Harnessing Knowledge to Ensure Food Safety

Opportunities to Improve the Nation's Food Safety Information Infrastructure

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FOREWORD

We live in the Information Age, which is marked by an explosion in the amount of information that exists, as well as rapid advances in the tools for its collection, management, analysis and communication. People working on food safety, like those in many fields, now face an abundance of information generated by diverse institutions and individuals for a wide range of purposes. This presents both opportunities and challenges.

The *great opportunity* lies in the fact that food safety in the United States can be improved if those working to reduce foodborne illness–in government, industry, academia and the consumer community–are informed by the best available science, data and analysis. The *difficult challenge* is to be sure the information generated is what these diverse practitioners really need *and* to provide timely access to the information in a useful form.

Meeting this information challenge is crucial, because ensuring food safety is, at its core, a matter of collecting and making good use of information to identify, understand and prevent food safety problems.

This report addresses today's food safety information challenge by recommending ways to improve the functioning of what we have termed the "food safety information infrastructure" (FSII), which encompasses the many public and private institutions, programs and processes through which information is collected, made accessible, and actively shared to ensure food safety.

The project from which this report emanates was funded by the Robert Wood Johnson Foundation, which has long worked to improve how information is generated and used to help meet public health objectives. With the Foundation's support, we were able to convene, in a series of four workshops, a wide range of food safety experts from federal, state and local governments, the food industry, academia and the consumer community to discuss information needs and ways to better meet them. In workshop presentations and discussions, other in-person meetings and interviews, teleconferences, email conversations and comments on our drafts, a large community of individuals helped us understand current food safety information practices and the constraints under which individuals and institutions operate in collecting and sharing information.

Participants in the project also offered many ideas for how to overcome these constraints and specific suggestions for improving the generation and flow of information across the food safety system. We

base many of our conclusions and recommendations in this report on their input. We emphasize, however, that, although we tried to include as many perspectives as possible in our project, we could not capture them all. In addition, while the recommendations spelled out in Section Five of the report draw heavily on the input we received throughout the project and are intended to address the expressed needs of the community, we, alone, are responsible and fairly accountable for their specific content.

One of the first things we learned from the food safety community is that the FSII in the United States is even more multi-faceted and complex than we thought at the outset of the project, and significantly improving it will be more difficult than we initially thought. While technical issues abound, we found that improving the FSII is primarily a matter of redefining roles and relationships among its many participants and creating incentives and mechanisms for agencies and individuals to collaborate more closely and to act on their common interest in improving the food safety system as a whole. Our recommendations focus largely on these matters.

Improving the FSII will certainly not be easy, but the time is right to tackle it. We hope our report will contribute to progress by increasing understanding of the central role of information in ensuring food safety and stimulating discussion of both constraints and opportunities for improvement in how we meet our food safety information needs.

We will continue to welcome any and all comments on this report and ideas for improving the nation's food safety information infrastructure.

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ABBREVIATIONS AND ACRONYMS

AAFHV	American Association of Food Hygiene Veterinarians
ACS	American Chemical Society
ADA	American Dietetic Association
AEB	American Egg Board
AFDO	Association of Food and Drug Officials
AFI	Association of Food Industries
AGRICOLA	Agricultural Online Access (NAL)
AMI	American Meat Institute
AMS	Agricultural Marketing Service (USDA)
APHA	American Public Health Association
APHIS	Animal and Plant Health Inspection Service (USDA)
APHL	Association of Public Health Laboratories
ARIS	Agricultural Research Information System (USDA/ARS)
ARS	Agricultural Research Service (USDA)
ASCP	American Society for Clinical Pathology
ASM	American Society for Microbiology
ASTHO	Association of State and Territorial Health Officials
BIFCO	Beef Industry Food Safety Council
CCID	Coordinating Center for Infectious Disease (CDC)
CDC	U.S. Centers for Disease Control and Prevention
CFA	Consumer Federation of America
CFI	Center for Foodborne Illness Research & Prevention
CFP	Conference for Food Protection
CFS	Center for Food Safety
CFSAN	Center for Food Safety and Applied Nutrition (FDA)
CIFOR	Council to Improve Foodborne Outbreak Response
ComBase	Combined Database for Food Microbiology (USDA/ARS)
CRIS	Current Research Information System (USDA/CSREES)
CSFII	Continuing Survey of Food Intakes by Individuals
CSPI	Center for Science in the Public Interest
CSREES	Cooperative State Research, Education and Extension Service (USDA)

CSTE	Council of State and Territorial Epidemiologists
CU	Consumers Union
CVM	Center for Veterinary Medicine (FDA)
DALY	Disability Adjusted Life-Year
DHS	U.S. Department of Homeland Security
DOD	U.S. Department of Defense
eFORS	Electronic Foodborne Outbreak Reporting System
eLEXNET	Electronic Laboratory Exchange Network
EPA	U.S. Environmental Protection Agency
ERS	Economic Research Service (USDA)
ETOXNET	The Extension Toxicology Network
FDA	U.S. Food and Drug Administration
FERN	Food Emergency Response Network
FMI	Food Marketing Institute
FNS	Food and Nutrition Service (USDA)
FOIA	Freedom of Information Act
FoodNet	Foodborne Diseases Active Surveillance Network
FSII	Food Safety Information Infrastructure
FSIS	Food Safety and Inspection Service (USDA)
FSRC	Food Safety Research Consortium
FSRIO	Food Safety Research Information Office (USDA/ARS/NAL)
GAO	U.S. Government Accountability Office
GAP	Government Accountability Project
GMA	Grocery Manufacturers Association
HACCP	Hazard Analysis and Critical Control Points
HHS	U.S. Department of Health and Human Services
IAFP	International Association for Food Protection
IDDBA	International Dairy-Deli-Bakery Association
IDFA	International Dairy Foods Association
IDSA	Infectious Diseases Society of America
IFIC	International Food Information Council Foundation
IFT	Institute of Food Technologists
ILSI	International Life Sciences Institute
IOM	Institute of Medicine
IQA	Information Quality Act
JIFSAN	Joint Institute for Food Safety and Applied Nutrition
LRN	Laboratory Response Network (CDC)
MDP	Microbiological Data Program (USDA/AMS)
MMWR	Morbidity and Mortality Weekly Report (CDC)
NACCHO	National Association of County and City Health Officials
NAL	National Agricultural Library
NARMS	National Antimicrobial Resistance Monitoring System (CDC, FDA, USDA)
NAS	National Academy of Sciences
NASDA	National Association of State Departments of Agriculture
NAW	National Association of Wholesaler-Distributors
NCBA	National Cattlemen's Beef Association

NCC	National Chicken Council
NCEH	National Center for Environmental Health (CDC)
NCHS	National Center for Health Statistics (CDC)
NCL	National Consumers League
NCTR	National Center for Toxicological Research (FDA)
NCZVED	National Center for Zoonotic, Vector-Borne, and Enteric Diseases (CDC)
NEDSS	National Electronic Disease Surveillance (CDC)
NEHA	National Environmental Health Association
NFI	National Fisheries Institute
NHANES	National Health and Nutrition Examination Survey (CDC)
NIH	National Institutes of Health (HHS)
NMA	National Meat Association
NPB	National Pork Board
NPPC	National Pork Producers Council
NRA	National Restaurant Association
NTF	National Turkey Federation
NTP	National Toxicology Program (NIH)
OAR	Office of Air and Radiation (EPA)
OMB	Office of Management and Budget
OPPTS	Office of Prevention, Pesticides, and Toxic Substances (EPA)
ORA	Office of Regulatory Affairs (FDA)
ORD	Office of Research and Development (EPA)
OutbreakNet	Outbreak Network for Foodborne Diseases Surveillance and Response (CDC)
OW	Office of Water (EPA)
PDP	Pesticide Data Program (USDA/AMS)
PFGE	Pulsed-Field Gel Electrophoresis
PFSE	Partnership for Food Safety Education
PHIN	Public Health Information Network (CDC)
PLoS	Public Library of Science
PMA	Produce Marketing Association
PRA	Paperwork Reduction Act\
PulseNet	National Molecular Subtyping Network for Foodborne Disease Surveillance (CDC)
QALY	Quality Adjusted Life-Year
QMRA	Quantitative Microbial Risk Assessment
RSS	Really Simple Syndication
RWJF	Robert Wood Johnson Foundation
S.T.O.P.	Safe Tables Our Priority
SER	Society for Epidemiologic Research
SOT	Society of Toxicology
SRA	Society for Risk Analysis
TESS	Toxic Exposure Surveillance System (CDC/NCEH)
UFPA	United Fresh Produce Association
USDA	U.S. Department of Agriculture
USPOULTRY	U.S. Poultry and Egg Association

EXECUTIVE SUMMARY

Introduction

Ensuring the safety of the food supply is centrally important to the public's health and underpins the success of the nation's trillion dollar food and agriculture industries. Food safety is also one of our most dynamic public health challenges due to changing technologies and consumer practices and the globalizing food supply.

Over the last two decades, food safety experts and practitioners have made great progress in understanding food safety as a "farm-to-table" challenge that requires science-based efforts all across the food system to prevent foodborne illness. And, today, policymakers are considering how to enhance the government's role in ensuring food safety and better harness the capacity and primary duty of the food industry to make food safe.

For all actors in the food safety system—public and private—the effectiveness of what they do depends on the quality of the information they have on potential hazards and how to minimize them. Thus, any effort to improve the food safety system must address how a wide range of institutions and individuals meet their information needs.

In this context, the Robert Wood Johnson Foundation funded a project under the auspices of the university-based Food Safety Research Consortium to examine and make recommendations for improving the nation's "food safety information infrastructure" (FSII), defined to encompass all public and private institutions, programs and processes through which information is collected, made accessible and actively shared to ensure food safety. Through the project, a diverse collection of food safety experts and stakeholders came together for a series of workshops to discuss information needs and ways to better meet them.

This report and its recommendations are based largely on those workshop discussions, though the authors alone are responsible for the content of the report. Our hope is this report will provide the basis for further dialogue and actions to improve the use of information to ensure food safety.

Vision for the Food Safety Information Infrastructure

The food safety system and, in turn, the FSII, are comprised of many thousands of institutions and individuals at all levels of government, throughout the food industry and academia, in the public health and consumer communities, and, increasingly, in the international community, all of which are involved in collecting and using food safety information. They connect to and depend on each other in many ways, but operate, for the most part, independently.

The FSII is, therefore, best understood as a highly dispersed and decentralized network, rather than an integrated and managed system. The decentralized nature of the FSII has strengths that should be preserved, but it also complicates coordination in the collection of specific research or test data and other types of information, as well as the sharing of information, required for the success of a science-based, farm-to-table food safety system.

Thus, to better meet the information needs of all participants in the food safety system, *we envision an FSII that, through the better coordinated and connected efforts of many public and private parties, generates useful and timely information and makes it readily accessible to those who need it*. It is a system characterized by information not only being generated and used well within organizations but also flowing among organizations to enhance the overall effectiveness of the food safety system.

Based on our workshop discussions, we believe an FSII functioning in these ways would improve the contribution that participants all across the food system can make to ensuring food safety.

Today's Food Safety Information Infrastructure

The complexity and decentralization of today's FSII mean that initiatives to improve it face serious challenges. Nevertheless, a number of recent efforts suggest that progress is not only possible but already underway.

Challenges

Achieving the vision of an improved FSII is made difficult by the following realities of the food safety system and the FSII:

- **Many Information Types**, ranging from data on human disease rates and food contamination to information on the availability and cost of preventive measures and food safety practices in industry and among consumers.
- **Many Information Sources and Scientific Disciplines**, including government research and regulatory agencies, food companies and academic researchers and disciplines including veterinary medicine, epidemiology, food science, microbiology, risk analysis and economics.
- **Many Organizations and Actors**, including:
  - Multiple agencies of the U.S. Food and Drug Administration (FDA), U.S. Centers for Disease Control and Prevention (CDC), U.S. Department of Agriculture (USDA) and U.S. Environmental Protection Agency (EPA);

- Departments of health, agriculture and the environment and public health laboratories across the 50 states;
- Nearly 3,000 local health departments and retail inspection agencies;
- Millions of agricultural producers, hundreds of thousands of food processors, retailers and restaurants, and dozens of associations representing various segments of the food and agriculture industries;
- A wide range of government and university-based food safety researchers;
- Consumer representatives and organized victims of foodborne illness; and
- Overseas actors, including food producers, foreign regulators and international organizations.

- **Complexity of Information Needs**, for addressing both immediate problems, such as outbreak response and forward-looking analytical needs, such as microbial risk analysis.

Recent Progress

Today's understanding of food safety as a farm-to-table "system" challenge requiring science-based, preventive solutions has resulted in greatly expanded and, in some cases, more sophisticated information collection efforts by government and industry. These include:

- Improved foodborne illness surveillance and outbreak identification and reporting by CDC and state and local agencies, including increased use of electronic reporting systems, standardization of laboratory methods and ongoing efforts to improve coordination of outbreak response;
- More extensive food safety research, collection of contamination data and marshaling of other information for risk analysis by regulatory agencies;
- Rapid expansion of microbial testing and scientific validation of control measures by the food industry; and
- Increasing use of modern information technology and the Internet to compile information and make it accessible.

Constraints on Success

Despite recent progress, our analysis of the current FSII and discussions at the project workshops revealed important constraints on achieving the vision of better coordinated generation and wider dissemination and sharing of food safety information. Fundamentally, the FSII is constrained by the fact it is comprised of thousands of institutions collecting data for their own purposes, in accordance with long-established practices, and without adequate incentive to change those practices and incur the inevitable added costs.

The resulting reality of the FSII presents a number of specific constraints that should be addressed.

Lack of Mechanisms for Planning and Coordinating Information Collection

- Government food safety research is, at best, loosely coordinated and not sufficiently accountable to government regulators, policy makers and industry food safety managers.

- The management of food safety epidemiology is highly decentralized, mostly reactive to outbreaks, and not planned in close collaboration with government policy makers and industry food safety managers who can devise prevention strategies.
- Food contamination data are collected by many government agencies, food companies and researchers without coordination or concern for how the data might be aggregated or compared.

Institutional Obstacles to Information Sharing

- Government agencies generally lack a mandate and resources to collaborate on collecting or sharing information.
- Government agencies at all levels operate under legal constraints on information gathering and sharing, including privacy laws, protections against disclosing confidential business information and such federal measures as the Paperwork Reduction Act (PRA) and the Information Quality Act (IQA).
- Government agencies and others that collect information typically have a sense of ownership that can hinder information sharing.
- The food industry has competitive, liability and other business reasons to be reticent about sharing information.
- Academic publishing traditions result in large amounts of publicly funded research data not being accessible readily, or at all, to others who might find it useful.

Technical Constraints on Information Sharing

- The lack of standardized approaches to data collection—such as sampling protocols, sample collection methods and laboratory test methods—make it difficult and often impossible to compare or aggregate data from diverse sources.
- The incompatibility of diverse information systems and data formats complicates and sometimes prevents the meaningful compilation and sharing of otherwise similar data.

Recommendations

Our workshop discussions identified many specific issues and problems that stakeholders believe must be addressed to get the most value from existing food safety information and improve future information collection. We found, however, that most of the problems in the FSII are systemic in nature, meaning they are grounded in how the vast network of players in our decentralized food safety system see their roles, what their incentives are to act in particular ways and the obstacles that exist to acting differently. We believe that lasting solutions must respect and address these institutional realities and include mechanisms that facilitate diverse institutions working together in new ways.

Our recommendations thus include establishing a national FSII policy and program. This would provide both "top-down" leadership to catalyze change in the government's approach to food safety information and "bottom-up" mechanisms for devising and implementing change. We also recommend actions and initiatives that respond directly to specific concerns and opportunities for improvement that we heard in the workshops. Some of these recommendations are broad cross-cutting initiatives that directly impact many institutions in the system, while others are more sharply

focused. We emphasize that the costs of implementing any of these recommendations may be significant and that how these costs are covered over the long term is an important consideration.

Our recommendations call for a major philosophical and practical shift in the current food safety system. Any such major change to a longstanding government program is inherently difficult to achieve and sustain. Launching the recommended transformation of the FSII will thus require high-level commitment, leadership and action from the Congress and the White House to provide the needed direction and resources. The sustainability of change will depend ultimately, however, on the program's success in meeting the information needs of food safety practitioners and stakeholders, including those in government, industry, academia and the consumer community.

Finally, our recommendations address the FSII from a broad public health perspective and with particular attention to how the many actors in the U.S. food safety system can better collaborate to reduce the well-documented burden of foodborne illness in the United States. We focus largely, therefore, on institutional roles, relationships and policies affecting the collection and sharing of food safety information. We ground the report as much as possible in the substance and science of food safety, but it is beyond our scope to address, for example, the need to improve the internal data management systems of government agencies or such important technical issues as how to improve the scientific quality of the data various parties generate.

We address the international dimension of food safety to the extent our recommendations for improving information collection, access and sharing relate as much to information about imported foods as about foods produced domestically. This project has not, however, examined the important question of how U.S.-based institutions might better interact with foreign companies and governments and international organizations. That question richly deserves its own study.

FSII National Policy and Program

Leadership from the federal government is critical to achieving our vision for the FSII's role in ensuring food safety, but no federal agency is charged with providing it. We thus recommend that the federal government, via legislation or executive order, make it the duty of all federal food safety agencies, whether involved in regulation, surveillance, or research, to:

- Foster coordinated approaches to collecting food safety information among federal, state and local agencies;
- Consider the larger needs of the food safety system in planning information collection; and
- Maximize access to and active sharing of food safety information among government agencies and with the private sector.

We recommend the federal government create two mechanisms for implementing this new FSII policy: the FSII Council and the FSII Stakeholder Forum. We also recommend a series of priority actions be addressed as part of the national program, listed in Box ES.1.

FSII Council

The FSII Council would be an intergovernmental body housed in the U.S. Department of Health and Human Services (HHS) and composed of the senior food safety official from the key federal agencies, centers and offices and at least an equal number of representatives of state and local food

safety agencies. The Council should have a line item in the HHS budget with an initial authorization in the range of $25 million to fund its own base activities and catalyze initiatives to improve the FSII.

The primary responsibility of the Council would be to convene, coordinate and otherwise provide needed support to agencies in fulfilling their new responsibilities under the national FSII policy. Specific duties would include:

1. Seeking regular input on information needs from all participants in the food safety system;
2. Prioritizing, planning and coordinating implementation of actions to improve the collection and flow of food safety information;
3. Identifying any legislative or policy changes required to carry out needed actions;
4. Estimating costs and benefits associated with needed actions; and
5. Reporting annually to Congress and public regarding food safety information needs, progress in improving the FSII and key obstacles.

Box ES.1—Priority Actions of the FSII National Program

Participants in our project workshops made a number of suggestions for improving government practices related to information access. We recommend that Congress (or the president) direct the FSII Council, in consultation with the Stakeholder Forum, to consider and prioritize the following possible actions:

1. Prompt reporting and deeper access to CDC's outbreak and surveillance data, including online public access to national outbreak data collected via eFORS;
2. Treating FoodNet data as a public resource and making it promptly available and user-friendly to all interested parties in the public and private sectors, limited only by appropriate protection of patient privacy;
3. Expanding participation in eLEXNET by government laboratories, and possibly non-government laboratories as well, and, eventually, creating a means to make the information available online to the public;
4. Creating mechanisms to aggregate, analyze and share among jurisdictions the inspection, enforcement and recall information generated by federal, state and local agencies, including harmonized inspection reporting criteria and searchable online databases; state and local agencies, including harmonized inspection reporting criteria and searchable online databases;
5. Clarifying and strengthening protocols for rapid information sharing in outbreak situations among public agencies, with the food industry and the public, to ensure timely access to information needed to contain outbreaks and prevent future ones;
6. Greatly expanding the commissioning of state and local officials by FDA and other agencies to help foster information access and sharing during illness outbreaks, compliance investigations and other settings;
7. Amending or interpreting the IQA so as not to affect the release of information to other public agencies;
8. Making fully public information concerning research activities performed or funded by federal agencies, in particular USDA's Agriculture Research Information System (ARIS);
9. Standardizing and harmonizing sampling methods and laboratory procedures to enable data and results to be compared; and
10. Generally improving public Web access to publicly generated datasets.

FSII Stakeholder Forum

While the federal government has both the duty and capacity to catalyze and support improvement in the FSII, meaningful progress on most issues will not be possible without the participation of practitioners and experts from all elements of the food safety system. To facilitate this participation, an FSII Stakeholder Forum should be established under the auspices of the FSII Council.

The Forum would play a consultative role, facilitate the exchange of information and promote implementation of various programs and policies. In its consultative role, the Forum would be a principal means by which the Council would gather input on information needs and suggestions for improving the FSII. The Forum would facilitate the exchange of information by providing a setting in which members of the food safety community could identify common problems and share best practices, including advances in information technology that can facilitate data sharing.

The Forum could also serve as a mechanism for implementation of specific initiatives. For example, the Forum could facilitate dialogue and collaboration across institutional lines in efforts to standardize data collection methods.

Specific Initiatives

With or without the establishment of a new national policy and program to improve the FSII, the following are specific actions that could be taken to better meet the information needs of the food safety system. All are spelled out more fully in Section Five of the report.

1. Create a Food Safety Epidemiology User Group

In collaboration with state and local health officials, CDC should sponsor and lead the creation of a Food Safety Epidemiology User Group to ensure that publicly funded food safety epidemiology is as demand-driven as possible and of the greatest value feasible to those working to improve food safety. The User Group would include participants from throughout the food safety community, including those in government regulatory agencies, industry, academia and consumer advocacy. The User Group would work to prioritize the data and analytical needs of the food safety community and ensure data from publicly funded epidemiology are made accessible in the most timely and useful manner possible.

2. Create a "Network of Networks" to Improve the Interconnectivity of the Food Safety Web

To increase awareness of food safety information sources and overcome the "stove pipe" effect of isolated food safety databases, the food safety community should collaborate to create a "network of networks" for food safety information. Such a network would be based on a gateway Web site that would include a browseable and searchable directory of food safety databases and other information sources across the food safety system. The goal would be to support the diversity of the current FSII but improve the ability of those within the food safety community to find the information they seek.

3. Create a Database for Tracking Research and Data Collection

The federal government, acting through the proposed FSII Council and Stakeholder Forum or other suitable mechanism, should develop and maintain an online and searchable database of past and on-going food safety research and data collection and analysis activities, focused on subjects of current interest to food safety practitioners. The database should enable interested parties to find out what data are being collected across the system and what research is being performed on a particular topic of interest, whether the activity is conducted by the federal government, university researchers, or others. The database should include research and data collection and analysis activities related to particular pathogens, foods or commodities, and interventions–information practitioners could use to understand hazards and how to prevent them. The idea is not to duplicate published scientific literature, but to supplement it with up-to-date information.

4. Conduct Targeted Analyses to Identify Knowledge and Information Gaps

The federal government, through the FSII Council and Stakeholders Forum or other mechanism, should take the lead in conducting or sponsoring targeted analyses and systematic reviews of existing information to identify trends in research activities, unnecessary overlap in research and significant data gaps.

5. Initiate Dialogue to Prioritize Information Needs

Building on the research database and analyses outlined above, the federal government should drive an ongoing community and dialogue-based process to identify and prioritize the information needs of the food safety system. One approach to achieving such a dialogue would be to hold an annual research and data conference, bringing together representatives of major funding organizations together with representatives of regulatory and public health agencies, private industry, consumers and scientists from the research community. This gathering should not be a simple research update, but rather a focused and well-facilitated discussion of research and data collection required to solve current food safety problems, leading to as much agreement as possible on what needs to be done.

6. Increase Access to Information and Publications Resulting from Publicly Funded Food Safety Research

Data, analysis and other information from publicly funded food safety research, including academic research, have potential public health value. They should not be considered the proprietary resource of the researcher, but rather should be publicly available on a timely and complete basis, subject to some reasonable protection of the researcher's right to "first publication."

Achieving this will require efforts by researchers, their funders and the publishers of their work. We recommend the following:

1. The academic and government research community should use online data repositories to supplement peer-reviewed journal articles as the vehicle for publishing data from food safety research.
2. Government research grants should mandate that all peer-reviewed journal articles made possible by publicly funded research—whether generated by public officials, academic

researchers or those in the private sector–be made freely and publicly available online within a year of original publication, along with the data utilized within these publications.

3. Government and other research funders should take steps to ensure that complete data, not just articles, resulting from their investments are made available to others once the research projects are completed.
4. Journal publishers should work to ensure broader and less costly access to articles and also consider alternatives to current practices that would make research data available earlier and more broadly.

7. Increase Access to Industry-Generated Food Safety Information

The food industry should work with government and academic researchers to identify specific problems whose solutions might be advanced by access to industry-generated food safety data and other information and to find workable solutions to make such information available in an appropriate form.

Conclusion

There are no panaceas for improving the FSII. Our project workshops and other outreach to the food safety community revealed, however, both strong interest in the FSII's problems and many good ideas to help solve them. We hope the recommendations outlined here do justice to both the problem and possible solutions and help foster change that puts more and improved information in the hands of people who can use it to better ensure the safety of the American food supply.

SECTION ONE: INTRODUCTION

Background

The last twenty years have been a period of remarkable change and learning in the food safety system. The most fundamental change has been a broadening of our understanding of the food safety challenge and the approaches we must take to meet it.

For most of the 20th century, into the 1980s, the food safety system focused primarily on basic sanitation, chemical contaminants and food additives. Most industry and government participants in the system could work fairly comfortably and effectively in relative isolation. Companies could focus on the conditions in their plants and whether their raw materials and products met applicable limits for sanitary quality and chemical residues. Food safety agencies could focus on their traditional inspection and enforcement activities.

Beginning in the late 1980s, things changed. Concerns about seafood safety, followed by outbreaks of illness associated with bacteria in ground beef, poultry and produce put the spotlight on the public health problem of foodborne illness caused by microbial pathogens, which pose a completely different kind of challenge for the food safety system. Pathogens can enter at almost any point on the farm-to-table continuum; they can grow; and they can be killed. Thus, whether someone gets sick depends on a range of interconnected events and behaviors across the system, which, taken together, determine whether dangerous levels of an organism will be present at the point of consumption.

As outlined in the 1998 Institute of Medicine (IOM) report, *Ensuring Safe Food From Production to Consumption*,[1] this expanded understanding of food safety calls for action at points all across the food system—at production, processing, transport, retail sale and final consumption—where pathogens can enter food and grow or be reduced; and it makes everyone from farmers to consumers important participants in a more inter-connected food safety system. Traditional concerns about basic sanitation and chemical safety remain very important, but the premium today is on devising integrated, farm-to-table strategies for preventing foodborne illness.

1 Institute of Medicine (IOM). 1998. Ensuring Safe Food from Production to Consumption. National Academy Press: Washington, DC.

The food safety challenge has been complicated further by the rapid globalization of the food supply, with food safety in the United States being affected by events and behaviors overseas that cause chemical or microbial contamination of imported produce, seafood and other food items on which Americans rely. Recent concerns about terrorist attacks on the food supply have further complicated the food safety task and affected almost every party involved in food safety, from firms that must protect their supply chains from tampering to emergency responders at all levels of government managing outbreak situations. Preventing foodborne illness in the United States thus increasingly depends on the actions and interactions of many entities, domestic and foreign, working throughout the global food system.

Each of the many participants in today's food safety system has a distinct role to play, but they all have one thing in common: the effectiveness of what they do depends on information. Up and down the line, actors in the system depend on information about potential hazards and how to minimize them, and, in the end, every actor is only as good as the information on which they base their actions. This broader understanding of food safety permits us—indeed, requires us—to *think of the food safety system as an information system.*

And, increasingly large volumes of food safety information are being produced every day. This includes information generated by practitioners in industry and in government regulatory agencies and health departments, as they go about trying to manage today's more complex food safety problems, as well as those whose job it is to produce information for practitioners, such as those involved in foodborne illness surveillance at all levels of government and food safety researchers in government and academia.

Defining "Food Safety Information Infrastructure"

In this report, we refer to all these actors and the many public and private institutions, programs and processes through which food safety information are collected, made accessible and actively shared as the "food safety information infrastructure" (FSII). Box 1.1 contains a glossary of terms that helps explain the scope of this term and others.

Box 1.1—FSII Glossary

Food Safety Information Infrastructure: The many public and private institutions, programs and processes through which data and other information are collected, made accessible and actively shared to ensure food safety.

Food Safety Data: Collections of facts, such as numbers, that are generally the result of some measurement.

Food Safety Information: Includes food safety data as well as the broad array of compilations, analyses, reports and other information items related to food safety.

Ensure Food Safety: Includes all activities along the farm-to-table continuum that ensure food is safe for consumption.

Information Collection: Acquisition of information related to food safety, including: activities that produce primary information, such as illness surveillance or survey elicitation; activities involving the assembly or compilation of information from primary sources, such as creation of databases; and analytical activities based on primary or secondary data, such as risk assessments.

Information Access: Making food safety information available passively to the wider food safety community, such as by posting on Web sites or publishing in journals

Information Sharing: Actively sharing food safety information with others, generally for a specific purpose, such as collaboration on a research study or risk assessment or to solve a specific problem.

Our FSII glossary focuses on issues of information access and sharing, because, even with today's proliferation of information, food safety practitioners often lack ready access to the information they need to help ensure food safety. In some cases, the information does not exist, or, for lack of resources or other reasons, has not been entered into accessible databases. In others instances, the party needing information may not know where to find it, or there may be legal, policy, business, bureaucratic or technical reasons why the information is not accessible. Regardless, *any instance in which practitioners cannot obtain the information they need to do their jobs is a missed opportunity to improve food safety*.

The FSII Project and Report: Purpose and Scope

To help take advantage of opportunities to better ensure food safety, this report recommends specific improvements in the nation's food safety information infrastructure. These recommendations stem from a project funded by the Robert Wood Johnson Foundation to engage the food safety community in dialogue to identify outstanding food safety information needs and how to fulfill them by improving the FSII. The dialogue took place primarily during four workshops that brought together a broad cross section of food safety practitioners and experts from federal, state and local agencies, the food industry, academia and the consumer community (see Appendix A for workshop agendas and participants).

One of the important lessons we learned early in the project was that the FSII is far too complex—in terms of the number of institutions and interests involved and the depth and difficulty of the issues—

to address comprehensively in a single project or report. For example, government agencies operate many information systems to support their internal program management activities, such as FDA's internal systems for monitoring food imports and the internal data systems public health laboratories use to manage their programs. The protection of the food supply from intentional acts of contamination is an important post-9/11 concern. And workshop participants and individuals commenting on drafts of this report raised a number of important scientific and technical issues concerning how food safety data are collected and analyzed. All of these activities and issues are important and relate in some way to the FSII and concerns addressed in this report.

In this report, however, we have chosen to focus on how diverse actors within the U.S. food safety system can improve the collection and sharing of food safety information to prevent foodborne illness associated with unintentional food contamination. We thus have approached the many issues the current FSII raises from this broad public health perspective and with a particular interest in how the many institutions and actors in the U.S. food safety system can improve their collaboration to prevent the well-documented burden of foodborne illness our country bears every year.

For this reason, our analysis and recommendations focus to a large degree on institutional roles, relationships and policies affecting the collection and sharing of food safety information. We ground the report as much as possible in the substance and science of food safety, but it is beyond our scope to address the many important technical issues that relate to the FSII, such as ways to improve the scientific quality of the data various parties generate.

We have also chosen not to address fully the international dimension of the FSII. The globalization of the food supply and recent wave of food safety problems associated with imported foods and ingredients certainly make food safety an international problem. Our recommendations address this reality in that our proposed institutional mechanisms, policies and initiatives for improving the FSII in the United States relate as much to information about imported foods as about foods produced domestically.

This project has not, however, examined the activities of foreign governments and international food safety bodies, such as the United Nations' Codex Alimentarius Commission, that are increasingly relevant to food safety in the United States. Nor have we addressed how U.S.-based institutions might better interact with foreign companies, governments and international organizations. These international activities and issues richly deserve study but remain outside the scope of this report, primarily for practical reasons of time and resources. We also believe the United States has much to do to put its own food safety information house in order as the foundation for improving data flows internationally.

Our understanding of the FSII benefited enormously from the discussions we witnessed among workshop participants, on which the recommendations we make in Section Five of this report are largely based. We did not, however, ask the workshop participants to sign on to the recommendations and many of the recommendations reflect our own efforts to capture what we learned in the project and to convert those lessons into actionable recommendations. Thus, while we believe our recommendations are responsive to the needs and ideas of the community, it is important to reiterate that we alone are responsible for their content.

As a prelude to presenting our recommendations in Section Five, we lay out in Sections Two and Three a vision for the role information can play in a more effective food safety system and what changes are needed to bring this vision to fruition. In Section Four, we analyze constraints under which the FSII

currently operates. Like our recommendations, the vision and analysis in these sections draws heavily on the workshop discussions, supplemented by our own research and by the emerging consensus on the need for a more prevention-oriented, risk-based food safety system.

The Basis for Progress

One thing is clear: Changing the status quo on food safety information will not be easy. The FSII is an extraordinarily complex web of individuals and institutions—encompassing government, industry, academia and consumers—all of which play distinct roles in the food safety system and FSII. Their natural tendency is to focus on their individual roles, rather than the needs and challenges of the whole system. Moreover, when participants try to take advantage of the synergies that can come from improving data access and sharing, they incur added costs and often encounter legal, business and bureaucratic barriers, several of which we note in Section Three of this report.

Despite the barriers, however, there are reasons for optimism about the prospects for progress. To start, many practitioners in government and industry recognize they need more and better information to do their jobs. This stems from the broader understanding of food safety as a "systems" problem whose solution requires science-based preventive efforts, and that understanding is coupled with the realization that the information needed for such efforts must come from many sources. We see emerging demand among stakeholders for improvement in the FSII.

Second, new tools for collecting and managing information make it feasible to collect, manage and disseminate in useful forms larger amounts of valuable information than ever before. Efforts to better coordinate the collection and sharing of information are more likely than ever to yield value for improving food safety.

Finally, public policy is beginning to recognize the central role of information in implementing the modern vision of a science- and risk-based approach to food safety. The FDA Food Protection Plan and the White House Import Safety Action Plan, issued together in November 2007, both emphasize the role of information in preventing food safety problems. Policy-level awareness is crucial because many of the barriers to a better functioning FSII are the product of public policy, or could be remedied by it.

By discerning the demand for change in information practices and forging policies that respond wisely to this demand, progress to improve the FSII can be achieved. We hope our recommendations, and the dialogue with the community that led up to them, will contribute to that progress.

SECTION TWO:
INFORMATION'S ROLE IN ENSURING FOOD SAFETY

The starting point for developing recommendations to improve the FSII is a clear vision for the food safety system and the role of information in that system, as outlined in this section.

A Modern Vision for the Food Safety System

The IOM's 1998 *Ensuring Safe Food* report crystallized a vision for a modern, science- and risk-based approach to food safety that had been developing among food safety experts during the 1990s. Today, the broad outline of the IOM vision is widely embraced among experts and policymakers alike, as reflected in:

- A 2003 IOM follow-up report on scientific criteria and standards for food safety;[2]
- Numerous reports by the Government Accountability Office (GAO);[3,4,5,6]
- The Food Safety Strategic Plan issued in 2001 by the Clinton Administration's Council on Food Safety;[7]
- The Action Plan for Import Safety and the FDA Food Protection Plan announced by President Bush in November 2007;[8,9]

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2 Institute of Medicine (IOM). 2003. Scientific criteria to ensure safe food. Washington: National Academy Press; May.

3 U.S. General Accounting Office (GAO). 1997. Food Safety: Fundamental Changes Needed to Improve Food Safety. GAO/RCED-97-249R. Washington, DC. September 9.

4 U.S. General Accounting Office (GAO). 2001. Food Safety and Security—Fundamental Changes Needed to Ensure Safe Food. GAO-02-47T. Washington, DC. October 10.

5 U.S. General Accounting Office (GAO). 2004. Federal Food Safety and Security System: Fundamental Restructuring is Needed to Address Fragmentation and Overlap. GAO-04-588T. Washington, DC. March 30.

6 U.S. General Accounting Office (GAO). 2005. Oversight of Food Safety Activities: Federal Agencies Should Pursue Opportunities to Reduce Overlap and Better Leverage Resources. GAO-05-213. Washington, DC. March.

7 President's Council on Food Safety. 2001. Food Safety Strategic Plan. Washington, DC. January 19.

8 Interagency Working Group on Import Safety. November 2007. Action Plan for Import Safety: A roadmap for continual improvement. Report to the President. Washington, DC.

9 Food and Drug Administration (FDA). November 2007. Food Protection Plan: An integrated strategy for protecting the nation's food supply. U.S. Department of Health and Human Services, Washington, DC.

- The directive establishing a national policy for the defense of agriculture and food signed by President Bush in 2004;[10]
- Recent positions on food safety reform taken by the food industry;[11] and
- Reform ideas being advanced by consumer leaders.[12]

In this widely shared vision, the key functional elements of a modern, science- and risk-based approach—one that is effective in ensuring food safety—include:

- **Taking a farm-to-table approach** to preventing food safety problems;
- **Using risk analysis** to better understand potential hazards, design interventions and prioritize prevention efforts;
- **Collecting data to support risk analysis** through monitoring the food supply for potentially harmful contaminants and other hazards, foodborne illness surveillance and food safety research;
- **Harnessing the primary role of food producers, processors, retailers and consumers** in preventing food safety problems;
- **Implementing preventive process control**, such as Hazard Analysis and Critical Control Points (HACCP), through the food industry;
- **Establishing and enforcing science-based food safety standards** through government food safety agencies;
- **Integrating food safety efforts** among federal, state and local food safety agencies;
- **Expanding international collaboration** with national governments in major export countries and international food safety bodies;
- **Allocating government food safety efforts and resources in relation to risk** and opportunities to reduce risk; and
- **Observing sound food safety practices** at the final preparation and consumption stage through well-informed commercial food handlers and consumers.

In this report, we embrace these functional elements and the broader vision they embody as the basis for defining the food safety system's information needs and considering ways these needs can be better met.

Types and Sources of Needed Information

Information Types

Every functional element of a modern, science- and risk-based approach to food safety depends on information, which comes in many types and from many sources. The landscape of information utilized by participants in the food safety system is vast and complicated; to help describe it, we

10 Bush, George W. 2004. Homeland Security Presidential Directive-9: "Defense of United States Agriculture and Food." January 30. Available from: http://www.whitehouse.gov/news/releases/2004/02/20040203-2.html (last viewed 4/2/2008).

11 Grocery Manufacturers Association (GMA). September 2007. A Commitment to Consumers to Ensure the Safety of Imported Foods: Four Pillars of Public-Private Partnership. Washington, DC.

12 De Waal, C.S., and D.W. Plunkett. 2007. Building a Modern Food Safety System For FDA Regulated Foods. Center for Science in the Public Interest (CSPI) White Paper. Washington, DC.

developed a simple food safety information typology, focusing on the kinds of information generated by data collection and analysis. The typology, discussed in Section Three and described in more detail in Appendix B, includes a few dozen specific types of information grouped into eight broad categories:

1. *Human Health*, including, but not limited to, disease incidence data, the results of epidemiological investigations, clinical information on outcomes and sequelae, and information that attributes illnesses to causal pathogens and food vehicles;
2. *Measurements of Contamination*, including, but not limited to, the prevalence and levels of microbial and chemical contamination of animals, plants, foods and the environment;
3. *Indicators of Contamination*, including, but not limited to, sanitation inspection results, analytical data on fecal contamination, inspection reports, animal disposition information and recall datasets;
4. *Hazard Identification*, including, but not limited to, toxicity testing and research on detection methods for microbiological and chemical hazards, information on bacterial growth and decline in various environments, and microbial subtyping efforts;
5. *Modeling*, including, but not limited to, predictive microbiology, dose-response modeling, exposure assessments, and risk assessments for chemicals, pathogens, toxins or other naturally occurring contaminants;
6. *Trade and Industry*, including, but not limited to information on industrial practices, facility registration, product tracebacks, and estimates of intervention efficacy and costs;
7. *Consumers and Workers*, including, but not limited to, information on consumer and worker behavior with respect to food handling and preparation, consumer perceptions of risk, food consumption patterns, and demographics; and
8. *Food and Environment*, including, but not limited to information on food composition and other characteristics of food and the environment that influence food safety.

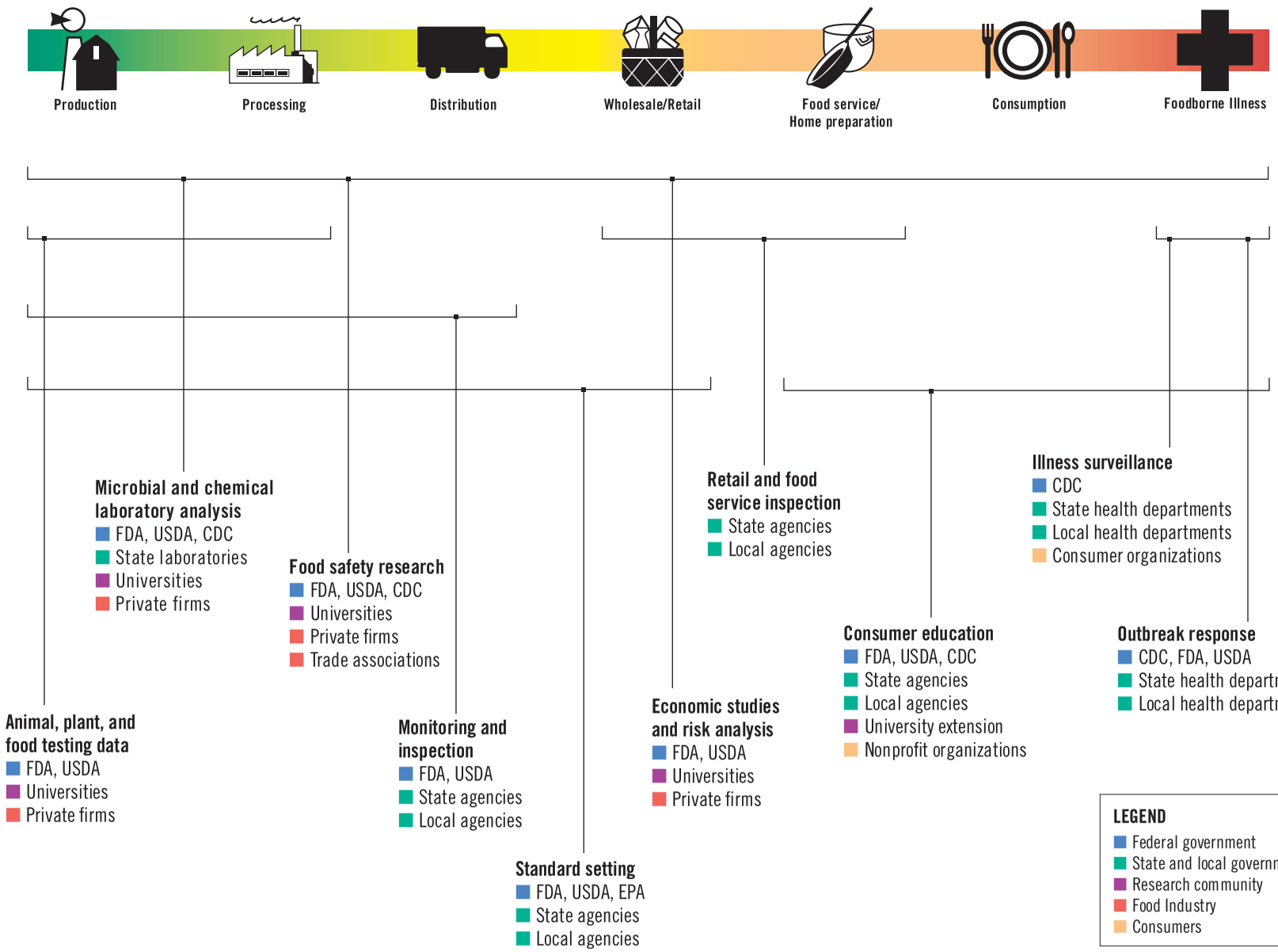
Information Sources

The modern vision of how to ensure food safety includes not only a wide range of information categories and types, but also a complex network of participants working in diverse but interdependent capacities who are constantly generating, exchanging and using information to improve food safety.

As illustrated in Figure 2.1, the participants include those involved directly in the farm-to-table food system—such as food producers, processors, retailers and consumers—whose everyday activities directly affect food safety. Most of these hands-on participants generate information in the course of their work in the food safety system, and all rely upon information generated by others.

The FSII also includes many other institutions in government, academia and the consumer and nonprofit communities that interact with the food system. Their crucial activities include providing regulatory oversight, educating consumers, conducting food safety research, responding to and investigating outbreaks, and performing laboratory analyses on food samples and isolates from animals and human cases of illness. Like those working directly in the food system, the institutions and individuals performing these roles both generate food safety information and are dependent on information generated by others.

Figure 2.1—Food Safety Institutions and Information Activities along the Farm-to-Table System



While we focus in this report on U.S.-based institutions and activities, the FSII certainly has an international dimension due to our heavy reliance on imports of seafood, produce and other components of the food supply. The resulting reality is that some of the information needed to ensure food safety in the United States is generated overseas by foreign participants in the global food system.

Role of the FSII in Ensuring Food Safety

We have outlined a vision for the food safety system and identified the wide range of information types and institutions that comprise the FSII. Now, the questions are: What aspirations do we have for how the FSII should function to support the food safety system? And, what value would a well-functioning FSII have for participants across the system? The answers to these questions are essential to framing our recommendations to improve the FSII, and we draw our answers, again, from the discussion of information needs at the four project workshops.

Aspirational Goals for the FSII

We propose five aspirational goals for how information should be collected, made accessible and shared to help fulfill the vision of a modern, science- and risk-based food safety system:

1. *Foodborne illness surveillance, outbreak investigations and other epidemiology efforts* are planned collaboratively with stakeholders to produce information that links illnesses with particular pathogens, foods and, when possible, root causes of illness outbreaks; such information is available on a timely and detailed basis to all in the food safety community who can use it to prevent problems.
2. *Public data collection on contamination* and other safety-related attributes of the food supply is planned and coordinated to produce information that both government and industry need to identify and prevent hazards; such information is made available on a timely and complete basis.
3. *Food safety research* conducted by government and academia is focused on providing tools that food safety practitioners in government and industry can use to devise and implement effective prevention strategies; research results are made available on a timely and complete basis.
4. *Data generated by food companies* on specific hazards and the effectiveness of interventions are made available to those who can use it to ensure food safety, with appropriate protection of the particular company's legitimate business interests.
5. *Data-sharing mechanisms* exist to foster broader awareness of and ready access to existing food safety information among participants across the food safety system.

In short, *the key attributes of a well-functioning FSII are, first, that it produces the right information and, second, that it provides this information on a timely basis and in a compatible form to people who can use it to help ensure food safety*. It is a system characterized by information not only being generated and used well within an organization, but also by flowing freely between organizations to enhance the overall effectiveness of the food safety system.

An FSII functioning in this ideal manner could have benefits for food safety across the entire system and major implications for how participants in the system perform. But information yields benefits

only to the extent it is used to improve food safety; thus, efforts to improve the FSII should be guided by practitioners, who know best how to enhance it through improved data collection and access.

Potential Value of an Enhanced FSII for Food System Participants

These examples illustrate how a well-functioning FSII—one that is responsive to the needs of food safety practitioners—could benefit participants all across the farm-to-table food system.

Agricultural Producers

- Producers of food animals and crops would have timely access to epidemiological and contamination data needed to understand specific hazards associated with the animal feed they use and food they produce.
- Public agencies and producers would generate and share information on animal production practices, water quality, wildlife and manure management, and other environmental risk factors to inform strategies for minimizing such risks.
- Publicly funded food safety research would be better planned and directed to produce effective on-farm preventive measures for the most significant hazards.

Processors

- HACCP managers would have access to up-to-date epidemiological and contamination data to support hazard analyses and selection of controls for their HACCP plans.
- Companies would have access to current data on the effectiveness of particular interventions and controls, as developed by government and academic researchers and other food companies.
- In outbreak situations, companies would have the information needed to support farm-to-table traceability of their products and effectively manage recalls.

Retailers

- Food safety managers in grocery stores and restaurant chains would have ready access to contamination, traceability and recall information needed to manage and ensure the safety of their supply chains.
- Information on emerging problems and patterns of violations detected through state and local retail inspection findings and other activities would be available to retail food safety managers, for use in evaluating and ensuring the safety of their own operations.
- The best, most current information on safe retail handling practices and technologies would be readily available on a timely basis and communicated effectively to commercial food handlers.

Consumers

- Education on safe handling practices would reach consumers more widely and effectively.
- Consumers would have the information they need to make informed decisions about what to feed their families, based upon knowledge about the risks associated with certain products, specific retail or service establishments, and food handling and preparation practices.
- In recall situations, consumers would have ready electronic access to recall information tailored to their communities.

- Consumers and families who experience a foodborne illness would have access to the best available information to receive proper medical care and understand the cause of their illness.

Value and Implications for Other Participants and Functions

In addition to the value an enhanced FSII would deliver to hands-on participants in the food system, it would also support other key food safety functions, such as:

Standard Setting—Public officials charged with setting regulatory standards would have the information they need to target standard setting where it can do the most good, set scientifically defensible standards that will be effective in ensuring food safety, and update them as warranted by changing conditions and new information.

Inspection and Enforcement—Federal, state and local officials would have the information they need to set inspection and enforcement priorities and deploy their resources where they can have the greatest impact in reducing foodborne illness. Inspection findings and other data generated through compliance activity would be available to inform both government and industry about emerging problems and practices to prevent them.

Research—Academic and private sector researchers working on intervention technologies and prevention strategies would have more complete and timely access to the publicly generated information needed to perform their research.

Conclusion

While the aspirational goals and potential benefits of an enhanced FSII as outlined in this section set a strategic direction that most stakeholders in the food safety system can embrace, the actual change process is a challenging one. It requires not only a vision of where we want to go, but a realistic appraisal of where we are and what has to change in order to make progress. We turn to those topics in the next section of the report.

SECTION THREE:
TODAY'S FSII—THE NEED FOR CHANGE

Introduction

At the outset of this project, we thought it would be possible to document with reasonable completeness the institutions and activities that comprise the food safety information infrastructure in the United States. We quickly realized, however, that the FSII is far too complex for that. It not only involves many different types of information, institutions and information collection activities, but is also an extraordinarily decentralized network of participants and activities.

The complexity and decentralization of the FSII are facts of life that mirror the complexity and decentralization of our federal system of government and our national economy. These basic features will not and, to a large extent, should not change. After all, hazards arise and opportunities for prevention occur in very specific settings throughout the vast food system, meaning that achieving a safe food supply will always depend on the actions of many independent participants, with each generating and seeking the information they need to play their particular role in the system. Moreover, many productive connections and collaborations have evolved over the years in the complex web of the FSII, especially among federal, state and local agencies, that help the food safety system function.

Still, we learned that the complexity and decentralization of the FSII present serious challenges for fulfilling our vision of a more effective food safety system—one that takes better advantage of information that exists or could be collected to more effectively prevent food safety problems. In fact, we find that, due to its complexity and decentralization, the FSII remains largely uncoordinated. It is, in many ways, a system of "stove pipes" in which sources of information remain isolated and disconnected from one another and insufficiently accessible to their potential users. Participants generally lack sufficient incentives and mechanisms to generate and share information in ways that improve the food safety system as a whole.

In this section, we highlight features of the FSII that create this need for change. We illustrate the challenges posed by the complexity and decentralization of the FSII, the information demands the FSII must meet, and some of the constraints under which participants in the FSII work. We also note the opportunities for progress suggested by a range of activities already underway to improve the collection and dissemination of food safety information.

Complexity of Food Safety Information

The complexity of the FSII begins with the many types of information that are required to implement a modern, science- and risk-based approach to preventing foodborne illness, as shown in the typology of food safety information shown in Table 3.1. This table focuses primarily on the kinds of information generated by data collection and analysis and is described in further detail in Appendix B. While not exhaustive, it illustrates the wide range and multidisciplinary nature of the information a modern food safety system requires.

Table 3.1—Categories and Types of Food Safety Information

Human Health	Illness Surveillance Medical/Clinical Host Factors	Attribution Health Valuation
Measurements of Contamination	Microbial Contamination Chemical Contamination	Other Contamination Contamination of Imports
Indicators of Contamination	Animal Health/Disposition Recalls and Violations	Sanitation and Inspection
Hazard Identification	Pathogen Subtyping Pathogen Biology	Food Toxicology
Modeling	Predictive Microbiology Hazard Characterization	Exposure Assessment Risk Assessments
Trade and Industry	Facilities and Processes Food Safety System Management Traceback Intervention Efficacy	Intervention Costs Economic Impacts International Trade
Consumers and Workers	Food Consumption Consumer & Worker Behavior	Risk Perception/Communication Population and Demographics
Food and Environment	Food Composition & Characteristics	Environmental Characteristics

The diversity of information types naturally means that the information comes from diverse sources, and most information types have multiple users, adding additional complexity to the FSII. For example, most health data is collected by thousands of local and state health departments across the country, with CDC providing support and compiling data on a national basis. The data is of significant value, however, to government regulators and private sector risk managers to devise effective preventive measures targeted at the most significant illnesses, food vehicles and risk factors.

Similarly, many types of data on contamination of food and the surrounding environment are collected by local, state and federal agencies, food producers and processors, and academic researchers—all of whom are also potential users of contamination data for understanding the hazards associated with particular commodities or production and processing systems, determining changes in prevalence of pathogens or chemicals over time, and assessing the effectiveness of interventions.

This same pattern occurs with all of the information categories and types listed in Table 3.1, with many kinds of information coming from many sources and being used by a range of parties for multiple purposes.

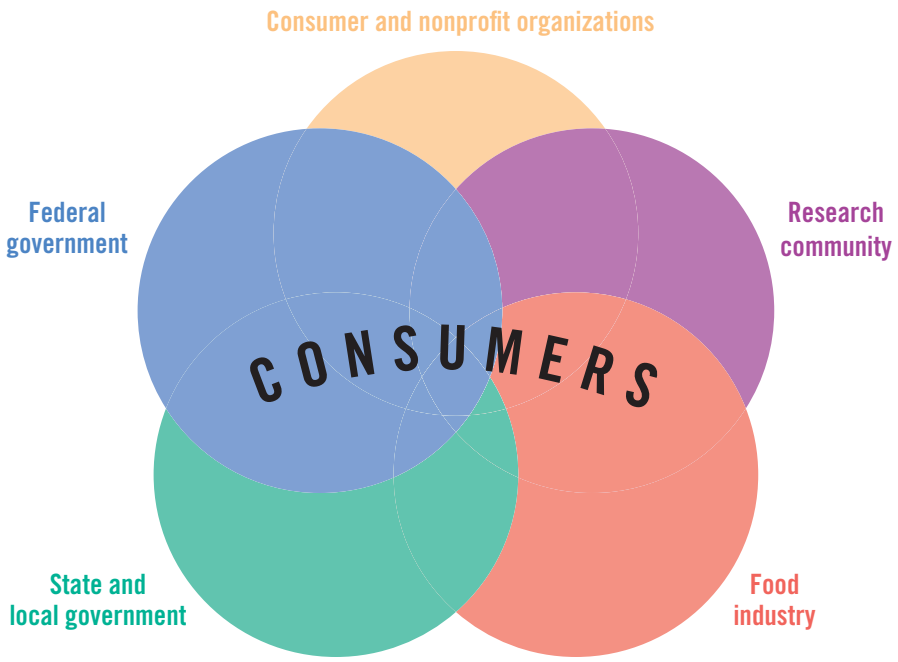
Institutional Complexity and Decentralization

Perhaps the most challenging element of complexity in the U.S. food safety system and the FSII is the number, diversity and decentralization of institutions that play important roles. This point is often illustrated by noting the many separate federal agencies that work on food safety. But the federal role is just the tip of the iceberg, as the food safety system also includes regulators and public health officials in all fifty states; nearly 3,000 local public health agencies; tens of thousands of food producers, processors and retailers; hundreds of food safety researchers and research programs in academia, government and industry; and a number of consumer and nonprofit organizations.

All of these "sectors" must be taken into account in understanding and considering how to improve the FSII, as each has its own primary orientation and focus. Government agencies at every level are responsible for protecting public health and, as shown previously in Figure 2.1, their broad range of activities include, but are not limited to, standard setting, inspection and compliance, outbreak response and illness surveillance, consumer education, risk analysis, and food safety research. Firms in the food industry, on the other hand, are focused primarily on managing the safety of their own operations and supply chains, and on obtaining the information needed to do so. Academic researchers seek to improve food safety by advancing knowledge in basic science, as well as through applied research intended to respond to the needs of government, industry and the public. Nonprofit organizations advocate for the interests of consumers and play an important role in educational outreach.

As illustrated by Figure 3.1, despite such important differences, these sectors have overlapping roles and responsibilities and are dependent on one another. Each sector relies upon the others for infor-

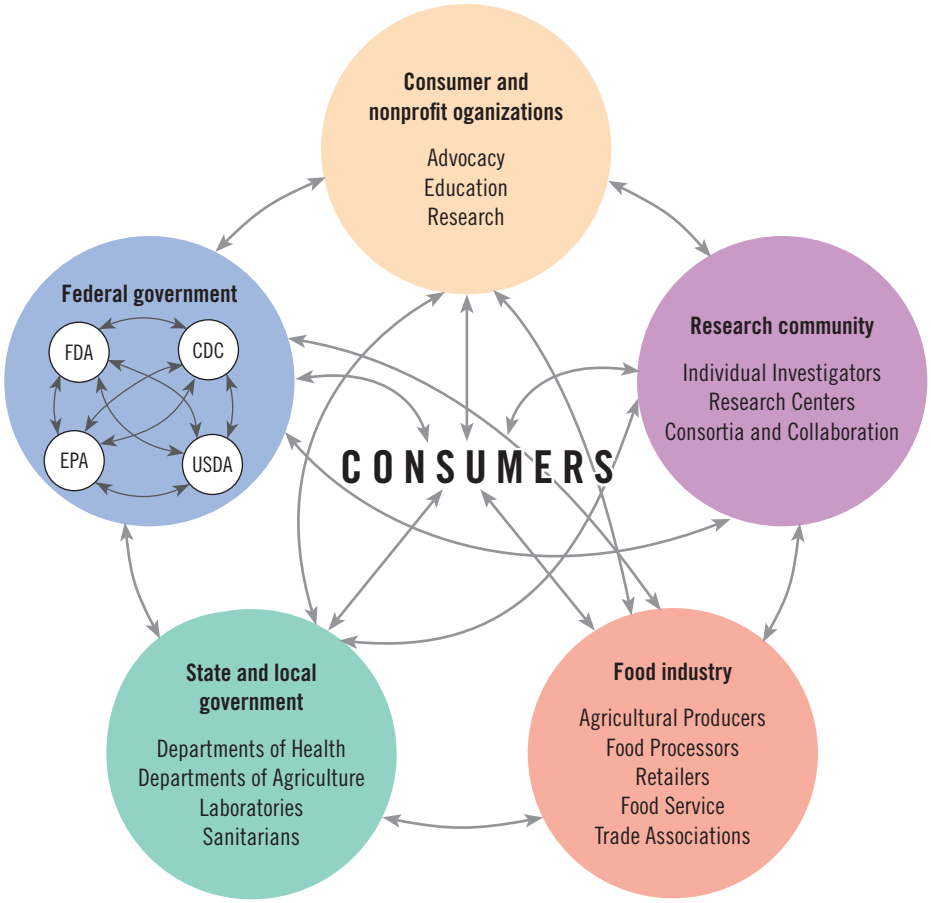
Figure 3.1—Overlapping and Interdependent Sectors of the FSII



mation it cannot or does not collect on its own, and many food safety problems require collaboration between institutions from multiple sectors in order to solve them. All of us are, as consumers, the beneficiaries of food safety efforts by these many institutions, but we are also the direct recipients of information collected by these sectors, including educational materials on proper food handling practices, inspection scores for local restaurants or news about a recent outbreak.

Such a broad brush description of the FSII does not adequately convey its complexities or interactions. For that, it is necessary to break these sectors down and examine them in more depth. For example, the federal government includes four primary food safety agencies: FDA, USDA's Food Safety Inspection Service (FSIS), EPA, and CDC.[13] State and local governments also perform their food safety functions

Figure 3.2—Major Institutions and Information Flows of the FSII



13 These are not the only federal agencies involved in food safety. For example, the Department of Homeland Security (DHS) coordinates the efforts of the core food safety agencies on intentional contamination resulting from food bioterrorism and, through its Customs and Border Protection Service, collaborates with FDA and USDA on oversight of food imports. The National Oceanic and Atmospheric Administration (NOAA) operates a voluntary seafood inspection program to strengthen market confidence in seafood safety. The Department of Defense (DOD) even has a food safety research program and other programs in place to ensure the safety of food for the military.

through multiple institutions including public health and agriculture departments, public health laboratories and sanitarians, who may be housed in environmental departments.

The food industry includes firms along the entire farm-to-table system, including agricultural producers of food crops and livestock, food processors and packers, distribution networks, retailers, wholesalers, and the food service industry (restaurants and caterers). Individual firms differ in size and complexity, from small family owned businesses to international corporations. This sector also includes the trade associations that represent the industry and often generate and serve as conduits for food safety information.

Academia includes individuals at universities and other research institutions, larger research programs at these institutions, and consortia or collaborations among individuals and universities. Consumer and nonprofit organizations are primarily represented by those who advocate for consumers or victims of foodborne illness, those who primarily serve consumers through educational outreach, and those who seek to improve food safety through research.

Though institutions operate primarily in their own spheres or sectors, they also interact with each other to varying degrees as the flow of information among them is critical to their relationships and the success of their missions. The simplified diagram in Figure 3.2 illustrates the major types of institutions in each of these sectors and suggests, by way of arrows, that information is shared among sectors, as well as between institutions within the same sector.

Of course, this diagram only hints at the institutional complexity of the FSII, its decentralization, and the extent of necessary interactions among its participants. The following highlights of key institutions help complete the picture.

Federal Government

The responsibility for national leadership on food safety is divided among the FDA, USDA, EPA and CDC. Within the FDA, USDA and EPA, there are multiple centers, offices and agencies with significant and distinct food safety responsibilities and roles in generating and using food safety information. Web site contact information for the major federal agencies, centers and offices can be found in Box 3.1 on page 35.

Food and Drug Administration

FDA has by far the broadest and most diverse food safety jurisdiction of any entity in the national food safety system and its information needs and data collection activities reflect this breadth and diversity. FDA is the one agency that has farm-to-table regulatory authority and responsibility for the foods and food safety hazards it regulates domestically, and which oversees the enormous volume of imported seafood, produce, food ingredients, and other imported food products on which Americans rely. FDA's total food-related budget, to oversee not only the safety but also the proper labeling of 80 percent of the U.S. food supply, is about $550 million.

FDA's central 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, or the safety of food as affected by potentially hazardous chemicals or microorganisms. FDA also provides pre-market oversight of most substances that are added to food intentionally or knowingly—such as food and color additives, nutrient formulations in infant formula, and animal

drug residues—through programs requiring sponsors to provide FDA much of the information it needs to perform its pre-market review.

FDA's most pressing food safety challenges today, however, involve unintentional hazards for which there are no sponsors to generate or provide the information needed to ensure food safety. These include chemicals like dioxins, mercury and lead, and microorganisms like *Listeria*, *Salmonella*, and *E. coli* O157:H7. The burden thus rests on FDA to obtain the information needed to develop and set appropriate standards, whether for preventive controls during processing or limits on contamination of the food itself, and to enforce those standards based on deployment of scarce resources for inspection and compliance activities.

As shown in Figure 3.3, FDA performs its food safety functions, including the gathering of information needed to do its job, through five major components:

- **Office of the Commissioner—**The Associate Commissioner for Foods advises the FDA Commissioner on food safety policy and strategy and is responsible, on behalf of the Commissioner, for coordinating agency-wide implementation of FDA's 2007 Food Protection Plan and FDA's role in the government-wide Action Plan for Import Safety.
- **Center for Food Safety and Applied Nutrition (CFSAN)—**CFSAN is typically considered the "lead" food safety unit of FDA. CFSAN is responsible for developing FDA initiatives to reduce the risk of foodborne illness, including standard setting and compliance strategies for domestically produced and imported products. CFSAN also has food defense responsibilities and manages most of FDA's pre-market approval programs for substances added purposefully to food.

  In these far-reaching capacities, CFSAN must generate or otherwise acquire food safety information of essentially every kind presented in Table 3.1. Since CFSAN has limited internal research capacity and little funding for external research, it depends on other FDA units, federal agencies and academia to generate much of the data needed to identify, assess and prevent hazards.
- **Center for Veterinary Medicine (CVM)—**CVM regulates pet food and its ingredients, as well as animal drugs, feed and feed additives, all of which can affect the safety of meat, milk and eggs. CVM is similar to CFSAN in that it is responsible for setting policy and mounting initiatives in its area of jurisdiction. Much of its work is done through pre-market approval systems for animal drugs and feed additives, but like CFSAN, CVM also must generate data on its own or look to sources other than industry sponsors for the wide range of information needed to make risk assessments and set policies.
- **Office of Regulatory Affairs (ORA)—**ORA functions primarily as the enforcement arm of FDA through a nationwide field force of investigators, compliance officers and laboratories. In this capacity, ORA's routine field activities include inspections through which observations of industry practices are made and food samples are collected for compliance testing, both on a "for cause" basis and through targeted "compliance programs" designed by CFSAN and ORA. It also generates information not related to enforcement that CFSAN and CVM require to set priorities and mount prevention efforts. These include surveys such as those underlying the CFSAN Total Diet Study and the CFSAN Pesticide Program Residue Monitoring Database. ORA, in partnership with USDA/FSIS, manages the Food Emergency Response Network (FERN), which integrates food testing laboratories at the federal, state and local level to respond to intentional or inadvertent food contamination events.

  ORA is not accountable to CFSAN or CVM, but reports directly to the Commissioner of FDA, so CFSAN and CVM can request but cannot require that their information needs and priorities be

Figure 3.3—Primary Food Safety Agencies and Roles within FDA

Office of the Commissioner

Associate Commissioner for Foods

CFSAN	CVM	ORA	NCTR
Primary FDA food safety agency	Pet food and ingredients	Enforcement	Toxicological research
Standard setting	Animal feed and drugs	Inspection	Animal toxicity
Compliance strategies	Standard setting	Facility registration	Detection methods
Food defense	Pre-market approval	Compliance testing	Risk assessment
Pre-market approval	Internal research	Laboratory management	
Risk assessment	NARMS	Laboratory data systems (FERN, eLEXNET)	
Food recalls		Total Diet Study	
Model food code		Pesticide Residue Monitoring	
Consumer education			

met. Due to the competing priorities of field managers, including many demands outside of food safety (such as inspection needs for drugs and medical devices), it is a constant challenge for ORA to gather the data needed by CFSAN and CVM.

- **National Center for Toxicological Research (NCTR)**—NCTR, based in Jefferson, Arkansas, is a world-class toxicological research facility supporting the FDA food safety mission by conducting major animal toxicity studies and developing new methods for detecting and assessing the risks of foodborne hazards. NCTR reports to a deputy commissioner in the Office of the Commissioner and is responsible for responding to the research needs of all the FDA centers, which creates some of the same challenges of competing priorities that CFSAN and CVM face in their work with ORA.

U.S. Department of Agriculture

The primary function of the USDA is to manage programs supporting the nation's farmers, agricultural economy and rural development, including stewardship of the national forest system. USDA is also a major purchaser of food for the government's National School Lunch Program and, as shown in Figure 3.4, houses at least eight agencies with food safety responsibilities.

The Food Safety and Inspection Service (FSIS) is by far the largest food safety unit within USDA, with an annual budget of about $1 billion. FSIS has the very specific, statutorily-defined food safety mission to ensure the safety of meat, poultry and processed egg products, primarily through inspection and regulatory oversight over the nation's more than 6,000 meat and poultry slaughter and processing establishments.[14] FSIS is mandated to visually examine every carcass passing through slaughter plants and to inspect all processing plants daily. Unlike FDA, FSIS has no jurisdiction of farms, and it generally defers to FDA and the states to oversee food safety at retail.

14 This authority is provided by the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. Full text can be found at: http://www.fsis.usda.gov/regulations_&_policies/Federal_Meat_Inspection_Act/index.asp (last viewed 3/28/2008)

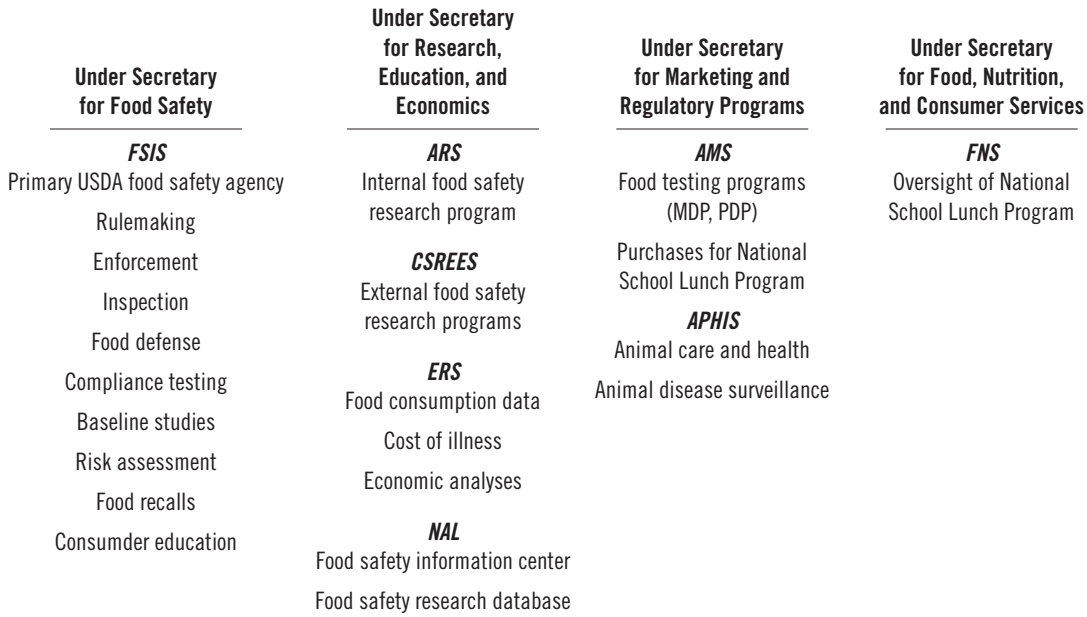
Most of the information FSIS generates and uses relate to its in-plant inspection program. FSIS performs baseline surveys to determine national incidence rates of pathogens in specific products, regularly samples carcasses and raw ground product for particular pathogens (e.g., *Salmonella*, *Campylobacter, E. coli* O157:H7), and tests ready-to-eat products for foodborne pathogens (e.g., *Salmonella, E. coli* O157:H7, *Listeria monocytogenes)*. FSIS has also generated significant information in the form of quantitative microbial risk assessments and other analyses used to support rulemaking and priority setting.

While FSIS collects data, it is not authorized to conduct food safety research (such as to learn about the behavior of particular pathogens or develop new intervention technologies) and relies on USDA's Agricultural Research Service for that information. FSIS relies on other agencies for a host of other information gathering it needs as well, such as the Animal and Plant Health Inspection Service (APHIS) for current information on animal disease. FSIS works with EPA and FDA to test meat and poultry products for pesticides, animal drugs and chemical contaminants. FSIS participates in and relies upon CDC-managed surveillance systems in order to better detect illnesses, manage recalls and understand attribution. FSIS also utilizes information from academic research, consumers, industry and other parties in the food safety system.

The other USDA agencies involved in food safety include:

- **Animal and Plant Health Inspection Service (APHIS)—**Though lacking food safety jurisdiction, APHIS regulates animal care programs and generates data on animal health which FSIS, FDA and industry can use to improve human food safety. Such programs include the National Animal Health Surveillance System (NAHSS) and the National Animal Health Monitoring System (NAHMS).
- **Agricultural Research Service (ARS)—**ARS is an in-house USDA research organization that has a larger food safety research budget than any other federal agency and is charged with meeting the research needs of FSIS, FDA and the private sector.
- **Cooperative State Research, Education and Extension Service (CSREES)—**CSREES provides funding primarily to land-grant universities for research, education and extension activities related to food safety, virtually all of which involve generating and/or disseminating information on food safety hazards and means to minimize them.
- **Food and Nutrition Service (FNS)—**FNS provides oversight of the National School Lunch Program, including related food safety efforts.
- **Economic Research Service (ERS)—**The ERS food safety program is an important source of information on the economic costs of foodborne illness, the costs and benefits of efforts to reduce the risk of illness, and economic aspects of the food and agriculture sectors of the economy that affect food safety, including prospects for innovation to improve food safety.
- **Agricultural Marketing Service (AMS)—**As purchaser of foods for the National School Lunch Program and other federal feeding programs, AMS has established safety-related quality specifications for such commodities as ground beef. In collaboration with FSIS, FDA, CDC and state agencies, AMS manages the Microbiological Data Program (MDP) and the Pesticide Data Program (PDP), both of which generate important food safety information.
- **National Agricultural Library (NAL)—**Based in ARS, the NAL houses the Food Safety Research Information Office (FSRIO), established by Congress in 1997 to serve as a repository of food safety information, resources and databases.

Figure 3.4—Primary Food Safety Agencies and Roles within USDA



Environmental Protection Agency

EPA's primary role in food safety is to regulate the safety of pesticide residues in food, but, like FDA and USDA, multiple EPA offices are involved in matters related to food safety and generate and/or use food safety information:

- **Office of Prevention, Pesticides, and Toxic Substances (OPPTS)**—OPPTS establishes legal limits (or "tolerances") on the amount of particular pesticides permitted to be present in food and, in that capacity, makes more decisions related to the safety of chemicals in food than FDA or any other federal agency.
- **Office of Water (OW)—**OW sets standards to ensure the safety of water used for drinking and in food processing, and bases some of its water pollution standards (such as for mercury) on risks associated with the pollutant in fish. OW is also responsible for developing standards for reclaimed water, which relate to its use for irrigation. Similarly, EPA's **Office of Air and Radiation (OAR)** bases its evaluations of air pollutants such as mercury and dioxins in part on food safety risks.
- **Office of Research and Development (ORD)**—ORD sets testing priorities and conducts risk assessments related to assuring the safety of pesticides in food, and performs microbial risk assessments on waterborne pathogens.

Centers for Disease Control and Prevention

CDC's primary role in the food safety system involves the generation, compilation and analysis of information on the incidence of human illness associated with foodborne pathogens—information of critical importance to all participants in the food safety system. CDC works with state and local

health officials and food safety regulatory agencies on large outbreak investigations and manages at least 20 national or regional surveillance systems that target one or more foodborne pathogens.[15] This large number of systems relates to the structure of organizational responsibilities within CDC, but also reflects the generally fragmented nature of surveillance activities and information. CDC's food safety-related work is distributed across several organizations within CDC, but most of it is coordinated through the Food Safety Office of the National Center for Zoonotic, Vector-Borne, and Enteric Diseases (NCZVED) within CDC's new Coordinating Center for Infectious Disease (CCID).

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: the Foodborne Diseases Active Surveillance Network (FoodNet), PulseNet and OutbreakNet.

- **FoodNet—**FoodNet is an active surveillance system for foodborne illness that CDC manages in collaboration with FDA, FSIS and ten sentinel sites located across the country.[16,17] In addition to providing more accurate and complete information on disease burdens and trends, FoodNet performs case-control studies and focused follow-up surveys to better understand risk factors for illness and to attribute illnesses to foods.
- **PulseNet**—PulseNet is a national network of federal, state and local laboratories coordinated by CDC that uses PFGE (pulsed-field gel electrophoresis) molecular fingerprinting and a shared database to promptly recognize and help contain outbreaks of foodborne illness.[18]
- **OutbreakNet and the Electronic Foodborne Outbreak Reporting System (eFORS)—**OutbreakNet refers to the human network of public health epidemiologists at all levels of government who investigate outbreaks of foodborne illness. Data from each outbreak are submitted to CDC by state and local health officials using the Electronic Foodborne Outbreak Reporting System (eFORS). CDC manages the compilation of national data based upon these reported outbreaks.[19]

CDC manages a number of other programs more broadly related to public health but also relevant for food safety. They include, among others:

- The Toxic Exposure Surveillance System (TESS), run by CDC's National Center for Environmental Health (NCEH), collects important data related to exposure to pesticides through food and other sources.[20]

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15 CDC's 20 surveillance systems include: Botulism Surveillance System, CaliciNet, Creutzfeldt-Jakob Disease Surveillance System, the Epidemic Information Exchange (Epi-X), the *Escherichia coli* (*E. coli*) O157:H7 Outbreak Surveillance System, the Foodborne Disease Outbreak Surveillance System, FoodNet, the National Antimicrobial Resistance Monitoring System for Enteric Bacteria, the National Giardiasis Surveillance System, the National Notifiable Diseases Surveillance System, the National *Salmonella* Surveillance System, the National *Shigella* Surveillance System, PulseNet, the *Salmonella* Enteritidis Outbreak Surveillance System, the Sentinel Counties Study of Viral Hepatitis, the Surveillance Outbreak Detection Algorithm, the Trichinellosis (Trichinosis) Surveillance System, the Typhoid Fever Surveillance System, the *Vibrio* Surveillance System and the Viral Hepatitis Surveillance Program.

16 The FoodNet sites coincide with CDC Emerging Infections Program (EIP) covering parts of California and Colorado, Connecticut, Georgia, Maryland, Minnesota, New Mexico, New York, Oregon and Tennessee.

17 http://www.cdc.gov/foodnet/index.htm (last viewed 12/27/07) FoodNet documents cases of foodborne illness caused by *Campylobacter, Cryptosporidium, Cyclospora*, Shiga toxin-producing *E.Coli* (STEC) including *E. coli* 0157, *Listeria, Salmonella, Shigella, Vibrio* and *Yersinia*.

18 http://www.cdc.gov/pulsenet/ (last viewed 12/29/07)

19 http://www.cdc.gov/foodborneoutbreaks/outbreak_data.htm (last viewed 1/18/2008)

20 Watson WA, Litovitz TL, Belson MG, Funk Wolkin AB, Patel M, et al. 2005. "The Toxic Exposure Surveillance System (TESS): Risk assessment and real-time toxicovigilance across United States poison centers." *Toxicology and Applied Pharmacology* 207(2:S1): 604-610.

- The National Center for Health Statistics (NCHS) runs a number of programs intended to monitor the health of Americans. One important program is NHANES (National Health and Nutrition Examination Survey), which gathers the data behind the What We Eat in America (WWEIA) dietary intake survey.[21] This data provides the basis for food consumption utilized in risk assessments by FSIS, FDA and others.
- The Laboratory Response Network (LRN) coordinates local, state, federal, military and international laboratories to respond to bioterrorism, chemical terrorism and other public health emergencies.[22]
- The Public Health Information Network (PHIN) is an initiative to improve public health information system interoperability by establishing best practices, promoting standards, defining functional requirements and developing technical specifications.[23]

Box 3.1—Federal Food Safety Agency Websites

Food and Drug Administration:	http://www.fda.gov
CFSAN	http://www.cfsan.fda.gov
CVM	http://www.fda.gov/cvm/default.html
ORA	http://www.fda.gov/ora
NCTR	http://www.fda.gov/nctr
U.S. Department of Agriculture	http://www.usda.gov
FSIS	http://www.fsis.usda.gov
APHIS	http://www.aphis.usda.gov
ARS	http://www.ars.usda.gov
CSREES	http://www.csrees.usda.gov
ERS	http://www.ers.usda.gov
AMS	http://www.ams.usda.gov
NAL	http://www.nal.usda.gov
Environmental Protection Agency	http://www.epa.gov
OPPTS	http://www.epa.gov/oppts
OW	http://www.epa.gov/ow
ORD	http://www.epa.gov/ord/index.htm
Centers for Disease Control and Prevention	http://www.cdc.gov
NCZVED	http://www.cdc.gov/nczved
FoodNet	http://www.cdc.gov/foodnet
PulseNet	http://www.cdc.gov/pulsenet
Outbreak	http://www.cdc.gov/foodborneoutbreaks

21 http://www.cdc.gov/nchs/about/major/nhanes/faqs.htm (last viewed 3/29/2008)

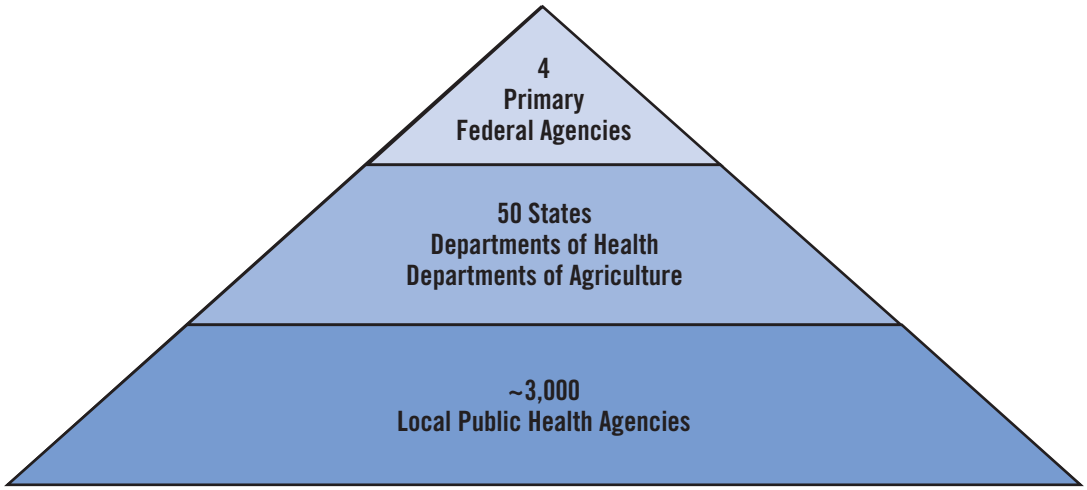
22 http://www.bt.cdc.gov/lrn/ (last viewed 3/28/2008)

23 http://www.cdc.gov/phin/ (last viewed 3/27/2008)

State and Local Government

As plentiful and important as they are, the federal food safety agencies sit at the top of a much larger pyramid of state and local agencies working on food safety (see Figure 3.5).[24] At the local level alone, there are over 3,000 public health agencies, plus state-level departments of health and agriculture (and other agencies) in all 50 states, working on the frontline of government food safety oversight.

Figure 3.5—Local, State and Federal Food Safety Responsibilities



It is difficult to generalize about the institutional arrangements through which state and local governments do their food safety work. At the state level, food safety regulatory functions, including setting of policies and enforcement from the farm through retail, may be carried out by departments of health, agriculture, environment, business regulation or some combination of these. States may lead or partner with local health departments in illness surveillance and outbreak response. In addition, state public health and agricultural laboratories play critical roles in testing both clinical and food specimens for food safety purposes.

At the local level, public health departments normally carry out restaurant inspections and other local food safety activities, though sanitarians and inspectors may also work out of departments of environment or environmental health. In some states, local health departments work independently, while in others they work under the authority of the state or under a mixed system of state and local control.

State Agencies

State-level agencies perform a wide range of food safety functions addressing both prevention and response to food safety problems. All of these functions involve in various ways the generation and/or transfer of food safety information, including:

24 NACCHO (National Association of City and County Health Officials). 2006. 2005 National Profile of Local Health Departments. Washington, DC. Available from: http://www.naccho.org/topics/infrastructure/2005Profile.cfm (last viewed 3/29/2008).

- Lead responsibility, in collaboration with local health departments and sometimes CDC, of many major outbreak investigations.
- Frontline responsibility for ongoing foodborne illness surveillance, working both independently and in collaboration with CDC and localities on FoodNet, PulseNet, OutbreakNet and other surveillance initiatives.
- The great majority of all food-related laboratory testing, including testing for pathogens in clinical isolates and chemical and microbial contaminants in food.
- More than 80 percent of all non-retail food establishment inspections, other than in meat and poultry establishments, including the majority of "FDA inspections" conducted by state agencies under contract with FDA.
- Farm inspections of animal health and other conditions related to food safety, including primary jurisdiction for enforcement of federal pesticide use restrictions, which relate directly to the possibility of unsafe residues in food.
- Food safety education for consumers and commercial participants in the food safety system.

Local Agencies

The thousands of local health departments and food inspection agencies across the country tend to focus their regulatory functions on retail establishments, but also perform a range of food safety functions, including:

- First responders and lead investigators on local outbreaks and active involvement with state and federal agencies on larger, multi-jurisdictional outbreaks.
- Frontline responsibility for reporting foodborne diseases and other local activities essential to ongoing foodborne illness surveillance.
- Food safety laboratory functions in some jurisdictions.
- Licensing and virtually all inspections of grocery stores and restaurants to ensure good sanitation and other food safety standards are observed.
- Frontline source of food safety information and education for consumers, retailers and food service establishments.

Put simply, state and local agencies are the foundation of the nation's food safety system, and meeting the information needs of the thousands of these health professionals working on food safety should be a primary goal of efforts to improve the FSII.

To further illustrate the diversity and complexity of activity at the state and local levels, we provide in Box 3.2 a list of some of the major professional organizations that represent state and local officials. These organizations are also, in their own right, parts of the FSII. In addition to representing state agencies and officials at the national level, they provide the means for communication and data sharing among states, localities and the federal government. They also gather data on state and local activities, provide leadership on issues of data harmonization and standardization, and provide food safety information and training for their members. These organizations hold annual meetings, large conferences and small workshops that play a key role in information sharing between members. Many organizations also represent or engage individuals from other sectors of the food safety system, including academic researchers and industry.

Box 3.2—Major Public Sector Professional Organizations in Food Safety

American Public Health Association (APHA)	http://www.apha.org
Association of Food and Drug Officials (AFDO)	http://www.afdo.org
Association of Public Health Laboratories (APHL)	http://www.aphl.org
Association of State and Territorial Health Officials (ASTHO)	http://www.astho.org
Conference for Food Protection (CFP)	http://www.foodprotect.org
Council of State and Territorial Epidemiologists (CSTE)	http://www.cste.org
International Association for Food Protection (IAFP)	http://www.foodprotection.org
National Association of County & City Health Officials (NACCHO)	http://www.naccho.org
National Association of State Departments of Agriculture (NASDA)	http://www.nasda.org
National Environmental Health Association (NEHA)	http://www.neha.org

Industry

The U.S. food industry is an enormously complex, $1.1 trillion economic activity encompassing 2.1 million farms, 25,000 food and beverage processors, 33,000 wholesalers, 113,000 food and beverage retailers, and 378,000 restaurants or other food service establishments.[25] In addition, some 200,000 foreign food establishments have registered with FDA as potential exporters to the United States. Each of these actors has a role to play in food safety and therefore they are all, to widely varying degrees, part of the FSII as users and, in some cases, generators of food safety information.

Agricultural producers and public health officials alike are increasingly aware of the role on-farm practices can play in both creating and minimizing food safety risks and, therefore, are increasingly seeking information to understand and prevent food safety problems that arise in particular crops or animal production settings.

Food processors, especially those implementing HACCP, have long been in need of information to identify the particular hazards that may arise in their operations and to identify, validate and monitor controls to minimize those hazards. Processors depend on a wide range of sources for this information, from CDC, FDA and FSIS to the scientific literature. In some areas, such as meat and poultry processing, companies have also become significant generators of data, as they conduct their own microbial and chemical testing of raw materials, in-process materials and finished products, and as they verify and validate the effectiveness of their food safety interventions.

25 Economic Research Service (ERS). 2007. U.S. Food Marketing System: Recent Developments, 1997-2006. United States Department of Agriculture, ERS Report 42. Page 2. Available at http://www.ers.usda.gov/publications/err42/err42.pdf (last viewed 1/29/2008)

Box 3.3—Major Trade Associations and Private-Sector Organizations

American Egg Board	http://www.aeb.org
American Meat Institute	http://www.meatami.com
Association of Food Industries	http://afi.mytradeassociation.org
Beef Industry Food Safety Council	http://www.bifsco.org
Food Marketing Institute	http://www.fmi.org
Grocery Manufacturers Association	http://www.gmabrands.com
International Dairy Foods Association	http://www.idfa.org
International Dairy-Deli-Bakery Association	http://www.iddba.org
National Association of Wholesaler-Distributors	http://www.naw.org
National Cattlemen's Beef Association	http://www.beef.org
National Chicken Council	http://www.nationalchickencouncil.com
National Fisheries Institute	http://www.aboutseafood.com
National Meat Association	http://nmaonline.org
National Pork Board	http://www.pork.org
National Pork Producers Council	http://www.nppc.org
National Restaurant Association	http://www.restaurant.org
National Turkey Federation	http://www.eatturkey.com
Produce Marketing Association	http://www.pma.com
United Fresh Produce Association	http://www.unitedfresh.org
U.S. Poultry and Egg Association	http://www.poultryegg.org

At the retail level, many companies that operate chains of grocery stores or restaurants actively manage their supply chains to ensure the safety of the food they purchase. This requires access to information on potential hazards. Companies and their suppliers generate information to verify that applicable safety-related purchase specifications are being met.

The industry's food safety information needs and practices are as diverse as the industry itself. They vary based on the foods and commodities involved (such as raw lettuce, ground beef, frozen pizza, peanut butter, cereal and ice cream), as well as the sector of the farm-to-table food continuum (including growers, animal producers, slaughter operations, value-added food processors, truckers, grocery stores and restaurants). In addition, the major regulatory differences across both of these dimensions create different information needs, and the wide range of firm sizes and resources for food safety results in differing capacities to meet those needs.

This diversity is suggested to some extent by the simple listing in Box 3.3 of some of the many trade associations and other organizations serving the food industry. Some of these organizations play important roles in disseminating food safety information among their members through publications, conferences, training sessions and other means. Each of their Web sites is a source of information on sector-specific food safety issues.

Research Community

The food safety research community includes all federal and some state agencies, the food industry and academia. For purposes of this discussion, we must distinguish research from simple data col-

lection. While the latter includes efforts such as compiling databases on incidence and levels of contamination of specific chemicals or pathogens in foods, food safety research includes efforts to build a broader understanding of the nature and origin of potential hazards and how to prevent them.

As discussed earlier, the federal government conducts or sponsors food safety research through CDC, FDA, ARS and CSREES, among other agencies. Though it does not maintain an explicit food safety research agenda, the National Institutes of Health (NIH) funds a great deal of basic research relevant to food safety, as well as research on dietary supplements, nanotechnology and other food-related concerns. In the food industry, some companies conduct or sponsor research of their own and some trade associations pool their member companies' resources to conduct research on issues of concern to a particular sector.

The academic research community is another important part of the picture. There are hundreds of public and private universities with research programs on or related to food safety, including at least one land-grant university in each state that manages a cooperative extension program that may, itself, have offices or laboratories spread throughout the state.[26]

Food safety research is not only diverse institutionally, it is also truly multidisciplinary. It encompasses chemistry, microbiology, pathology, toxicology, genetics and other natural and medical sciences, food science, engineering, agriculture, epidemiology and public health, statistics, computer science, decision and risk analysis, law, economics and other social sciences. Because academic institutions are usually organized by discipline, a single university may have researchers working on separate food safety projects in a number of departments, schools or colleges.

This tendency toward fragmentation of food safety research in the academic community results in significant information stove piping, which can result in barriers to interdisciplinary research and food safety problem solving. For example, properly addressing produce safety requires input from food scientists, plant physiologists, plant pathologists, agronomists, wildlife specialists, environmental engineers and many others with relevant expertise.

This fragmentation is compounded by the range and number of funding vehicles for food safety research. As mentioned previously, CSREES maintains a number of competitive grant programs in or related to food safety, and NIH supports basic research related to it. The National Toxicology Program (NTP), an interagency program within HHS that is comprised of key components of NIH, CDC and FDA, is a major funding source for toxicology studies. FDA, FSIS and state and local agencies occasionally fund applied projects extramurally, as do firms and the research arms of trade associations. Academic researchers increasingly set their research agendas in accordance with an individualized "follow the money" strategy and thus the diversity of research funders, each with its own agenda, fosters a system of food safety research in which many players act independently from one another.

There are a number of scientific and professional associations and societies that serve the research communities and play an important role in information sharing. Many of these associations hold annual conferences with scientific presentations, panels and poster sessions that serve as a primary vehicle for researchers to share their research findings with colleagues. Many publish scientific journals as well. For example, the International Association for Food Protection (IAFP) is comprised of over 3,000 members from 50 countries, publishes the Journal of Food Protection and Food Protection Trends, and holds an annual education conference and topical symposia. Many of these associations

26 http://www.csrees.usda.gov/qlinks/partners/state_partners.html (last viewed 1/28/2008)

are focused on a specific scientific discipline; food safety is but one component of a broader agenda. Some major associations and societies are listed in Box 3.4.

Box 3.4—Some Scientific Societies and Professional Associations in Food Safety

American Chemical Society (ACS)	http://www.acs.org
American Dietetic Association (ADA)	http://www.eatright.org
American Society for Clinical Pathology (ASCP)	http://www.ascp.org
American Society for Microbiology (ASM)	http://www.asm.org
American Association of Food Hygiene Veterinarians	http://www.avma.org/aafhv
Infectious Diseases Society of America (IDSA)	http://www.idsociety.org
International Food Information Council Foundation (IFIC)	http://www.ific.org
International Life Sciences Institute (ILSI)	http://www.ilsina.org
Institute of Food Technologists (IFT)	http://www.ift.org
International Association for Food Protection (IAFP)	http://www.foodprotection.org
Society for Epidemiologic Research (SER)	http://www.epiresearch.org
Society for Risk Analysis (SRA)	http://www.sra.org
Society of Toxicology (SOT)	http://www.toxicology.org

Consumers

Consumers play an important role in food safety, not only because they bear the risk of illness when a food is contaminated, but also because without properly handling, storing and preparing foods, they may introduce or compound the risk to themselves or others. They are connected, therefore, to the FSII first as recipients of information, such as restaurant inspection reports or information on food product recalls or ongoing outbreaks, that they may use to avoid hazards, as well as information on proper cooking temperatures and other safe food handling practices that they may use to improve their own behavior.

While consumers do not ordinarily collect food safety data, they are the focus of a number of different data collection activities. For example, foodborne illness victims are the focus of epidemiological investigations, while consumers are surveyed to find out information about their food consumption patterns, food handling and preparation practices or their perceptions or knowledge about risks. Consumers also generate valuable food safety information in the form of complaints to food companies and regulatory agencies and by reports of adverse health events to physicians or local health departments.

Beyond individual consumers, organizations that represent and advocate for consumers and foodborne illness victims play important roles in the FSII as they request and analyze data from other sources, generate datasets on their own, and serve as a conduit between the food safety system and consumers. For example, the Center for Science in the Public Interest (CSPI) produces a regularly updated Outbreak Alert, which lists and analyzes foodborne outbreaks in the United States, and maintains a searchable, online database on them. The data compiled in CSPI's document was requested from CDC, sometimes via FOIA requests, as well as from state and local governments, and

pulled from media stories when other data were not available.[27] Safe Tables Our Priorities (S.T.O.P.) recently announced it will create a national registry of foodborne illness survivors who have long-term health problems, which it hopes will serve as a data source for scientific researchers.[28]

Consumer education is another key activity of such organizations. For example, the FightBAC campaign about safe food handling and preparation is produced by the Partnership for Food Safety Education (PFSE), a collaboration of over 20 trade associations, professional organizations and consumer advocacy groups.[29] A number of consumer organizations are listed in Box 3.5.

Box 3.5—Consumer Organizations in Food Safety

Center for Food Safety (CFS)	http://www.centerforfoodsafety.org
Center for Foodborne Illness Research & Prevention (CFI)	http://www.foodborneillness.org
Center for Science in the Public Interest (CSPI)	http://www.cspinet.org/foodsafety
Consumer Federation of America (CFA)	http://www.consumerfed.org
Consumers Union (CU)	http://www.consumersunion.org
Food and Water Watch	http://www.foodandwaterwatch.org
Government Accountability Project (GAP)	http://www.whistleblower.org
National Consumers League (NCL)	http://www.nclnet.org/food
Safe Tables Our Priority (S.T.O.P.)	http://www.safetables.org

The Need for Information Sharing

The preceding discussion of food safety data types and institutions, coupled with our vision for a modern, science- and risk-based food safety system, make clear why the sharing of food safety information is so important. In broad terms, we have a dispersed network of public and private institutions that are good at generating and using information for their own particular purposes, but effective prevention of foodborne illness often requires integrating data and other information from multiple sources for common purposes.

Two examples underscore this point: foodborne outbreak response (Figure 3.6) and microbial risk assessment and management (Figure 3.7). These are critical and recurring functions of the food safety system, and, in both cases, the quality of the food safety analysis and action depends on timely access to the full range of needed information. These figures are not intended to fully capture either scenario, but rather are highly simplified and illustrative diagrams intended primarily to show, in broad terms, the flow of many kinds of information from many sources that enter these processes (from the left) and emerge from them (on the right).

27 Center for Science in the Public Interest (CSPI). 2007. Outbreak Alert! 2007: Closing the Gaps in our Federal Food Safety Net. Washington, DC. Available from http://www.cspinet.org/foodsafety/outbreak_report_2007.html

28 Neergaard, L. 2008. "Food Poisoning Can Be Long-Term Problem." Associated Press. January 21. Available at: http://ap.google.com/article/ALeqM5iSxdgd9SwKcoSArikR4UzdnMAfOQD8UADJ800 (last viewed 1/28/2008)

29 http://www.fightbac.org (last viewed 3/28/2008)

Foodborne Outbreak Response

As depicted in the simplified and illustrative diagram in Figure 3.6, the public health response to foodborne outbreaks begins with the detection of illnesses, involves investigations into their causes, runs through the taking of control measures, such as the issuance of recalls, and concludes with follow-up efforts. Lessons from investigations may then inform long-term preventive efforts. Many outbreak investigations are incomplete and constrained by time, resources and available information. The figure suggests these points regarding information flow:

- A wide range of information types are needed throughout the process, from original reporting of illness, to microbial testing of products, to estimating the costs of the outbreak.
- Without rapid sharing of information, multi-jurisdictional or multi-state outbreaks may be wrongly interpreted as individual cases of sporadic illness.
- Information needed in outbreak investigations come from many sources at all levels of government and from the private sector and academia, though most are collected by the public sector.
- Certain kinds of information may need to come from multiple sources or sectors and different datasets, such as microbial prevalence and incidence data that may come from federal government databases as well as from testing performed by the private sector and/or academia.
- Timeliness of information exchange is critical; each step in the process requires information to move forward quickly enough to help prevent future cases.
- Dissemination of information by federal, state and/or local agencies is needed on an ongoing basis to manage the outbreak process, inform the general public and provide the basis for future prevention efforts.
- While the figure focuses on the public sector role in outbreak response, members of the food industry whose products are involved play critical roles in generating and using information in an outbreak response situation, both to manage any needed recall and identify needed corrective measures.
- Without effective mechanisms in place to ensure that accurate and complete information is available when and where it is needed, the product recall or other outbreak response may be wrong in its focus and scope and too late to prevent illnesses.
- In many outbreak situations, root causes are not identified and complete final reports are not prepared due to competing demands for scarce resources, which means that outbreak investigations too often do not produce information that can be used to plan future prevention efforts.

Microbial Risk Analysis

Microbial risk analysis, including risk assessment, risk management and risk communication is an inherently and intensely data-driven process, with a wide array of information being required from many sources. While outbreak response places a heavy premium on the timeliness with which needed information is available to analysts and decision makers, the process of risk assessment and risk management for microbial pathogens is slower and more deliberative, with greater emphasis on the breadth, depth and utility of data to support science-based decisions. As in any public health decision process, timeliness remains important, but decision makers must balance the need for timely decisions with the desire for the best possible scientific basis for those decisions.

Figure 3.6—Information Flow in an Illustrative Foodborne Outbreak Investigation: Potential Input and Output of Information by Data Type and Sector

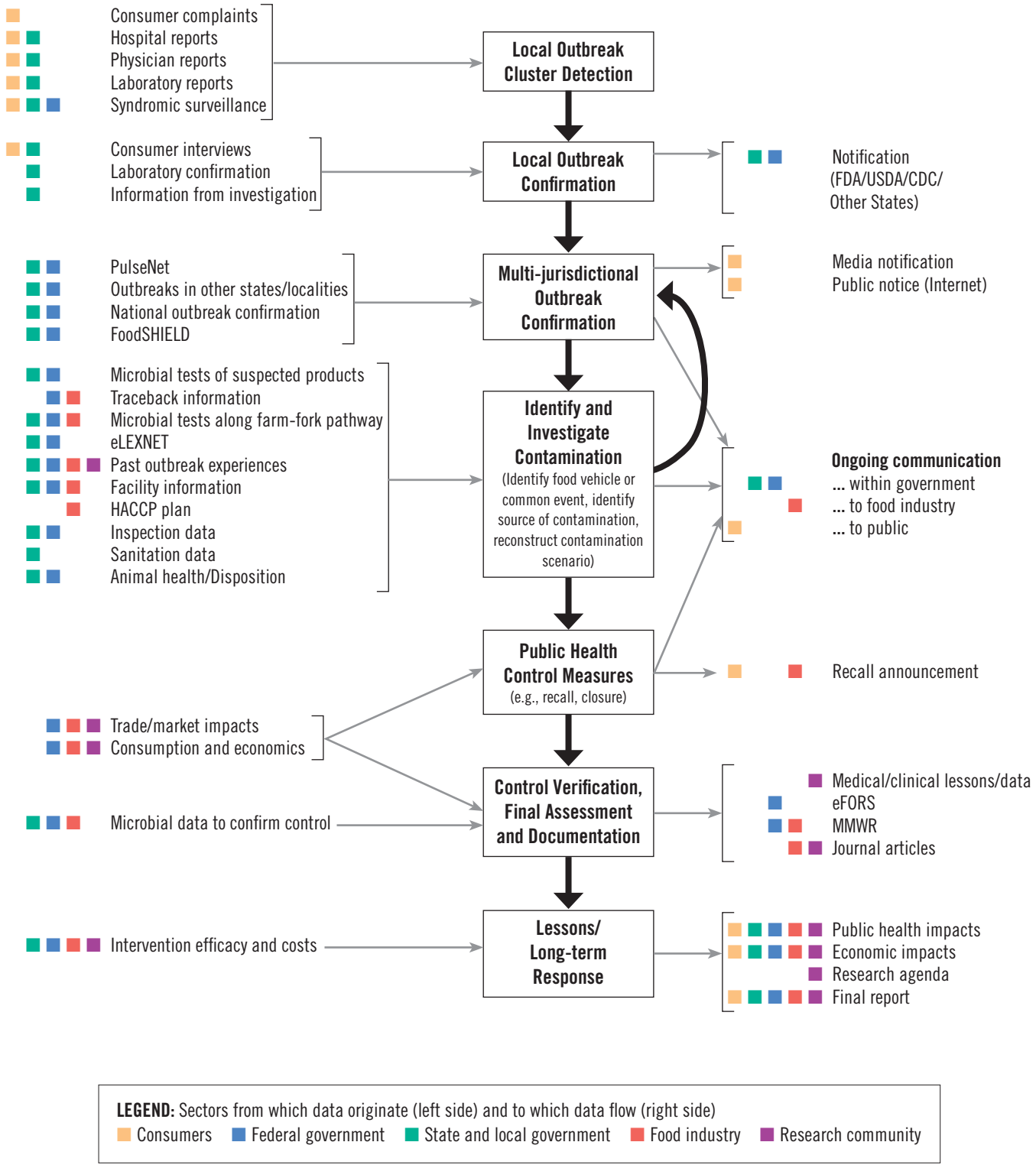


Figure 3.7—Information Flow in an Illustrative Quantitative Microbial Risk Assessment: Potential Input and Output of Information by Data Type and Sectors

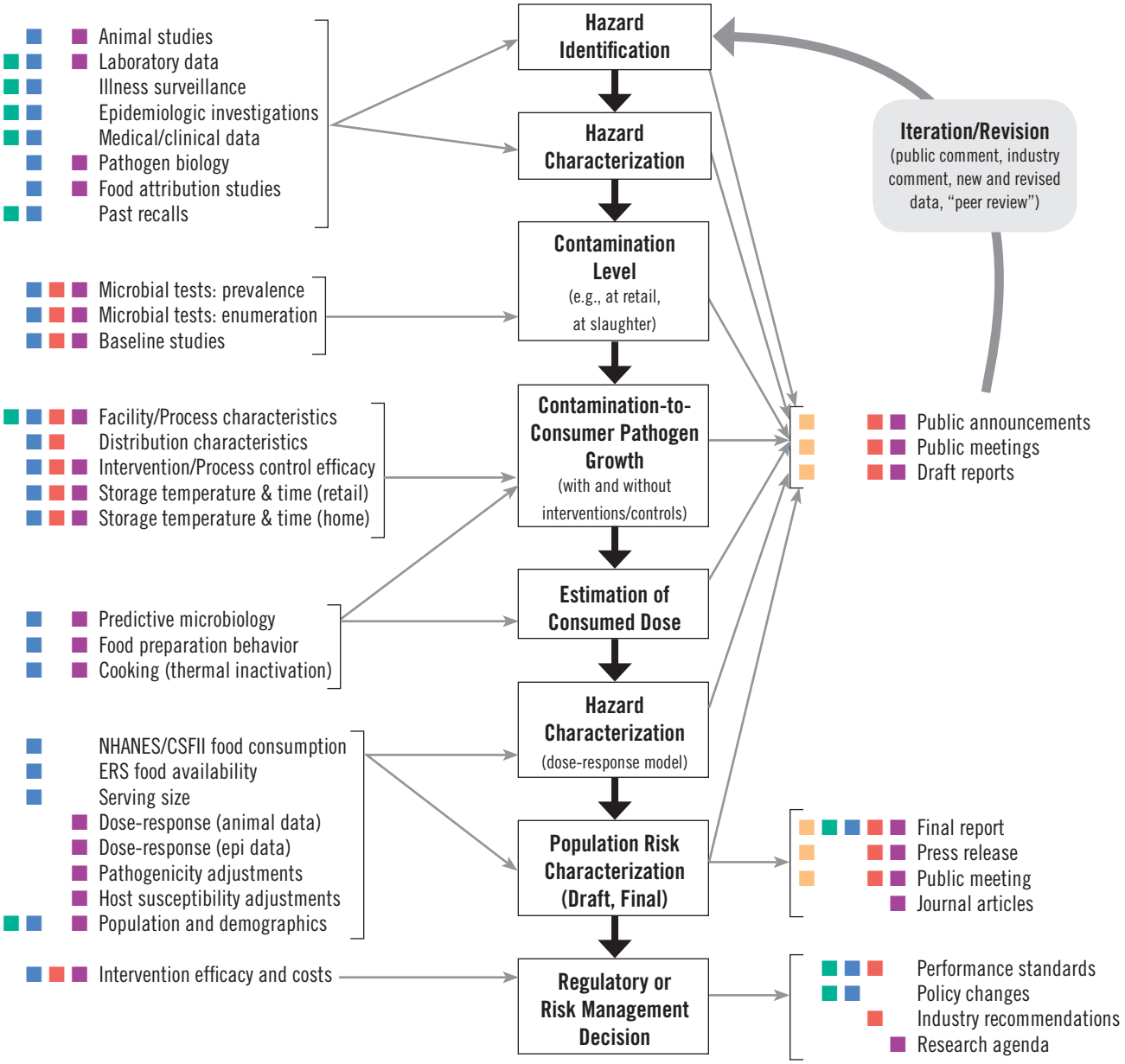


Figure 3.7 depicts, in highly simplified form, information flow in a hypothetical quantitative microbial risk assessment (QMRA). This diagram is not intended to define or describe in detail the various stages of risk analysis, or to serve to adequately capture all of the information that might be utilized in any given analysis, but rather to illustrate how some of the information flows in a QMRA. This figure suggests the following observations:

- Compared to outbreaks, an even larger array of information sources typically come into play in microbial risk analysis, including data from government and academic researchers, and potentially from industry. Information about practices during production, processing, distribution, retail, food service, and by consumers may be utilized.
- Because there may be multiple and conflicting sources for many of the types of information used in risk assessment, risk assessors must be able to choose the most appropriate dataset, aggregate or average across values, or otherwise perform sensitivity and uncertainty analyses to account for data gaps or conflicts.
- Unlike in an outbreak situation, the public is not usually informed on an ongoing basis, but rather during or following key stages in the analysis, and feedback is explicitly brought back into the process through risk communication efforts.
- The iterative nature of a risk assessment allows for interagency and external peer review and validation of the approach and the data used.
- If needed data does not exist or is not accessible, the quality and utility of the risk analysis will be impaired and the process, including any needed risk management steps, may be delayed.

Recent Progress in Data Access and Sharing

As discussed in the next section of this report, there are many reasons why the availability and flow of information in today's FSII is not optimal. It is important to recognize also, however, that many channels exist for making information accessible, and that new information management tools have improved the ability to share information efficiently and easily.

Traditional Tools

The traditional approach to disseminating the results of food safety research and information collection activities is through their written publication, either in refereed journal articles or non-refereed reports.

Journal Articles

Refereed journals provide a critical outlet for sharing information produced by the research community. Articles in refereed journals generally summarize research and results and go through a peer review process, which helps ensure the underlying data, though not typically presented, has been collected in an appropriate manner and that the reported results are sound. These are advantages for some audiences and purposes in that journal articles may be more "actionable" than datasets alone.

Readers of these articles may wish to perform their own analyses, or use the unpublished data for additional studies. Risk assessors, for example, prefer raw data over summary data. In such cases, the

traditional tendency of journal articles not to include primary data is a disadvantage. This is beginning to change, however, as some journals now allow authors to upload electronic appendices, including datasets, to their online versions and can, in this way, serve as accessible repositories of data.

Annual Reports and Similar Publications

Reports or other similar types of written publications produced by individuals or institutions involved in research or data collection are a more flexible format for disseminating food safety information, and are often used by government agencies. For ongoing or periodic data collection programs, annual reports can be used to disseminate findings on a regular basis. Reports do not have the space limitations of journals and thus can include substantially more data tables and figures based on the data. Examples of useful reports include CDC's annual FoodNet report;[30] FSIS reports on its baseline studies on the national prevalence and levels of bacteria in particular products;[31] and the annual reports from the National Antimicrobial Resistance Monitoring System (NARMS) prepared collaboratively by CDC, FDA and USDA.

Current Web-Based Information Tools

As with any effort today to make information more widely accessible, the future of the FSII is on the Internet. And, increasingly, so is the present. Almost without exception, even the traditional tools for disseminating information—journal articles and reports—are posted on a Web site and thus are available electronically. Nearly all journals can be searched via online indices such as PubMed and AGRICOLA, and most provide full text versions of articles for download to subscribers or for a fee. Many data collection initiatives, such as FoodNet, USDA's MDP and FDA's Health and Diet Survey, to name a few, have created online repositories where annual reports and other publications can be found in a single place. Similarly, NACCHO has created a Model Practices Database, which serves as a repository of publications relevant for local public health agencies. Some examples of these new methods of accessing traditional mechanisms are shown in Box 3.6.

In addition, modern information management technology enables the dissemination and exchange of data in unprecedented forms. Our far-from-complete canvas of the World Wide Web revealed nearly 100 online databases and tools for making food safety information available in ways that would not have been possible before. These tools are being used most commonly by government agencies at all levels but also by universities, industry and the public interest community. Some of the key Web-based tools are listed in Box 3.6 and a more complete listing can be found in Appendix C.

Web-accessible Datasets

We include in the category of Web-accessible datasets compilations of data that are in searchable or otherwise analyzable database formats, such as those of Microsoft Excel, tab- or comma-delimited text files, SQL Server, Access or Oracle databases. Such online databases can provide much more complete information than summary tables in written reports and are useful for analytical purposes in ways—such as creating data tables customized to the needs of the user—that data in printable but fixed formats, such as PDFs, are not.

30 http://www.cdc.gov/foodnet/reports.htm

31 http://www.fsis.usda.gov/Science/Baseline_Data/index.asp (last viewed 1/28/2008)

For example, CDC's summary national "line listing" data for foodborne outbreaks is in a PDF format, and data for each year is published separately.[32] The Center for Science in the Public Interest (CSPI) annual report on outbreaks is more dynamic and accessible. It includes newly available data for the current year as well as data from previous years,[33] and makes much of the underlying data freely available via a searchable database on the CSPI Web site.[34]

As reflected in Box 3.6, FDA, USDA and other organizations maintain a number of online databases. One particularly robust tool is ComBase, the Combined Database for Predictive Microbiology, which includes data and predictive models of microorganisms in various food environments.[35] ComBase is the result of collaboration between USDA's ARS and food safety institutes in the United Kingdom and Australia. It allows users, such as those in small food firms attempting to build food safety management systems, to search the database for growth and inactivation models for a particular pathogen in a particular product under certain conditions, such as temperature and pH. Launched in 2003, ComBase is freely available and even allows registered users to upload their own microbial models.

Web Directories and Information Gateways

Most of the Web-accessible data-sets in Box 3.6 and Appendix C have been developed independently of each other and are available primarily through isolated and disconnected Web sites. The growing abundance of such Web sites, which is a reflection of the many food safety institutions in the country and the proliferation of data collection programs, makes it difficult to find needed information unless searchers know exactly what they are looking for and who maintains it.

This is a data awareness problem that is beginning to be addressed by some Web directories or "information gateways" that attempt to cut across the tangled network of data and better connect individuals and institutions with the information they need. The "Gateway to Government Food Safety Information" is one such Web site that provides links to select food safety information from federal, state and local government agencies and may be thought of as a directory or yellow pages for the general public.[36]

A more targeted gateway is provided by FoodRisk.org,[37] formerly known as the Food Safety Risk Analysis Clearinghouse. FoodRisk.org is a project of the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), a collaborative venture between the University of Maryland and FDA's CFSAN. This publicly accessible Web site was formed to collect and catalog data and methodology pertaining to food safety risk analysis provided by federal and state agencies, trade associations, private sector firms, academia, and international sources. FoodRisk.org links to relevant databases on food safety from around the world, and unlike foodsafety.gov, is not restricted to government sources of information.

The Food Safety Research Information Office (FSRIO) of the National Agricultural Library (NAL) maintains the Food Safety Research Projects Database,[38] another targeted directory or gateway con-

32 http://www.cdc.gov/foodborneoutbreaks/outbreak_data.htm (last viewed 3/17/2008)

33 Center for Science in the Public Interest (CSPI). 2007. Outbreak Alert! 2007: Closing the Gaps in our Federal Food Safety Net. Washington, DC.

34 http://www.cspinet.org/foodsafety/outbreak/pathogen.php (last viewed 3/17/2008)

35 http://portal.arserrc.gov/PMIPHome.aspx (last viewed 3/17/2008)

36 http://www.foodsafety.gov (last viewed 3/28/2008)

37 http://www.foodrisk.org (last viewed 3/28/2008)

38 http://fsrio.nal.usda.gov/quicksearch.php (last viewed 3/28/2008)

Box 3.6—Examples of Online Mechanisms to Share Food Safety Information

Indices of journal publications	
NAL Journal Index for AGRICOLA	http://agricola.nal.usda.gov
NLM PubMed Journal Index	http://www.ncbi.nlm.nih.gov/PubMed
Online program-specific repositories of annual reports and publications	
CDC FoodNet	http://www.cdc.gov/foodnet
FDA Health and Diet Survey	http://www.cfsan.fda.gov/~comm/crnutri.html
NACCHO Model Practices Database	http://www.naccho.org/topics modelpractices/database
NARMS (Antimicrobial Resistance)	http://www.fda.gov/cvm/narms_pg.html
USDA Baseline (Microbiological) Data	http://www.fsis.usda.gov/Science/Baseline_Data
Web-accessible data-sets	
CDC Summary Outbreak Data	http://www.cdc.gov/foodborneoutbreaks
ComBase (pathogen behavior)	http://www.combase.cc
CSPI Outbreak Database	http://www.cspinet.org/foodsafety/outbreak
EPA Fish Advisories	http://epa.gov/waterscience/fish/advisories /index.html
ETOXNET (Toxicity Information)	http://extoxnet.orst.edu/ghindex.html
FDA Pesticide Residue Database:	http://www.cfsan.fda.gov/~dms/pesrpts.html
FDA Total Diet Study	http://www.cfsan.fda.gov/~comm/tds-toc.html
FDA and USDA Food Recalls	http://www.recalls.gov/food.html
NHANES Dietary Intake Data	http://www.ars.usda.gov/Services/docs htm?docid=15044
Restaurant Inspection Scores Listings	http://www.healthinspections.com
USDA ERS Food Availability Data	http://www.ers.usda.gov/data/ foodconsumption
USDA PDP (Pesticide Data Program)	http://www.ams.usda.gov/science/pdp
Web Site directories and information gateways	
FoodRisk.org (JIFSAN)	http://www.foodrisk.org
FoodSHIELD	http://www.foodshield.org
Government Food Safety Gateway	http://www.foodsafety.gov
International Food Safety Network	http://www.foodsafety.ksu.edu/en
NAL Food Safety Research Database	http://fsrio.nal.usda.gov/index.php
Electronic networks and reporting systems	
eLEXNET (food analytes)	https://www.elexnet.com/elex/index.jsp
CDC eFORS (outbreak surveillance)	http://www.cdc.gov/foodborneoutbreaks/index.htm
CDC NEDSS (disease surveillance)	http://www.cdc.gov/nedss
CDC PulseNet (PFGE subtyping)	http://www.cdc.gov/pulsenet

sisting of over 1700 research abstracts from institutions such as ARS, CSREES, NIH, CDC and FDA, as well as some from academia and the private sector. The database is searchable through the FSRIO Web site and links to other resources and publications associated with specific projects.

Finally, FoodSHIELD,[39] developed by the University of Minnesota's National Center for Food Protection and Defense, is a Web-based platform that allows government laboratories and regulatory agencies to share information about their expertise and capacities to respond to emergencies, particularly intentional threats to the safety of the food supply. Though relatively narrow in its original purpose, and largely inaccessible to those outside of public health agencies, FoodSHIELD shows the potential for Web-based tools to create information sharing communities online.

Electronic Networks and Reporting Systems

While online data-sets and Web directories make information published by a particular party accessible to the general public or to specific food safety communities, electronic networks and reporting systems permit real-time information sharing among participants in these systems. Such systems can dramatically speed up reporting functions and decentralize control over information, making the resulting data much more of a communally maintained property. The most prominent examples of such electronic networks and reporting systems are maintained by CDC and FDA.

CDC's eFORS is a Web-based system now used by officials in all 50 states to submit data on outbreaks to CDC, replacing a paper-based system. The new system includes improved forms for more consistent reporting and more active efforts to ensure the closure of investigations and reporting of results. The result has been a significant increase in the number of reported outbreaks and a potentially very valuable information resource for food safety risk managers. The next step, now being explored at CDC, is to make the eFORS database fully accessible and analyzable online.

As noted earlier, PulseNet is a CDC-coordinated network of federal, state and local laboratories that use PFGE molecular fingerprinting and a shared electronic database to promptly recognize and help contain outbreaks of foodborne illness. Participating laboratories can view results from nearby states and request detailed analysis by CDC scientists to rapidly determine whether PFGE patterns of bacteria isolated from sick individuals are similar and, therefore, likely linked to a common food source. By fostering more frequent and rapid detection of outbreaks and fostering real-time communication and data sharing among federal, state and local health officials, PulseNet provides critical information needed both to contain ongoing outbreaks and help identify areas where implementation of new preventive measures may prevent future outbreaks.

Another example of a restricted (government use only) data sharing system is the Electronic Laboratory Exchange Network (eLEXNET) maintained by FDA. eLEXNET is a Web-based information network allowing health officials at over 100 participating federal, state and local agencies to compare, share and coordinate laboratory findings about pathogens, chemicals and other analytes in food. Ready access to such a database supports the efforts of food safety officials at all levels to both investigate and mount initiatives to prevent food safety problems. eLEXNET also serves as the data capture and communication system for FERN.

39 http://www.foodshield.org (last viewed 3/28/2008)

Emerging Web Technologies

In addition to the aforementioned Web-based approaches to making data-sets and other forms of information more accessible and more easily shared among parties, there are a number of new and rapidly evolving and emerging Web-based technologies that may revolutionize how food safety information is shared. Although these so-called "Web 2.0" technologies are not extensively used today for data sharing, there are a few new tools worth noting.

One technology that is increasingly utilized by those in the food safety system is the syndication of Web site content through "Web feeds." Feeds allow users to keep track of updates to Web pages by "subscribing" to these feeds via a Web-based or stand-alone "feed aggregator" such as Google Reader[40] or Bloglines.[41] Feeds are particularly useful for breaking news situations or when sites are updated rarely. FDA, USDA, CDC and others maintain a number of news feeds, some of which are listed in Box 3.7. A person subscribing to FDA's recall feed, for example, gets a notice when a new recall is announced. Feeds have great potential utility to announce when data have been updated. For example, CDC could create feeds that would let subscribers know when new data, such as updated foodborne outbreak "line listings," are published on the Web.

Another area that is growing is the increasing use of online data visualization, particularly the use of mapping software. For example, HealthMap[42] aggregates disparate data sources on infectious disease (including foodborne outbreaks and recalls) and presents the data as an interactive map and data tool allowing users to explore the embedded information. Similarly, a user-generated map is available through Google, identifying cities and counties that disclose restaurant health scores and providing links to those Web sites.[43] For Los Angeles and San Francisco,[44] Google Maps now includes health inspection scores for some restaurants. Another example of online data visualization is provided by Many Eyes,[45] a Web site providing a platform for users to upload data, produce graphical analyses and share them with others. Although Many Eyes is a general data tool, there is already a food safety "hub" to which users have uploaded data and produced visualizations.[46] All of these sites allow users to easily access and interpret information that otherwise might be difficult or time-consuming to obtain, and to explore the data in new ways.

Other Web 2.0 technologies, such as "wikis," collaborative tools, blogs, social bookmarking and social networking are increasingly utilized by scientists, researchers and professionals in many fields.[47] Though not currently used extensively for food safety information sharing, these tools are likely to become important moving forward. For example, the nanoHUB Web site serves the nanotechnology community by providing a number of resources, including online presentations, teaching materials, animations, podcasts, collaborative workspaces and online simulation tools to share research results.[48] Similarly, myExperiment is a scientific networking Web site that allows users to share detailed

40 http://www.google.com/reader/ (last viewed 2/28/08)
41 http://www.bloglines.com/ (last viewed 2/28/08)
42 http://healthmap.org/en (last viewed 3/03/08)
43 http://maps.google.com/maps/ms?msa=0&msid=105416090121327158168.000001132b797f407faa3 (last viewed 3/02/08)
44 http://maps.google.com/maps?f=l&hl=en&geocode=&q=food+cleanscores&near=Los+Angeles,+CA (last viewed 2/28/08)
45 http://services.alphaworks.ibm.com/manyeyes (last viewed 3/04/08)
46 http://services.alphaworks.ibm.com/manyeyes/topichub/Ik76IsOtha6zbmwdejgI2~ (last viewed 3/04/08)
47 Gewin, V. (2008). The new networking nexus. *Nature*, 451: 1024-25. February 20.
48 http://www.nanohub.org/ (last viewed 3/28/2008)

"workflows," which are customary protocols for standardizing data, running simulations or conducting statistical analysis on large data-sets.[49] The Web site Connotea allows researchers to manage their literature and Web references online and share articles with colleagues,[50] while SciVee invites scientists to link published journal articles to video presentations about their work.[51]

Box 3.7—Examples of Web Sites Using Emerging Technologies to Facilitate Information Sharing

Food safety syndicated feeds (e.g. RSS)	
FDA news and recall feeds	http://www.fda.gov/oc/rss
USDA news and research feeds	http://www.usda.gov/wps/portal?navid=RSS FEEDS
NAL FSRIO feeds	http://fsrio.nal.usda.gov/rss_feeds.php
CDC feeds	http://www2a.cdc.gov/podcasts/rss.asp
Iowa State University feeds	http://www.extension.iastate.edu/foodsafety/rss
FoodRisk.org news feed	http://foodrisk.org/about/rss/foodrisk.xml
Other Web 2.0 sites in food safety	
HealthMap disease alerts	http://healthmap.org/en
Google Maps (Los Angeles)	http://maps.google.com/maps?q=San+Francisco,+CA
Many Eyes food safety hub	http://services.alphaworks.ibm.com/manyeyes/topichub/Ik76IsOtha6zbmwdejgI2~
Pageflakes food safety pagecast	http://www.pageflakes.com/foodsafety
Food Poisoning Blog (Marler Clark)	http://www.foodpoisonblog.com
Not in My Food Blog	http://www.consumersunion.org/blogs/nimf
Perishable Pundit	http://www.perishablepundit.com/
Web 2.0 examples outside of food safety	
Wikipedia	http://en.wikipedia.org
Citizendium	http://en.citizendium.org
Connotea	http://www.connotea.org
MyExperiment	http://www.myexperiment.org
NanoHUB	http://www.nanohub.org
SciVee	http://www.scivee.org

There are a number of food safety blogs (some are listed in Box 3.7), but these currently focus on opinion and personal analysis. The technology could be utilized in other ways, however. Similarly, the open-source "wiki" technology that drives user-driven online encyclopedias such as Wikipedia, which is unedited and user-maintained, and Citizendium, which utilizes editors to validate user-generated content, could be exploited by the food safety community to create Web-based repositories of food safety information and knowledge. The NAL has set up a proof-of-concept Web site that utilizes numerous Web 2.0 services and technologies (RSS feeds, wikis, maps, data visualization,

49 http://www.myexperiment.org/ (last viewed 3/28/2008)
50 http://www.connotea.org/ (last viewed 3/28/2008)
51 http:scivee.tv/ (last viewed 3/28/08)

social bookmarks, tag clouds, etc.) to pull content from multiple Web sites and make it available in one central location.[52] Regardless of whether any of these particular technologies become important tools for the sharing of food safety information and data, other technologies are likely to emerge that will prove useful.

Conclusion

The recent efforts to improve the FSII give a hint of what is possible with new commitment and information tools. Our recommendations in Section Five seek to capitalize on both. First, however, it is important to clarify the constraints and problems facing the FSII and why concerted effort is needed to build a better functioning FSII. Those points are addressed in the next section.

52 http://www.pageflakes.com/foodsafety (last viewed 3/28/2008)

SECTION FOUR:
CONSTRAINTS ON IMPROVING THE FSII

Introduction

As explained in Section Two of this report, the key attributes of a well-functioning FSII are that it produces the information practitioners need and provides it on a timely basis and in a useful form so it can be used to prevent problems and help ensure food safety. It is a system characterized by information not only being generated and used well within organizations but also flowing among organizations to enhance the overall effectiveness of the food safety system.

For all the good work of the many thousands of actors in the food safety system, including the important progress that we have seen recently, anyone who has worked within the system has seen ways the FSII falls short of our aspirations. No one in particular is at fault for this shortfall. It is rather a product of the fundamental reality of the FSII as a vast, complex and decentralized web of highly diverse institutions, each working on food safety within its own role and with its own focus, and lacking incentives or mechanisms to collaborate for mutual advantage.

This reality of decentralization has its benefits, but also means that desirable change will be difficult to come by. Based on discussions in our project workshops, however, we think that improvement in the FSII is not only desirable, but possible, if we are realistic about the system's constraints and devise solutions that directly address them.

In this section of the report, we outline some of the major constraints facing the FSII—ones our recommendations in Section Five are designed to address. We begin with constraints that apply generally across the system and conclude with some that are specific to government, industry and academia. These constraints are summarized in Box 4.1.

General Constraints

We see four general constraints on the success of the FSII: (1) lack of mechanisms for planning and coordination of information collection, (2) institutional obstacles to information sharing, (3) technical

obstacles to information sharing, and (4) the economic costs involved in any improvement of the FSII. All of these need to be taken seriously and addressed in any recommendations to improve the FSII.

Box 4.1—Summary of Constraints

General Constraints

- Lack of Mechanisms for Planning and Coordination of Information Collection
  - Research programs are not accountable to regulatory agency needs
  - Foodborne illness surveillance is not responsive to stakeholder needs
  - Data on microbial and chemical contamination are not aggregated
- Institutional Obstacles to Information Sharing
  - Institutional focus and priorities
  - Legal, business, cultural and bureaucratic obstacles
  - Power of the status quo
- Technical Constraints on Information Sharing
  - Lack of standardized approaches to data collection
  - Lack of harmonization in data systems
  - Lack of available tools to aggregate diverse data
- Economic Cost of Improved Information Sharing
  - Materials and equipment costs are significant
  - Costs borne by information providers, with benefits accrued by recipients

Specific Constraints on Individual Sectors

- Government Issues and Constraints
  - Lack of a Mandate and Resources for Coordination and Data Sharing
  - Legal Constraints on Information Access and Sharing
  - Privacy laws
  - Confidential business information
  - Information Quality Act (IQA)
  - Paperwork Reduction Act (PRA)
  - Agency Culture and Established Practices
  - Sense of data ownership
  - Professional first-to-publish culture
- Food Industry Constraints on Information Sharing
  - Proprietary or competitive value
  - Concern about data misuse or misinterpretation
  - Concern about punitive action by government or victim lawsuits
- Academic Constraints on Information Sharing
  - No professional reward for providing data, only for publication of results
  - Lack of available repositories
  - Delays in publication of peer-review journal articles
  - Bias against publication of negative data
  - Barriers to journal access—difficult and expensive to obtain

Lack of Mechanisms for Planning and Coordination of Information Collection

An important feature of a successful FSII would be that government-sponsored food safety research and information collection is systematically planned and coordinated to produce the information that

both government and industry need to play their parts in preventing foodborne illness. The FSII currently lacks sufficient mechanisms to make this happen.

Most government-sponsored *food safety research* at the federal level is carried out through intramural and extramural programs at USDA that are organizationally separate from and not directly accountable to those in government responsible for managing food safety risks. And, while there is informal dialogue about research needs, there is no formal, accountable interagency planning process. Likewise, when the food industry confronts a new food safety challenge, such as the problem of pathogen contamination facing the produce industry, there is no established mechanism for planning and coordinating the government and industry research on measures needed to solve it.

Most foodborne illness investigations are carried out by state and local agencies to contain outbreaks, rather than through a planned process intended to maximize the value of information the investigation can generate. Through the Council to Improve Foodborne Outbreak Response (CIFOR),[53] these agencies are working together with federal partners to improve the flow of information within the public sector, particularly across jurisdictional lines. Nonetheless, they lack mechanisms and resources to work systematically with the food industry on the necessary follow-up investigations to identify root causes and better inform future preventive efforts. The FoodNet system is a step forward in our ability to collect reliable data on foodborne illness, independent of outbreaks, and involves active planning of data collection among the CDC scientists and state agencies that run the 10 FoodNet sites. However, this planning process does not actively involve food industry risk managers who have their own epidemiology data needs and priorities.

Finally, many government agencies and food companies invest substantial effort *data collection on chemical and microbial contamination of food*. If aggregated, this data would provide a much more robust picture of the nature and distribution of hazards across the food supply than we have today. This data is typically collected, however, for specific purposes and with little consideration of how it might contribute to an overall understanding of food safety risks and opportunities to reduce them. This is understandable and to some extent unavoidable for institutional, cost and technical reasons, as we discuss further below. Opportunities exist, however, to plan certain types of data collection, such as environmental and baseline surveys or ongoing monitoring programs, in ways that make the resulting data more widely useful, not only to the full range of government agencies but to industry and academia as well. There is little impetus and no established structure in the system for this kind of effort.

The lack of mechanisms for planning and coordination of information collection is a natural consequence of the complexity and decentralization of the FSII. These realities are likely to remain. The question is how to take advantage of targeted opportunities to improve planning and coordination of information collection to better serve diverse participants and the system as a whole.

53 CIFOR is a multidisciplinary working group comprised of food safety officials in all levels of government who collaborate "to improve methods at the local, state, and federal levels to detect, investigate, control, and prevent foodborne disease outbreaks." It is co-chaired by the CSTE and NACCHO, and receives funding support from CDC. http://www.cifor.us/ (last viewed 3/29/08)

Institutional Obstacles to Information Sharing

In addition to better planning and coordination of information collection, our goals for the FSII include more open access to and active sharing of existing food safety information. Any effort to improve information sharing should take into account, however, the forces that influence the behavior of institutions and individuals in the food safety system and make such information sharing difficult. At least three such forces apply across the board to government, industry and academic generators of food safety information.

The first is the simple reality of *institutional focus and priorities*. As described in Section Three, government agencies, food companies and food safety researchers all collect information for their own specific purposes using methods of collection and reporting that are suitable for those purposes. Even government food safety agencies, which certainly have an interest in helping other institutions play their food safety roles, naturally give priority to meeting their own information needs and programmatic goals, rather than devising ways to share information with others.

In the case of CDC, for example, the traditional focus has been on reporting incidence rates of illness associated with specific pathogens and publishing further summaries and analysis in journal article form, rather than making detailed epidemiologic data available for analysis by others. In the case of FDA and FSIS, contamination data is collected primarily to support each agency's regulatory and enforcement functions, rather than to inform their state and local counterparts or industry.

Information sharing by the food industry and academia is similarly constrained by the reality of why they collect information in the first place. In the case of food companies, it is to better mange their own food safety systems, not to produce databases for use by others. In the case of academic researchers, it is to support the achievement of publishable research results, not to provide raw data to government or industry analysts.

Among government, industry and academic participants in the food safety system, we find an increasing recognition of their interdependence and the need to collaborate on food safety; some progress has certainly been made on information sharing. Due to the scarcity of time and financial resources all institutions face, however, making it a higher priority will likely require both expanding each institution's understanding of its food safety role and taking specific steps to ensure that information sharing helps them play that role.

Even if information sharing enjoys a new priority, institutions still operate under a range of *legal, business, cultural and bureaucratic obstacles* that need to be addressed. We are referring here to, for example, the legal limits placed on government by privacy and trade secret laws and, at the federal level, by the recently enacted IQA. We also include the food industry's concerns about protecting business-sensitive proprietary information and avoiding legal and regulatory liability that could potentially arise from sharing food safety information. In CDC and academia, institutional cultures and professional pressures contribute to individuals and organizations taking a proprietary interest in data they generate. Public and private institutions alike express concerns about their information being misinterpreted or misused by others. Any serious effort to improve the FSII, and information sharing in particular, must address these very real constraints.

A third cross-cutting obstacle to information sharing is simply *the power of the status quo*. Elevating the priority of information sharing and addressing specific legal, business and other constraints are important steps, but, even with such efforts, human nature makes changing long-established ways of

doing things very difficult. And many of the practices surrounding the collection and sharing of food safety information have been in place for a long time, ranging from traditional approaches to outbreak investigations and CDC's management of outbreak data to the food industry's protectiveness of food safety information it generates. Significant change in the status quo requires sustained, institutionalized effort and leadership, not just an earnest but transient willingness to change.

A number of the items we describe here as institutional obstacles to information sharing were discussed in our workshops in terms of a lack of trust, primarily among institutions and individuals that shared data would be properly understood, interpreted and used. Lack of trust, or confidence, that efforts to share information will be rewarded seems also to help explain the difficulty of changing longstanding practices.

Technical Constraints on Information Sharing

Even when these institutional obstacles are addressed, and organizations have the will to publish or share their data, significant technical obstacles may limit the utility of these data once they are shared. These obstacles have to do largely with the diverse ways that data is collected and stored and the challenges that arise in aggregating and meaningfully analyzing data from diverse sources.

A central premise underlying interest in improving the FSII is that specific information collected by one party for that party's particular purpose can have value for other parties in the food safety system, possibly for different purposes. For example, data collected by the government on pathogen incidence and levels might be of use to food companies in assessing their own performance in relation to national averages, and the government might benefit from access to aggregated data from industry pathogen testing.

Another example: data from outbreak investigations conducted by different state health departments around the country can be, and has been, aggregated to provide information on the incidence of outbreaks nationally associated with particular pathogen-food combinations. While the value of outbreak attribution is somewhat limited by the fact that outbreaks are not representative of sporadic illnesses, such information is still vital for targeting and prioritizing efforts to reduce foodborne illness.

The utility of data for such purposes is often constrained, or even eliminated, however, by the *lack of standardized approaches to data collection*. For example, in the case of gathering microbial test data for a particular pathogen on a particular product, different approaches can be taken on how products are selected for sampling (random versus "for cause"), how samples are actually collected (swab versus rinse), the measurement outcome (positive/negative prevalence versus quantification of microbial load), and especially the specific type of test and test protocol used to make the measurement. Variations in any of these methods across datasets may make it difficult or impossible to compare the data or aggregate them to draw the bigger picture of contamination rates or levels, or for other purposes.

Non-standardized approaches to data collection are also an obstacle to aggregating epidemiological data from outbreak investigations. For example, while great strides have been made in standardizing laboratory methods used in foodborne outbreak investigations, allowing for the creation of nationally aggregated datasets, little effort has been made to standardize the way food vehicles are reported. Each individual investigator simply lists the foods or ingredients found or suspected to have been contaminated. As a result, for example, "hamburger" may mean "ground beef" or "hamburger sandwich," an important distinction considering the latter may contain lettuce, tomatoes, a bun or other ingre-

dients associated with foodborne illness. Standardizing the reporting of food vehicles would substantially improve our ability to estimate the rates of illness attributable to particular pathogen-food combinations.

To be able to combine and compare similar data, it is likely that standardized approaches to data gathering will have to be developed and employed by the numerous individual parties engaged in that activity. But, while standardization seems an obvious goal to those interested in aggregating information from multiple sources, the original collectors of data are not always supportive, for a number of reasons. Chief among them is the concern that by standardizing for the greater good, the data may have less value to the original collector. For example, a local or state epidemiologist may feel the standardized form or approach is less protective of the public health of their locality or state because it ignores critical aspects relevant to the local population. Similarly, an individual firm may not want to use a standardized testing approach that costs more than a lower cost method that is adequate for its needs or better suited to its specific conditions.

Standardization is a pervasive issue in data collection and management, and has been a topic in food safety for years. Efforts to develop standardized methods are time- and energy-consuming, however, and rarely without honest disagreement among experts and practitioners. Agreement is even more challenging in areas such as microbial testing where the science is rapidly evolving and numerous technologies are competing in the marketplace. Care must be exercised so efforts to standardize do not impede further innovation in test methods. Well-targeted efforts to expand standardization are needed, however, to get full value from the investment government and industry make in collecting food safety data. It may be possible to find compromises that avoid strict "one size fits all" approaches to standardization in favor of flexible systems that set some bounds on the most important data characteristics (such as for the most important variables) but which allow greater freedom to add or change other components.

Another technical constraint on data sharing is the *lack of harmonization of data systems.* Just as there may be differences in how data is collected, there may be differences in how it is stored. This inconsistency stems, in part, from the many different software platforms available for data management which use different structural approaches to store data and may or may not "talk" with one another. In addition, regardless of platform, the format of the data may differ in terms of what variables are recorded or the format of these variables. Basically, the data may not "line up;" for example, two databases may record the same variable using incompatible ranges, such as 0-10 and 10-20 in one dataset and 0-7,7-13,14-20 in another. Some of these issues can be resolved through translation tables or features of modern data analysis software, but it is possible that differences in data formats could preclude proper aggregation.

Costs of Improved Information Sharing

The economic reality of cost will always be an obstacle to any institution's willingness and ability to share information. And meaningful sharing of food safety information certainly imposes costs, such as for standardizing data collection methods to make sharing data technically feasible and for putting information in a form suitable for sharing without jeopardizing the legitimate interests of the institution that generated it.

The potential material and equipment costs are significant by themselves, and may include computer workstations, data storage hardware, off-the-shelf or custom-built software for data entry, data man-

agement and analysis, computer networking infrastructure, and additional hardware and software for Web sites. Labor costs may be even higher, with highly skilled workers needed to, among other activities: develop data collection protocols; perform field and laboratory work; design, develop, and maintain the data management and information systems; design data entry and other user interfaces; enter data into the systems; clean and validate the data; perform necessary analyses; and respond to incoming data requests.

Compared to the investment that many government and private organizations make in generating information, the incremental cost of making the information more readily and usefully available may be relatively modest, at least in some cases. Unless the costs are covered, however, the desired information sharing is unlikely to occur. This is particularly true, as is often the case, when the benefit of information sharing goes more to the parties receiving the information than those who generate and share it, and thus incur the costs. In those cases, consideration needs to be given to how those costs can be minimized or covered, as well as to providing incentives or benefits to those who are willing to share their information to support improvement in the overall food safety system.

Specific Constraints in Government, Industry and Academia

In addition to the general constraints on information sharing or the utility of information once it has been shared, government, industry and academia each operate under constraints specific to them.

Government Issues and Constraints

Government agencies are central to the FSII. They collect extensive food safety information for their own use and some, such as CDC, ARS and CSREES, generate information primarily for use by others; as government agencies, all must act in the broad public interest. It is appropriate, therefore, to look to government for leadership in improving the functioning of the FSII. All government agencies work, however, under policy, resource, cultural and legal constraints that make coordinated planning of information collection and sharing easier said than done. Some of these constraints are briefly outlined here.

Lack of a Mandate and Resources for Coordination and Information Sharing

In the U.S. government, executive branch agencies focus on carrying out what they consider their core legislative mandate, and of course they depend on the legislature for the resources they need to do their assigned job. To be successful in the political and policy process, food safety agencies must consistently meet the expectations of the legislature, which in turn requires being responsive to their public stakeholders, including consumers and the food industry.

Efforts to improve the FSII are generally not prevented by the core food safety mandates of federal, state and local agencies. We know many agencies participate in such efforts, but they have no clear mandate or dedicated resources to do so. Additionally, in today's food safety environment, characterized by expanding domestic and international food safety challenges and diminishing resources, our food safety agencies commonly find themselves overburdened with competing priorities and responsibilities that are at the core of their current mandates and stakeholder expectations.

For FDA, this means responding well to the crisis of the moment, be it an outbreak of illness associated with tainted lettuce from California or unsafe chemical residues in fish from China. For FSIS, it means meeting its strict statutory inspection mandate. For CDC and its counterparts in state and local health departments, it means investigating and managing the latest outbreaks of foodborne illness. Activities without immediately measurable benefits or which have benefits secondary to those required by the core mandate of the agency (such as improving the functioning of the entire food safety system through broader coordination on data collection and improved information sharing) will, on any given day, take a backseat.

As a general rule, therefore, such activities as interagency planning of research and data collection, producing public-use data-sets, publishing information in a timely manner, making information accessible through Web sites, and responding to information requests are secondary priorities to most food safety agencies. They typically lose out in the competition for scarce resources and management attention to emergency response, inspection activities, or other core functions. This reality of life for federal agencies will not change until improving the collection and use of food safety information on a system-wide basis becomes a part of the mandate for food safety agencies and Congress provides resources for this purpose.

Legal Constraints on Information Access and Sharing

Federal, state and local agencies are subject to legal constraints affecting their ability to share food safety information, including laws intended to protect personal privacy and confidential business information, and ensure the quality of information released by the federal government.

Privacy Laws—Under federal, state and local privacy statutes, governments are generally precluded from disclosing personal information about individuals, such as might be obtained during a health department's investigation of a foodborne disease outbreak. CDC and the state and local health departments must thoroughly protect patient privacy and operate under agreed-upon guidelines that require, for example, careful review and deletion of any potentially identifying information prior to releasing records.

While it is important to protect patient privacy, the resulting thorough review of records inevitably slows the availability of epidemiological data for analysis and reduces the amount of information available to other food safety agencies and analysts. For instance, these procedures often hinder access to non-confidential information that may be a part of the same dataset. In addition, it may not always be clear which data require protection for privacy purposes, particularly in cases for which the data include geographic identifiers or other information that could help identify a specific patient even if he or she were not identified explicitly. Furthermore, the labor-intensive review process imposes costs on resource-poor agencies that create a disincentive to even consider preparing data for release.

Laws Protecting Confidential Business Information—Under the Freedom of Information Act (FOIA) at the federal level and similar FOIA or "government in the sunshine" laws at the state and local levels, agencies are precluded from disclosing confidential, commercially valuable business information. There is room to debate the types of food safety-related information that fall within this disclosure exemption, but possibilities include descriptions of a company's food safety procedures as they relate to a particular product, or microbial test data on environmental or product samples taken from a company's plant. Federal, state and local agencies commonly obtain such information through epide-

miological investigations or regulatory inspections. For purposes of food safety information sharing, the practical results of the protection afforded confidential business information are, similar to the privacy laws, the imposition of staff costs for pre-disclosure review, delays in disclosure of information, and limitations on what can be disclosed. This is another case in which one legitimate set of values is balanced against another in a way that complicates information sharing.

The Information Quality Act (IQA)—Also known as the Data Quality Act (DQA), the IQA was enacted as a two-sentence rider in the consolidated appropriations bill for FY2001. It mandated the Office of Management and Budget (OMB) to "provide policy and procedural guidance to federal agencies for ensuring and maximizing the quality, objectivity, utility and integrity of information (including statistical information) disseminated by federal agencies."[54] OMB subsequently issued detailed guidelines on how the IQA is to be implemented.[55] The IQA is designed to ensure that information used in regulatory decisions meets quality standards, but it may also adversely impact the broader flow of information from federal agencies to the public.

In short, under the OMB guidelines, the release of information that has potentially significant economic impact may be required to undergo some type of pre-release peer review, the nature of which depends on the significance of the data. Private parties who feel affected by a release may challenge the agency and, if successful, force withdrawal of information that does not meet certain quality standards.

Exactly how the IQA and the OMB guidelines apply as a strictly legal matter to release of various types of food safety information remains to be seen as implementation of this relatively new law unfolds. Some of the thresholds and flexibilities provided in the OMB guidelines would likely shield many routine disclosures of food safety information, such as recall information, from the more time-consuming IQA procedures. Moreover, major risk assessments for which IQA peer review might be required would ordinarily be put through some appropriate peer review anyway.

Nevertheless, the IQA adds another procedural requirement that agencies must address as they consider any significant release of food safety information and another reason for caution in sharing such information. We heard anecdotal concerns that the IQA might deter agencies from seeking data from external sources, such as other agencies or sources, since they would not be as able to verify that the data were developed and reported in accordance with the applicable data quality standards. This result would run directly counter to the need for much wider sharing of information to improve food safety.

During our project workshops, many experts expressed concern about the impact of the IQA on the flow of food safety information. These concerns should be addressed so that the legitimate interest in ensuring information quality does not unnecessarily hinder the ability of agencies to obtain and share information needed to ensure food safety.

The Paperwork Reduction Act (PRA)—The PRA[56] regulates the paperwork burdens federal agencies can impose on the public and affects the ability of food safety agencies to obtain information from the food industry. Under this law, agencies must obtain approval from OMB for surveys or other broad solicitations of information and, to get approval, must demonstrate the information cannot

54 Consolidated Appropriations Act, 2001 (H.R. 4577) (Pub.L. 106-554)

55 OMB, "Issuance of OMB's 'Final Information Quality Bulletin for Peer Review' (December 4, 2004)(http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf) (last viewed 4/16/08).

56 44 U.S.C. 3501 et seq.

be obtained in other, less burdensome ways. As a result, for example, if FDA or USDA wanted to survey companies in a segment of the industry concerning current best practices for controlling a particular hazard, it would have to obtain OMB approval through a process that agency staff consider overly onerous and a strong disincentive to even considering such surveys. The criteria used by OMB to determine whether or not a survey is a "burden" are not well defined, so the denial by OMB of a survey to collect critical information to inform federal food safety decisions can appear arbitrary.

Agency Culture and Established Practices

Beyond the very concrete constraints on data sharing imposed by legislative mandates, scarcity of resources, and legal requirements, there are some more subtle constraints that arise as a product of what might be termed agency "culture."

One category of cultural constraints relate to a sense agencies sometimes have of information "ownership." This arises in different ways at different agencies. In general, agencies, laboratories and individuals responsible for generating or collecting data have a tendency to feel they own the information, or at least should be able to control it, due to the amount of time, labor and money they expended to gather it. They may hesitate to give up control of what they perceive as theirs, though in reality the data is publicly owned, and it may clearly be in the public's interest for it to be shared openly.

The sense of ownership and efforts to closely control information are of course influenced by some of the privacy, FOIA and other legal requirements cited earlier, and the legitimate interest agency workers have in not violating those requirements. The generators of information are also understandably concerned that it could be misinterpreted or misused by those who either do not understand the data and its limitations or who have an agenda to use the data in ways the generator of the data would consider unjustified.

Moreover, regulatory agencies, such as FDA, collect much of their food safety information, such as observations of conditions and practices in a food processing plant or microbial test data, in connection with regulatory inspections that have the potential to lead to enforcement action. In those cases, the agency is entitled to withhold the information under the FOI Act as long as it is part of an "open investigatory file," and the agency has a legitimate interest in controlling the data in order to protect a possible enforcement case.

In some agencies, notably CDC, a sense of data "ownership" comes from a professional culture that rewards agency staff for publishing research results in peer reviewed journal articles. In the case of food safety epidemiology, the data at issue are typically surveillance data, such as compilations of outbreak data submitted by states or data generated through FoodNet. CDC compiles these data at the national level and regularly reports summary results. CDC scientists also tap this rich body of data to generate more detailed analyses and research articles. The professional rewards associated with academic publishing create an incentive for CDC staff not to release the more detailed data until they have time to prepare and publish articles based on it. While it is in everyone's interest for agencies to publish analyses of data that are of the highest scientific quality and can pass the muster of the peer review process, timeliness of access to information generated with public funds is important as well.

It is important to note that the interest in journal publication is by no means the only reason that CDC is historically slow in making available detailed food safety epidemiology data. Externally imposed legal requirements, scarce funding and many competing priorities for CDC staff time are

also important factors. CDC also deserves credit for its plans to pursue more rapid and in-depth access to its repository of foodborne outbreak data (eFORS).

For all agencies with information of potential value to others in the food safety system, however, the only effective counter to a sense of information ownership that impedes sharing is a new culture of public ownership. The presumption should be that information generated with public resources is properly in the public domain and should be available on a timely basis and in a useful form to those who can utilize the information to help ensure food safety. There will still be legitimate factors, like privacy concerns, that properly limit disclosure, but the presumption should be that the information belongs and should be made available to the public.

Food Industry Constraints on Information Sharing

Over the past 15 years or so, the food industry has dramatically increased the amount of food safety information it generates. This includes the much greater use of microbial testing as a process control and verification tool, as well as the gathering of information about environmental risk factors, improved production practices and process controls, and intervention efficacy. This information may be valuable not only to the firms that generate it but also to others throughout the food safety system. As with information collected by government, however, there are a number of obstacles to industry sharing its information.

Unlike publicly funded information collected by the government, information collected by private firms or trade associations is private and proprietary and does not "belong" to the public. While it can be argued that it may have important public health benefits to the extent the information enables government to make better decisions and allows consumers to make more informed choices, there is no inherent right of anyone other than these firms to use the information. Rather, there is an inherent right of the owners of information to use the data as they see fit. The costs of information collection are significant, and firms want to get as much value for their investment as possible, while minimizing their costs, which may mean keeping the information private.

There may be a number of possible business, public relations, regulatory and liability reasons why a company would want to keep information private. First, detailed information on a company's food safety systems or product-specific data generated by those systems may be deemed to have value for the company's competitors, who might use the information to improve the quality and effectiveness of their own operations. This would be particularly true if one company had invested in proprietary food safety technology and wanted to protect that investment in a very competitive marketplace. In some sectors, however, such as the beef industry, leading companies have recognized they have a mutual interest in ensuring all companies in the sector produce safe food to maintain public confidence. As a result, they have declared food safety a "non-competitive" issue and actively share information within the industry.

Companies might also be concerned that information they generate will be misinterpreted or misused in a public relations setting, advertently or inadvertently, if it is shared with others. As discussed earlier, the way in which information is collected may limit its utility or meaning when taken out of context or used for other purposes, such as where targeted sampling and microbial testing is misconstrued as representative of overall conditions in a plant. Once such data becomes public, however, the risk it will be used or conveyed in a way the company would consider misleading is real and beyond the company's control. For example, a researcher might use the data in a risk assessment and report

the results in a way that might trouble the original owner of the data, or a news reporter might report isolated results or summary statistics without understanding how to interpret the information.

Companies might be concerned about how a regulatory agency will use information that the company shares voluntarily. Specifically, companies might worry that their information will be used for what the company might consider a punitive enforcement purpose rather than for a broader purpose, such as to make better decisions down the road, to focus efforts towards the biggest problems, or to aggregate their information with that of other companies.

Similarly, a company might be concerned that information from their operation would be used in lawsuits filed on behalf of victims of foodborne illness and that misconstrued information might result in frivolous lawsuits based on false connections between an outbreak and, for example, sampling data.

These reasons for keeping information private can readily add up to a situation in which a company sees the various forms of potential costs exceeding any possible gain from sharing. To improve sharing of private information, efforts would be needed to decrease the risks and to increase the benefits for companies. One approach to reducing downside risks is to use a third party to aggregate information across companies and remove company or plant identifiable information. Creating positive incentives for companies to voluntarily share food safety information, beyond the knowledge they may be helping the system as a whole, may be more difficult. The clearer the benefit to food safety of sharing particular information, however, the more likely companies will be to cooperate.

Academic Constraints on Information Sharing

The academic research community is an important part of the FSII, as a generator of basic knowledge relevant to understanding food safety hazards and possible interventions, and a resource for meeting specific government and industry information needs. Like government and industry, academia has its own interests and established practices that inhibit timely and complete access to the information researchers generate.

The academic norm of publishing research results in peer reviewed scientific journals plays an important role in validating research and providing permanent and proper archiving of results. It also is the chief means of measuring an individual researcher's productivity and reputation.

As discussed in Section Three, journal articles typically include the researcher's analysis and conclusions based on data the researcher or others have generated. Academic researchers are rewarded professionally for providing novel analyses or reaching new conclusions, not for generating datasets. Articles might include, therefore, a brief summary or description of the underlying data, but not incorporate typically large volumes of primary research data, such as microbial test data or detailed measurements of all factors related to assessing an intervention's effectiveness. As a result, large volumes of primary research data generated through academic research are not generally shared in any systematic way with others.

Recently, the academic community and journal editors have recognized that other researchers, analysts and experts may need access to data underlying a journal article to further validate results, perform additional analyses, or compare to data from other studies. Some journals now allow authors to upload electronic appendices, including datasets, to their online versions which serve as accessible

repositories of data. This is a positive step, though tying data access to journal publication has inherent limitations that affect not only the timeliness of access to underlying data but also to the researcher's analysis and findings.

One such limitation is the generally slow nature of journal publication. Delays can be caused by a number of parties in the system, including journal and publisher staff, editors, reviewers or even authors themselves. In all, the peer review process may delay publication for a year or longer, particularly when one considers the impacts of rejections and requests to "revise and resubmit," which further delay publication. While the process is an important check on the quality of research, it puts potentially important data and results out of reach for extended periods in often fast-moving fields of research. Research that was cutting edge when it began may be outdated or impractical by the time it is published. This is particularly true for "practical" research on industry practices. One complaint from industry is that they see a large number of publications evaluating aspects of processes they no longer use.

Another limitation is caused by "publication bias," wherein research is rewarded less for its potential utility than for how "novel" it is. A study that generates potentially large amounts of useful data but has not yet produced findings that editors or reviewers find novel may not find a publishing outlet at all, with the data typically remaining unavailable to other researchers. Negative results are generally difficult to publish, but may be very valuable to those attempting to understand the risks across the system.

Even when published, journal articles and any accompanying data may be difficult or expensive to obtain, especially for those outside of academia. There are increasing numbers of scientific journals, and more and more journals are being published by for-profit publishers. This has increased the costs of journals, and even many university and college libraries have had to cut back on subscriptions.

In response to the high and increasing costs of journals, and to the difficulties experienced in accessing obscure journals, there has been a growing "open access" movement calling for free online journals to replace costly print journals.[57] A related movement calls for publicly funded research to become more accessible. Under one legislative proposal, eleven federal agencies with extramural research budgets over $100 million would require grant recipients to publish their work, online and free, within six months of publication elsewhere;[58] and NIH recently announced a policy requiring all articles resulting from research funded in whole or in part by NIH to be made available in a free digital archive within 12 months of publication.[59]

While such open access efforts might solve some of the problems of accessibility, they do nothing about the fact there is no systematic approach to ensuring prompt publication of academic research data or otherwise making it accessible on a timely basis to other researchers or analysts in government and industry.

Finally, intellectual property concerns can be a constraint on information sharing by food safety researchers. Researchers whose work could lead to patentable inventions—such as new microbial test methods or intervention technologies—have incentives not to disclose their potential inventions pre-

57 Guerrero, R., and M. Piqueras. 2004. "Open access: A turning point in scientific publication." International Microbiology 7:157-161.

58 Federal Research Public Access Act of 2006 (FRPAA) (S.2695)

59 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html (last viewed 1/28/2008)

maturely. While the patent system serves the legitimate purpose of stimulating innovation by granting inventors the reward of exclusive marketing rights for a period of time, it can have the secondary consequence of slowing the dissemination of information that could have value to others in meeting important social needs, such as ensuring food safety.

Conclusion

The constraints and problems outlined here are considerable and will not be easily overcome. Any progress will be gradual and come only with concerted effort on the part of many parties working in the food safety system. The recommendations in the next step call for such a coordinated effort, confronting the many constraints and problems outlined here, and seeking to leverage many opportunities for improving the FSII.

SECTION FIVE:
RECOMMENDATIONS FOR IMPROVING THE FSII

Introduction

In this concluding section, we offer recommendations for improving the FSII. Our recommendations are based on discussions that took place throughout the FSII project among government, industry, academic and consumer experts, backed up by our own analysis of the FSII and the constraints and opportunities confronting it. Before revealing our recommendations, however, a few general observations are in order.

First, we were struck throughout by the high enthusiasm for working to improve the FSII among key experts in all levels of government, the food industry, academia and the consumer community. This reflects, we believe, the central role that information plays in the day-to-day activity of people working in the food safety system and the reality, as illustrated in Sections Three and Four of this report, that today's FSII falls short of meeting important information needs.

This enthusiasm across a range of experts will be crucial to making significant positive changes to the FSII, but it must be coupled with an appreciation among policymakers, at the agency-head and political level, of information's role in food safety. In this regard, we think it very promising that the recently issued FDA Food Protection Plan and the White House Action Plan for Import Safety both recognize the central role of improved information systems in modernizing the food safety system.[60,61]

60 FDA (Food and Drug Administration). November 2007. Food Protection Plan: An integrated strategy for protecting the nation's food supply. U.S. Department of Health and Human Services, Washington, DC.

61 Interagency Working Group on Import Safety. November 2007. Action Plan for Import Safety: A roadmap for continual improvement. Report to the President. Washington, DC.

Second, the four workshops we convened during this project generated many good ideas for improving the FSII. They ranged from scientific and technological ideas for improving data collection and management to much broader ideas about changing roles and relationships within the FSII to improve data collection, access and sharing. We are grateful to workshop participants because, without their ideas, the project could not have achieved its primary goal of identifying opportunities to improve the FSII.

The recommendations outlined in this section are both a distillation and a synthesis of what we heard in the workshops: a distillation, in that not everything we heard met the tests of broad interest and practical feasibility; and a synthesis, in that we have put the ideas together and developed recommendations that meld multiple ideas, including our own. Thus, while we think that many of the participants in the project will embrace the general direction of our recommendations, and we hope many of the details, they are our recommendations for which no one else need feel responsible.

Finally, one of the core themes emerging from this project is that many of the most important issues needing to be addressed to improve the FSII relate to institutional roles and relationships. At the outset of this project, we expected the recommendations from the project would address a relatively short list of specific, high-priority problems related to information collection, access and sharing that could be solved by bringing the right group of motivated parties to the table to work out details of better ways to operate. Some such ideas did emerge and are included here.

We found, however, that most of the problems in the FSII are systemic or institutional in nature, meaning they are grounded in how the vast network of players in our decentralized food safety system see their roles, what their incentives are to act in particular ways, and the obstacles that exist to acting differently. We believe that lasting solutions must respect and address these institutional realities and must include mechanisms that facilitate diverse institutions working together in new ways.

Our recommendations thus include the establishment of a national FSII policy and program that is intended to provide both "top-down" leadership and catalyst for change in the government's approach to food safety information, as well as "bottom-up" mechanisms for devising and implementing it. We also recommend a number of initiatives intended to respond directly to specific concerns and opportunities for improvement that we heard in the workshops. Some of these are cross-cutting efforts that impact the entire system, while others are more sharply focused. These recommendations are summarized in Box 5.1.

Initiating and maintaining such efforts requires new or shifted resources, but discretionary resources tend to be limited across the food safety system, especially within government. We emphasize throughout our recommendations, therefore, that coverage of costs must be considered for every recommendation we make.

FSII National Policy and Program

One of the most persistent issues that surfaced during the FSII project concerns possible sources of leadership and initiative to improve the FSII. The FSII is composed of many institutions at all levels of government and in the private sector, none of which represents or is responsible for the entire system. As documented in Section Three, therefore, the current state of information collection, access and sharing is the product of many diverse institutions carrying out their particular roles in the food safety

Box 5.1—Summary of Recommendations

FSII National Policy and Program

Legislation (or executive order) to enact a national policy that would:

- Foster coordinated, inter-governmental approaches to collecting food safety information;
- Consider the whole food safety system in information collection activities; and
- Maximize access to and active sharing of food safety information.

Mechanisms to enact the national policy:

- FSII Council
  - Intergovernmental body composed of heads of federal food safety agencies and representatives of state and local food safety agencies
  - Coordinate and implement actions needed to fulfill FSII policy responsibilities
- FSII Stakeholder Forum
  - Administrated by FSII Council, but led by third party, such as NAS
  - No fixed membership, but a tool for convening the food safety community
  - Principle vehicle for dialogue and collaboration to enact improvements to FSII

Priority areas should include:

- Improving collection of and accessibility to public information, including CDC outbreak data, FoodNet data, eLEXNET, and public inspection, enforcement, and recall information;
- Strengthening protocols for information sharing during outbreaks;
- Expanding commissioning of state and local officials by FDA;
- Amending or interpret IQA;
- Making USDA research information systems, such as ARIS, fully public; and
- Working toward standardizing and harmonizing sampling and laboratory procedures

Specific Initiatives to Improve the FSII

1. Create a food safety epidemiology user group, to address:
   - Improving surveillance and analysis to meet stakeholder needs
   - Increasing timeliness and depth of information access
2. Create a "network of networks" to improve interconnectivity of the food safety web
   - Collaborative relationships between Web sites and information owners
   - Standardized summary pages and organized structure for browsing
3. Create database for tracking research and information collection
   - Build on USDA/NAL/FSRIO database to include more research projects and to include additional information collection activities
4. Conduct targeted analyses to identify knowledge and information gaps
   - Utilize database of research to analyze trends
   - Use "systematic reviews" to deeply examine specific knowledge areas
5. Initiate dialogue to prioritize information needs
   - Engage community to identify research priorities
6. Increase access to information and publications resulting from publicly funded food safety research
   - Researchers, publishers, and funders should develop and utilize online data repositories
   - "Open access" to publicly funded research and move to free-and-open model of publication
   - Increase back-catalog of online journals
7. Increase access to industry-generated food safety information
   - Identify specific problem-areas or information needs that industry data could address
   - Develop guidelines or "business rules" to govern information collection and sharing

system but lacking the mandate, incentives or resources to address food safety information issues as a system-wide challenge.

Logically, the responsibility for leadership on improving the FSII should begin at the national level. The federal food safety agencies, including FDA, FSIS, EPA, CDC, ARS and CSREES, all play major roles as generators and users of food safety information, and their policies and practices can affect how information flows throughout the system. There is, however, no federal policy or commitment to better coordinate public information collection and expand access to existing information, and no federal agency has been given the job of improving the FSII. Thus, our first recommendation calls for a national policy and program to improve the FSII.

Congress currently has before it several proposals to reform the nation's food safety system, including modernizing the statutory mandates of FDA and FSIS and unifying the federal program under a single agency. While unifying food safety agencies under a single roof would facilitate improvements in information sharing, this alone would not solve the problem. In today's FSII, problems occur with information sharing among offices of the same agency, and the need for improvement extends well beyond federal agencies to include state and local agencies, industry, academia and consumers. Improvements to the FSII are thus necessary regardless of how or when the unification issue is resolved, and we should not wait to take action.

For this reason, our recommendations take the basic structure of the federal food safety system as it is, though most of the recommendations would remain just as relevant, perhaps with some modification, if the federal agencies were unified.

While national leadership is essential, it is neither possible nor desirable to change the fundamental character of the FSII as a highly decentralized set of public and private institutions collecting and using information primarily to support their particular roles in the food safety system. Rather, sustainable improvement in the FSII can be achieved only if the federal agencies have the mandate and the mechanisms to work in partnership with state and local governments, the food industry, academia and consumers. We recommend, therefore, legislation establishing the principles and goals of the FSII, creating an inter-governmental FSII Council with prescribed duties, and establishing a FSII Stakeholder Forum to foster collaboration among stakeholders at all levels on the design and implementation of specific improvements.

Finally, while we call for legislation because we believe political commitment and a congressional mandate are needed to bring about sustainable change, we recognize that most of our recommendations for a national policy and program could be implemented through a presidential executive order. In the short run, this may be a more practical mechanism and certainly deserves consideration.

National Policy and the Responsibility of Federal Agencies

The legislation (or executive order) should make it the policy of the federal government and duty of all federal food safety agencies, whether involved in regulation, surveillance, or research, to:

1. Foster coordinated and collaborative approaches to collecting food safety information;
2. Consider the needs of the food safety system as a whole in planning information collection activities; and

3. Maximize access to and active sharing of food safety information among government agencies and with the private sector.

The new policy should reaffirm the presumption that food safety information generated with public resources is in the public domain and should be readily available to those who seek it, while not overriding established protections for private or confidential information.

Mechanisms

The legislation (or executive order) should create two mechanisms to implement the national policy: an inter-governmental FSII Council with prescribed duties and a broad-based FSII Stakeholder Forum to foster collaboration among the many parties in the system on information sharing issues.

FSII Council

The FSII Council would be an inter-governmental body composed of the most senior food safety official of the key federal agencies, including at least FDA, USDA, EPA, CDC and DHS; the heads of key offices and centers within these agencies such as CFSAN, ORA and CVM within FDA and FSIS, ARS and CSREES within USDA; and at least an equal number of representatives of state and local food safety agencies. The Secretary of HHS would appoint representatives of state and local agencies based on nominations from the professional organizations representing state and local officials involved in food safety, such as AFDO, APHL, ASTHO, CSTE, NACCHO, NASDA and NEHA. The Council's chairmanship would rotate annually among the members, but the Council would have a full-time executive director and staff, appointed by the Secretary of HHS in consultation with Council members. The Council staff would include liaisons to the key congressional committees. The Council would have a line item in the HHS budget with an initial authorization in the range of $25 million to fund its own base activities, as outlined below, and catalyze initiatives to improve the FSII. Operational improvements in the FSII at the agency level would require separate and likely more substantial investments.

The primary responsibility of the Council would be to convene, coordinate and perform other functions needed to support the agencies in fulfilling their new responsibilities under the national FSII policy. The Council's specific duties would include:

1. Seeking regular input on information needs from all participants in the food safety system, including agencies at all levels of government, the food industry, the research community and consumers;
2. Prioritizing, planning and coordinating implementation of actions to improve the collection and flow of food safety information;
3. Identifying any legislative or policy changes needed to carry out required actions, including reducing legal or policy obstacles to and providing positive incentives for collaboration and information sharing;
4. Estimating the costs and benefits associated with needed actions; and
5. Reporting annually to Congress and the public on food safety information needs, progress in improving the FSII, and key obstacles to progress.

FSII Stakeholder Forum

While the federal government has both the duty and capacity to drive improvement in the FSII, the active participation of practitioners and experts from state and local government, academia, industry and consumers is necessary to make meaningful progress on many issues. To facilitate this participation, a FSII Stakeholder Forum should be established under the auspices of the FSII Council. This recommendation responds directly to the desire expressed by many participants in our FSII project for an on-going mechanism to make information collection and access more responsive to user needs, and to foster dialogue and collaboration on FSII issues among the public and private participants in the food safety system.

The Forum would have no fixed membership but function, rather, as a tool for convening interested members of the food safety community on both a regular and ad hoc basis. It would be overseen administratively and funded through the Council, but its management would be contracted out to an independent body, such as the National Academy of Sciences.

The Forum would play consultative, information exchange and implementing roles. In its consultative role, it would be a principle vehicle through which the Council would gain input on information needs and priorities for improving the FSII. In its information exchange role, it would provide a setting in which members of the food safety community could discuss common problems and share best practices, including advances in information technology that can facilitate data sharing.

The Forum could also serve as a mechanism for implementation of specific initiatives that require broad dialogue and collaboration, such as deciding when standardization of data collection and reporting methods would be worth the effort, as well as devising standardized approaches that satisfy diverse needs.

Priority Actions of the FSII National Program

Participants in our project workshops made a number of suggestions for improving government practices related to information access and sharing. We recommend that Congress (or the president) direct the FSII Council, in consultation with the FSII Stakeholder Forum, to consider and prioritize the following possible actions:

1. Prompt reporting and deeper access to CDC's outbreak and surveillance data, including online public access to national outbreak data collected via eFORS;
2. Treating FoodNet data as a public resource and making it promptly available and user-friendly to all interested parties in the public and private sectors, limited only by appropriate protection of patient privacy;
3. Expanding participation in eLEXNET by government laboratories, and possibly non-government laboratories as well, and, eventually, creating a means to make the information available online to the public;
4. Creating mechanisms to aggregate, analyze and share among jurisdictions the inspection, enforcement and recall information generated by federal, state and local agencies, including harmonized inspection reporting criteria and searchable online databases; state and local agencies, including harmonized inspection reporting criteria and searchable online databases;

5. Clarifying and strengthening protocols for rapid information sharing in outbreak situations among public agencies, with the food industry and the public, to ensure timely access to information needed to contain outbreaks and prevent future ones;
6. Greatly expanding the commissioning of state and local officials by FDA and other agencies to help foster information access and sharing during illness outbreaks, compliance investigations and other settings;
7. Amending or interpreting the IQA so as not to affect the release of information to other public agencies;
8. Making fully public information concerning research activities performed or funded by federal agencies, in particular USDA's Agriculture Research Information System (ARIS);
9. Standardizing and harmonizing sampling methods and laboratory procedures to enable data and results to be compared; and
10. Generally improving public Web access to publicly generated data-sets.

The FSII Council should report publicly on the value and feasibility of these actions and its plans for pursuing them.

The Difficulty and Sustainability of a New National Policy and Program

We believe a new national policy and program along the lines outlined here are a necessary response to the current state of the FSII and the opportunity we have to better ensure food safety by improving the way the many elements of the FSII work together. Such a policy and program represent a major shift in philosophy and practice, however, and any such major change in the status quo of longstanding government programs is inherently difficult to achieve. It will require high-level commitment, leadership and action by Congress and the executive branch to both drive the policy change and provide the resources needed to implement it. Our hope is that recent events and the clear shortcomings of the current system will provide sufficient motivation for change.

To deliver lasting value, however, any new policy and program must be sustained, which requires continued support from political leaders in Congress and the White House to provide resources. In the case of a new national policy and program for the FSII, sustainability will depend, ultimately, on the success of the program in meeting the information needs of practitioners at all levels of government and in the food industry, the consumer community and academia. If the program succeeds in that regard, the political support needed to sustain it will likely be there. If the program fails to deliver benefits that practitioners value, the program should and likely will be abandoned.

This practical test of sustainability—whether practitioners get better access to the information they need to ensure food safety—should also apply to the specific initiatives that follow.

Specific Initiatives to Increase the Value of Food Safety Information

Participants throughout the food safety system conduct extensive research and collect volumes of information aimed at better understanding hazards and interventions to control them, but the food

safety system is not getting full value from these efforts. In addition to the national FSII policy and program, we recommend seven initiatives that would significantly improve the way information is collected, made accessible and actively shared throughout the system. Any of these initiatives could be implemented and return value regardless of whether the proposed national FSII policy and program goes forward.

The first two recommendations are broad cross-cutting initiatives that would involve and be a benefit to much of the food safety community. The first is the creation of a food safety epidemiology user group by CDC to reflect the critical role of epidemiology data in the efforts of the entire food safety community to understand foodborne illness and its causes and to design effective preventive measures. The second is the creation of a "network of networks" and associated gateway Web site that would provide a convenient and efficient way for interested parties to find and access datasets and other forms of information from sources that are currently dispersed and disconnected.

The remaining five recommendations involve specific institutions within the system and are intended to improve coordination in research and information collection, and to improve access to academic and industry data. As discussed in Section Three, food safety research and information collection are undertaken through a fragmented network of government and private institutions for a wide range of purposes. It would be neither feasible nor desirable to centrally direct all such work, but many participants in our project workshops expressed interest in taking steps to ensure that the whole system gets maximum value from its investment in food safety information.

Moreover, experience has taught that many food safety problems cannot be solved without well-planned research and data collection applied in a concerted way directly to the problem at hand. This need has been demonstrated most recently in the context of produce safety, with the recognized need to better define risk pathways and determine specific control criteria and interventions to ensure safety throughout production and processing. The purpose of the recommendations that follow is to foster the kind of intentional, coordinated research, data collection and analysis required to solve such food safety problems, and to ensure the results of these activities are accessible to all in the community.

Specifically, we recommend the food safety community should, through various institutional mechanisms:

- Create and maintain a database for comprehensive and ongoing tracking of research and information collection;
- Conduct targeted analyses to identify knowledge and data gaps related to specific food safety problems;
- Initiate a dialogue-based process to make more systematic assessments of information needs and to identify research priorities;
- Create mechanisms and provide incentives for the academic community to increase accessibility to research data, particularly when such research is publicly funded; and
- Find collaborative approaches to using industry-generated information to help solve specific food safety problems.

1. Create a Food Safety Epidemiology User Group

CDC should create a Food Safety Epidemiology User Group to ensure publicly funded food safety epidemiology is as demand-driven as possible and of the greatest feasible value to those working to improve food safety. The User Group would include state and local health officials and the entire food safety community, and aim to prioritize the data and analytical needs of the community and ensure information from publicly funded epidemiology is increasingly made accessible in a timely and meaningful manner.

Motivation

The FSII workshops and discussions revealed the exceptional importance placed on outbreak and surveillance data by the entire food safety community, including federal regulatory agencies, state and local agencies, the food industry, consumer advocates and food safety researchers. Epidemiological data and analyses are, or could be, used by these parties for such critical purposes as attributing illnesses to foods, mapping trends in illness, understanding contributing risk factors from farm to fork, identifying and targeting interventions to reduce foodborne illness, and setting priorities for allocating public and private food safety resources.

The unique role and importance of epidemiological information make it essential that the collection of the information be designed to meet the needs of all those who use it and that the information be of high quality and widely accessible in a timely manner. This is difficult because, like other aspects of the FSII, food safety epidemiology is highly decentralized, with states and localities collecting most of the data and most of the data storage and analysis being done by CDC.

CDC works with state and local health officials to define characteristics of illness surveillance and outbreak investigations, and works through CIFOR on specific ways to improve the epidemiological response to outbreaks. Other stakeholders who utilize or might utilize epidemiological data, however, including those in the food industry, academia and consumer organizations, are not regularly engaged in planning surveillance programs or follow-up investigations. In our project workshops, a number of participants expressed interest in closer collaboration on such matters with CDC and its state and local partners.

There is also a perception in the food safety community that data aggregated by CDC is not made available to potential users in a timely fashion or sufficient detail. This perception is particularly strong with respect to the eFORS database of foodborne illness outbreaks, which CDC has expressed interest in making more promptly and fully available. CDC reports results from the FoodNet active surveillance system for foodborne illness more rapidly, through preliminary and finalized annual reports. Some have expressed interest, however, in more timely and deeper access to FoodNet information than is currently available in these reports, so they can rapidly learn as much as possible about how to prevent illness based on the best available information.

One of the clearest messages from the FSII workshops concerned the need for the nation's food safety epidemiology enterprise to be increasingly demand-driven, with all stakeholders more actively engaged in planning the collection, analysis and dissemination of data on foodborne illness and its causes. To their great credit, food safety leaders at CDC and state epidemiologists have participated actively in the FSII project, with CDC leading the discussion at one of the workshops on ways to improve access to CDC data and be more responsive to stakeholder needs. CDC's continued leadership on this issue will be essential to progress. The idea outlined below is intended to support and

advance that leadership by creating a true partnership involving CDC, state and local officials and the broader stakeholder community, and enabling the entire community to share in defining and fulfilling their foodborne disease surveillance, investigation and analytical needs.

Implementation

CDC should take the lead in forming a Food Safety Epidemiology User Group as a vehicle through which the information and analytical needs of the food safety community can be publicly voiced and properly addressed on an ongoing basis and a true partnership developed. Unlike CIFOR or OutbreakNet, this User Group should include representation from parties who are not often "at the table" when it comes to decisions about how surveillance systems are designed and implemented, or how information is shared or disseminated, including food industry firms and trade associations, consumer and victim advocates, food safety researchers and members of numerous offices within FDA and USDA. In addition to these parties, the User Group should also include state and local officials and their national associations, such as AFDO, APHL, ASTHO, CSTE, NACCHO, NASDA and NEHA. Congress should provide CDC with funds to engage a neutral third-party to facilitate discussions and development of recommendations serving the widest possible interests.

The mandate of the User Group would be to address, on a continuing basis, two questions concerning the utility and accessibility of information: (1) How can the collection and analysis of surveillance and outbreak information be improved so the information has greater value to improving food safety?; and (2) How can the timeliness, ease and depth of access to the information be improved?

Examples of issues concerning the utility of information derived from surveillance and investigations that the User Group could address include:

- Whether further pathogens should be added to the existing list covered by FoodNet;
- Which pathogens most require attribution studies in FoodNet;
- Whether and how food vehicles should be standardized in outbreak reporting forms;
- What information should be collected during outbreak investigations;
- What targeted information collection and analysis should be undertaken to support analysis of root causes and design of preventive measures; and
- What analyses CDC should perform on the data it collects.

With regard to improving the accessibility of information, a number of ideas and issues arose during the workshops that could be addressed by the User Group. One frequently raised topic was the need to enhance CDC's current Web-based repository of foodborne outbreak data (eFORS) to make it more complete, easier to use and more timely. Currently, data are published in the form of a large number of separate PDF files of summary "line listings" tables, which require substantial effort to convert into a format amenable to analysis. Further, data are published 15 months after the end of a calendar year, to accommodate state reporting delays and data validation procedures; as a result, an outbreak occurring in January 2007 will not be published as a line listing until March of 2009. Possible improvements to address these and other issues affecting access to outbreak information that the User Group could consider include CDC acting to:

- Publish data in standard tabular formats such as spreadsheets or tab-delimited text files;

- Publish documentation alongside the dataset explaining the data fields and how to properly interpret the information;
- Develop an interface allowing users to search subsets of full datasets, such as all outbreaks for a particular pathogen, from a certain state, or within some range of years;
- Publish all relevant and appropriate data fields collected by CDC, and not just the limited fields in the summary line listings, including data on contributing factors, pathogen subtype, and age and gender information; and
- Publish preliminary data more quickly, perhaps quarterly, until data are finalized.

In addition to convening regularly to address the questions of utility and accessibility of food safety epidemiology data, the User Group could serve as a sounding board when CDC and/or state and local officials are considering changes in their surveillance and investigation activities related to food safety.

2. Create a "Network of Networks" to Improve the Interconnectivity of the Food Safety Web

To increase awareness of food safety information sources and overcome the stove pipe effect of isolated food safety databases, the food safety community should collaborate to create a "network of networks" for food safety information, consisting of a gateway Web site allowing users to browse and search a directory of food safety data collection activities and information sources across all elements of the food safety system. Such a network would maintain the diversity of the current FSII but improve the ability to find relevant information.

Motivation

As discussed in Section Three, food safety information is collected and analyzed by a range of institutions concerned with a wide array of hazards, foods and points on the farm-to-table continuum. These information collection activities tend to have a specific purpose and focus and have resulted in a large number of food safety Web sites and electronic networks operating in isolation from others in the system (see Appendix C).

The stove pipe effect that results is largely an issue of awareness. People can not infer what information is available and how to access it. While the diversity of information sources, perspectives and Web sites is an important strength of the FSII, the lack of awareness and interconnectivity among them is a significant weakness.

The "awareness" issue arose repeatedly during our project workshops as a problem that must be addressed by increasing both human interaction (such as through an FSII Stakeholder Forum) and system interconnectivity, such as through a "network of networks." There was also clear consensus that the current diversity of information sources is both an unavoidable reality and a genuine strength of the food safety system and the FSII. It is therefore preferable to create a hub Web site that links up existing resources rather than attempt to create a single, unified Web site that would serve as a comprehensive information repository, a goal that is neither feasible nor desirable.

Implementation

The "network of networks" for food safety information (hereafter the "FSII Network") would be built upon the central premise of a hub Web site housing a directory of food safety information, collection activities and information sources from all entities of the food safety system, public and private. This Web site would serve as a gateway for browsing and searching, as well as a focal point to link together otherwise disconnected information sources. Key to the success of the FSII Network in improving awareness is for each individual information source or Web site to link back to the hub Web site. Without linking back, those searching for information can only move in one direction (from the gateway to an individual data source) and the network would not sufficiently solve the stove pipe effect of isolated datasets.

Among the key features of the FSII Network are collaborative relationships, standardized summary pages for each connected information source, and an organized structure for browsing.

- *Collaborative Relationships*—Although the technological aspects of the FSII Network are important, its success would depend most fundamentally on building collaborative relationships among key players in the food safety system who share the aspiration of improved interconnectivity, especially the many actors who are currently operating food safety Web sites or managing databases. These actors and other members of the food safety community would have to agree to collaborate in the development of the hub Web site and promote it by placing links on their own Web sites.
- *Standardized Summary Pages*—The hub Web site would include a directory of information sources across the system built upon standardized summary pages for each source. Each summary page could include basic information about each information collection activity that answers the standard "who, what, when, where, why and how" questions about the information source, including a list of relevant publications, and provides information on how to access the information being collected. Direct links to external Web sites would be an essential component of the directory and summaries.
- *Organized Structure for Browsing*—Due to the depth and breadth of information available, the directory should be built around an organized structure that would allow for numerous ways to find the information, such as browsing by institution, type of information, pathogen, place in the farm-to-table continuum, or food product, to name a few. In addition to this organized structure, the directory should allow searching by freeform keywords or "tags."

Because the development and sustainability of the FSII Network depends on buy-in across the food safety community, it must be developed and managed through a broad-based, bottom-up mechanism—such as the FSII Stakeholder Forum—and a widely representative steering committee comprised of actors from across the food safety system. The FSII Network could be explicitly connected to the proposed FSII Stakeholder Forum, with the network Web site serving as the internet home for the Forum; The FSII Network could also be developed independently of the Forum. In any case, some entity must be willing and able to play the catalytic, leadership role and be responsible for ensuring that adequate, sustainable funding is available.

Finally, the possibility of building upon one or more existing Web sites, rather than duplicating the capabilities of existing sites, should be explored. For example, the JIFSAN Web site "FoodRisk.org" and the NAL's Food Safety Information Center (FSIC) Web site already serve as centralized resources

for food safety information, have searchable directory structures that may be amenable, and have been actively engaged on issues involving the food safety information infrastructure.[62,63]

3. Create a Database for Tracking Research and Information Collection

The federal government, acting through the proposed FSII Council and Stakeholder Forum or other suitable mechanism, should develop and maintain a Food Safety Research Tracking System, which would be a Web-accessible and searchable database of past and ongoing food safety research and information collection activities, focused on subjects of current interest to food safety practitioners. The goal is to make it simple for practitioners to learn what information is being collected across the system and what research is underway on a particular topic of interest, whether that research is being performed or funded by the federal government, an individual researcher through a grant from a foundation, or a private company.

The Tracking System should include research and information collection activities related to particular pathogens, foods or commodities, and interventions—information practitioners could use to understand hazards and how to prevent them. The idea is to supplement, not duplicate, indices of published scientific literature. The database would be useful because it would include information about ongoing research prior to publication, which may not appear in the literature until years after the work is completed, plus include information collection activities that are not regularly published in journal articles.

The Tracking System could supplement the recommended FSII Network by providing access to information that might otherwise be unknown to many, or difficult to obtain. It could be linked to, or be a part of, the FSII Network. The proposed database is different from the FSII Network, however; the latter is a gateway designed to ease access to information from existing Web sites and data sources, while the Tracking System includes information not published elsewhere and would, therefore, require an active and ongoing effort to compile information on research and information collection activities.

The Tracking System should build on the significant contribution of the Research Projects Database[64] created and maintained by the National Agricultural Library (NAL). This database contains some 1700 summary notes on research activities, primarily by the federal government. Though updated somewhat regularly, research funded or performed by those outside USDA is quite underrepresented, and routine data collection activities are excluded. Current funding for maintaining the NAL database seems insufficient to make it comprehensive enough to be useful as a reliable tracking system for research activities.

By building awareness and providing access to both completed and ongoing research and data collection activities, the Tracking System would also support analysis of gaps in available data, and influence knowledge and planning for future efforts. Knowledge of past and current research on a particular topic is crucial to identifying the important unanswered questions and avoiding duplication of effort. It can also spur collaboration among researchers who might otherwise pursue efforts in parallel.

62 http://www.foodrisk.org (last viewed 4/12/2008)

63 http://foodsafety.nal.usda.gov/ (last viewed 4/12/2008)

64 http://fsrio.nal.usda.gov/quicksearch.php (last viewed 2/28/08)

The task of building and maintaining the database should be contracted out to an organization with the independence, credibility and technical competence to design and manage it in a way that meets the diverse needs of the community. In doing so, however, the government should make a long-term funding commitment to the database. Certainly, the progress and utility of the project should be evaluated over time, with provision for making changes or terminating it if not successful, but the one-time creation of a database that is not regularly updated would be of limited value.

4. Conduct Targeted Analyses to Identify Knowledge and Information Gaps

One of the primary reasons for creating a database on past, recent and ongoing research and data collection is to support analyses of what is known about particular problems to better inform decisions about the further research and information collection needed to solve the problems. What is known about the hazards and possible interventions associated with leafy greens production, for example, suggests a host of questions about vectors of contamination and effective preventive measures that must be answered through well-targeted research and information collection.

The proposed research database should make it easier for any entity in government, industry or academia to conduct analyses of the state of knowledge and knowledge gaps on key problems. To better inform all participants in the food safety system, however, the federal government, through the FSII Council and Stakeholders Forum or other mechanism, should take the lead in conducting or sponsoring targeted analyses of existing information in the research database. Such analyses might look for trends in research activities, unnecessary overlap in research, and significant research gaps.

These analyses could be supplemented through what are termed "systematic reviews"— targeted in-depth reviews of the published scientific literature—to identify research priorities and data gaps in specific areas.[65] Systematic reviews have the capacity to go deeper than any analysis of overall research activities by looking not only at the subjects of research, but the results. Systematic reviews may identify areas where similar research projects come to different conclusions or by which subtle differences in methods result in significant differences in results, indicating further research may be needed to reduce uncertainties or resolve disparities. As a form of meta-analysis, systematic reviews should use methodological standards to evaluate quality, as have been developed and utilized in the medical community.[66]

5. Initiate Dialogue to Prioritize Information Needs

Through the FSII Council and Stakeholder Forum or other mechanisms, the federal government should drive a continuing community-based and dialogue-oriented process to identify and prioritize the information needs of the food safety system. The proposed database and meta-analyses outlined above would support such a process, but many participants in our project workshops called for active dialogue among diverse stakeholders to better define information needs and priorities among actors in the food safety system.

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65 Denagamage TN, O'Connor AM, Sargeant JM, Rajić A, McKean JD. 2007. "Efficacy of vaccination to reduce salmonella prevalence in live and slaughtered Swine: a systematic review of literature from 1979 to 2007." *Foodborne Pathogens and Disease* 4(4):539-49.

66 Sargeant JA, Torrence ME, Rajić A, O'Connor AM, Williams J. 2006. Methodological quality assessment of review articles evaluating interventions to improve microbial food safety. *Foodborne Pathogens and Disease* 3(4): 447-456.

Such dialogue would help ensure, for example, that government baseline surveys of food contamination are relevant and useful; that the information needed to address the most pressing problems is well defined; and that both government and academic food safety research more effectively meets the needs of food safety practitioners.

It would be neither desirable nor feasible to establish a single, centralized priority list of food safety information needs. The goal should not be to micro-manage research or to seek universal consensus. The food safety system's stakeholders and their goals are too diverse, and research and data collection are likely to remain decentralized to a large degree. It should be possible, however, through an inclusive, continuing dialogue process to build a common understanding from a system-wide perspective of the most significant food safety problems and the information most urgently needed to address particular problems or categories of problems, such as the risks posed by important commodities or pathogens. Such dialogue and understanding would help alter the research and data collection priorities of particular institutions and lead to new opportunities to coordinate and collaborate on research to achieve shared goals.

One approach to achieving such dialogue would be to hold an annual research and data collection conference, bringing representatives of major funding organizations together with representatives of regulatory and public health agencies, private industry, consumers and scientists from the research community. The conference should not be a simple research update with presentations on current and planned work but rather a focused and well-facilitated discussion of research and data collection required to solve current food safety problems, leading as much as possible to agreement on what needs to be done. It would be important to convene the conference annually because the challenges facing the food safety system evolve rapidly, and knowledge generation must evolve with them. An important contribution of such an annual conference is the building of relationships among diverse generators and users of food safety information, which can occur meaningfully only over a period of years.

The ongoing work needed to prepare and conduct this dialogue process should be contracted out by the federal government to a neutral institution with the required scientific credibility and process management skills.

6. Increase Access to Information and Publications Resulting from Publicly Funded Food Safety Research

Data from publicly funded food safety research, including academic research, has potential public health value. They should not be considered the proprietary resource of the researcher, but rather a public resource that should be publicly available on a timely and complete basis, subject to some reasonable protection of the researcher's right to "first publication."

Achieving this will require efforts by researchers, those who fund their work, and those who publish the results. We recommend the following:

The academic and government research community, including individual researchers, should take the initiative to use online data repositories to supplement peer reviewed journal articles as the vehicle for publishing data from food safety research. This could include taking advantage of existing repositories, such as ComBase or FoodRisk.org, and developing new ones.

Public research funding agencies should mandate all peer reviewed journal articles for research that have been funded in full or in part through taxpayer dollars be made freely and publicly available

online within a year of original publication through agency-run repositories. Such a public access policy has recently been instituted at NIH.[67] Congress should require this of other research funding agencies; foundations and other private funders of research should consider similar initiatives.

Public agencies, research foundations and others who fund research and the collection of data should move to ensure complete data resulting from their investments, not just articles, are made available to others once the research projects are completed. One example of such a mandate is provided by genetics journals, most of which require researchers to submit their DNA sequences to NIH's GenBank prior to publication.[68] Funders should consider creating their own Web-based data repositories for their funded projects and should consider mandating and enforcing timelines for the online publication of data associated with research. Such deadlines would encourage researchers to publish their results promptly, to ensure that their articles are published prior to their data being available for others to analyze.

Publishers should make efforts to facilitate and promote greater use of data repositories for datasets associated with published articles, whether these repositories (or online supplements) are hosted in-house or elsewhere. Publishers might also consider making this sort of data publication a condition of article publication. Similarly, publishers should consider alternatives to current practices that would make data available earlier and more broadly without hindering peer review. Such actions might include allowing authors to publish general information online or in other non-peer reviewed publications without invalidating the "first time published" rule of most journals.

Publishers should also work to ensure broader access to articles. For example, they could increase the number of back issues available online to ensure current researchers do not replicate previous work. When possible, journal owners should consider moving toward an "open access" policy, such as is promoted by the non-profit Public Library of Science (PLoS), which publishes six peer reviewed online journals freely and openly accessible to the public.[69] CDC's Emerging Infectious Diseases journal is also publicly available in electronic format free of charge. Any of these changes will of course require alternative funding mechanisms to meet the unavoidable costs of journal publication.

7. Increase Access to Industry-Generated Food Safety Information

The food industry should work with government and academic researchers to identify specific problems whose solutions might be advanced by industry-generated information and find workable means to make such information available in an appropriate form.

Food processing companies and other entities within the food industry generate substantial information on product and environmental contamination, intervention effectiveness, and other topics in the course of managing their production and food safety systems. Such information might also help improve food safety beyond the particular company's operations. Government agencies, for example, might be able to use the information to better understand food safety problems and solutions, support specific policy decisions, ensure risk assessments represent real-world conditions, or aid outbreak

67 http://publicaccess.nih.gov/ (last viewed 4/16/2008)

68 http://www.ncbi.nlm.nih.gov/Genbank/ (last viewed 3/28/2008)

69 http://www.plos.org/ (last viewed 3/28/2008)

investigations. The research community might be able to use the information to pursue questions relevant to the private sector, as well as to the system as a whole.

The workshops identified serious technical and business constraints on the use of such information for purposes other than those for which it was originally collected. These constraints include the fact that diverse methods of collection and laboratory analysis make comparison and aggregation of such information difficult, if not impossible, and the legitimate business interest companies have in protecting proprietary or otherwise sensitive information.

Nevertheless, industry participants in the workshops expressed interest in collaborating with government agencies and academic researchers to identify specific problems for which industry information might be useful in devising solutions and exploring how it could be shared. In addition to addressing one or more specific problems, such collaboration and accompanying dialogue could result in more generalized "business rules" or agreed-upon principles that might govern the collection and access to industry information in the future.

Conclusion

There are no panaceas for the problem of improving the FSII. Our project workshops and other outreach to the food safety community revealed, however, both high interest in the problem and many good ideas to help solve it. We hope the recommendations outlined here do justice to both the problem and possible solutions, and that they help foster change that can make a real difference for food safety.

APPENDIX A:
WORKSHOP AGENDAS AND PARTICIPANT LISTS

The FSII Project convened four workshops to bring the food safety stakeholder community together to identify issues and discuss opportunities for improvement in the food safety information infrastructure. The first three workshops focused on three key sectors of food safety information producers and users—the public sector, the private sector and the research community—while the final workshop focused on the specific mechanisms for sharing or providing access to information. Each workshop was planned collaboratively with relevant cross-sections of the food safety community, who composed the workshop planning committees. CDC was a significant leader in planning the first workshop, while GMA helped organize and convene the second workshop. Researchers from numerous universities helped guide the third workshop, while the fourth was planned by a committee pulled from major food safety information sharing initiatives in government and academia.

This appendix provides the detailed agendas for the following four workshops, as well as a listing of participants who attended them (and their affiliations at the time):*

Workshop 1: *Public Sector Food Safety Data Collection, Access and Sharing*
November 2-3, 2006, Decatur, GA, 51 participants

Workshop 2: *Industry Interests and Issues*
December 13, 2006, Washington, DC, 26 participants

Workshop 3: *The Research Community's Role in Collection, Access and Sharing of Food Safety Information*
February 1, 2007, Baltimore, MD, 24 participants

Workshop 4: *Mechanisms for Improved Food Safety Data Access and Sharing*
March 2, 2007, Washington, DC, 34 participants

* More materials from these workshops are available at http://www.thefsrc.org/FSII/events.htm

Workshop 1: Public Sector Food Safety Data Collection, Access and Sharing

November 2-3, 2006
Decatur, GA

Goals and Agenda

The goals of this workshop are to: (1) foster cross-sector dialogue among public and private stakeholders on their shared interests in improving the food safety information infrastructure (FSII) as it operates in the public sector, (2) develop a deeper understanding of key topics stakeholders have selected as important to improving the FSII, and (3) identify and analyze specific, realistic opportunities to improve the FSII.

The workshop will include about 50 invited participants from federal, state and local government; the food industry; academia and the research community; and the public health and public interest communities. It will be conducted in a roundtable format to promote discussion among all participants.

THURSDAY, NOVEMBER 2

7:30 – 8:30 *Breakfast*
Continental breakfast to be served outside of meeting room

8:30 – 9:00 am *Introduction*
Led by: Mike Taylor, University of Maryland School of Medicine
Michael Batz, University of Maryland School of Medicine
- Welcome and introductions
- Goals of the workshop in relation to the overall FSII project
- Observations on public data collection and access by FSII project staff

9:00 – 10:30 am ***Session 1: Public Health Illness Surveillance: How Can It Better Meet Stakeholder Needs?***
Led by: Chris Braden, Centers for Disease Control and Prevention
Kelly Hise, Centers for Disease Control and Prevention
Elaine Scallan, Centers for Disease Control and Prevention
Rob Tauxe, Centers for Disease Control and Prevention

Using FoodNet, OutbreakNet (including eFORS, the Electronic Foodborne Outbreak Reporting System) and PulseNet as examples to focus the discussion, this session intends to stimulate discussion about how national systems of foodborne illness surveillance can better meet stakeholder needs. It will engage participants in discussion of such questions as:
- What do stakeholders need from the foodborne illness surveillance systems managed by CDC?
- To what extent are stakeholder needs being met?
- How might the different foodborne illness surveillance systems be refined or expanded?

- How might the timeliness and depth of access to foodborne illness surveillance data be improved?
- What are the key constraints (e.g., legal, policy, bureaucratic, resource) on CDC's ability to collect, report and share data from different surveillance systems?
- What are the realistic opportunities to overcome constraints?

10:30 – 10:45 am *Break*

10:45 – 12:00 pm ***Session 1 (Continued): Public Health Illness Surveillance***

12:00 – 1:00 pm *Lunch*

1:00 – 3:00 pm ***Session 2: Frontline Management: Data Needs of State and Local Government***

Led by: Rob Blake, DeKalb County Board of Health, Georgia
Dale Morse, New York State Department of Health

State and local government agencies are on the food safety frontline in detecting and investigating individual cases and outbreaks, preparing for emerging problems (including intentional contamination), and implementing prevention and control measures. This session will explore opportunities to improve their access to the data they need by addressing these questions:

- What do state and local officials see as their key unmet data needs for the detection, investigation, prevention and control of foodborne illnesses, outbreaks, and emerging problems? Who should be responsible for meeting those needs?
- How can the quantity and quality of needed data and timeliness of access be improved?
- Are there needs and opportunities to improve sharing of data among health, regulatory, and agricultural agencies, and related laboratories, at the state and local levels?
- In multi-jurisdictional outbreak situations, what particular obstacles to data access and sharing arise? How can they be overcome?

3:00 – 3:15 pm *Break*

3:15 – 5:00 pm ***Session 3: Regulatory Data: Can It Have Utility for Other Purposes?***

Led by: Paul Allwood, Minnesota Department of Health
Margaret Glavin, Office of Regulatory Affairs, FDA
Loren Lange, Food Safety and Inspection Service, USDA

Federal, state, and local regulatory agencies collect substantial food safety data through their inspection, compliance, and monitoring programs that at least potentially could be useful to other stakeholders. The purpose of this session is to explore whether and how such regulatory data might have broader uses to improve food safety by addressing such questions as:

- What do other public and private stakeholders see as the potential utility of regulatory food safety data for non-regulatory purposes?

- What incentives would regulatory agencies have for sharing such data?
- Given the great diversity in how data are collected among federal, state and local agencies, what efforts or changes in current practice would be needed to make regulatory data useful for other purposes?
- What are the chief constraints (e.g., legal, regulatory, resource) on improving access to and utility of regulatory data for other purposes?
- What are the realistic opportunities or pathways for overcoming those constraints?

FRIDAY, NOVEMBER 3

7:30 – 8:30 *Breakfast*

Continental breakfast to be served outside of meeting room

8:30 – 10:00 am ***Session 4: System-Wide Management: Meeting Data Needs for a Systems Approach to Food Safety***

Led by: Michael Batz, University of Maryland School of Medicine

Risk managers in the public and private sectors seek to understand the causes and opportunities for prevention of foodborne illness on a farm-to-table "systems" basis, whether to better allocate resources, target interventions, or manage supply chains. A systems approach requires data, however, that no one participant in the system may have incentive or capability to generate and share. This session will explore needs and opportunities for improving the public sector role in collection of and access to such data, by considering these questions:

- What are the priority needs of public and private stakeholders for data to support a systems approach to improving food safety?
- In general, what roles and responsibilities is it reasonable to expect federal agencies to undertake in producing and making available food safety data to meet these needs?
- Specifically, what should be the roles and responsibilities of federal agencies in:
- Conducting baseline studies?
- Building public use data sets?
- Maintaining inventories/repositories of relevant data, information, and analysis?
- What is the potential utility of state and local data for "systems" approaches to improving food safety?
- What are the obstacles and opportunities at the state and local level for generating and sharing such data?

10:00 – 10:15 am *Break*

10:15 – 10:30 am ***Discussion of Draft FSII Survey***
Led by: Jan Powell, University of Maryland School of Medicine

10:30 – 12:00 pm ***Session 5: Standardization of Data Collection and Reporting***
Led by: Glenn Morris, University of Maryland School of Medicine

There is wide diversity among agencies at all levels of government in how food safety data are collected and reported, including differences in sampling protocols, testing technology and procedure, pathogen coding and other nomenclature issues, and reporting formats and systems. It is widely recognized that greater standardization in these areas is a foundational step toward improving data access and the utility of data for multiple purposes. The opportunity to make progress in this area will be explored in this session by asking such questions as:

- Why pursue standardization? What are the interests and realistic goals that might be advanced by any such effort?
- What are the highest priority and most realistic opportunities to pursue standardization?
- What institutions should take the lead?
- What are the major constraints? And what are the pathways and opportunities for overcoming them?

12:00 – 1:00 pm *Lunch*

1:00 – 2:30 pm ***Concluding Discussion: Key Opportunities for Improving Public Data Collection, Access and Sharing***
Led by: Mike Taylor, University of Maryland School of Medicine

This concluding discussion will produce an inventory of opportunities for improving the public sector role in the FSII, including "outside the box" ideas for addressing issues and taking advantage of opportunities identified in the workshop and a realistic appraisal of productive next steps.

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Safe Tables Our Priority

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Marin Schweizer
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Mike Taylor
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Ewen Todd
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Michigan State University

Workshop 2: Industry Interests and Issues

December 13, 2006
Washington, DC

Meeting Goals and Agenda

The FSII Workshop on Food Industry Interests and Issues is being organized in collaboration with the Grocery Manufacturers Association (GMA) and will examine the role of the food industry in the food safety information infrastructure. The workshop goals are to:

- Understand how food industry data needs can be better met through interaction within the private sector and among industry, government, and academic institutions; and
- Understand whether and how industry-generated food safety data might be useful to and could be shared with other stakeholders, public and private, to improve food safety.

To facilitate discussion, this invitation-only workshop will be limited to 30 participants, with the majority drawn from the food production, processing, and retail industries, and the balance from government, academia, public health, and consumer organizations.

8:30-9:00	***Introductions and Background*** (led by Craig Henry and Mike Taylor) *Welcome and introductions of participants* Brief background on and status of the FSII project Review of agenda and goals for the workshop
9:00-10:30	***Industry Data Collection, Data Needs, and Perspectives*** (led by Randy Huffman and Jenny Scott) This 90-minute session will include three brief presentations that provide background on food industry data collection and data needs and industry perspectives on opportunities to improve the food safety information infrastructure. • Current practices in food safety data collection, including types and purposes of data collection—Randy Huffman • Food industry data needs and data sources for food safety system management—Dane Bernard • Results of GMA survey of industry perspectives on FSII issues—Jenny Scott
10:30-10:45	*Coffee Break*
10:45- 12:15	***Opportunities to Better Meet Food Industry Data Needs*** (led by Bill Sveum and Tim Freier) This is a discussion session that is intended to elicit ideas from all participants about how food industry data needs can be better met. Questions for discussion include: • What are the food industry's highest priority, unmet food safety data needs?

- What sources or combination of sources—industry, government, or academia—are best suited to meet these needs?
- How specifically could industry data needs be better met through improving practices and interactions involving:
  - Industry colleagues and groups?
  - Government surveillance, research, and regulatory agencies at all levels?
  - Academic researchers and institutions?

12:15-1:15 *Lunch*

1:15-3:00 ***Opportunities for Wider Sharing of Food Industry Data***
(led by Craig Henry and Catherine Woteki)

This discussion is intended to assess whether and under what circumstances industry-generated food safety data could be shared within industry and with other food safety stakeholders for purposes of improving food safety. Questions for discussion include:

- What utility might industry-generated data have for others?
- How is that utility limited by the purpose and manner of the data collection?
- What are the key constraints (technical, legal, regulatory, business, resource, etc.) on industry sharing of food safety data?
- For what purposes and under what conditions might food industry sharing of data be possible?

3:00-3:15 *Coffee Break*

3:15-4:30 ***Synthesis and Possible Next Steps***
(led by Pat Verduin and Mike Taylor)

The purpose of this session is to distill as many concrete ideas as possible for practical steps that could be taken to improve how the food industry interacts with the food safety information infrastructure to improve food safety.

Workshop 2 Participant List

Food Industry

Dane Bernard
Keystone Foods

Scott Burnett
Ecolab

Yuhuan Chen
Grocery Manufacturers Association

Tim Freier
Cargill

Dave Gombas
United Fresh Produce Association

Craig Henry
Grocery Manufacturers Association

Randy Huffman
AMI Foundation

Mike Robach
Cargill

Jenny Scott
Grocery Manufacturers Association

Bill Sveum
Kraft

Katie Swanson
Ecolab

Pat Verduin
Grocery Manufacturers Association

Catherine Woteki
Mars

Consumer

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Government

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Frank Busta
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Mike Doyle
University of Georgia

Mike Taylor
University of Maryland

Workshop 3: Research Community Role in Collection, Access and Sharing of Food Safety Information

February 1, 2007
Baltimore, MD

Meeting Goals and Agenda

This workshop will bring together members of the academic, government, and private sector research community and other stakeholders to discuss the important role of the research community in generating, making accessible, and actively sharing data for the purpose of improving food safety. The goals of the workshop are to: (1) discuss research roles and agenda setting, (2) identify data needs within the research community, (3) discuss issues related to making data generated through research accessible and timely, and (4) identify realistic opportunities to enhance how research data are collected, made accessible, and actively shared to improve food safety.

7:30-8:30 am — *Breakfast*

8:30-9:00 am — *Introduction and Background*
Led by: Mike Taylor, University of Maryland Baltimore (UMB)

- Welcome and introductions of participants
- Brief background on and status of the FSII project
- Review of agenda and goals for the workshop

9:00-10:30 am — *The food safety research agenda: What is the role of the research community in the food safety information infrastructure?*
Led by: Bob Buchanan, Food and Drug Administration
Dave Gombas, United Fresh Produce Association
John Sofos, Colorado State University

The food safety research community is comprised of diverse public and private institutions that necessarily respond to diverse incentives and mandates. The purpose of this session is to review the roles of these institutions, understand how their research priorities and agendas are set, and discuss strengths and weaknesses in how current food safety research contributes to the goal of improving food safety. Three brief presentations will provide background on food safety research in academia, government, and the private sector.

Questions for discussion:

- What are the distinct roles of each research sector in the generation, use and sharing of food safety information?
- How does the agenda for food safety research get set and is there a need for improvement?
- What are the strengths and weaknesses in the current data generating efforts of the research community?

- What are the key constraints on improving the quantity and quality of food safety data generated by the food safety research community?
- What are the key opportunities for improvement?

10:30-10:45 am *Coffee Break*

10:45-12:15 pm *Data needs of the food safety research community*
Led by: Julie Caswell, University of Massachusetts
Jan Singleton, Cooperative State Research, Education and Extension Service/USDA
Chris Wozniak, Cooperative State Research, Education and Extension Service/USDA

Each research sector or institution often needs data generated by other research institutions or non-research generators of food safety data, such as regulatory agencies and the private sector, to fulfill their food safety agenda. This requires an awareness of and ready access to potential data sources. The purpose of this session is to discuss the food safety research community's data needs and whether it is currently getting the data it needs to fulfill its research role.

Questions for discussion:
- What government and private sector data and information are needed by the research community?
- To what extent are the research community's data and information needs currently being met?
- What are the constraints on the research community getting the data and information it needs?
- What are there realistic opportunities to improve the research community's awareness of and access to data collected by the government, other researchers, and the private sector?

12:15-1:15 pm *Lunch*

1:15-3:00 pm *Accessibility and timeliness of data generated by the research community*
Led by: Linda Harris, University of California, Davis
Tim Jones, Tennessee Department of Health
John Sofos, Colorado State University

The purpose of this session is to discuss how food safety information generated by the research community is made available to stakeholders.

Questions for discussion:
- What are the strengths and weaknesses of current approaches to disseminating food safety data generated by the research community?
- What are the constraints for improving the timeliness and accessibility of data generated by the research community?
- What are the opportunities for improving the timeliness of and access to data generated by the research community?

3:00-3:15 pm	*Coffee Break*
3:15-4:30 pm	*Synthesis and Possible Next Steps* Led by: Mike Taylor, UMB Jan Powell, UMB Michael Batz, UMB

The goal of this session is to review critical issues identified by the research community with respect to generation, use and sharing of food safety information, and to create a list of realistic opportunities to enhance the role of research in improving food safety.

Workshop 3 Participant List

Academia and Research

Michael Batz
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Christine Bruhn
University of California, Davis

Julie Caswell
University of Massachusetts

Craig Harris
Michigan State University

Linda Harris
University of California, Davis

Helen Jensen
Iowa State University

Glenn Morris
University of Maryland School of Medicine

Jan Powell
University of Maryland School of Medicine

Mike Taylor
University of Maryland School of Medicine

John Sofos
Colorado State University

Federal Government

Sean Altekruse
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Bob Buchanan
Food and Drug Administration

Loren Lange
Food Safety and Inspection Service/USDA

James Lindsay
Agricultural Research Service/USDA

Jan Singleton
Cooperative State Research, Education and Extension Service/USDA

Tara Smith
National Agricultural Library/ USDA

Chris Wozniak
Cooperative State Research, Education and Extension Service/USDA

State and Local Government

Tim Jones
Tennessee Department of Health

Consumer

Farida Bhuiya
Center for Science in the Public Interest

Donna Rosenbaum
Safe Tables Our Priority (S.T.O.P.)

Industry

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United Fresh Produce Association

Craig Henry
Grocery Manufacturers Association

Marie Latulippe
International Life Sciences Institute North America (ILSI NA)
Jenny Scott
Grocery Manufacturers Association

Workshop 4: Mechanisms for Improved Food Safety Data Access and Sharing

March 2, 2007
Washington, DC

Meeting Goals and Agenda

This small invite-only workshop will bring together members of the food safety community to discuss possible improvements in the means by which food safety information is shared or made accessible. We hope for around 30 participants and presenters, including representatives of federal, state, and local government agencies, the private sector, the research community, and consumers.

The first three workshops in the FSII project focused on the major parties collecting and sharing data—federal, state, and local agencies in the public sector, firms and associations in the private sector, and academics and others in the research community—whereas this workshop will focus on the "mechanisms" that facilitate the sharing of data among these and other parties. The "mechanisms" are often technological in nature, such as data networks or Web sites, but are reliant on agreements and understandings between institutions or organizations that are inherently non-technological.

Thus, the workshop will discuss not only the possibilities and limitations of technological solutions for data sharing, but also the underlying conditions that will work to enable or preclude their development and/or success. The workshop is focused around a small number of concrete examples of current mechanisms to ensure a practical discussion of the issues. The first two sessions of the workshop are focused on discussing aspects of seven mechanisms for information sharing and access. A third session furthers these discussions, while a fourth session focuses on the institutional roles and resource needs with respect to developing and maintaining such mechanisms. The ultimate goal of the workshop is to develop specific, realistic ideas for how information systems and other mechanisms can be further developed to improve data access and information sharing.

7:30 – 8:30 am	*Breakfast*
8:30 – 9:00 am	***Introduction and Background*** ***Welcome and introductions of participants*** ***Brief background on and status of the FSII project*** ***Review of agenda and goals for the workshop***
9:00 – 10:15 am	***Databases and electronic networks: Information systems for improved food safety*** Presentations: *eLEXNET (Electronic Laboratory Exchange Network)* —Ellen Olson, Office of Regulatory Affairs, FDA *eFORS (Electronic Foodborne Outbreak Reporting System)* —Tracy Ayers, Centers for Disease Control and Prevention *ComBase (Combined Database for Food Microbiology) & PMP (Pathogen Modeling Program)* —Vijay Juneja, Agricultural Research Service, USDA

This session will focus on how information systems—such as databases and electronic networks—foster information sharing and access. Put simply, information systems are means for recording, storing, and integrating information in a single place. They may connect different kinds of data, or the same data type collected in different places, by different parties, or over time. The goal of the session is to use three examples to learn some practical lessons applicable to the broader FSII, such as when certain approaches are likely to be useful, and when they may not. Questions to answer about each of the three systems include:

- Why was the system originally created? Who uses it?
- How has the system developed over time?
- What obstacles, problems, or issues have been encountered in the development and subsequent use of the mechanism? How have they been overcome?
- What factors (legal, policy, business, technical, resources, etc) most impacted the development of the system? What factors impact its continued operation?
- How has the system improved the sharing of information? How is this measured?
- What are the incentives for information partners to participate in the system?
- Does the system have restricted access? If so, why, and who has access? What are the benefits, limitations, and obstacles to broader access?
- Have there been any unexpected benefits to the system? Any unexpected downsides?
- How can the system be improved?
- What lessons can be learned from this system that can be broadly applied to the FSII?

10:15 – 10:30 am *Break*

10:30 – 12:00 pm ***Food Safety Web Sites and Listservs: Using the Internet to Share and Disseminate Information***

Presentations:

Foodrisk.org (formerly the JIFSAN Food Safety Risk Analysis Clearinghouse)
—Steven Gendel, Center for Food Safety and Applied Nutrition, FDA

Food Safety Information at the National Agricultural Laboratory
—Yvette Alonso, National Agricultural Library, USDA

International Food Safety Network
—Doug Powell, Kansas State University

FoodSHIELD
—William Krueger, Minnesota Department of Agriculture

This session will focus on the use of Web sites to foster the sharing of and access to information. Whereas the first session will target databases and electronic networks, the purpose here is to discuss the use of the Web in a broader context. Web sites can be used in a number of ways: as repositories for data, as gateways or hubs to track information, to filter news and information related to food safety, or to improve avenues of communication. The goal of the session is to use four examples to learn some practical lessons applicable to the broader FSII, such as when certain approaches are likely to be useful, and when they may not. Questions to answer about each of the four systems include:

- Why was the Web site originally created? Who uses it?
- How has the Web site developed over time?
- What obstacles, problems, or issues have been encountered in the development and subsequent use of the mechanism? How have they been overcome?
- What factors (legal, policy, business, technical, resources, etc) most impacted the development of the Web site? What factors impact its continued operation?
- How has the Web site improved the sharing of information? How is this measured?
- What are the incentives for information partners to participate in the Web site?
- Does the Web site have restricted access? If so, why, and who has access? What are the benefits, limitations, and obstacles to broader access?
- Have there been any unexpected benefits to the Web site? Any unexpected downsides?
- How can the Web site be improved?
- What lessons can be learned from this Web site that can be broadly applied to the FSII?

12:00 – 12:45 pm *Lunch*

12:45 – 1:30 pm ***Discussion: Databases, Electronic Networks, and Food Safety Web Sites***
Led by: Mike Batz

This session is intended to continue the conversations begun in the morning. The goal is to broaden the discussion beyond the seven example mechanisms. Central questions to be discussed in this session include:

- What is the current and potential utility of databases, electronic networks, Web sites, and other information systems for improving food safety?
- What are the key factors (legal, policy, business, technical, resources, etc) limiting the utility of such mechanisms, both inherently and as seen in current practice?
- What does experience to date suggest about how these mechanisms can be more useful in the future?

1:30 – 2:45 pm

Institutional roles and resource needs: Who will build mechanisms, and how will they be funded?

Led by: Mike Taylor

This session will focus on the real challenges of institutional roles and resource constraints in moving forward to improve the food safety information infrastructure. Databases, electronic networks, Web sites, public-use data sets, and other mechanisms may be the technological means by which data are shared, but their success is reliant upon solid agreements between parties, incentives among participants to ensure their active use, and commitments for the resources necessary to develop and maintain them. This is a particularly difficult problem given the number of stakeholders and institutions involved across the public, private, research, and consumer sectors, and the diversity of missions and funding realities among these institutions. Likewise, improvements to the system may be in numerous parties' interest, but it is unclear who can, could, or should take the lead in making improvements, or the roles of other institutions in the process. The central questions for this session are:

- What conditions justify investments in mechanisms for improved data access and sharing?
- What is the likelihood such investments will be cost-effective, and under what conditions?
- With respect to different kinds of data collected by different institutions, what institution(s) should take the lead in developing mechanisms?
- What role can third parties—namely institutions or agencies other than those responsible for data collection—play in improving broader sharing of these data?
- What opportunities and obstacles exist for funding of improvements to the food safety information infrastructure?

2:45 – 3:00 pm

Break

3:00 – 3:45 pm

Synthesis and Next Steps

Led by: Mike Taylor and Mike Batz

The goals of this final session are to (1) identify the most critical issues affecting the use of technological and non-technological mechanisms for food safety data access and sharing, and (2) create a list of realistic opportunities on which further effort may be fruitful.

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APPENDIX B:
TYPES OF FOOD SAFETY INFORMATION

To illustrate the universe of food safety information that is collected and used by the many institutions of the FSII, we have created a two-tier typology, as shown in Table B.1. This typology, which includes 32 specific types of information in eight broad categories, is intended to give a sense of the diversity of information generated through data collection, research and analysis. *The typology does not capture the broader approaches used to convey the information, such as educational outreach or guidance documents, but focuses on the data upon which such efforts are based. Furthermore, it is far from exhaustive and oversimplifies the many methodological approaches and scientific disciplines that underlie an effective food safety system.*

In this appendix, we provide further explanation of the eight broad categories of food safety information—including which institutions tend to gather them–and present descriptions and examples of the 32 more narrowly defined types of information that encompass these categories.

Table B.1—Food Safety Information Typology

Human Health	Illness Surveillance Medical/Clinical Host Factors	Attribution Health Valuation
Measurements of Contamination	Microbial Contamination Chemical Contamination	Other Contamination Contamination of Imports
Indicators of Contamination	Animal Health/Disposition Recalls and Violations	Sanitation and Inspection
Hazard Identification	Pathogen Subtyping Pathogen Biology	Food Toxicology
Modeling	Predictive Microbiology Hazard Characterization	Exposure Assessment Risk Assessments
Trade and Industry	Facilities and Processes Food Safety System Management Traceback Intervention Efficacy	Intervention Costs Economic Impacts International Trade
Consumers and Workers	Food Consumption Consumer & Worker Behavior	Risk Perception/Communication Population and Demographics
Food and Environment	Food Composition & Characteristics	Environmental Characteristics

Human Health

The primary goal of the food safety system is to protect human health. Information on human health outcomes, therefore, is one of the most important categories of information required to ensure food safety. We describe five types of human health information in Table B.2.

Table B.2—Types of Information on Human Health

1. Illness Surveillance	Surveillance of human illnesses, including those from outbreaks or sporadic cases, adverse event reporting data, laboratory-confirmed testing data, patient characteristics (age, gender), basic patient outcomes (hospitalization, death), including underreporting information
2. Medical/Clinical	Details on illness beyond incidence, including percent who have certain conditions, treatment options, etc, such as symptoms, severities, outcomes, durations, drug treatments, etc
3. Host Factors	Characteristics of persons that affect whether or not they may become ill—age, gender, race, diet, immunocompromised (e.g. AIDS), existing medical conditions
4. Attribution	Connecting human illnesses with sources of illness (beyond etiology) such as food vehicles or animal reservoirs (food attribution), contributing factors, location of food preparation and consumption, or other risk factors.
5. Health Valuation	Valuing illness in monetary or HRQL (Health Related Quality of Life) measures. Economic data include medical costs, productivity losses, & willingness-to-pay, while HRQL include QALYs, DALYs, etc

Human data are collected primarily by local and state health departments, through passive or active surveillance and outbreak investigations, with CDC providing support to this data collection and compiling information on a national basis. Follow-up case-control studies by federal agencies or academia provide a further method of increasing the richness of human health information collected after sporadic illnesses or outbreaks. Human health data provide information on the incidence and severity of foodborne illness, attribution of illnesses to particular pathogens and foods, the economic costs of illness and the valuation of health outcomes in dollars or QALYs. Human health information permits both government and private sector risk managers to target their food safety efforts on the most significant illnesses, food vehicles and risk factors. They can also be used to follow disease trends over time, which may help determine the public health efficacy of food safety interventions.

Measurements of Contamination

Of increasing importance to preventive efforts in food safety are measurements of contamination of food, animals, plants, and the near-environment throughout the farm-to-Table Bontinuum. These types of information include testing for microbial, chemical or other hazards in the pre- and post-harvest stages of food processing, in terms of prevalence or levels. Four types of measurements of contamination are shown in Table B.3.

Table B.3—Types of Information on Measurements of Contamination

6. Microbial Contamination	Prevalence or levels (counts) of pathogens measured on live food animals or plants (e.g. measurements taken from flocks of animals, or on the vegetable farm prior to processing), on animals post-slaughter or plants post-harvest (e.g. during processing, packaging, transportation, retail, in the kitchen), or from the environment (e.g. in public water, the air, in animal feed, on processor equipment, on cutting board)
7. Chemical Contamination	Prevalence or levels of chemical residues (antibiotics, pesticides, sulfonamides, etc) on live food animals or plants (e.g. measurements taken from flocks of animals, or on the vegetable farm), animals post-slaughter or plants post-harvest (e.g. processing, packaging, retail, in preparation), or from the environment (e.g. in public water, the air, in animal feed, on processor equipment, on cutting board)
8. Other Contamination	Prevalence or levels on post-slaughter animals or post-harvest plants of contaminants other than pathogens or chemicals, such as naturally occurring contaminants, metals, physical objects, rodent excreta, insect parts, radionuclides, etc.
9. Contamination of imports	Prevalence or levels of pathogens or chemical residues (antibiotics, pesticides, etc) measured on imported food or at point of production or processing in source countries

Contamination data are collected by local, state and federal agencies as a routine part of their inspection and compliance activities, as well as through planned surveys or studies to determine baseline prevalence of pathogens or chemicals in particular foods and measure trends over time. Food producers and processors also collect chemical and microbial contamination data for their own food safety management purposes, to meet regulatory requirements, or satisfy customer requirements and third-party audits. For government, industry and researchers, contamination data are critical to understanding the hazards that must be addressed in particular commodities or production and processing systems, determining changes in prevalence of pathogens or chemicals over time, and assessing the effectiveness of interventions.

Indicators of Contamination

Certain observations made and actions taken by government agencies can serve as indirect indicators or signals of contamination problems, either in combination with or in the absence of direct measurements of contamination made through testing. Three broad types of indicators are shown in Table B.4.

Table B.4—Types of Information on Indicators of Contamination

10. Animal Health/ Disposition	Information on animal illnesses—animal diseases and health issues including reports of when animals are condemned as unfit for human consumption (ante mortem or post mortem).
11. Recalls and Violations	Information on foods recalled due to pathogen or chemical contamination, or data on firm violations of regulatory standards for pathogens or chemical residues
12. Sanitation and Inspection	Combination of environmental data and sanitation behavior throughout food production, processing, storage, and preparation, including retail establishments and restaurants

These indirect indicators provide an additional source of food safety information both government and industry can use to understand potential hazards and plan interventions. For example, animal health and disposition data, which are collected as part of federal meat and poultry slaughter inspection, in addition to observations made during sanitation inspections conducted at retail and in processing establishments, can help identify conditions and practices that may relate to potential food safety problems.

Similarly, it may be possible to learn from information gathered from voluntary food recalls or other violations of regulatory standards. One might be able to draw from these information trends or patterns that can improve understanding of food safety problems and solutions.

Information on process controls (such as time/temperature data) may also serve to indicate a potential hazard, as can "systems" models using predictive microbiology. These types of information are described later.

Hazard Identification

The ability to detect and understand characteristics of foodborne hazards is crucial for both government and industry in designing effective prevention and control measures, and considerable effort is invested by government, industry and academic scientists to develop tools and generate data for this purpose. Three broad types of such tools and information are described in Table B.5.

Table B.5—Types of Information on Hazard Identification

13. Detection Methods	Research into methods for the detection and quantification of pathogens, toxins, and chemical residues on foods, animals, or in environments, including information on test sensitivity and specificity.
14. Pathogen Subtyping	Microbial fingerprinting for detailed identification of isolates, including phenotyping and genotyping: serology, phage typing, PFGE, etc. Method is used in prevalence testing, for source attribution, etc.
15. Pathogen Biology	Understanding pathogen characteristics, namely factors influencing pathogen survival, growth, virulence traits, and emergence (e.g. microbial genetics, microbial ecology, epidemiology), including information on antimicrobial resistance.
16. Food Toxicology	Understanding toxicological makeup of foods, including the factors during production, processing, and preparation of food that influence the generation or elimination of toxins in the consumed product.

Improved detection methods are in demand by both government and industry. The purpose of developing new and improved detection methodologies is to increase the sensitivity (ability to detect small amounts) and specificity (accurately identifying specific chemical or microbial contaminants) of tests, as well as increase the volume of testing a laboratory can conduct (throughput), and decrease the time and expense associated with running tests. Government efforts also focus on standardization of sampling and laboratory methodologies, which allows for the comparison of similarly collected test results obtained by different laboratories.

Molecular fingerprinting of pathogens (i.e., determining pathogen subtypes) is instrumental in outbreak investigations. Investigators may use subtyping of clinical isolates to identify and group the victims of a specific contamination event, especially in national or multi-state outbreak situations, as has been done using PFGE patterns through CDC's PulseNet. When two individuals become ill due to the same specific strain at the same time, it is highly probably that they share a common cause.

Similarly, microbial fingerprinting can be used to confirm the food vehicle when the clinical subtype is the same as the subtype found on a tested food. For certain pathogens and strains, subtyping can be used to identify the animal reservoir for that strain, which can be used in attribution analysis. Subtyping is also important for determining the incidence and prevalence of very specifically identified groups of organisms and tracking them in the environment and within human populations.

The study of pathogen biology is principally carried out by government and academia to provide information on how pathogens cause harm and function and survive in the environment. This information is critical to understanding foodborne hazards. It is used in predictive models used by

industry to manage food safety controls and in risk assessments produced by government to evaluate public health impacts or define performance standards. It is also used in the development of new intervention strategies for both preventing and treating foodborne illness. Chemical toxicity testing and toxicology research are important activities of government, industry and academia and provide information critical to safety assessments of chemicals in food.

Modeling

Increasingly, computer modeling is an important tool for food safety. Risk assessments are used by government to evaluate the predicted public health benefits associated with regulatory policies (such as process performance standards or the allocation of inspection resources). Likewise, industry may use models that incorporate predictive microbiology and information on process controls to manage their systems. We use the generic term "modeling" to encompass the breadth of analyses that can be used to predict hazard behavior in an environment or to assess risk to human health of such hazards. Four broad types of analyses are described in Table B.6.

Table B.6—Types of Information on Modeling

17. Predictive Microbiology	Quantitative modeling of pathogens in various food environments used to estimate bacterial growth, decline, or inactivation under various conditions, namely those relevant to food production, processing, distribution, and storage; based largely upon pathogen biology studies described previously
18. Hazard Characterization	(Dose-Response Modeling) The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food.* May be based upon laboratory or epidemiologic studies.
19. Exposure Assessment	The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food or other sources.* These may be based upon "systems" models that incorporate predictive microbiology, environmental conditions, contamination data, food consumption patterns and other information.
20. Risk Assessment	The qualitative and/or quantitative estimation of the probability of occurrence and severity of known or potential adverse health effects in a given population, based upon hazard identification, hazard characterization, and exposure assessment.*

* Note: This is the definition provided by Codex Alimentarius Commission[70]

Predictive microbiology is used by industry and others to estimate how pathogens may behave in a particular food or processing environment. Such models depend heavily on the types of pathogen biology studies described previously. Examples of predictive models can be found in the ARS Pre-

70 Joint FAO/WHO Food Standards Programme. Codex Alimentarius Commission. Procedural Manual. 12th ed. Rome: Food and Agriculture Organization of the United Nations : World Health Organization, 2001. Available online at: http://www.fao.org/DOCREP/005/Y2200E/y2200e00.htm (Last viewed 3/28/2008).

71 http://portal.arserrc.gov/PMIPHome.aspx (last viewed 3/28/2008)

72 http://www.combase.cc/ (last viewed 3/28/2008)

dictive Microbiology Information Portal (PMIP),[71] which was developed to assist small firms use such information, and the affiliated ComBase, a Web-based tool that is the result of collaboration between ARS and food safety institutes in the United Kingdom and Australia.[72]

The information needed for hazard characterization (dose-response), exposure assessments and risk assessment comes from many sources and is frequently collected for other purposes. It includes the raw data itself, as well as the analyses that build upon these data to create new information.

One major type of modeling information is that resulting from studies that attempt to measure the relationship between exposure to a specified level of a microbial or chemical hazard and the corresponding acute and chronic health outcomes due to this exposure. These dose-response and concentration-response studies are critical to estimating the public health impacts in risk assessments.

Human health data (epidemiology) generated by state and local health departments and CDC is used in modeling, as is information on contamination rates and levels of hazards in foods that has been collected by government regulatory agencies and private firms. Additional types of data used in modeling include pathogen biology, chemical toxicity, food consumption, food composition and environmental characteristics, most of which are generated by government and academic researchers.

These kinds of information are then integrated into analyses to assess exposure to a chemical or microbial hazard and to perform risk assessments using dose-response models. Risk assessments are developed primarily by federal agencies, non-governmental organizations and academic researchers.

Trade and Industry

Information on the food industry and its activities that are important for efforts to ensure food safety range from general information on food production and processing practices to data on HACCP and other food safety management programs, the effectiveness and cost of food safety interventions, and the economic impact of food safety problems and solutions. These types of information relate to systems from food production through to preparation in food service environments. Seven types of information on trade and industry are described in Table B.7.

Table B.7—Types of Information on Trade and Industry

21. Food Safety System Management	Information regarding performance and nature of food safety management practices and systems (e.g. HACCP), including process control data (e.g. temperature control data, pH), as well as information on pathogen transfer (e.g. cross-contamination) throughout the farm-to-Table Bontinuum.
22. Traceback	Information that allows foods found to be contaminated to be traced back through the food system to the farm or processing facility.
23. Intervention Efficacy	Effectiveness of interventions, such as specific new technologies, equipment improvements, process changes, and regulatory actions, as well as unintentional consequences of interventions.
24. Intervention Costs	Direct costs of specific intervention technologies, process changes, or changes to food safety system management.
25. Economic impacts	Direct costs to a firm or firms due to a food safety intervention, as well as analyses of impacts on the economy due to food safety regulations, interventions, management practices, or contamination events (intentional or unintentional), including indirect costs such as market loss.
26 International Trade	Quantities and locations of food imports and exports, and other related information necessary to measure impact of contaminated imports and exports

The food industry, government and academia all collect such information for a wide variety of purposes. The industry collects and uses some types of this information simply for business purposes but also to support their own food safety management systems, though the extent of information collection depends significantly on the industry sector, company size, the commodity in question, and food safety risk. Information on the feasibility, effectiveness and cost of food safety interventions is vital for both public and private purposes and is generated by the industry, government agencies and the academic and scientific research communities. Local, state and federal governments need a wide variety of industry-related information to design, implement and evaluate regulatory and public health programs.

Consumers and Workers

Human behavior is a key component of the food safety system. Consumers, in particular, are both beneficiaries of and participants in efforts to ensure food safety. Information on consumer behaviors and perceptions is important to estimating food safety risks to the population, identifying and evaluating interventions, and ensuring consumers have the knowledge to handle food safely. In addition to consumers, however, information on the behaviors, perceptions and knowledge of food workers throughout the system is important, from food service employees of restaurants and caterers back to those involved in on-farm production. Four types of information on behavior and consumption are shown in Table B.8.

Table B.8—Types of Information on Consumers and Workers

27. Food Consumption	Quantities of food consumed, produced, sold, etc, for different populations and consumption environments (e.g., home vs. restaurant)
28. Consumer & Worker Behavior	Characterizing consumer and food worker activities such as food storage, handling, preparation, etc, as well as consumer sensitivity to price, shopping patterns, and market behavior
29. Risk Perception/ Communication	Characterizing consumer and worker perceptions, preferences, and beliefs about foodborne risks, including food safety knowledge, risk aversion, and research or educational activities communicating risks to consumers.
30. Population and Demographics	Information about population and demographics such as age, gender, race, income, immunocompromised status, etc

For example, information on food consumption patterns and population demographics contribute directly to risk assessment and identification of at-risk populations. Knowledge about consumer practices and perceptions are essential to the development of educational initiatives and risk communication activities aimed at improving consumer food safety practices.

Information in this broad category is collected by government, industry and academia, though, as a general rule, population-level data on consumption patterns and demographics are collected largely by or on behalf of the federal government.

Food and Environment

Information on food characteristics and composition, such as nutrient content, and on environmental characteristics, such as weather, is collected primarily for purposes outside of food safety, but may be used in conjunction with other data to inform an understanding of food safety risks. For example, nutrient content or other aspects of food composition may affect bacterial growth or host susceptibility, and information on flooding may indicate pathways for upstream runoff that can contaminate produce. These two types of food and environment information are shown in Table A-9.

Table B.9—Types of Information on Food and Environment

31. Food Composition and Characteristics	Chemical properties of foods such as nutrients, acidity, water content and other characteristics that may be related to food safety (e.g. characteristics that may mitigate or increase risk)
32. Environmental Characteristics	Measurements of temperature, humidity, pH, etc—may be taken from public environment (i.e., oceans, soil, air) or private environment (i.e., on the farm, in the plant)

APPENDIX C:
MECHANISMS FOR FOOD SAFETY INFORMATION SHARING

This is a basic (and incomplete) listing of existing mechanisms for sharing or accessing food safety information, including current databases, reporting systems, electronic networks, Web sites, information repositories, and other information systems. Most of those listed are national in scope, and many are managed by federal agencies. These mechanisms are organized by the type of information they contain, though many systems have multiple or overlapping functions. This list is not exhaustive.

1. Information Gateways

International Food Safety Network
http://www.foodsafety.ksu.edu/en/
Foodsafe Discussion Group
http://www.foodsafetyweb.info/foodsafe/index.php
FoodSHIELD
http://www.foodshield.org/
FoodRisk.org (formerly the JIFSAN Food Safety Risk Analysis Clearinghouse)
http://www.foodrisk.org
Gateway to Government Food Safety Information
http://www.foodsafety.gov/

2. Directories of Activities

Health and Human Services Data Resources
http://aspe.hhs.gov/datacncl/datadir/
USDA/ARS/NAL/Food Safety Research Information Office (FSRIO) Web site
http://fsrio.nal.usda.gov/index.php
USDA/CSREES Current Research Information System (CRIS)
http://cris.csrees.usda.gov/
USDA/CSREES National Integrated Food Safety Initiative (NIFSI) Accomplishment Reporting System
http://www.idea.iastate.edu/foodsafety/project_directory.asp

3. Microbial Contamination (Food, Plants or Animals)

eLEXNET
https://www.elexnet.com/elex/index.jsp
FERN Methods Repository
Not available online to the public
USDA AMS Microbiological Data Program (MDP)
http://www.ams.usda.gov/science/MPO/Download.htm
USDA FSIS Microbiological Baseline Data
http://www.fsis.usda.gov/Science/Baseline_Data/index.asp
USDA FSIS Microbiological Results of Raw Ground Beef Products Analyzed for ***E. coli*** O157:H7
http://www.fsis.usda.gov/Science/ecoli_o157_summary_tables/index.asp
USDA FSIS *E. coli* O157:H7 Contamination Summary
http://www.fsis.usda.gov/Science/2006_Ecoli_Positive_Results/index.asp
USDA- FSIS *Salmonella* Serotype Analysis
http://www.fsis.usda.gov/Science/Serotypes_Profile_Salmonella_Isolates/index.asp, http://www.fsis.usda.gov/PDF/Serotypes_Profile_Salmonella_Tables_&_Figures.pdf
USDA Microbiological and Residues Contamination Information System (MARCIS)
Not available online
USDA Pathogen Reduction Enforcement Program (PREP)
Not available online
GenBank
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=Nucleotide
NIH- NIAID- National Microbial Pathogen Data Resource Center (NMPDR)
http://www.nmpdr.org/
DHS National Bio-Surveillance Integration System (NBIS)
Not available online

4. Chemical Contamination (Food, Plants or Animals)

eLEXNET
see Microbial Contamination section
FERN Methods Repository
see Microbial Contamination section
The Food Animal Residue Avoidance Databank (FARAD):
http://www.farad.org/
FDA Pesticide Program Residue Monitoring Database
http://www.cfsan.fda.gov/~dms/pesrpts.html
FAO and WHO's Acrylamide in Food Network
http://www.acrylamide-food.org/
NERL Human Exposure Database System (HEDS)
Not available online to the public
USDA/FDA National Residue Program
http://www.fsis.usda.gov/Science/2003_Red_Book/index.asp
FDA FEEDCON
Not available online
USDA NASS Agricultural Chemical Use Database
http://www.pestmanagement.info/nass/

USDA Pesticide Data Program (PDP)
http://www.ams.usda.gov/science/pdp/Download.htm
Pesticide Recordkeeping Program
Not available online
EPA Pesticide Fate Database
http://cfpub.epa.gov/pfate/home.cfm
EPA National Pesticide Information Retrieval System
http://aboutnpirs.ceris.purdue.edu/
EPA Pesticide Products Database
http://ppis.ceris.purdue.edu/htbin/ppisprod.com
EPA EXtension TOXicology NETwork (ETOXNET)
http://extoxnet.orst.edu/
CDC ATSDR Toxicological Profiles
http://www.atsdr.cdc.gov/toxpro2.html
GMA Database on Pesticide Residues and Food Consumption
Not available online
FDA-CSFAN Total Diet Study
http://www.cfsan.fda.gov/~comm/tds-toc.html
EFSA Database on Polycyclic Aromatic Hydrocarbons (PAH)
http://www.efsa.europa.eu/en/science/data_collection/pah.html

5. Pathogen Characteristics and Predictive Microbiology

ComBase (Combined Database for Predictive Microbiology)
http://www.combase.cc/
National Antimicrobial Resistance Monitoring System- Enteric Bacteria (NARMS)
http://www.fda.gov/cvm/narms_pg.html
http://www.cdc.gov/narms/
http://www.ars.usda.gov/Main/docs.htm?docid=6750

6. Public Health Surveillance

CDC Healthy People 2010
http://wonder.cdc.gov/data2010/focus.htm
CDC FoodNet
http://www.cdc.gov/foodnet/
CDC PulseNet
http://www.cdc.gov/pulsenet/index.htm
CDC Electronic Foodborne Outbreak Reporting System (eFORS)
http://www.cdc.gov/foodborneoutbreaks/us_outb.htm
CDC Foodborne Outbreak Response and Surveillance Unit Web site
http://www.cdc.gov/foodborneoutbreaks/index.htm
CDC Laboratory Information Tracking and Reporting System (LITS)
http://www.cdc.gov/ncidod/dbmd/litsplus/default.htm
CDC DPDx
http://www.dpd.cdc.gov/dpdx/Default.htm

CDC BioSense[73]
Not available online
CDC National Electronic Telecommunications System for Surveillance (NETSS)
http://www.cdc.gov/epo/dphsi/netss.htm
CDC National Electronic Disease Surveillance System (NEDSS)
http://www.cdc.gov/nedss/
CDC Public Health Laboratory Information System (PHLIS)
http://www.cdc.gov/ncidod/dbmd/phlisdata/default.htm
CDC Epidemic Information Exchange (Epi-X)
http://www.cdc.gov/mmwr/epix/epix.html#ancMenu
CDC Sentinel Counties Study of Viral Hepatitis
Not available online
CDC Viral Hepatitis Surveillance Program
http://www.cdc.gov/ncidod/diseases/hepatitis/resource/index.htm
CDC *Vibrio* Surveillance System
Not available online
CDC Creutzfeldt-Jakob Disease Surveillance System
Not available online; information at http://aspe.hhs.gov/datacncl/datadir/cdc4.htm#cjd
CFSAN Adverse Reaction Monitoring System (ARMS)
Not available online
Center for Science in the Public Interest (CSPI) Outbreak Alert
http://www.cspinet.org/foodsafety/outbreak_report.html
Florida Department of Health EpiCom
https://www.epicomfl.net/
Pennsylvania Electronic Disease Surveillance System PA-NEDSS
http://www.dsf.health.state.pa.us/health/cwp/view.asp?Q=230681
WHO Salm-Surv
http://www.who.int/salmsurv/FAQ1/en/index.html

7. Risk Assessment and Risk Analysis

Foodrisk.org (formerly known as the Food Safety Risk Analysis Clearinghouse)
http://www.foodrisk.org/databases.cfm
Interagency Risk Assessment Committee
http://www.foodrisk.org/IRAC/index.cfm
USDA/FSIS Risk Assessments
http://www.fsis.usda.gov/Science/Risk_Assessments/index.asp
EPA Integrated Risk Information Surveillance System (IRIS)
http://www.epa.gov/iris
Cumulative and Aggregate Risk Evaluation System (CARES)
http://www.infoscientific.com/software_main.htm#cares

73 Sokolow L, Grady N, Walker D, et al. Deciphering data anomalies in BioSense. In: Syndromic surveillance: reports from a national conference, 2004. MMWR 2005;54(Suppl):133--9. Available from: http://www.cdc.gov/mmwr/preview/mmwrhtml/su5401a21.htm (Last viewed 3/28/2008)

8. Food Consumption

NHANES Dietary Survey: What We Eat In America (WWEIA)
http://www.cdc.gov/nchs/about/major/nhanes/faqs.htm
USDA ERS Food Availability
http://www.ers.usda.gov/data/foodconsumption/FoodAvailIndex.htm
EPA/USDA-ARS Food Commodity Intake Database (FCID)
Available on CD ROM
USDA ERS Nutrient Availability
http://www.ers.usda.gov/data/foodconsumption/NutrientAvailIndex.htm
USDA ERS Food Guide Pyramid Servings
http://www.ers.usda.gov/data/foodconsumption/FoodGuideIndex.htm

9. Inspections

FDA Bioresearch Monitoring (BIMO) program
State and local restaurant inspection listings
http://www.spiesonline.net/restaurant-inspection.shtml
State Web site examples
Florida restaurant disciplinary activity reports
http://www.myflorida.com/dbpr/hr/rdars/index.shtml
South Carolina restaurant scores
http://www.scdhec.net/health/envhlth/food_protection/scores.htm
Tennessee statewide restaurant inspection scores
http://tn.state.gegov.com/tennessee/

County Web site examples
DeKalb County, GA, restaurant scores (requires registration)
http://atlanta.digitalhealthdepartment.com/dekalb/
King County (Seattle), WA searchable database of restaurant inspections
http://www.decadeonline.com/main.phtml?agency=skc
Washoe County (Reno), NV searchable database of restaurant inspections
http://www.rgj.com/rails/inspections/

City and locality Web site examples
Austin, TX, restaurant inspection scores
http://www.ci.austin.tx.us/health/restaurant/search.cfm
Boston, MA, searchable database of restaurant inspections
http://www.cityofboston.gov/isd/health/mfc/search.asp
New York City, NY, restaurant inspection results (requires registration)
http://www.nyc.gov/html/doh/html/rii/index.shtml

USDA FSIS Eligible Foreign Establishment List
http://www.fsis.usda.gov/Regulations_&_Policies/Eligible_Foreign_Establishments/index.asp
National Advisory Committee on Meat and Poultry Inspection Reports
http://www.fsis.usda.gov/Regulations_&_Policies/National_Advisory_Committee_on_Meat_&_Poultry
DHS - Customs and Border Protection Databases
http://www.cbp.gov

10. Recalls, Violations and Advisories

USDA FSIS Recalls
http://www.fsis.usda.gov/Fsis_Recalls/index.asp
Open Federal Case Listings
http://www.fsis.usda.gov/Fsis_Recalls/Open_Federal_Cases/index.asp
USDA FSIS Open Retail Recall Cases
http://www.fsis.usda.gov/Fsis_Recalls/Open_Retail_Recall_Cases/index.asp
USDA FSIS Recall Case Archive
http://www.fsis.usda.gov/Fsis_Recalls/Recall_Case_Archive/index.asp
USDA FSIS The Meat, Poultry and Egg Product Inspection Directory
http://www.fsis.usda.gov/Regulations_&_Policies/Meat_Poultry_Egg_Inspection_Directory
USDA FSIS Residue Violator Alert List
http://www.fsis.usda.gov/PDF/Residue_Violators_List.pdf
FSIS Residue Violation Information System (RVIS)
Not available online
EPA National Listing of Fish Consumption Advisories:
http://epa.gov/waterscience/fish/advisories/index.html

11. Animal Health/Disposition

USDA FSIS Animal Disposition Reporting System
http://www.fsis.usda.gov/Science/Animal_Disposition_Reporting_System/index.asp
USDA- APHIS National Animal Disease Program Surveillance
http://www.aphis.usda.gov/vs/nahps/surveillance/
USDA National Animal Health Laboratory Network
http://www.csrees.usda.gov/nea/ag_biosecurity/in_focus/apb_if_healthlab.html

12. Economics

USDA Economics and Statistics System
http://usda.mannlib.cornell.edu/
University of Connecticut Food Marketing Policy Center (FMPC)
http://www.fmpc.uconn.edu/publications/
USDA-ERS Foodborne Illness Cost Calculator
http://www.ers.usda.gov/Data/FoodBorneIllness/

13. Consumer and Worker Behavior

USDA-ERS Hamburger Doneness and Consumer Preferences
http://www.ers.usda.gov/Data/hamburger/
FDA- CFSAN Health and Diet Survey
http://www.cfsan.fda.gov/~comm/crnutri.html
Audits International/FDA Cold Temperature Evaluation Interactive Database
http://www.foodrisk.org/exclusives/audits/Temperature/index.html

14. Food Safety System Management

USDA-ERS Food Safety Technologies and HACCP Compliance Survey
http://www.ers.usda.gov/Data/HACCPSurvey/
FDA National Seafood HACCP Database
http://www.cfsan.fda.gov/~comm/seaeval2.html
EHNIS – Environmental Health Specialists Network (EHS-Net)/ Environmental Health Specialists Network Information System (EHNIS)
http://www.cdc.gov/nceh/ehs/EHSNet/

15. Agricultural and Food Production Practices

USDA ERS Crop Production Practices
http://www.ers.usda.gov/Data/ARMS/CropOverview.htm
USDA NASS Census of Agriculture
http://www.nass.usda.gov/Census_of_Agriculture/index.asp
USDA NASS Slaughter Totals
http://usda.mannlib.cornell.edu/reports/nassr/livestock/pls-bb/2006/lstk0206.pdf

16. Directories of Publications or Web Sites

The FDA Publications Database
http://www.accessdata.fda.gov/RIS/RISWEB.ISA
National Advisory Committee on Microbiological Criteria for Foods (NACMCF)
http://www.fsis.usda.gov/Regulations_&_Policies/National_Advisory_Committee_on_Microbiological/
NCFST Publications Database
http://www.ncfst.iit.edu/publications/staff_publications.html
NCFST C. Botulinum Bibliography Database
http://www.ncfst.iit.edu/search/search_our_database.html
http://www.ncfst.iit.edu/CBOT/cbotbibl.html
UC Davis WIFSS *E. coli*- Lettuce Research Database
http://wifss.ucdavis.edu/pathogens_toxins.html
Union of Concerned Scientists Genetic Engineering Links
http://www.ucsusa.org/food_and_environment/genetic_engineering/genetic-engineering-links.html
Union of Concerned Scientists Antibiotics and Food Links
http://www.ucsusa.org/food_and_environment/antibiotics_and_food/antibiotic-resistance-links.html

17. Repositories of Standards, Guidelines and Practices

AOAC International Standardized Methods Guidelines
http://www.aoac.org
The Codex Alimentarius
http://www.codexalimentarius.net/web/standard_list.do?lang=en
CIFOR Food Safety Clearinghouse
http://www.cifor.us/clearinghouse/index.cfm
CSTE State Viral Hepatitis Plans
http://www.cste.org/HepatitisPlans/HepatitisPlanspage.htm
The International Portal on Food Safety, Animal and Plant Health
http://www.ipfsaph.org/En/default.jsp

FSRC

The Food Safety Research Consortium is a multidisciplinary collaboration between eight research institutions to improve the U.S. food safety system. The Consortium is developing new analytical approaches to make food safety decision making more science- and risk-based, including tools for allocating resources, setting priorities, and devising interventions.
www.thefsrc.org

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