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The Potential Consequences of Public Release of Food Safety and Inspection Service Establishment-Specific Data

Committee on a Study of Food Safety and Other Consequences of Publishing Establishment-Specific Data

> Board on Agriculture and Natural Resources Division on Earth and Life Studies

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Preface

Public release of establishment-specific data is not a new concept for some federal and state regulatory agencies, but it is new to the Food Safety and Inspection Service (FSIS). Hence, FSIS will need to consider many issues, and it is our hope that this report will be of value as the agency pursues public data release in a manner that promotes transparency and ultimately results in improvements in public health. We suspect that our conclusions will also be relevant to other food-safety agencies as they move down the path of increasing stakeholder engagement through formal data-release programs.

I would like to thank the committee members, whose diverse expertise made for thoughtprovoking discussion. Their commitment to listening to the views of others and drafting a document that was both comprehensive and universally accepted is greatly appreciated. I would also like to thank FSIS personnel, who kept in contact with the committee over the course of deliberations, providing both formal and informal input regarding the structure of their current data systems and their vision for the future, which includes release of establishment-specific data. Likewise, representatives of the meat and poultry industry provided honest discussion with respect to their concerns and suggestions for future public data release.

Thanks also to the staff of the Board on Agriculture and Natural Resources and the Food and Nutrition Board of the National Academies, especially to study directors Camilla Ables and Maria Oria, for keeping the committee on task and coordinating deliberations and document review. Special thanks to Kati Reimer, who planned the meetings and facilitated communications, always with enthusiasm and a smile. Finally, I thank Robin Schoen, whose insights on study protocol helped us to produce a relevant consensus document. In short, whereas the committee provided the brain power, the staff was able to make that into something of value to the scientific and regulatory food-safety community at large. For that, I am deeply grateful.

> Lee-Ann Jaykus, PhD, *Chair* Committee on a Study of Food Safety and Other Consequences of Publishing Establishment-Specific Data

The Potential Consequences of Public Release of Food Safety and Inspection Service Establishment-Specific Data

Acknowledgments

This report has been reviewed in draft form by persons chosen for their diverse perspectives and technical expertise in accordance with procedures approved by the National Research Council Report Review Committee. The purpose of the independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards of objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We thank the following for their review of the report:

Gina R. Bellinger, Food Safety Net Services Dane Bernard, Keystone Foods, LLC Jerry Bowman, Institute of Food Technologists Christine Bruhn, University of California, Davis James Hamilton, Duke University Neal H. Hooker, St. Joseph's University Ian Jenson, Meat & Livestock Australia William Keene, Oregon Public Health Division Barbara Masters, OFW Law Greg Paoli, Risk Sciences International John R. Ruby, JBS USA, LLC

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The review of the report was overseen by Robert Gravani, Cornell University, and Elaine Larson, Columbia University. Appointed by the National Research Council, they were responsible for making certain that an independent examination of the report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of the report rests with the author committee and the institution.

The Potential Consequences of Public Release of Food Safety and Inspection Service Establishment-Specific Data

Abbreviations and Acronyms

AMSAgricultural Marketing ServiceCDCCenters for Disease Control and PreventionCSPICenter for Science in the Public InterestCSVcomma-separated valuesECHOEnforcement and Compliance History OnlineEPAEnvironmental Protection AgencyFDAFood and Drug AdministrationFOIAFreedom of Information ActFOODFoodborne Outbreak Online DatabaseFoodNetFoodborne Diseases Active Surveillance NetworkFSAFood Safety AssessmentFSISFood Safety and Inspection ServiceHACCPHazard Analysis and Critical Control PointHTMLhyper text markup languageIDEAIntegrated Data for Enforcement AnalysisIICsinspectors-in-chargeIOMInstitute of MedicineLADPHLos Angeles Department of Public HealthMSHAMine Safety and Health AdministrationNACMPINational Advisory Committee on Meat and Poultry InspectionNIHNational Institutes of HealthNRnoncompliance recordOMBOffice of Program Evaluation, Enforcement and ReviewOSHAOccupational Safety and Health AdministrationPDFportable document formatPDFportable document formatPDFPosticid Data ProgramPHISPublic Health Information SystemPRPathogen ReductionRFRReportable Food RegistryRTEready-to-eatTRIToxic Release InventoryUSDAUS Department of Agriculture	AERS	Adverse Event Reporting System	
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The Potential Consequences of Public Release of Food Safety and Inspection Service Establishment-Specific Data

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Summary

The Food Safety and Inspection Service (FSIS) is the regulatory agency in the US Department of Agriculture that is responsible for ensuring that meat, poultry, and processed egg products produced domestically or imported into the United States are safe, wholesome, and properly labeled. The agency's mission is carried out by issuing and enforcing food-safety regulations; conducting facility and product inspections, including sampling and testing; responding to foodborne-disease outbreaks; and conducting communication, education, and food-defense activities. FSIS collects a voluminous amount of data in support of its regulatory functions, but the two major types of FSIS data that are currently being considered for public release are sampling and testing data (derived from standard laboratory tests) and inspection and enforcement data (derived from text written by inspectors). Some of those data are already released to the public in aggregated form but not in disaggregated, establishment-specific form.

In recent years, the Obama administration has implemented measures to facilitate openness in government, including the requirement that federal agencies publish information on line and provide public access to information in a timely manner; in a form that can be easily retrieved, downloaded, indexed, and searched with tools that are available on the Internet; and without the need for Freedom of Information Act (FOIA) requests. In response to the directive to post high-quality data, FSIS asked the National Research Council to conduct a study to examine the potential food-safety benefits and other consequences of making establishment-specific data publicly available on the Internet (see Box S-1 for the statement of task).

BOX S-1

Statement of Task

A study committee will examine the potential food-safety benefits and other consequences of making establishment-specific data sets publicly available on the Internet. For each type of establishment-specific data set provided to the committee, the study will:

1. Identify the likely positive and negative impacts or trade-offs of making the data available to the general public, including how factors such as level of aggregation, timing of release, level of completeness, and characterization of the data or context in which the data are presented might affect their utility in improving food safety.

2. Examine potential ways that food-safety benefits and other effects of publicly posting the data might be measured.

The committee will prepare a brief report of its findings.

As part of the information-gathering phase of the study, the Committee on a Study of Food Safety and Other Consequences of Publishing Establishment-Specific Data met with representatives of FSIS; a representative of the US Environmental Protection Agency Toxics Release Program, which has experience in public posting of establishment-specific data; and members of the meat and poultry industries. Although there is some evidence on the effects of release of some types of FSIS data (for example, recalls), the committee's approach to assessing the likely advantages and disadvantages of routine posting of establishment-specific FSIS data was to review evidence of effects based on the experience of other government agencies in releasing such data. The committee also identified general data-release issues that need to be considered and, in light of the unique nature of FSIS data, deliberated on the value of giving the public access to establishment-specific data, with a focus on effects on food safety and public health.

The committee's major findings and conclusions are as follows:

- Public release of regulatory data is motivated by two broad purposes. The first addresses the public's right to know about the actions of government. The second, "targeted transparency", seeks to use information disclosure as a means of achieving specific public-policy objectives. The committee concluded that both those purposes are relevant to the desire of FSIS to release establishment-specific data and that an effective disclosure policy will contribute to increased transparency to stakeholders. In addition, releasing establishment-specific data might also favorably affect public health in ways whose assessment could be contingent on the development of measures specifically designed to evaluate the effects.
- The committee identified several examples in which federal, state, or local agencies release detailed data that are directly linked to the performance of individual facilities or firms or to their products. In many cases, those data originate in regulatory (compliance and enforcement) activities. Three relevant examples are efforts supported by the US Department of Labor (for example, in the Mine Safety and Health Administration), by the US Environmental Protection Agency (for example, in Enforcement and Compliance History Online [ECHO]), and by several state and local public-health departments (for example, through restaurant hygiene and inspection grading). The committee concluded that FSIS would benefit from consultation with those agencies and could build on their effective practices when designing a public-data release program.
- There is a substantial body of literature on the effects of disclosing establishment-specific regulatory information similar to that collected by FSIS. The literature suggests that release of these sorts of data can have important benefits. Through a review of the literature on the experience of other public agencies, the committee identified a number of potential benefits of public release of establishment-specific FSIS data, including providing incentives to protect brand reputation in food safety or to protect or enhance customer base and profitability; allowing downstream users to identify companies whose performance records are below and above the industry average and potentially to create economic pressure to improve food safety; providing better insights into strengths and weaknesses of different processing practices, which could lead to industrywide improvements in food-safety practices; enhancing performance benchmarking; and improving the consistency of inspector performance. The committee concluded that

public release of FSIS establishment-specific data, by themselves or in combination with other privately or publicly available data, could yield valuable insights that go beyond the regulatory uses for which the data were collected.

- The committee concluded that the available evidence of adverse effects of public release of establishment-specific data by other government agencies is insufficient to predict specific problems that would be inherent in the release of establishmentspecific data by FSIS. In the absence of information specific to FSIS, the committee identified a number of costs or unintended consequences that public release of establishment-specific data might have, including the financial commitment associated with designing and maintaining a useful data-disclosure system; the drawing of inappropriate conclusions as a result of misinterpretation of the data, particularly if appropriate context is not provided to users; adverse effects on international trade; revelation of proprietary or confidential information from the data; and adverse effects on inspector performance. Those unintended consequences might adversely affect some stakeholder groups, but other groups might not consider them adverse. For example, although the literature suggests that disclosure of information about the performance of a specific facility has the potential to affect the facility's profitability, it is precisely this possibility that creates an incentive for improved performance, which would constitute a benefit from the perspective of the public.
- On the basis of its review of information and its deliberations, the committee concluded that there are strong arguments supporting public release of establishment-specific FSIS data, especially data that are subject to release under FOIA, unless there is compelling evidence that it is not in the public interest to release them.
- The committee concluded that to maximize its effectiveness and minimize its potential adverse unintended consequences, data disclosure needs to be guided by a carefully designed information-disclosure strategy. The committee also concluded that effective disclosure systems are designed to allow continuous improvement as users gain a better understanding of how the data might be used and as the agency responds to stakeholder input. The disclosure strategy would consider the utility of the data to be released, how to release them (for example, their presentation), and how to ensure that the data are continuously updated and improved. The committee identified some key features of an effective information-disclosure plan, including ensuring the integrity of the data (requiring the development of protocols to ensure that the data are accurate, timely, and likely to be useful before posting); providing precise and appropriate definitions of what is being quantified and adequate documentation of context (to mitigate the potential for misinterpretation of data); providing support for the analysis of the data by users (at a minimum providing the data in machine-readable form to facilitate third-party analysis); and providing precautions to prevent the linking of portions of the data in ways that would allow users to deduce confidential information about particular establishments. For all data types, it is important to seek periodic input from stakeholders (industrial, academic, and consumer) to understand their needs and

concerns. Focus groups targeted to key stakeholders may be an effective means of accomplishing that.

- As part of its charge, the committee examined the issues specific to the public release of two types of FSIS establishment-specific data: sampling and testing data (derived from standard laboratory tests) and inspection and enforcement data (derived from text written by inspectors). In their deliberations, committee members expressed different views about the implications of releasing inspection and enforcement data, which are subjective. A minority noted that minimizing the potential adverse consequences of releasing this type of establishment-specific data would be especially challenging, citing concerns about inspector variability, the potential for misinterpretation of the data, and confidentiality issues. The majority, however, believed strongly that public access to this type of data could help to identify variability in inspector performance and enforcement outcomes and ultimately facilitate more uniform inspection.
- In keeping with the purpose of attaining targeted transparency, public release of establishment-specific data is expected to result in improvement in food-safety efforts on the part of industry and government and ultimately have beneficial public-health outcomes. Although it is not possible to make a direct causal link between public data access and specific food-safety improvements, the committee concluded that measures of other outcomes of public release of establishment-specific data are available and that documenting those outcomes could provide insights into the relationship between data release and food safety. For example, public release of establishment-specific data could result in increased compliance with regulatory requirements, and FSIS could measure this. There are also ways of measuring the extent to which released data are used, for example, number of Web downloads, peer-reviewed reports generated, and policy changes.

1

Background

The Food Safety and Inspection Service (FSIS) is the regulatory agency in the US Department of Agriculture (USDA) that is responsible for ensuring that meat, poultry, and processed egg products produced domestically or imported into the United States are safe, wholesome, and properly labeled. FSIS's legal authority to perform its regulatory function is derived from four food-safety statutes, namely the Federal Meat Inspection Act (1906), the Poultry Products Inspection Act (1957), the Egg Products Inspection Act (1970), and voluntary inspection under the Agricultural Marketing Act (1946). Aside from those acts, executive orders, small-business protection laws, and other guidelines that apply to all federal agencies (FSIS, 2010a) allow FSIS to conduct its food safety-related activities.

The agency's mission is carried out by issuing and enforcing food-safety regulations, conducting facility and product inspections (including sampling and testing), responding to foodborne-disease outbreaks (by requesting the initiation of food recalls and participating in epidemiological investigations), and conducting communication, education, and food-defense activities. FSIS has almost 8,000 front-line employees (inspectors, veterinarians, supervisors, and enforcement investigations and analysis officers) that routinely collect data over the course of their sampling, inspection, and verification activities. Data are collected on all federally regulated processing or slaughter establishments and other facilities that are involved in the supply chain (such as warehouses, transporters, and retail stores).

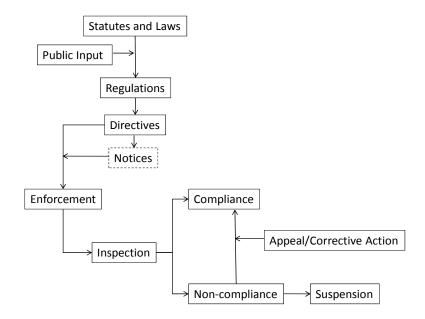
THE FOOD SAFETY AND INSPECTION SERVICE REGULATORY FRAMEWORK

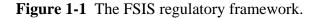
FSIS establishes and enforces regulations that allow it to implement the federal statutes and laws related to food safety. Regulations are created through a process in which the public is given an opportunity to review and comment on a proposed regulation (it is posted in the *Federal Register*). Public comments are then considered by FSIS before it publishes a final regulation (also called a final rule). For each regulation, there is an effective date by which members of the regulated industry must be in compliance. Over the course of time, FSIS issues multiple directives that guide inspection staff as to how to implement a regulation, addressing such issues as the mechanisms of inspection, decision-making, documentation, and enforcement. For a newly emergent problem that is not covered by a regulation, FSIS issues directives and notices whose purpose is to provide an interim means of addressing the problem until a more comprehensive policy can be created (FSIS, 2007).

The statutes underlying FSIS's responsibility for ensuring compliance with federal foodsafety regulations require that FSIS inspection personnel be present on the premises of all facilities that produce meat, poultry, or processed egg products. FSIS inspection personnel must be present at slaughter facilities at all times during their operations. FSIS inspection personnel must be present at processing facilities one time during a day on which meat and poultry products are processed. If an inspector observes noncompliance issues during his or her routine inspection activities, the following enforcement process is followed:

- An inspector-in-charge (IIC) informs the facility of noncompliance with a regulation by issuing a noncompliance report (NR).
- Facility management is notified by the IIC that its products will not be given the "mark of inspection" until inspection personnel can make the determination that the products are not adulterated. Inspection Program Personnel have the authority to retain products at the establishment, or reject equipment for use, until they can make such a determination.
- On a planned basis and when there is an indicated cause, District Offices (DO) assign Enforcement, Investigation, and Analysis Officers (EIAO) to conduct Comprehensive Food Safety Assessments at establishments and document any regulatory or statutory instances of noncompliance found, following which, the DO will initiate appropriate enforcement actions up to the withdrawal of an establishment's grant of inspection.

Every facility is advised to address an NR promptly through corrective or preventive action or submission of an appeal. Failure of a facility to comply with a regulation despite notice and guidance from FSIS can result in the issuance of a notice of suspension that will apply to the entire facility or parts of the facility in question (FSIS, 1998). Figure 1-1 depicts the FSIS regulatory framework.





During the course of inspections and followup enforcement actions, FSIS collects a large volume of food-safety–related data, some of which are available to the public via the Internet. The data are usually posted in an aggregated form (for example, by geographic region, pathogen, or product type), but FSIS is considering providing the public with access to the data in a disaggregated form, that is, establishment-specific data. The present report examines important issues for consideration by FSIS as it deliberates on posting establishment-specific data. A detailed description of the statement of task, the study rationale, and the committee's approach to the study are described in the next sections.

STATEMENT OF TASK

FSIS asked the National Research Council to conduct a study and convene an ad hoc committee to evaluate the effects of making establishment-specific data publicly available on the Internet. The specific statement of task, developed with input from the National Research Council Standing Committee on the Use of Public Health Data in FSIS Food Safety Programs, is as follows:

A study committee will examine the potential food-safety benefits and other consequences of making establishment-specific data sets publicly available on the Internet. For each type of establishment-specific data set provided to the committee, the study will

1. Identify the likely positive and negative impacts or trade-offs of making the data available to the general public, including how factors such as level of aggregation, timing of release, level of completeness, and characterization of the data or context in which the data are presented might affect their utility in improving food safety.

2. Examine potential ways that food-safety benefits and other effects of publicly posting the data might be measured.

The committee will prepare a brief report of its findings.

STUDY RATIONALE

The Obama administration has implemented an administrationwide focus on increasing accountability, accessibility, and transparency. In early 2009, a *Memorandum on Transparency and Open Government*² that expressed the administration's commitment to ensuring public trust in the government through "a system of transparency, public participation, and collaboration" was issued by President Obama. In the same year, a *Memorandum for Heads of Executive Departments and Agencies* was issued by the Office of Management and Budget (OMB). That memorandum included a list of steps to be taken by agencies in support of facilitating openness in government, including the requirement that each agency publish information on line in a timely manner and in a form that can be easily retrieved, downloaded, indexed, and searched with tools available on the Internet; use modern technology to share information that can be used by the public without the need for Freedom of Information Act (FOIA) requests; and post high-value data that have not been previously made available to the public via the Internet or in a downloadable format (see Appendix B for the full text of the OMB memorandum).

As a followup to the 2009 memorandum, President Obama in 2011 issued a *Memorandum on Regulatory Compliance*³ that requires "agencies with broad regulatory compliance and administrative enforcement responsibilities to develop a plan to make public information concerning their regulatory compliance and enforcement activities accessible, downloadable, and searchable online". The 2011 memorandum also stated that data should be made available on a centralized platform, for example, via www.data.gov.

As first steps toward transparency and following the 2011 presidential mandate, agencies and departments have identified select datasets and shared them with the public and have begun to develop their transparency plans. The secretary of USDA has embraced the administration's initiative and has developed an Open Government Web site⁴ and a plan⁵ for implementing President Obama's Open Government Initiative; this plan will be updated as decisions are made on how to implement the open government concept effectively.

²Dated January 21, 2009; published in the Federal Register, Volume 74, No. 15.

³Dated January 18, 2011; published in the Federal Register, Volume 76, No. 14.

⁴See http://www.usda.gov/open (accessed on July 22, 2011).

⁵See

http://www.usda.gov/open/Blog.nsf/dx/USDA_Open_Government_Plan.pdf/\$file/USDA_Open_Government_Plan.pdf (accessed July 22, 2011).

The idea of increased transparency is not completely new to FSIS. Although its mission is regulatory, rather than solely information-gathering, the agency had been making inspection and sampling data publicly available on its Web site⁶ even before the current administration took office. However, as the committee explains in the next chapter, most of the FSIS data provided to the public through the agency's Web site are aggregated (for example, by geographic region, production type, establishment size, and pathogen), and in most cases information for linking data to specific establishments is insufficient.⁷ All of the aggregated and disaggregated data that FSIS collects, with some exceptions (such as corporate proprietary data), can be obtained by the public through FOIA (FSIS, 2010b), but responding to numerous FOIA requests can be time-consuming and expensive for the agency, and initiating a request can be expensive for the requester.

The three memoranda, the creation of www.data.gov and the push to post high-quality data on the Web site, and the constant requests for information through FOIA are the main reasons that FSIS is now considering the feasibility and value of posting establishment-specific data publicly. FSIS first consulted the National Advisory Committee on Meat and Poultry Inspection Subcommittee on Data Collection, Analysis, and Transparency for advice in 2010. That subcommittee was asked to deliberate about which data to share, the primary audiences that might access these data, and the specific periods to include in such data-sharing efforts. In its report, the subcommittee acknowledged that it was unable to address several of the charge questions adequately, given the complexities of the issue and the short turnaround time for issuing its report. Accordingly, the subcommittee recommended that "FSIS obtain guidance from NAS [the National Academy of Sciences], NACMCF [the National Advisory Committee on Microbiological Committee for Foods], or other entities with recognized expertise in data management and analysis to improve data accessibility and usefulness for internal as well as external stakeholders."⁸

THE COMMITTEE'S APPROACH

A 12-member ad hoc committee with expertise in food safety and microbiology, public health, meat and poultry processing, risk assessment, risk communication, statistics, data disclosure, economics, and transparency in governance was convened. The committee met twice (May 11–12 and July 7–8, 2011, in Washington, DC) to gather information and to deliberate on the study topic. At the first meeting, the committee met with representatives of FSIS to obtain background information on the various FSIS regulatory activities and to get clarification of the rationale and scope of the study. At that meeting, the committee also had the opportunity to learn about the US Environmental Protection Agency Toxics Release Inventory Program (as an example of sharing of establishment-specific data with the public), the meat and poultry industry's perspective on the posting of establishment-specific data, and critical issues associated

⁶ See http://www.fsis.usda.gov/Science/Data_Collection_&_Reports/index.asp (accessed May 30, 2011).

⁷It is now widely understood that aggregation does not necessarily prevent identification of individual records. For example, see A. Machanavajjhala, J. Gehrke, D. Kifer, and M. Venkitasubramaniam. l-diversity: Privacy beyond *k*-anonymity. In Proceedings of the 22nd International Conference on Data Engineering Workshops, ICDE, page 24, 2006.

⁸See http://www.fsis.usda.gov/OPPDE/NACMPI/Sep2010/Data_Subcommittee_Final_Report.pdf (accessed June 13, 2011).

with public risk perception and communication. At the second meeting, the committee met again with an FSIS representative to get clarification on FSIS data types.

The committee recognized that the issue of data-sharing is not peculiar to FSIS and that many agencies have formal data-sharing programs in various stages of maturity. Furthermore, there is a body of scientific literature on the potential effects (both beneficial and adverse) of public data access (see Chapter 3). FSIS collects a large volume of data in support of its regulatory functions (see Chapter 2 for details). Those sorts of data can be categorized as related to inspection and enforcement, to sampling and testing, to consumer complaints, and to company or establishment business information. After consultation with the agency, the committee chose to focus most of its deliberations on the first two categories (inspection and enforcement and sampling and testing) because consumer complaint data are sparse whereas company business information is considered proprietary. FSIS also limited the breadth of the study by listing topics that are outside the scope: origin and collection of data, information-technology systems, types of data that merit collection, and legal aspects of posting the data. In addition, FSIS suggested that the committee provide general guidance for decision-making with regard to providing public access to establishment-specific data.

Because there is no information on the effects of the data now posted by FSIS, the general approach taken by the committee was to review evidence of effects on the basis of the experience of other government agencies in releasing establishment-specific data. To the extent possible, pertinent examples of public data-sharing were identified and studied with respect to the basis of their establishment; their target audiences, the means and level of data aggregation and analysis provided for public access, and, in the case of mature programs, the evolution of public data disclosure. The committee also reviewed the evidence on the effects of public release of establishment-specific data and, on the basis of this analysis, drew some conclusions about the potential effects of releasing FSIS data. The committee briefly discussed specific data-release issues with regard to two of FSIS's data categories: sampling and testing data and inspection and enforcement data. Considering the nature of FSIS data, the committee then deliberated on the value of giving the public access to establishment-specific data, focusing on effects on food safety and public health. In this report, the committee shares its findings and conclusions about the benefits and potential adverse unintended consequences of releasing FSIS establishmentspecific data to the public and identifies key issues for consideration in developing a data-release program.

This report is organized into four chapters. Chapter 2 provides an overview of the concept of transparency and a description of relevant FSIS data that might be posted for open access. Chapter 3 describes pertinent examples of public data-sharing (outside FSIS) and the literature on the effects of releasing establishment-specific data. Chapter 4 synthesizes the materials presented in Chapters 2 and 3 and suggests specific issues for consideration by FSIS as it approaches the public release of establishment-specific data.

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FSIS. 2010b. Freedom of Information Act. Available at http://www.fsis.usda.gov/foia/Reading_Room_Index/index.asp). Accessed May 30, 2011 The Potential Consequences of Public Release of Food Safety and Inspection Service Establishment-Specific Data

Transparency and Food Safety and Inspection Service Data-Sharing

TRANSPARENCY AND DISCLOSURE OF DATA

Generally, the release of data like those being contemplated by the Food Safety and Inspection Service (FSIS) is motivated by two broad purposes. The first reflects the principle that public access to information about the activities of government is basic to democratic governance. The Freedom of Information Act (FOIA), enacted in 1966 and amended later, exemplifies the broad aim of transparency and the public's "right to know".⁹ Although the term "right to know" might have various interpretations, the committee uses it as it pertains to the broad public interest in access to information regarding government activities, including its regulatory activities. In this regard, the report is identifying the public interest in providing access to information arising from inspections that can be used broadly by the public for purposes ranging from research by academics to investigative journalism by the media. This is in contrast with the second broad purpose: "targeted transparency" which deals with the release of information to achieve specific outcomes of public benefit (e.g. risk reduction from exposures). As a prime example of targeted transparency, the Bhopal accident led to the passage of the Toxic Release Inventory, which is a disclosure policy directed at the provision of emission information to reduce exposures to potentially dangerous chemicals from manufacturers. In short, this is an example of a response to a public health risk that was addressed through the requirement of disclosure of specific types of information.

Although the vast majority of data collected by FSIS are not made publicly available, some can be accessed through FOIA.¹⁰ FSIS data that *may be* obtained through FOIA requests include the following:

⁹The Freedom of Information Act, Pub. L. 89-487, July 4, 1966, 80 Stat. 250 (codified as amended at 5 USC § 552(b) 2000). See Fung et al. (2007), pp. 25–29, for a discussion of the origins of disclosure policies.

¹⁰Although strictly speaking these data are already available via FOIA, such a change in policy would represent more than a mere increase in the dissemination of disaggregated data. Making this information readily available in a digital format makes it accessible to a far wider set of users and useful for a potentially broader set of purposes. Throughout this report, therefore, the committee uses the term *disclosure* (rather than *dissemination*) in describing the provision of FSIS information via the Internet.

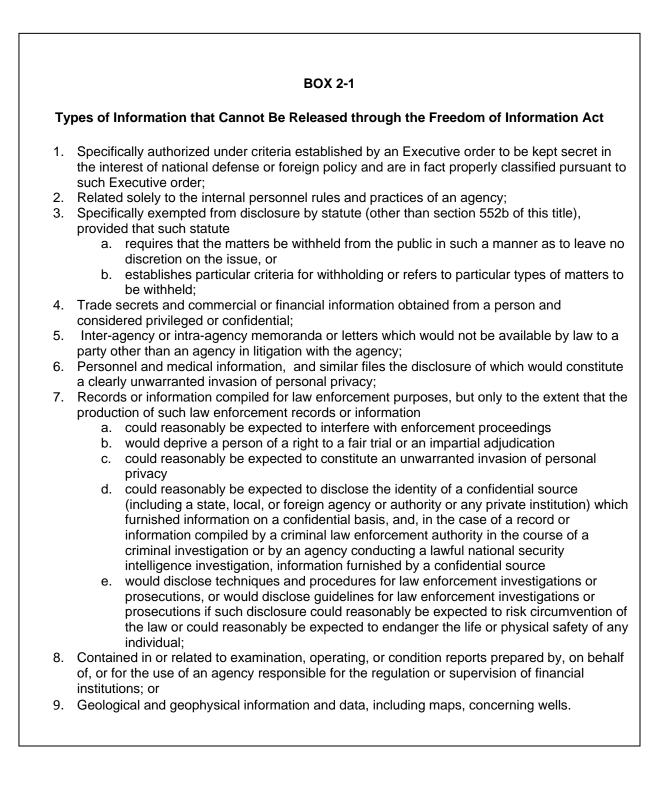
- Microbiological sampling and testing data (for example, testing for *Escherichia coli* O157:H7, *Salmonella* and *Listeria monocytogenes*).
- Residue sampling and testing data (for example, testing for drug, pesticide and other chemical residues).
- Facility-specific noncompliance records (NRs) identified during routine inspection activities.
- Food-safety assessments (FSAs), evaluations of the entirety of a facility's food-safety program, including the nature and source of raw materials, processes, the environment, and all other aspects included under the Hazard Analysis Critical Control Points (HACCP)¹¹ plan.
- Facility-specific HACCP verifications.
- Foodborne-disease outbreak investigation closeout reports.

Depending on the individual circumstance (case by case), portions of the data listed above may be withheld under one or more FOIA exemptions. The specific reasons for denying FOIA requests for data or for not releasing data in their entirety or original form are given in Box 2-1.¹² FSIS has a Web site¹³ that provides FOIA reports annually, disclosing summary information on the number of initial FOIA requests received, their dispositions, and information on appeals of denials of information. The Web site details the number of requests that were denied and their FOIA exemption categories. For example, in 2004 and 2005, the most common reasons for denying FSIS FOIA requests were (in descending frequency) exemptions 6, 4, 7c, and 2 (see Box 2-1).

¹¹HACCP is a system for managing the safety of food through the analysis and control of biologic, chemical, and physical hazards (NRC, 2010).

¹²The Freedom of Information Act 5 USC § 552, As Amended By Public Law 104-231, 110 Stat. 3048. See http://www.justice.gov/oip/foia_updates/Vol_XVII_4/page2.htm (accessed June 18, 2011).

¹³See http://www.fsis.usda.gov/FOIA/2004_FOIA_Report/index.asp (accessed June 20, 2011).



The second broad purpose of information release is to achieve specific public-policy objectives. Such disclosure is a form of "targeted transparency". Lessons can be drawn from a wide variety of targeted-transparency policies that have been enacted in the last 3 decades (Fung et al., 2007). The drivers that make disclosure or transparency effective or not are influenced by the behavior of three sets of actors: the parties disclosing information either voluntarily or because of mandated requirements (usually private businesses), the parties that use the disclosed information (consumers, workers, investors, and academic researchers), and the parties that act as the providers, aggregators, or conduits of information (such as the disclosers themselves, the government, and third-party providers). Whether disclosure will ultimately improve the public outcomes of concern depends in large part on the behavior of those three sets of parties, which in turn depends on the specific problem under consideration.

Fung et al. (2007) describe the critical interactions between users and disclosers as constituting an "action cycle".¹⁴ The action cycle is driven by how embedded the information is in the decision-making processes of users and disclosers. As Figure 2-1 illustrates, the effect of a targeted transparency policy (or information disclosure in general) depends first on how users understand and integrate information into their decisions, which translate into changes in their behavior (such as the products that they buy or the activities that they undertake). Actions taken by users, in turn, have effects if they are perceived and then acted on by the disclosers. That depends heavily on whether disclosers are able to discern changes caused by disclosure and how much those changes alter business performance.¹⁵ Finally, effectiveness is determined by the degree to which changes in discloser behavior or shifting of activities from those whose disclosure is required to others that might have undesirable outcomes).

¹⁴Dranove and Jin (2010) cover similar ground on the drivers of transparency effectiveness but bring in a great deal of additional research (theoretical and empirical) published in the last 3–4 years. Although they classify the drivers of the effects of quality disclosure in somewhat different terms that are rooted in more formal economic theory, they identify similar explanatory factors that affect when disclosure policies (voluntary or mandatory) are most likely to improve social outcomes.

¹⁵This step of the action cycle is in many respects similar to firms' expected response to any form of regulation that is, it is driven by the perceived benefits of responding relative to the costs of doing so. The difference is that behavior change arises from a more complex chain of events under transparency policies than under traditional standards-based regulation. See Levin et al. (2009) for a related discussion.

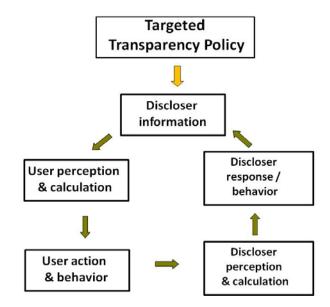


Figure 2-1 Transparency action cycle. Source: Fung et al. (2007).

For transparency policies to be effective in changing regulated actors' behavior in the direction specified by public policies, the empirical research summarized by Fung et al. (2007) and Dranove and Jin (2010) points to a set of stringent conditions regarding how information is presented, interpreted, and incorporated in decision-making. Not surprisingly, many transparency policies fall short in that the various requirements of the action cycle fail to be met, either because of poor policy design or because of the poor fit between the identified policy problem and the use of disclosure as a tool to address it. Disclosure or transparency initiatives must be crafted with a clear understanding of who the users of information are and how they will respond to information; the profile of the disclosers, the markets in which they operate, and their incentives to respond to the provision of more information about them; and the part that the government and other third-party actors may play in providing the information or aggregating it into a form most useful to consumers or other users.

TYPES OF DATA COLLECTED BY THE FOOD SAFETY AND INSPECTION SERVICE

Government agencies can disclose many types of data. For purposes of general overview, the committee identified three general data categories:

Category 1: Data arising from the activities of agencies as part of their normal enforcement and compliance efforts.

Category 2: Data arising from the outcomes of enforcement and compliance efforts that have been interpreted by others for use by end users.

Category 3: Data collected by agencies from voluntary programs that are not associated with normal enforcement and compliance efforts but are nonetheless intended to provide information.

In general, decisions regarding public data release will depend on which data type is at issue. Data are collected by FSIS in association with its mission to monitor the safety of domestic and imported meat, poultry, and processed egg products and in the process of its routine inspection, sampling or testing, and enforcement activities. FSIS uses its data as the basis for determining the effectiveness of its oversight activities, primarily through the implementation of Pathogen Reduction (PR) HACCP programs. In consultation with FSIS, the committee identified two major FSIS data types to be considered for public release:

- Inspection and enforcement data, which are collected by inspectors whenever a facility is in operation. These data are collected to ensure that performance standards are being met and that an establishment is controlling its processes in an appropriate manner. Data in this category include NRs and Food Safety Administrative Actions.
- Analytical data, also called sampling or testing data, which are collected in support of verification and enforcement and include the incidence of key foodborne pathogens—such as *Salmonella*, *E. coli* O157:H7, and *L. monocytogenes*. Data on residue sampling and testing are also in this category (See Box 2-2 for more details on specific FSIS pathogen sampling and testing programs that provide these data).

According to the broad data categories presented above, all the data that FSIS is considering for establishment-specific public access arise from current activities of the agency as parts of its normal enforcement and compliance efforts. That is, the data are being collected as part of FSIS's mandated inspection requirements. The vast majority of data are microbiological. The data are detailed further in Tables 2-1 and 2-2. Tables 2-3 and 2-4 are examples of establishment-specific microbiological data that FSIS is considering for public release.

Note that FSIS is not considering the release of establishment-specific data from baseline studies, which constitute a form of microbiological sampling and testing intended to provide background information to inform future regulations or to evaluate the efficacy of existing regulation. Likewise, release of establishment-specific molecular typing data, which would require collaboration with other food-safety agencies, is not being considered by FSIS. FSIS recognizes that these data types might be considered in the future, but release of establishment-specific data from baseline studies and molecular typing would pose a different set of issues; by agency request, they were considered outside the committee's deliberations.

Box 2-2

FSIS Pathogen Sampling and Testing Programs

Escherichia coli O157:H7 testing program. For regulatory purposes, FSIS initiated a microbiological testing program in 1994 for detecting *E. coli* O157:H7 in raw ground beef. The program's original objective was to stimulate industry testing and other actions to reduce the presence of *E. coli* O157:H7 in raw ground beef. At present, product sampling is among several activities conducted by FSIS for verifying the effectiveness of HACCP systems. *E. coli* O157:H7 is classified as an adulterant by FSIS, so finding it in a food product has specific regulatory consequences. If it is found, the implicated lot of ground beef must be segregated and then sent to a renderer, a landfill, or an establishment that will cook it in compliance with FSIS regulations. Data from this program include results of testing of verification samples and followup samples (taken after a positive finding) taken from federal, retail, and import establishments. Details of the program can be found at

http://www.fsis.usda.gov/Science/Ground_Beef_E.Coli_Testing_Results/index.asp.

Salmonella testing programs. FSIS collects Salmonella data as part of a variety of programs (http://www.fsis.usda.gov/Science/Microbiology/index.asp), including its Salmonella verification testing program for raw meat and poultry and its ready-to-eat meat (RTE) and poultry products testing program. Although also pathogenic, Salmonella, unlike *E. coli* O157:H7, is not classified as an adulterant by FSIS. Therefore, its presence in raw meat does not have lot-specific consequences but is used by FSIS as an indicator of process control. Process control is evaluated by a processing establishment's performance on "Salmonella sets" or a series of Salmonella tests. The level of performance expected on a Salmonella set is determined for different classes of FSIS-regulated products on the basis of the historical performance of the industry related to those classes. Establishments that "pass" their Salmonella sets are viewed as having their process under control; plants that fail are viewed as having processes that are out of control and are placed under a greater degree of regulatory scrutiny with specific consequences, including a review of their HACCP plans.

Listeria monocytogenes testing programs. Unlike *E. coli* O157:H7 and *Salmonella, L. monocytogenes* is an important source of concern not in raw meat and poultry but rather in cooked meat and poultry products that are processed in such a way that its growth is not inhibited. Finished products, food-contact surfaces, and nonfood environments can all be tested for *Listeria*. Since 1983, FSIS has conducted regulatory microbiological testing programs focused on *L. monocytogenes* contamination of RTE meat and poultry products. Those programs have evolved; the most recent iterations include the RTE001 project (implemented in 2005), in which establishments are chosen for sampling based on the different risk factors for *L. monocytogenes* contamination. In 2006, a second project, designated RLm, was initiated on the basis of risk factors referred to as phase 2 of *L. monocytogenes* risk-based sampling. RLm includes sampling of products, products, product-contact surfaces, and environmental surfaces in combination with a comprehensive FSA. More details on the *L. monocytogenes* testing program can be found at

http://www.fsis.usda.gov/Science/Micro_Testing_RTE/index.asp.

USES AND USERS OF FOOD SAFETY AND INSPECTION SERVICE DATA AND DATA-SHARING EFFORTS

Some of the data collected by FSIS in establishment-specific form are already publicly available as HTML or PDF documents accessible on the FSIS Web site.¹⁶ That is the case, for instance, for some data from verification and laboratory testing programs and for quarterly enforcement-report data (see Tables 2-1 and 2-2). However, the vast majority of FSIS data released to the public are in aggregated form. For example, summary data on FSIS slaughter inspections (such as number of head slaughtered and live and dressed weights) are posted by the National Agricultural Statistics Service (NASS) on its Web site.¹⁷ Monthly and annual slaughter-volume data are provided in an aggregated form by class of animal, state, region, or type of facility. Enforcement data are released in aggregated or summarized form in FSIS quarterly enforcement reports. Import and export data collected by other federal agencies can also be found on the FSIS Web site.

Although the data gathered by FSIS from plant inspections and product or environmental testing are used as the basis for ensuring the safety of meat, poultry, and processed egg products that go into general commerce, they serve—or might serve—other public purposes. For instance, the data can be analyzed for trends and anomalies that might indicate current or emerging food-safety problems. FSIS has a Data Analysis and Integration group (DAIG) in the Office of Data Integration and Food Protection.¹⁸ The DAIG's primary role is to "coordinate . . . the Agency's data collection, analysis, and integration activities across all program areas". It is "responsible for evaluating individual FSIS data streams, ensuring data analyses are consistent and of high quality, and conducting data analyses to inform Agency decisions; in addition to processing ad hoc and Freedom of Information Act data requests" (FSIS, 2010c).

The data can also be used in support of food-attribution estimates (estimates of the proportion of cases of particular diseases that are associated with specific food products). Food attribution is one of the objectives of the Foodborne Diseases Active Surveillance Network (FoodNet),¹⁹ a program that involves the Centers for Disease Control and Prevention, 10 state health departments, FSIS, and the US Food and Drug Administration. The US Department of Agriculture (USDA) Agricultural Marketing Service (AMS), which procures meat for various federal food and nutrition programs, uses FSIS data in its vendor-evaluation process to ensure that it contracts only with establishments that can produce or process safe and wholesome products (M. E. O'Connor, USDA AMS, Washington, DC, personal communication, June 2, 2011). The NASS uses data collected through the FSIS Electronic Animal Disposition Report System (eADRS) for estimating total red-meat production in the United States; these data are posted on its Web site. Production estimates for the various classes of livestock are used by USDA and the livestock industry in determining future meat supplies and producer prices. Estimates are also used by agricultural economists in their analysis and research programs (NASS, 2009).

¹⁶See http://www.fsis.usda.gov/science/Data_Collection_&_Reports/index.asp (accessed June 12, 2011).

¹⁷See http://www.nass.usda.gov/Surveys/Guide_to_NASS_Surveys/Livestock_Slaughter/index.asp (accessed June 14, 2011).

¹⁸See http:// www.fsis.usda.gov/about/ODIFP/index.asp (accessed August 17, 2011).

¹⁹See http://www.cdc.gov/foodnet/ (accessed June 20, 2011).

The main users of FSIS data are consumer-advocacy groups, companies and industry associations, the news media, and academics. Individual consumers may not be willing or able to invest the time and effort necessary to analyze FSIS data, but consumer groups or others can perform this function on their behalf and disseminate FSIS data and analyses of data to the public. Consumer-advocacy groups have used FSIS data to educate consumers about the safety of meat and poultry products and to inform public-policy decision-making (see CSPI, 2002; FWW, 2006; FWW, 2010). In most cases reviewed by the committee, the information used for those purposes arose from FOIA requests.

Food processors and retailers could potentially use FSIS data to inform sourcing decisions and to manage risks associated with their supply chains. Industry groups might use them in a similar manner and serve as collective agents in analyzing information for members and potentially for education or even for self-regulation. Companies may seek to use the information to determine how they rank relative to their peers and for competitive advantage.

Both the traditional news media and emerging Internet news organizations (such as ProPublica) may draw on disaggregated data in developing stories about food safety. This source of disaggregated data may be of particular importance given the contraction in the number of traditional local news reporters.

Finally, academic researchers are an important user group. For example, FSIS data obtained through FOIA have been used in peer-reviewed publications (see Nelson, 2009; White and Moore, 2009) and meeting presentations (M. Ellis, University of Illinois, Urbana, IL, personal communication, August 12, 2011). Academicians have perhaps the broadest interest in establishment-specific data, analyzing it in ways to discern patterns, distributions, and data complexity that would not be possible with aggregated data. Such analyses can support risk-assessment efforts, epidemiological attribution, and public-policy decision-making.

THE ROLE OF THE FOOD SAFETY AND INSPECTION SERVICE PUBLIC HEALTH INFORMATION SYSTEM

With so many data being produced daily, it is important for FSIS to have a means of archiving its data, preferably in a form that can be readily updated and is searchable. FSIS has recently embarked on an effort to develop a data analytics system called the Public Health Information System (PHIS) (FSIS, 2010a). The PHIS was created in response to a 2007 recommendation from the USDA Office of the Inspector General for the purpose of improving FSIS's inspection systems and developing an integrated data infrastructure (FSIS, 2010b).

The PHIS was designed to

- Serve as a repository for data gathered from all domestic inspections and import and export inspections.
- Help FSIS to have a consistent, data-driven inspection, auditing, and scheduling system.

- Support predictive analytics by facilitating timely analysis of data from multiple sources, thereby enhancing FSIS's ability to determine trends, patterns, and anomalies for the purpose of identifying emerging food-safety problems.
- Facilitate more effective coordination within FSIS, between FSIS and other federal agencies, and between FSIS and industry to improve investigations and contaminant trace-back activities.

The PHIS is not accessible to the general public. It can currently be accessed by FSIS personnel. FSIS plans to provide access, on a restricted basis, to other federal agencies (only after authorization through a memorandum of understanding) and to private entities that have been granted authorization by FSIS to view data about their own establishments. Data in the PHIS that are accessible to other federal agencies and private establishments may also be obtained by the public through FOIA requests. FSIS was clear that any public data-sharing efforts would not be designed through direct interface with the PHIS but rather that data would be accessible through export to a portal, such as data.gov.

In summary, FSIS releases large amounts of data, usually in aggregated form, in periodic releases or as summaries. The question is whether the benefits of augmenting existing disclosure to include establishment-specific data would outweigh the potential costs.

Table 2-1 FSIS Analytica	al (Samp	Table 2-1 FSIS Analytical (Sampling and Testing) Data That Are Under Consideration for Establishment-Specific Release ^a	nent-Specific Release ^a
Data Type	Desci	Description of Data	Current Status of Public Posting
Results of microbiological	Data	Data include	Data posted only in
testing program for Escherichia coli O157:H7	•	List of positive results on raw ground beef and raw ground beef components tested for <i>E. coli</i> O157:H7 in current year (sample source given, not establishment name)	aggregated form
	•	Results of analysis of raw ground beef and raw ground beef component samples for E . <i>coli</i> O157:H7 and comparison with last year's totals	
	•	Summary of microbiological results on raw ground beef products analyzed for <i>E. coli</i> O157:H7 (summarized by year from 1994 to present)	
Results of RTE meat and	Data	Data include	Data posted only in
poultry testing	•	Percentage positive <i>Salmonella</i> tests of RTE meat and poultry products, 1990–2000, 2001–2002, 2003, 2004, 2005, 2006, 2007 (by product)	aggregated form
	•	Percentage positive <i>L. monocytogenes</i> tests of RTE meat and poultry products, 1990–2000, 2001–2002; 2003, 2004, 2005, 2006, 2007 (by product)	
	•	Percentage positive <i>Salmonella</i> tests of RTE meat and poultry, 2008 (by product type, not establishment-specific)	
	•	Percentage positive <i>L. monocytogenes</i> tests of RTE meat and poultry, 2008 (by product type, not establishment-specific)	
	•	Percentage positive <i>Salmonella</i> tests of RTE meat and poultry, 2009, 2010 (number of positives per number of samples taken; no data on different product types)	

The Potential Consequences of Public Release of Food Safety and Inspection Service Establishment-Specific Data

data on different product types)	f data analysis for The RLm risk-based sampling program covers sampling and testing of Data posted only in <i>isteria</i> products, product-contact surfaces, and environmental surfaces; data include aggregated form	<i>sgenes</i> (RLm) risk- • Incidence and categorization of positive <i>Lm</i> samples from sampled establishments	• Types, sources, and pulsed-field gel electrophoretic subtyping of <i>Lm</i> isolates from positive samples.	• Descriptive summaries with respect to <i>Lm</i> control alternatives used by the establishment, establishment HACCP size, establishment production volume, FSIS district, geographic location of establishment, season or month of sample collection, and trends in percentage of positive results from April 2006 (program inception) through 2008	E Data include	verification • Incidence and categorization of <i>Salmonella</i> -positive samples from aggregated form of all meat and sampled establishments in the two programs	(sampling and • Trends in percentage of positive results in 2005–2008	ogram based on ment risk factors); • Types and sources of positive samples	results on • Serogroups and serotypes of <i>Salmonella</i> isolates from positive samples	• Descriptive summaries with respect to establishment HACCP size, establishment production volumes, <i>Lm</i> control alternatives used by establishment, geographic location of establishment, and month (and season) of sample collection
	Results of data analysis for routine <i>Listeria</i>	monocytogenes (RLm) risk- based sampling program			Analysis of ALLRTE	(random verification sampling of all meat and poultry products) and	RTE001 (sampling and	testing program based on establishment risk factors);	sampling results on Salmonella spp.	

Percentage positive *L. monocytogenes* tests of RTE meat and poultry, 2009, 2010 (number of positives per number of samples taken; no

•

Data posted only in aggregated form	Monthly reporting is establishment-specific; quarterly and annual reports are posted only in aggregated form	Data posted only in aggregated form	Data posted on a per- establishment basis
 Data includes Percentage positive for <i>Salmonella</i> in pasteurized egg products, 1995–2009 (liquid, frozen, or dried egg products) Results of FSIS pasteurized egg products testing program, <i>Salmonella</i> serotypes, 1995–2009 	 Verification that establishments are meeting performance standards for <i>Salmonella</i>: data include Monthly reports for Category 3 young chicken (broiler) establishments; Category 3 establishments are those which have results from most recent completed sample set that exceed the standard for <i>Salmonella</i> in young chickens Quarterly progress report on <i>Salmonella</i> testing of selected raw meat and poultry products (by product class, establishment size, or type of establishment) Annual progress report on <i>Salmonella</i> testing of raw meat and poultry products (by product class, establishment size, or type of establishment) 	Serotype profile of <i>Salmonella</i> isolates from meat and poultry products, annual reports (1998–2010) and quarterly reports	Residue violators repeat list (Part I) contains names of persons or establishments responsible for having more than one residue (drug, pesticide, or other chemical) violation in animals presented at slaughter and tissue, residue, value, and tolerance (to assist FSIS inspection personnel)
Results from microbiological testing program for pasteurized egg products	Results from <i>Salmonella</i> verification testing program for raw meat and poultry	Serotyping of salmonellae from meat and poultry products	Residue violators alert list

	Data posted only in aggregated form	Data not establishment- specific	
Residue violators repeat list (Part II) contains names of producers (listed by state) responsible for having more than one residue (drug, pesticide, or other chemical) violation in animals presented at slaughter (for livestock markets and establishments)	Information gathered through periodic surveys for dioxins, furans, and dioxin- like polychlorinated biphenyls (PCBs); data include toxic equivalent values for dioxins and furans and for dioxin-like PCBs; states where animals were produced are listed for each sample (market hogs, steer or heifer, young chicken, and young turkey)	Sampling plan (number of samples collected), products analyzed in laboratory, and laboratory test results, 2009	
	Dioxin and dioxin-like chemicals in the US domestic meat and poultry supply	FSIS testing results on melamine in retail meat and poultry	^a Years are calendar years.

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Table 2-2 FSIS Inspec	Table 2-2 FSIS Inspection and Enforcement Data That Are Under Consideration for Establishment-Specific Release ^a	ecific Release ^a
Data Type	Description of Data	Current Status of Public Posting
Quarterly enforcement reports (1998–2011)	 Noncompliance records and appeals Port of entry re-inspection Product control actions (condemnations and detentions, food-recall announcements) Notices of prohibited activity (activities not given) Administrative actions (basis of action given) Civil actions (action summary provided) Criminal actions (action summary provided) 	Noncompliance records and appeals; product-control actions are aggregated in quarterly enforcement reports Notices of prohibited activity, administrative actions, civil actions, and criminal actions are all posted in establishment- specific form
Eligible countries, products, and certified establishments	 List of eligible countries and types of meat, poultry, or egg products eligible for export to the United States. List of foreign establishments certified to export meat, poultry, or egg products to United States Foreign audit reports: comprehensive audits of foreign-country inspection systems 	Names of countries and products given Names of eligible establishments given by country Names of audited establishments given by country
FSIS import data ^a Years are calendar years.	Volume of imported meat, poultry, and egg products presented for re-inspection by FSIS at port of entry, 2005–2010	Weight data given by country

The Potential Consequences of Public Release of Food Safety and Inspection Service Establishment-Specific Data

Table 2-3 I	Example of Establi Establishment	ishment-Specific <i>I</i> Establishment	Table 2-3 Example of Establishment-Specific <i>E. coli</i> 0157:H7 Data Under Consideration for Public Posting by FSIS Establishment Establishment Collection Product	ler Consider Sampling	ration for Pu Collect ion	blic Posting Product	g by FSIS	
Form Id	Number	Name ^a	Sample Source Name	Project	Date	Name	Analysis	Result
30000001	MI	Establishment 1	Product-Raw-Ground, Comminuted or Otherwise Nonintact-Beef	MT43	10/21/11 0:00	Ground beef patties	E. coli 0157:H7	Negative
30000002	M2	Establishment 2	Product-Raw-Ground, Comminuted or Otherwise Nonintact-Beef	MT43	10/21/11 0:00	Ground beef	E. coli 0157:H7	Negative
30000003	M3	Establishment 3	Product-Raw-Ground, Comminuted or Otherwise Nonintact-Beef	MT43	10/24/11 0:00	Ground beef	E. coli 0157:H7	Negative
30000004	M4	Establishment 4	Product-Raw-Ground, Comminuted or Otherwise Nonintact-Beef	MT43	10/24/11 0:00	Ground beef	E. coli 0157:H7	Negative
30000005	MS	Establishment 5	Product-Raw-Intact-Beef	MT50	10/24/11 0:00	Beef trimmings	E. coli 0157:H7	Positive
30000006	M6	Establishment 6	Product-Raw-Ground, Comminuted or Otherwise Nonintact-Beef	MT43	10/24/11 0:00	Raw ground beef	E. coli 0157:H7	Positive
30000007	M7	Establishment 7	Product-Raw-Ground, Comminuted or Otherwise Nonintact-Beef	MT43	10/24/11 0:00	Coarse ground beef	E. coli 0157:H7	Negative
30000008	M8	Establishment 8	Product-Raw-Ground, Comminuted or Otherwise Nonintact-Beef	MT43	10/24/11 0:00	Ground beef	E. coli 0157:H7	Negative
30000009	6W	Establishment 9	Product-Raw-Ground, Comminuted or Otherwise Nonintact-Beef	MT43	10/24/11 0:00	Ground beef	E. coli 0157:H7	Negative

30000010	M10	Establishment 10	Product-Raw-Ground, Comminuted or Otherwise Nonintact-Beef	MT43	10/24/11 0:00	Ground beef	E. coli 0157:H7	Negative
30000011	MII	Establishment 11	Product-Raw-Ground, Comminuted or Otherwise Nonintact-Beef	MT43	10/24/11 0:00	Ground beef patties	E. coli 0157:H7	Negative
30000012	M12	Establishment 12	Product-Raw-Intact-Beef	MT50	10/24/11 0:00	Beef trimmings	E. coli 0157:H7	Negative
30000013	M13	Establishment 13	Product-Raw-Ground, Comminuted or Otherwise Nonintact-Beef	MT43	10/24/11 0:00	Ground beef	E. coli 0157:H7	Negative
30000014	M14	Establishment 14	Product-Raw-Ground, Comminuted or Otherwise Nonintact-Beef	MT43	10/24/11 0:00	Ground beef	E. coli 0157:H7	Negative
^a Actual establis	shment names will ap	pear in this column wh	^a Actual establishment names will appear in this column when FSIS posts the data.					

Table 2-4 E	Example of Establ	lishment-Specific.	Example of Establishment-Specific Salmonella Data Under Consideration for Public Posting by FSIS	Consideration	n for Public Pos	ting by FSI	S	
Form Id	Establishment Number	Establishment Name ^a	Sample Source Name	Sampling Project	Collect ion Date	Product Name	Analysis	Result
30000015	M16	Establishment 16	Product-RTE-Other Fully Cooked, Not Sliced-Beef	RTE001	10/26/11 0:00	Brisket	Salmonella	Negative
30000016	M17	Establishment 17	Product-RTE-Fully Cooked, Sausage Products-Combination species	ALLRTE	10/26/11 0:00	Chili	Salmonella	Negative
30000017	M18	Establishment 18	Product-RTE-Fully Cooked, Sausage Products-Pork	ALLRTE	10/26/11 0:00	Sausage	Salmonella	Negative
30000018	M19	Establishment 19	Product-RTE-Fully Cooked, Hot Dog Products-Combination species	RTE001	10/26/11 0:00	Wieners	Salmonella	Negative
30000019	M20	Establishment 20	Product-Raw-Ground, Comminuted or Otherwise Nonintact- Beef	MT43S	10/26/11 0:00	Ground beef	Salmonella	Negative
30000020	M21	Establishment 21	Product-RTE-Fully Cooked, Sausage Products-Beef	ALLRTE	10/26/11 0:00	Beef salami	Salmonella	Negative
30000021	M22	Establishment 22	Product-Raw-Ground, Comminuted or Otherwise Nonintact- Beef	MT43S	10/26/11 0:00	Ground beef	Salmonella	Negative
30000022	M23	Establishment 23	Product-Raw-Ground, Comminuted or	HC01_GB	10/26/11 0:00	Raw ground	Salmonella	Positive

	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
	Salmonella	Salmonella	Salmonella	Salmonella	Salmonella	Salmonella	Salmonella	Salmonella
veal	Ground beef	Ground beef	Ground beef	Caesar wrap	Cooked salami	Ground beef	Sausage	Wieners
	10/26/11 0:00	10/26/11 0:00	10/26/11 0:00	10/26/11 0:00	10/26/11 0:00	10/26/11 0:00	10/26/11 0:00	10/26/11 0:00
	MT43S	MT43S	MT43S	RTE001	ALLRTE	MT43S	ALLRTE	RTE001
Otherwise Nonintact- Beef	Product-Raw-Ground, Comminuted or Otherwise Nonintact- Beef	Product-Raw-Ground, Comminuted or Otherwise Nonintact- Beef	Product-Raw-Ground, Comminuted or Otherwise Nonintact- Beef	Product-RTE-Fully Cooked, Meat+Nonmeat Multicomponent- Chicken	Product-RTE-Other Fully Cooked, Not Sliced-Combination species	Product-Raw-Ground, Comminuted or Otherwise Nonintact- Beef	Product-RTE-Fully Cooked, Sausage Products-Pork	Product-RTE-Fully Cooked, Hot Dog
	Establishment 24	Establishment 25	Establishment 26	Establishment 27	Establishment 28	Establishment 29	Establishment 30	Establishment 31
	M24	M25	M26	M27	M28	M29	M30	M31
	30000023	30000024	30000025	30000026	30000027	30000028	30000029	30000030

	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative	Negative
	Salmonella	Salmonella	Salmonella	Salmonella	Salmonella	Salmonella	Salmonella	Salmonella	Salmonella
	Cooked beef patty	Smoked sausage	Patties	Sausage gravy	Beef chili	Ground beef	Meatballs	Ground beef	Smoked sausage
	10/26/11 0:00	10/26/11 0:00	10/26/11 0:00	10/26/11 0:00	10/26/11 0:00	10/26/11 0:00	10/26/11 0:00	10/26/11 0:00	10/26/11 0:00
	ALLRTE	RTE001	RTE001	ALLRTE	ALLRTE	MT43S	ALLRTE	MT43S	RTE001
Products-Turkey	Product-RTE-Fully Cooked, Meat+Nonmeat Multicomponent-Beef	Product-RTE-Fully Cooked, Sausage Products-Combination species	Product-RTE	Product-RTE-Fully Cooked, Sausage Products-Pork	Product-RTE	Product-Raw-Ground, Comminuted or Otherwise Nonintact- Beef	Product-RTE-Other Fully Cooked, Not Sliced-Combination species	Product-Raw-Ground, Comminuted or Otherwise Nonintact- Beef	Product-RTE-Fully Cooked, Sausage Products-Combination species
	Establishment 32	Establishment 33	Establishment 34	Establishment 35	Establishment 36	Establishment 37	Establishment 38	Establishment 39	Establishment 40
	M32	M33	M34	M35	M36	M37	M38	M39	M40
	30000031	30000032	30000033	30000034	30000035	30000036	30000037	30000038	30000039

30000040	M41	Establishment 41	Product-RTE-Other Fully Cooked, Not Sliced-Pork	RTE001	10/26/11 0:00	Canadian bacon	Salmonella	Negative
30000042	M43	Establishment 43	Product-RTE-Fully Cooked, Hot Dog Products-Beef	RTE001	10/26/11 0:00	Beef frankfurters	Salmonella	Negative
30000043	M44	Establishment 44	Product-RTE-Fully Cooked, Hot Dog Products-Combination species	RTE001	10/26/11 0:00	Pork and beef frankfurters	Salmonella	Negative
30000044	M45	Establishment 45	Product-Raw-Ground, Comminuted or Otherwise Nonintact- Beef	MT43S	10/26/11 0:00	Ground beef	Salmonella	Negative
30000045	M46	Establishment 46	Product-Raw-Ground, Comminuted or Otherwise Nonintact- Beef	HC01_GB	10/26/11 0:00	Ground beef	Salmonella	Negative
30000046	M47	Establishment 47	Product-Raw-Ground, Comminuted or Otherwise Nonintact- Beef	MT43S	10/27/11 0:00	Ground beef	Salmonella	Negative
^a Actual establis	shment names will a	appear in this column w	^a Actual establishment names will appear in this column when FSIS posts the data.					

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Experience with Public Posting of Government Data

INTRODUCTION

The concept of publicly posting government-generated data to provide direct public access to information is not new. In response to calls for increased transparency and increased provision of information, several government agencies, including regulatory agencies responsible for protecting human health and safety, regularly post detailed data on the Internet. In some cases, the data are related to individual firms or facilities; in other cases, they are specific to commodities or products or to events. Although one could argue that government data are public by default and only under special circumstances should they be restricted, the committee began its assessment from a more neutral ground and by considering potential benefits of and concerns with releasing data, as this was the task given to the committee.

This chapter briefly summarizes several examples of public posting of detailed (disaggregated or establishment-specific) data. It also reviews some of the literature on the use and effects of data releases. Currently, there are no empirical data on the effects (both positive and adverse) of releasing establishment-specific FSIS data on the Internet. Therefore, the committee reviewed the existing evidence on the benefits and costs of public release of data by other government agencies. The review is meant to be illustrative rather than exhaustive. We focus on the posting of data that stem directly from regulatory activities (Category 1) but also briefly discuss the information public posting of derived from some prior analysis of data (Category 2) and the posting of voluntarily provided data (Category 3).²⁰ In addition to the examples discussed in this chapter, there are numerous other examples of public release by government agencies of safety-related data on products or firms; some of these are briefly summarized in Box 3-1.

Box 3-1

Examples of Sharing of Safety-Related Data on the Internet

Airborne Contaminants. The Occupational Safety and Health Administration posts some of its compliance-monitoring information on airborne contaminants released from personal, area, and bulk samples in industrial sites. URL: http://www.osha.gov/opengov/healthsamples.html.

Hospital Measures of Outcome of Care. Medicare publishes hospital-specific rates of outcome of care, which indicate what happened after patients with particular conditions were treated in the hospital. URL: http://data.medicare.gov/dataset/Hospital-Outcome-Of-Care-Measures/f24z-mvb9.

Safety in the Transportation Industry. The Bureau of Transportation Statistics publishes multiple datasets on transportation accidents and exposure to safety risks (for example, measured in aviation incidents, accidents, or fatalities). URL: http://www.bts.gov/programs/safety/index.html.

Safety of Nuclear Plants. The Nuclear Regulatory Commission posts plant-specific safety-inspection reports and licensees' performance indicators. URL: http://www.nrc.gov/NRR/OVERSIGHT/ASSESS/index.html.

Safety of Motor Vehicles and Equipment. The National Highway Traffic Safety Administration posts consumer, ratings tires data on safetv for the such as of cars and (http://www.safercar.gov/Vehicle+Shoppers/5-Star+Safety+Ratings/2011-Newer+Vehicles and http://www.safercar.gov/Vehicle+Shoppers/Tires/Tires+Rating)

and children's car seats (http://www.nhtsa.gov/Safety/Ease-of-Use); a list of all vehicle, equipment, and tire safety-recall campaigns from 1966 to the present (http://www-odi.nhtsa.dot.gov/recalls/); consumer complaints related to the safety of motor vehicles and motor-vehicle equipment (http://www-odi.nhtsa.dot.gov/complaints/); and investigations of specific vehicles, tires, and equipment (http://www-odi.nhtsa.dot.gov/cars/problems/defect/defectsearch.cfm).

²⁰As described in Chapter 2, Category 1 data arise from the activities of agencies as part of their normal enforcement and compliance efforts. Category 2 data arise from the outcomes of enforcement and compliance efforts that have been interpreted by others for use by end users. Category 3 data are collected by agencies from voluntary programs not in conjunction with normal enforcement and compliance efforts but nonetheless intended to provide information.

EXAMPLES OF COLLECTION AND RELEASE OF DATA BY REGULATORY AGENCIES

US Department of Labor

As part of the broader Open Government initiatives of the Obama administration, various agencies of the US Department of Labor (DOL) have expanded direct public access to their inspection and enforcement data, which are posted on a comprehensive Web site.²¹ The data underlying the site arise primarily from the enforcement activities of the agencies. Each agency offers different types of information and levels of detail to the public, which reflect differences in agency mission, nature of the regulatory process, sophistication of data collection, and administrative processes, such as case-review procedures.²² The agencies provide a variety of information, including details about the inspected entity (such as industry, firm and establishment size, and single-plant vs. multiplant status), characteristics (such as time spent and type of inspection activity) and outcomes of the investigation (such as standards violated, severity of violations, and penalties assessed), and related administrative processes (appeals and their results). Accordingly, the data on the site are primarily in Category 1.

The site is regularly expanded and improved. Prior updates have focused on making it easier for users to search by common criteria, such as company name or industry grouping. That potentially provides information about the compliance behavior of a specific employer or industry for a range of workplace laws. DOL is planning a number of future updates to increase usability, including display of data through maps and interactive "dashboards" and engaging public users of the data in finding "innovative ways of using DOL's enforcement data to promote worker's safety and protect worker's rights".²³

In addition to the information on the comprehensive DOL Web site, some of the individual agencies in DOL post detailed facility-specific safety data. For purposes of illustration, we focus here on the Mine Safety and Health Administration (MSHA). MSHA is responsible for the enforcement of health and safety standards for underground and surface metal and nonmetal mines. Compliance with detailed health and safety requirements is determined through physical inspection of mining facilities, interviews with mine operators and with workers and their representatives (in unionized mines), and review of administrative information. Inspectors also sample dust and air.

The most extensive mine-level data available to the public are published on the MSHA Web site.²⁴ Those data originate in the electronic information systems maintained by the agency. The data are stored in 16 linked databases that provide information on inspections, citations, penalties, and abatement requirements. The site also provides mine-level data on fatalities and

²¹See http://ogesdw.dol.gov/ (accessed June 7, 2011).

²²With respect to the latter dimension, agencies vary according to when the results of completed inspections and investigations are publicly posted. The Wage and Hour Division posts only cases that are considered "closed" (for example, all appeals of the investigators' findings have been resolved). In contrast, the Mine Safety and Health Administration posts inspection data even when a mine operator or other party is appealing parts of a decision, such as penalties.

²³See http://ogesdw.dol.gov/coming_soon (accessed June 7, 2011).

²⁴See http://www.msha.gov/drs/drshome.htm (accessed June 7, 2011).

injuries, air sampling results, such mine-level characteristics as geology and type of mining technology, and detailed information on ownership and management of mining activities.

The publicly available data span from 1983 to the present and are updated weekly. MSHA also provides information on closed and active inspections, including cases in which mine operators have contested penalties or abatement orders. Data can be searched by any of the characteristics of mine operation, ownership, inspection finding, and so on; the data can be downloaded as extracts; and data from the various databases can be combined by using a common mine-level identifier system.

US Environmental Protection Agency

In 2003, the US Environmental Protection Agency (EPA) launched its Enforcement and Compliance History Online (ECHO),²⁵ a Web-based platform that provides easy access to EPA and state data on environmental compliance and performance of over 800,000 individual facilities in the United States. The Web interface draws on an underlying dataset, the Integrated Data for Enforcement Analysis (IDEA), which integrates data from five enforcement and compliance history datasets. Users can use ECHO to search for facility-specific data by location (ZIP code) or other identifiers. It is designed primarily for situations in which a user is interested in information on a relatively small number of facilities, but users who want to review larger amounts of data can access the raw data from IDEA. The data are updated monthly.

The content of ECHO and its user capabilities have evolved. ECHO now allows Webbased access to the following types of facility-specific data:

- Inspection, violation, and enforcement data, including the number and dates of individual inspections, compliance status by quarter, and penalties imposed during the preceding 5 years.
- Data on EPA enforcement cases.
- Data on violations of the Safe Drinking Water Act, including the publication of a list of all water suppliers deemed to be "serious violators".
- Toxics Release Inventory (TRI) data, which are mandatory, self-reported releases of designated toxic chemicals by facility.
- National Emissions Inventory data with information about estimates of air pollutants from point, nonpoint, and mobile sources in the United States, for example, data from state and local agencies, data on on-road sources from the Federal Highway Administration, and fuel-use data from the Department of Energy.
- Detailed water-quality reports on facilities that have permits under the Clean Water Act and information on noncompliance with effluent limits.

In addition to detailed facility-level data, ECHO includes more aggregated summary reports that provide information about trends and state-level analyses.

²⁵See http://www.epa-echo.gov/echo/about_data.html (accessed June 8, 2011).

EPA reports that in its first year ECHO provided information in response to over a million search requests.²⁶ It identifies members of the public, corporations, investors, and researchers as possible user groups. In addition, EPA notes that provision of data to the public creates an incentive for government agencies to improve the reporting of violations and for facilities to take steps to correct violations.

Although EPA has worked continuously to enhance the usefulness of the data in ECHO, some of the reported data are in "raw" form and can be difficult for users to interpret. For example, the TRI data are reported in pounds released annually with no direct means of converting the releases to a more useful measure, such as associated health risk. Efforts have been made to convey health risk to end users, but the current information is not easy to find and is not detailed and quantitative enough for end users to use to estimate the risk to which a person might be exposed. Data disclosure, however, is likely to evolve and improve once shortcomings are identified.

Food and Drug Administration

The Food and Drug Administration (FDA) has several databases that are available to the public. They include data on inspections and enforcement (Category 1) and voluntarily reported information on actual or potential adverse events (Category 3). FDA also collects some microbiological sampling and testing data, but these are not generally available to the public.

Although FDA has posted summary data for many years, it announced in May 2011 that it would disclose additional inspection information on FDA-regulated food products, including the compliance status of specific firms as determined by FDA inspectors during inspections and followup reviews for compliance. FDA made that information available to the public through a searchable database on the its Web site, which includes the names and addresses of inspected facilities, the dates of inspection, the types of FDA-regulated products involved, final inspection classification, and a summary of the most common inspection observations, although not in great detail.²⁷ The information is substantially equivalent to the information now provided by the US Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) on administrative actions (USDA FSIS, 2010; see Appendix C). FDA also provides access through its Web site²⁸ to facility-specific information, such as letters that warn firms that violations have been identified and must be corrected, and enforcement reports that contain information on actions, such as recalls, taken in connection with regulatory activities. Aggregated information about enforcement activities is also found on the FDA Web site. FDA justified the disclosure of the information on the grounds that it would help to provide the public with a rationale for the agency's enforcement actions, help consumers and industry stakeholders to make informed choices in the marketplace, encourage industry compliance, and generally improve transparency of agency actions to be consistent with administration policies.

In addition to Category 1 enforcement and compliance data, FDA collects other safetyrelated data from health-care professionals, public-health officials, consumers, and the food

²⁶See

http://yosemite.epa.gov/opa/admpress.nsf/b1ab9f485b098972852562e7004dc686/e6bf84f19616f3b985256de30055a fcd?OpenDocument (accessed June 8, 2011).

²⁷See www.accessdata.fda.gov/scripts/inspsearch/ (accessed July 25, 2011).

²⁸See http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/ucm254426.htm (accessed July 25, 2011).

industry.²⁹ For example, information on potential or actual adverse events is collected by FDA through the Reportable Food Registry (RFR)³⁰ for foods and through the Adverse Event Reporting System (AERS)³¹ for drugs, biologics, and dietary supplements. Industry must report adverse events to the RFR. Raw data from the RFR are not released to the public, but FDA has posted two reports since RFR was implemented: a first-7-months report (September 2009–March 2010) and the annual report (September 2009–September 2010) with summary information aggregated in various forms, such as total entries by commodity or by commodity and hazard. FDA also posts quarterly data files from AERS on its Web site and summary statistics for each year. Although the information is not company-specific or facility-specific, the release of information about adverse events can affect individual firms and entire industries whose production is linked in some way to the events.

State and Local Public-Health Agencies

Regulation of restaurant hygiene falls under the jurisdiction of public-health officials in state, county, or city governments. In particular, local governments establish and implement food-safety standards for institutional food-service establishments, restaurants, retail food stores, and other retail food establishments; FDA, through its issuance of the *Food Code*, advises them on food-safety guidelines (FDA, 1993;,1997;, 2001; 2005; 2009), inspector training, and foodborne-illness risk factors (FDA, 2000; 2004; 2009). Those regulatory activities play a critical role in ensuring food safety.³²

²⁹FDA collaborates with the National Institutes of Health (NIH) to administer a database of federally and privately supported clinical trials at ClinicalTrials.gov. The database contains 108,486 trials sponsored by NIH, other federal agencies, and private industry. Studies listed in the database are conducted in all 50 states and in 174 countries. Users can access information on current clinical trials, including participant flow, baseline characteristics, outcome measures and statistical analyses, adverse-events information, administrative information, and study results when available.

³⁰The RFR is a new database administered by FDA. Required by Congress, it is an electronic portal for the food industry and public-health officials to report when there is a reasonable probability that an article of food will cause serious adverse health consequences. URL: www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/default.htm (accessed July 25, 2011).

³¹AERS contains over 4 million reports of adverse events from 1969 to the present.

³²Restaurant hygiene has been linked to foodborne disease, so restaurant inspection has been studied as a tool to reduce the occurrence outbreaks. For example, FDA (2000) checked 895 food establishments across the United States and found that restaurants and retail store delicatessens were in compliance with the five risk factors emphasized in the 1997 FDA Food Code only 60–74% of the time. In comparison, the average compliance record for other food establishments (hospitals, nursing homes, elementary schools, and other departments of retail food stores) ranged from 76 to 83%. Two followup reports (FDA, 2004, 2009) indicated that some of the risk factors identified in the 2000 report (such as improper food temperature, poor personal hygiene, and contaminated equipment) remained in need of attention despite some improvement (FDA, 2010). In 2007, the Center for Science in the Public Interest examined over 530 inspection reports in 20 cities and found that over 66% of restaurants had at least one high-risk violation (CSPI, 2008). Those statistics suggest that restaurant hygiene is an important contributor to outbreaks of foodborne disease.

Public access to restaurant hygiene-inspection outcomes (Category 1 data) varies greatly among regions and over time. The most traditional way to share data is "available on request". In some cities (such as Pittsburgh and Washington, DC, before 2011), inspection outcomes are available only through the Freedom of Information Act (FOIA), which requires written requests and can take up to 6 months for receipt of a final report (CSPI, 2008). In other places (such as Atlanta and San Francisco), restaurants are required to keep copies of the most recent inspection reports and provide them on request by consumers. Alternatively, disaggregated inspection outcomes can be posted on an on-line searchable database; access to these data requires consumers to initiate an on-line search. Many states and large cities—including Virginia, Florida, Boston, Chicago, Denver, Philadelphia, and Washington, DC—have adopted on-line posting.

Several jurisdictions have recently adopted methods that help to deliver restaurant hygiene-inspection results directly to consumers at the point of sale—the front door or window of the restaurant. For example, North Carolina, South Carolina, Tennessee, Las Vegas, St. Louis, Los Angeles, New York City, and some international cities, such as Beijing and Toronto, require storefront posting of hygiene information. The information can be in the form of a numerical score of the most recent inspection (usually of a total of 100 points) or broad categories (A–B–C or pass–conditional pass–closed) based on the numerical scores. The regulatory agency or some other body must define how the raw inspection results or scores will be used to define the relevant categories (for example, Category 2, for which the government agency interprets the disaggregated hygiene data and provides them in a more actionable form for consumers).

REPORTING OF FOOD-SAFETY DATA BY NONREGULATORY AGENCIES

As noted above, although many of the detailed data related to food safety are collected and reported by regulatory agencies as they engage in normal compliance and enforcementrelated activities (Category 1 data) or are interpreted for consumers (Category 2 data), some agencies, such as the Centers for Disease Control and Prevention (CDC) and the USDA Agricultural Marketing Service (AMS), collect and report food-safety data that are generally reported to them by others, including consumers and health-care professionals. Because reporting is often voluntary, those data would typically fall into Category 3. The CDC and AMS data are not linked to individual firms or facilities and thereby differ from FSIS data. They have the potential to be of benefit to the public but can also affect related firms and industries.

Centers for Disease Control and Prevention

Much of the public-health surveillance for foodborne disease, including outbreaks, is conducted by state and local health departments. For multistate foodborne-illness outbreak investigations, CDC plays a prominent role in surveillance and investigation. CDC does not have authority to mandate that states report their surveillance data to it, but it has developed a system whereby state and local health departments voluntarily report outbreak data to it. CDC maintains aggregated and case-based disaggregated foodborne-illness surveillance data in multiple databases. No personal identifiers are maintained by CDC. Some of the data are publicly accessible, and others are available only through FOIA.

In 2009, CDC launched the Foodborne Outbreak Online Database (FOOD),³³ which is designed to allow the public direct access to state-level information on foodborne outbreaks. The database spans 1998–2008 and is updated periodically. FOOD enables the public to search and download data on reported outbreaks as an XML file. It does not identify specific establishments involved in outbreaks.

A recent report suggested that the FOOD data have several limitations.³⁴ For example, state health departments may update the data at any time, so these entries are never considered "final". The rigor with which state health departments collect and report data can vary widely and some users of the data have noted inconsistencies in the dataset. In addition, data are not updated in real time, so the most current data available are usually several years old.

CDC also collects surveillance data through the Foodborne Diseases Active Surveillance Network (FoodNet) program. FoodNet is a partnership of 10 state and local health departments, CDC, FDA, and USDA that conducts population-based surveillance for laboratory-confirmed infections commonly implicated in foodborne disease. CDC releases annual summaries of FoodNet data in a published report but does not make the raw data publicly available, although they can be requested through FOIA.

Agricultural Marketing Service

The Monitoring Programs Office of USDA's AMS is responsible for managing the Pesticide Data Program (PDP),³⁵ a voluntary program that was implemented in 1991 to test food commodities for pesticide residues. The PDP is based on a sampling plan with a rigorous statistical design to ensure the reliability of the data for use in exposure assessments. However, the pesticide databases are commodity-specific rather than establishment-specific.

Every year, the AMS publishes on line a report summarizing the PDP data. It includes the study design for data collection for the relevant year, details about how data are reported, a summary of the results, the history of commodities tested, and the raw commodity-level data. Requests for PDP information are received from many parties, including other government agencies and various organizations, and the staff of the Monitoring Programs Office generates specific reports for these queries. However, users can also import the data into database-management software and conduct their own analyses.

The PDP was not designed for the purpose of enforcing regulations. The major user of the PDP data is EPA, which uses them in its pesticide risk assessments and to estimate whether human exposure exceeds safety standards.³⁶ FDA is informed of residues that exceed tolerances

³³See http://wwwn.cdc.gov/foodborneoutbreaks/ (accessed June 8, 2011).

³⁴See http://www.aei.org/docLib/REG-2011-02-g.pdf (accessed June 8, 2011).

³⁵See

http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateC&navID=PDPOviewBox2Link 1&rightNav1=PDPOviewBox2Link1&topNav=&leftNav=ScienceandLaboratories&page=PesticideDataProgram&r esultType=&acct=pestcddataprg (accessed on June 23, 2011).

³⁶Other groups also use the data to provide information to the lay public about pesticide residues in foods (see, for example, http://www.ewg.org/foodnews/), and researchers have conducted analyses with the PDP residue data (see, for example, Punzi et al., 2005; Baker et al., 2002; Kuchler et al., 1996).

or that have no tolerances. The program is voluntary (AMS has no regulatory authority to require participation in the program) and works with 12 state agencies that are responsible for sample collection and analysis. Five states were selected initially because they were diverse geographic areas; the list was later expanded to 12 states to increase the sampling data points (M. Lamont, USDA AMS, Manassas, VA, personal communication, July 20, 2011).

REPORTED EFFECTS OF RELEASING ESTABLISHMENT-SPECIFIC DATA

The overview above suggests that other government agencies have already had considerable experience with the release of detailed data. The academic literature also has examined the pros and cons of information disclosure in many contexts, including disclosure of establishment-specific regulatory information similar to the FSIS data and disclosure of productspecific information that may be traced back to manufacturers. The committee reviewed the many National Research Council and Institute of Medicine reports on data-sharing (for example, NRC, 1985; NRC and the Social Science Research Council, 1993; IOM, 1996; NRC, 2000; 2001, 2005; NAS, 2009; IOM and NRC, 2010). The reports have a somewhat different focus, and none addresses directly the issue of publicly releasing data gathered originally for regulatory purposes; for example, NRC (1985) focuses on data-sharing among researchers. However, many of the issues associated with data-sharing in other settings, as discussed in these National Research Council reports and related documents, do address benefits and concerns related to the process and point to conclusions that are similar to those discussed here and in Chapter 4. For example, the report Sharing Research Data (NRC, 1985) considers the benefits and costs of data-sharing among researchers. The noted benefits include promoting and improving research that leads to better decisions and improving measurement and data-collection methods. The costs include technical obstacles to sharing data and the costs of documentation and training. The entities that own and disclose data may go beyond regulatory agencies (to manufacturers and third-party certifiers), but lessons learned from the broader literature can help us to anticipate the specific potential effects of releasing establishment-specific FSIS data.

As discussed in Chapter 2, the effectiveness of any transparency system is based on whether the information that it provides is "embedded" in the action cycle of users (such as consumers) and disclosers (such as businesses) of the information (Fung et al., 2007). On the positive side, the literature suggests that information disclosure may enable consumers to make more informed choices. Analysis of specific policies yields numerous examples of information affecting consumer choice. The public posting of hygiene inspection outcomes has resulted in increased sensitivity to restaurant hygiene (Jin and Leslie, 2003). In the health-care domain, substantial patient sorting has been observed in response to the disclosure of cardiac-surgery outcomes associated with hospitals and doctors (Dranove et al., 2003). Increased consumption of fiber-rich cereals has occurred on disclosure of the nutrition content of food products (Ippolito and Mathios, 1990).

In addition, there is evidence that disclosure of firm-specific or facility-specific information can motivate firms to improve their performance, at least along the disclosed dimensions. For example, evidence shows that public posting of restaurant hygiene information led to better public-health outcomes in Los Angeles and Toronto (Jin and Leslie, 2003; Simon et al., 2005; Serapiglia et al., 2007). EPA TRI disclosure led to substantial improvements in environmental performance (Konar and Cohen, 1997). Likewise, for large Massachusetts water

suppliers, the mandatory public provision of information about violations of drinking-water standards resulted in a 30–44% reduction in total violations and a 40–57% reduction in more severe health violations (Bennear and Olmstead, 2008). A recent study of state voluntary site-cleanup programs revealed that public disclosure of contaminated sites is an efficient tool for promoting participation of property managers and developers in site remediation (Blackman et al., 2010). Patten (2002) further argues that release of establishment-level TRI data generated public-policy pressure that led to increased environmental disclosure by TRI firms. Those improvements can be in response to consumer pressures of the type discussed in the previous paragraph, pressures from input markets (such as investors and suppliers), and actual or threatened regulatory pressures (Fung et al., 2007).

Release of establishment-level data has also generated research opportunities. For example, researchers have used establishment-level enforcement data to examine the effectiveness of inspection programs in a variety of contexts, including mine safety (Kniesner and Leeth, 2004), occupational safety (Bartel and Thomas, 1985; Gray and Jones, 1991; Weil, 1996; 2001), nuclear safety (Feinstein, 1989), seafood safety (Alberini et al., 2008), air and water pollution (Magat and Viscusi, 1990; Gray and Deily, 1996; Earnhart, 2004), and pharmaceutical production (Macher et al., 2011). Establishment-level data have also been used to study issues not directly related to enforcement, such as the link between air pollution and fetal or infant mortality (Agarwal et al., 2010), the effectiveness of nonregulatory programs (e.g., Arora and Cason, 1996), environmental justice (Daniels and Friedman, 1999; Dolinoy and Miranda, 2004), interjurisdictional pollution effects (Helland and Whitford, 2003), and the effects of physician prescription of drug combinations on competition among pharmaceutical firms (Lucarelli et al. 2010).

The evidence reviewed suggests that public disclosure of establishment-specific data can have important social benefits. However, as with all regulatory interventions, some parties may be adversely affected by public data disclosure. Different parties have different perspectives on what constitutes an adverse effect. In fact, a negative for one party might be viewed as a positive by another or ultimately considered as a positive by the public at large. One potential adverse effect is related to the market. For example, a body of literature demonstrates that some firms suffered reductions in their stock prices immediately after public release of data (e.g., Hamilton, 1995; 2005). There are similar examples of the effect of food recalls on stock prices (e.g., Salin and Hooker, 2001; Thomsem and McKenzie, 2001). Konar and Cohen (1997) reported that firms more adversely affected by the release of TRI data were later more likely to reduce their toxic releases; this suggests that the adverse effects of the data release motivated firms to improve their performance (in response to pressure from investors in capital markets). Thus, the adverse effect on some firms may ultimately generate benefits for the broader community.

Some researchers have raised concerns about potential adverse effects of disclosure due to misinterpretation or lack of understanding of the data. If that occurs, the disclosure might not have the intended effect. For example, the terrorist color-coded threat advisory system that was enacted shortly after the 9/11 attacks and was in effect until early 2011 provided vague information that tended to cause confusion, alarm, or eventually disregard by the public but little evidence of reduction of risk to the public (Fung et al., 2007). The implication, however, is not that the data should not be released but rather that the data should be provided in a meaningful and understandable form.

Another concern raised in the literature is that information disclosure may encourage firms to improve on the reported outcomes but reduce performance regarding unreported outcomes, especially when the omitted outcomes are unreported because of measurement difficulty rather than because of lack of importance. This type of distortionary behavior has been documented in a number of contexts. For example, Khanna et al. (1998) showed that release of TRI information reduced on-site releases of toxic substances but increased transfers of the same substances to off-site locations. As a result, in that particular case, the authors concluded that the overall effect on the amount of toxic waste generated was negligible. Similar examples can be found in the context of medical outcomes (Dranove et al., 2003) and school performance (Haney, 2000; Deere and Strayer, 2001; Jacob and Levitt, 2003; Hanushek and Raymond, 2005; Jacob, 2005; Cullen and Reback, 2006; Figlio and Getzler, 2006). The potential for distortionary behavior suggests that agencies contemplating public data disclosure should anticipate such responses by firms and design information collection and disclosure policies that will reduce that kind of behavior.

Information disclosure not only has the potential to distort firm behavior but can add pressure on the people (such as inspectors) who generate data in the field. On the one hand, inspectors may be under closer scrutiny and thus pressured to do their jobs in a more precise and consistent way. For example, there is evidence that increased public attention after the Three Mile Island accident increased inspector detection rates (Feinstein, 1989); this suggests that public attention on inspection may motivate inspectors to do a better job. On the other hand, firms identifiable in the disclosure data have incentives to ask for leniency of the inspectors who are assigned to their facilities. Anecdotal evidence has shown inspector bribery after Los Angeles County adopted restaurant hygiene report cards, and data plots raise concern about leniency regarding the cutoffs of letter grades (90 for A and 80 for B, Jin and Leslie, 2003; 2005).

The concern about inspector bias and potential bribery brings up issues regarding heterogeneity in inspector performance. In nuclear-safety inspection (Feinstein, 1989) and inspection of pharmaceutical manufacturing plants (Macher et al., 2011), researchers have found that inspector identity or inspector demographics, experience, or training is important in explaining inspection outcomes. That suggests that inspectors vary in their ability to detect or their preference in detecting violations. Although the committee is not aware of any published study that documents the effect of data disclosure on inspector behavior, public attention after data disclosure may highlight the existence of inspector heterogeneity and motivate the provision of additional training and standardization to enhance inspection consistency.

Ironically, distorted firm and inspector behavior that occurs as a consequence of information disclosure suggests that the disclosed data are useful at least in the perception of primary data users. That highlights the importance of what to disclose, how to disclose it (including how to protect the identities of individual inspectors), and what additional support might be needed from FSIS to facilitate proper data use. The experience of reporting hospital outcomes may be informative. Given the complexity of raw data and consumer demand for easy-to-read information, hospital outcomes are often reported in averages. However, the precision of an average measure varies greatly with sample size, frequency of the measured event, and the pool of subjects that contribute to the sample. Researchers have shown that measurement problems can compromise the usefulness of disclosed data (Iezzoni, 1997; Kane and Staiger, 2002), but disclosure brings measurement issues to the forefront and thereby promotes research that can lead to improvements.

Restaurant hygiene report cards provide another useful lesson: that many factors contribute to the effectiveness of data disclosure. For example, in addition to issuing grade cards, Los Angeles County adopted an easy-to-read format for the grade cards, inspected some

restaurants more frequently, provided restaurant inspectors with additional training, and put in more effort to educate restaurant owners and staff (LADPH, 2008). Several studies have found that sanitary conditions in restaurants could be improved through more frequent inspections and enhanced education efforts (Bader et al., 1978; Mathias et al., 1995; Cotterchio et al., 1998; Allwood et al., 1999; Cates et al., 2009; Hislop and Shaw, 2009). The Los Angeles restaurant hygiene report cards were motivated by a CBS 2 news program that revealed, through the use of hidden cameras, the unsanitary conditions in restaurant kitchens. That TV exposé³⁷ increased consumer awareness of restaurant hygiene, drew attention to the weakness of the existing system, and intensified political pressure for regulatory change. Another factor that potentially contributed to the success of Los Angeles grade cards is that the stringent inspection codes matched specific violations to defined numerical point deductions, which minimized the subjectivity of hygiene inspections. This system contributed to a more standardized evaluation among restaurants and inspectors, and increased consumer confidence in the grade cards.

On-line posting has become a new norm for data disclosure because of its low cost and the ease of user access. Research is needed to examine the advantages and disadvantages of online posting relative to those of other methods of disclosure, such as posted restaurant report cards or published hospital rankings. The Internet facilitates posting of large amounts of data and allows user customization, but access to the Internet is probably skewed toward a set of the population (those of higher income and those who are better educated) and often requires expertise and effort by end users to analyze and interpret the data correctly.³⁸ However, the investment of time and expertise required to analyze and interpret large datasets appropriately is not peculiar to their release on the Internet, and the costs and knowledge necessary to obtain the same data through FOIA requests are potentially even greater barriers to the dissemination of the information.

At a minimum, posting data on the Internet would make it easier for the public to know what kinds of information have been collected and are available and perhaps to gain some initial understanding of the quality, complexity, and potential usability of the data for specific purposes. Hence, the public may avoid the current costs of obtaining data through a FOIA request that would ultimately be unsuitable for their needs. However, posting on the internet may increase the potential for misinterpretation, if only by virtue of the fact that releasing data more broadly (via the Internet) will result in a higher number of users and uses. The experience of other federal agencies in posting data suggests the benefit of providing that information in formats and with

³⁷Behind the Kitchen Door: Joel Grover Investigation. First Broadcast November 1997.

³⁸The original discussion of the "digital divide" arose as a result of a survey conducted by the National Telecommunication and Information Administration (NTIA) of the US Department of Commerce in 1994 that showed differences in use of the emerging Internet by income and demographic characteristics. A second survey by NTIA in 1998 (with the subtile "Defining the Digital Divide") provided further evidence of gaps in use. The surveys precipitated studies in the United States, the United Kingdom, and elsewhere that look into the causes and consequences of differential use (see, for example, Norris, P. 2001, Digital Divide, Civic Engagement, Information Poverty, and the Internet Worldwide. Cambridge, UK: Cambridge University Press). How much the gap has narrowed in recent years with respect to income, ethnicity, and age is controversial.

documentation that facilitate its analysis and interpretation. The committee believes that FSIS would be best suited to determine how to address misinterpretation of data on a case-by-case basis.

SUMMARY

A number of federal agencies (none with specific food-safety jurisdiction) release detailed data that are directly linked to the performance of individual facilities or firms or to the products that they produce. In many cases, the data originate in regulatory (compliance and enforcement) activities. A substantial body of literature documents the effects of the public release of data and their uses. The literature suggests that release of facility-specific performance data can have both benefits and costs (or unintended adverse consequences).

Major benefits include enabling users to make more informed choices, motivating facilities to improve their performance, and provision of data for use in research studies of regulatory effectiveness and other performance-related issues. The possible costs of public disclosure of information include adverse effects on profitability, but it is precisely this possibility that creates an incentive for facilities to improve their performance. The literature has also raised concerns about some perhaps unintended consequences, including the potential for data misinterpretation, the incentive for establishments whose data are disclosed to "game the system", ³⁹ and potential pressure on inspector performance.

Based on its review of the entirety of the extant literature, the committee concluded that the potential adverse impacts, while possible, were largely anecdotal or speculative, and are not backed up by any significant systematic evidence. On the other hand, the positive benefits are more credibly backed up by the scientific literature. Therefore, the current evidence of adverse effects is insufficient for predicting specific problems that would be inherent in the release of establishment-specific FSIS data. The committee believes that the potential for adverse effects is not necessarily insurmountable but highlights the need to pay careful attention to the design of an information-disclosure strategy. For example, potential adverse effects may be minimized if the disclosing entity (FSIS) is careful to ensure the integrity of the data and provides precise and appropriate definitions of what is being quantified, adequate documentation of context, a means by which to support analysis of the data by users, and precautionary measures to prevent the linking of portions of the data in ways that would allow users to deduce confidential information about particular establishments. It is clear that the most effective disclosure systems improve in quality, quantity, and scope as users gain a better understanding of how the data might be used.

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³⁹To adjust their strategies to minimize public disclosure.

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Public Release of Food Safety and Inspection Service Establishment-Specific Data

The release of establishment-specific Food Safety and Inspective Service (FSIS) data would provide public access to detailed sampling and testing data and inspection and enforcement data. As discussed in Chapter 2, those data, with few exceptions, have been available to the public only in aggregated form without establishment-level detail. Under the "right to know" principles of the Freedom of Information Act (FOIA), the government is obliged to provide data solicited by the public except in particular cases (such as personal or medical information and trade secrets; see Chapter 2, Box 2-1). Thus, many of the establishment-specific data that FSIS might release are available through FOIA requests. However, the availability of the data unless the requests is limited by the request process and a requester's exclusive use of the data unless the requester chooses to share them. Thus, public release of data by posting on the Internet would result in a fundamentally changed information environment, including more information and potentially more users and uses.

The experience of other federal agencies that have posted detailed data (reviewed in Chapter 3) suggests that there may be benefits, as well as some potentially adverse unintended consequences, of posting establishment-specific data that FSIS collects as part of its regulatory mission. The conclusions of Chapter 3 also suggest that the benefits can grow and that the concerns stemming from adverse consequences can be mitigated through careful design of data release. That implies the need for a strategic plan designed to guide the agency in its choice of data to release, how to release them, and the means by which to ensure that data are continuously updated and improved.

The purpose of this chapter is three-fold: to discuss the potential benefits and adverse consequences of releasing establishment-specific FSIS data; to present issues related to data release that FSIS may want to consider during the development of a strategic data-release plan, including approaches to measuring the public-health and other relevant effects of data release; and to present the committee's findings and conclusions regarding the public release of establishment-specific FSIS data.

POSSIBLE BENEFITS, COSTS, AND UNINTENDED ADVERSE CONSEQUENCES

The committee identified a number of favorable outcomes that might be anticipated as a consequence of the public release of FSIS establishment-specific data. At the most basic level, such release would directly serve the first broad purpose of transparency in supporting the public's right to know. It would also serve the second broad purpose of transparency in helping to achieve specific public-policy goals. In the latter role of "targeted transparency", the major effects of expanded data access would include the potential for better decision-making based on improved information and stronger incentives for both the agency and food companies to improve their performance.

Although it has not been definitively documented, one of the expected advantages of providing public access to establishment-specific FSIS data is the improvement of public health. That appears to have been the case for the Environmental Protection Agency's release of Toxics Release Inventory data and the publication of restaurant-inspection data (see Chapter 3). Releasing establishment-specific FSIS data could potentially motivate individual companies and sectors of the food industry to improve their overall food safety efforts. For example, data release could provide incentives to protect brand reputation in food safety and to protect or enhance customer base and profitability; allow downstream purchasers and consumers or public-interest organizations to identify companies whose performance records were consistently above or below the industry average and potentially create economic pressure to improve food safety; provide better insights into strengths and weaknesses of different processing practices, which could lead to industrywide improvements in food safety practices; enhance performance benchmarking by individual companies, sectors, and the industry as a whole, including efforts by individual companies that are seeking to avoid being identified as "below average"; and improve the consistency of inspector performance.

Even if individual firms do not change their behavior in response to data posting, overall food safety could improve if information about performance leads consumers to favor high-performing establishments and hence causes a shift in the composition of the market. In addition to providing incentives for the private sector, release of establishment-specific data could help to identify needs for improvement in regulatory practices, and this might result in activities that lead to improved public-health outcomes. For example, industry representatives raised concerns about variation in enforcement practices among inspectors and districts. Analysis of enforcement data could help to identify variability in enforcement outcomes (if present) of comparable facilities. It could also help to identify effective practices in regulated facilities that could be more broadly adopted. As in other systems that provide establishment-level enforcement data, a coding system could be developed to protect the identities of individual inspectors and still achieve the above outcomes.

Public release of establishment-specific FSIS data, by themselves or in combination with other privately or publicly available data, could yield valuable insights that go well beyond the regulatory uses for which the data were collected. For example, establishment-specific FSIS microbial testing data might be combined with region-specific climate data in an effort to develop better predictive risk models of pathogen load as a function of environmental conditions. Making establishment-specific data publicly available might provide information that would be useful for training the next generation of researchers, regulators, and industry food-safety

experts. The ability to analyze establishment-specific data would probably create a network of third-party analysts who, because of their familiarity with the data and their structure, could help FSIS to mine its own data and help individual companies or industry sectors to use the data to improve their practices. By publicly releasing establishment-level data, FSIS would be sharing with stakeholders, particularly those in the academic and industrial sectors, the opportunity to perform data analysis. Those groups may be able to use the data in conjunction with other sources of information to yield new insights or conclusions that could have significance for food safety and public health. Public release of FSIS establishment-specific data could also lead to improved public understanding of the considerable efforts made by FSIS and the industry to ensure food safety. For example, if data release could be linked to specific improvements in food safety, it might promote public perceptions of and confidence in the safety and integrity of the food supply and in the companies and regulatory agencies that are responsible for ensuring them.

The benefits of releasing establishment-specific FSIS data must be balanced against the potential unintended adverse consequences. Several of those were noted by industry representatives who spoke to the committee in the open session of its first meeting. For example, there was concern about the potential for misinterpretation of data. FSIS data are complex, and appropriate analysis of them would require considerable training and skill in statistical analysis. Making sense of the data also requires knowledge and experience to put them into an appropriate context. Without such knowledge and experience, users could misinterpret the data, reach unwarranted conclusions, or take the data out of context in an effort to support predetermined positions. For example, FSIS publishes the results of microbiological sampling of ready-to-eat (RTE) meat and poultry products.⁴⁰ In discussing those data, FSIS (USDA/FSIS, 2011) stated that the agency "does not view the results of regulatory testing as estimates of national product prevalence". However, the data are often misused by the industry, mass media, and other organizations as the basis for calculating pathogen prevalence in products.

Adverse effects on brand reputation could also occur as a consequence of public release of establishment-specific data. It is possible that those effects will be experienced differently and as a function of organization size. Larger organizations with more sophisticated corporate communication functions or hired public-relations agencies will probably be able to establish clear systems to explain violations. But smaller organizations that do not have the resources to support such communication efforts might experience more lasting damage to brand reputation. In short, it may be that the smaller companies are not unwilling to talk about food safety but just do not know how to do it effectively. To minimize the potential for adverse consequences of the public release of establishment-specific data on small and very small establishments, FSIS could provide adequate documentation and explanation of both a noted deficiency and the possible outcomes of such a deficiency.

Industry representatives were also concerned that releasing establishment-specific pathogen-testing data could affect international trade. For example, foreign countries might use publicly available FSIS testing data to bar entry of products from specific establishments on the grounds of presumed risks to public health.⁴¹ In the absence of a similar requirement to release comparable data from their own countries' companies, determining the true food-safety benefit of barring import of products from select US companies would be difficult. The World Trade

⁴⁰See "The FSIS Microbiological Testing Program for Ready-to-Eat (RTE) Meat and Poultry Products, 1990–2010" at http://www.fsis.usda.gov/science/Micro_Testing_RTE/index.asp#results05 (accessed August 17, 2011).

⁴¹For example, foreign countries could conceivably use establishment-specific data to delist US establishments and effective eliminate some international markets for select establishments and commodities.

Organization would eventually decide such disputes, but the short-term economic consequences for individual firms could be substantial. The committee notes, however, that just as data on US-based establishments would be released, FSIS data collected from foreign-plant inspections would be released, as would data collected as part of FSIS imported-product testing and approval or refusal. The effects of the release of establishment-specific data on imported products and on US exports are unknown. However, if the release of data leads to improved food safety of both domestic supplies and exports, the benefits would be realized not only by US consumers but by foreign consumers.

Another concern is related to the unintentional release of proprietary or confidential information. For example, Food Safety Assessments (FSAs) often correspond to specific components of an establishment's Hazard Analysis and Critical Control Points (HACCP) plan. Hence, they may reveal details that are considered proprietary by the establishment or include sensitive food-defense information. Clearly, the unintentional release of such information would need to be guarded against, for example, by redaction of sensitive information before the release of establishment-specific data.

Similarly, the agency would need to take precautions to avoid the possibility that portions of the data could be linked in ways that would allow users to deduce confidential information about particular establishments, such as FSIS inspection patterns, regulatory assignments, or sampling regimes. For example, FSIS may choose to release data on enforcement actions only after they have been completed, but real-time release of establishment-specific microbial-testing data could reveal that additional testing had been ordered for a particular establishment, which would indicate a new enforcement action. In that respect, the facility's response to the corrective action and its resolution would also need to be released.

Experience (see Chapter 3) suggests that public data release can affect inspector behavior both favorably and unfavorably. For example, the public release of information could put more FSIS pressure on inspectors to ensure the quality and consistency of their work. That could have the beneficial effect of reducing variation in enforcement procedures that does not further the agency's mission. Or, if increased transparency of enforcement increases the stakes of their outcomes, inspectors may face more pressure from firms regarding their outcomes (as has been documented in, for example, restaurant hygiene).

Finally, public release of establishment-specific FSIS data in whole or in part does not ensure that they will be useful or used. To make them so, FSIS will need to define a timetable for data release and commit the resources necessary to ensure the accessibility, quality, timeliness, and usefulness of the data. The costs could theoretically be offset, at least in part, by reduction in resources now dedicated to responding to FOIA requests. Each year, FSIS spends about 20,000 hours and over \$500,000 in complying with about 500 FOIA requests.⁴² That cost is supposed to be compensated by external parties (requesters)⁴³, but the committee learned that there are exemptions to FOIA compensation , and it appears that current compensation is well below the actual cost of providing such data (J. Reed, USDA-FSIS, Washington, DC, personal communication, July 7, 2011). Public data release might save the agency some of the time and money spent in operating the current FOIA system. However, there is a risk that an open system will trigger more in-depth FOIA requests once reporters or other interested parties begin to

⁴²The committee derived these estimates on the basis of the listing of FOIA requests

⁽http://www.fsis.usda.gov/PDF/FOIA_Requests.pdf) and the information on making a FOIA request at the FSIS Web site (http://www.fsis.usda.gov/FOIA/FOIA_Request/index.asp) (accessed July 8, 2011).

⁴³ Fees collected by FSIS for FOIA requests are sent to the US Department of the Treasury.

peruse the information. Another challenge in making establishment-specific FSIS data publicly available is that although FOIA requests may decrease, there may be a much larger need for public-affairs staff to handle news-media requests that might be associated with the new data and an increased need for an agency spokesperson to help the news media or the public interpret information.

The above discussion shows that both benefits and unintended adverse consequences could result from providing the public with access to data on individual FSIS-regulated establishments. As discussed in Chapter 3, guidance from a carefully designed data-disclosure strategic plan, as discussed in the next section, could maximize the effectiveness and minimize the potential adverse consequences of sharing establishment-specific data. Because effective data release requires cooperation among FSIS, industry, and the stakeholders most likely to use the data, the development of the strategic plan would benefit from their input. And because data themselves evolve, as do their uses, FSIS may also want to consider the need for continuous improvements based on industry and user feedback and agency response to that feedback. Only with such communication can FSIS maximize the value of public release of establishment-level data.

STRATEGIC PLANNING OF DATA RELEASE

As noted above, the committee believes in the development of a strategic plan for public release of establishment-specific data. The plan would be part of a larger comprehensive strategic plan for data collection, management, and analysis. FSIS has a start on such an overall plan in its Strategic Data Analysis Plan for Domestic Inspection (USDA/FSIS, 2010), and inclusion of a public data-release component would be appropriate. Below are some key issues to be considered in developing a data-disclosure strategic plan.

Identifying Potential Users

Multiple parties potentially have an interest in FSIS establishment-specific data. They include consumers, the mass media, consumer groups, parties along the entire food-supply chain (such as suppliers, producers, processors, distributors, retailers, and food-service operators), third-party inspectors, researchers, and other government agencies. The parties differ in how they would use FSIS data and in how information will be embedded in their decisions (if at all). For example, it is doubtful that individual consumers would have the ability to (or even want to) sift through FSIS data to trace connections between establishment-specific inspections and choices made at the supermarket. Some third-party groups will probably have greater desire or ability to translate information into a more useful form for ultimate consumer use. Consumers in particular are inundated with information, including that having to do with food safety. Although the public's right to know is paramount, the reality is that the vast majority of the public does not access government data on the Internet (Smith, 2010). A more likely scenario is that the data will be used by the mass media to create news stories that will then be passed on to the consumer either in traditional print format or by newer social-media channels.

For food processors, retailers, and food-service operators, the data could be valuable in making sourcing decisions and managing risks associated with their supply chains. This group

would probably be more capable of analyzing detailed data provided by FSIS and integrating them into monitoring, sourcing, and other core business decisions. Industry groups and trade associations might play a similar role, serving as collective agents in analyzing information for members and potentially using data for education or even for self-regulation.

Researchers in multiple disciplines have broad aims—shaped by disciplinary interests, academic activity, and public-policy evaluation—for gaining access to more detailed FSIS data. The research community would analyze the reliability and correlation of FSIS data to other food-safety data. Other US government agencies and international entities may also analyze and draw lessons from the released data.

The criteria for choosing which datasets to make public are directly related to the potential users. The many parties that may use the data will use them in different and creative ways that agency planners themselves might not foresee. Although the committee believes that it will be difficult for FSIS to predict the full array of users and uses of the data, it also recognizes the importance of determining the utility of data for different users. The committee believes that this situation presents a strong argument for pursuing the broadest possible data release at the most disaggregated level. Users can always aggregate data for their analytic needs, but they cannot access disaggregate detail from aggregated data.

Databases, Linking, and Facilitating Analysis

FSIS establishment-specific data are held in a number of data tables in the Public Health Information System (PHIS) (described in Chapter 2) and in older and diverse legacy data systems (for example, the Performance Based Information System and the Automated Import Information System). The data format and categories in the PHIS and various legacy systems are not necessarily compatible. Unless that problem is addressed, users of the publicly released data might find them difficult to analyze.

The desire to analyze multiple databases can result in linking problems. For example, a linking problem could occur if a user wanted to know whether FSIS administrative actions (see Tables 1, 2, 3, and 4 in Appendix C) have any relationship to FSIS food-safety adjudicatory actions (see Table 5 in Appendix C). The only way to perform that analysis now would be to extract the data from the tables manually, parse the establishment number from each field, and then manually join them in a query. Creation of a relational database format that allows linking of different datasets is likely to be the most effective means of facilitating that kind of analysis. Such a relational database would provide linking up front, saving time and reducing errors. In addition, release of the data in formats amenable to statistical analysis (such as, .xls and .csv), rather than in .pdf or text formats, would allow broader user audience. Of course, the publicly accessible database would also need to be highly secure and protected from modification or hacking.

FSIS will need to address the extent to which it will provide bridges between legacy data systems and data held in the PHIS, which represent different eras and different versions of related programs. The agency will also need to provide guidance on how these datasets can be combined in a way that is both valid and useful and that does not introduce systematic errors. However, building bridges between different data systems need not necessarily be a prerequisite for data release. Different users can develop different ways to standardize or adjust data as part of their own uses of the released data.

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Mechanics of Data Release

The Internet provides a low-cost and flexible form of disclosure, and, as detailed earlier in this report, a variety of federal agencies have already developed sophisticated sites for data disclosure. The experience of other federal agencies has shown the importance of providing data to the extent possible in machine-readable formats (rather than in static forms, such as PDFs, that do not lend themselves easily to analysis) to enhance their utility to users. Posting on the Internet can also facilitate the timely release of data, but must be approached cautiously and with careful planning. On the one hand, it could be argued that there is no reason not to release data as soon as they are available. On the other hand, premature release of a dataset might mean that valuable data are missing; this would make it difficult for a user to complete a comprehensive analysis or to place the data in their proper context. FSIS will need to balance timely release with the need for completeness.

The best data-sharing sites provide not only technical details but context for the variables in the datasets. Describing the methods of data collection, sources of variability, and changes in procedures that affect data consistency can be helpful for those analyzing and interpreting the data. In addition, various federal agencies and departments, such as the Department of Labor (DOL), are reaching out to potential users to assist them in developing sites and "apps" that will improve the utility of data released to the public.⁴⁴

Providing Context for Interpretation

Adequate context of how data were collected and their limitations is important for the use and interpretation of released data. For example, it is well known that *Escherichia coli* O157:H7 prevalence fluctuates by region and season. An analyst who compares data from two establishments from which the data were collected at different times of the year or in different regions, without an appreciation of temporal and geographic influences on pathogen prevalence, might conclude that one establishment had a better ability to control the pathogen when the opposite might be true.

The agency is well aware of the need for such guidance, as evidenced by statements on the page linked to its quarterly enforcement report.⁴⁵ Statements like the following are provided:

"It is important to recognize that this [report] is only one aspect of the Agency's mission to protect public health through food safety."

"FSIS does not view the results of regulatory testing as estimates of national product prevalence."

"This report is a snapshot in time of a dynamic process. . . . Matters shown as under appeal may be resolved. . . . Other actions could be appealed or closed."

⁴⁴See, for example, http://challenge.gov/Labor/201-dol-informaction-app-challenge (accessed August 7, 2011).

⁴⁵See http://www.fsis.usda.gov/regulations_&_policies/QER_Q1_FY2011/index.asp (accessed August 5, 2011).

While an extensive discussion of risk communication is beyond the scope of this report, and has been covered in a previous report by the National Research Council,⁴⁶ it is a vital component of the implementation and sustainability of the data-disclosure program. In particular, in the context of releasing establishment-specific data, it should be acknowledged that much of the public has a poor understanding of microbiology, microbial risks, food processing hygiene, and foodborne diseases (Hallman, 2008). Moreover, many people who are likely to be interested in understanding its meaning may have difficulty interpreting numerical data. Studies suggest that many people have difficulty grasping the magnitudes of very large and very small numbers (e.g. parts per million), and have a hard time interpreting the meanings of fractions, proportions, and probabilities (Paulos, 1988). As such, communications of risk involving mathematical operations or statistical descriptions may not be easily understood by non-expert audiences.

Indeed, a variety of stakeholders will be interested in food safety, as identified in Chapter 3, and would probably value assistance in data interpretation if it were made available. To mitigate the risk of misinterpretation of data and records, it may be useful for FSIS to plan the rollout of the release of establishment-specific data in a graduated manner to help key audiences to know what to expect of the data-release program and to prepare them to interpret the data accurately. For example, the agency might wish to develop a series of recorded webinars and other formal materials that would help those visiting the Web site to understand what is being presented. The risk of misinterpretation may also be mitigated by third parties in scientific societies, academe, or independent auditing agencies. Therefore, it may be useful to identify independent third parties who are able to interpret FSIS data appropriately ahead of the rollout of an open system and to make them publicly known. E-mail alerts could also be useful in positioning information. These could be set up so that individual stakeholders could opt in to receive content or audience-specific alerts or could be sent to targeted audiences, such as key mass-media outlets, academics, industry, advocacy organizations, trade associations, and scientific societies.

CONSIDERATIONS FOR RELEASE OF FOOD SAFETY AND INSPECTION SERVICE ESTABLISHMENT-SPECIFIC DATA

Sampling and Testing Data

FSIS routinely collects sampling and testing data on the foodborne pathogens *E. coli* O157:H7, *Salmonella*, and *Listeria monocytogenes*⁴⁷ and on the presence and concentration of chemicals and residues. Microbial sampling and testing data can be divided into two broad categories: those used for regulatory purposes and those used for baseline studies. As mentioned in Chapter 2, FSIS is not considering the public release of establishment-level baseline data on pathogen prevalence. Therefore, the ensuing discussion will focus on data produced for

⁴⁶ The Commission on Risk Perception and Communication, Commission on Behavioral and Social Sciences and Education, Commission on Physical Sciences, Mathematics, and Resources, and National Research Council. 1989. Improving Risk Communication. Washington, DC: National Academy Press.

⁴⁷See http://www.fsis.usda.gov/Science/Microbiology/index.asp (accessed August 5, 2011).

regulatory purposes. A brief description of various regulatory sampling and testing databases can be found in Chapter 2, Box 2-2.

FSIS now posts the data from its *E. coli* O157:H7 ground-beef testing program in a summarized or aggregated form.⁴⁸ The reports do not disclose the establishment unless there is a recall of finished product. Public release of establishment-level data might include the disposition of recalled and otherwise embargoed product. For example, if a product that was not in commerce tested positive for *E. coli* O157:H7, the report could indicate whether the product was diverted to a processing facility that fully cooked the meat or whether the raw product was destroyed, in accordance with FSIS regulations.

FSIS is publishing results of completed sample sets from its *Salmonella* verification program for young chicken (broiler) and turkey slaughter establishments in performance Category 3;⁴⁹ this category consists of establishments whose *Salmonella* prevalence exceeds the performance standard. The posted data include Product Class (for example, broilers), Establishment Number, Company Name, City and State, Date of Sample Set Analysis Completion, Most Current FSIS Set Result (but only repeating the category definition, not providing exact numbers), and Previous FSIS Set Result (following the same format). To be complete, public release of those data would also include establishments in Category 1 (whose *Salmonella* prevalence is at or below half the performance standard) and Category 2 (whose *Salmonella* prevalence is above half but not over the performance standard) and the level of detail discussed above for *E. coli* O157:H7 testing, including sampling dates. It is also important that released data include the regulatory thresholds on which data categorizations are based. For example, effective July 1, 2011, FSIS increased the stringency of the *Salmonella* performance standards in effect for a particular test set.

FSIS publishes highly aggregated summaries of L. monocytogenes sampling and testing of products, product-contact surfaces, and environmental surfaces. For example, an aggregated report⁵⁰ shows Number of Samples, Number of Positives, and Percent Positive for the three L. monocytogenes testing programs (ALLRTE, RTE001, and RLm). A more detailed but still aggregated report is the Percent Positive Listeria monocytogenes Tests for RTE Meat and Poultry by Product Category.⁵¹ Again, as discussed for the two other pathogen-testing programs, the committee concluded that for establishment-specific test results for L. monocytogenes to have the greatest benefit to users outside the agency, the report would include detailed information on the testing regime and results. As part of its regulatory activities, FSIS tests meat, poultry, and processed egg products destined for human consumption for the presence of antibiotics, sulfonamides, various other drugs, pesticides, and environmental chemicals in. It also tests for the presence of such contaminants as dioxin. More information on those programs can be found at the FSIS Web site.⁵² With the exception of the Residue Repeat Violator Lists (which include production facility name and address, animal type, tissue sampled, residue type, level of residue, and tolerance level that was exceeded), FSIS usually provides public access to chemical and residue testing results as reports of aggregated data, sometimes with detailed statistical analyses,

⁴⁸See http://www.fsis.usda.gov/Science/Ecoli_O157_Summary_Tables/index.asp (accessed August 5, 2011).

⁴⁹See http://www.fsis.usda.gov/PDF/Category_3_Broilers.pdf (accessed August 5, 2011).

⁵⁰See http://www.fsis.usda.gov/Science/Table24_RTE_Listeria_2009/index.asp and

http://www.fsis.usda.gov/Science/micro_testing_rte/index.asp (accessed August 5, 2011).

⁵¹See http://www.fsis.usda.gov/Science/Table22_Micro_Testing_RTE_2008/index.asp (accessed August 5, 2011).

⁵²See http://www.fsis.usda.gov/Science/Chemistry/index.asp (accessed August 5, 2011).

but with little or no access to establishment-specific or product-specific information. If FSIS decides to post establishment-specific data on chemical residues, it might want to consider posting the names of facilities without violations with the information listed above.

Inspection and Enforcement Data

Inspection and enforcement data include noncompliance records (NRs) and administrative actions (i.e., notices of intended enforcement or NOIEs). FSIS publicly releases these data in aggregated or summarized form in its quarterly enforcement reports. Release of these data in a more disaggregated and publicly available form might resemble that shown, for example, in Tables 5a and b; Table 7; and Table 8 of that report.⁵³ Since these serve as useful examples for discussion of the data, they are reproduced as Tables 6, 7, 1, and 2 in Appendix C. Briefly, Appendix C Tables 6 and 7 provide the number of detentions and the pounds of product involved in these actions for meat, poultry, and egg products; Appendix C Table 6 provides information on detentions made by the Office of Program Evaluation, Enforcement, and Review (OPEER), while Appendix C Table 7 provides the detention information for the Office of International Affairs (OIA). For establishment-specific data to have maximum benefit to users, inclusion of company names and addresses as well as the reason(s) for the product detention, would be important. Appendix C Table 1 provides quarterly totals of the number of establishments with administrative actions, while a more detailed summary by establishment, sorted by size is presented in Appendix C Table 2 (note that this table refers to large establishments, but similar tables corresponding to small and very small establishments are available in the original report). These include regulatory control actions, withholding actions, and suspensions. The current reporting system indicates the number of assessments performed and the number of actions taken; the publicly posted quarterly enforcement system reports identify the establishment, the action taken, and the basis for action. While considerable detail is provided in these tables, including the establishment name and the date and type of event, as well as its basis, some specific yet important information is missing. For example, an exact description of the basis for action (e.g., the specific nature of the Standard Sanitary Operating Procedure or HACCP failure) is not provided.

It must be noted that industry representatives who spoke during the open session of the first committee meeting expressed strong reservations about the public release of both types of data. For example, NRs are free-form, text-based descriptions of deficiencies written by inspectors. Some industry stakeholders believe that they are subjective and that their frequency and quality vary by inspector and by district. There was also concern that the data could be taken out of context, particularly if a user were not privy to relevant background information regarding establishment operations, history, or events that occurred before the NR was issued. Industry representatives also cited considerable variation in FSAs. They expressed concerns that many FSAs relate to and reveal specific components of an establishment's HACCP system that are considered proprietary. For example, if an establishment is performing validation or testing new equipment or procedures, the data collected are considered proprietary and are not normally subject to a FOIA request or to other forms of public release. In those cases, such sensitive information would need to be redacted from FSA data before public release.

⁵³ See http://www.fsis.usda.gov/regulations_&_policies/QER_Q1_FY2011/index.asp (accessed August 5, 2011).

Committee deliberations revealed additional concerns about public release of NR and FSA data. Specifically, there was concern that if appropriate care were not taken with inspector coding issues, the data could be used to produce inspection comparisons within and between establishments even after inspector names were redacted. Public access to NRs and FSAs may also place front-line inspectors under increased scrutiny not only by the industry and FSIS supervisory staff but by the public.

Despite the subjective nature of FSIS enforcement data, the committee noted that inspector-based data are generated in many regulatory arenas and have previously been released to the public. For example, the data released by DOL (for example, the Mine Safety and Health Administration [MSHA]; see Chapter 3) reflect investigators' assessments of mine operators' compliance with specific federal regulations, which often require some subjective judgment. In the short term, it may be necessary for FSIS to differentiate between NRs written by different inspection personnel or regions in initial public release efforts. The committee notes that the PHIS could make the NR and FSA reporting processes less subjective; this would ultimately result in greater consistency between inspections and inspectors.

Product Recalls

FSIS publicly posts recall information on its website.⁵⁴ Recall notification reports are issued for Class III recalls (i.e., recalls done for food which when consumed will not cause adverse health consequences). Recall releases, which are also sent to the media, are issued for Class II recalls (i.e., recalls done for food which when consumed may pose a *remote* probability of adverse health consequences) and Class I recalls (i.e., recalls done for food which when consumed poses a *reasonable* probability of health problems or death). Unlike most other data collected and posted by FSIS, recall information is used directly by consumers. Recalls are undertaken when there is a reasonable likelihood of injury to the public, so it is in the interest of public health to include as much detail as possible. A recall-notification report contains the name of the establishment, the establishment location, the type and quantity of the product, and the reason for the recall. When multiple product types are involved, name and product size, package establishment number, and general information about where the products were sold are provided. The recall notifications also include contact information for both the product manufacturer and FSIS.

Recall-notification reports give some general background and guidance to consumers on the reasons for the recalls. They are updated periodically, in some cases daily. In addition, FSIS maintains a recall archive,⁵⁵ which lists all the recalls by year, beginning in 1994. Except for the earlier years (1994–1995), the archive links a recall to the recall-notification report that includes all the previously mentioned details. The data provided are useful for consumers who are seeking information about an individual product. The major issue relative to enhanced release of recall data is the need for the data to be in machine-readable format so that they can be linked to the other types of establishment-specific datasets.

⁵⁴See http://www.fsis.usda.gov/Fsis_Recalls/index.asp (accessed August 5, 2011).

⁵⁵See http://www.fsis.usda.gov/Fsis_Recalls/Recall_Case_Archive/index.asp (accessed August 5, 2011).

MEASURING THE POTENTIAL EFFECTS OF THE RELEASE OF ESTABLISHMENT-SPECIFIC FOOD SAFETY AND INSPECTION SERVICE DATA

The first focus of government food-safety programs is on the protection of and improvement in public health. Food-safety regulatory programs have other effects as well, such as effects on domestic and international food markets, consumer and public perceptions of food safety, and individual and institutional trust in the integrity of the food-supply system (IOM and NRC, 2010; Ragona et al., 2011; Ruzante et al., 2010). The systematic release and analysis of FSIS data at the establishment level may have effects in all those arenas, and such effects are difficult to measure, but metrics for determining effects would be an important component of a data-disclosure strategic plan.

From a public-health perspective, it remains difficult to establish a direct link between a single regulatory action or food-safety intervention and specific public-health outcomes. However, there are instances in which implementation of food-safety policies has been followed by measurable improvements in public health, albeit true causality has not been established. For example, the implementation of restaurant grade cards appears to be associated with a decrease in foodborne-illness hospitalizations (Jin and Leslie, 2003; Simon et al., 2005). Changes in the processing of poultry (specifically, the requirement for freezing) in New Zealand have been temporally associated with declines in human campylobacteriosis (Sears et al., 2011). In the United States, a decrease in the incidence of foodborne illness was observed in the years after the implementation of the Pathogen Reduction/HACCP Rule in 1997 (CDC, 2004; White et al., 2007). However, in the case of *E. coli* O157:H7, the declines in incidence could have been associated with multiple factors and not just with the adoption of HACCP (CDC, 2011).

The link between those observations and the specific changes in processing practices has yet to be proved. The committee recognizes that the United States does not have the data or intervention analysis systems in place that could directly measure the potential public-health (or other) effects of specific activities in the FSIS food-safety programs (Batz et al., 2011; IOM and NRC, 2010). Thus, it is not now possible to measure directly the value of a public data-release program for improvements in food safety and public health. Nonetheless, that challenge is of great interest to all stakeholders. The committee understands that FSIS, the Food and Drug Administration, and the Centers for Disease Control and Prevention have embarked on a collaborative effort to develop food-safety metrics (FDA, 2010) so that public-health effects of food-safety activities can be measured better, and it encourages FSIS and other federal public-health agencies to continue and expand on these efforts.

Although it is difficult to link the release of data with public-health outcomes directly, there are metrics that could potentially provide a means of approximating the value of public data release. For example, such tangible measures as incidence of positive pathogen-testing results or indicators of process integrity could be used as intermediate food-safety metrics. Metrics on the use of publicly released data could also be collected. These might logically include the number of Web downloads, reported and peer-reviewed reports generated, policy changes, and changes in industry practices. Qualitative measures are also necessary, including assessment of how data are interpreted and used by stakeholders. Determining how data are being used also could fall on the agency public-affairs staff, who are best equipped to interpret news-media stories or e-mail inquiries from the public. In all cases, such metrics would serve as a way to measure the value associated with public release of FSIS establishment-specific data.

MAJOR FINDINGS AND CONCLUSIONS

- Public release of regulatory data is motivated by two broad purposes. The first addresses the public's "right to know" about the actions of government. The second, "targeted transparency", seeks to use information disclosure as a means of achieving specific public-policy objectives. The committee concluded that both purposes are relevant to the desire of FSIS to release establishment-specific data and that an effective disclosure policy would contribute to increased transparency to stakeholders. Releasing establishment-specific data might also affect public health favorably; this could be assessed, contingent on the development of measures specifically designed to evaluate such effects.
- The committee identified several examples of links between release of detailed data by federal, state, or local agencies and the performance of individual facilities or firms or their products. In many cases, those data originate in regulatory (compliance and enforcement) activities. Three relevant examples are efforts supported by DOL (for example, in MSHA) the Environmental Protection Agency (for example, Enforcement and Compliance History Online [ECHO]), and several state and local public-health departments (for example, with respect to restaurant hygiene and inspection grading). The committee concluded that FSIS would benefit from consultation with those agencies and could build on their effective practices when designing a public data release program.
- There is a substantial body of literature documenting the effects of disclosing establishment-specific regulatory information similar to that collected by FSIS. The literature suggests that release of those sorts of data can have substantial benefits. On the basis of a review of literature on the experience of other public agencies, the committee identified a number of potential benefits of public release of establishment-specific FSIS data, including providing incentives to protect brand reputation in food safety and to protect or enhance customer base and profitability; allowing downstream users to identify companies with performance records below and above the industry average and to create economic pressure to improve food safety; providing better insights into strengths and weaknesses of different processing practices, which could lead to industrywide improvements in food-safety practices; enhancing performance benchmarking; and improving the consistency of inspector performance. The committee concluded that public release of FSIS establishment-specific data, by themselves or in combination with other privately or publicly available data, could yield valuable insights that go beyond the regulatory uses for which the data were collected.
- The committee concluded that the available evidence of adverse effects of public release of establishment-specific data by *other* government agencies is insufficient to predict specific problems that would be inherent in the release of establishment-specific data by FSIS. In the absence of information specific to FSIS, the committee identified a number of possible costs or unintended consequences of public release of establishment-specific data, including the financial commitment associated with designing and maintaining a useful data-disclosure system; the drawing of inappropriate conclusions as a result of misinterpretation of the data, particularly if appropriate context

is not provided to users; adverse effects on international trade; the risk that proprietary or confidential information could be deduced from the data; and adverse effects on inspector performance. Those unintended consequences might affect some stakeholder groups, but other groups may not consider them adverse. For example, although the literature suggests that disclosure of information about the performance of a specific facility has the potential to affect the facility's profitability, it is precisely this possibility that creates an incentive for improved performance, which would constitute a benefit from the perspective of the public.

- On the basis of its review of information and its deliberations, the committee concluded that strong arguments support public release of establishment-specific FSIS data, especially data that are now subject to release through FOIA, unless there is compelling evidence that such release is not in the public interest.
- The committee concluded that to maximize its effectiveness and minimize its potential adverse unintended consequences, data disclosure needs to be guided by a carefully designed information-disclosure strategy. The committee also concluded that effective disclosure systems should be designed to allow continuous improvement as users gain a better understanding of how the data might be used and FSIS responds to stakeholder input. The disclosure strategy would consider the utility of the data to be released, how to release them (for example, their presentation), and how to ensure that the data are continuously updated and improved. The committee identified some key features of an effective information-disclosure plan, including ensuring the integrity of the data (requiring the development of protocols to ensure that they are accurate, timely, and likely to be useful before posting), providing precise and appropriate definitions of what is being quantified and adequate documentation of context (to mitigate the potential for misinterpretation of data), providing support for the analysis of the data by users (at a minimum providing them in machine-readable form to facilitate third-party analysis), and providing precautionary measures to prevent the linking of portions of the data in ways that would allow users to deduce confidential information about particular establishments. For all data types, it will be important to seek periodic input from stakeholders (industrial, academic, and consumer) to understand their needs and concerns. Focus groups targeted to key stakeholders may be an effective means of accomplishing that.
- As part of its charge, the committee examined the issues specific to the public release of two types of FSIS establishment-specific data: sampling and testing data (derived from standard laboratory tests) and inspection and enforcement data (derived from text written by inspectors). In their deliberations, committee members expressed different views about the implications of releasing inspection and enforcement data, which are subjective in nature. A minority noted that minimizing the potential adverse consequences of releasing this type of data on an establishment-specific basis would be especially challenging, citing concerns about inspector variability, the potential for misinterpretation of the data, and confidentiality issues. The majority, however, believed strongly that public access to this type of data could help to identify

variability in inspector performance and enforcement outcomes and ultimately facilitate more uniform inspection.

• In keeping with the purpose of attaining targeted transparency, public release of establishment-specific data is expected to result in improvement in food-safety efforts on the part of industry and government and ultimately to result in beneficial public-health outcomes. Although it is not possible to make a direct causal link between public data access and specific food-safety improvements, the committee concluded that measures of other outcomes of public release of establishment-specific data are available and that documenting those outcomes could provide insights into the relationship between data release and food safety. For example, public release of establishment-specific data could result in increased compliance with regulatory requirements, and FSIS could measure this. There are also ways of measuring the extent to which released data are used (such as number of Web downloads, peer-reviewed reports generated, and policy changes).

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Appendixes

The Potential Consequences of Public Release of Food Safety and Inspection Service Establishment-Specific Data

APPENDIX A

Committee Member Biographies

Lee-Ann Jaykus (Chair), PhD, is a professor in the Department of Food, Bioprocessing, and Nutrition Sciences and the Department of Microbiology of North Carolina State University. Her current research efforts are diverse and include the development of molecular methods to detect foodborne pathogens (Noroviruses, hepatitis A virus, and such bacterial agents as *Campylobacter* and *Salmonella*) in foods, such as preanalytical sample processing; investigation of persistence and transfer of pathogens in the food-preparation environment; and the application of quantitative microbial risk-assessment methods to food safety. Dr. Jaykus has collaborated on large, multi-institutional projects to investigate the prevalence of pathogens in domestic and imported fresh produce and to study the ecology of pathogenic Vibrio species in molluscan shellfish that originate in the Gulf of Mexico. Her professional memberships include the International Association for Food Protection (which she serves as president), the American Society for Microbiology, the Institute of Food Technologists, the Society for Risk Analysis, and the Council for Agricultural Science and Technology. Dr. Jaykus served as a member of the National Advisory Committee on Microbiological Criteria for Foods; the joint National Research Council-Institute of Medicine Standing Committee for the Review of Food Safety and Defense Risk Assessments, Analyses, and Data; the National Research Council Committee for Review of the Food Safety and Inspection Service (FSIS) Risk-Based Approach to Public Health Attribution; and the joint National Research Council-Institute of Medicine Committee on the Review of the Food and Drug Administration's Role in Ensuring Safe Food. Dr. Jaykus earned her PhD in environmental science and engineering in the School of Public Health of the University of North Carolina at Chapel Hill.

Julie A. Caswell, PhD, is a professor in and the chair of the Department of Resource Economics at the University of Massachusetts Amherst. Her research interests include the operation of domestic and international food systems, analysis of food-system efficiency, and evaluation of government policy as it affects systems operation and performance, with emphasis on the economics of food quality, safety, and nutrition. Dr. Caswell has provided her expertise on food-safety and labeling issues to the Organisation for Economic Co-operation and Development and to the UN Food and Agriculture Organization. She has held numerous senior positions with the Agricultural and Applied Economics Association and the Northeastern Agricultural and Resource Economics Association and was a Fulbright Distinguished Lecturer in Italy in 2009. Dr. Caswell has served on several joint National Research Council–Institute of Medicine committees: the Committee on Implications of Dioxin in the Food Supply (2001–2003), the Committee on the Review of the Food and Drug Administration's Role in Ensuring Safe Food (2008–2011), the Food Forum (2005–2010), the Planning Committee on Future Trends in Food Safety: Changing Market Forces, Emerging Safety Issues, and Economic Impact (2008), and the Committee on Nutrient Relationships in Seafood: Selections to Balance Benefits and Risks (2004–2006). Dr. Caswell holds a joint PhD in agricultural economics and economics from the University of Wisconsin–Madison.

James S. Dickson, PhD, is a professor in the Department of Animal Science of Iowa State University (ISU). He has 18 years of tenure at ISU and served as the chair of the Department of Microbiology from 1998 to 2003. Before his career at ISU, Dr. Dickson held a post with the US Department of Agriculture (USDA) Agricultural Research Service as a research food technologist and lead scientist. His research focuses on microbiological safety of food of animal origin, sanitization of these foods, and postprocessing survival of bacteria in foods. Dr. Dickson developed predictive *Salmonella* growth-control models that are cost-effective and of interest to USDA regulatory programs. He is a certified Hazard Analysis Critical Control Points instructor and has participated in a variety of local and international training courses, including those for food-industry audiences in Japan, China, and Singapore. Dr. Dickson served on the joint National Research Council–Institute of Medicine Committee on the Review of the Use of Scientific Criteria and Performance Standards for Safe Food and was chair of the joint National Research Council–Institute of Microbiology in 1994 and is a member of the American Society for Microbiology and the Institute of Food Technologists. Dr. Dickson holds a PhD in food science and technology from the University of Nebraska.

John R. Dunn, PhD, DVM, is the deputy state epidemiologist in the Communicable and Environmental Diseases Services of the Tennessee Department of Health. He has held the position of state public-health veterinarian since 2007 and is the director of foodborne, vector-borne, and zoonotic diseases. Dr. Dunn also serves as an adjunct professor in the Department of Comparative Medicine of the University of Tennessee College of Veterinary Medicine and as an assistant clinical professor of preventive medicine in the Department of Preventive Medicine of Vanderbilt University School of Medicine. He is a member of the National Association of State Public Health Veterinarians, the American Veterinary Medical Association, and the Council of State and Territorial Epidemiologists. Among the honors he has received is the Centers for Disease Control and Prevention Distinguished Service Award in 2006. He serves as the committee cochair of the National Association of State Public Health Veterinarians Compendium of Measures to Prevent Disease Associated with Animals in Public Settings and chairman of the Tennessee Food Safety Taskforce. Dr. Dunn received his PhD in epidemiology and DVM from Louisiana State University.

Stephen Fienberg (NAS), PhD, is Maurice Falk University Professor of Statistics and Social Science at Carnegie Mellon University. His principal research interests lie in the development of statistical methods, especially for problems involving categorical variables. Initially, he worked on the general statistical theory of log-linear models for categorical data, including approaches appropriate for disclosure, estimating the size of populations, and Bayesian approaches to the analysis of contingency tables. His research on disclosure limitation for categorical data, and on confidentiality privacy and security more broadly, has led to the creation of a new on-line journal, the *Journal of Privacy and Confidentiality*, of which he is editor-in-chief. Dr. Fienberg serves on the editorial board of the *Proceedings of the National Academy of Sciences of the United States of America* and was elected a member of NAS in 1999. He is also a fellow of the American Academy of Arts and Sciences and of the Royal Society of Canada. He has served on 29 National Research Council, NAS, and Institute of Medicine committees and panels. He chaired the Committee on National Statistics in 1981–1987 and has served as cochair of the Report Review Committee since 2012. Dr. Fienberg received a PhD in statistics from Harvard University.

William K. Hallman, PhD, is chair of the Department of Human Ecology and director of the Food Policy Institute of Rutgers, the State University of New Jersey. He is a member of the Graduate Faculties of Psychology, Nutritional Sciences, and Planning and Public Policy at Rutgers. Recent research projects have looked at consumer perceptions and behaviors related to agricultural biotechnology, animal cloning, avian influenza, accidental and intentional food-contamination incidents, and food recalls. Dr. Hallman recently served on the National Research Council Committee on an Evaluation of the Food Safety Requirements of the Federal Purchase Ground Beef Program. His current research projects include studies of public perceptions of and responses to food-safety risks, the use of nanotechnology in food, public understanding of health claims made for food products, and food safety and security among homebound elderly Americans. Dr. Hallman serves on the Executive Committee of Rutgers Against Hunger (RAH) and helped to found the New Brunswick Community Farmers Market. His recent honors include the 2009 Robert Wood Johnson Foundation Investigator Award in Health Policy Research. He earned his PhD in experimental and social psychology from the University of South Carolina.

Ginger Zhe Jin, PhD, is an associate professor in the Department of Economics of the University of Maryland (UMD). Before her appointment at UMD in 2000, Dr. Jin received her PhD in economics from the University of California, Los Angeles. Her primary fields of research are industrial organization, evaluating the role of information in population health, and family economics. Most of her research focuses on information asymmetry among economic agents and how to provide information to overcome the information problem. In 2003, she examined the effect of hygiene report cards on restaurant hygiene and foodborne illness in Los Angeles. Dr. Jin's other seminal studies include rating of health-care organizations, advertising and learning about prescription drugs, on-line trading, and the interfamilial interaction between parents and children. She is now working on peer-to-peer lending, research misconduct, inspector behavior in regulatory enforcement, and several projects related to China's economic development, health insurance, and air quality. Among her honors is serving, since 2008, as coeditor of the *Journal of Economics and Management Strategy* and *International Journal of Industrial Organization*. She has been a faculty research fellow of the National Bureau of Economic Research since 2005.

Gale Prince, BS, has more than 40 years of experience in food safety, quality control, sanitation, workplace safety, and regulatory compliance. He spent nearly 30 years at the Kroger Company as director of corporate regulatory affairs, where his major responsibilities included regulatory matters related to food and product safety and crisis management related to product safety for manufacturing plants and retail stores. Mr. Prince serves on numerous boards and committees, including the Food Protection Committee of the Food Marketing Institute and the Food Technical and Regulatory Affairs Committee of the American Bakers Association. Mr. Prince has served on the Board of Directors of the United Fresh Fruit and Vegetable Association and the Suspicious Orders Task Force of the US Department of Justice Drug Enforcement Agency. He is an honorary lifetime member and past president of the International Association for Food Protection, and the Institute of Food Technologists. He has received several awards for his expertise, including the IAFP Harry Haverland Citation Award in 2006 and other awards from the US Food and Drug Administration and the Association of Food and Drug Officials. Mr. Prince received a BS degree from Iowa State University.

Donald Schaffner, PhD, is an extension specialist in food science and a professor in the Department of Food Science of Rutgers, the State University of New Jersey. His research interests include quantitative microbial risk assessment and predictive food microbiology. He is the author of more than 100 peer-reviewed publications, book chapters, and abstracts and has received almost \$5 million in grants and contracts. Dr. Schaffner has educated thousands of food-industry professionals through numerous short courses and workshops in the United States and more than a dozen other countries. He has served on committees with the UN World Health Organization (WHO) and Food and Agriculture Organization (FAO). He is a past member of joint National Research Council–Institute of Medicine committees, including the Standing Committee on the Use of Public Health Data in U.S. Department of Agriculture's Food Safety and Inspection Service Food Safety Programs, and has chaired two expert workshops on microbial risk for WHO–FAO. Dr. Schaffner is an editor of the journal *Applied and Environmental Microbiology*. He was elected a fellow of the Institute of Food Technologists in 2010 and was elected the secretary of the International Association for Food Protection in 2010, a 5-year commitment ending with his service as the president of the organization. Dr. Schaffner holds a PhD in food science and technology from the University of Georgia.

Kathleen Segerson, PhD, is the Philip E. Austin Professor of Economics at the University of Connecticut. She has been a full professor at the university since 1996. She was the head of the Department of Economics from 2001 to 2005. Dr. Segerson specializes in natural-resource economics, in particular, the economics of environmental regulation. She is a member of the Chartered Executive Board of the Environmental Protection Agency's Science Advisory Board and previously served as the vice chair of the Advisory Board's Committee on Valuing the Protection of Ecological Services and Systems. She was a member of the US General Accounting Office's Expert Panel on Climate Change Economics from 2007 to 2008 and often serves on external review committees for the US Department of Agriculture. She has also served on three National Research Council study committees: the Committee on Assessing and Valuing the Services of Aquatic and Related Terrestrial Ecosystems (2002-2004), the Committee on the Causes and Management of Coastal Eutrophication (1998–2000), and the Committee on Improving Principles and Guidelines for Waste Resources Planning by the U.S. Army Corps of Engineers (2008– 2010). She serves on the Board on Agriculture and Natural Resources of the National Academies. In 2008, she was named a fellow by both the Agricultural and Applied Economics Association and the Association of Environmental and Resource Economists. Dr. Segerson earned a PhD from Cornell University in 1984.

Christopher A. Waldrop, MPH, is the director of the Food Policy Institute of the Consumer Federation of America, a nonprofit association. He directs research, analysis, advocacy, and media outreach for all food-policy activities at the institute. He regularly monitors food-safety activities of the US Department of Agriculture, the US Food and Drug Administration (FDA), and Congress, where he advocates for strong food-safety protections for consumers. He also coordinates the Safe Food Coalition, a group of consumer, trade-union, and foodborne-illness victim organizations dedicated to reducing foodborne illness by improving government food-inspection programs. Mr. Waldrop served on two joint National Research Council-Institute of Medicine committees: the Committee on Review of the Methodology Proposed by the Food Safety and Inspection Service (FSIS) for Follow-Up Surveillance of In-Commerce Businesses and the Committee on Review of the Methodology Proposed by the Food Safety and Inspection Service for Risk-Based Regulation of In-Commerce Activities. He is a member of the Transatlantic Consumer Dialogue and serves on the Board of Directors of the Partnership for Food Safety Education, a nonprofit organization dedicated to providing consumers with information about safe foodhandling practices. Mr. Waldrop also serves on the FDA Food Advisory Committee, which advises the commissioner on emerging food-safety, food-science, nutrition, and other policy-related health issues. Mr. Waldrop has an advertising degree from Texas Tech University and an MPH from Johns Hopkins University. He served as a Peace Corps volunteer in Ghana as a community health educator.

David Weil, PhD, is a professor of economics and Everett W. Lord Distinguished Faculty Scholar at the Boston University School of Management. He also serves as codirector of the Transparency Policy Project at the Ash Institute of Harvard Kennedy School. His research spans regulatory and labor-market policy, industrial and labor relations, occupational safety and health, and transparency policy. He has written three books, including *Full Disclosure: The Perils and Promise of Transparency* (Cambridge University Press, 2007) and the award-winning *Stitch in Time: Lean Retailing and the Transformation of Manufacturing* (Oxford University Press, 1999). In addition, he is the author of over 75 articles and publications in a variety of refereed economics, public-policy, management, and industrial-relations journals and books and numerous publications in nonacademic outlets. Dr. Weil has worked as an adviser to the US Department of Labor (DOL) Wage and Hour Division, the Occupational Safety and Health Administration, and a number of other government agencies. He also served as mediator and adviser in a variety of labor-union and labor-management settings around the world, including the National Planning Association Working Group on Workplace Regulation (1995). His research has been supported by the National Science Foundation, DOL, the National Institutes of Health, the Russell Sage Foundation, the

National Institute for Occupational Safety and Health, the Alfred P. Sloan Foundation, and the Smith Richardson Foundation. Dr. Weil received his PhD in public policy from Harvard University.

The Potential Consequences of Public Release of Food Safety and Inspection Service Establishment-Specific Data

APPENDIX B

Office of Management and Budget Memorandum for the Heads of Executive Departments and Agencies



EXECUTIVE OFFICE OF THE PRESIDENT OFFICE OF MANAGEMENT AND BUDGET WASHINGTON, D.C. 20503

December 8, 2009

M-10-06

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES FROM: Peter R. Orszag

SUBJECT: Open Government Directive

In the Memorandum on Transparency and Open Government, issued on January 21, 2009, the President instructed the Director of the Office of Management and Budget (OMB) to issue an Open Government Directive. Responding to that instruction, this memorandum is intended to direct executive departments and agencies to take specific actions to implement the principles of transparency, participation, and collaboration set forth in the President's Memorandum. This Directive was informed by recommendations from the Federal Chief Technology Officer, who solicited public comment through the White House Open Government Initiative.

The three principles of transparency, participation, and collaboration form the cornerstone of an open government. Transparency promotes accountability by providing the public with information about what the Government is doing. Participation allows members of the public to contribute ideas and expertise so that their government can make policies with the benefit of information that is widely dispersed in society. Collaboration improves the effectiveness of Government by encouraging partnerships and cooperation within the Federal Government, across levels of government, and between the Government and private institutions.

This Open Government Directive establishes deadlines for action. But because of the presumption of openness that the President has endorsed, agencies are encouraged to advance their open government initiatives well ahead of those deadlines. In addition to the steps delineated in this memorandum, Attorney General Eric Holder earlier this year issued new guidelines¹ for agencies with regard to the Freedom of Information Act (FOIA). With those guidelines, the Attorney General reinforced the principle that openness is the Federal Government's default position for FOIA issues.

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¹ http://www.usdoj.gov/ag/foia-memo-march2009.pdf

This memorandum requires executive departments and agencies to take the following steps toward the goal of creating a more open government:

1. Publish Government Information Online

To increase accountability, promote informed participation by the public, and create economic opportunity, each agency shall take prompt steps to expand access to information by making it available online in open formats.² With respect to information, the presumption shall be in favor of openness (to the extent permitted by law and subject to valid privacy, confidentiality, security, or other restrictions).

- a. Agencies shall respect the presumption of openness by publishing information online (in addition to any other planned or mandated publication methods) and by preserving and maintaining electronic information, consistent with the Federal Records Act and other applicable law and policy. Timely publication of information is an essential component of transparency. Delays should not be viewed as an inevitable and insurmountable consequence of high demand.
- b. To the extent practicable and subject to valid restrictions, agencies should publish information online in an open format that can be retrieved, downloaded, indexed, and searched by commonly used web search applications. An open format is one that is platform independent, machine readable, and made available to the public without restrictions that would impede the re-use of that information.
- c. To the extent practical and subject to valid restrictions, agencies should proactively use modern technology to disseminate useful information, rather than waiting for specific requests under FOIA.
- d. Within 45 days, each agency shall identify and publish online in an open format at least three high-value data sets (see attachment section 3.a.i) and register those data sets via Data.gov. These must be data sets not previously available online or in a downloadable format.
- e. Within 60 days, each agency shall create an Open Government Webpage located at <u>http://www.[agency].gov/open</u> to serve as the gateway for agency activities related to the Open Government Directive and shall maintain and update that webpage in a timely fashion.

² The Federal Government has defined information in OMB Circular A-130, "Management of Federal Information Resources," as any communication or representation of knowledge such as facts, data, or opinions presented in any medium or format.

- f. Each Open Government Webpage shall incorporate a mechanism for the public to:
 - i. Give feedback on and assessment of the quality of published information;
 - ii. Provide input about which information to prioritize for publication; and
 - Provide input on the agency's Open Government Plan (see 3.a.).
- g. Each agency shall respond to public input received on its Open Government Webpage on a regular basis.
- Each agency shall publish its annual Freedom of Information Act Report in an open format on its Open Government Webpage in addition to any other planned dissemination methods.
- Each agency with a significant pending backlog of outstanding Freedom of Information requests shall take steps to reduce any such backlog by ten percent each year.
- Each agency shall comply with guidance on implementing specific Presidential open government initiatives, such as Data.gov, eRulemaking, IT Dashboard, Recovery.gov, and USAspending.gov.

2. Improve the Quality of Government Information

To improve the quality of government information available to the public, senior leaders should make certain that the information conforms to OMB guidance on information quality³ and that adequate systems and processes are in place within the agencies to promote such conformity.

a. Within 45 days, each agency, in consultation with OMB, shall designate a highlevel senior official to be accountable for the quality and objectivity⁴ of, and internal controls over, the Federal spending information publicly disseminated

³ Information Quality Act, Pub. L. No. 106-554, section 515; see also, "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies" (67 FR 8452) and your agency's Information Quality Act guidelines.

⁴ The Federal Government has defined quality and objectivity in, "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies" (67 FR 8452). Quality is "...the encompassing term, of which 'utility,' 'objectivity,' and 'integrity' are the constituents." "'Objectivity' focuses on whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased."

through such public venues as USAspending.gov or other similar websites. The official shall participate in the agency's Senior Management Council, or similar governance structure, for the agency-wide internal control assessment pursuant to the Federal Managers' Financial Integrity Act.⁵

- b. Within 60 days, the Deputy Director for Management at OMB will issue, through separate guidance or as part of any planned comprehensive management guidance, a framework for the quality of Federal spending information publicly disseminated through such public venues as USAspending.gov or other similar websites. The framework shall require agencies to submit plans with details of the internal controls implemented over information quality, including system and process changes, and the integration of these controls within the agency's existing infrastructure. An assessment will later be made as to whether additional guidance on implementing OMB guidance on information quality is necessary to cover other types of government information disseminated to the public.
- c. Within 120 days, the Deputy Director for Management at OMB will issue, through separate guidance or as part of any planned comprehensive management guidance, a longer-term comprehensive strategy for Federal spending transparency, including the Federal Funding Accountability Transparency Act and the American Reinvestment and Recovery Act. This guidance will identify the method for agencies to report quarterly on their progress toward improving their information quality.

3. Create and Institutionalize a Culture of Open Government

To create an unprecedented and sustained level of openness and accountability in every agency, senior leaders should strive to incorporate the values of transparency, participation, and collaboration into the ongoing work of their agency. Achieving a more open government will require the various professional disciplines within the Government – such as policy, legal, procurement, finance, and technology operations – to work together to define and to develop open government solutions. Integration of various disciplines facilitates organization-wide and lasting change in the way that Government works.

a. Within 120 days, each agency shall develop and publish on its Open Government Webpage an Open Government Plan that will describe how it will improve transparency and integrate public participation and collaboration into its activities.

⁵ The implementing guidance for the Federal Managers' Financial Integrity Act can be found in OMB Circular A-123, "Management's Responsibility for Internal Control."

Additional details on the required content of this plan are attached. Each agency's plan shall be updated every two years.

- b. Within 60 days, the Federal Chief Information Officer and the Federal Chief Technology Officer shall create an Open Government Dashboard on <u>www.whitehouse.gov/open</u>. The Open Government Dashboard will make available each agency's Open Government Plan, together with aggregate statistics and visualizations designed to provide an assessment of the state of open government in the Executive Branch and progress over time toward meeting the deadlines for action outlined in this Directive.
- c. Within 45 days, the Deputy Director for Management at OMB, the Federal Chief Information Officer, and the Federal Chief Technology Officer will establish a working group that focuses on transparency, accountability, participation, and collaboration within the Federal Government. This group, with senior level representation from program and management offices throughout the Government, will serve several critical functions, including:
 - Providing a forum to share best practices on innovative ideas to promote transparency, including system and process solutions for information collection, aggregation, validation, and dissemination;
 - Coordinating efforts to implement existing mandates for Federal spending transparency, including the Federal Funding Accountability Transparency Act and the American Reinvestment and Recovery Act; and
 - iii. Providing a forum to share best practices on innovative ideas to promote participation and collaboration, including how to experiment with new technologies, take advantage of the expertise and insight of people both inside and outside the Federal Government, and form high-impact collaborations with researchers, the private sector, and civil society.
- d. Within 90 days, the Deputy Director for Management at OMB will issue, through separate guidance or as part of any planned comprehensive management guidance, a framework for how agencies can use challenges, prizes, and other incentive-backed strategies to find innovative or cost-effective solutions to improving open government.

4. Create an Enabling Policy Framework for Open Government

Emerging technologies open new forms of communication between a government and the people. It is important that policies evolve to realize the potential of technology for open government.

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a. Within 120 days, the Administrator of the Office of Information and Regulatory Affairs (OIRA), in consultation with the Federal Chief Information Officer and the Federal Chief Technology Officer, will review existing OMB policies, such as Paperwork Reduction Act guidance and privacy guidance, to identify impediments to open government and to the use of new technologies and, where necessary, issue clarifying guidance and/or propose revisions to such policies, to promote greater openness in government.

Nothing in this Directive shall be construed to supersede existing requirements for review and clearance of pre-decisional information by the Director of the Office of Management and Budget relating to legislative, budgetary, administrative, and regulatory materials. Moreover, nothing in this Directive shall be construed to suggest that the presumption of openness precludes the legitimate protection of information whose release would threaten national security, invade personal privacy, breach confidentiality, or damage other genuinely compelling interests.

If you have any questions regarding this memorandum, please direct them to <u>opengov@omb.eop.gov</u> or call Nicholas Fraser, Information Policy Branch, Office of Information and Regulatory Affairs, Office of Management and Budget at (202) 395-3785.

Attachment

Open Government Plan

- Formulating the Plan: Your agency's Open Government Plan is the public roadmap that details how your agency will incorporate the principles of the President's January 21, 2009, Memorandum on Transparency and Open Government into the core mission objectives of your agency. The Plan should reflect the input of (a) senior policy, legal, and technology leadership in your agency and (b) the general public and open government experts. It should detail the specific actions that your agency will undertake and the timeline on which it will do so.
- Publishing the Plan: Consistent with the deadlines set forth in this Directive, the Plan should be published online on the agency's Open Government Webpage in an open format that enables the public to download, analyze, and visualize any information and data in the Plan.

3. Components of the Plan:

- a. Transparency: Your agency's Open Government Plan should explain in detail how your agency will improve transparency. It should describe steps the agency will take to conduct its work more openly and publish its information online, including any proposed changes to internal management and administrative policies to improve transparency. Specifically, as part of your Plan to enhance information dissemination, your agency should describe how it is currently meeting its legal information dissemination obligations,⁶ and how it plans to improve its existing information dissemination practices by providing:
 - i. A strategic action plan for transparency that (1) inventories agency high-value information currently available for download; (2) fosters the public's use of this information to increase public knowledge and promote public scrutiny of agency services; and (3) identifies high value information not yet available and establishes a reasonable timeline for publication online in open formats with specific target dates. High-value information is information that can be used to increase agency accountability and responsiveness; improve public knowledge of the agency and its operations; further the core mission of

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⁶ Paperwork Reduction Act, Pub L. No. 104-13, section 3506(d).

the agency; create economic opportunity; or respond to need and demand as identified through public consultation.

- ii. In cases where the agency provides public information maintained in electronic format, a plan for timely publication of the underlying data. This underlying data should be in an open format and as granular as possible, consistent with statutory responsibilities and subject to valid privacy, confidentiality, security, or other restrictions. Your agency should also identify key audiences for its information and their needs, and endeavor to publish high-value information for each of those audiences in the most accessible forms and formats. In particular, information created or commissioned by the Government for educational use by teachers or students and made available online should clearly demarcate the public's right to use, modify, and distribute the information.
- iii. Details as to how your agency is complying with transparency initiative guidance such as Data.gov, eRulemaking, IT Dashboard, Recovery.gov, and USAspending.gov. Where gaps exist, the agency should detail the steps the agency is taking and the timing to meet the requirements for each initiative.
- iv. Details of proposed actions to be taken, with clear milestones, to inform the public of significant actions and business of your agency, such as through agency public meetings, briefings, press conferences on the Internet, and periodic national town hall meetings.
- v. A link to a publicly available website that shows how your agency is meeting its existing records management requirements.⁷ These requirements serve as the foundation for your agency's records management program, which includes such activities as identifying and scheduling all electronic records,⁸ and ensuring the timely transfer of all permanently valuable records to the National Archives.
- vi. A link to a website that includes (1) a description of your staffing, organizational structure, and process for analyzing and responding to FOIA requests; (2) an assessment of your agency's capacity to analyze, coordinate, and respond to such requests in a timely manner,

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⁷ 36 CFR Subchapter B - Records Management.

⁸ E-Government Act of 2002, Pub L. No. 107-347, section 207(e).

together with proposed changes, technological resources, or reforms that your agency determines are needed to strengthen your response processes; and (3) if your agency has a significant backlog, milestones that detail how your agency will reduce its pending backlog of outstanding FOIA requests by at least ten percent each year. Providing prompt responses to FOIA requests keeps the public apprised of specific informational matters they seek.

- vii. A description or link to a webpage that describes your staffing, organizational structure, and process for analyzing and responding to Congressional requests for information.
- viii. A link to a publicly available webpage where the public can learn about your agency's declassification programs, learn how to access declassified materials, and provide input about what types of information should be prioritized for declassification, as appropriate. Declassification of government information that no longer needs protection, in accordance with established procedures, is essential to the free flow of information.⁹
- b. Participation: To create more informed and effective policies, the Federal Government should promote opportunities for the public to participate throughout the decision-making process. Your agency's Open Government Plan should explain in detail how your agency will improve participation, including steps your agency will take to revise its current practices to increase opportunities for public participation in and feedback on the agency's core mission activities. The specific details should include proposed changes to internal management and administrative policies to improve participation.
 - The Plan should include descriptions of and links to appropriate websites where the public can engage in existing participatory processes of your agency.
 - The Plan should include proposals for new feedback mechanisms, including innovative tools and practices that create new and easier methods for public engagement.
- c. Collaboration: Your agency's Open Government Plan should explain in detail how your agency will improve collaboration, including steps the agency

⁹Executive Order 12958, Classified National Security Information.

will take to revise its current practices to further cooperation with other Federal and non-Federal governmental agencies, the public, and non-profit and private entities in fulfilling the agency's core mission activities. The specific details should include proposed changes to internal management and administrative policies to improve collaboration.

- The Plan should include proposals to use technology platforms to improve collaboration among people within and outside your agency.
- The Plan should include descriptions of and links to appropriate websites where the public can learn about existing collaboration efforts of your agency.
- iii. The Plan should include innovative methods, such as prizes and competitions, to obtain ideas from and to increase collaboration with those in the private sector, non-profit, and academic communities.
- d. Flagship Initiative: Each agency's Open Government Plan should describe at least one specific, new transparency, participation, or collaboration initiative that your agency is currently implementing (or that will be implemented before the next update of the Open Government Plan). That description should include:
 - An overview of the initiative, how it addresses one or more of the three openness principles, and how it aims to improve agency operations;
 - An explanation of how your agency engages or plans to engage the public and maintain dialogue with interested parties who could contribute innovative ideas to the initiative;
 - iii. If appropriate, identification of any partners external to your agency with whom you directly collaborate on the initiative;
 - iv. An account of how your agency plans to measure improved transparency, participation, and/or collaboration through this initiative; and
 - An explanation of the steps your agency is taking to make the initiative sustainable and allow for continued improvement.
- e. Public and Agency Involvement: Your agency's Open Government Plan should include, but not be limited to, the requirements set forth in this

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attachment. Extensive public and employee engagement should take place during the formation of this plan, which should lead to the incorporation of relevant and useful ideas developed in that dialogue. Public engagement should continue to be part of your agency's periodic review and modification of its plan. Your agency should respond to public feedback on a regular basis.

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APPENDIX C

FSIS Tables

TABLE 1 Administrative Actions Summary by Quarter for FY 2011^a

FY 2011	(October 2	010 – September	2011)
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Quarter	Total Establishments	Total Actions Initiated	Total Actions Closed
First Quarter (Oct – Dec 2010)	237	95	90
Second Quarter (Jan – Mar 2011)			
Third Quarter (Apr – Jun 2011)			
Fourth Quarter (Jul – Sep 2011)			
TOTAL	237	95	90

^a Corresponds to Table 7, Available at http://www.fsis.usda.gov/PDF/QER_Q1_FY11_Tables1-19.pdf.

Administrative Actions Taken or Pending at Large Plants	stral Suspension Suspension Basis for Action Closure Appeals and in Effect in Abeyance	SSOP HACCP SPS INH INT Other LOI LOW	3/10 X X X X	11/1/10 11/5/10 x x	x On 11/2/10, a withholding action was taken.	x On 8/20/10, a withholding action was taken.	12/26/10 × ×	x x x withholding action was taken.	9/1/10 12/27/10	7/7/10 7/8/10 x 11/8/10 On 7/19/10, the firm appealed the suspension. On s
Administrative							12/26/10			
	Deferral		10/3/10							
	NOIE		9/8/10							
	Establishment/	Establishment Number Location	AGRI STAR MEAT & POULTRY 04653A M04653A P POSTVILLE, IA	CARGILL MEAT SOLUTIONS 00086R M FORT MORGAN, CO	CARGILL MEAT SOLUTIONS 00086M M SCHUYLER,NE	CARGILL MEAT SOLUTIONS CORP 00086K M DODGE CITY, KS	CARGILL MEAT SOLUTIONS CORP 09400 M WYALUSING, PA	CARGILL MEAT SOLUTIONS CORPORATION 00086E M FRIONA, TX	CARGILL MEAT SOLUTIONS, INC 00085B M BEARDSTOWN, IL	CAROLINA PRIDE FOODS, INC 00242 M06685 P GREENWOOD, SC

TABLE 2 Administrative Actions: Large Establishments (October 2010 -December 2010)^b

			Administrative	Administrative Actions Taken or Pending at Small Plants	n or Per	iding at S	mall P	lants					
Establishment/Establishment Number Location	NOIE	Deferral	Suspension in Effect	Suspension in Abeyance		Bas	Basis for Action	ction			Ö	Closure	Appeals and Actions
					SSOP	HACCP	SPS	HNI	INT	Other	LOI	LOW	
AA MEAT PRODUCTS CORPORATION 21492 M21492 P MAYWOOD, CA					×		×						
AFA FOODS INC 21520 M FORT WORTH, TX	10/8/10	10/29/10	6/25/10	6/30/10		х							
AFA FOODS INC 13116 M FORT WORTH, TX	10/14/10	10/29/10			×	х							
ALDERFER INC 01330 M01330 P HARLEYSVILLE, PA	6/17/10	7/11/10				×						12/21/10	
ALLIED POULTRY CO INC DBA ALLIED PRINGLE FOODS SALES CO 09050 M0950 P OAKLAND, CA	5/27/10	6/17/10			×	×							
APPLE VALLEY FARMS 04894 M04894 P FRESNO, CA	7/23/10	8/27/10				х	×						
ARKANSAS DEPT OF CORRECTIONS 10624 M GRADY, AR	10/12/10	11/1/10				×	×						
BAILEY FOODS LLC 20129 M BAILEY, NC			11/17/10	11/18/10	×			×					
^c Corresponds to Table 9, Available at http://www.fsis.usda.gov/PDF/QER_Q1_FY11_Tables1-19.pdf	ailable at h	ttp://www.	fsis.usda.gov/l	PDF/QER_Q1	_FY11	_Tables1	-19.pd	f					

TABLE 3 Administrative Actions: Small Establishments (October 2010 -December 2010)^c

		-	Administrative Actions Taken or Pending at Very Small Plants	Actions Take	n or Penc	ling at Ver	y Small	Plants	~				
Establishment/Establishment Number Location	NOIE	Deferral	Suspension in Effect	Suspension in Abeyance		Bas	Basis for Action	ction			ö	Closure	Appeals and Actions
					SSOP	HACCP	SPS	HNI	INT	Other	ГO	LOW	
A & S SON INC 07885 M07885 P KEANSBURG, NJ			11/22/10	11/24/10	×	×	×		×				
ADAM'S FARM SLAUGHTER LLC 05497 M ATHOL, MA	6/1/10	6/17/10				х						11/10/10	
ALMA MEATS LLC 08728A M 08728A P ALMA, MO	1/15/10	1/25/10	5/11/10	5/17/10		×	×						
			5/28/10	6/4/10	×	×	×						
			7/14/10	7/27/10	×	×	×						On 5/28/10, suspension was reinstated.
AMERICAN KITCHEN DELIGHTS, INC. 17439 M17439 P HARVEY, IL			7/20/10	7/23/10	×		×					10/25/10	On 7/14/10, suspension was reinstated.
AMERICAN MEAT PROCESSING 02999 M SPRINGFIELD, MO	12/3/10	12/20/10				×							

TABLE 4 Administrative Actions: Very Small Establishments (October 2010 -December 2010)^d

			Administrative	Administrative Actions Taken or Pending at Very Small Plants	n or Pend	ling at Ver	y Small	Plants					
Establishment/Establishment Number Location	NOIE	Deferral	Suspension in Effect	Suspension in Abeyance		Bas	Basis for Action	ction			ö	Closure	Appeals and Actions
					SSOP	HACCP	SPS	INH INT	INT	Other	LOI	LOW	
ANNEX FOOD COMPANY, INC 05880 M05880 P PORTLAND, OR	12/23/10					×							
^d Corresponds to Table 10 Available at http://www.feis.usda.cov/DDE/DEP_01_EV11_Tables1_10_ndf	vailable at	httn://www	v feie neda anv	V/PDF/OFR (1 FV1	Tablec1	-10 nd						

Corresponds to Table 10, Available at http://www.fsis.usda.gov/PDF/QER_Q1_FY11_Tables1-19.pdf

TABLE 5 Food Safety Adjudicatory Actions (October 2010 -December 2010)^e

Establishment	Administrative Complaint	Administrative Hearing	Consent Order	Decision and Order	Action Summary
JERRY HAYES MEATS, INC. NEWARK VALLEY, NY	08/27/10		12/23/10		On December 23, 2010, Jerry Hayes Meats, Inc. entered into a Consent Decision (Order) with FSIS. The Order requires strict measures by the establishment, including revised food safety plans, <i>Escherichia coli</i> Biotype 1 and <i>E. coli</i> 0157:H7 sampling and testing programs, Specified Risk Materials program, ongoing audits, training, and recordkeeping to ensure compliance with FSIS statutory and regulatory requirements. Previously, on August 27, 2010, FSIS filed a complaint to withdraw Federal inspection services based on the establishment's recurring failures to meet FSIS public health requirements and repetitive violations of Agency statutory and regulatory requirements.
STAGNO'S MEAT COMPANY RICHARD A. STAGNO, PRESIDENT BRIAN R. STAGNO, VICE PRESIDENT 02875 M MODESTO, CA	09/10/10				On October 13, 2010, FSIS withdrew inspection service. Previously, on September 10, 2010, FSIS filed a complaint to withdraw Federal inspection services from Stagno's Meat Company. On August 13, 2010, FSIS issued a Notice of Summary Withdrawal of Federal inspection service to Stagno's Meat Company. The action was based on the establishment's recurring violations of statutory and regulatory requirements and the terms of the November 16, 2007, Consent Decision.
^e Corresponds to Table 11, Available at http://www.fsis.usda.gov/PDF/QER_Q1_FY11_Tables1-19.pdf.	11, Available at http:	//www.fsis.usda.gov/	PDF/QER_Q1_FY1	l_Tables1-19.p	df.

R First Quarter n (Oct - Dec 2010) Number of Pounds Number of Pounds Num 191,377 31 191,377 st 15 72,596 st 10 7,546 st 10 7,546	Second Quarter (Jan – Mar 2011) hber of Pounds entions Detained	Third Quarter					
Pounds Numbe Detained Detent Detained Detent 191,377 5 72,596 7 72,596 121,431		(Apr – Jun 2011)	uarter ר 2011)	Fourth Quarter (Jul – Sep 2011)	luarter p 2011)	Total FY 2011	/ 2011
31 19 st 15 7 10 12 st 10 12		Number of Detentions	Pounds Detained	Number of Detentions	Pounds Detained	Number of Detentions	Pounds Detained
15 7 10 10 12						31	191,377
10 12						15	72,596
10						10	7,546
						10	121,431
Northeast 7 3,319						7	3,319
TOTAL 73 396,269 0	0	0	0	0	0	73	396,269

TABLE 6 OPEER Detention Actions for Meat, Poultry, and Egg Products in Each Region by Quarter for FY 2011^f

			<u> </u>	:Y 2010 (Octo	FY 2010 (October 2010 – September 2011)	tember 2011)				
OIA	First Quarter (Oct – Dec 2010)	luarter ec 2010)	Second Quarter (Jan – Mar 2011)	Quarter ir 2011)	Third Quarter (Apr – Jun 2011)	uarter n 2011)	Fourth Quarter (Jul – Sep 2011)	uarter o 2011)	Total FY 2011	, 2011
Region	Number of Detentions	Pounds Detained	Number of Detentions	Pounds Detained	Number of Detentions	Pounds Detained	Number of Detentions	Pounds Detained	Number of Detentions	Pounds Detained
Western	20	283,197							20	283,197
Southern	0	0							0	0
Northeast	S	16,292							£	16,292
Northern	2	42							2	42
TOTAL	27	299,531	0	0	0	0	0	0	27	299,531

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TABLE 7 OIA Detention Actions for Meat, Poultry, and Egg Products in Each Region by Quarter for FY2011^g

The Potential Consequences of Public Release of Food Safety and Inspection Service Establishment-Specific Data