



LESSONS FROM DENMARK, THE NETHERLANDS, AND THE UNITED KINGDOM ON CREATING A MORE COORDINATED AND INTEGRATED APPROACH TO FOOD SAFETY INFORMATION



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Executive Summary

Introduction

During the past 20 years, those working to prevent foodborne illnesses in the United States—whether in government, industry, academia, or the consumer advocacy community—have made major progress in understanding food safety as a farm-to-fork challenge that necessitates science-based efforts throughout the system. Numerous reports have called for a more risk-informed and data-driven approach to U.S. food safety, and legislation currently being considered in Congress includes provisions to strengthen the scientific basis of the nation’s food safety system.

A science- and risk-driven approach is built upon a foundation of data. Those working in food safety often face the dual problems of both too much and too little information; they must cope with an explosion of information from individuals and organizations, but the specific information they require may not be available or accessible—if it has been collected at all. While positive efforts in the United States are attempting to address these challenges, serious obstacles remain. Ultimately, improving the risk basis of the U.S. food safety system will require a more coordinated and integrated approach to collecting, managing, analyzing, and communicating food safety information.

These challenges are not unique to the United States, and the efforts of other countries to institute programs, policies, and practices to support a risk-informed system can inform similar efforts in this country. In particular, the bovine spongiform encephalopathy (BSE), or “mad cow disease,” epidemic and large *Salmonella* outbreaks in the 1990s led to major changes in the food safety systems of Europe. The reforms of the past decade also have had significant implications for the role of risk analysis in food safety decision-making and, subsequently, have affected the way that data are collected and analyzed to support policy.

This report focuses on food safety activities in three countries: Denmark, the Netherlands, and the United Kingdom. The food safety efforts of these case-study countries are highly respected, and all three countries have undertaken significant reform to improve the science and analytical basis of their food safety decisions. This report also draws lessons from efforts at the European Union (EU) level.

The purpose of this report is not to directly compare the food safety systems of the United States and these three European countries nor to suggest that the United States should seek to employ a European approach to food safety. Rather, the goal is to learn from a decade of significant food safety reforms in Europe, with a focus on examples of programs, policies, and activities that could improve food safety in the United States.

Motivation

Foodborne illnesses remain an important cause of morbidity and mortality in the United States, related both to acute illnesses and to associated chronic sequelae. Furthermore, major contamination outbreaks in recent years, associated with a spectrum of foods, have created anxiety among consumers.

Concerns about foodborne illnesses and efforts to improve U.S. food safety are nothing new. The past 30 years have brought many calls for the modernization of the food safety system to better reflect changes in food production, consumption patterns, and scientific understanding. U.S. food safety laws were written more than 100 years ago, and the need for change has been iterated in more than a dozen major reports by expert bodies both inside and outside of government, such as the National Academy of Sciences (NAS) and the U.S. Government Accountability Office (GAO) (see, for example: GAO 1992, 2001, 2004, 2005; NAS 1985, 1987, 1998, 2003).

These reports share, for the most part, a similar vision for a modern food safety system that is oriented toward public health and prevention, that embraces a farm-to-table approach, and that is based upon the best available science and information. Many call for risk-based allocation of resources and the prioritization of opportunities to reduce risk, as well as for improved coordination and integration of federal, state, and local efforts. They also recommend a system that is more responsive to emerging issues and that focuses on stopping outbreaks quickly and effectively.

Moreover, a modern food safety system may be defined as one that attempts to address policy questions, not only through subjective opinion, but through explicit consideration of objective information. This idea was expressed in the 2008 report from the Food Safety Research Consortium, *Harnessing Knowledge to Ensure Food Safety*:

Each of the many participants in today's food safety system has a distinct role to play, but they all have one thing in common: the effectiveness of what they do depends on information. Up and down the line, actors in the system depend on information about potential hazards and how to minimize them, and, in the end, actors are only as good as the information on which they base their actions. This broader understanding of food safety permits us—indeed, requires us—to think of the food safety system as an information system (Taylor and Batz 2008).

The Information Infrastructure

As part of the team that published *Harnessing Knowledge to Ensure Food Safety*, we explored how to improve what we termed the nation's "food safety information infrastructure" or FSII, which is made up of "the many public and private institutions, programs, and processes through which information is collected, made accessible, and actively shared to ensure food safety in the United States" (Taylor and Batz, p.xi). As part of that project, we learned about how food safety information is currently collected, managed, and used. To briefly summarize our findings:

- The U.S. food safety information infrastructure is vastly complex and largely decentralized.
 - Few mechanisms for planning and coordinating data collection exist. Food safety epidemiology is decentralized and largely reactive to outbreaks. It is not planned in coordination with those in regulatory agencies or with those in the food industry who devise preventive strategies.
- Numerous institutional obstacles hinder information-sharing.
 - Government agencies lack the mandate and resources to collaborate on collecting or sharing information, and legal constraints, such as privacy laws, make sharing data more difficult. Further, those who collect data often have a sense of ownership and can be reluctant to share their findings.
- Technical obstacles hinder data aggregation and integration.
 - The lack of standardized approaches to data collection, including sampling protocols and analytical methods, makes it difficult or impossible to compare data from diverse sources.
 - Compilation of data is complicated or made impossible by the incompatibility of data formats and information systems.

Methodology and Approach

In our prior research into the U.S. food safety information infrastructure, we became aware of efforts in other countries to improve the information base of their food safety systems. We sought to clarify what their activities might be, and we quickly identified efforts, ranging from individual research projects to major institutional overhauls, in countries as nearby as Canada and as far away as New Zealand.

With funding from the Produce Safety Project, an initiative of The Pew Charitable Trusts at Georgetown University in Washington, D.C., we decided to concentrate on a limited number of case-study countries for which we would review the scientific literature and conduct telephone and in-person interviews.

We decided to focus on Europe because we could examine a few individual countries there as well as the broader EU food safety framework. We chose the United Kingdom, Denmark, and the Netherlands for our individual countries for reasons including the recommendations of colleagues and the promising aspects of their information-driven programs. For example, we were aware of a Danish program for attributing human cases of salmonellosis to animal sources, of a large Netherlands project aimed at prioritizing interventions to reduce cases of *Campylobacter*, and of a British project to analyze the relative risk of various hazards in the food chain. Furthermore, all three countries had undergone major reforms to their food safety institutions in the past decade.

We identified three basic questions for our case studies:

1. How have reforms in the EU and the case-study countries affected the collection, management, analysis, and communication of food safety information?
2. To what extent do the EU and the case-study countries employ coordinated and integrated approaches to food safety information?
3. How are public health surveillance data and epidemiological research used within the food safety system, particularly with respect to preventive activities?

To answer these questions, we first examined the relevant peer-reviewed literature and read government and academic reports on the collection of food safety data, research, and policymaking in Europe. We then traveled to Denmark, the Netherlands, and the United Kingdom to interview experts and government officials from food safety, public health, and scientific institutions, and, to the extent possible, to witness the systems for ourselves. We also conducted phone interviews with experts in the United States and in other countries and had follow-up conversations with our European colleagues. We have asked for comments on our findings and incorporated the feedback we've received into our report.

Our goal was to discover what we could learn from the experiences of these European countries, and what actions, if any, could be taken from their experiences and used to improve the information foundation of the U.S. food safety system.

Comparing U.S. and EU Food Safety Systems

The U.S. and European approaches to food safety are far more alike than they are different. Rates of foodborne illnesses are generally similar in both spheres, and no substantial data suggest that food consumed in the United States is any safer or less safe than that consumed in Europe.

Yet direct comparisons between the U.S. and European food safety systems are problematic. The United States has more than twice the area of the European Union, but only 60 percent of the EU's population (300 million versus 500 million). Comparing the United States to individual EU countries is even more jarring: The United Kingdom is the size of Michigan, yet its population equals that of California and Texas combined. The closest U.S. state to Denmark in size and population is Tennessee, and the Netherlands is the size of Indiana but with about three times as many people. The appendices provide detailed background on food safety systems in Europe and the case-study countries.

The uniqueness of the EU political and legal framework further complicates the situation. The European food safety system can be described as “multilevel” (Ansell and Vogel 2006). It is made up of supranational bodies, such as the European Food Safety Authority (EFSA), and of the national bodies of the 27 EU member states, as well as the provincial and local agencies within those countries. Food safety policies are set at the EU level, but the programs for achieving targets are designed, implemented, and enforced at the national level.

On its face, this multilevel governance mirrors the relationship between the federal government and state agencies within the United States, but EU member states arguably maintain more sovereignty than U.S. states. Further, while the U.S. states have important differences in institutional structures, legal frameworks, and policies, the differences in governance among EU states are far more complex. These same reasons make it difficult to compare the United States to individual European countries. Significant cultural, demographic, and sociopolitical differences also exist between European countries and the United States.

Findings

As described in detail in Chapter 2, we found that some European reforms have directly affected the collection, management, analysis, and communication of food safety information. In examining efforts within Denmark, the Netherlands, and the United Kingdom, we have identified policies and activities that have improved the information foundation required for food safety policy that is science-based, risk-informed, and data-driven. These findings are summarized in Table 1 below.

Table 1: Summary of Findings

1	The consolidation and centralization of food safety authority has improved information flows supportive of science- and risk-based policy.
2	Annual reports provide policymakers and stakeholders with unified analysis of pathogen surveillance in humans, animals, food, and feed.
3	Integrated approaches to data collection, collation, and analysis include advanced food attribution programs that combine human data with animal and food data.
4	The European Union and some EU countries employ coordinated surveillance programs for pathogens in animals, food, and feed.
5	Independent scientific institutes facilitate integrated approaches to managing and analyzing data.
6	Regulatory agencies prioritize and partially coordinate research programs.
7	Risk analysis is the defined process for policy decision-making.
8	Programs and policies employ transparency and public participation as key principles.
9	The European Union has extensive traceability requirements and has made major investments in next-generation systems.

Consolidation and centralization

Centralization of authority at the EU level through the European Food Safety Authority (EFSA) has led to increased coordination of data programs and increased integration of data across countries, as well as to the harmonization of surveillance and regulation. Major differences in national food safety systems across Europe remain, however. Some member states, including Denmark, the Netherlands, and the United Kingdom, have consolidated food safety authority within a single regulatory and inspection agency. These consolidation reforms have reduced duplication and fragmentation of effort, but the reality of the “single food agency” has been overstated; in all three case-study countries, key responsibilities related to food safety remain spread across several agencies. Nevertheless, consolidation reforms have helped to clarify the roles and responsibilities of these agencies and have led to increased coordination and integration of food safety information.

Annual reports

The EU publishes an integrated annual report that presents data collected from all member countries on foodborne disease, foodborne outbreaks, and pathogen surveillance in food and food animals. These reports are notable in part because they aggregate across so many countries, but also because they combine two key types of data that are rarely presented in the same place: data on human illnesses, which are collected through public health surveillance systems; and data on the contamination of food and food animals, which are collected by regulatory agencies. Some member countries, such as Denmark, the Netherlands, and the United Kingdom, routinely publish their own annual or biannual reports, which are even more extensive than the EU-wide reports. The United Kingdom also publishes an annual report on all science and research conducted by its Food Standards Agency (FSA). These reports represent a major step forward in the routine communication of scientific food safety information not only among governments, but with the public, the food industry, and policymakers who use the information in planning and prioritization.

Integrated data systems and analysis

Denmark, the Netherlands, and the United Kingdom employ integrated approaches to information management and analysis, including multi-agency databases and food attribution models that explicitly combine and analyze data from human illnesses with data from food and animals. These models focus on pathogen subtyping to link pathogen strains from humans with those from animals. These integrated approaches to data and analysis facilitate integrated annual reports.

Coordinated data collection

The European Union employs standardized EU-wide baseline surveys to estimate the prevalence and levels of pathogenic contamination in arrays of foods and sets minimum requirements for routine pathogen surveillance for selected pathogens and food animals. These coordinated studies are used to set targets and develop microbial standards in food-animal production. Some member countries, such as Denmark, maintain more extensive routine monitoring programs than required by the EU. These coordinated food-animal surveillance systems have been critical to enabling integrated analysis.

Independent scientific institutes

In all three case-study countries, risk assessment is housed in independent governmental science bodies that are separate from risk-management agencies. These bodies maintain the lead roles in data collection and analysis and are responsible for both the surveillance of human illnesses and data on microbiological hazards in animals, food, and feed. This arrangement creates a critical mass of information and expertise; improves the coordination, flow, and integration of relevant data; and facilitates advanced analyses.

Coordinated research priorities

Although research and data collection are largely conducted by independent scientific and risk-assessment institutes and agencies in Denmark, the Netherlands, and the United Kingdom, much of the funding for these activities flows through policy and risk-management agencies. Regulatory decision-makers, therefore, set broad priorities for scientific programs across government agencies and ensure that research, data collection, analyses, and reporting are responsive to policymakers' needs.

Basis in risk analysis

The European Union and many member countries, including Denmark, the Netherlands, and the United Kingdom, embrace risk analysis as a formal process to inform food safety policy and decision-making, including the delineation of responsibilities for risk management, risk assessment, and risk communication. For microbial hazards, this has largely resulted in more data-driven policy, as mandatory risk assessments have required scientific support and data collection. Public health surveillance data are used by the EFSA and some member states in policymaking and decision contexts, including priority setting, resource allocation, policy development, and program management.

Transparency and public participation

Transparency and public participation are key principles of European food safety systems, particularly of the EFSA and of the United Kingdom's FSA, and are a means of gaining and maintaining the public confidence. To increase transparency and participation, agencies coordinate with stakeholders and advisory committees, hold open management meetings, and publish extensively, including meeting minutes, evidence and analyses supporting decisions, and planning and prioritization documents.

Traceability

Mandatory traceability is a foundational principle of EU food safety law; all food and feed must be traceable “one-up, one-down,”¹ by food and feed businesses, including importers. Unlike in the United States, primary producers and restaurants are not excluded from these requirements, and mandatory animal-identification systems are in place for livestock. The EU has invested €100 million in nine traceability research projects, including efforts aimed at developing integrated traceability systems and harmonizing existing systems.

Recommendations

The Case for Major Institutional Reform

We found that reforms aimed at consolidating food safety authority were critical to building a strengthened role for information-driven analysis and decision-making in Denmark, the Netherlands, and the United Kingdom. It would be premature to recommend an overhaul of U.S. food safety institutions based on three brief case studies, but our findings and prior research suggest that the creation of a Cabinet-level food safety agency in the United States would be a major, and perhaps necessary, step toward a science- and risk-based food safety system. To be effective, such a Cabinet-level agency would need to coordinate regulatory and inspection programs of the food safety offices of the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) and maintain funding lines to agencies to ensure appropriate data inflows. It also would need to have broad authority to allocate resources, prioritize preventative efforts, and coordinate data collection and research.

¹ “One-up, one-down” traceability is an approach in which food companies must maintain records to identify from whom they obtained input products or ingredients and to whom they sold their food products.

Similarly, although the scientific research and analyses conducted within FDA and USDA's Food Safety and Inspection Service (FSIS) are of high quality, expertise is spread across two rather small divisions and remains separated from the epidemiologists within the foodborne group of the Centers for Disease Control and Prevention (CDC). The fragmentation of data and analytical capacity among CDC, FDA, and FSIS makes it nearly impossible to maintain integrated programs geared toward linking human and food-animal surveillance data. Our findings in Denmark, the Netherlands, and the United Kingdom show the strength of maintaining single institutions to oversee scientific advice. Combined with a Cabinet-level food safety agency, such an institution in the United States could greatly improve scientific coordination and integration. A new, independent Federal Institute for Food Safety Risk Analysis, staffed mostly by scientists and analysts within FDA, USDA, and CDC food safety groups, would support a risk-based food system through integrated research, data collection, and analysis.

Within the existing systems, and/or in conjunction with the creation of an independent Federal Institute for Food-Safety Risk Analysis, we would make the following specific recommendations, as detailed in Chapter 3:

Produce unified annual reports of foodborne pathogen surveillance in humans, animals, food, and feed.

- Mandate (and fund) CDC, FDA, and USDA to collaborate on an annual report that presents, in a single, consumer-friendly volume, aggregated data and analysis on surveillance of human foodborne illnesses, including outbreaks, and on the surveillance of pathogens in animals, food, and feed. These reports should include routinely updated national estimates of the incidence of disease caused by major foodborne pathogens.

Improve farm-to-fork microbial surveillance of domestic and imported food.

- Develop a unified national surveillance plan for food contamination, incorporating advanced subtyping of isolates and with increased investment in routine monitoring, baseline studies, and food surveys.

Increase capacity for integrated food attribution analysis.

- Develop a unified strategy for estimating the relative contribution of various foods to the overall foodborne disease burden (i.e., food attribution analysis) by:
 - Creating and funding a common working group to integrate and analyze data from CDC, FDA, and USDA.
 - Integrating pathogen subtyping data from food, animals and feed into PulseNet, a CDC-coordinated network of federal, state and local laboratories. Also, adopt additional subtyping methods into PulseNet, and explicitly link PulseNet to outbreak data.
- Develop a unified strategy to support setting broad priorities across and within food safety agencies.
- Provide funding pathways to ensure access to data and analyses.

Improve the coordination of food safety research.

- Develop a unified long-term strategic vision of food safety research needs and publish annual prioritized lists of specific needs, with the integration of risk regulators into the setting of research priorities.

Improve transparency and public participation.

- Establish transparency policies that increase publication of data and analyses used to support decisions.
- Increase stakeholder engagement and public participation in analytical activities beyond major risk assessments.



Improve the effectiveness of trace-back and trace-forward data for outbreak response.

- Extend traceability requirements back to the farm and forward through food service.
- Develop standardized recordkeeping formats to facilitate harmonized data and create incentives for electronic recordkeeping.

Introduction

A Persistent and Vexing Problem

Foodborne illnesses remain an important cause of morbidity and mortality in the United States, related both to acute illness and to associated chronic sequelae. Despite some advances, recent data suggest foodborne illnesses are no longer in decline. In recent years, major food outbreaks have been associated with a spectrum of foods, including meat and poultry, fresh produce, canned goods, processed foods, and refrigerated and frozen foods (see Table 2 for a listing of some major outbreaks in the past three years). In 2010, additional outbreaks or recalls have been caused by contaminated black and red pepper, cheese, beef, pecans, frozen chicken potpies, instant noodles, ready-to-eat meats, and HVP, or hydrolyzed vegetable protein.²

Table 2: Major U.S. foodborne illness outbreaks, 2006-2009

Year	Pathogen	Minimum Impact
Aug.-Sept. 2006	<i>E. coli</i> O157:H7 in bagged spinach	199 ill in 26 states, three deaths; \$200 million in damages
Sept. 2006	<i>Salmonella</i> Typhimurium in tomatoes	190 ill, 24 hospitalized
2006	<i>Salmonella</i> Newport in tomatoes	115 ill, eight hospitalized
Nov.-Dec. 2006	<i>E. coli</i> O157:H7 in iceberg lettuce at Taco Bell, originally thought to be associated with green onions	71 ill
Feb. 2007	<i>Salmonella</i> in Peter Pan peanut butter	425 ill in 25 states; recall cost, \$50-\$60 million
June 2007	<i>Salmonella</i> in Veggie Booty snack	65 ill in 20 states
2007	<i>E. coli</i> O157:H7 in frozen ground-beef patties	40 ill
2007	<i>Salmonella</i> I4,[5],12:i:- in frozen potpies	401 ill (reported), 65 hospitalized
2007	<i>Clostridium botulinum</i> in canned chili sauce	eight ill
Apr. 2008	<i>Salmonella</i> in cantaloupes from Honduras	60 ill in 16 states
2008	<i>Salmonella</i> Saintpaul in imported jalapeno and serrano peppers (and possibly tomatoes)	1,442 ill in 43 states, 286 hospitalizations, two deaths (possible). Florida tomato producers lost about \$100 million

² <http://www.fda.gov/safety/recalls/default.htm>

Year	Pathogen	Minimum Impact
Jan. 2009	<i>Salmonella</i> Typhimurium in peanut butter and peanut paste (nearly 4,000 products recalled)	690 ill in 46 states, more than 20 percent hospitalized, estimated nine deaths
2009	<i>Salmonella</i> Newport in ground beef	800,000 lbs. of beef recalled
2009	<i>E. coli</i> O157:H7 in ground beef	23 reported ill, at least 12 hospitalized
Aug.-Sept. 2009	<i>E. coli</i> O157:H7 in refrigerated raw cookie dough	80 ill, 35 hospitalized, 10 severe with Hemolytic Uremic Syndrome, no deaths

The problem goes beyond outbreaks, however. Last year, the CDC reported that “progress toward the national health objectives has plateaued, suggesting that fundamental problems with bacterial and parasitic contamination are not being resolved” (CDC 2009a). More recently, the CDC reported that “FoodNet surveillance data for 2009 show reductions in the incidence of STEC O157 and *Shigella* infections, but little or no recent progress for other pathogens” (CDC 2010).

As a consequence, consumer confidence has eroded. A 2008 poll found that 80 percent of Americans were concerned or very concerned about food safety (Consumer Reports 2008), and a poll conducted in the wake of the peanut butter outbreak found that fewer than one in four consumers believed that the U.S. food supply was safer than it was a year earlier (FIC 2009).

Changing Times

Concerns about foodborne illnesses and efforts to improve the safety of the food supply are nothing new. When Upton Sinclair penned *The Jungle* more than 100 years ago, the resulting public outcry spurred the passage of the Pure Food and Drugs Act and the Federal Meat Inspection Act of 1906.³ These laws, since amended, are the foundation of today’s food safety system, which is comprised of more than 200 federal laws and a dozen federal agencies (NAS 1998).

The production, delivery, and consumption of food changed dramatically during the 20th century, as technological strides improved agricultural production and processing, as Americans increasingly ate meals away from home, as small regional production expanded into global supply chains run by multinational corporations, and as demographic and socioeconomic shifts resulted in changes in eating patterns, such as the increased consumption of fresh fruits and vegetables.

The same technological, economic, and social changes that have transformed the food system have been mirrored, particularly in recent years, by changes in how we think about food safety. For much of the 20th century, the food safety system in the United States was focused on basic sanitation, chemical contaminants, and food additives. But by the 1990s, concerns about seafood safety, and outbreaks of illnesses involving ground beef, poultry, produce, and

³ Federal Meat Inspection Act of 1906 (United States Statutes at Large (59th Cong., Sess. I, Chapter 3913; cited as 34 Stat. 674)), and Pure Food and Drugs Act of 1906 (United States Statutes at Large (59th Cong., Sess. I, Chapter 3915; cited as 34 Stat. 768))

other products focused concerns more directly on the public health effects of pathogenic microorganisms. Pathogens present a much different challenge than prior concerns because they can enter anywhere along the complex food chain from production to consumption, after which they can grow or be killed.

These challenges and changes have been driven home by recent U.S. outbreaks in spinach, iceberg lettuce, green onions, tomatoes, serrano peppers, cantaloupe, and other fresh fruits and vegetables. These outbreaks have been acutely worrisome to consumers who often consume raw fresh fruits and vegetables (cooking often is the only way to remove or inactivate pathogens).

Produce is increasingly associated with foodborne illnesses and outbreaks (Lynch et al. 2009, Hanning et al. 2008, Gerner-Smidt and Whichard 2008, Rangel et al. 2005, Tauxe 1997). In an analysis of foodborne outbreaks from 1990 to 2003, the Center for Science in the Public Interest (CSPI) found that 20 percent of all cases were linked to contaminated produce (DeWaal et al 2006). The CSPI, along with the Consumer Federation of America (CFA) and the Produce Safety Project at Georgetown University (funder of this report) have begun advocating for mandatory and enforceable safety standards for produce sold in the United States, both domestic and imported. The FDA has committed to proposing such a rule by October 2010. Others have gone so far as to recommend the irradiation of leafy greens and other produce (Maki 2008, Osterholm and Norgan 2004). The GAO further has recommended improvements needed in FDA oversight of produce safety (GAO 2008).

A Modern Food Safety System

For the past 30 years, many calls have been issued for the modernization of the food safety system. The need for change has been voiced in a dozen or more major reports by expert bodies inside and outside of government, such as the GAO, the NAS, the Science Board of the FDA, and the Trust for America's Health (TFAH) (see, for example: GAO 1992, 2001, 2004, 2005; NAS 1985, 1987, 1998, 2003; FDA Science Board 2008; TFAH 2009).

Most of these reports share a similar vision for a modern food safety system oriented toward the public health and prevention that embraces a farm-to-table approach and that is based upon the best available science and information. Many call for risk-based allocation of resources and the prioritization of opportunities to reduce risk, as well as for improved coordination and integration of federal, state, and local efforts. They also recommend a system that is more responsive to emerging issues and that is focused on stopping outbreaks quickly and effectively.

Although many have called for a more risk- and science-based food safety system, no definition of what such a system entails is universally accepted. In general, however, it may be characterized as one that:

- Defines “risk” in public health terms. It recognizes that the primary goal of food safety policy is to protect the public health, and, therefore, policies, programs, and analyses should measure risk as the likelihood and severity of adverse impacts on human health.
- Prioritizes efforts and limited resources for an array of hazards. It ensures that surveillance, regulatory, and research resources are allocated to maximize effectiveness by prioritizing opportunities and directing efforts to address the most serious foodborne risks and achieve the greatest reductions in those risks.
- Continuously evaluates programs and policies for efficacy. It uses information it collects and analyses on the surveillance of human disease and on food and animals to evaluate whether programs are functioning as intended and predicted and to measure the effects of food safety interventions on public health.

- Considers factors beyond risk. It recognizes that analyses to support resource allocation or other policy decisions will never be the sole source of information that drives policy; factors such as feasibility, practicality, cost-effectiveness, public acceptance, and other economic and social factors also play important roles in public health decisions.
- Takes a farm-to-table approach. It recognizes that contamination can occur anywhere along the long food supply chain and that contributing factors from primary production through final preparation can lead to pathogen growth or decline or to cross-contamination of other foods.
- Is grounded in the principles of risk analysis. It embraces a risk-analysis framework in decisions and rule-making, including explicit consideration of risk management, risk assessment, and risk communication. Such assessments must be based on the best available science and undertaken in an objective, independent, and transparent manner.
- Is data driven. It seeks and employs objective data and analysis to inform and support decisions and policies through an information foundation that is empirical, quantitative, and real-time, with identification of data needs and design of data systems all based on strong analytic underpinnings.
- Invests in science, data, and analysis. It is sufficiently funded to invest in improving the data and analytical methodologies that support the assessment, comparison, and reduction of foodborne hazards, recognizing that setting priorities involves subjective judgments and uncertainty, but that continual efforts should be made to improve the scientific basis of those judgments and help reduce that uncertainty.

A modern food safety system is also one that is organized around a clear set of policy questions, such as:

1. What are the risks in the food supply, and where are they?
2. Which of these risks represents the greatest burden on public health?
3. What factors along the farm-to-consumption continuum affect the introduction, amplification, and reduction of pathogenic contamination?
4. Where are the opportunities to reduce risk?
5. Which interventions are feasible? Which are most cost-effective?
6. How can resources be best allocated to protect the public health?

Moreover, a modern food safety system attempts to answer such questions not through subjective opinion, but through objective information. As Taylor and Batz (2008) wrote:

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

Put another way, a modern food safety system is dependent upon the knowledge and information gleaned from objective data collection, analysis, and research. This is because prevention depends upon decision-makers being able to make informed choices despite the vast complexities in the system. Analysis is an inherently integrative tool that

helps to make sense out of a complicated mess of signals; information from anywhere in the system—published literature, new research, existing data programs, confidential private data—may be combined to provide insights that would otherwise not be apparent. This is particularly true when analysis consolidates the available science toward answering a specific risk-management question.

Improving the Information Base

In a prior report, we (working with others) described the food safety-information infrastructure (FSII) in the United States (Taylor and Batz 2008). In that effort, we discussed the landscape of federal, state, and local agencies, private companies and trade associations, academic research programs, and nonprofit and advocacy organizations that comprise the food safety system and that collect and use information to make decisions. We described the challenges preventing information from getting to the parties that need it, with a focus on public-sector decision-makers, and we made recommendations for improving the way such information is shared across this fragmented system.

Indeed, improved data sharing has been a theme of recent efforts to reform food safety. It was a key component of a bill introduced by then-Sen. Barack Obama,⁴ and it is a theme that was picked up by President Obama's Food Safety Working Group. In July 2009, the group identified three core principles to “guide the development of a modern, coordinated food safety system,” the second of which was the importance of good data and analysis (FSWG 2009). The group wrote, “High-quality information will help leading agencies know which foods are at risk; which solutions should be put into place; and who should be responsible.”

In the course of the FSII project, we became aware of efforts in other countries to improve the information base of their food safety systems. We sought to clarify this anecdotal knowledge and gain a fuller understanding of what activities might be underway, and we quickly identified efforts, ranging from individual research projects to major institutional overhauls, in countries as nearby as Canada and as far away as New Zealand.

With funding from the Produce Safety Project, an initiative of the Pew Charitable Trusts at Georgetown University, we decided to focus on a few case-study countries for which we would review the scientific literature and conduct telephone and in-person interviews.

We decided to focus on Europe because we could examine a few individual countries there as well as the broader European Union food safety framework. We chose the United Kingdom, Denmark, and the Netherlands for our individual countries for reasons including recommendations of colleagues and our knowledge of their programs. For example, we were aware of the Danish program for attributing human cases of salmonellosis to animal sources (Wegener et al. 2003) and of a large project aimed at prioritizing interventions to reduce cases of *Campylobacter* in the Netherlands (Havelaar et al. 2007b). We also were familiar with a British project to analyze the relative risk of various hazards in the food chain (FSA 2010a).

Furthermore, all three of these countries recently had undergone major reforms to their food safety institutions. When Denmark created the Danish Zoonosis Centre (DZC) in 1994, it was the first of its kind, a cross-government collaborative institute dedicated to integrated surveillance of pathogens in humans, food, and feed. The creation of the Food Standards Agency (FSA) in the United Kingdom in 2000 ushered in an era of consolidation of food safety responsibilities throughout Europe and helped drive the creation of the European Food Safety Authority (EFSA) and the EU approach to food safety. The Netherlands consolidated food safety in 2002 and has been a leader in risk-based policy; it is one of just a few countries to maintain both a risk-assessment group within its regulatory agency and a large, independent scientific institute responsible for major risk-assessment projects.

⁴ The Improving Food-borne Illness Surveillance and Response Act of 2008, S. 3358, 110th Cong. (2008).

The principal goal of our informal case studies was to identify programs, policies, and projects that led to a stronger information base for a more coordinated and integrated approach to food safety. We started with three basic questions:

1. How have reforms in the European Union and our case-study countries affected the collection, management, analysis, and communication of food safety information?
2. To what extent do the EU and the case-study countries employ coordinated and integrated approaches to food safety information?
3. How are public health surveillance data and epidemiological research used within the food safety system, particularly with respect to preventative activities?

Based on the answers to these questions, what can we learn from their experiences? And, what actions, if any, can we take to improve the information foundation of the U.S. food safety system?

To address these questions, we examined the relevant peer-reviewed literature and read government and academic reports on food safety data collection, research, and policymaking in Europe. We then traveled to Denmark, the Netherlands, and the United Kingdom to interview experts and government officials from food safety regulatory bodies, public health agencies, and scientific institutes, and to the extent possible, to witness their systems for ourselves. We also conducted phone interviews with experts in the United States and in other countries and had follow-up conversations with our European colleagues. We asked for comments on our findings and have incorporated the feedback into our report.

Chapter 2 describes specific food safety information activities organized into distilled findings, and Chapter 3 presents recommendations to improve the science and risk basis of the U.S. food safety system, specifically by moving toward a more coordinated and integrated approach to collecting, collating, and analyzing food safety information. Important support materials are provided in the appendices. Appendix A provides an overview of the European food safety system, while Appendix B provides similar overviews of the food safety systems of Denmark, the Netherlands, and the United Kingdom.

Findings

The past decade has been one of significant change in European food safety, both at the national and EU levels. Since the late 1990s, many European countries have undertaken major reforms and consolidated their food safety agencies (GAO 2005), including Austria, Denmark, Finland, Germany, Ireland, the Netherlands, Spain, and the United Kingdom. At the same time, the European Union has been making a parallel effort to centralize and harmonize its food safety efforts (Leibovitch 2008). The 27 European Union member states are shown in Figure 1 and include the three countries that are the focus of this report.

Figure 1: Map of the European Union, case-study countries highlighted



Appendix A provides an overview of food safety in the European Union, with a focus on how 10 years of reforms have created a more science- and risk-based approach to food safety. It describes the motivations for reform as they relate to science and trust and the general laws and regulations that form the basis of European food safety. The appendix describes in some detail the important roles of the European Food Safety Authority (EFSA) and the European Centers for Disease Control and Prevention (ECDC), as well as the information that flows between these bodies and the EU member states.

Appendix B provides a similar overview of the food safety systems of Denmark, the Netherlands, and the United Kingdom with a focus on how regulatory and institutional reform have affected information flow and scientific analysis in support of risk-based food safety. Each of these countries has consolidated food safety authority in the past decade, and the appendix describes the roles of and relationships among relevant institutions, with a focus on how food safety information is collected, managed, shared, and analyzed.

In particular, Appendix B describes Denmark's Veterinary and Food Administration (DVFA), Statens Serum Institut (SSI), and its National Food Institute (DTU Food) and explores the critical role of DTU Food in conducting integrated surveillance and analysis. In The Netherlands, the Food and Consumer Product Safety Authority (VWA) and scientific institutes such as the RIKILT Institute for Food Safety and the National Institute for Public Health and the Environment (RIVM) perform similar functions, while in the United Kingdom, the Food Standards Agency (FSA) works closely with both the Health Protection Agency (HPA) and the Department for Environment, Food, and Rural Affairs (Defra).

The observations described in these appendices led to nine specific findings:

Finding 1: Consolidation and centralization.

Centralization of authority at the EU level through EFSA has led to increased coordination of data programs and increased integration of data across countries, as well as to the harmonization of surveillance and regulation. Major differences in national food safety systems across Europe remain, however. Some member states, including Denmark, the Netherlands, and the United Kingdom, have consolidated food safety authority within a single regulatory and inspection agency. These consolidations have reduced duplication and fragmentation of efforts, but the reality of the “single food agency” has been overstated; in all three case-study countries, key responsibilities related to food safety remain spread across several agencies. Nevertheless, consolidation reforms have helped to clarify roles and responsibilities and led to increased coordination and integration of food safety information.

Food scares in the 1990s, primarily BSE, or “mad cow disease,” but also outbreaks associated with other pathogens and chemical contaminants, led to a major loss of consumer confidence in the safety of the European food supply and the institutions charged with overseeing food safety. As a consequence, many countries consolidated their food safety agencies and enacted major reforms to win back public support. At the same time, these scares highlighted the need for reform at the EU level and spurred the unprecedented creation of a set of supranational laws, regulations, and institutions dedicated to food safety. Many reforms enacted at the national level of the member states mirrored those at the EU level.

Ten years ago, information sharing among European countries on food safety was largely ad hoc. Food was primarily a trade issue, with obvious economic and cultural characteristics. One country had little incentive to tell another country, for example, that one of its exported products was contaminated or to conduct surveillance of a food product using the same analytic laboratory methods used by a neighboring country. What harmonization existed was largely due to extensive professional networks of scientists.

The creation of EFSA in 2003 (described in Appendix A) and efforts to address *Salmonella* across a variety of food chains are evidence of a new, more coordinated, integrated approach to food safety at the EU level. For example, in EU-wide baseline surveys of numerous animal products for *Salmonella* (described in Finding 3), each country is required to collect the same data using the same methodology, ensuring not only that data are comparable, but that they address the key question of how to set an EU-wide target for the prevalence of a pathogen in a given product. Networks of European Union and national reference laboratories facilitate analytical harmonization, and financial and technical aid are available to countries without the necessary resources or infrastructure. Such data collection is both coordinated—that is, designed to be able to address a policy question—and integrated—that is, eventually pulled together in one place.

Not all data are so precisely coordinated or of equal quality across member states, but attempts are made to integrate the most relevant. Every year, each member country is mandated to report to EFSA its surveillance of certain pathogens in certain products, and it is mandated to report to the ECDC its surveillance of human illnesses caused by certain pathogens. Given differences in national public health systems and food monitoring programs, these data are not gathered in exactly the same way. For each country, data may come from multiple programs in multiple agencies, requiring integration at the national level. The EFSA and ECDC then compile the information into unified annual reports, and EFSA produces a combined report. This routine updating of some of the most relevant data on human illnesses and food contamination and their compilation in a single volume for the EU is a significant and important example of the increased role of information in European food safety.

In addition to centralization of authority and coordination at the EU level, consolidation of food safety agencies at the national level has been a major theme of reform in Europe during the past 10 years or so. The GAO has published at least two reports that detail how and why countries in Europe and elsewhere have consolidated their food safety agencies (2005, 2008). In addition to Denmark, the Netherlands, and the United Kingdom, other European countries that have consolidated food safety responsibilities include Ireland, Germany, Austria, Portugal, and Spain.

As shown in Appendix B, although Denmark, the Netherlands, and the United Kingdom have consolidated their food safety systems, to call them “single food agencies” might be overstating. Although most food agencies consolidate rulemaking authority and inspection responsibilities, they still rely on other agencies to investigate outbreaks, perform laboratory analyses, undertake bench or social science research, conduct risk assessments, and fulfill other needs. In some cases, some relevant responsibilities are still conducted outside of the consolidated food agency, such as oversight of imports, feed safety, animal health, pesticide residues, or veterinary drugs.

Therefore, while these European countries have reduced institutional fragmentation, this change seems to be not so much about consolidation as about improving coordination, communication, and interaction. The reorganizations have clarified institutional roles and more effectively delineated the relationships between institutions. We also found, unsurprisingly, that consolidation has eased some of the burden of inter-agency communication: Fewer “turf” battles and legal barriers mean that data are more readily shared among consolidated agencies.

A somewhat separate issue from consolidation is the independence of risk management from industry promotion. In the United Kingdom, FSA is an independent department that is answerable to an appointed board rather than directly reporting to a minister. In this regard, FSA is unique. In the Netherlands, although the food safety regulators and inspectors are within the agricultural ministry, much of their funding comes from the health ministry, which may set targets and goals for food safety. In Denmark, although food safety regulatory and inspection responsibilities are now consolidated into a single agency, this agency falls within the Ministry of Food, Agriculture, and Fisheries, which is also responsible for the promotion of Danish food and farmers.

Finding 2: Annual reports.

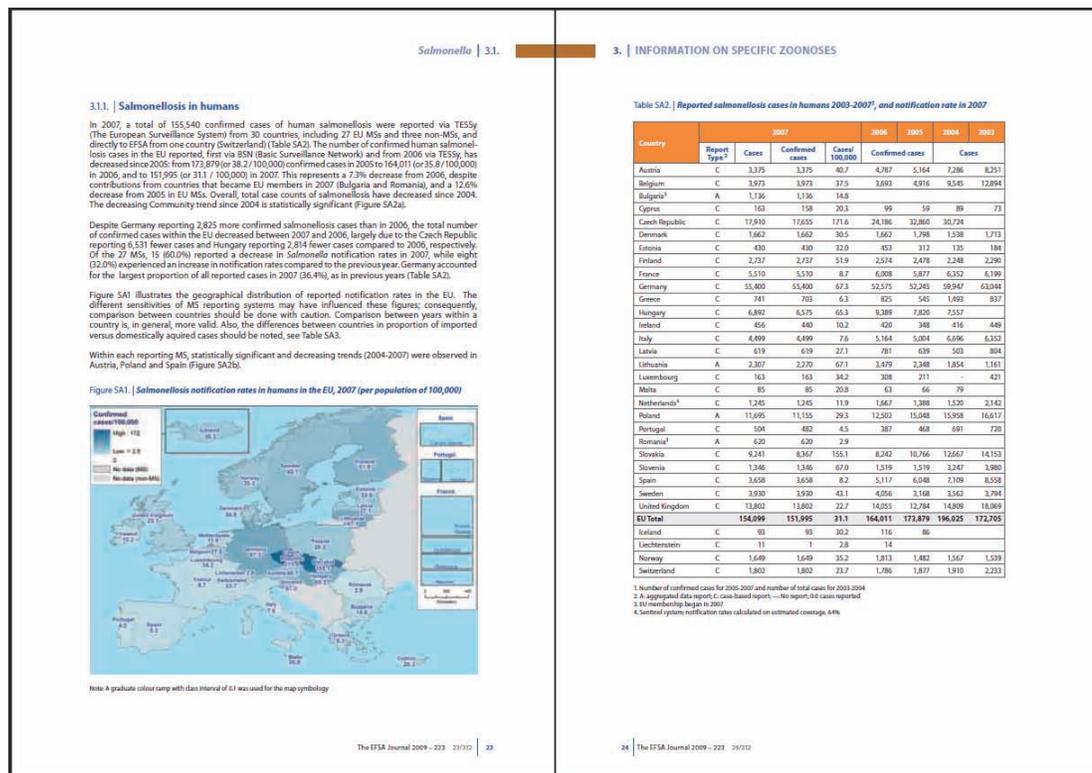
The EU publishes an integrated annual report that presents data collected from all member countries on foodborne disease, foodborne outbreaks, and pathogen surveillance in food and food animals. These reports are notable in part because they aggregate across so many countries, but also because they combine two key types of data that are rarely presented in the same place: data on human illnesses, which are collected through public health surveillance systems; and data on contamination of food and food animals, which are collected by regulatory agencies. Some member countries, such as Denmark, the Netherlands, and the United Kingdom, routinely publish their own annual or biannual reports, which are more extensive than the EU-wide reports. The United Kingdom also publishes an annual report on

LESSONS FROM DENMARK, THE NETHERLANDS, AND THE UNITED KINGDOM ON CREATING A MORE COORDINATED AND INTEGRATED APPROACH TO FOOD SAFETY INFORMATION

all science and research conducted by its FSA. These reports represent a major step forward in the routine communication of scientific food safety information not only among governments, but with the public, the food industry, and policymakers who use the information in planning and prioritization.

Every year, the EU publishes an integrated community report that details the surveillance of zoonotic and foodborne pathogens in all EU member countries as well as a few other European nations (EFSA/ECDC 2008, 2009a, 2009b, 2010). These substantive reports are a significant undertaking, involving data from more than 30 countries on 10 pathogens, and they include information on foodborne outbreaks, human disease surveillance, and the monitoring of animals, food, and feed. These annual reports are rich in data tables and graphs, but they are also professionally produced to be approachable and readable for a wide audience. They are published in hard copy and made available online.⁵ A couple of example pages from the Community Summary Report on Trends and Sources of Zoonoses and Zoonotic Agents in the European Union in 2007 (2009a) are presented in 2.

Figure 2: Pages from the EU’s annual report on zoonoses for 2007



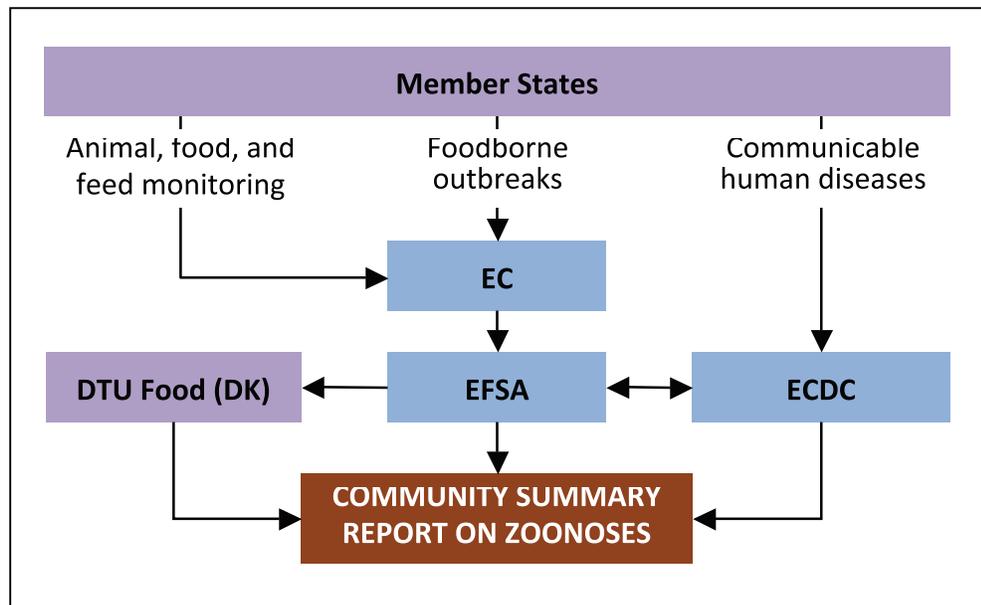
Source: EFSA/ECDC 2009a.

These annual reports are mandated in the EU’s General Food Law of 2002. The system for the collection of data on pathogens in food, animals, and feed is based on the Zoonosis Directive 2003/99/EC1. This directive obligates member states to collect relevant and, when applicable, comparable data on zoonoses, antimicrobial resistance, and foodborne outbreaks. Countries also are required to assess trends and sources of pathogens and to transmit an annual report to the EFSA for compilation (EFSA/ECDC 2009a). Human disease surveillance by countries and

⁵ Annual EU community summary reports on zoonoses and foodborne outbreaks from 2004 through 2008 (published in January 2010) are available from <http://www.efsa.europa.eu/en/scdocs/scpublications.htm>.

reporting to the European Commission are defined by Decision 2000/96/EC, Decision 2119/98/EC2, and by subsequent amendments that set up a network for epidemiological surveillance at the European Community level. Since 2005, these data have been sent by countries to the new European Centers for Disease Control and Prevention via TESSy, an electronic reporting network for communicable disease at the EU level (Ekdahl et al. 2007). The EFSA and ECDC collaborate on the combined report, with the assistance of the EFSA's Zoonoses Collaboration Centre, which is DTU Food in Denmark. Figure 3 shows the flow of data in producing the report.

Figure 3: Data flow for EU summary reports on zoonoses



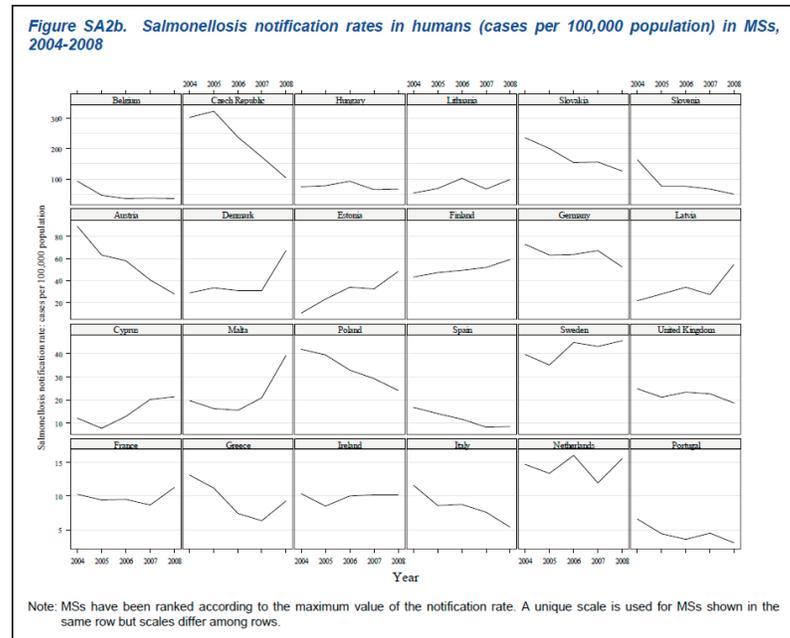
Source: adapted from EFSA/ECDC 2009a.

While EU member states are mandated to collect these data and produce reports for submission to the EU, some also produce expanded national reports that go into significantly more detail than required by the European Union. For example, Denmark's annual zoonoses report presents additional topics every year (DTU Food 2007, 2009a, 2009b). The report for 2007 included the data tables submitted to the European Commission (EC), but also sections on trends and sources (attribution) of human salmonellosis, new surveillance activities for *Campylobacter*, outbreaks of special interest, and intensified control of *Salmonella* and *Campylobacter* in fresh meat (DTU Food 2009a). In the Netherlands, the National Institute for Public Health and the Environment publishes regular reports on national surveillance of zoonotic pathogens, as well as an annual report on trends of gastroenteritis (e.g., Pelt et al. 2008, 2009).

These annual reports, particularly at the EU level, are important. Each serves as a gateway for a tremendous amount of information that would otherwise be impossible or immensely difficult to piece together. Indeed, many pieces of data would not otherwise see the light of day, because the report forces countries to gather, organize, analyze, and disseminate critical data on a regular and timely basis. Without such a report, even countries with excellent surveillance systems might not make the effort to publish such data on a regular basis and likely would not publish all their findings in one place. The result would be numerous reports for each country on each surveillance system and monitoring program. By publishing data from so many countries together, and including data from multiple years, one can see spatial distributions, as well as time trends, within countries and across Europe. For example,

Figure 4 is drawn from the community summary report for 2008. It shows *Salmonella* notification rates in humans for 24 countries across four years.

Figure 4: Example of cross-national multiyear data from an EU zoonoses report



Note: These are rates of notification, not incidence, as health systems and rates of underreporting differ between countries; source: EFSA/ECDC 2010.

Likewise, by including human, food, animal, and feed data in one place, analysts and general readers alike can identify patterns that might otherwise not be apparent. The production of an integrated report also pushes those collecting and managing information to harmonize methods and standardize data systems. The reports lead to a shared understanding of the “world” of foodborne illnesses for a given year, as everyone works from the same numbers.

The United States has no such integrated reports on foodborne pathogens. Indeed, it does not regularly publish reports on human surveillance of foodborne pathogens or on the monitoring of animals or foods that include data from multiple surveillance programs. Rather, each data-collection program publishes its own data, in its own format, in its own time, sometimes after a delay of years. For example, human surveillance data are published by CDC in separate reports for FoodNet, OutbreakNet, and for surveillance of nationally notifiable diseases. Although FoodNet publishes brief preliminary findings in April for the year prior (e.g., CDC 2009a, 2010), final reports sometimes are not published for years: For example, the 2005 report (along with 2006 and 2007 reports) was not made available until March 2010, and even then, it lacked detailed data tables.⁶ Traditionally, the CDC has published surveillance summaries for foodborne outbreaks every five years or so (e.g., Bean et al. 1996; Olsen et al. 2000; Lynch et al. 2006), with summarized line-listing tables available roughly two years after the year in question (e.g., 2006 line listings were published in 2009).⁷ In 2009, the CDC released a searchable database of outbreak surveillance data⁸ and published a single-year surveillance summary for the first time, but it was for 2006 (CDC 2009b).

⁶ <http://www.cdc.gov/foodnet/reports.htm>

⁷ http://www.cdc.gov/outbreaknet/surveillance_data.html

⁸ <http://wwwn.cdc.gov/foodborneoutbreaks/>

Publication of surveillance of food and animals is even less coordinated, with multiple studies, many of them one-time surveys and few based on randomly collected samples, conducted every year by different programs and agencies within both FDA and the USDA.

The only clear example of a U.S. attempt to publish human, animal, and food surveillance data side-by-side is the executive report for NARMS, the National Antimicrobial Resistance Monitoring System (FDA 2009a). NARMS is jointly run by the CDC (human surveillance), the FDA's Center for Veterinary Medicine (CVM), which deals with retail meat, and the USDA's Agricultural Research Service (ARS), which deals with carcasses during slaughter. The combined reports take a long time to produce (the 2006 report was published in October 2009).

Finding 3: Integrated surveillance and analysis.

Denmark, the Netherlands, and the United Kingdom employ integrated approaches to information management and analysis, including multi-agency databases and food attribution models that explicitly combine and analyze data from human illness with data from food and animals. These models focus on pathogen subtyping to link pathogen strains from humans with those from animals. These integrated approaches to data and analysis facilitate integrated annual reports.

European countries are increasingly developing integrated approaches to managing and aggregating data that combine information from multiple surveillance and data-collection programs. Largely predicated on pathogen subtyping, these systems are used for integrated analysis of both human and animal-food data, particularly for the purposes of attributing illnesses to sources.

Integrated surveillance systems

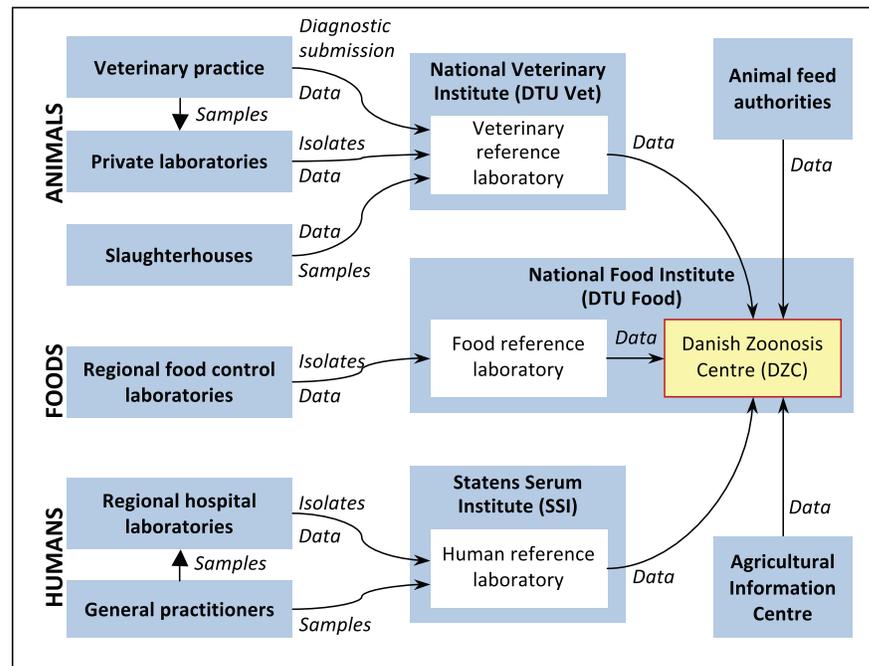
Foodborne disease surveillance and epidemiology are strong in our case-study countries of Denmark, the Netherlands, and the United Kingdom. Many of these systems are described in detail in Appendix B. Approaches to foodborne disease surveillance — general or sentinel, continuous or intermittent, active or passive (Wong et al. 2004) — can vary, and most countries in Europe employ multiple systems (as does the United States). These systems generally include outbreak surveillance, passive reporting of “notifiable” diseases to the government, and active monitoring of hospitals, physicians, and laboratories for certain pathogens (Molnar et al. 2006). Some countries also conduct community or cohort studies to look for specific patterns.

Disease surveillance was mandated at the European level in 1998 by Decision No. 2119/98/EC. Throughout the 1990s, dedicated surveillance networks (DSNs) arose to collect data on specific diseases. By 2005, the EU had 17 largely independent and uncoordinated networks, which then became the responsibility of the ECDC. Specific to foodborne disease, Salm-Net was created in 1994 as an electronic database for *Salmonella* surveillance and harmonization of phage typing among all EU member states (Fisher 1995; Peters et al. 2003). It was replaced in 1998 by Enter-Net, which first expanded surveillance to verocytotoxin-producing *E. coli* (VTEC) O157 and then to *Campylobacter* (Fisher 1999; Fisher and Meakins 2006; Enter-Net 2006, 2007).

The ECDC recently started using an integrated system that replaces the networks previously employed. The European Surveillance System (TESSy) is a metadata-driven information system to collect, validate, analyze, and disseminate surveillance data from all 27 EU member states and three other countries in the European Economic Area. TESSy employs standardized data collection and reporting and provides a “one-stop shop” for retrieving data on disease incidence (Amato-Gauci and Ammon 2008).

Some countries employ even greater integration of surveillance. In Denmark, for example, the Danish Zoonosis Centre captures surveillance data, isolates, and samples from humans, animals, foods, and feed, as shown in Figure 5.

Figure 5: Information flow in Denmark's integrated food and animal surveillance



Source: based on information from DTU Food

Both Europe and the United States make extensive use of pathogen subtyping in surveillance programs. In the United States, PulseNet, a CDC-coordinated network of federal, state, and local laboratories, uses pulsed field gel electrophoresis (PFGE) molecular fingerprinting and a shared electronic database to recognize and help contain outbreaks of foodborne illnesses (Gerner-Smidt et al. 2006). PulseNet has been instrumental in dealing with many large outbreaks in the United States, such as the *E. coli* O157:H7 outbreak in spinach in 2006 and the peanut butter *Salmonella* outbreak of 2008. In both cases, PulseNet was used to link small clusters in many states as part of large national outbreaks and to confirm that the strains found in patients matched those in contaminated products and in samples drawn from farms.

Although no comprehensive system is in place to enable the widespread use of molecular methods for linking outbreak clusters at the EU-level, European surveillance networks do make extensive use of pathogen subtyping, including serotyping, phage typing, PFGE, multilocus sequence typing (MLST) and multiple loci VNTR analysis (MLVA), and specific pathogen and subtyping method-specific databases are in use or in development. For example, the SalmGene system is a database of PFGE patterns for *Salmonella* Enteritidis; it was funded in 2001 by the European Union, hosted by the United Kingdom's Health Protection Agency, and involved data and analysis from nine participating countries (Fisher and Threlfall 2004). Online databases also have been developed for MLST⁹ and MLVA.¹⁰ Efforts have been made to develop PulseNet Europe as a viable network, including some initial EU funding for infrastructure, but its future is unclear (Swaminathan et al. 2006). The ECDC hopes eventually to incorporate algorithm-based cluster-detection approaches from PulseNet Europe into TESSy (Ammon and Tauxe 2007).

⁹ MLST databases include: <http://www.mlst.net>, <http://pubmlst.org>, <http://www.pasteur.fr/mlst>, and <http://mlst.ucc.ie/>

¹⁰ MLVA databases include: <http://mlva.u-psud.fr/>, <http://www.mlva.eu/>, <http://www.miru-vntrplus.org>, and <http://www.pasteur.fr/mlva>

As in the United States, subtyping has proven an invaluable component of foodborne disease surveillance in Europe, particularly in conjunction with trace-back data. For example, in 2005, an outbreak in the Netherlands caused by *Salmonella* Typhimurium DT104 was connected, via genetic fingerprinting, to an outbreak in Denmark (Kivi et al. 2007, Ethelberg et al. 2007). After noticing a spike in DT104 cases, the Netherlands initiated a novel, population-based, case-control study and identified preprocessed raw beef as a likely source of the problem. Scientists were not able to find any contaminated beef, but by using PFGE and MLVA patterns, Dutch authorities were able to determine that the strain was identical to a concurrent DT104 outbreak in Denmark, which had been traced to imported Italian beef carpaccio. The Danes were able to match a restaurant outbreak to data from extensive microbiological testing of imported meat products. A complex trace-back investigation was initiated through the Rapid Alert System for Food and Feed, and the beef was traced from Italy to some Dutch processors, who distributed it within the Netherlands, as well as in other countries. Eventually, the product was re-imported to the Netherlands, further processed, and exported to Denmark, where it caused the outbreak. In addition to these two outbreaks, the same meats were distributed throughout Europe, where they also likely caused illnesses that were never identified as connected (Ammon and Tauxe 2007).

Integrated attribution analysis

Preventive food safety policy requires that decision-makers have a holistic understanding of the determinants of foodborne illnesses, including which etiologic agents are causing illness and via which foods. Likewise, the burden of illness associated with specific pathogens and foods is necessary to properly evaluate the effectiveness of interventions in particular food chains. For both of these reasons, the growing consensus is that the attribution of human illnesses to specific sources and food vehicles is critical to effective food safety systems (Batz et al. 2005, FAO/WHO 2006, Pires et al. 2009).

Methods for food and source attribution are numerous (Batz et al. 2005, Pires et al. 2009), but those with the most promise are integrated approaches that take advantage of data from both human disease surveillance and from the monitoring of animals and food. Surveillance data often lack confirmation of the food vehicle that led to illness (except for some percentage of outbreaks) and generally provide only information about the pathogen. Likewise, monitoring data include no information about which contaminated foods ultimately led to illness, and simple extrapolations would be invalid. Individually, these data have limited value for attribution, but have tremendous value when combined.

One powerful example of this is the attribution model developed as part of the Danish *Salmonella* program (Hald et al. 2004). This integrated model uses serotyping and phage typing of human isolates and of samples drawn from monitoring programs of food and animals to essentially link matching “distinctive” strains from both databases. A mathematical model then attributes domestically acquired human *Salmonella* infections according to the prevalence of these strains in animals and consumption information. Researchers within the Danish Zoonosis Centre in DTU Food have been performing these analyses since 1994 and using the results to determine intervention strategies and to measure the efficacy of their control programs (Mølbak 2004).

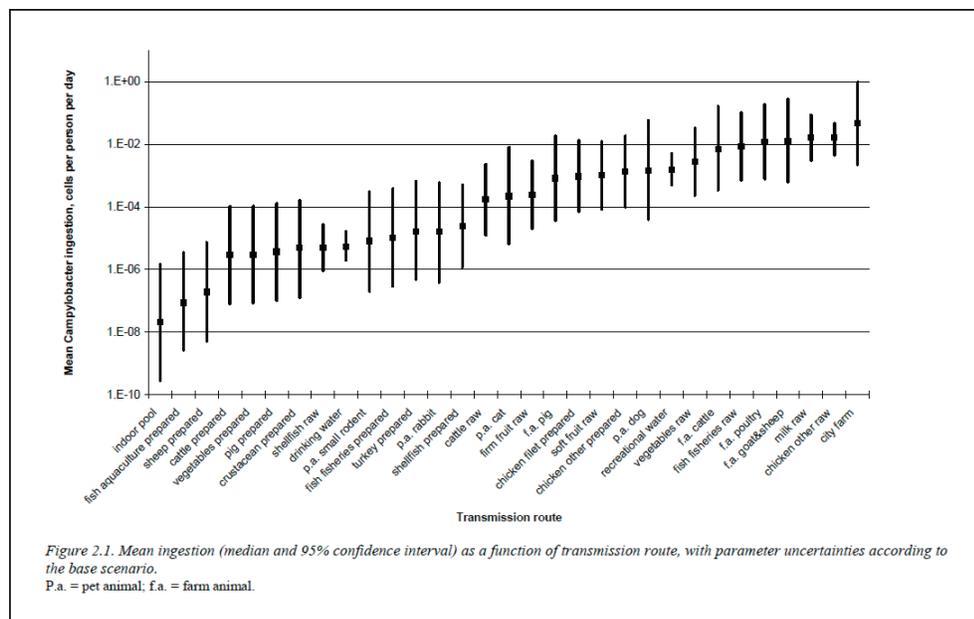
The Netherlands also has been using subtyping for 25 years to explicitly attribute cases of salmonellosis to food and animal sources, although it uses a simpler model than Denmark given its data availability (Pelt et al. 1999). In the United Kingdom, MLST is being used to connect *Campylobacter jejuni* isolates from humans to food animals that may serve as host species (Dingle et al. 2002, Didelot and Falush 2007, McCarthy et al. 2007). In New Zealand, researchers have used similar MLST approaches and modified the Danish “Hald model” for both *Campylobacter* and *Salmonella* (Kwan et al. 2008, French 2007, Mullner et al., 2009). EFSA has recently published a scientific opinion on source attribution of *Campylobacter* (EFSA 2010a).

It is important to note, however, that these subtyping attribution models are “reservoir” models that attribute illnesses only to animal reservoirs of zoonotic pathogens: That is, they do not attribute to the pathway of exposure or to the food vehicle at the time of exposure. The illnesses caused by the 2006 *E. coli* O157:H7 outbreak from contaminated spinach, for example, would have likely been attributed, in such a broad end-of-year analysis, to beef. Considering the importance of vegetables, fruit, and other nonanimal products associated with foodborne outbreaks and sporadic cases of illness, the subtyping approach has serious limitations (Batz et al. 2005).

Another approach that uses both microbiological and epidemiological data is comparative risk or exposure assessment. In such an approach, the human exposure to a particular pathogen is estimated for a set of sources, which may include food, water, and environmental routes. For each source, a mathematical model estimates exposures or illnesses based on pathogen prevalence or levels in that source (drawn from microbial surveys) and other factors, such as the growth or reduction in pathogen levels along the transmission route, food consumption patterns, and dose-response functions (Pires et al. 2008). For such models to be useful for attribution, the set of sources or routes modeled must be reasonably comprehensive, as attribution is based on relative differences in estimated exposure between routes.

The premiere use of exposure assessments for source attribution was conducted in the Netherlands for *Campylobacter* as part of the Dutch *Campylobacter* Risk Management and Assessment (CARMA) project (Evers et al. 2008). This model covered 31 transmission routes, including direct contact with animals and water, in addition to foodborne sources. The ranked results of the exposure assessment are shown in Figure 6.

Figure 6: Ranking of *Campylobacter* transmission routes in Dutch exposure assessment



Source: Nauta et al. (2005).

As noted, in many European countries, the integrated analysis of food and human data is eased by these data being maintained within the same institution. Researchers and epidemiologists spoke of numerous small investigative studies in addition to the large attribution work just described and indicated that these smaller investigations would often come about because when they had a question, they could go “down the hall” to look at the necessary data.

In the United States, data are largely disconnected, and integrated attribution studies are limited. The CDC maintains data on human illnesses, while the USDA's Food Safety and Inspection Service (FSIS), its Animal and Plant Health Inspection Service (APHIS), and its Agricultural Marketing Service (AMS) along with FDA's Center for Food Safety and Applied Nutrition (CFSAN) and other agencies maintain animal and food data. Although agencies sometimes work together on such data, human and animal data generally are collected and analyzed in isolation.

For example, PulseNet primarily contains PFGE patterns for a number of pathogens isolated from human cases of foodborne illnesses, although it also includes food isolates collected by FDA and some isolates drawn from food and animals during outbreak investigations. The USDA maintains VetNet, which contains PFGE patterns for pathogens isolated from food animals. Although CDC (which manages PulseNet) and USDA have a memorandum of understanding, and although VetNet was created some years ago in part to explicitly connect with PulseNet to answer questions of attribution, examples of such collaboration are limited. After five years of PulseNet and VetNet collecting similar and potentially connected data in parallel, no integrated studies comparing strains in these databases have been published.

FSIS and CDC did collaborate on an effort to apply the Danish attribution model using human isolates from the Public Health Laboratory Information System (PHLIS) and animal data from the FSIS in-plant sampling (Guo 2007). The results were of limited value, however, because of serious gaps in data across reservoirs and in available subtyping information.

The FDA, FSIS, and CDC also collaborated on a suite of 23 risk assessments for *Listeria monocytogenes* in ready-to-eat foods, including deli meats, dairy, produce, and seafood (CFSAN 2003). These risk assessments were not designed for attribution purposes (rather, for identifying and evaluating interventions), but the project did include significant integration of data and collaboration. Subsequently, the FSIS initiated a comparative-risk assessment for *Listeria monocytogenes* in prepackaged and retail-sliced deli meats and has recently embarked with the FDA on an interagency risk assessment to identify and evaluate additional interventions for retail-sliced deli meats (FSIS 2009, Kause 2009).

Finding 4: Coordinated data collection.

The European Union employs standardized EU-wide baseline surveys to estimate the prevalence and levels of pathogenic contamination in arrays of foods and sets minimum requirements for routine pathogen surveillance for selected pathogens and food animals. These coordinated studies are used to set targets and develop microbial standards in food-animal production. Some member countries, such as Denmark, maintain more extensive routine monitoring programs than required by the EU. These coordinated food-animal surveillance systems have been critical to enabling integrated analysis.

Monitoring programs across Europe vary widely. Some countries manage extensive, ongoing monitoring throughout the farm-to-table chain on a variety of animals and food products, as does Denmark for *Salmonella*. These coordinated sampling programs are designed to evaluate the effectiveness of control measures and to support integrated and combined analysis to estimate attribution of disease to specific animals. The success of the subtyping program largely depends on the intensity of the monitoring programs.

In addition, DTU Food and Denmark's Veterinary and Food Administration conduct surveys on specific food items. For example, in 2006, they conducted 14 microbiological studies, small and large: 100 samples in bivalve mollusks tested for *Salmonella* and *E. coli*; 500 samples in frozen imported berries tested for *Salmonella*, *Campylobacter*, and *E. coli*; 1,000 samples of fresh, chilled, retail pork tested for *Salmonella* and *Yersinia*; and more than 3,400 samples of imported poultry, beef, and pork tested for multiresistant *Salmonella* Typhimurium DT104 (DTU Food 2007).

Other countries, such as the United Kingdom and the Netherlands, perform routine monitoring, but more frequently conduct food surveys as needed. In such surveys, authorities are looking for emerging problems or want to quantify contamination rates of pathogens in specific types of products. For example, the United Kingdom's FSA published 38 food surveys from 2006 through 2009, including studies on *Campylobacter* and *Salmonella* in retail chicken, *Listeria monocytogenes* in smoked fish, and *Salmonella* in raw eggs.¹¹

The European Union has embarked on a comprehensive approach to reducing illnesses caused by *Salmonella* and *Campylobacter* based upon coordinated and integrated data collection, EU-wide target setting, and national-level control programs. This approach focuses on gathering data across and within all major animal food chains for each EU member state and using risk assessments to determine prevalence targets. Prevalence data are based upon baseline monitoring programs that are methodologically harmonized at the EU level but instituted by the competent authorities in each member state. Animal categories targeted for 2004-2008 included breeding flocks, laying hens, broilers, turkeys, slaughter pigs, and breeding pigs. This comprehensive process continues, with the European Commission going down the line of products in a slow but systematic manner (e.g., EFSA 2008b, 2009c, 2010b).

These data are then fed into quantitative microbial risk-assessment models developed to estimate the effects on human health of reductions in *Salmonella* prevalence in these products. Risk assessments for *Salmonella* in pigs, pork, and laying hens are expected to be published in 2010, while another for *Salmonella* in broiler chickens began in 2009. These risk models will then be used to support the setting of EU-wide targets for all these animal products. Although certain member countries (namely those with a high prevalence of *Salmonella* in shell eggs) have pushed back, most people we spoke with were supportive of the direction and rate of these programs.

In the United States, monitoring programs, baseline studies, and food surveys are conducted by agencies and programs within FDA and USDA. For example, APHIS oversees the National Animal Health Monitoring System (NAHMS), which conducts national studies on animal health and health-management practices in livestock and poultry production. Many of these studies are unrelated to food safety, but they do include some studies of human pathogens in animal production. Similarly, FSIS conducts baseline studies of human pathogens in raw meat and poultry products¹² and has regulatory (verification) microbiological testing programs for certain pathogens in animal food products.¹³ The AMS conducts surveys of human pathogens and pesticide residues in fruit and vegetables.¹⁴ In addition to these USDA programs, FDA conducts retail surveys and has its own microbiological-data-collection programs within CFSAN and CVM. The USDA and FDA also collaborate with CDC in NARMS. These programs generate important and useful data, but are not coordinated; they are not part of a comprehensive program to determine, for example, the prevalence of *Salmonella* subtypes across all food types (or other vectors, such as reptiles or environmental exposure) in order to prioritize interventions.

Finding 5: Independent scientific institutes.

In all three case-study countries, risk assessment is housed in independent governmental science bodies that are separate from risk-management agencies. These bodies maintain the lead roles in data collection and analyses and are responsible for both the surveillance of human illness and data on microbiological hazards in animals, food, and feed. This arrangement creates a critical mass of information and expertise; improves the coordination, flow, and integration of relevant data; and facilitates advanced analyses.

¹¹ <http://www.food.gov.uk/science/surveillance/>

¹² http://www.fsis.usda.gov/science/Baseline_Data/index.asp

¹³ <http://www.fsis.usda.gov/science/microbiology/index.asp>

¹⁴ <http://www.ams.usda.gov/AMSV1.0/science>

In all three case-study countries, the same scientific bodies are responsible for collecting and analyzing surveillance data on human illness and data on pathogen contamination of food and animals. The RIVM in the Netherlands, DTU Food in Denmark, and the HPA in the United Kingdom manage surveillance data on human illnesses, collect data on pathogens in animals and food, and maintain clinical and food laboratories that are central to their national surveillance systems. These institutes serve as natural locus points for food safety data and analysis. As a result, they conduct advanced attribution studies and other analyses that combine these many sources of data.

This is in contrast to the United States, which has a fragmented, disconnected system in which data are collected and maintained by many agencies and programs that may or may not communicate effectively (Taylor and Batz 2008). The CDC is the federal agency solely responsible for collecting human data, but it conducts no research or data collection on the prevalence of pathogens in food or food animals. The USDA and FDA conduct independent research on the contamination of animal carcasses and other foods in processing and retail, but even these studies may be conducted by a variety of agencies such as APHIS, ARS, and AMS within USDA and CVM and CFSAN within FDA. Data sharing among these agencies is improving, but remains an obstacle to data integration.

Another difference between the United States and the European Union is that in the EU, and in Denmark, the Netherlands, and the United Kingdom, risk assessment is explicitly separated from risk-management agencies, meaning that those providing scientific evaluation of foodborne hazards are situated independently, both organizationally and physically, from those choosing among policy alternatives. Although EFSA is tasked with providing independent scientific advice, it does not set regulatory policy. Likewise, the RIVM and DTU Food are independent scientific research and advisory institutes that perform risk assessments and other analyses for the Food and Consumer Product Safety Authority and the Veterinary and Food Administration, respectively. In the United Kingdom, FSA employs scientific advisory committees (SACs) comprised of independent, external experts to conduct risk assessments. It also contracts data collection and analyses to the HPA and the Defra.

The separation of risk assessment and risk management is intended to ensure the scientific quality and independence of scientific analysis and to provide greater transparency to consumers about food safety policymaking. It is intended to increase the public's confidence that the science is free from political influence, and it was motivated by the BSE crisis, in which government scientists knew about a problem but did not publicly announce it.

One concern about such a separation might be that risk assessments could diverge from risk management needs because of the distance required for communication. In our conversations, we found the opposite, however: The elucidation of responsibilities provided by institutional separation has forced managers to be clearer in defining risk-management questions, and it has freed risk assessors to make methodological choices based on the science, rather than the preferences of the risk manager.

A second concern is timelines — that this separation could impede the ability of risk managers to get quick answers in time-critical situations. In reality, however, risk-assessment agencies are in regular communication with risk-management agencies and are expected to be responsive in such circumstances. Nonetheless, in the Netherlands and the United Kingdom, FSA and VWA maintain analytical units in part to address such situations. In Denmark, DVFA does not maintain a risk-analysis unit, but any concern that might create is addressed principally through proximity: The agency is located, literally, across the courtyard from DTU Food.

Scientific research and risk assessment are conducted differently in the United States. Both the USDA and the FDA maintain in-house risk-assessment groups and laboratories and manage their own data-collection programs, such as retail surveys or baseline studies of animal carcasses' pathogen prevalence. The FDA maintains intramural research programs within CFSAN and CVM, and it supports some university-based research centers. The USDA's

intramural research is conducted by ARS, while the National Institute of Food and Agriculture (NIFA) funds grant-based extramural research; neither is answerable to the risk managers in FSIS. For projects beyond agency capacities, USDA and FDA maintain “umbrella contracts” with large consulting firms, which conduct task orders themselves or subcontract projects to smaller firms or university-based researchers.

To be clear, by noting these differences, we do not suggest that risk assessments in the United States are of low scientific quality or that they have been tainted by political influence. We do feel, however, that the institutional separation of risk assessment and risk management in case-study countries provides incentives for increased independence, scientific quality, and a clarified role of science in policymaking.

Finding 6: Coordinated research priorities.

Although research and data collection are largely conducted by independent scientific and risk-assessment institutes and agencies in Denmark, the Netherlands, and the United Kingdom, much of the funding for these activities flows through policy and risk-management agencies. Regulatory decision-makers, therefore, set broad priorities for scientific programs across government agencies and ensure that research, data collection, analyses, and reporting are responsive to policymakers’ needs.

As described previously, the food safety systems of Denmark, the Netherlands, and the United Kingdom rely upon independent institutes for scientific and risk-assessment expertise. At the same time, while these scientific advisory institutes are independent, they rely upon risk-management agencies for significant portions of their funding. The RIVM and the RIKILT in the Netherlands, DTU Food and DTU Vet in Denmark, and HPA and Defra in the United Kingdom conduct most of their analytical work under contract to VWA, DVFA, and FSA, respectively.

By controlling the purse strings, risk-management agencies can ensure that the work of independent institutes is directly responsive to their needs. The FSA, VWA, and DVFA regularly contract out work to independent researchers in universities or nonprofit research institutes, although this remains a rather small portion of their research funding stream. At the same time, institutes such as RIVM, DTU Food, and HPA maintain discretionary budgets that they can use to address issues or questions they deem important, regardless of the interest of risk managers. These institutions also fund research through competitive grant programs at the national, EU, and international level.

In the United States, some food safety research and analysis is conducted within or contracted out by FDA’s CFSAN or USDA’s FSIS and is directly responsive to risk-management needs. In-house risk assessments are one such example. Most food safety data collection and analysis funded by the federal government, however, is not coordinated by these risk-management agencies and has been criticized for not being responsive enough to policymakers’ needs (Taylor and Batz 2008). The large food safety research programs within the USDA’s ARS and its National Institute of Food and Agriculture are not guided by FDA or by FSIS. Although the agencies do provide input to program priorities (a situation that has improved dramatically during the past few years), research decisions within ARS are ultimately the subjective decisions of program management, while funding decisions for the NIFA competitive grants are made by review panels principally on the merits of the science. Similarly, the collection of food safety data and research conducted by other agencies, such as APHIS and AMS in USDA, and CVM in FDA, is not coordinated or prioritized based on the needs of risk managers in FSIS and CFSAN. The FDA and FSIS influence over the research programs within CDC is limited. Although FDA and FSIS participate in CDC programs such as PulseNet and FoodNet, most of the epidemiological research and analyses done by the agency is conducted independently.

Finding 7: Basis in risk analysis.

The EU and many member countries, including Denmark, the Netherlands, and the United Kingdom, embrace risk analysis as a formal process to inform food safety policy and decision-making, including specific delineation of responsibilities for risk management, risk assessment, and risk communication. For microbial hazards, this has largely resulted in more data-driven policy, as mandatory risk assessments have required scientific support and data collection. Public health surveillance data are used by the EFSA and some member states in policymaking and decision contexts, including priority setting, resource allocation, policy development, and program management.

Risk analysis is a foundational principle of EU food law and is the approach taken by Denmark, the Netherlands, and the United Kingdom. It is one of the primary principles listed in a European Commission white paper (2000), and its use is laid out in Article 6 of the General Food Law of 2002:

1. In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.¹⁵
2. Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective, and transparent manner.

Through its reliance on risk analysis, the EU has created a consistent framework for integrating scientific analysis into decision-making. This consensus approach means that the EU has a common language for approaching food safety issues.

In addition to quantitative and qualitative risk assessments conducted by EFSA, the Danish DZC, the Dutch RIVM and RIKILT, and Defra and HPA in the United Kingdom, European institutions have conducted studies to help set priorities. These applied analyses rely upon public health data from surveillance programs and related research and are used extensively by risk-management agencies in these countries. There are specific examples of the use of disease surveillance and advanced risk assessment to prioritize efforts, allocate resources, evaluate existing programs, and identify intervention opportunities.

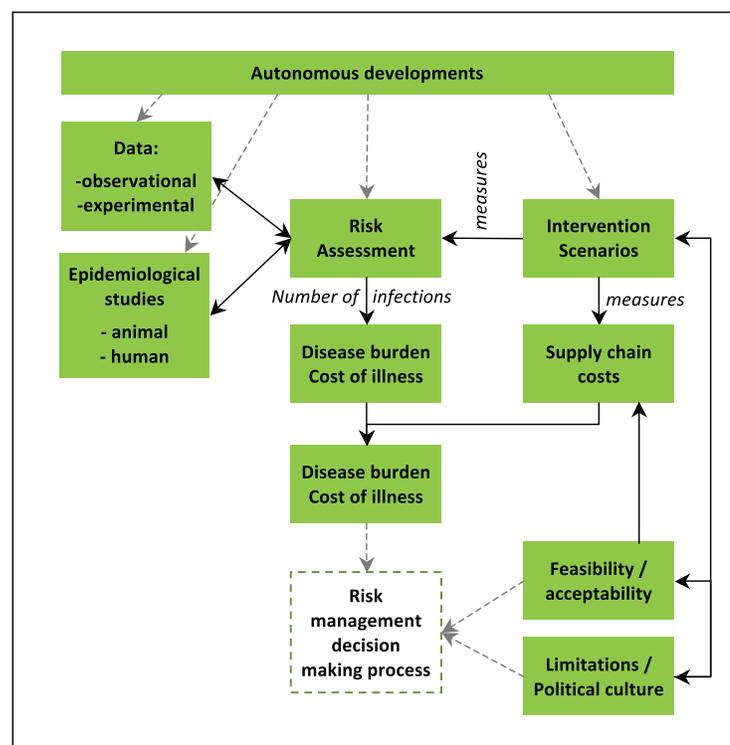
More than any other European country, the Netherlands has pursued priority setting based upon estimates of disease burden for various foodborne pathogens. For some major pathogens, it estimates the annual number of foodborne illnesses and quantifies the effects of these illnesses by using integrated measures of disease burden such as Disability Adjusted Life Years (DALYs) and economic measures (Kemmeren et al. 2006, Havelaar et al 2007, Haagsma et al. 2009). The Netherlands intends to conduct these analyses annually. Data for these studies are also accessible online (primarily in Dutch) at the National Public Health Compass, a gateway to information about health and disease, risk factors, and care and prevention in the Netherlands.¹⁶ These studies have affected national policy. In 2006 estimates (Kemmeren et al.), the Netherlands found that *Toxoplasma gondii* had the second largest effect on the public health of all foodborne pathogens. As a consequence, the VWA has pursued research aimed at reducing toxoplasmosis, including a study starting in 2008 to evaluate on-farm interventions and treatments during food processing.

¹⁵ As discussed in Appendix A, the EU follows the “precautionary principle” for risks for which scientific evidence is deemed insufficient to evaluate risk. In practical terms, this has been relevant for hot-button issues such as GMOs and hormones, where risk assessments have found low risks but where significant portions of the public are nonetheless opposed. The only foodborne disease for which the precautionary principle has been relevant is “mad cow disease,” or new variant Creutzfeldt-Jakob disease (nvCJD), because of consuming cattle with BSE.

¹⁶ <http://www.nationaalkompas.nl>

The CARMA project is another example of the Dutch approach. This large, complex, multi-institution project, centered at the RIVM, was a comprehensive attempt to estimate the burden of *Campylobacter* by various food and environmental routes and to design and evaluate potential interventions (Nauta et al. 2005). It included an array of 31 exposure assessments for various food and non-food routes, supplementary expert elicitations, examinations of 22 specific interventions from farm through preparation, detailed simulation models of chicken-processing lines and cross-contamination during preparation, and cost-effectiveness and cost-benefit studies. The primary project components are shown in Figure 7. CARMA identified some interventions, but policymakers are holding off on additional regulation until data can be validated (following industry concerns), and, possibly, until the European Commission acts based on a risk-assessment being conducted by the EFSA.

Figure 7: Primary analytical and data elements in the Dutch CARMA project



Notes: Dashed lines show information flows into and out of the project. Risk-assessment process and data-collection activities are iterative as analysis is refined.

Source: adapted from Havelaar et al. (2005).

In the United Kingdom, FSA employs risk analysis to prioritize its efforts. For example, analysts have supported resource allocation by developing risk profiles to target hygiene inspections toward high-risk premises, conducted risk-assessment modeling to identify interventions that would have the greatest impact in reducing foodborne disease, and performed analyses to evaluate existing BSE controls. These efforts use data on surveillance and other information to improve or measure the efficiency of the FSA's activities.

The FSA recently conducted a "food chain analysis" in response to a request from the FSA board to examine risk throughout the food chain (Brown and Cooper 2008, FSA 2010a). This study included two parts: a broad examination of the full food chain and detailed analyses of specific food chains to identify controls. Broad analyses included efforts to identify high-risk areas to inform strategic planning, points in the food chain with misalignment

of controls to risks, data gaps, and risk areas requiring more detailed analysis. Detailed analyses of *Campylobacter* in the chicken food chain and VTEC in the beef and lamb food chains were used to identify and evaluate potential controls. These analyses were used in the development of FSA's Strategy for 2010-2015 and its Science and Evidence Strategy 2010-2015 (2009, 2010b).

The FSA also has invested directly in disease surveillance to evaluate its performance as an agency with respect to achieving disease-reduction targets. For example, a primary driver for funding the IID2 study on infectious intestinal disease in the United Kingdom (described in Appendix B),¹⁷ was for FSA to attempt to measure progress in disease rates since the first IID study in the 1990s (FSA 2000).

As described previously, the Danish *Salmonella* program uses disease surveillance, food and animal monitoring, and advanced attribution methods to attribute cases of salmonellosis to specific food-animal reservoirs. Denmark uses these data to evaluate the performance of *Salmonella* controls in poultry, pork, beef, and eggs and to determine whether they need to pursue additional interventions (Wegener et al. 2003). Surveillance data are therefore directly used for policy development and accountability of program management.

At the EU level, public health surveillance data have been used to identify the top *Salmonella* "serotypes of public health significance" for use in *Salmonella* programs, just as similar data on serotypes in foods and animals have been used.

Another example of Europe's risk-based approach involves imports. As described by the GAO (2008), the EU and member countries have shifted from random, routine sampling during inspection of imports to a risk-based approach that targets resources according to food type, country of origin, and other factors. This approach is geared toward hazards of particular health concern and the food products with which they are associated, such as aflatoxins in corn, wheat, nuts, and beans, or pesticide residues on certain fresh fruits and vegetables. In Denmark, when a lot of imported meat is found to be contaminated with a pathogen, analysts conduct a same-day, case-by-case risk assessment based on the level of contamination to estimate the specific public health effect were the meat to be allowed into commerce. If the public health effects are above a specific threshold, the meat is rejected (Christensen 2010).

Risk analysis is also practiced extensively in the United States by both FDA and FSIS. As noted previously, both agencies maintain risk-assessment groups, which conduct analyses on agency data, principally in the form of quantitative microbial risk assessments. These have included risk assessments on different pathogen-product pathways and have been used to support rulemaking and, in the case of FSIS, inspection activities. These risk assessments include extensive outreach plans and are quite robust. Neither agency has published any broad priority setting analyses, however, which could be considered the equivalent of the ones done in the Netherlands or the United Kingdom. The U.S. groups do conduct analyses to support internal decision-making, but most are not published or available for review.

Finding 8: Transparency and public participation.

Transparency and public participation are key principles of European food safety systems, particularly of the EFSA and the United Kingdom's FSA, and are a means of gaining and maintaining public confidence. To increase transparency and participation, agencies coordinate with stakeholders and advisory committees, hold open management meetings, and publish extensively, including meeting

¹⁷ <http://www.iid2.org.uk>

minutes, evidence and analyses supporting decisions, and extensive planning and prioritization documents.

The EFSA's activities are guided by four key values, preserved in its founding regulation: scientific excellence, independence, relevance, and transparency and openness. Transparency and openness are seen as critical to citizen trust, particularly following the perceived opaqueness of many of the decisions made by European governments during the BSE crisis of the 1990s. Ways that EFSA attempts to be transparent and open include (Koeter 2004):

- Making management board meetings public.
- Publishing agendas and minutes for meetings of the management board, the advisory forum, the scientific committee, the scientific panels, and working groups.
- Webcasting meetings when possible.
- Publishing all scientific advice on the Web.
- Publishing names and affiliations of all panel members and experts.
- Maintaining a transparent process for the selection of experts.
- Holding discussion meetings with stakeholders.
- Disseminating information to multiple audiences.

The EFSA conducts research on the public's risk perception through the ongoing Eurobarometer study and works to bridge gaps between science and the consumer. It has published guidance and strategic planning documents on transparency, openness, and risk communication (e.g., EFSA 2003, 2005, 2006b, 2009d). In 2006, EFSA published an opinion on transparency in procedural aspects of risk assessment pertaining to how requests are handled, how independent scientists are selected, aspects of confidentiality, involvement of stakeholders, and more. In April 2009, it published an opinion on transparency in the scientific aspects of risk assessment. This new set of principles is principally focused on clarity of scientific explanations so that the scope, data types, data decisions, assumptions, calculations, and conclusions are intelligible to nontechnical audiences.

The United Kingdom's FSA similarly identifies openness as one of its four key values, the others being putting the consumer first, independence, and being science- and evidence-based. It follows a detailed policy on openness, which specifies the principles and means by which FSA will maintain transparency.¹⁸ A 2005 independent review of FSA's performance found that stakeholders' perceptions of the agency's efforts to be transparent and accessible were generally positive (FSA 2005). Like EFSA, FSA's board meetings are public, with minutes and all material and handouts available on the Web.

In the United States, policies concerning transparency and public participation are less consistent, although they are improving. For example, USDA and FDA already publish agendas, presentations, and minutes for advisory committees such as the National Advisory Committee on Microbiological Criteria of Foods (NACMCF) and FDA's Risk Communication Advisory Committee, as well as for most public meetings. The FDA's and FSIS's quantitative microbiological risk assessments tend to have well-defined stakeholder outreach plans, with public meetings throughout the process. In the risk assessments conducted for *Listeria* from 1999-2003, for example, the two agencies held four large public meetings at key stages in the process and made numerous announcements via their

¹⁸ http://www.food.gov.uk/aboutus/how_we_work/copopenbranch/

Web sites and in the Federal Register (see FDA/FSIS 2003, Appendix 1). For analyses that are not “full-blown” risk assessments, however, public meetings are less likely, and the data, models, and supporting analyses also are less likely to be made available to the public. Recently, the transparency of the FSIS’s decision-making was questioned following a New York Times story on the use of ammonia in processed beef (Moss 2009a, 2009b, Anderson 2010).

In the past year, FDA and USDA have made advances in improving policies for transparency and risk communication. In fall 2009, the FDA published a strategic plan for risk communication, which was intended to provide the agency with a coherent and consistent approach. The document lists three strategic goals: strengthen the science that supports effective risk communication; expand FDA’s capacity to generate, disseminate, and oversee effective risk communication; and optimize FDA policies on communicating risks and benefits (FDA 2009b). The FDA has also created a transparency task force to “develop recommendations for making useful and understandable information about FDA activities and decision-making more readily available to the public in a timely manner and in a user-friendly format” (FDA 2010). In April 2010, USDA released an Open Government Plan and an associated Web site (USDA 2010).¹⁹

Finding 9: Traceability.

Mandatory traceability is a foundational principle of EU food safety law; all food and feed must be traceable “one-up, one-down,” by food and feed businesses, including importers. Unlike in the United States, primary producers and restaurants are not excluded from these requirements, and mandatory animal-identification systems are in place for livestock. The EU has invested €100 million in nine traceability research projects, including efforts aimed at developing integrated traceability systems and harmonizing existing systems.

Traceability is a major component of EU food safety, originally laid out in the General Food Law, and requirements have been increasingly specified over time (EC 2007, 2010). The European Commission requires business operators to maintain the names and addresses of the suppliers and customers of all food and feed they handle. Business operators are encouraged to keep additional information, too, such as how much volume they handle, batch numbers, and more detailed descriptions of products (such as raw or processed). This “one-up, one-down,” approach to trace-back requires each member country to monitor business operators and set penalties if the operators fail to meet these requirements. Certain categories of products, such as produce, beef, fish, honey, and olive oil, have additional requirements. Rates of compliance among relevant firms is unknown, but differences among countries have been documented (IFT 2010).

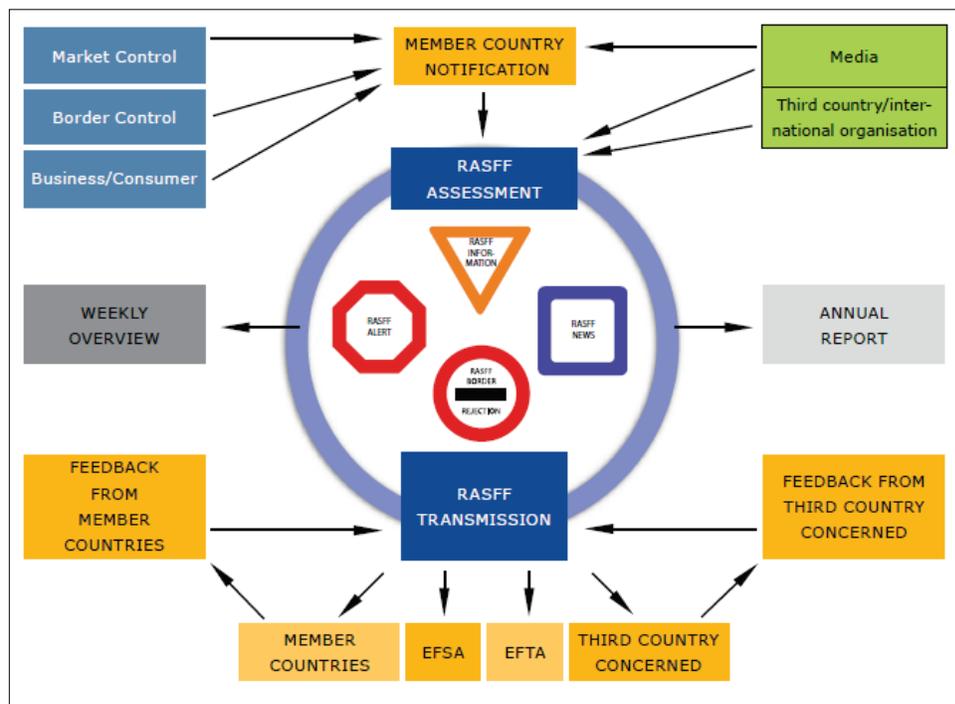
The U.S. and European Union approaches to traceability are fairly similar, although the EU requirements are more extensive. The European Union’s traceability requirements apply to all businesses trading food and feed from primary production through final sale to consumers and include farmers and brokers of bulk commodities. By contrast, the United States does not require recordkeeping in primary production or for animal feed and exempts some types of firms, such as nonprofit food establishments and small retailers (IFT 2010). As in Europe, compliance has been lacking; in a recent audit, the Department of Health and Human Services Office of the Inspector General (OIG) found that nearly 60 percent of inspected food facilities failed FDA requirements, and 25 percent were not even aware of traceability requirements (HHS 2009). The OIG was only able to fully trace 12.5 percent of examined products through the food chain and could not identify all the facilities that had handled 22.5 percent of such products.

¹⁹ <http://www.usda.gov/open/>

The EU has mandatory animal-identification systems for livestock and maintains a central database for tracking animals within the EU and from non-EU countries. The United States recently scrapped its National Animal Identification System (NAIS), a voluntary program that was announced in late 2003 following the first confirmed U.S. case of BSE. The USDA spent more than \$120 million on the NAIS, but because of opposition by the cattle industry and other issues, it achieved a participation rate of only 36 percent. Instead of the NAIS, the USDA recently announced that it will create a “flexible” state-led program for animals that are entering interstate commerce (APHIS 2010).

In addition to such traceability programs, the EU maintains the Rapid Alert System for Food and Feed (RASFF). RASFF was created by Article 50 of the General Food Law of 2002 to replace other systems (EC 2009). Now, whenever a member country is aware of a serious direct or indirect risk to human health because of a contaminated farm or feed, it is obligated to report the problem to the EC via the rapid alert system; the information then is quickly communicated to the other EU member states via an online database. The information flows of the RASFF are captured in Figure 8. The system is used extensively in multinational recalls and trace-back investigations, and it is connected with INFOSAN, a global alert system managed jointly by the World Health Organization and the United Nation’s Food and Agriculture Organization.

Figure 8: Schematic representation of RASFF information flow



Source: RASFF 2008 Annual Report (EC 2009).

A few cases in Europe have shown that these traceability requirements can be critical. In 2004, milk from a single Dutch farm was found to have high levels of dioxin. A trace-back investigation discovered that potato peels used as cattle feed were contaminated, and furthermore that they had been contaminated during processing using clay, which was used to separate high- and low-quality potatoes. The RASFF was used to notify other countries, as the contaminated clay had been supplied to food processing companies in Belgium, France, and Germany. More than

200 farms were eventually barred from trade, and contaminated products never reached consumers (EC 2005). In other cases, European investigators could not trace back products because of improper recordkeeping.

In the United States, electronic networks facilitate interstate communication, and multistate outbreaks or recalls involve federal agencies (Taylor and Batz 2008). Coordination and communication roles are established among the CDC, the FDA, and the FSIS and with the states in large outbreaks or recalls. Efforts continue to improve this protocol (CIFOR 2009). In many cases, multistate outbreaks were identified not via federal regulatory involvement, but through surveillance programs such as PulseNet and OutbreakNet. PulseNet, in particular, has the power to connect clusters of human illnesses across state lines, and it has been a valuable tool in many of the large outbreaks in recent years. Indeed, outbreaks that may have been reported as small and disconnected with unknown sources were instead connected into one outbreak and eventually traced to food products. Without an active Europe-wide surveillance system such as PulseNet, the EU is much less likely to identify multinational outbreaks.

The European Union has made significant investments in improving traceability. At least €114 million have been granted to nine traceability research projects, including the TRACE project, aimed at developing integrated traceability systems with a focus on food authenticity²⁰; the FoodTrace project, intended to develop a generic identification framework and network of databases to share information²¹; TRACEBACK, an attempt to create a standardized traceability system based on nanotech devices and integrated network architecture²²; and BIOTRACER, which has the objective of creating tools and models for improved tracing of accidental and intentional microbial contamination of feed and food.²³ Additional projects are aimed at developing novel approaches for food verification: DNA-TRACK,²⁴ GoeTraceAgri,²⁵ and OLIV-TRACK.²⁶ Furthermore, the EU has created an international forum, Promoting European Traceability Excellence and Research (PETER), to promote discussion among projects, to harmonize efforts, and to disseminate findings.²⁷

²⁰ <http://www.trace.eu.org>

²¹ <http://www.eufoodtrace.org>

²² <http://www.traceback-ip.eu>

²³ <http://www.biotracer.org>

²⁴ <http://www.dsa.unipr.it/foodhealth/dna-track/home.htm>

²⁵ <http://www.geotraceagri.net>

²⁶ <http://www.dsa.unipr.it/foodhealth/oliv-track>

²⁷ <http://www.eu-peter.org/>

Recommendations

Based on the findings outlined in Chapter 2, we have identified a number of opportunities to bolster the foundation of food safety information in the United States.

The Case for Major Institutional Reform

Although we make six recommendations for specific actions that should be taken to improve the U.S. food safety system, we feel it is important to also explore the potential benefits of more significant structural transformation. In particular, we discuss two major institutional reforms that would significantly improve the likelihood of achieving a science-based, risk-informed, data-driven, food safety system.

Prior work has described the U.S. food safety information infrastructure as fragmented, uncoordinated, and largely disconnected (Taylor and Batz 2008). Technical obstacles hinder data aggregation, but the most pressing and intractable challenges to collaboration and data sharing are institutional. As described in Finding 1, the consolidation of the food safety authority in Denmark, the Netherlands, and the United Kingdom, and the centralization of authority at the EU level, along with additional reforms, have led to a more coordinated and integrated approach to food safety information. The eight European nations that have consolidated regulatory and/or inspection agencies have reported efficiencies, greater information sharing, and improved consumer confidence.

We found that reforms aimed at consolidating food safety authority were critically important in building a strengthened role for information-driven analysis and decision-making in Denmark, the Netherlands, and the United Kingdom. We have come to believe that while our specific recommendations will go far to improve the risk basis of the U.S. food safety system, some of the most difficult and intractable challenges relate to the fragmented, disconnected, and uncoordinated nature of our major food safety institutions.

Thus, while it would be premature to recommend an overhaul of U.S. food safety institutions based on three brief case studies, our findings do suggest that institutional reform has played a critically important role in improving the risk-basis of European food safety. Likewise, the creation of a Cabinet-level food safety agency in the United States might be a major, or even necessary, step toward achieving the vision of a science- and risk-based food safety system. To be effective, such a Cabinet-level agency would need to coordinate regulatory and inspection programs of USDA and FDA food safety offices, maintain funding lines to agencies to ensure appropriate data inflows, and have broad authority to allocate resources, prioritize preventative efforts, and coordinate data collection and research. This agency should be mandated to employ a risk-analysis framework in food safety decision-making, recognizing the importance of and the need to consider additional factors such as social values, economic impacts, and political interests.

Similarly, although the scientific risk analyses conducted within the FDA and the FSIS are of high quality, expertise is spread across two rather small divisions and remains separated from the epidemiologists within CDC's foodborne group. The separation of data and analytical capacity among CDC, FDA, and FSIS makes it nearly impossible to maintain integrated programs geared toward linking human and food-animal surveillance data. Although we recommend specific actions to attempt to bridge the serious divides among agencies, our findings in Denmark, the Netherlands, and the United Kingdom show the strength of maintaining single institutes to oversee scientific advice.

Combined with a Cabinet-level food safety agency, such an institute in the United States could greatly improve scientific coordination and integration. An independent Federal Institute for Food Safety Risk Analysis would support a risk-based food system through research, data collection, and analysis. It would house the majority of

scientists and risk analysts currently working on food safety within FDA, FSIS, and CDC and would serve as the primary point of advice on scientific matters. The FDA and the FSIS should continue to maintain some analytical staff to conduct rapid turnaround analyses and to serve as “translators” for regulatory risk managers and risk assessors.

Specific Recommendations

We present six specific recommendations for improving the scientific foundation of the U.S. food safety system, summarized in Table 3.

Table 3: Summary of Recommendations

1	Produce unified, cross-agency annual reports on foodborne pathogen surveillance in humans, animals, food, and feed.
2	Improve farm-to-fork surveillance of domestic and imported food.
3	Increase capacity for integrated food attribution analysis and priority setting.
4	Improve the coordination of food safety research.
5	Improve transparency and public participation.
6	Improve the effectiveness of trace-back and trace-forward data for outbreak response.

These recommendations support a more unified model of collecting, managing, and analyzing the information necessary for a science- and risk-based food safety system. Some of our recommendations are straightforward and focused, while others are far reaching and will be difficult to implement. We emphasize that the costs of implementing any of these recommendations may be significant and that how these costs are covered in the long term is a critical consideration.

Recommendation 1: Produce unified cross-agency annual reports on foodborne pathogen surveillance in humans, animals, food, and feed.

The CDC, FDA, and USDA should be mandated (and funded) to: produce a unified cross-agency annual report that presents surveillance data on human foodborne illnesses, including outbreaks and sporadic cases, and on pathogen contamination in domestic and imported animals, food, and feed; present trends and provide the evidence basis for measuring food safety progress in a thorough, readable, consumer-friendly format; undertake routinely updated national estimates of the incidence of foodborne disease caused by major pathogens.

As described in the findings, the European Union and numerous EU member states produce highly informative and useful annual reports that combine—in a single place—data on foodborne disease and information on the prevalence of these same pathogens in animals and food. Thus, one can see trends in illness and contamination, pathogen by

pathogen, over time, presented in tables, graphs, and narrative analysis. These reports include important information on food safety and foodborne illnesses and are compiled every year and presented in an integrated manner.

Given the critical importance of the information captured in surveillance systems and the ultimate role it must play in a more evidence-based approach to food safety, and given the success of such reports overseas, we recommend that CDC, FDA, and USDA be funded and mandated to collaborate on an integrated annual report. Data on surveillance of human illness and of pathogens in animals and foods are currently spread across dozens of programs in numerous offices within the three agencies, each of which publishes its own reports, if it publishes at all. No routine effort is made to combine these data in a single place, to make sense of the data as a whole, or to present information in a way that would be useful to the educated public. Not only would unified reports greatly increase government transparency to consumers, they would provide policymakers with some evidence base for measuring progress on national food safety goals and would be valuable to those in the private sector. The very act of compiling them likely would result in better cooperation and understanding among those collecting and managing the data.

It is important that these reports be intelligible to educated consumers, not just to food safety experts. These reports could be an important educational tool that provides a means for those in government and industry, consumers, and others to have a common understanding of the best available data on foodborne illnesses and the contamination of foods. Such evidence also could serve as a tool to measure the progress of federal, state, and local food safety efforts. It is important that the report be organized not by what is most convenient for its creators, but by what makes the most sense for readers. Most important, data should be organized by pathogen, not program, to allow side-by-side comparisons of human, animal, and food data. The timeliness of such annual reports also would be critical; the goal should be publication within nine to 12 months, as longer delays decrease the value of the information. Another goal should be publication at the same time every year and in roughly the same format to allow cross-year comparisons.

More time consuming than collating and presenting surveillance data is the estimation of the incidence of foodborne illnesses by pathogen, as presented by Mead et al. (1999) and as currently being revised by CDC.²⁸ Looking at the European system, 10 years is too long between such estimates; the CDC (or a new, independent federal Institute for Food Safety Risk Analysis) should be funded to produce estimates of the incidence of foodborne illnesses, by pathogen on an annual or biannual basis and to present the results in these annual reports. The CDC should develop a protocol for routinely updating incidence estimates based on a semi-automated methodology that uses rolling data windows²⁹ and regularly updated model parameters such as underreporting multipliers. Annual incidence estimates likely would be of great value to national, state, and local policymakers, as well as to consumer advocates and those in industry.

Recommendation 2: Improve farm-to-table surveillance of domestic and imported food.

A national surveillance plan for food contamination should be developed. As part of this plan, the agencies should increase data on pathogens in food through routine monitoring, baseline studies, and food surveys. To support this national surveillance plan, the United States should invest in an integrated cross-agency surveillance network for animals, food, and feed to connect contamination data, and this network should support advanced subtyping of isolates.

²⁸ At time of publication, new estimates are in peer review.

²⁹ A “rolling window” is a statistical term that means that an estimate for a given year would be based on a shifted time interval from the same estimate for the previous year. For example, a given estimate for 2009 might be based on data from 2002-2007, while the same estimate for 2010 would be based on data from 2003-2008.

Since 1996, FoodNet, PulseNet, and other human surveillance programs have greatly improved our understanding of the incidence of foodborne disease. Our ability to properly attribute these illnesses to foods is hampered, however, by our comparatively meager investment in data on the prevalence and levels or counts of microbial and chemical contaminants throughout the food chain, including in feed, animals, and food.

Through EU-wide baseline studies and increasingly harmonized surveillance of animals and food products for pathogens, the European Union is moving toward a coordinated farm-to-table approach. In addition, some EU countries manage very aggressive monitoring programs, which have been instrumental in managing control programs, such as Denmark's efforts on *Salmonella* in food animals.

To better understand hazards in the food supply, the United States should increase the quantity and utility of data on pathogens in food. Our specific recommendations include:

- Developing a national surveillance plan. The FDA and USDA should collaborate on developing a national farm-to-table surveillance plan to unify the numerous, uncoordinated programs now collecting data on the pathogenic contamination of food, feed, and food animals. As part of this plan, the agencies should identify data gaps and prioritize new data programs.
- Expanding collection of data on the contamination of foods. Federal agencies should expand routine monitoring, baseline studies, and surveys of both FSIS- and FDA-regulated food products, including the testing of animals and feed and at multiple points between farm and table.
- Creating an integrated cross-agency surveillance network for food, animals, and feed. Significant investment should be made in a combined electronic network to capture and allow cross-analysis of data on the prevalence and levels or counts of microbial and chemical contaminants of domestic and imported food, including food animals, feed, produce, and processed goods.

Recommendation 3: Increase capacity for integrated food attribution analysis and priority setting.

A unified strategy should be developed for estimating the relative contribution of various foods to the overall foodborne disease burden (i.e., food attribution analysis). This effort should include integration of foodborne pathogen surveillance databases for human, animals, food, and feed, particularly the integration of subtyping data from nonhuman data into PulseNet. It also should provide for the creation of a common analysis group to integrate food attribution estimates based on subtyping, outbreak data, case-control studies, expert elicitation, and other methods. A unified strategy should be developed to support broad priority setting across and within the agencies dealing with foodborne illnesses. Funding pathways must be provided, too, to ensure access to data necessary for these analyses.

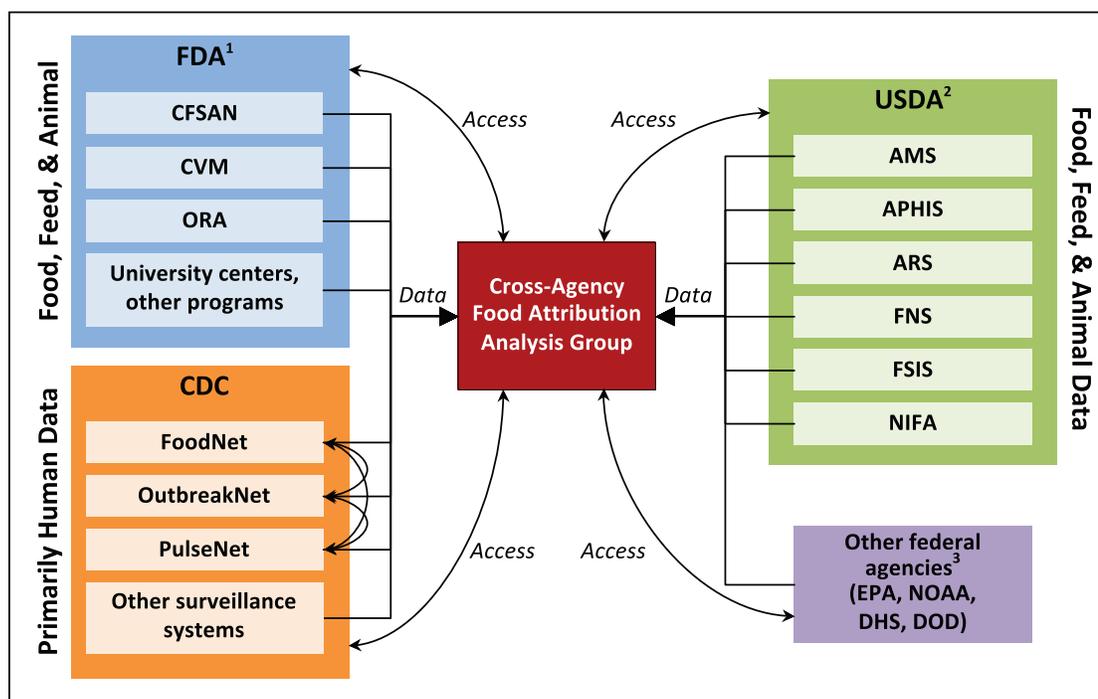
The FDA and the FSIS have a critical need for attribution analyses to prioritize efforts and to identify potential opportunities for preventative action. This need, and the need for greater efforts at informing priority setting through data-driven analysis, highlights the current lack of vehicles for necessary collaboration between the CDC and the agencies. The regulatory agencies are reliant upon information and analysis by the CDC on the incidence of disease and the attribution of these diseases to specific food vehicles, but the CDC is not directly answerable to either the FDA or the FSIS and has few incentives to provide such information within an expedited timeframe.

Furthermore, the CDC's foodborne group is routinely underfunded and therefore hard pressed to dedicate sufficient staff time to meet the needs of others. CDC epidemiologists have their own responsibilities, and their investigators are often too busy responding to outbreaks to conduct the analyses that may be of use to federal regulators. The

European Union has addressed these issues by creating a centralized analytic capacity and integrated surveillance and pathogen subtyping databases. It also has established funding pathways to permit analytic groups to “purchase” needed data or analysis from front-line agencies.

To address the need for data and analysis for food and source attribution, the agencies should create and substantially fund a cross-agency working group, administratively housed in the Department of Health and Human Services (given that FDA and CDC are HHS agencies). This analysis group, shown in Figure 9, should include those familiar with key databases from CDC, FDA, USDA, and other relevant agencies such as the Environmental Protection Agency (EPA) and the National Oceanic and Atmospheric Administration (NOAA). The group should have access to all relevant data to conduct attribution analyses and to create collaborative teams to address specific hazards or research needs.

Figure 9: Cross-agency food attribution analysis group built upon integrated data on foodborne pathogen surveillance in humans, food, animals, and feed



1 FDA: Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, Office of Regulatory Affairs.

2 USDA: Agricultural Marketing Service, Animal and Plant Health Inspection Service, Agricultural Research Service, Food, and Nutrition Service, Food Safety and Inspection Service, National Institute for Food and Agriculture.

3 Numerous other agencies include: Environmental Protection Agency, National Oceanic and Atmospheric Administration, Department of Homeland Security, Department of Defense.

The cross-agency food attribution analysis group should explore an array of methodological approaches and data sources, including the use of pathogen subtyping, analysis of aggregated outbreak data, sporadic case-control studies, comparative exposure assessment modeling, and expert elicitations (see Pires et al. 2009). By building on attribution studies and estimates of incidence of disease, the group should develop analyses to support priority setting within the agencies. Such analyses might take the form of risk-ranking models or burden-of-disease estimates connected to specific products within each agency’s purview (Mangen et al. 2009).

A key focus of attribution studies should be the use of pathogen subtyping, and the United States should invest in improvements to existing subtyping surveillance, namely PulseNet. Europe and the United States increasingly use microbial fingerprinting methods to link isolates drawn from human cases of foodborne illnesses to one another and to those drawn from contaminated animals and foods. In the United States, these approaches are used primarily in outbreak response via PulseNet, while in Europe, subtyping is used more preventively through source attribution models such as those in Denmark and the Netherlands.

PulseNet has grown dramatically since it was created in the late 1990s, and it has been a critical tool in identifying the causes of some recent large multistate outbreaks (e.g., *E. coli* O157:H7 in spinach, *Salmonella* Saintpaul in peanut butter). The number of PFGE patterns uploaded annually to PulseNet increased from about 10,000 in 1999 to more than 60,000 in 2007 (Tauxe 2009). These patterns have been largely used to identify outbreaks, but PulseNet has great potential to inform preventive food safety activities as well, as the data collected can be analyzed to broadly attribute illnesses to foods, to identify causes and patterns in strains as they relate to clinical outcomes, and to help identify emerging problems. Our specific recommendations to foster such uses for PulseNet include:

- Integrating PulseNet with similar subtyping databases for animals and foods. PulseNet should be explicitly integrated with similar databases on animals and foods, such as VetNet, with the goal of eventually developing a real-time integrated surveillance system for humans, animals, and foods to detect emerging problems. The FDA, FSIS, and CDC should have joint, unfettered access to the integrated database.
- Increasing adoption of alternative subtyping methods. Ongoing research suggests that subtyping methods beyond PFGE hold significant promise for detecting outbreaks and attributing illnesses to foods (e.g., Boxrud 2010). Building on prior efforts, PulseNet should aggressively pursue the investigation, standardization, and adoption of advanced subtyping approaches beyond PFGE. Much of the success of PulseNet is attributable to its harmonized approaches to laboratory analytics, and the program should continue to pursue such standardization for new methods of bacterial fingerprinting.
- Increasing linkages to outbreak data. PulseNet should be linked with real-time interview data from OutbreakNet to enable critical investigations of risk factors and source attribution. Such linkages could be explored through the OutbreakNet Sentinel Sites program.

The United States should further explore the potential for source-attribution studies based on microbial subtyping data in PulseNet and other networks, considering its increasing use and success worldwide to support pathogen-control programs. The FSIS and CDC collaborated on one such preliminary study, but did not have sufficient data for strong conclusions. It is likely that for source attribution to be successful in the United States, additional data on pathogen contamination will be needed (see Recommendation 4). The FDA and FSIS should identify pathogen-product pathways for which insufficient information is available to support source attribution by subtype.

As highlighted by the EU example, attributing illnesses to specific foods is a critical link in a risk-based system, because it is necessary to making informed prioritization decisions. However, better estimates will require greater collaboration among public health and regulatory agencies and an investment in the necessary studies.

Recommendation 4: Improve the coordination of food safety research.

There is a need for a unified, long-term strategic vision for food safety research, with publication of annual prioritized lists of specific needs. Research programs should better integrate risk regulators into the setting of research priorities.

In consolidated European systems, in which funding for research often flows through regulatory agencies to independent scientific institutes, we find a more coordinated approach to collecting food safety data than in the United States. Risk managers play an active role in defining and prioritizing research needs, and, in turn, the research portfolio within scientific institutes is responsive to policy needs.

Several steps can be taken to improve the coordination of data collection and food safety research in the United States. Our specific recommendations include:

- **Producing prioritized lists of research needs.** Agency regulators should take a larger, more active, and more coordinated role in developing the data to support a risk-based approach. The FDA and FSIS should develop a shared strategic vision of broad, long-term research and data needs. To do this, they should devise a process or mechanism by which they can examine a broad set of known data needs in order to identify which ones are the most critical. This process should include stakeholders and provide an opportunity for public input. The agencies should create annually updated prioritized lists of data gaps, data needs, and research priorities within and across program areas.
- **Increasing the role of risk regulators in research program priorities.** The FSIS and CFSAN should be given a greater role in defining research priorities in food safety research efforts across FDA and USDA, including within ARS and NIFA. Likewise, a mechanism should be developed to allow FSIS and CFSAN to provide independent comment on proposals submitted to competitive grant programs to be considered by review panels.
- **Increasing research budgets.** Moving toward a science-based approach to food safety requires an FDA and an FSIS that pursue new data and new science to address the data needs cited in their strategic plans. Congress should set aside line-item budgets for the agencies to pursue policy-oriented research and data collection in support of programs and policies. These expanded budgets should be used by the agencies to fill gaps in research left by other programs and to address emergencies and other time-critical needs. To build capacity while maintaining flexibility, these research funds should include both intramural and extramural components.

Recommendation 5: Improve transparency and public participation.

Agencies involved in food safety should establish transparency and public-participation policies that increase publication of data and analyses used to support decisions and that increase stakeholder engagement and public participation in analytical activities.

The transparency policies of EFSA, the United Kingdom's FSA, and other EU agencies have led to improved dissemination of science and analysis developed to support policy. Although the EU experience also shows that science and public perception are sometimes at odds, thus complicating decision-making for hot-button issues, this should not be an excuse for secretive decision-making. The goal should be to bridge this gap through education and more explanation, not less.

The FDA and USDA often disseminate findings from large data-collection programs (such as baseline studies) and incorporate stakeholders and the public in large pathogen-pathway risk assessments (such as those for *E. coli* O157:H7 in ground beef or *Listeria monocytogenes* in ready-to-eat meats). Less clarity and public engagement are evident, however, in the analytical process used to support smaller, though still important, decisions.

The FDA and USDA should collaborate to develop similar policies for transparency and public participation in the development of food safety policy, rulemaking, and risk analysis. These policies could build on the FDA's Strategic

Plan for Risk Communication and the efforts of its Transparency Task Force (FDA 2009b, 2010). The recently announced USDA open government initiative is a step in the right direction.³⁰ To improve transparency, the policy should promote: the timely disclosure of data sets, information, and analyses used to support changes in policy or operations; detailed public announcements upon the funding or initiation of research, data collection, and significant analyses, whether conducted internally or contracted externally; and improved coordination and access to such information via easy-to-find public Web portals. This policy should inform stakeholders and consumers about analytical activities and be useful in gathering information to improve these analyses. The policy should attempt to define some reasonable characteristics for determining when an analysis or decision requires public engagement. The policy further should explore the use of Web-based tools, such as online presentations and meetings, to engage stakeholder audiences on analytical activities of significant importance to agency decision-making.

Recommendation 6: Improve the effectiveness of trace-back and trace-forward data for outbreak response.

Traceability requirements should be extended back to the farm and forward to food service. The FDA and USDA should develop standard recordkeeping formats to facilitate harmonized data and create incentives for electronic recordkeeping.

An effective public health response during an outbreak or contamination incident demands that federal regulators be able to conduct rapid trace-forward and trace-back of suspected products moving through the food chain. Traceability data are critical pieces of the information puzzle. Lessons from Europe, independent studies of U.S. food traceability (e.g., IFT 2010, HHS 2009), and recent U.S. outbreaks make it clear that current U.S. requirements for tracing food products are insufficient.

To improve the capacity of federal agencies to access timely and accurate traceability information to support investigations and recalls, our recommendations include:

- Expanding traceability requirements along the farm-to-fork chain. Legislators should provide FDA with the statutory authority to require all firms in the food system, including farmers, food service establishments, and brokers, to maintain one-up, one-down, lot-specific records of food transactions with other businesses and to maintain internal traceability of lots within firms (e.g., between warehouses and retail operations).
- Enforcing existing requirements through enforceable audits. The FDA and USDA should be given the statutory authority to request records outside of emergency or outbreak situations in order to conduct enforcement audits of recordkeeping compliance.
- Standardizing recordkeeping formats. Federal agencies should standardize and specify key data elements and formats to be captured for any food transaction. The government shouldn't mandate particular technologies, but produce standards that ensure compatibility and inter-operability.
- Creating incentives or requirements for electronic recordkeeping. The FDA and USDA should create incentives, or requirements, for companies to maintain electronic records. Paper records can be difficult to obtain and manually stringing together information from them can be both challenging and time and resource intensive. These issues create delays in trace-back and trace-forward investigations.

³⁰ <http://www.usda.gov/open/>

Appendix A. The European Food Safety System

The past decade has been one of significant change in Europe, both at the national and EU levels. Since the late 1990s, European countries that have undertaken major reforms and consolidated their food safety agencies (GAO 2005) include Austria, Denmark, Finland, Germany, Ireland, the Netherlands, Spain, and the United Kingdom. At the same time, the European Union has centralized and harmonized its food safety efforts (Leibovitch 2008).

Overview of European Reform

To draw specific lessons from European food safety it is necessary to first understand the motivating forces that led to reform. Some efforts to improve and harmonize food safety at the EU level were attempted in the 1980s, but the steps were limited out of respect for socially important culinary cultures and to maintain free trade (Alemanno 2006, Leibovitch 2008).

Mad cow disease changed that. The BSE crisis collapsed the public trust in the United Kingdom and throughout Europe (Shears et al. 2001; Knowles et al. 2007). In addition to BSE, Europe also faced other food scares in the 1990s, most of which did not materialize in the United States. In particular, it saw rising rates and persistent outbreaks of *Salmonella* Enteritidis throughout its borders (Rabsch et al. 2001). In 1995 and 1996, Sweden had a nationwide outbreak of *E. coli* O157:H7 for which no source was identified. (Ziese et al. 1996). In 1996, Scotland, too, had a major outbreak of *E. coli* O157:H7 caused by cooked meat pies, which sickened 500 and led to 20 deaths (Pennington 2003). In Belgium in 1999, feed for chicken and other animals was found to be contaminated with dioxins, which led to major culls and recalls (Larebeke et al. 2001). Also in 1999 in Belgium, Coca-Cola was suspected of causing a large outbreak of illnesses among schoolchildren, although nothing was ever confirmed, and many speculate that the children's illnesses were sociogenic (Nemery et al. 2002). That same year, France had two large, nationwide outbreaks of *Listeria monocytogenes* (Valk et al. 2001).

In addition to concerns about microbiological hazards in foods, the 1980s and 1990s brought a rise in public sentiment opposed to genetically modified organisms (GMOs) and the use of growth hormones in cattle, such as recombinant bovine somatotropin (rBST). The outcry about these issues played an important role in public support for the overhaul of the European Union's food safety policies, although it has also led to continued conflicts between scientific risk assessments and public sentiment in areas outside of microbiological safety.

As a result of these incidents and changes in public sentiment, European food safety institutions undertook reforms (Buonanno 2006), summarized in Table 4.

Table 4: Timeline of recent events in EU food safety

1994	Denmark establishes its Danish Zoonosis Centre (DZC).
1996	The United Kingdom announces a link between vCJD and BSE, leading to an EU ban on British beef.
1997	The EU Parliament passes censure of the European Commission's handling of the BSE crises.
	The European Commission publishes a communication on consumer health and food safety and a green paper on the general principles of food law.
	Denmark creates a consolidated food safety agency (DVFA).
1998	The EU initiates a moratorium on GMOs.
1999	A dioxin scare in Belgium, a Coca-Cola scare in Belgium, <i>Listeria</i> outbreaks in France.
	France creates the French Food Safety Agency (AFFSA).
	Ireland establishes the Food Safety Authority of Ireland (FSAI).
	The EU Council of Ministers agrees to a permanent ban of rBST.
2000	The European Commission publishes a white paper on food safety, which proposes a new European agency for food safety.
	The United Kingdom creates the Food Standards Agency (FSA).
2002	The EU adopts the General Food Law.
	Germany creates the Federal Institute for Risk Assessment (BfR) and the Federal Office of Consumer Protection and Food Safety (BVL).
	Austria, Belgium, the Netherlands, and Spain create consolidated food safety agencies: the Austrian Agency for Health and Food Safety (AGES), the Federal Agency for Safety of the Food Chain (FASFC), the Food and Consumer Product Safety Authority (VWA), and the Spanish Agency for Food Security and Nutrition (AESAN).
2003	The EFSA is established in Parma, Italy.
2004	The EU passes hygiene regulations.
2005	The ECDC is established.
2006	Finland creates the Finnish Food Safety Authority (Evira).
2007	Denmark moves risk assessment into independent, university-based institutes.

In 1997, the president of the European Commission, Jacques Santer, came out in favor of an independent food safety agency (Alemanno 2008). In a speech to the European Parliament, he suggested basing this agency on the U.S. Food and Drug Administration (Santer 1997):

I also think that an independent agency, to meet the specific needs of the community but based on the positive aspects of the United States Food and Drug Administration, should be considered. Compliance with the principle of subsidiarity, to which we are all attached, must not be used as a pretext for obstructing the emergence of a credible European health protection system, as a necessary follow-on from the single market.

That same year, the European Commission published two papers that outlined the principles and objectives of a new approach to food safety that shifted from a basic principle of enabling food trade to one of protecting the public health (EC 1997a, 1997b, Vos 2000). In 1999, a report commissioned by the EC recommended the creation of the European Food and Public Health Authority (EFPHA), an independent and integrated agency that would have included risk management (e.g., regulatory authority), risk assessment, and disease response and surveillance (James et al. 1999). The authority essentially would have had the combined responsibilities of FDA, FSIS, and CDC, although with additional independence. This would have stripped the European Commission and the European Parliament, and therefore the EU member states, of legislative and executive power, so the idea of an independent regulatory authority was scrapped (Alemanno 2008).

In 2000, the EC published a white paper on food safety, which announced: “A radical new approach is proposed” (EC 2000a, p.3). The commission called for an independent European food safety authority and outlined eight principles to guide European food safety policy (p.8):

1. Food safety policy must be based on a “comprehensive, integrated approach” from farm to table.
2. Primary responsibility is with food operators, though all stakeholders, such as government and consumers, play important roles and have responsibilities.
3. Food safety relies upon “traceability of feed and food and their ingredients.”
4. “The comprehensive, integrated approach will lead to a more coherent, effective, and dynamic food policy” with increased transparency and accountability.
5. Food safety policy should be based upon risk analysis.
6. Food safety policy should be based upon the best available science, and scientific advice should be independent.
7. Where possible, the “precautionary principle” should be applied.
8. In decision-making, other factors relevant to public health or fairness in trade may be considered, such as environmental concerns, animal welfare, and sustainability.

These principles became the core of Regulation EC No. 178/2002, adopted by the Council of the EU and the European Parliament and known colloquially as the General Food Law of 2002.³¹ The law mandated a comprehensive farm-to-table approach, reliance upon risk analysis, scientific independence, traceability programs,

³¹ http://eur-lex.europa.eu/pri/en/oj/dat/2002/l_031/l_03120020201en00010024.pdf

and transparency. It created the Rapid Alert System for Food and Feed (RASFF), which is used to quickly notify other countries when any action is taken on a food risk, such as a recall, in an exported product.

Perhaps most important, the law created the European Food Safety Authority (EFSA),³² an independent agency that provides scientific advice to relevant bodies in the European Commission, such as those in the Directorate General for Public Health and Consumer Protection (known as DG-SANCO). The EFSA does not create or enforce regulations; rather, it performs risk assessments for the EC to test various standards and regulatory options, recommends standards, determines specifics of EU data programs, and performs analyses upon request for the commission and member countries. In addition, it collects obligatory food and feed surveillance data from member states for its annual surveillance report.

Some people have questioned the independence of EFSA because the EC evaluates its work for “coherence.” This suggests that the EC can stall or steer EFSA’s work if it doesn’t like its advice. Other people see an additional conflict built into the founding principles of the General Food Law. While principles 5 and 6 of the law call for the use of risk analysis and the best available science, principles 7 and 8 argue for taking precautions and the consideration of other factors. The commission published detailed guidance on when and how to apply the precautionary principle in relation to risk assessment (EC 2000b), but in practical terms, the principle provides cover for the dismissal of scientific analysis: When objective analyses reach conclusions that are politically unpopular, decision-makers can side with popular sentiment in the name of “precaution.” While this conflict has been apparent on hot-button issues such as GMOs and hormones, policy for microbiological safety, the principal concern of this report, has been far more driven by scientific analysis.

The EFSA was originally responsible for collecting human data on sporadic and outbreak cases in addition to data on food and feed, but this is now the responsibility of the European Centre for Disease Prevention and Control (ECDC), which was created in 2005.³³ The ECDC’s mission is to “identify, assess and communicate current and emerging threats to human health posed by infectious diseases” (Regulation (EC) No. 851/2004).³⁴ The ECDC coordinates multinational outbreak response within the European Union and manages surveillance programs for zoonotic and foodborne pathogens. The EFSA and ECDC collaborate on an annual community report on the surveillance of zoonoses, based upon data submitted by EU member states. According to our interviews, the creation of ECDC has improved human disease surveillance but has come at the cost of less-accessible data; EFSA working groups now have more difficulty obtaining human data than they did before the advent of ECDC.

Subsequent legislation has continued to reform the EU food safety system and to spell out initiatives (such as traceability) mandated by the 2002 law.

The EFSA and Member States

The EFSA, based in Parma, Italy, is a relatively small organization given the scope of its mandate, and concerns about its underfunding have been prevalent in the media and trade press (e.g., Phillips 2008, ElAmin 2007, Fletcher 2006). Its budget and staff have doubled in the past five years, however. In 2005, EFSA had a budget of €36 million, less than the €44 million originally promised, and a staff of 160, but the preliminary 2010 budget amounts to €74.4 million and the staff at the end of 2008 was 395 (EFSA 2006a, EFSA 2009a, EFSA 2009b).

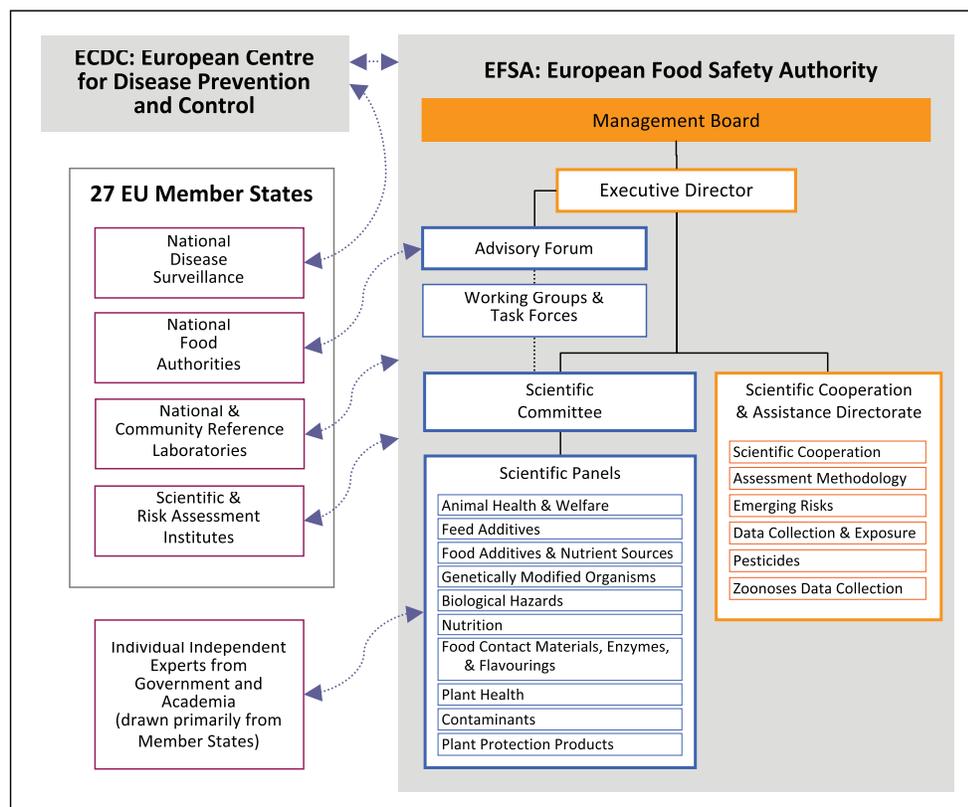
³² <http://www.efsa.europa.eu/>

³³ <http://ecdc.europa.eu/>

³⁴ http://ecdc.europa.eu/en/aboutus/Key%20Documents/0404_KD_Regulation_establishing_ECDC.pdf

The EFSA is a diffuse organization, with a relatively small staff based in Parma, Italy, and numerous panels, committees, and networks of experts and representatives from throughout Europe, as shown in Figure 10. It is led by a management board and an executive director. The 14 members of the board represent a rotating geographical subset of EU member states, and the board must include at least four members with backgrounds in consumer advocacy. The executive director oversees day-to-day operations and sets priorities for the workload. An advisory forum links EFSA and the member states, and it is composed of representatives of the states' national food agencies. The forum meets four times a year and advises the EFSA executive director on all aspects of the organization, including its work plan. A scientific committee and scientific panels form the core of EFSA. The scientific committee is composed of the chairs of the panels plus a handful of independent experts, and it is responsible for coordinating the work of the panels and maintaining consistency in scientific opinions. Ten EFSA panels are dedicated to a range of issues. Each panel has a maximum of 21 independent scientific experts who are not EFSA employees. Panelists are selected by the board on the proposal of the executive director and chosen through open competition among experts principally drawn from member states (though they do not act as representatives of their countries). The forum, the scientific committee, and the scientific panels are supported by the Scientific Cooperation and Assistance Directorate, created in 2008 and comprised of units with expertise in areas critical to the development of scientific opinions, such as risk-assessment methodology, data collection and exposure, and zoonoses surveillance.

Figure 10: Simplified diagram of primary EU-level food safety institutions and bodies



Source: created by authors based on EFSA (2010c)

The EFSA interacts with EU member state institutions and individual experts in several ways, as shown in Figure 10. In addition to direct participation in scientific panels, the scientific committee, and the advisory forum, experts may be consulted by ad hoc working groups and task forces created for specific issues and may participate in EFSA



networks designed to link expertise across the EU. The EC directly appoints community reference laboratories, which work with EFSA to improve technical capacity and harmonize methods throughout the system. Other “competent” organizations within the member states, such as scientific institutes, further engage with EFSA on specific projects.

Appendix B. Food Safety In Three European Countries

In this appendix, we describe the national food safety systems of Denmark, the Netherlands, and the United Kingdom. We present an overview of their institutions and their responsibilities, as well as their relevant recent history of institutional reform.

Denmark

The institutions that make up Denmark's food safety system have changed considerably during the past 15 years. In 1994, following large *Salmonella* outbreaks, Denmark established the Danish Zoonosis Centre (DZC) at the Danish Veterinary Institute (DVI) to systematically collect, collate, and analyze food safety data from throughout the food chain. The DZC was the first integrated surveillance institute of its kind in the world and has served as a model for other countries.

In 1997, Denmark also became one of the first countries to consolidate its food safety system, by creating the Danish Veterinary and Food Administration (DVFA) within its newly formed Ministry of Food, Agriculture, and Fisheries (MFLF). The major reorganization was intended to improve efficiency and effectiveness and communications with consumers (GAO 2005). In 2004, DVFA was moved to the Ministry of Family and Consumer Affairs, but was moved back to the MFLF in 2007 under another reorganization plan.

Today, the primary institutes and agencies responsible for food safety in Denmark are located within three ministries: the MFLF, the Ministry of the Interior and Health (SUM), and the Ministry of Science, Technology, and Innovation (VTU), as shown in Figure 11.

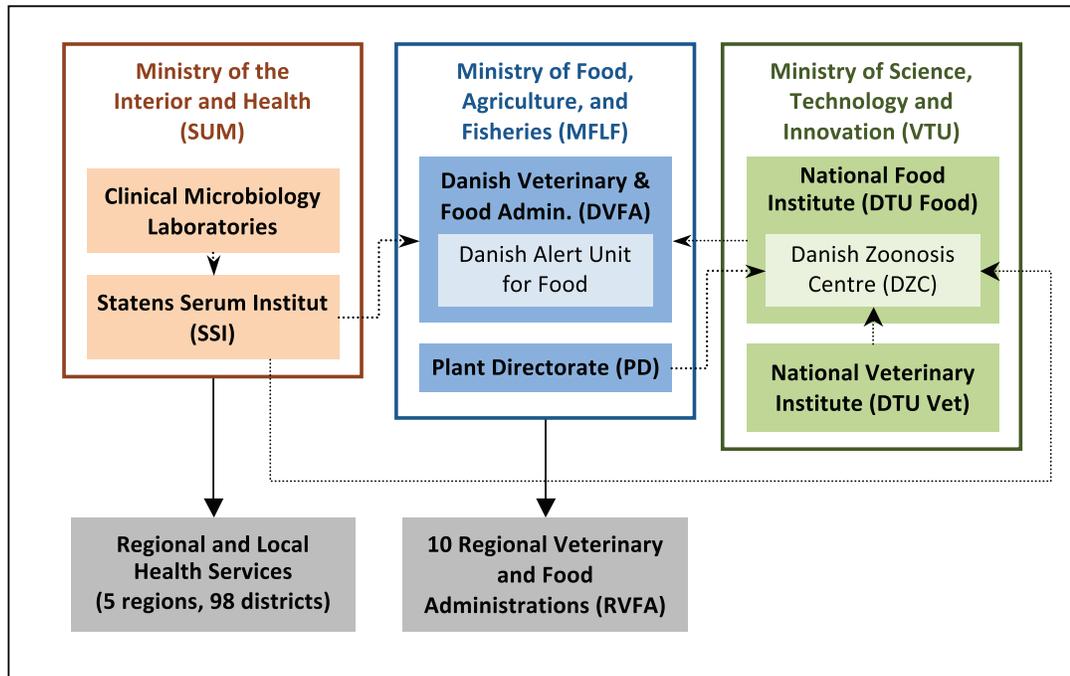
The DVFA is the lead food safety agency, responsible for managing foodborne risks based upon risk assessments and advice provided by independent scientific institutes. It develops and administers rules, regulations, and plans to control chemicals and pathogens in the food supply. DVFA inspectors based within 10 regional veterinary and food control authorities (RVFCA) are responsible for the inspection of animals, food, retail, and service establishments. The regional authorities further provide information to consumers, food companies, and veterinarians. The DVFA is also responsible for nutrition, including labeling, trade (import/export) issues, animal health, and, to a lesser extent, animal welfare. In 2006, Denmark created the Danish Alert Unit for Food (DAUF) within the DVFA to serve as a coordinating and communications body during food crises such as outbreaks.

SUM includes general practitioners, hospitals, a national board of health, and 15 regional medical officers of health. Perhaps more directly important for food safety, it also includes the Statens Serum Institut (SSI),³⁵ which is dedicated to monitoring and preventing infectious and congenital disease and is similar in many respects to the U.S. CDC. The SSI and SUM run the nation's clinical microbiology laboratories.

Denmark's scientific institutes are housed within VTU. Denmark undertook two reforms to fully separate food safety risk assessment from risk management. In 2004, risk assessment activities were removed from DVFA and DVI to form the Danish Institute for Food and Veterinary Research (DFVF). Then, in 2007, DFVF was moved from the Ministry of Food, Agriculture, and Fisheries to the Ministry of Science, Technology, and Innovation and merged with the Technical University of Denmark (DTU). The DFVF was split into two university institutes: the National Food Institute (DTU Food) and the National Veterinary Institute (DTU Vet).

³⁵ <http://www.ssi.dk/sw379.asp>

Figure 11: Simplified diagram of food safety authorities in Denmark



Note: Solid arrows indicate flow of authority and/or funding, while dotted arrows indicate primary information flows; source: adapted from DTU Food (2009b).

DTU Food's role as an independent institute is essentially to collect and synthesize information from throughout the system on a broad set of issues associated with food, analyze these data, and disseminate the results.³⁶ For foodborne pathogens, DTU Food has responsibilities in integrated pathogen and disease surveillance, epidemiological research, risk assessment, and diagnostic and analytical laboratory services. It is the national reference laboratory for a number of foodborne pathogens and serves as the EU reference laboratory for antimicrobial resistance.

Within DTU Food, DZC plays a coordinating role in zoonoses and foodborne pathogens by serving as a hub for DVFA, SSI, clinical and veterinary laboratories, environmental and public health authorities, and others.³⁷ The DZC is also the EFSA's Zoonosis Collaborating Centre, which means it collects, collates, and produces annual EU reports on surveillance of zoonoses in animals and food.

The Danish Environmental Protection Agency and the Danish Plant Directorate have responsibilities associated with food safety, and university research centers work with the government, including the Faculty of Agricultural Sciences and the National Environmental Research Institute, both at Aarhus University and at the Faculty of Life Sciences at the University of Copenhagen.

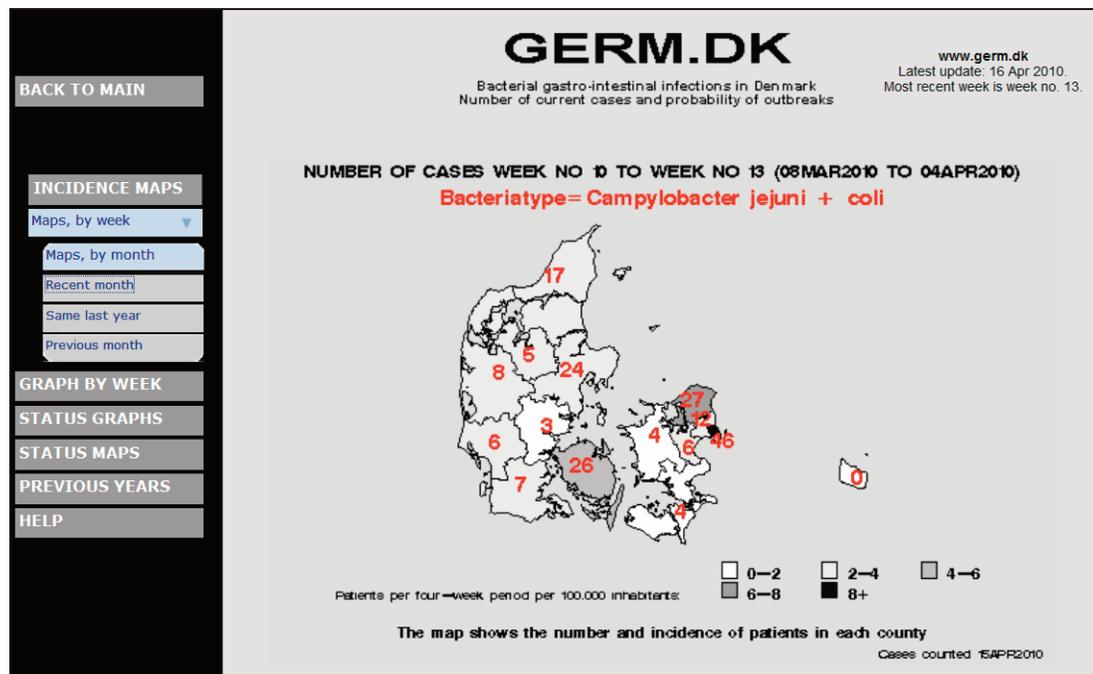
Denmark is recognized as a world leader in disease surveillance. Physicians report cases of certain diseases to the Department of Epidemiology within the Statens Serum Institut, while positive cases from all clinical laboratories are reported for these pathogens within one week to the Unit of Gastrointestinal Infections also within the SSI; there, they are entered into the Registry of Enteric Pathogens (REP). *Salmonella* and VTEC isolates are serotyped and genotyped by SSI laboratories and phage typed by DTU Food. In 2005, DTU Food, the SSI, and DVFA created a

³⁶ <http://www.food.dtu.dk/Default.aspx?ID=2227>

³⁷ <http://www.food.dtu.dk/Default.aspx?ID=8573>

joint online database that combined prior networks for foodborne and waterborne outbreaks; it is available to all Danish officials involved in foodborne outbreaks regardless of their agency. The SSI has also created the Gastroenteritis Monitor (<http://www.germ.dk>), a public Web site that is updated weekly with Danish laboratory surveillance data on foodborne illnesses and which can be viewed in tables, as graphs, and in maps. A screen-capture of the GERM Web site is shown in Figure 12.

Figure 12: Screen capture of Denmark's Gastroenteritis Monitor



Source: <http://www.germ.dk>.

The Netherlands

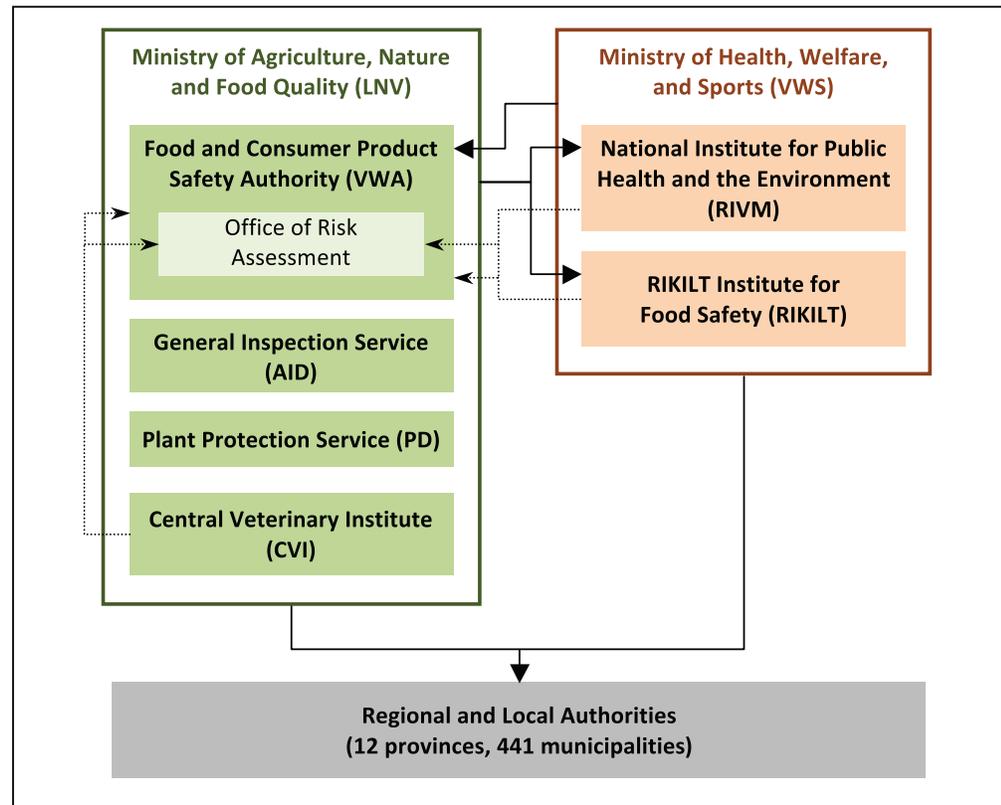
The Netherlands consolidated its food safety agencies in 2002 for three primary reasons: to improve efficiency, to comply with new EU legislation, and to respond to the public outcry following food safety scares, including BSE and dioxin in animal feed (GAO 2005). The Food and Consumer Product Safety Authority (VWA) consolidated enforcement by combining routine inspections from the health ministry with traditional meat inspection from the agricultural ministry. Additional modernization efforts aimed to move from “end-product testing” to “farm-to-consumption process controls” and to embrace more open and transparent risk analysis. The major institutions of Dutch food safety are shown in Figure 13.

The VWA is an independent agency based within the Ministry of Agriculture, Nature, and Food Quality (LNV), although it gets more than half of its funding from the Ministry of Health, Welfare, and Sport (VWS). The VWA is not responsible for setting regulatory targets or policies, as these responsibilities are handled by the ministries of agriculture (farm and feed) and health (post-slaughter).

Although its primary responsibility is enforcement — to use inspection and other tools to ensure compliance — VWA is also responsible for risk assessment and risk communication, and it includes an independent Office of Risk Assessment (ORA). About half of the risk assessments conducted or commissioned by ORA are self-initiated, while

the rest are required to support law enforcement or specific needs of the ministries. The ORA maintains some capacity to perform risk assessments in-house, but it generally relies upon the National Institute for Public Health and the Environment (RIVM) for more substantial analyses.

Figure 13: Simplified diagram of food safety authorities in the Netherlands



Note: Solid arrows indicate flow of authority and/or funding, while dotted arrows indicate primary information flows; source: based on information from BfR (2009) and RIVM.

The RIVM is a large, independent scientific research and advisory institute with more than 1,500 employees who work in public health, infectious disease, nutrition, and environmental protection.³⁸ It is based within the health ministry, although much of its funding comes through VWA, which is based in the agricultural ministry. From an information and analytical standpoint, RIVM is the central food safety research and surveillance body in the Netherlands. It has two primary roles. The first is as a critical piece in the response and surveillance system; RIVM manages surveillance of foodborne disease, performs epidemiological research, and serves as a national and international reference laboratory for *Salmonella* and residues on food. Its second role is in applied research and risk assessment; RIVM conducts formal risk assessments for VWA and the health ministry, as well as additional risk research.

The RIKILT Institute for Food Safety (RIKILT), affiliated with Wageningen University, is an independent research institute that focuses on pesticide and veterinary residues, feed safety, and analysis of GMOs.³⁹ Like RIVM, RIKILT is a “house” agency of VWA and provides scientific advice to VWA and the ministries. The RIKILT and RIVM have

³⁸ <http://www.rivm.nl/en/>

³⁹ <http://www.rikilt.wur.nl/UK/>

recently reorganized and consolidated staffs; RIVM is now responsible for microbiological hazards in food and feed, while RIKILT is responsible for chemical hazards.

Other Dutch agencies and research organizations participate in public-sector food safety, such as the Plant Protection Service (PD), the Landbouw-Economisch Instituut (LEI), and the Institute for Environmental Studies (IVM) at Vrije University.

The Netherlands has surveillance programs for zoonoses and foodborne pathogens (Valkenburgh et al. 2007). It monitors some foodborne pathogens on a sentinel basis through the participation of a subset of regional public health laboratories (PHLs). For example, 16 of these laboratories, representing 64 percent of the Dutch population, report *Salmonella* (Enter-Net 2007), while 50 percent of the Dutch population is covered for *Campylobacter*. *E. coli* O157:H7 and other VTEC and *Listeria monocytogenes* are reported by all laboratories, with additional data from subsequent epidemiological interviews.

The Netherlands has conducted additional epidemiological studies, including nationwide estimates of the burden of gastroenteritis based on cohort studies (Wit et al. 2001a), large case-control studies on *Campylobacter* and *Salmonella* (Doorduyn et al. 2006a, Nauta et al. 2005), and general-practitioner reporting studies (Wit et al. 2001b, Brandhof 2006).

The United Kingdom

The United Kingdom was one of the first European countries to undergo major food safety reform. The scandal surrounding the government's response to the BSE crisis of the late 1990s resulted in an unprecedented loss of public confidence in the Ministry of Agriculture, Fisheries, and Food (MAFF). As one scholar noted, "Indeed, rarely had a national government ministry in the developed world achieved such global infamy" (Rothstein 2006, p.154).

The Food Standards Agency (FSA) was created in 2000 as a nonministerial government department, independent of the agricultural ministry, in response to the widespread public belief that prior decisions on food safety were made in the best interest of industry rather than of consumers (GAO 2005).⁴⁰ The FSA also addressed two other major problems of the old regime: institutional fragmentation and opaqueness of decision-making. The FSA set out three guiding principles in line with these issues: "putting consumers first," "openness," and "independence."

The FSA is notable as one of the few food safety agencies that has true autonomy. The FSA doesn't report to any minister, but instead to a board composed of 13 members who are appointed by the health secretary. Board meetings are held monthly and are open to the public; presentations and reports are available on FSA's Web site. As previously discussed, DVFA in Denmark and VWA in the Netherlands both report to the agriculture minister, as do the consolidated food safety agencies in Germany, France, Ireland, Canada, and New Zealand (GAO 2005, 2008).

The United Kingdom recently further consolidated food safety functions within FSA by dissolving the Meat Hygiene Service (MHS) and incorporating its staff and responsibilities for inspecting animals, carcasses, and offals during production, in slaughter, and in processing (for meat safety and animal health and welfare) throughout England, Scotland, and Wales.⁴¹ Until April 1, 2010, MHS was an executive agency of FSA, which meant its budgeting and administration were separate from other FSA operations. Meat inspection will continue to be the largest component of FSA in terms of staff and budget.

⁴⁰ <http://www.food.gov.uk/>

⁴¹ <http://www.food.gov.uk/news/newsarchive/2010/mar/ogroup>

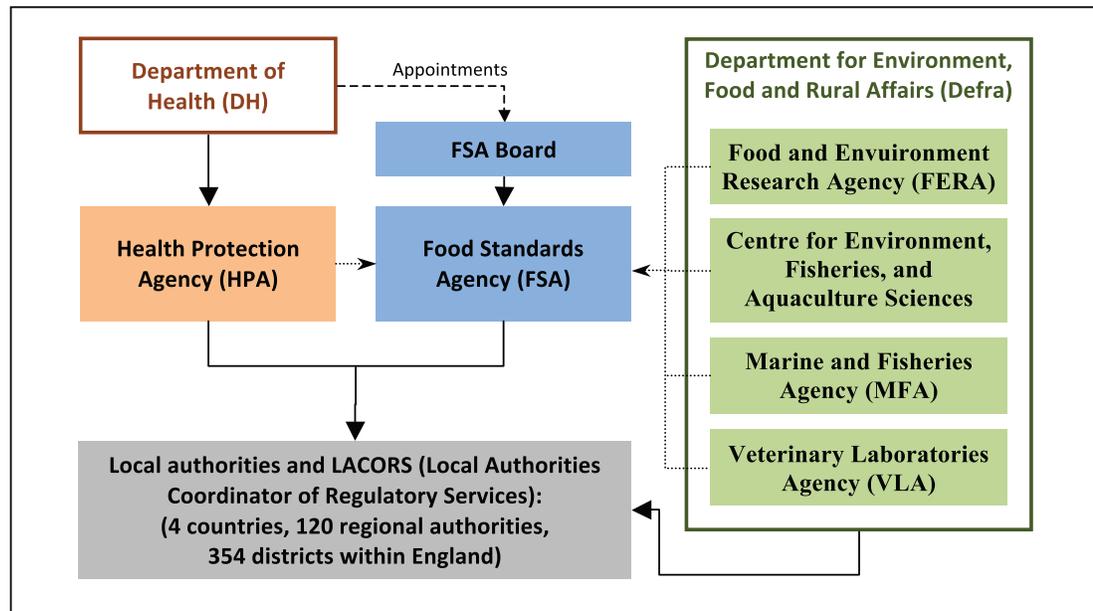
The FSA's primary responsibilities are standard setting, inspection, risk analysis, education, and public outreach. It also sets inspection policy for nonmeat foods such as fruit, vegetables, feed, and processed goods. Local inspection authorities perform these inspections, but they are overseen by FSA, which sets codes of practice and conducts audits. The FSA employs analysts (including economists, statisticians, operational researchers, and social science researchers) in a central team (analysis and research division) to provide analytical support for its activities. The work has included using risk analysis and other approaches to help with priority setting and resource allocation and to identify potential policy interventions.

The FSA doesn't maintain its own laboratory capacity, but it works closely with the Health Protection Agency (HPA) and the Department for Environment, Food, and Rural Affairs (Defra) for such services, as shown in Figure 14. The HPA was created in 2003 as a semi-autonomous "special health authority" of the National Health Service, but became an independent nondepartmental agency in 2005.⁴² Like FSA, it is an "arm's length" body, although it is funded through the Department of Health and answers to the secretary of state of health and to the United Kingdom's chief medical officer. The HPA is the United Kingdom's primary public health body, chiefly concerned with protection against infectious disease, chemical exposure, and radiological hazards. Three divisions of HPA work on food safety. The Centre for Infections has a similar role in food safety to that of the CDC in the United States: Both are responsible for the surveillance of human disease, outbreak investigations, and some epidemiological research. The Local and Regional Services (LaRS) division of HPA is responsible for the investigation and control of outbreaks at the local level. The HPA's Regional Microbiology Network (RMN) is composed of specialist laboratories that conduct diagnostic work on clinical isolates referred from physicians and on food samples taken during outbreak investigations, food surveys, and research projects.

Unlike the CDC, however, HPA conducts microbiological food surveys in retail products and risk assessments. Some food surveys are done under contract for FSA, while others are conducted on its own initiative. These studies are usually conducted by working with local authorities who collect the samples and submit them to control laboratories. The HPA has conducted risk assessments for *Salmonella* in pooled egg mixtures or shell eggs and *Listeria monocytogenes* in specialty meats.

⁴² <http://www.hpa.org.uk/>

Figure 14: Simplified diagram of food safety authorities in the United Kingdom



Note: Solid arrows indicate flow of authority and/or funding, while dotted arrows indicate primary information flows; source: based on information from BfR (2009), FSA, and HPA.

The Defra is the United Kingdom's department that is responsible for environmental protection, agriculture, fisheries, and rural communities.⁴³ Food production is one of its major focuses, including research and surveillance of some human hazards, such as abattoir and food-animal studies on microbial and chemical hazards. The Defra has food safety responsibilities, such as feed safety, animal health, animal and animal product imports, beef labeling, organic standards, and residues of chemicals and veterinary drugs. It conducts both chemical and microbiological risk assessments, and its numerous agencies perform food safety work under contract to FSA or under their own initiative, including the Food and Environment Research Agency (FERA, known prior to April 2009 as the Central Science Laboratory), the Centre for Environment, Fisheries, and Aquaculture Science (CEFAS), the Marine and Fisheries Agency (MFA), and the Veterinary Laboratories Agency (VLA).

In the United Kingdom, clinical laboratories voluntarily report data on confirmed cases to HPA, which maintains surveillance on more than 4,000 pathogens. The HPA also manages nationwide outbreak surveillance, which it learns about through national laboratory reporting and from consultants in communicable disease control, environmental health officers, microbiologists, and HPA reference laboratories.

Other institutions also work with FSA and EFSA. The EU Food Safety Almanac lists 36 that are involved in EFSA networks, including some of the agencies just discussed as well as the Institute of Food Research (IFR), a nonprofit research organization, colleges and university-based research centers, public laboratories, and some private laboratory services (BfR, 2009).

The United Kingdom published a major report in 2000 on the incidence of intestinal infectious disease (IID) in England (Tam et al 2003, FSA 2000). It was a complex and comprehensive community-based study conducted by a large collaborative group that included academic researchers, national health bodies, and local health authorities.

⁴³ <http://www.defra.gov.uk/>

It involved nearly 10,000 patients selected randomly from 70 general practitioners' offices. Through surveys, follow-up questionnaires, and studies of physician and laboratory behavior, the study was able to quantify underreporting at each stage of the reporting pyramid (e.g., likelihoods that an ill person goes to the doctor, that the doctor takes a stool sample, that the organism is identified, that the finding is reported). It found that 20 percent of the population of England suffered from foodborne illnesses annually, an incidence approximately 100 times higher than reported by surveillance systems alone. A second IID study (IID2) is underway under commission by the FSA; this study will expand the community to the entirety of the United Kingdom and involves improvements to study design.⁴⁴

The Produce Safety Project commissioned the writing of this report and is responsible for its content. PSP would like to acknowledge and thank for his review of this report: Dr. Morris Potter, formerly of the Centers for Disease Control and Prevention. The views in this report do not necessarily reflect the views of the reviewer or of The Pew Charitable Trusts.

⁴⁴ <http://www.iid2.org.uk/>

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