials involved in outbreak investigations widely support the establishment of a mechanism and protocol for managing multi-state outbreaks collaboratively, with an appropriate level of federal leadership and direction.

Finding 22: HHS Legal Authority

Under the Public Health Service Act and the federal government’s spending powers, the Secretary of Health and Human Services has ample legal authority to play a national leadership role on surveillance and outbreak response, including establishing standards for foodborne illness surveillance and reporting and establishing mechanisms for managing multi-state outbreaks.

Comment: While there is a long history of deference to state and local primacy on public health, including the investigation of foodborne illness, Congress has provided the Secretary of HHS abundant discretionary legal authority to conduct and lead foodborne illness surveillance and outbreak investigations from the federal level as needed to protect the health of the nation. Under the federal government's spending power, the Secretary can also condition the transfer of federal funds to a state or locality on the receiving agency meeting specified federal requirements. The issue is how the Secretary should use these powers to ensure that the country's food safety epidemiology and other data needs are being met while relying, necessarily and properly, on the state and local agencies that are the backbone of the nation's food safety system and epidemiology infrastructure.

FINDINGS ON REGULATION AND INSPECTION

Finding 23: State and Local Oversight of Retail Food Safety

The current allocation of responsibilities for food safety at the retail level among federal, state, and local agencies is appropriate, but there are wide disparities among state and local agencies in their capacity and performance in implementing the FDA Food Code.

Comment: The federal-state-local partnership approach to food safety regulation in restaurants and grocery stores reflects the wide support for having nationally consistent, science-based standards for retail food safety (as embodied in the FDA Food Code) and the practical inability of federal authorities to provide meaningful inspection and enforcement in the almost one million retail food outlets in the United States.¹¹¹ The regulatory model is correct, and it has achieved much in improving retail food safety, but the fact that some 3,000 state and local agencies with differing resource commitments, priorities, and other local factors are involved in the program results in disparities in capacity and in level and quality of performance.

For example, many states and localities have not adopted the most recent version of the Food Code, and inspection rates and approaches vary. Further, although nationally recognized credentials for food safety professionals exist and many environmental health professionals have acquired these credentials, many states do not require these credentials to practice in the field of environmental health as it relates to food safety. Currently there are no mandatory national standards or federal funding incentives for credentialing environmental health professionals conducting food safety inspections or carrying out other duties in retail food regulatory programs.

Further, although nationally recognized credentials for food safety professionals exist and many environmental health professionals have acquired these credentials, many states do not require these credentials to practice in the field of environmental health as it relates to food safety. Currently there are no mandatory national standards or federal funding incentives for credentialing environmental health professionals conducting food safety inspections or carrying out other duties in retail food regulatory programs.

Finding 24: FDA's Retail Food Regulatory Program Standards

FDA's Retail Food Regulatory Program Standards can be an effective tool for elevating the quality and consistency of Food Code implementation nationwide, but many states and localities lack the resources

and incentives to participate in the program and to make the capacity investments needed to meet the standards.

Comment: The quality improvement framework of the Retail Food Regulatory Program Standards program—including performance standards, agency self-assessments, and independent verification audits—can be a powerful tool for achieving a consistent and high level of performance among state and local agencies in implementing the Food Code. It is similar to the National Public Health Performance Standards Program in which a number of state and local health departments participate as a tool for improving the quality of their public health programs. To be effective, however, participation in the Retail Food Regulatory Program Standards program needs to be broadened. Currently only a small percentage of the approximately 3,000 eligible agencies are enrolled, and FDA's goal is to have 450 or 15% enrolled by October 1, 2010.¹¹² Enrollment is low in part due to the costs incurred in preparing for and completing the assessment and audit processes themselves. Agencies may also be deterred from participating because they lack the administrative buy-in, resources, institutional capacities, and/or incentives needed to meet the program's performance standards.

Finding 25: State Role in Food Processing Inspection

State agencies conduct about 80% of all inspections in food manufacturing facilities and can play an increasingly important inspection role in a nationally integrated food safety system, but the capacity of states varies, inspection practices are not standardized, and some have questioned federal reliance on state inspections in the absence of transparent mechanisms to establish accountability for a consistently high level of state performance in enforcing food safety standards.

Comment: In addition to the many manufacturing inspections states conduct on their own, FDA relies on state agencies to conduct, under contract, about 50% of FDA's food manufacturing facility inspections that FDA counts as its own. This reliance on the states is a practical necessity given FDA's staffing limits, and it can be an effective way to leverage state resources to provide the desired levels of inspection coverage in a more integrated national system. Just as there is variability in state and local practices and capacities for epidemiology and retail oversight, however, there is variability in how states conduct and report the results of inspections. In 2000, the HHS Inspector General issued a report highlighting this variability and laid out FDA's shortcomings in overseeing FDA-state contract and partnership inspections, with the Inspector General ultimately calling for greater FDA oversight and accountability in these programs.¹¹³ Moreover, consumer groups have questioned whether some state agencies, being closer to their local business community, are consistently rigorous in enforcing food safety standards.

FDA has historically attempted to ensure through its contracts with state agencies that state inspections meet an appropriate standard. Until recently, however, FDA has not had a transparent mechanism for independent verification that states have acceptable inspection capacities and programs.

Finding 26: FDA's Manufactured Food Regulatory Program Standards

FDA's Manufactured Food Regulatory Program Standards can be an effective tool for elevating the quality and consistency of state inspections and regulatory efforts in food processing facilities, but many states lack the additional resources and incentives to participate in the program and to make the capacity investments needed to meet the standards.

Comment: The recently launched Manufactured Food Regulatory Program Standards initiative is patterned after the retail standards program. Its standards cover all aspects of a state's program capacity

and effectiveness in inspection, enforcement, and laboratory support, as well as self-assessment and independent verification procedures. FDA intends to make a state's enrollment in the program, and, ultimately, satisfaction of the standards, a prerequisite for receiving an FDA contract to conduct inspections, which can be an important step in ensuring standardized inspections of food manufacturing facilities. This is a sound approach, but it does not by itself address the resource and capacity issues states face in going through the assessment and verification processes and making any improvements needed to meet the standards. Moreover, to the extent FDA broadens its reliance on state inspections, the number of states that would be challenged to enroll in and satisfy the requirements of the Manufactured Food Regulatory Program Standards program would only increase.

Finding 27: State and Local Food Safety Laws

State and local food safety regulatory laws reflect many of the same limitations of federal food safety laws, especially in terms of not being focused adequately on prevention, and they were generally not written with a view toward supporting the central role of states and localities in an integrated national food safety system.

Comment: State and local food safety laws parallel the federal law in the sense that they consist primarily of legal tools for detecting and correcting problems rather than a prevention mandate and modern, science-based tools for prevention. Nor do state and local laws typically address the role of state and local agencies as part of an integrated national system. As federal legislative reform moves forward to address both prevention and better integration of the system, parallel reforms of state and local laws will have to be considered.

IV. RECOMMENDATIONS TO STRENGTHEN STATE AND LOCAL ROLES

The findings in Section III highlight the wide range of institutional issues that must be addressed to achieve the vision of an integrated national food safety system, including: (1) how federal, state, and local agencies understand their roles and relationships, (2) how state and local agencies acquire the capacities to perform their roles, and (3) how agencies at all levels can better interact as parts of an integrated national food safety system. The following recommendations focus largely on these institutional issues, and in particular on the necessary leadership role of the federal government in building an integrated national system.

The most fundamental prerequisite for fulfilling the potential of state and local agencies in an integrated national food safety system is high-level political commitment to that goal and accountability for achieving it. That is why our first recommendation is for a congressional mandate that makes the Secretary of HHS responsible for leading in that direction, in collaboration with states and localities. Building such a system also requires, however, sustained action by federal, state, and local governments to create the mechanisms and capacities needed for a truly integrated food safety system, as outlined in the recommendations.

In addition to the institutional or “system” issues addressed in the recommendations, there are many specific food safety policy issues and possible initiatives that also are important to the effectiveness of the food safety system and the strengthening of state and local roles. A number of these surfaced in the workshops convened for this project and are captured in the two workshop reports prepared by ASTHO-NACCHO and AFDO (Appendices B and C).

One of the central themes of the following recommendations is that a strengthened federal leadership role on food safety must serve to empower state and local agencies and enhance what they do on food safety, not displace it. As emphasized in this report’s findings, state and local agencies are the foundation of the national system and the essential frontline in any national effort to prevent and contain foodborne illness. Addressing their institutional needs and strengthening the federal-state-local partnership on food safety is thus a prerequisite to the success of the national system.

Another recurring theme and issue concerns the source of federal-level leadership to achieve the vision of an integrated national food safety system. Many of the recommendations call for action by Congress on the ground that significant, sustainable change in the policies and practices of federal agencies, which is needed, is more likely to be achieved if called for and supported by Congress. Moreover, a number of recommendations require new resources, which must come from Congress.

On the other hand, many of the actions that we call on Congress to take could be taken by the Secretary of HHS or other executive branch officials without waiting for congressional action. This fact is illustrated by the bill introduced in the 110th Congress by then-Senator Barack Obama

(S.3358), which would go a long way toward providing the needed congressional mandate to strengthen and integrate state and local roles as key components of a national food safety system. Most of its specific provisions could be implemented administratively, however, by the Secretary of HHS, provided adequate resources were available. In the discussion that follows, we note such opportunities for Secretarial initiative even when congressional action would be ideal.

In the end, of course, effective federal leadership on food safety requires both congressional and executive action and an ongoing collaboration between the two branches.

Like our findings, the recommendations below are organized into three categories: general recommendations, recommendations regarding surveillance and outbreak response, and recommendations on regulation and inspection.

GENERAL RECOMMENDATIONS

Recommendation 1: Congressional Mandate

Congress should give the Secretary of HHS a legislative mandate to lead the development of an integrated, national food safety system that incorporates and enhances the food safety capacity of state and local agencies.

Comment: Meaningful food safety reform, including a sustained movement toward an integrated national food safety system, is most likely to occur with a strong congressional mandate and the lodging of clear accountability in the executive branch. HHS, as the federal government's health department with jurisdiction over 80% of the food supply and most imported food, is where this mandate and accountability should be placed. Through CDC and FDA, HHS already has more extensive working relationships on food safety with state and local agencies than other federal departments and thus is in the best position to lead capacity building and other efforts to better integrate the food safety system. This mandate for HHS would not displace the important interactions that USDA and EPA have with the states on meat and poultry inspection and pesticide enforcement, and it is essential that HHS collaborate fully in its efforts with these agencies and other federal agencies with a role in food safety. And, of course, to be successful in its leadership role, HHS must work in close collaboration with state and local officials.

While the Secretary of HHS can and should exert leadership to build an integrated national food safety system, experience teaches that such system change is unlikely to be sustained without a congressional mandate and support.

Recommendation 2: Focal Point for HHS Food Safety Leadership

Congress should direct HHS to unify the management of FDA's food safety functions under a single official with direct access to the Secretary of HHS whose fulltime job is food safety and who would have clear authority, responsibility, and accountability for leading HHS food safety activities.

Comment: In order to play its leadership role on food safety, HHS needs to have an organizational focal point and management structure that is empowered and accountable to provide that leadership.

The current fragmentation of FDA's organization and management structure and the lack of a single fulltime food safety official with line management authority over all of FDA's food safety components are obstacles to such empowerment and accountability. It also creates confusion and inefficiency in FDA's dealings with state and local agencies, as some of their interactions occur with CFSAN, some with ORA headquarters units, and some with FDA field offices. While the recently-created position of Associate Commissioner for Foods has responsibility for coordinating implementation of FDA's Food Protection Plan, there is no single official working fulltime on food safety with the management authority and accountability for producing an integrated and optimal overall food safety effort, in both day-to-day operations and implementation of new initiatives, such as outlined in these recommendations.

Solving these organizational and management problems at the federal level is an important part of strengthening the federal-state-local partnership and making efforts at all levels more effective. To be successful, the official leading food safety at HHS/FDA would have to work closely with state and local officials, through such mechanisms as the Food Safety Leadership Council (see below), and coordinate with CDC, the USDA Under Secretary for Food Safety, EPA food safety officials, and DHS on food defense matters related to FDA-regulated products.

While congressional action on this recommendation would be desirable, the Secretary of HHS could through administrative action change reporting relationships to create an empowered food safety leadership position within FDA and HHS. Rep. Rosa DeLauro has proposed to create a separate Food Safety Administration within HHS (H.R. 7143, 110th Cong.) to both empower an accountable food safety official and put the HHS food safety function on the same level organizationally as the FDA Commissioner, who would continue to regulate medical products. That idea would require legislation and was not addressed in this project.

Recommendation 3: Food Safety Leadership Council

Congress should establish and fund an inter-governmental Food Safety Leadership Council to foster federal-state-local collaboration in the design and implementation of an integrated national food safety system.

Comment: The Council would be chaired by the Secretary of HHS or his designee and composed of the top food safety officials from FDA, CDC, USDA, EPA, and DHS; heads of key sub-components of those agencies; and at least an equal number of representatives of state and local food safety agencies. The state and local officials would be appointed by the Secretary based on nominations from the relevant professional organizations, including AFDO, APHL, ASTHO, CSTE, NACCHO, NASDA, and NEHA. The role of the Council would include advising HHS on system-level issues, needs, and solutions; serving as a vehicle for two-way communication and policy coordination among federal, state, and local officials; overseeing implementation of many of the recommendations outlined below; and monitoring and reporting on progress in building a more integrated, prevention-oriented system. This high-level policy body would not duplicate or replace the critical technical work done by such existing bodies as CIFOR.

The Secretary could establish a Food Safety Leadership Council administratively, but a body established by Congress would likely have more standing and clout and thus be more attractive to state and local officials. Congress would have to provide operating funds to support the convening and staffing of such a council.

Recommendation 4: Prioritizing Capacity Building Needs

The Secretary, in consultation with the Food Safety Leadership Council and in collaboration with appropriate professional organizations, should conduct a survey of the current food safety capacities of state and local agencies—including staffing and skill levels, laboratory capacities, information systems, legal authorities, and organizational arrangements—and, on the basis of the survey, identify and prioritize capacity building and other state and local needs that must be met to fulfill their roles in the national food safety system.

Comment: Capacity building among state and local agencies is essential to implementing an integrated system that is both effective and efficient. The starting point for capacity building is a more complete understanding of current capacities and priorities for improvement. Previous survey efforts by GAO, AFDO, and CSTE have tended to focus on particular elements of food safety capacity or otherwise be limited methodologically. Because accurate and complete capacity information is inherently difficult to compile, the proposed survey should not only be planned in close collaboration with the Food Safety Leadership Council but carried out through appropriate professional organizations, such as AFDO, APHL, ASTHO, NACCHO, and NEHA, and in consultation with CIFOR and other expert bodies. Another approach might be for GAO to conduct or assist with the survey.

The Food Safety Leadership Council should play a central role in setting capacity-building priorities, based on the survey and the expert judgments of Council members.

Recommendation 5: Five-Year Integration Plan and Benchmarks

Congress should direct HHS to develop, based on the capacity survey and consultations with the Food Safety Leadership Council, a five-year plan for better integrating federal, state, and local food safety efforts and improving state and local capacity for that purpose. The integration plan should be based on mutually agreed criteria and benchmarks for such matters as timeliness of outbreak investigations, frequency of retail inspection, food safety staffing and skill levels, laboratory capacity, and information systems.

Comment: The requirement for HHS to develop a long-term plan with clear goals and benchmarks would help ensure key obstacles to a more integrated system are identified and addressed and that capacity building investments are well-targeted and justified. A plan also provides a basis for Congress to consider and meet HHS food safety funding needs, as well as to monitor progress and hold HHS accountable for achieving the goals. The plan should be updated biennially through a public process to ensure it remains current with respect to evolving science and needs.

A key element of the planning process must be the development of specific and regularly updated criteria and benchmarks for assessing the adequacy of state and local food safety capacities and performance. Such criteria and benchmarks can also be used to monitor progress in capacity and performance to help ensure that new resources are well used.

Illustrative examples of criteria (or performance indicators) include the timeliness of a health department's processing of reports of foodborne illness, adequacy of laboratory capacity and performance, and success in completing outbreak investigations, as well as the frequency of retail or processing establishment inspections, the adequacy of the training and equipment needed for inspections to be effective, and the sufficiency of any needed compliance action. Benchmarks (or metrics) are the quantitative measures of performance with respect to the criteria (or performance

indicator) and include such things as the specific inspection frequency that is deemed adequate (such as semi-annual inspection of retail establishments).

Important work has been done to identify the criteria that should be considered in judging the adequacy of resources, including by CIFOR in its draft Guidelines for Foodborne Outbreak Response and by FDA and its state and local partners in the retail and manufactured food regulatory program standards. Specific benchmarks or metrics, however, still need to be developed, and the cost of meeting those benchmarks estimated. This work should be done collaboratively under the auspices of the Food Safety Leadership Council. Since inspection frequency and other priority-setting and performance measures addressed in the plan should be risk-based, further work would be needed to devise standardized and realistically feasible approaches to characterizing and comparing risks.

The Secretary of HHS can certainly launch planning efforts independent of Congress. Because the integration plan is intended to provide a template for determining resource needs, however, development of the plan will be a more meaningful exercise if the plan is called for by Congress.

Recommendation 6: Joint Funding Responsibility

Congress should declare that the federal government has a responsibility to support the capacity building needed to strengthen the performance of state and local agencies in the national food safety system and has a shared responsibility with the states to adequately fund food safety programs and capacity building, in accordance with the integration plan and benchmarks called for in Recommendation 5.

Comment: In fulfillment of their role as primary protectors of public health, state and local agencies have a duty to invest in food safety capacity to address inherently local needs, such as retail oversight and response to local outbreaks. In light of the strong national interest in food safety and the reality that what happens at the local level can affect food safety at the national level, the federal government also has an interest and duty to help ensure that an adequate base of resources and capacity is consistently available among state and local agencies nationwide. In particular, state and local agencies should not be expected to bear on their own the additional costs involved in improving their contribution to the national food safety program. Moreover, the federal government should take account of and avoid disrupting state-level, fee-based revenue streams for food safety agencies as it considers possible user-fee approaches to funding the federal regulatory program.

Determining optimal resource and capacity levels at state and local levels and fairly allocating funding responsibilities will be difficult, both in design and implementation. By establishing the principle and policy of joint responsibility for funding food safety and requiring a capacity building plan based on mutually agreed criteria and benchmarks (as in Recommendation 5), Congress can begin the process.

Recommendation 7: Federal Funding and Matching Grant Program

To help carry out the federal responsibility for state and local capacity building, Congress should authorize and establish an appropriation line item for FDA to provide federal funding to the states in the form of a food safety block grant specifically aimed at improving state and local food safety collaboration and capacity. In addition, Congress should establish a matching grant program to foster improvement and innovation beyond base capacity building.

Comment: The principle of joint funding and any plan for capacity building need funding vehicles if they are to be implemented and not simply be another unfunded federal mandate. Federal funding and any

matching grant program should be structured creatively and flexibly to provide incentives for state and local agencies to make appropriate investments in their own food safety capacity, as well as becoming full partners with the federal government in building a more integrated and more capable national system.

For example, a portion of available federal funding could be provided in the form of food safety block grants on a per capita basis to support basic capacity building, in accordance with and contingent on state and local plans to work toward satisfying the base criteria and benchmarks. States that seek to go beyond the benchmarks or have innovative plans to address particular issues having both local and national significance could seek additional funding through a matching grant program. Federal funding of any kind should be structured with a view toward fostering federal-state-local capacity and collaboration.

Any new federal funding or matching grant program should be coordinated with food safety-related federal funding currently going to a state through CDC's Epidemiology and Laboratory Capacity (ELC) and PulseNet and FoodNet programs, as well as through FDA's contract inspection program and its initiatives to create incentives for quality improvement in state regulatory programs through the retail and manufacturing program standards discussed in Findings 23 and 25.

An initial annual funding level of \$100 million, growing in \$50 million increments over five years to \$350 million, would make a significant contribution to improving the national food safety system.

Recommendation 8: State and Local Funding

State and local governments should maintain stable funding streams sufficient to meet their responsibility for funding of food safety programs, in keeping with agreed criteria and benchmarks for food safety capacity and performance.

Comment: There is no one correct model for state and local funding of food safety, with most states relying on some mix of appropriated general revenue funds and fees connected with licensing, inspection, or other activities. The success of state and local food safety programs depends, however, on having a funding stream that is large and stable enough to support both current operations and investments in human capacity (such as recruitment and training of qualified staff) and technical infrastructure (such as laboratories and information systems). Every state legislature and, where appropriate within a state, local government, should make a commitment to meet or exceed the agreed-upon criteria and benchmarks for food safety capacity and performance, and they should develop a resource plan for meeting that commitment through a blend of federal, state, and local funding. As suggested in the comment under Recommendation 7, federal funding would be contingent on state and local commitments to adopt and work toward fulfilling their resource plan.

Recommendation 9: State and Local Focal Points for Integration

State and local governments should better integrate their own surveillance, outbreak response, and food safety regulatory and inspection activities, and each state should establish a focal point for better linking and integrating the state's food safety activities with the national system.

Comment: The organizational complexity and fragmentation that impairs food safety performance at the federal level is mirrored at the state and local levels. State and local governments carry out their food safety responsibilities through multiple organizations—such as health departments, public health

laboratories, and agriculture and consumer protection departments—that may not seamlessly coordinate or share information among themselves and that interact with the federal government through numerous channels. Current organizational arrangements vary widely and there is no one ideal way to organize state and local food safety functions, given diverse histories and needs across the country. Breaking down barriers to collaboration and optimal use of resources, and ensuring a consistent commitment and focus on the public health goal of preventing illness, is as important at the state and local levels, however, as it is at the federal level; and interaction among all levels of government could be more efficient and effective if each jurisdiction had a designated focal point for integrating its efforts internally and linking local and state efforts with the federal program.

Recommendation 10: Model State and Local Food Safety Law

State and local governments should collaborate on the development and widespread adoption of a model state and local food safety law that addresses all aspects of state and local roles in food safety, modernizes food safety regulatory laws to adopt a more preventive and risk-based approach, clarifies the roles of state and local agencies in a more integrated system, and legally empowers state and local agencies to work more collaboratively among themselves and with the federal government.

Comment: Just as statutory reform is needed at the federal level to shift to a more preventive, science- and risk-based food safety system that better integrates federal, state, and local efforts, parallel reform is needed at the state and local levels. While the Food Code is based on enforcing the duty of retail establishments to implement modern systems and practices that prevent food safety problems, federal and state laws governing food manufacturing generally are not: they provide tools for reacting to problems rather than codify a standard for implementing modern preventive controls. Nor do current laws generally make integration of federal, state, and local efforts a duty of food safety agencies.

A model law would help stimulate the legal reforms needed for more effective and consistent state and local prevention efforts and better integration with federal efforts. It should both modernize state and local food safety authorities and remove legal and other obstacles to collaboration and full partnership across jurisdictions. The model law should be developed through an inclusive process involving federal, state, and local agencies and other stakeholders in the food safety system. Design of a model food safety law will have to take into account the fact that some states have centralized systems of government, with significant state control over local programs, while others operate on the “home rule” model, which makes local programs largely autonomous.

In addition to addressing state and local legal issues, any effort to develop a model food safety law should identify federal legal issues that affect state and local programs, such as federal rules that affect information sharing with the states and the need for updated regulations and/or guidance concerning implementation of good manufacturing practices, HACCP, and retail sanitation programs.

Recommendation 11: Food Safety Leadership and Training Institute

HHS, in collaboration with the Food Safety Leadership Council, should establish a Food Safety Leadership and Training Institute focused on building among food safety professionals at all levels a common vision for the nation’s food safety system and the leadership skills, network of relationships, and trust needed for an integrated system to succeed.

Comment: New policies and mechanisms for collaboration are not enough to fulfill the vision of an integrated national food safety system. It also requires a new culture of collaboration that enables people

and organizations to work together in more productive ways; and this depends on food safety leaders and managers in federal, state, and local agencies having a common vision and the leadership tools to achieve it. The Food Safety Leadership and Training Institute would help meet this need by providing a central gathering place for the development and training of current and future leaders of the food safety system. The Institute's primary focus would be on fostering a common food safety vision and collaboration across organizational lines and building the cross-cutting knowledge and leadership skills that managers in a more integrated food safety system need to be successful. It should become part of the country's existing network of public health leadership institutes.¹¹⁴

There is also a need to bolster technical skills training and professional credentialing for food safety inspectors and other environmental health professionals working on food safety. These matters are currently addressed to varying degrees by existing organizations and programs, such as those run by CDC, NEHA, and FDA's Office of Regulatory Affairs, and the proposed Institute is not intended to duplicate any such existing programs. With regard to skills training, however, there is a need for greater coordination and support of core technical training, as well as new approaches to gaining expertise on advanced topics that will be increasingly important as food safety reform unfolds, such as assessing the effectiveness of preventive controls. The development and implementation of training curricula geared to meeting FDA's retail and manufactured food regulatory program standards is another important priority as a means of ensuring that high and consistent standards of performance are met by regulators across the food safety system.

While the proposed Institute is not intended to be the sole or even primary provider of technical training, it could collaborate with other training organizations in developing curricula for both leadership and technical skills training to help advance the vision of a national integrated food safety system and a common understanding of the skills required to implement it. The Institute could also play an active role along with other food safety training entities and local capacities in promoting training standards, credentialing programs, and other efforts that provide incentives for state and local officials to invest in the training required to implement a more effective, integrated food safety system.

RECOMMENDATIONS ON SURVEILLANCE AND OUTBREAK RESPONSE

Through surveillance activities and outbreak response, epidemiologists, environmental health professionals, and regulators at all levels generate considerable information on foodborne illness, its causes, and how it can be prevented—information that is vital to the success of the nation's food safety system. The timeliness, quality, and accessibility of that information, and thus its usefulness, are affected by the capacities and practices of the agencies and personnel who gather it. To better leverage these efforts and significantly enhance their contribution to preventing foodborne illness, Congress and HHS should act in several ways to strengthen and more fully integrate foodborne illness data collection and outbreak response activities, in the context of both surveillance and outbreak response.

Recommendation 12: National Foodborne Illness Data Program

Congress should direct the Secretary of HHS to create, in consultation with the Food Safety Leadership Council and in collaboration with the states, a National Foodborne Illness Data Program that builds on existing efforts of the CDC, states and localities, and CIFOR, but with the goal of significantly expanding

the contribution of food safety epidemiology and other data collection to understanding and preventing foodborne illness. The Program's elements should include:

- *A foodborne illness data user group comprised of federal, state, and local regulatory and health officials, food industry and consumer representatives, and members of academia and the public; the group's charge should be to advise the Program on the information needs of parties working to prevent foodborne illness;*
- *Increased investment in FoodNet, and other foodborne illness surveillance;*
- *Increased investment in EHS-Net and in focused outbreak follow-up investigations aimed at producing data to guide prevention;*
- *National requirements and incentives for illness reporting by state and local agencies and, where appropriate, health professionals, standardization of data collection and reporting methods, local illness and outbreak follow up, submission of isolates to PulseNet, and other efforts to improve the quantity and quality of data on foodborne illness;*
- *Consistent with privacy protection, timely and seamless sharing of data from FoodNet, PulseNet, other surveillance activities and outbreak investigations among federal, state, and local health and regulatory agencies and, as much as possible, the food industry and public;*
- *Establishment of food safety epidemiology capacity criteria for state and local agencies and state public health laboratories (including staff qualifications and training, staffing levels, and facilities) and federal investment in building their capacity and preparedness; and,*
- *Promotion of collaboration and capacity sharing among state health agencies and laboratories by improving information systems and reducing legal obstacles to exchange of information, laboratory capacity, and staff.*

Comment: Implementation of a national program comprised of these elements would transform how foodborne illness data are collected and used in the United States. Most of the real work would remain decentralized, but it would be conducted within a common framework in terms of how data are collected and shared. Moreover, the program would have a clear charge and new mechanisms for ensuring that food safety practitioners—environmental health professionals, food safety regulators, industry food safety managers, and researchers—promptly get the information they determine they need to prevent foodborne illness. Enhancing the contribution of foodborne illness data collection in these ways is essential for a food safety system that is intended to be based on science- and risk-based prevention.

Recommendation 13: Regional Foodborne Outbreak Response Centers

HHS, working through CDC and FDA and in collaboration with states and localities, should establish a network of regional, federally-funded foodborne outbreak response centers to ensure an integrated “systems” approach to outbreak response and follow-up investigations. The centers would be staffed fulltime with a multi-disciplinary team of federal, state, and local epidemiologists, environmental health experts, regulatory officials, and food safety communicators (all federally funded) for purposes of: (1) supporting state and local agencies in their day-to-day foodborne illness surveillance and response activities; (2) improving the thoroughness and timeliness of outbreak detection, response, and follow-up investigation to inform future prevention; and (3) establishing the relationships, expertise, continuity, and surge capacity needed to ensure well-coordinated and effective response to major outbreaks.

Comment: Timely and thorough detection, containment, and follow-up investigation of illness outbreaks are key to immediate protection of public health and generating the information needed for future

prevention. Yet, states have uneven and, as a general rule, inadequate capacity for this work, and, at the federal level, CDC, FDA, and USDA also lack capacity, including mechanisms to foster the multi-disciplinary, cross-agency collaboration that is typically required. Most significantly for a prevention-oriented food safety system, there is no focal point and insufficient capacity in the current system for timely follow-up investigations in which environmental health professionals, in collaboration with other experts, can investigate root causes of outbreaks to inform future prevention.

The proposed regional foodborne outbreak response centers would address these problems. They would increase overall capacity in the system and foster the coordination and collaboration that is essential for the system to work well. Their specific functions would include:

- Providing expert technical consultation and support for state and local agencies on foodborne illness outbreak detection, response, and investigatory follow up;
- Supporting training for state and local epidemiologists, environmental health professionals, healthcare providers, and others involved in gathering and using data on foodborne illness and illness outbreaks for both containment and future prevention;
- Ensuring, in collaboration with CDC and the states, comprehensive and timely PFGE cluster screening and follow up to improve early outbreak detection;
- Providing states and localities surge capacity, including added manpower and expertise, when needed to support their management and follow up investigation of local outbreaks;
- Providing surge capacity and, when designated in accordance with Recommendation 14 (below), playing the lead role in managing regional and national outbreaks;
- Providing food safety communication specialists highly trained in risk communication to assist FDA, USDA, CDC, states, and localities in quickly developing culturally and linguistically appropriate messaging for industry and the public about foodborne illness outbreaks and the risks associated with implicated food products; and,
- Working with federal, state, and local agencies to improve the timeliness and depth of follow-up investigations to discover the root causes of outbreaks and opportunities for prevention, including developing and piloting new investigative techniques that yield more information useful for planning prevention.

CDC would remain the national-level focal point for coordination of foodborne illness surveillance, building national databases, and providing national leadership on the epidemiological aspects of outbreak detection and response, but the regional centers would provide a mechanism for operationalizing cross-agency collaboration on outbreak response and an integrated, “systems” approach to investigation of root causes and opportunities for prevention.

The location, number, and staffing levels of the centers require further consideration. One possibility is that at least some staff could be attached to the center on a “virtual” basis rather than being physically co-located. A key to the success of the centers, however, is that the staff be committed fulltime to their work so they can develop specialized expertise and bring it closer to the ground with a level of flexibility, efficiency, and continuity not currently achieved.

The centers would require significant resources, but the investment is justified by the public health and economic benefits of detecting, responding well to, and learning from illness outbreaks.

Recommendation 14: Protocols for Managing Multi-state Outbreaks

HHS, in consultation with the Food Safety Leadership Council and working with states and localities, should establish protocols for managing multi-state outbreaks, including clear definition of federal, state, and local roles; mechanisms for collaboration; and criteria for triggering federal-level management of outbreaks.

Comment: The national impact of major multi-state outbreaks of foodborne illness, such as the 2008 *Salmonella* Saintpaul and 2008-2009 *Salmonella* Typhimurium outbreaks, demands a planned national response rather than ad hoc crisis management. While states traditionally take the lead in most outbreak investigations, HHS should use its ample legal authority to establish clear and binding procedures for managing multi-state outbreaks. The goal is not to have a rigid one-size-fits-all model for managing multi-state outbreaks, because, depending on the circumstances, it might be preferable for the management lead to remain with a state, be lodged with a regional center, or move to the federal level. The aim rather is to have a clear mechanism and accountability at the federal level for making and implementing decisions about management of multi-state outbreaks. The criteria for triggering federal management must be developed in close consultation with state and local officials.

It is important to note that clarity of process and responsibility is needed not only to clarify federal, state, and local roles but also to clarify roles among the federal agencies in multi-state outbreak situations. The aim here should include better integrating the epidemiological function of identifying the food vehicle(s), which CDC oversees, and the containment and regulatory functions that are the purview of FDA and USDA. One possibility for coordination across the system would be to re-establish FORCG (the Foodborne Illness Outbreak Response Coordinating Group), which was formed in 1998 by HHS, USDA, and EPA, and included state and local representatives.

Recommendation 15: Traceability Requirements

Congress, with input from experts, should establish traceability requirements that permit federal, state, and local officials to rapidly obtain from food companies reliable information on the source of commodities, ingredients, and finished products.

Comment: Traceback information is vital to protect public health in many cases because it helps confirm the food vehicle and get to the root cause of an outbreak. Congress should thus require food processors, wholesalers, distributors, and retailers to establish modern electronic systems that enable them to provide FDA and other authorized investigators with complete traceback information, within prescribed commodity-specific timeframes established by regulation. The idea is to make documented, reliable traceback a duty food companies are required to meet using the best available technology, rather than a sometimes cumbersome and slow government investigation. Due regard should be given to making the traceback requirement feasible for small businesses.

Recommendation 16: Implementation of CIFOR Guidelines

HHS, working through CDC and FDA and in collaboration with the Food Safety Leadership Council, should support and build on CIFOR's continuing efforts to define and foster implementation of best practices for foodborne outbreak response.

Comment: CIFOR represents an important investment in bringing federal, state, and local officials together to work on improving foodborne outbreak response and should remain the primary vehicle

for that purpose, but with greater support to expedite its work. CIFOR should be an integral part of the recommended National Foodborne Illness Data Program and should work within that program and with the Food Safety Leadership Council to ensure that the widest possible range of stakeholder interests and views are considered in its recommendations.

RECOMMENDATIONS ON REGULATION AND INSPECTION

Recommendation 17: Uniform Standards and Joint Enforcement

HHS and the states should declare as a matter of policy that the establishment and enforcement of nationally uniform food safety standards is a common goal and joint responsibility of federal, state, and local governments, with the federal government bearing primary responsibility for establishing science-based standards for preventing foodborne illness and states and localities preserving full legal power to adopt and directly enforce federal standards and establish their own.

Comment: This policy is generally in operation today, as evidenced most clearly in the FDA adoption and state and local implementation of the Food Code for retail food safety. The policy is fundamentally important, because it provides the foundation for a national food safety system that works in an integrated way to prevent foodborne illness.

Beyond generating knowledge that can be used for prevention and outbreak response, the government's primary mode of intervention to prevent food safety problems is the setting and enforcement of food safety standards. These include broad, cross-cutting standards, such as the Food Code, and requirements for preventive controls in manufacturing establishments, as well as performance standards aimed at minimizing specific hazards, such as mercury in fish or *Listeria* in ready-to-eat foods.

The purpose of having nationally uniform standards is to ensure that a consistent, science-based, and high level of public health protection is provided nationwide. The purpose of making enforcement a joint responsibility is to harness the resources, motivation, and proximity of state and local governments to the millions of operators in today's vast food system. And, preserving the prerogative of states to set their own standards, consistent with the Supremacy and Commerce Clauses, is integral to our federal system of public health and food safety protection.

Recommendation 18: Integration and Modernization of Food Manufacturing Regulatory Programs

HHS/FDA, working in collaboration with state and local agencies, should develop and implement a plan for integrating and modernizing federal and state food manufacturing regulatory programs for facilities under FDA's jurisdiction. The plan should:

- *Build on the traditional roles of state agencies and clearly define roles and responsibilities of federal and state inspection agencies in an integrated national system;*
- *Develop new risk-based and technologically advanced approaches to inspection that ensure better use is made of inspection resources across the system to enforce food safety standards;*
- *Leverage federal resources by making cost-effective use of state inspection capacity to achieve adequate inspection frequencies in food processing establishments;*
- *Greatly expand the commissioning of state inspectors and enforcement officials so they can*

work seamlessly with federal authorities to enforce food safety standards and help achieve national food safety goals;

- *To assure consistent technical skill levels among federal, state, and local inspection agencies, adopt national standards and create federal funding incentives for credentialing environmental health professionals conducting food safety inspections or carrying out other duties in retail food regulatory programs;*
- *Address and minimize legal, technical, and bureaucratic barriers to the free flow and active sharing of food safety data and information among federal, state, and local inspection agencies and invest in the systems needed to support data sharing;*
- *Incorporate standardized approaches to conducting various types of inspections and reporting inspection results;*
- *Address and minimize legal and technical obstacles to federal reliance in enforcement cases on laboratory results and other data generated by state agencies; and,*
- *Ensure that public health protection is the first priority of all food safety inspection and enforcement activities and that there are clear standards and guidance to ensure effective use of enforcement tools to protect public health.*

Comment: The theme running through all of these recommendations is that the food safety system as a whole will be more effective in implementing standards (and thus preventing foodborne illness) if the system's collective inspection and information resources are applied in a more integrated and collaborative way—as if they were, in fact, all part of one well-networked food safety system. These recommendations for integrating food manufacturing regulatory programs are not intended to alter the necessary responsibility and autonomy of state and local agencies in dealing with local public health problems and regulatory concerns. Rather, the intent is to improve the effectiveness and efficiency of both federal and state agencies in meeting their responsibilities for food safety in processing facilities.

A sub-theme is the need to modernize food safety inspection. In this age of preventive process control, rapid advances in microbial testing technology, and robust data management systems, opportunities exist to dramatically increase the efficiency and effectiveness of inspections for protecting public health, including better tailoring inspection techniques to particular facility types and product risk profiles. Federal, state, and local agencies should work in partnership to develop and implement more modern inspection techniques.

Subject to funding availability, the Secretary could develop and implement a plan for much closer collaboration with state food safety regulatory programs without an express mandate from Congress. Some statutory changes might be needed, however, to permit the free flow of certain kinds of information.

Recommendation 19: Implementation of Program Standards

HHS/FDA should make the full implementation of the Retail Food Regulatory Program Standards and the Manufactured Food Regulatory Program Standards a central component of its plan for building an integrated national food safety system and inspection program and should provide needed resources and incentives for state and local governments to participate.

Comment: FDA's retail and manufactured foods program standards provide a systematic framework for capacity building, performance improvement, and accountability among state and local agencies, all of which is important to enhancing their roles in an integrated national system. Broad participation in these programs is thus in the national interest, but the programs' self-assessment and certification processes

impose costs on state and local agencies, which can be a barrier to participation. Moreover, meeting the standards may require even greater investments in capacity. The federal government should provide incentives for participation by providing technical assistance, helping defray the costs of the process itself, and by giving priority in the FDA capacity building matching grant program to jurisdictions that have committed themselves to the standards programs and are actively working to achieve certification.

The standards should be updated periodically as justified by changing science and other factors affecting how state and local agencies should implement their programs. Participation and ultimately successful certification under the manufactured foods program should become a requirement for states conducting contract inspections for FDA.

V. CONCLUSION

There are no shortcuts to an integrated national food safety system. It requires commitment, resources, and sustained effort. The potential benefits are great, however, and food safety reform at the federal level will remain an incomplete solution to today's food safety challenges unless state and local roles are strengthened and better integrated into the national food safety system.

The recommendations in this report address many of the system changes needed to fulfill the vision of an integrated national food safety system. We hope the report will help stimulate policymakers to act.

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APPENDICES

APPENDIX A: PROJECT PARTICIPANTS

A-1: GW Public Symposium, June 17, 2008

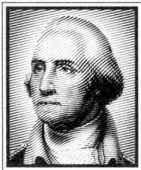
A-2: ASTHO-NACCHO Foodborne Surveillance and
Outbreak Response Workshop, July 1, 2008

A-3: AFDO Inspection and Regulatory Activities Workshop,
July 14–15, 2008

A-4: GW Workshop to Review Draft Report and Recommendations,
December 5, 2008

APPENDIX B: ASTHO-NACCHO FOODBORNE SURVEILLANCE AND OUTBREAK RESPONSE WORKSHOP REPORT

APPENDIX C: AFDO INSPECTION AND REGULATORY ACTIVITIES WORKSHOP REPORT



Enhancing the Roles of State and Local Agencies in Food Safety and Food Safety Reform

Public Symposium
June 17, 2008

Expected Attendees

Janet Angbazo

The George Washington University

Kristina Barlow

Food Safety and Inspection Service
U.S. Department of Agriculture

Cynthia A. Barnes

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Workshop - July 1, 2008
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Enhancing the Roles of State and Local Government in an Integrated Prevention-Oriented Food Safety System

Inspection and Regulatory Activities Workshop July 14th and 15th, 2008

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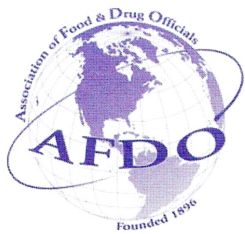
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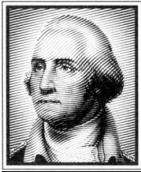
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Enhancing the Roles of State and Local Agencies in an Integrated National Food Safety System

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Enhancing State and Local Roles in Food Safety

Summary Report of the Joint ASTHO-NACCHO Foodborne Illness Surveillance & Outbreak Response Workshop July 1 2008

Introduction

Foodborne illness continues to threaten the health and wellbeing of Americans. The Centers for Disease Control and Prevention (CDC) estimates that each year 76,000,000 people fall ill as a direct result to the consumption of contaminated food. Of these who get sick, an estimated 325,000 are hospitalized with 5,000 deaths annually.¹ The economic impacts of foodborne diseases are estimated at \$35 billion dollars in medical costs and lost productivity.² Over 250 different foodborne illnesses are known to endanger human health. Three known pathogens in particular, Salmonella, Listeria, and Toxoplasma, are considered responsible for 1,500 deaths each year. Unknown agents are believed to account for 62 million illnesses and 3,200 deaths.³

State, Territorial, and Local Health Departments play a critical role in preventing and responding to foodborne illnesses, be it multi-jurisdictional or localized outbreaks. Through activities such as inspecting restaurants, grocery stores and food processing plants; providing food worker and consumer education; conducting surveillance; investigating and containing illness outbreaks and taking regulatory action to remove unsafe or unsanitary products from the market, state and local agencies are much closer to consumers than federal agencies and must respond to food safety concerns in their communities.

Recognizing the vital role of state and local agencies, the Robert Wood Johnson Foundation (RWJF) has funded a project to bring together state and local health, agriculture, and laboratory officials, their federal counterparts, the food industry, and consumer groups to develop an agenda for enhancing state and local food safety roles in the context of national food safety reform. The George Washington University School of Public Health and Health Services with RWJF funding, has supported the Association of Food and Drug Officials (AFDO), the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the University of Florida Emerging Pathogens Institute to conduct the project activities.

The broad goal of the project is to ensure that the essential role of state and local agencies in the nation's overall food safety system is fully understood and considered by federal policymakers in both the legislative and executive branches as the national dialogue on food safety reform continues. By advancing a concrete agenda, the project will ensure that the food safety reform debate moves beyond generalities about partnership and collaboration and address the specific changes that are necessary to strengthen the state and local roles in an integrated, prevention-oriented food safety system.

To get direct input from state and local health departments, the Association of State and Territorial Health Officials and the National Association of County and City Health Officials convened a joint workshop to discuss how to enhance the roles of state and local public health in foodborne illness surveillance and outbreak response on July 1, 2008. The goals of this workshop were to evaluate current activities and roles of state and local health departments in foodborne illness surveillance and outbreak response and

¹ Mead, P., et. al. "Food-Related Illness and Death in the United States" Emerging Infectious Diseases, 1999; 5 (5) 607-25. Available online: <http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm>

² World Health Organization. Factsheet: Food Safety and Foodborne Illness. <http://www.who.int/mediacentre/factsheets/fs237/en/> Accessed March 3, 2008.

³ Mead, P., et. al. "Food-Related Illness and Death in the United States" Emerging Infectious Diseases, 1999; 5 (5) 607-25. Available online: <http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm>

develop recommendations to enhance these roles in the context of a more integrated, national food safety system.

Participants in the workshop reviewed fictional case studies (based on reality) that discussed state and local health agency roles in foodborne illness surveillance and outbreak response and provided personal experience to meet the following objectives:

- Outline the current and optimal roles of state and local agencies in foodborne illness surveillance and outbreak response;
- Identify obstacles state and local health departments face in playing their optimal roles;
- Develop a consensus and recommend specific steps that can be taken (on national, state and local levels) to overcome identified obstacles and to strengthen the state and local roles and interaction and collaboration among health departments at all levels.

This summary provides an overall discussion of the barriers that were identified and the recommendations state and local health leaders consider to be crucial in order to create a more effective, seamless food safety system.

Participants

Experts and stakeholders from state and local health and agriculture departments with experience in the various aspects of protecting the public's health against foodborne illness (i.e. regulatory, epidemiological, etc.) participated in this workshop. There were 10 state and 11 local experts and practitioners in attendance. Representatives from industry, consumer advocacy organizations, and federal agencies were also in attendance. For a complete listing of the workshop participants, please see the Appendix.

Methodology

The one-day workshop was divided into two halves. The first half of the workshop consisted of three break-out discussions around a specific scenario, aimed at getting participants to discuss the roles of state and local health departments in foodborne illness surveillance and outbreak response activities. Participants described the optimal roles of state and local health departments, identified barriers to an effective food safety system as it related to the case, and recommended ways a strengthened public health role would have resulted in a more successful outcome.

The second half consisted of a facilitated discussion among all the participants. Based on their real-life experiences, participants were asked to list the barriers and breakdowns in the foodborne illness surveillance and response system and develop concrete recommendations to better integrate and enhance state and local roles in the food safety system.

Participants developed the recommendations through a consensus process. This was done through a nominal group process of listing all of the recommendations out and having participants vote and prioritize the recommendations. The top rated recommendations from the workshop are included in this report.

Summary of Discussion

Discussion of challenges and barriers to an effective food safety system emerged during both the case study break-out groups as well as the facilitated discussion. Problems and barriers identified during the workshop discussion centered around four major categories: Resources, Capacity, Communication, and Roles and Responsibilities.

Below is an overall discussion of the major themes that emerged for each category:

Resources

Unquestionably, resources were the number one topic of discussion around enhancing state and local roles in food safety. In general, participants noted that limited financial resources from federal agencies were a considerable barrier. Federal funding streams that support state and local health departments

Summary Report of the Joint ASTHO-NACCHO Workshop on Enhancing State and Local Roles in Food Safety July 2008
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were identified as being inconsistent and not done in a coordinated manner. Participants agreed that the funding that exists to support state and local public health was not sufficient to support capacity to prevent and respond to major foodborne illnesses. There lacks a national understanding of what state and local public health capacity should be.

Human resources were a second major barrier identified by participants. There lacks a dedicated 'food safety' workforce. Many who conduct food safety activities are overburdened with other responsibilities, often unrelated to food safety. This is especially the case at the local public health level where some local health departments may only have a handful of staff to provide all public health services, of which food safety is just one component. Participants identified a need for more consistent training for health department staff on food safety, outbreak response, and recalls. Lastly, participants noted that turnover and shortages in the workforce, the inability to keep high performing staff, and the lack of leadership development opportunities for younger staff remained significant barriers to health departments' food safety programs.

Capacity

Throughout the workshop discussion, participants continuously noted that there is no identified baseline capacity for state and local health departments to conduct food safety activities. Participants acknowledged that creating a methodology for such a baseline may be difficult to do, but would help establish a more consistent understanding of performance and resource need for state and local health departments.

One specific area identified was a gap in capacity that exists between states that receive funding through FoodNet and those that do not. FoodNet, short for the Foodborne Diseases Active Surveillance Network (FoodNet), consists of active surveillance for foodborne diseases to create a better understanding of the epidemiology of foodborne illness. CDC funds ten sites at the state and local level to conduct foodborne disease surveillance through FoodNet. The project also collaborates with the U.S. Department of Agriculture (USDA), and the Food and Drug Administration (FDA).[†] Participants emphasized that expanding the capacity supported by FoodNet to all states would greatly enhance state and local capacity to understand and respond to foodborne illness outbreaks.

Participants also noted that there has been a significant improvement in terms of surveillance and laboratory capacity with the creation of PulseNet.[†] States now have a mechanism to link strains of foodborne pathogens and better identify large multi-state outbreaks. However, participants did note inconsistent laboratory practices still remain, especially between private and public laboratories, and underscored the need for an increase in laboratory professionals to work in the labs. They also noted a need to improve expertise to interpret PulseNet data and apply it in the field and the need for surge capacity to assist with response to large multi-jurisdictional outbreaks based on the capacity of the local or state health department.

Communication

Participants spent considerable time discussing the issue of communication during foodborne illness outbreaks, especially in the context of large, multi-jurisdictional outbreaks. Systematic communication between governmental agencies, industry, health care providers, and the general public was identified as a key barrier to an effective food safety system.

Risk communication with the general public during large-scale foodborne illness outbreaks remains a key challenge for state and local agencies. In some cases, when there are many agencies involved there are often just as many different messages delivered to the general public. This causes confusion and

* For more information please visit: <http://www.cdc.gov/foodnet>.

[†] PulseNet is a national network of public health and food regulatory agency laboratories coordinated by the Centers for Disease Control and Prevention (CDC). The network consists of: state health departments, local health departments, and federal agencies (CDC, USDA/FSIS, FDA). For more information please visit: <http://www.cdc.gov/pulsenet/>

inconsistency in response. Participants noted a need for unified messages which would require identified roles as to who would develop and deliver these messages to the general public.

A lack of coordination between federal, state, and local agencies also posed communication challenges between agencies. Participants noted that a lack of a good chain of communication creates significant barriers to a seamless and consistent information flow during a large outbreak, especially when there are many unknowns involved and regulatory rules to adhere.

Lastly, participants discussed a lack of general food safety awareness as a key barrier. Participants called for increased food safety trainings especially for the clinical sector, public officials, and the general public.

Coordination: Roles and Responsibilities

Significant discussion during the workshop centered on the roles and responsibilities of all actors during an outbreak. The discussion focused on who was accountable during what stage of an outbreak. The participants acknowledged the fact that no clear roles or responsibilities for national outbreaks are outlined. While guidance documents such as the Council to Improve Foodborne Outbreak Response (CIFOR) Guidelines will be helpful, it does not delineate national leadership in terms of large scale multi-jurisdictional outbreaks. This is less of an issue for small, localized foodborne illness outbreaks.

Participants stressed the variability and understanding of roles of federal agencies during foodborne illness outbreaks and called for a more centralized approach to a solution for multi-jurisdictional outbreaks. Participants agreed that a defined role for federal leadership in establishing these responsibilities is needed. In addition, the use of incident command systems (ICS) during large scale outbreaks was brought up by several participants. Participants suggested and endorsed the concept of creating epidemiological strike teams to lead investigations and response during large multi-jurisdictional outbreaks. This would help minimize some of the coordination issues that often arise in outbreaks across jurisdictions.

Lastly, participants noted that post-outbreak after-action reports are rarely completed and leave little opportunity to draw upon lessons learned from an outbreak.

Key Recommendations

Throughout the workshop, several themes on how to strengthen state and local roles in a more integrated, prevention-oriented food safety system surfaced. From these key topics, the workshop participants completed an exercise helping them to develop their key recommendations on improving interaction and collaboration among health departments involved in foodborne illness surveillance and outbreak response.

Similar to the discussion, four major themes emerged around discussion of recommendations. These themes included: **1) Resources; 2) Capacity; 3) Workforce; and 4) Communication and Coordination.**

Below are the specific recommendations from the workshop for each category:

1. Resources

- 1.1. Provide funding to allow all states to participate in FoodNet.
- 1.2. Reallocate resources between FoodNet states and non-FoodNet states to better even out state capabilities.
- 1.3. Create incentives for private labs to timely test isolates and submit to states for surveillance purposes.
- 1.4. Create incentives to ensure that isolates from states get put into PulseNet—very few from states currently being submitted from food Agriculture labs.
- 1.5. Provide funding to states and locals for stool sampling to eliminate costs to the public and medical providers/insurance (e.g. Norovirus lab tests).

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- 1.6. Allow emergency preparedness funds to be used for food safety issues, including personnel committed 100% to public health emergency preparedness, to provide a continuous stream of funding and resources for food safety programs at the state and local level.

2. Capacity

- 2.1. Develop a mechanism to determine capacity at state and local level to adequately address foodborne illness burden prior to an occurrence of an outbreak, including identification of lead agencies/investigators. The federal government should support relationship building at the state and local level to enhance trust and joint responsibility.
- 2.2. Provide funding to states and locals to build capacity among states and locals for foodborne illness outbreaks.
- 2.3. Provide and enhance staffing guidelines and how to allocate staff per capita across the US and provide funding/incentives to help states and locals meet these guidelines.
- 2.4. Create a systematic approach to foodborne outbreaks to be activated when the outbreak extends beyond the scope of routine state and local investigation, (e.g. Federal cluster-investigation teams should assist the states and locals in assessing PFGE clusters to evaluate which cases merit increased attention, virtual incident command).
- 2.5. Develop guidelines to prioritize state and local food safety resources such as a population based algorithm.
- 2.6. Fund state/local/regional teams to work directly with PFGE results in a real-time basis, such that there is one database, not multiple databases.
- 2.7. Create quick reaction strike teams for foodborne outbreaks.
- 2.8. Develop performance expectations for federal/state/local levels for timely provision of data, reports, and analysis of investigation, using a foodborne response tracking system that focuses on After Action Reports and closes the loop on foodborne illness investigations while at the same time provides an avenue for collecting lessons learned from state and local health departments.
- 2.9. Further enforce the continuous quality and accountability improvement cycle to enhance prevention and response to a foodborne illness outbreak.
- 2.10. Provide technology, equipment, and travel support to states and locals to do high quality surveillance and response including small and/or remote jurisdictions.
- 2.11. Provide training to state and local environmental health staff to conduct an epidemiology-based environmental investigation during an outbreak.

3. Workforce

- 3.1. Funding and training should be provided for establishing state, local and federal liaisons.
- 3.2. Develop a closer connection between state and local public health professionals, healthcare professionals/medical community, and policy makers, by incorporating training and networking opportunities on the job and in a university setting.
- 3.3. Require that federal food safety employees do "rotations" between different state and local governments that could potentially tie to promotion/advancement).
- 3.4. Expand and fund Epi Ready and PulseNet training for outbreak teams that include state and locals.
- 3.5. Sustained funding for recruitment, training and retention of trained food safety professionals and employees at the state and local levels (e.g. PulseNet Specialists).
- 3.6. Reclassify health inspectors such that they are not classified as wage grade and can be compensated in outbreak investigations with overtime pay.
- 3.7. Require that all food workers have paid sick leave. Consider retail penalties, such as fines, for poor food handling practices (e.g. for ill food workers on duty).
- 3.8. Provide opportunities for state and locals to participate in cross-disciplinary training.

4. Communication and Coordination

- 4.1. Fund/host regular meetings among federal, state, local public health information officers to address specifically communications during foodborne illness outbreak. Meetings may also include other healthcare professionals involved in foodborne illness surveillance and outbreak response.

- 4.2. CDC should create a web portal to post outbreaks/investigations around the country where states and locals can contribute, include discussion forums. This would be more accessible to public health professionals than Epi-X and would have list serve capabilities. The goal would be to create a central repository for data and eliminate the current multiple databases.
- 4.3. CDC should create fact sheets to post in doctor/hospital waiting or treatment rooms to educate patients and providers on foodborne illness (i.e., viral/bacterial incubation periods, prevention strategies).
- 4.4. State and local agencies should better integrate epidemiologists on their local board(s) of health and their environmental health departments in foodborne illness outbreak and surveillance activities.
- 4.5. Increase training for medical doctors, healthcare professionals and retail/food service providers on food safety and the need to collect stool samples and report possible foodborne illnesses to their state and local health departments; tie to education in medical/nursing/public health programs, continuing education, and license renewals.
- 4.6. Delineate roles and responsibilities before an outbreak, both between and within agencies (vertical and horizontal coordination).
- 4.7. Create guidelines that addresses specifically how states should handle multi-jurisdictional outbreaks (who is in charge, outbreak teams, communication links, sharing data and resources, lab activities, interviewing, managing the outbreak, follow-up after the outbreak is over; communications from the agencies to the public).
- 4.8. Endorse and support adoption of CIFOR guidelines.
- 4.9. Establish guidelines for when and how to implement Incident Command System (ICS) and emergency response in a foodborne illness outbreak investigations; CDC should develop ICS model for outbreaks.
- 4.10. Establish guidelines regarding how states should assist one another during outbreaks and during shortages in lab capacity.
- 4.11. Develop standard operating procedure among all levels for management of multi-jurisdictional outbreaks and recalls.
- 4.12. Develop standard messages and coordinate talking points that can improve communication with consumers and demonstrate the importance of public health to policy makers during a foodborne illness outbreak.
- 4.13. Require timely after-action review and reports to apply lessons learned and implement appropriate policy changes.

Conclusion

State and local health departments recognize and understand the critical role that they play in keeping the public safe from foodborne illness. The Joint ASTHO-NACCHO Foodborne Illness Surveillance & Outbreak Response Workshop provided an avenue for public health professionals and food safety experts to discuss the surveillance and outbreak response components of the food safety system from the perspective of the state and local level. Throughout the workshop, several themes on how to strengthen state and local roles in a more integrated, prevention-oriented food safety system surfaced. From these themes, the workshop participants developed key recommendations on how to improve the system to be more integrated. Of all four categories, the need for additional resources was ranked highest by the workshop participants. The capability of state and local health departments in preventing foodborne illness and promoting health of the population would be enhanced with a consistent stream of funding.

The recommendations presented above provides further evidence for policy makers and food safety leaders as to the critical importance and need for enhancing the state and local public health roles in an integrated, prevention-oriented food safety system. These recommendations and a wider report of the overall project will present national policy recommendations on improving state and local roles in the overall food safety system beyond traditional public health roles. The report is scheduled to be available in 2009. ASTHO and NACCHO are committed to supporting their member agencies in food safety activities and look forward to continuing to engage stakeholders and partners on improving the nation's food safety system.

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More information about the project can be found on the Food Safety Research Consortium (FSRC) website: http://www.thefsrc.org/statelocal_project.htm



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Enhancing the Roles of State and Local Government in an Integrated, Prevention-Oriented Food Safety System

A Project of the George Washington University School of Public Health and Health Services, Funded by the Robert Wood Johnson Foundation

Summary Report of the Inspection and Regulatory Activities Workshop Date and Location: July 14 and 15, 2008 in Las Vegas, NV

Introduction

Increased concerns about the safety of fresh produce and visible failures in oversight of imported food ingredients have prompted calls for food safety legal and policy reform at the federal level, with a focus on strengthening the prevention mandate, legal authority, and resources of the Food and Drug Administration's food safety program. The success of FDA and other food safety agencies at the federal level depends to a large extent, however, on effective coordination and collaboration with food safety regulators and health officials at the state and local level.

Among federal policymakers, however, the food safety roles of state and local agencies and the issues they face are not as well understood as they should be. The need for federal-state-local "partnership" and "collaboration" is recognized and often voiced, but, absent some affirmative effort, federal food safety reform is unlikely to address the roles and needs of state and local agencies with the specificity required to achieve real progress.

Thus, at the same time food safety reform agendas are being pursued at the federal level, it is critical to define and advance an agenda for modernizing and strengthening the roles of state and local agencies, regarding both their community-based food safety efforts and their further integration into the nation's food safety system.

This project will develop and communicate an agenda for change in these areas to ensure that state and local food safety roles, including their present and potential contribution to the nation's overall food safety system, are fully understood and considered by federal policymakers in both the legislative and executive branches as food safety reform unfolds. By advancing a concrete agenda, the project will help ensure that the food safety reform debate moves beyond generalities about partnership and collaboration and addresses the specific changes that are needed to strengthen the state and local roles in an integrated, prevention-oriented food safety system.

Project Goals

The overarching goal of this project is to improve food safety in the United States by developing and communicating an agenda for legal and policy reform, improved practices, and the enhanced resources needed to make state and local agencies full and effective partners in a more integrated, prevention-oriented food safety system. The more specific goal is a consensus-based, analytically well-supported agenda that will have credibility and impact on its own in the national food safety debate and also be an information tool for state and local officials working within their own political processes and at the national level to improve their food safety programs.

Specific Project Objectives

The project will achieve its goals by bringing together state and local officials, their federal counterparts, and diverse stakeholders of the food safety system, including the food industry and consumer groups, to:

1. Formulate and express a modern vision of the role of state and local government in an integrated, prevention-oriented food safety system;
2. Identify gaps or constraints in current law, policy and practice at the federal, state and local levels that inhibit fulfillment of that vision;
3. Recommend changes in law, policy, and practice that are needed to enhance the effectiveness of state and local agencies in addressing food safety problems at the local, state and national level;
4. Identify specific opportunities to improve collaboration among state, local, and federal agencies; and
5. Describe current funding patterns and resource needs at the state and local level.

Inspection and Regulatory Activities Workshop

The Association of Food and Drug Officials (AFDO) hosted a workshop to involve state and local regulatory officials in developing the reform agenda by addressing inspection and regulatory issues. Participants included stakeholders from state and local food regulatory programs, their federal agency counterparts, academia, and consumer advocacy organizations. Workshop topics included:

- What individual states and localities are doing now in their regulatory and inspection programs to address existing gaps in the current food safety system and how such innovations might be applied nationally;
- The optimal roles and responsibilities for state and local food safety regulatory and inspection programs in an integrated, national food safety system;
- The basic legal authorities, policies, and institutional arrangements state and local agencies should have to play their roles in a nationally integrated food safety system;
- Other elements – such as model codes or uniform laws, adequate funding for states and localities, and enhanced collaboration with federal agencies – that are needed for a nationally integrated system to be successful;
- The key gains in public health and consumer protection that could result from a nationally integrated system, the major obstacles to achieving those gains, and proposed solutions.

Workshop Outcomes

The workshop framed the topics by identifying gaps and constraints that prevent the full participation of state and local governments in an integrated, prevention-oriented food safety system. Following are the identified gaps and constraints, with recommended actions:

Identified Gaps

#1 Lack of enforceable science/risk based standards for domestic and imported high risk fruits and vegetables.

Other language used to identify this gap:

- Lack of oversight at the grower level for fruits/vegetables.
- Ineffective regulation and inspection on farms of ready-to-eat high risk products.
- Pesticide misuse involving food, crops, and animals.
- Cooperative program doesn't exist for on-farm food safety...packinghouses too.
- Many GAPS need to be made requirements for high risk products such as leafy greens and tomatoes that are frequently involved in outbreaks.
- There is no on-farm government authority.
- Need routine/regular review of standards and adjusting and strengthening to better protect public health.
- Farms – no porta toilet, locations, lack of enforceable standards, lack of consistency and regulation.

Recommendations:

1. An AFDO funded workgroup to address produce with science based, mandatory, enforceable standards.
2. Develop on-farm standards at the federal level. States do on-farm inspections.
3. Push forward with AFDO Model Code. Define completion date and have FDA already poised to put in into play with regulations.
4. Decide which model to use at foreign farms..."equal to" USDA model or certification model.
5. FDA develops on-farm federal food safety standards.

#2 Lack of strategic control of imported foods.

Other language used to identify this gap:

- Assure safety of imports.
- Imports in domestic commerce

- Inability to differentiate: imports, commodity type, country and company in 246,000 traditional retail outlets.
- Lack of inspections of product.
- Lack of foreign establishment inspections.
- System not adequately automated or risk based.
- Surveillance sampling not adequately planned – inadequate capacity for the analyses that should be done.
- Focus on imports broadly when domestic is also an issue.
- Imported foods not monitored very well.

Recommendations:

1. Science/risk based standards for food imports. “Fast track” in exchange for validated, audited and sampling-based food safety management systems.
2. Require government or 3rd party audits to enter the country.
3. The import “rider” on state contracts is a good way to start into the process – need for import training for domestic surveillance.
4. Fund State programs to regulate imports in domestic commerce.
5. Develop standards to permit 3rd party inspections.
6. Facilitate entry of product from countries with strong regulatory programs closely matching our own – have them certify imports.
7. Develop certification for private labs to improve analytical surveillance.
8. Fast track IT/data modernization risk based systems.

#3 Lack of federal funding of state/local food program infrastructure.

Recommendations:

1. Increase FDA budget – allow legal authority to issue civil fines then set policies that are fair/uniform.
2. States should accredit local programs that are delegated authority.
3. Feds should accredit state programs that are delegated authority (contracts).
4. Look at funding models for programs: 1/3 from state/local taxes, 1/3 from fees, 1/3 from state/federal government budgets.
5. Funding isn’t necessary for FDA to accept state/local lab results and for information sharing.
6. Line item baseline federal funding for state regulatory programs, not fee for service.
7. Put more flexibility into state program funding mechanisms.
8. Contract with IOM to do study of all state laws and regulations.

#4 Lack of oversight of food transportation

Other language used to identify this gap:

- Transportation of food long distances; no regs over transporters for temp control; no training widely available.

Recommendations:

1. DHS has the \$\$\$\$. Verify the threat, engage the administration in January, get proper funds reallocated.
2. Engage the transportation industry.
3. Develop a FDA-state cooperative program for food distribution.

#5 Inefficient recall system.

Other language used to identify this gap:

- No mandatory recall authority.
- Recall or FBI information sharing: state and local agencies go to industry for information that should be provided by FDA or USDA.
- FDA products need a plant# like USDA products to make recalls less confusing and more effective. For example, New Era recall very confusing.
- Too many "volunteer" programs.
- FDA lacks adequate authority to order recalls.
- Lack of adequate communication sharing.
- Recall systems are in need of re-engineering.
- Recalls are "one size fits all." Policies need to be expanded for the different circumstances.
- Need comprehensive traceback system.

Recommendations:

1. Traceability systems.
2. Mandatory recall authority.
3. Mandatory traceability systems enacted.
4. Mandatory recall authority granted.
5. More "mandatory" programs.
6. Build an electronic recall management system accessible by all stakeholders. Use FoodSHIELD as a starting platform.
7. Traceback pilot program/working group
8. Congress provides mandatory recall authority
9. Develop a national database for foodborne illness complaints associated with commercially processed foods.
10. FDA and USDA should work with all stakeholders to define weak points and fix them.
11. Utilize state model for recalls (NC, NY); usually effective. This is bottom up. Top down FDA recalls need work.

#6 Lack of adequate training: standards, certification, delivery and funding.

Other language used to identify this gap:

- Inadequate training.
- Lack of training standards for local regulators.
- Currently no educational standard or professional preparation at the university level

Recommendations:

1. Create a training academy for food professionals (classroom, virtual, certification, OJT).
2. Create a college curriculum to prepare professional food safety candidates.
3. Increase funding.
4. Mandate certification of all food inspection personnel and lab analysts.
5. Develop training and certification programs with various specializations – HACCP, LACF, Imports, etc.
6. Work through FDA Districts and regionally based associations like AFDO, NACCHO, ASTHO to deliver to each state.
7. Centralize training location for standardization, yet tailored local delivery. “JIFSAN on steroids.”
8. Streamline or reduce conflicts between food code requirements and the manufactured food requirements.
9. Industry must continue to be part of any solution.
10. Hire professionals and provide adequate training.
11. Funding source for state based trainers.
12. Food Safety Leadership Institute.
13. FDA provide auditor to state on loan for evaluation of programs – CDC/EIS Officer model.
14. Create a job shadowing or sabbatical program to have state/local/fed/industry professionals gain experience at all levels.

#7 Lack of commitment and willingness re the flow of information.

Other language used to identify this gap:

- Data sharing and application
- Lack of metrics to measure progress. Is it illness/consumable units, number of menu-facilities with “material issues”, number of retailers with “material issues”?
- Attribution information: knowing the pathogens is useful, but we don’t do enough to identify the foods.
- Inability or inefficient information exchange.

Recommendations:

1. Standardized, centralized process and IS systems.
2. Share inspection histories.
3. Have electronic systems that can be accessed by fed/state/local; examples: recalls, inspections, imports.
4. Adopt ICS for major investigations (recalls, FBI, and others) to improve coordination and information between federal, state, local.
5. Accept state lab data.
6. Fund development of software that will manipulate data from multiple data sources so that data can be shared across jurisdictions.
7. Microbiological testing is rapidly changing with new technology, but what do the results actually mean? Are they validated methods upon which court actions can be upheld? For example, USDA AMS MDP test results.

#8 Lack of risk based, timely, and consistent federal standards.

Other language used to identify this gap:

- Lack of HACCP for all food processors (inconsistently applied).
- Lack of FDA regulations and updated regulations – GMPs, GAPs and GMPs for produce, transportation, smoked fish, salvage, etc.
- Lack of nutritional standards; floor, not ceiling.
- No formal protocol for investigations crossing state lines; use of state investigation and lab results.

Recommendations:

1. Devote needed resources to set, then adopt, standards...standing workgroup, outside experts?
2. Federal standards for food contaminants other than pesticides and antibiotics.
3. Uniform restaurant/retail inspection criteria – a “critical violation” in one state is not in another...can’t compare across jurisdictions.
4. Identify weaknesses in programs and publicly identify if compliance is not reached in a reasonable timeframe.

#9 Lack of a system designed to encourage communication and cooperation.

Other language used to identify this gap:

- Inability, or lack of concern, of local, state, and fed politicians to effectively address issued based on science and public health reality.
- Interference of the local and state politicians to prevent regulation of their friend’s facilities.
- Lack of coordination and response.
- Lack of communication between state and local agencies.
- Moving away from science based decision making to those driven by political and or social consumer pressure. Can never do it all, but need to do what is important.
- Lack of consensus building for all levels – engaging all stakeholders; if you are not on board with NFSS, why not?
- Lack of meaningful enforcement tools.
- Uneven inspection across states/localities.
- Inconsistent application of state retail regs among local agencies who have adopted the same code.
- Unwillingness of states and locals to engage.
- All states are not created equally; i.e., state/local responsibility.
- No consequence for 3rd party increasing risk/hazard. Example: non-point source contamination – changed CAFO practices E. coli.
- Disconnect between local food program and state epi regarding FBD investigations.
- Lack of OTJ work between feds/states/locals.

Recommendations:

1. Clearly define roles among regulatory agencies in a system designed to encourage cooperation and communication.

2. Develop system for assessing priorities in an integrated food safety system.
3. Better communication between stakeholders.
4. Clarify roles and responsibilities.
5. Need accountability of roles.
6. Coordination between federal, state and local agencies.

Identified Constraints

#1 Lack of an adequate, sustainable, and flexible program funding.

Other language used to identify this constraint:

- No transparency of program financials.
- Not enough support for state/local programs.
- Funding often based on numbers of inspections, not outcomes that matter.
- Need funding to work toward FDA voluntary standards.
- Inadequate funding.
- State funding depends on population, food production, and state ability to raise revenue.
- No civil penalties and fines on companies that routinely violate food safety laws and GMPs.
- Lack of political rewards for supporting increased funding.
- How much are we currently spending on food safety? Can't justify more until we can say what current situation is at fed/state/local level.
- Lack of sufficient government resources.

Recommendations:

1. Funding should be based on outcomes, not "beans" or other inputs. But must be rational and flexible.
2. Put state program funding as line item in federal budget.
3. Assess staffing dedicated to food safety nationally and compare to what it should be.
4. Use a good model showing results can be obtained and sustained with consistent funding.
5. Federal funding should include states that participate in national efforts such as retail food prog stds to encourage uniformity.
6. Line item federal budget for state program operations, not fee for service contracts.
7. Develop federal funding formula for states and locals that encourages them to raise matching funds, hire and retain workforce, and train people.
8. Federal agencies should have "line item" in their budgets to/for support of state and local programs.
9. Federal funds for locals that makes adoption of the food code a prerequisite.
10. Enact laws that would allow governments to levy civil penalties and fines.
11. FDA set aside \$\$ with broad options for states to utilize for staff, travel, etc.
12. More flexibility to funding travel necessary for training state regulators.
13. Introduce in a federal statute that funds dedicated to pay state inspection of food must to the food regulatory agency performing those duties.
14. Need public health based funding models...how much should the taxpayer support? How much should industry pay?

#2 Resource prioritization

Other language used to identify this constraint:

- Lack of leadership in helping/assisting neighboring jurisdictions to be more engaged in an integrated food safety system.
- Lack of flexible resources & legal restraints.
- Minimum standards are defined more by minimum resources than by minimum level of protection; e.g., poor performing states/localities influence what others think is “minimal.”
- Resources being reduced.

Recommendations:

1. Assess resources nationally & develop guidelines for effective staffing levels.
2. Use commissioned state personnel in development phase for new/revised regs.
3. More transparency in current resource allocation at fed/state/local level.
4. Private funding to programs that need improvement or are high hazard areas that need sustainability to help protect and promote safe food production.
5. Modeling/analysis to compare risks and benefits.
6. FDA leverage with state by using state labs to verify new methodologies.

#3 Inability to accept state inspection and lab data.

Other language used to identify this constraint:

- Feds not accepting state lab results.
- Failure to use state lab analyses by our federal partners; i.e., failure to leverage resources.

Recommendations:

1. Acceptance of state inspection and analytical and compliance data.
2. Develop criteria for acceptance and hold states accountable.
3. Secretary Leavitt stated on July 9 at the import safety summit that HHS would address the unacceptable fragmented siloed federal IT system. Now is the time to make sure state need are dealt with too.
4. Leveraging acceptance by FDA of electronic copies of inspections, reports, labels, photos, etc.
5. Lessons from CDC on the epi/surveillance side?
6. Establish criteria for acceptance of state lab data.
7. Coordinate evaluation of national corporations and chains.
8. Develop a database for all processor inspections with access by all regulatory officials.
9. Petition FDA and USDA to publish guidance on requirements for state lab results to be accepted.
10. Develop data standards for capturing into from inspections/investigations as prerequisite to data sharing.
11. Use FoodSHIELD for posting recall distribution information.

#4 Compatibility of IT systems.

Other language used to identify this constraint:

- Inability to share inspection data across jurisdictions.
- Lack of timely or broad publication of data that can be used by others in the system.
- Inability to utilize state/local regulatory data for federal regulatory action.
- Varying reporting methods/documents.
- Decisions made by uneducated federal, state, and local politicians.

Recommendations:

1. In this day and age, why can't we have a web based regulatory information retrieval system that pulls information from multiple systems – inspections, recalls, sampling, etc.

#5 Legal restrictions on information sharing.

Other language used to identify this constraint:

- Propriety information is a formulation, not a distribution list for industry.
- Inability to share distribution information with states/consumers.
- Need distribution lists for recalls to conduct effectiveness checks.
- Concern that sharing preliminary information to all levels could result in a “leak” of incorrect information to the media who would then criticize the government when the information changes.

Recommendations:

1. Remove limitation on sharing distribution lists with states and on sharing retail consignees with consumers.
2. Change law/policy to share recall distribution information.
3. States need to attempt to modify state FOI to allow for confidential information security/limited releases.
4. Have distribution consignee lists to track recalled product for effectiveness checks and to publish store names publicly that may have received recalled product.
5. Change the law.
6. Voice concerns to federal legislators then provide mandates to congress to change law.
7. Information sharing: recall distribution information, policy development, inventories and inspection histories.

#6 Acceptance of new roles and responsibilities.

Other language used to identify this constraint:

- Roles and responsibilities are unclear.
- Resistance to change by agencies, political leaders, industry, consumers.
- Lack of trust between feds/states/locals.
- Apathy in some jurisdictions to participate in an integrated food safety system.
- General lack of cajones.
- State and local cross responsibility.

- Since epi is done by communicable disease programs, there is a tendency to view outbreaks in a linear fashion and the food regulatory response has to wait until the epi is done – should be concurrent.
- No place for stakeholders to discuss and make recommendations regarding food safety system gaps. Solution is to use AFDO.
- Lack of trust.
- Politics trumps public health.
- Trust, turf, fear.
- Fear of calling out poor performers. We rarely are willing to stand up and say which states and localities don't do a good job.
- "Their" program needs to be changed, not mine. NIMBY.
- Stovepiped lines of communication.

Recommendations:

1. Eliminate antiquated programs or processes that drain resources and state/federal levels.
2. Public health and safety should trump politics.
3. A "food safety council" that includes members from all aspects of the system and meets regularly could help communication and build trust.
4. Create more opportunities to network at all levels – job shadow programs.
5. Establish workgroup/study changes to laws need to effect/define roles and responsibilities to avoid unintended consequences.

#7 Lack of uniformity in carrying out standards.

Other language used to identify this constraint:

- Lack of state health department leadership providing interpretations of retail regs when disagreements are evident between local agencies.
- Need accountability in assuring that states carry out manufactured standards program effectively.
- Trade practices undermining tough standards and the precautionary principle.
- Lack of law and application interpretations.
- Lack of meaningful enforcement tools.

Recommendations:

1. Workgroup meeting to prioritize what to standardize. Has this been done?
2. Go to IOM or similar for study of state laws/regs.
3. Publish interpretations.
4. Establish more robust system for FDA to assure state programs are effective and carrying out program standards.
5. FDA needs to complete egg safety regs.

#8 Complex regulatory structures.

Other language used to identify this constraint:

- Differing organizational structures for food regulatory programs.

- Complexity of FDA structure...cooperative programs versus DFSR.
- State and local agency structure and resources.

Recommendations:

No specific recommendations made.

#9 Lack of training

Other language used to identify this constraint:

- Inconsistency in Food Code adoption (not all states adopt; not all states adopt latest version).
- Lack of communication during outbreaks & lack of coordinated voice.
- Funding challenges/state and federal budget constraints.
- In emergency response, states view economic recovery as a consideration for a food business or commodity, while federal partners stop after response.
- Lack of standardized advanced training.
- Programs don't invest due to budget constraints.
- Training is not an issue – more than enough out there now.
- FDA lost expertise.
- Out of state training: agency travel caps, \$\$ in FDA for training, FDA loss of expertise.

Recommendations:

1. Federal & state legislators and their staff need to have a stronger knowledge and understanding of the food safety system community and regulations.
2. Staff turnover makes it difficult to keep congressional and state legislators knowledgeable.
3. Develop in conjunction with a third party, a joint industry/state/federal training program offering face-to-face and webinar training.
4. Continue building on ORA-U course and beef up FDA training branch and USDA.
5. More train-the-trainer courses to move the knowledge.
6. Develop national standards for certifying inspectors/agency employees on various jobs.
7. Develop federally sanctioned and supported mechanism for accrediting certification organizations.
8. Fed/state incentives; e.g., certified people in R & D for federal funding per program standards.
9. Pilot programs to fine tune and jump start system; special outreach for underserved and poor areas.
10. Establish national training center with leadership institute.
11. More funding for state based trainers.
12. Match training need to each employee. Show improved performance.
13. Travel grants to attend ORA-U courses.

#10 Outdated regulatory system

Other language used to identify this constraint:

- The foundation of the system is outdated and outmoded.

- Current system of food safety is based on physical and chemical contamination identification through inspection.
- Previous solutions were knee jerk reactions that failed to address root causes and flaws within the system.
- Lack of knowledge at federal/state policy maker level of food safety in the US.

Recommendations:

1. HACCP based approach should be applied uniformly.
2. Revise the GMPs.
3. Revise the GMPs and prioritize risks.
4. Identify key individuals to work on modernization. Develop recommendations. Move them forward.
5. Consolidate overlapping regulatory areas.
6. HHS secretary contacts all state governors to get buy in to a national food safety system.
7. The food safety system must address microbiological hazards and not focus on physical and chemical hazards as much to be modern and effective.
8. FDA and USDA should be freed up to be able to focus on things like imports, provide tech assistance to states, work with states on continuous improvement. Delegate to states.
9. Agencies and their activities need to revolve around the concept that they are part of an overall system.

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