

June 2008

FOOD SAFETY

Selected Countries' Systems Can Offer Insights into Ensuring Import Safety and Responding to Foodborne Illness



G A O

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Highlights of [GAO-08-794](#), a report to congressional requesters

Why GAO Did This Study

Like other nations, the United States faces growing food safety challenges resulting from at least three major trends. First, imported food makes up a growing share of the food supply. Second, consumers are increasingly eating foods that are raw or have had minimal processing and that are often associated with foodborne illness. Third, changing demographic patterns mean that more of the U.S. population is, and increasingly will be, susceptible to foodborne illness. In 2005, GAO reported on the approaches and challenges seven countries faced in reorganizing and consolidating food safety functions. Since then, the European Union (EU) has taken on a larger role in overseeing food safety within its 27 member states.

GAO was asked to describe how Canada, the EU, Germany, Ireland, Japan, the Netherlands, and the United Kingdom (UK) (1) ensure the safety of imported food, (2) respond to outbreaks of foodborne illness, and (3) measure the effectiveness of their reorganized food safety systems. GAO also asked experts in these countries and the EU to identify emerging food safety challenges that they expect to face over the next decade. In doing this work, GAO did not evaluate the countries' management of their food safety systems or explicitly compare their efforts with those of the United States.

To view the full product, including the scope and methodology, click on [GAO-08-794](#). For more information, contact Lisa Shames at (202) 512-3841 or shamesl@gao.gov.

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What GAO Found

The countries GAO examined have a comprehensive approach to ensuring the safety of imported food. Specifically, they focus on the entire food supply chain, from “farm to table;” place primary responsibility for food safety on producers; separate risk assessment and risk management; use a risk-based inspection system; and take steps to ensure that certain food imports meet equivalent safety standards. Under the farm-to-table approach, for example, food safety laws cover every stage of the food production process, starting with how animals are raised and ending when food reaches the consumer. All countries GAO reviewed focus import inspections on the foods likeliest to pose the greatest risk. The EU, for example, requires that all imports of live animals and products of animal origin—which are considered high risk—enter the EU through approved border inspection posts.

Several of the selected countries reported that three elements of their food safety systems are critical in helping them respond to outbreaks of foodborne illness. These elements are traceback procedures, cooperative arrangements between government veterinarians and public health officials, and mandatory recall authority. In EU member states, all food must be traceable “one step forward and one step back” so industry and government can quickly track any food products to minimize harm to public health and reduce the economic impact on industry. Food and feed business operators must be able to document the names and addresses of the supplier and customer, as well as the nature of the product and date of delivery. Officials in several countries told GAO that mandatory recall authority—the legal authority to remove, or require another party to remove, a product from the market—is rarely used but is an important part of the food safety system because it is the last stop in the supply chain.

None of the selected countries had comprehensively evaluated its reorganized food safety system, although several track certain indicators, such as the number of inspections, enforcement actions, and foodborne illness. However, some countries' national audit offices (GAO's counterparts) have evaluated specific aspects of their countries' systems. For example, the UK audit office found that the country's Food Standards Agency had improved public confidence, a stated objective. The EU's Food and Veterinary Office has conducted numerous reviews of aspects of all EU countries' food safety systems and identified areas needing improvement. Most of the selected countries use proxy measures, such as public opinion surveys, to assess their effectiveness. Public opinion in several countries has improved in recent years. Countries' industry and consumer stakeholders also generally had positive views of the reorganized food safety systems.

Experts identified food safety challenges that they expect to face over the next decade. These include climate change; demographic change, with increases in elderly people and immigration; and new types of foods, such as ready-to-eat salads, that may result in more incidents of foodborne illness.

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	Abbreviations	
	BSE	bovine spongiform encephalopathy
	BVL	Federal Office of Consumer Protection and Food Safety
	CFIA	Canadian Food Inspection Agency
	DAFF	Department of Agriculture, Fisheries, and Food
	DG-SANCO	Directorate General for Health and Consumer Protection
	EC	European Commission
	ECDC	European Centre for Disease Prevention and Control

EEA	European Economic Area
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
EU	European Union
FDA	Food and Drug Administration
FSAI	Food Safety Authority of Ireland
FSC	Food Safety Commission
FVO	Food and Veterinary Office
GDP	gross domestic product
HACCP	Hazard Analysis and Critical Control Point
HC	Health Canada
HPA	Health Protection Agency
HPSC	Health Protection Surveillance Centre
MAFF	Ministry of Agriculture, Forestry, and Fisheries
MHLW	Ministry of Health, Labor, and Welfare
NMFS	National Marine Fisheries Service
RFID	Radio-Frequency Identification
RIVM	National Institute for Public Health and the Environment
SALSA	Safe Food for Local Suppliers Association
SPS	Sanitary and Phytosanitary
TRACES	Trade Control and Expert System
UK	United Kingdom
USDA	U.S. Department of Agriculture
VWA	Food and Consumer Product Safety Authority
WTO	World Trade Organization

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United States Government Accountability Office
Washington, DC 20548

June 10, 2008

The Honorable Richard J. Durbin
United States Senate

The Honorable Rosa L. DeLauro
Chair
Subcommittee on Agriculture, Rural Development, Food and
Drug Administration, and Related Agencies
Committee on Appropriations
House of Representatives

Like other nations, the United States faces growing food safety challenges resulting from at least three major trends. First, imported food makes up a growing share of the food supply. According to an analysis by the U.S. Department of Agriculture (USDA), the dollar value of agricultural imports to the United States for consumption increased by about 53 percent in just 4 years, from \$46 billion in fiscal year 2003 to \$70 billion in fiscal year 2007. The United States also trades with more than 150 countries and territories, with food products coming into more than 300 U.S. ports. USDA estimates that approximately 60 percent of the fresh fruits and vegetables consumed in the United States is imported, as is 75 percent of the seafood. Second, we are increasingly eating foods that are consumed raw or with minimal processing and that are often associated with foodborne illness. For example, according to USDA, leafy greens such as spinach are the category of produce most likely to be associated with an outbreak, and the average consumer ate 2.4 pounds of fresh spinach in 2005—a 180 percent increase over 1992. Third, changing demographic patterns mean that more of the U.S. population is, and increasingly will be, susceptible to foodborne illness. The U.S. population is aging, and older people tend to be more vulnerable to foodborne illness than younger ones. The risk of severe and life-threatening symptoms from infections caused by foodborne pathogens is also higher for young children, pregnant women, and immune-compromised individuals. According to the Food and Drug Administration (FDA), these groups make up about 20 to 25 percent of the U.S. population.

Recent outbreaks of foodborne illness have focused public attention on the increasing potential for widespread dissemination of contaminated products. For example, beginning in September 2006, the United States experienced an outbreak of *E. coli* associated with the consumption of tainted spinach grown in California; this outbreak resulted in confirmed

illnesses and deaths. Widespread outbreaks of other foodborne illnesses, such as *Salmonella*, have also occurred from contaminated peanut butter and tomatoes. In addition, there have been problems with certain meat products, resulting in recalls (which in the United States are nonmandatory). Although the number of recalls has declined in recent years, the quantity of meat and poultry recalled has increased sharply. Meat and poultry product recalls declined from 125 in 2002 to 58 in 2007. However, 2 of the 6 biggest meat recalls in U.S. history occurred in a 6-month period, between October 2007 and February 2008.

In the United States, 15 different federal agencies are responsible for food safety. Two agencies, USDA and FDA, have primary responsibility. USDA is responsible for the safety of meat, poultry, and certain egg products, while FDA is responsible for the safety of virtually all other foods, including milk, seafood, and fruits and vegetables. Food safety responsibility is further divided among the 50 states, which may have their own statutes, regulations, and agencies for regulating and inspecting the safety and quality of food products. Over the past 30 years, we have detailed problems with the current fragmented federal food safety system and reported that the system has caused inconsistent oversight, ineffective coordination, and inefficient use of resources. This fragmentation calls into question whether the government can plan more strategically to inspect food production processes, identify and react more quickly to outbreaks of foodborne illness, and focus on promoting the safety and integrity of the nation's food supply. This fragmentation is the key reason that we added federal oversight of food safety to our *High-Risk Series* in January 2007 and called for a governmentwide examination of the food safety system.¹ We recommended, among other things, that Congress enact comprehensive, uniform, and risk-based food safety legislation and commission the National Academy of Sciences or a blue ribbon panel to conduct a detailed analysis of alternative organizational structures for food safety.

In 2005, we reported on the approaches and challenges seven countries faced in consolidating food safety functions.² These countries were Canada, Denmark, Germany, Ireland, the Netherlands, New Zealand, and the United Kingdom (UK). Some of these countries reorganized their food

¹GAO, *High-Risk Series: An Update*, [GAO-07-310](#) (Washington, D.C.: January 2007).

²GAO, *Food Safety: Experiences of Seven Countries in Consolidating Their Food Safety Systems*, [GAO-05-212](#) (Washington, D.C.: Feb. 22, 2005).

safety systems in response to public concern about the safety of the food supply during outbreaks of bovine spongiform encephalopathy (BSE, also known as mad cow disease) and, in the case of the European countries, widespread dioxin contamination in chicken products during the 1990s. Some countries—notably Canada, Denmark, and New Zealand—reorganized to improve the overall effectiveness of their systems. Since our 2005 report, the food safety system of the European Union (EU) has been fully integrated and is regulated by legislation that applies to all 27 member states. Japan also reorganized part of its food safety system in 2003, creating a new agency, the Food Safety Commission, to assess the health risks associated with food. Even with updated measures in place, however, it is not possible to totally eliminate all foodborne pathogens from the food supply. For example, incidents of *E. coli* have increased slightly in the EU over the past 10 years, and in early 2008, a number of Japanese citizens became seriously ill after eating frozen dumplings imported from China that contained a dangerous level of pesticides.

In this context, you asked us to describe (1) how 6 countries (Canada, Germany, Ireland, Japan, the Netherlands, and the UK) that have reorganized their food safety systems and the EU ensure the safety of imported food, (2) what these countries and the EU consider to be the most critical elements in helping them respond to recent outbreaks of foodborne illness, and (3) how they measure the effectiveness of their reorganized food safety systems, as well as how effective the reorganized systems have been in minimizing harm to public health from outbreaks of foodborne illness. In addition, we asked experts in these 6 countries and the EU to identify what they consider to be some of the most important emerging food safety challenges they expect to face over the next decade.

To address these questions, we collected and reviewed laws and directives, and analyzed agencies' annual reports, performance reports, strategic plans, official brochures, and guidance documents on policies and procedures from these 6 countries and the EU. We also met with food safety officials, industry experts, and consumer advocacy representatives in Belgium (for the EU), Canada, Germany, Ireland, Japan, the Netherlands, and the UK. Canada, Germany, Ireland, the Netherlands, and the UK were selected because we had reviewed those countries in our 2005 report. They were selected then because they had reorganized their food safety systems within the past 10 years and, like the United States, had high per capita income, and their consumers had high expectations for food safety. We added Japan because it also has a high per capita income and recently reorganized part of its food safety system. We added the EU because of its major role in coordinating member countries' food safety

activities. In this report, we refer to the changes to their food safety systems that the selected countries have made as reorganization. In describing the changes to systems of Canada, Germany, Ireland, the Netherlands, and the UK, however, we use the countries' term, which is consolidation.

After we collected the information, we prepared appendixes that described each country's and the EU's food safety system. We then sent the draft appendixes to officials in those countries for review and comment. We received comments from at least one agency (food safety or public health) in 6 of the selected countries. Japan did not provide comments. After receiving their feedback and making revisions, where appropriate, we sent the appendixes to representatives of the various countries' national audit offices. We also sent copies of the report to the Department of Agriculture, the Department of State, the Food and Drug Administration, and the Office of the U.S. Trade Representative for their review; we incorporated their comments as appropriate.

The information on countries' food safety systems in this report, including descriptions of laws, is based largely on interviews with and documentation provided by food safety officials as well as food industry or consumer stakeholders from the countries we examined. Most of the information obtained was qualitative. We did not compare any elements of these countries' systems to the United States' system—although in some cases, country officials told us that aspects of their food safety systems were similar to aspects of the U.S. system—and we did not independently evaluate the effectiveness of any of the programs or systems described. We also did not independently verify the foreign laws and directives discussed. Instead, we relied on our discussions with foreign officials and the documents we collected. We recognize that the selected countries have much smaller populations and also differ from the United States in climate and agricultural production as well as in organizational structure. However, these countries and the United States have at least one important similarity: All are high-income countries where consumers have high expectations for food safety. We conducted our work from July 2007 to June 2008 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the work to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our objectives. Detailed information on each country's and the EU's food safety systems can be found in appendix I. In this report, when we refer to selected countries, we mean the 6 countries

named above and the EU. Of the 6 countries, 4—Germany, Ireland, the Netherlands, and the UK—are EU member states.

Results in Brief

The selected countries have a comprehensive, risk-based approach to ensuring the safety of imported food. Specifically, they focus on the entire food supply chain, from “farm to table;” place primary responsibility for food safety on food producers with the government providing oversight; separate risk assessment and risk management; employ a risk-based inspection system; and take steps to ensure that certain food imports meet equivalent food safety standards. More specifically, we found the following:

- *Farm-to-table oversight.* Under this approach, the entire food production process is regulated, starting with how animals are raised on the farm and ending when food reaches the final consumer. For example, according to EU sources, under the EU’s integrated farm-to-table approach, food and feed laws cover all stages of production, processing, and distribution. The laws also cover imported products from the primary production of a food, through its storage, transport, sale, or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale, and supply of feed. We were told that this is a comprehensive and integrated approach that focuses on the prevention of problems throughout the food chain.
- *Producer responsibility.* The burden for food safety in most of the selected countries lies primarily with food producers, rather than with inspectors, although inspectors play an active role in overseeing compliance. This principle applies to both domestic and imported products. We were told that like the farm-to-table concept, producer accountability is a proactive approach that focuses on prevention.
- *Separate risk assessment and risk management.* To create independent safeguards, the EU and some countries created separate agencies for (1) risk assessment—scientific evaluation of all known and potential adverse health effects resulting from foodborne hazards—and (2) risk management—the process for weighing policy alternatives to accept or minimize assessed risks and select appropriate responses. In addition, some of the countries also separated their risk management agencies from those that promote industry in order to ensure independence. For example, before they reorganized, risk management in Ireland, Japan, and the UK had been conducted by the same agency that oversaw agricultural

production, and consumers perceived that these dual responsibilities presented conflicting priorities.

- *Risk-based inspection systems.* The selected countries focus their inspection of imports on the foods most likely to pose the greatest risk. A risk-based approach is critical in light of the volume of products in the food supply. The EU, for example, requires that all imports of live animals and products of animal origin—which are considered high risk—enter the EU through approved border inspection posts. These shipments cannot clear the port without veterinary approval. Shipments containing products the EU considers lower risk, such as fruits, vegetables, cereals, and spices, must meet less stringent requirements. The EU and Japan require that importers bear the cost of disposing of or reinspecting noncompliant food products.
- *Certain food imports must meet equivalent safety standards.* Each of the selected countries takes steps to ensure that certain types of food—most often, meat or animal products—meet equivalent food safety standards. Japan also has specific arrangements with some governments to certify exports of certain high-risk products. According to Japanese officials, under a Japanese-Chinese agreement, for example, the Chinese government certifies Chinese spinach processors, who in turn oversee the practices of local farmers and test the product at three stages of production. Chinese authorities then conduct preshipment tests on the spinach before exporting, confirming that the exporter has observed the proper procedures on pesticide management. The spinach may be inspected again once it arrives in Japanese ports.

Several of the selected countries generally reported that three elements of their food safety systems are critical in helping them respond to outbreaks of foodborne illnesses. These elements include traceback procedures, cooperative arrangements between government veterinarians and public health officials, and mandatory recall authority.

- *Traceback procedures.* All food and feed must be traceable “one step forward and one step back” in EU member states so industry and governments can quickly track any questionable food or feed products to minimize harm to public health and reduce the economic impact on industry. Food and feed business operators must be able to document the names and addresses of the supplier and customer, as well as the nature of the product and date of delivery. They are also required to have in place systems and procedures that allow for this information to be made available to government officials on demand. Exporters in trading partner (non-EU) countries do not need to meet this requirement, except under

certain circumstances, but EU importers should be able to identify their direct supplier in trading partner countries. In addition, the selected countries also have mandatory animal identification programs for certain livestock species.

- *Cooperation between government veterinarians and public health officials.* In light of highly pathogenic avian influenza, BSE, and recognition of the connection between animal and human diseases, such cooperation has been critical in tracking the source of zoonotic (animal-to-human) diseases in some countries. For example, in the UK, the Veterinary Laboratories Agency has several memorandums of understanding with the Health Protection Agency, the UK agency that monitors outbreaks of infectious diseases, to conduct research. The agencies also support joint efforts to standardize laboratory methods and databases. The Veterinary Laboratories Agency can also assist in cases where a direct or indirect animal source is suspected in outbreaks of zoonotic diseases and where veterinary investigation or intervention could help reduce risks to the public. For example, according to UK officials, during the investigation of a 2004 outbreak of an antibiotic-resistant strain of *Salmonella* among cattle on an English farm, rapid communication of test results and epidemiological information between the Health Protection Agency and the Veterinary Laboratories Agency led to containment of the outbreak before it could spread to humans.
- *Mandatory recall authority.* Officials in several countries told us that mandatory recall authority—the legal authority to remove, or require another party to remove—a product from the market is rarely used. However, according to a Canadian industry representative, this authority is an important part of the food safety system because it is the last stop in the supply chain. Moreover, as Canadian government officials indicated, they rarely need to exercise mandatory recall authority because the threat of such a recall generally prompts food suppliers to remove products from the market.

None of the selected countries had conducted a comprehensive evaluation of its reorganized food safety system, but most countries track certain indicators, such as the number of inspections conducted, the number of enforcement actions taken, and the number of foodborne illness outbreaks. However, most of the selected countries have assessed specific aspects of their food safety systems. For example, some of the countries' national audit offices had evaluated specific aspects of their countries' food safety systems, and Health Canada has assessed some elements of the Canadian system. In the EU, the Food and Veterinary Office has conducted numerous reviews of certain aspects of member

countries' food safety systems. For example, in June 2005, the office assessed the import control system and four operating border inspection posts in Germany. It found that import controls were generally applied correctly in the posts visited, with only minor shortcomings. However, the office also found that supervision of imports that do not comply with EU regulations was inadequate, traceability was not reliable, and exit of these noncompliant products from the EU was not ensured. It also found that there were significant deficiencies at some of the border inspection facilities. As a result of the audit, Germany took steps to address the shortcomings. Most of these countries also use proxy measures, such as consumer surveys, to assess their effectiveness, and the public impression of food safety has improved in several countries in recent years. Finally, stakeholders we interviewed cited the benefits of their country's reorganized food safety system.

Experts in the selected countries identified a number of challenges related to food safety that they expect to face over the next decade, with climate change the most frequently identified challenge. Specifically, they indicated that climate change may result in an increase in foodborne pathogens that thrive in warmer conditions, such as the *Vibrio* bacterium in oysters. Furthermore, some officials expressed concern that their populations are aging, and older people are more vulnerable to foodborne illness than younger ones. Additionally, the emergence of new types of foods—for example, ready-to-eat foods, including those that do not require cooking and therefore may retain pathogens—may result in illness.

Background

In the United States, USDA and FDA have primary responsibility for ensuring the safety of domestic and imported foods. USDA is responsible for the safety of meat, poultry, and certain egg products and for performing certain food quality inspections and certifications that include food safety elements. FDA is responsible for the safety of all other foods, including milk, seafood, and fruits and vegetables. In addition, the Environmental Protection Agency (EPA) sets limits on the amount of pesticide residues that are allowed in food, and the National Marine Fisheries Service (NMFS) within the Department of Commerce provides fee-for-service inspections of seafood safety and quality. The Department of Homeland Security is responsible for coordinating agencies' food security activities, including at U.S. borders. The U.S. Centers for Disease Control and Prevention is responsible for monitoring, identifying, and investigating foodborne disease problems and for working with FDA, NMFS, USDA, state and local public health departments, universities, and industry to develop control methods.

In January 2007, we added the federal oversight of food safety to our *High-Risk Series*, which is intended to raise the priority and visibility of government programs that are in need of broad-based transformation to achieve greater economy, efficiency, effectiveness, accountability, and sustainability. Over the past 30 years, we have detailed problems with the current fragmented federal food safety system and reported that the system has caused inconsistent oversight, ineffective coordination, and inefficient use of resources, all of which suggest that the federal oversight of food safety should be designated as a high-risk area. The fragmented nature of the federal food oversight system raises the question of whether the government can plan more strategically to inspect food production processes, identify and react more quickly to outbreaks of foodborne illnesses, and focus on promoting the safety and integrity of the nation's food supply.

As in the United States, government agencies in other countries also share responsibility for their nation's food safety. In February 2005, we reported on the experiences of several countries in reorganizing their food safety systems. Food safety officials in the countries we selected said they faced similar divisions of responsibilities and that their countries' reorganizations were intended to address this problem. The countries streamlined and consolidated their food safety functions, establishing a single agency to lead food safety management or enforcement of food safety legislation. Table 1 lists the reasons each country gave for consolidating its food safety responsibilities.

Table 1: Reasons for Consolidating Food Safety Responsibilities

Canada	Canada consolidated its food safety system to (1) improve effectiveness by making inspections and enforcement more consistent, clarifying responsibilities, and enhancing reporting to the Canadian Parliament, (2) improve efficiency by reducing duplication and overlap in food safety activities, and (3) reduce federal spending.
Denmark	Denmark consolidated its food safety system to improve effectiveness (e.g., communication with consumers and consistency of inspections) and to improve efficiency (e.g., move resources to high-risk areas and reduce overlaps in responsibilities).
Germany	Germany consolidated its food safety system in response to public concerns about food safety stemming from the discovery of BSE in 2000 and other food safety problems. An additional objective was improved compliance with EU food safety legislation.
Ireland	Officials stated that Ireland consolidated responsibility for food safety and food law enforcement within a single national agency to address public concern about food safety stemming from food scares and the detection of BSE in Ireland. Also, some consumers perceived that the ministry that was responsible for inspecting farms and meatpacking plants had favored the interests of the food industry over consumer protection.
The Netherlands	The Netherlands consolidated its food safety system out of a need to reduce overlap and improve coordination among the Dutch government's multiple food safety entities, as well as public concern about food safety stemming from the dioxin contamination of animal feed, BSE, and other animal diseases. Officials noted that the need to comply with recently adopted EU legislation also motivated the Netherlands' consolidation.
New Zealand	New Zealand consolidated its food safety system to improve effectiveness in several areas, including coordination within the food safety system, and to eliminate inconsistencies in the country's oversight of domestic food, imports, and exports.
The UK	Officials stated that the UK consolidated its food safety system due to a loss of public confidence in food safety, which largely resulted from the government's perceived mishandling of the BSE outbreak. By early 1999, the human form of BSE, variant Creutzfeldt-Jakob disease, had caused 35 deaths. It was widely perceived that the fragmented and decentralized food safety system allowed this outbreak to occur. According to a consumer organization representative, consumers believed that the Ministry of Agriculture, Fisheries, and Food—which had dual responsibilities to promote the agricultural and food industry as well as to regulate food safety—favored industry over consumers in making decisions related to food safety.

Source: [GAO-05-212](#).

Although the countries whose food safety systems we reviewed are much smaller in population than the United States, they, like the United States, are high-income countries whose consumers have very high expectations for food safety.

Most of the countries we selected for this review are members of the EU and, as such, are subject to applicable requirements of EU food safety legislation. The development and implementation of EU food safety legislation is the responsibility of the Brussels-based Directorate General for Health and Consumer Protection (referred to by its French acronym, DG-SANCO). In 2002 the EU also created a new independent food safety institution, the European Food Safety Authority (EFSA), which is responsible for providing independent scientific advice on all matters related to food and animal feed safety. In April 2004, the EU adopted

additional, comprehensive food safety legislation that became effective on January 1, 2006. Together with the earlier regulation establishing EFSA, the legislation was intended to create a single, transparent set of EU food safety rules applicable to both animal and nonanimal products. Since that time, individual EU countries have worked to bring their national food safety laws in line with EU requirements—a process referred to as harmonization.

These selected countries also face the challenge of foodborne illness caused by known hazards as well as new threats. To address these challenges, the United States and other countries have undertaken certain measures to protect human health. These measures include the use of a science-based safety system for certain food products, known as Hazard Analysis and Critical Control Point (HACCP), and the requirement that exporting nations meet food safety standards similar to the importing country's own standards. A HACCP system is designed to improve the safety of food by having industry identify and control biological, chemical, and physical hazards in products before they enter the market. In the United States, USDA established HACCP requirements for meat and poultry establishments in 1996. FDA implemented similar HACCP requirements for seafood in 1997 and for juice in 2002. Under the HACCP system, processing firms must identify hazards that are reasonably likely to occur and must develop and implement plans to control those hazards. HACCP systems, under USDA and FDA regulations, are not required for other stages of production, such as on the farm. In general, the federal food safety regulation begins at the point of processing, rather than on the farm itself.

With regard to equivalent food safety standards between countries, the Agreement on the Application of Sanitary and Phytosanitary Measures—entered into force with the establishment of the World Trade Organization (WTO) on January 1, 1995—affirms that member countries are allowed to adopt and enforce measures necessary to protect human, animal, or plant life or health, provided, among other things, the measures are based and maintained on scientific principles and evidence, do not arbitrarily or unjustifiably discriminate among WTO members, and are not applied in a manner that would constitute a disguised restriction on international trade. In turn, member countries are expected to accept the sanitary or phytosanitary measures of other member countries as equivalent if the exporting member objectively demonstrates that its measures achieve the importing member's appropriate level of sanitary or phytosanitary protection. Members are encouraged to use relevant international standards and work toward harmonization—that is, the adoption of

common sanitary or phytosanitary measures—to facilitate trade. Consistent with the principles of the sanitary and phytosanitary agreement, many countries use equivalency agreements to certify that their food safety systems are equivalent to those of the country importing products. All countries in our review are parties to the WTO and to the Agreement on the Application of Sanitary and Phytosanitary Measures.

In response to these increasing challenges, FDA and other U.S. agencies recently released plans that discuss the oversight of food safety. In November 2007, FDA released its *Food Protection Plan*, which sets forth FDA’s framework for overseeing the safety of food.³ Concurrently, a 12-agency working group presented to the President its *Action Plan for Import Safety*, which contains, among other things, recommendations for improving the safety of food imports entering the United States.⁴ Both plans spell out numerous actions FDA plans or is requesting authority to take to enhance food safety, including writing new food protection guidelines for industry and helping foreign countries improve their regulatory systems.

Selected Countries Have a Comprehensive, Risk-Based Approach to Import Safety

The selected countries have a comprehensive, risk-based approach to ensuring the safety of imported food that focuses on the entire food supply chain, from “farm to table.” The selected countries emphasize prevention, placing primary responsibility for food safety on food producers, with government bodies providing oversight. Some of these countries separate risk analysis and risk management, and some also separate food safety from the promotion of agricultural trade. Each country also employs a risk-based inspection system so that foods with increased risk receive the most attention. The selected countries also take steps to ensure certain food imports meet equivalent food safety standards.

The Selected Countries’ Food Safety Systems Are Based on Farm-To-Table Oversight

The selected countries have generally adopted a farm-to-table approach, under which the entire food production process is regulated, starting with how animals are raised on the farm and ending when food reaches the final consumer. Farm-to-table oversight in the selected countries applies to both domestic and imported foods. We were told that farm-to-table is a

³Department of Health and Human Services, U.S. Food and Drug Administration, *Food Protection Plan* (Washington, D.C.: 2007).

⁴Interagency Working Group on Import Safety, *Action Plan for Import Safety* (Washington, D.C.: 2007).

comprehensive and integrated approach that focuses on prevention of problems throughout the food chain. In the EU, for example, according to EU sources, food and feed laws under this approach (referred to in the EU as “farm to fork”) cover all stages of production (including farming), processing, and distribution. According to these sources, EU laws also cover imported products from the primary production of a food, through its storage, transport, sale, or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale, and supply of feed. Individual EU member states, through their bodies charged with food safety oversight (referred to as competent authorities), ensure surveillance and control of food and feed operators, and the European Commission (EC—the administrative, implementing, and enforcement body of the EU) tests the performance of member states’ control capacities through audits and inspections. Farms and food producers in non-EU countries that export to the EU must observe the same safety standards that apply in the EU in order to export their products.

Canada also takes a farm-to-table approach to food safety to safeguard not just the food supply but also the plants and animals upon which safe food depends. Products subject to inspection by the Canadian Food Inspection Agency range from agricultural inputs, such as seeds, feeds, and fertilizers; to fresh foods, including meat, fish, eggs, grains, dairy products, fruit and vegetables; and prepared and packaged foods. The government also works with commodity sectors to develop and review food safety plans. At the consumer end of the spectrum, the food safety agency educates Canadians about safe food-handling practices and various food safety risks through its Web site, food safety fact sheets, and the Canadian Partnership for Consumer Food Safety Education, a group of industry, consumer, and government organizations that jointly develop and implement a national program to educate consumers on how to safely handle food. Moreover, in December 2007, Canada’s Prime Minister announced the new Food and Consumer Product Safety Action Plan aimed at strengthening and modernizing Canada’s safety system for health, consumer, and food products. The plan responds to changes in trade, industry supply chains, and consumer buying patterns. Under the plan, the government will implement programs focused on prevention, targeting highest risks, and promoting rapid response. Among other things, the initiative will involve working with industries, provinces, and territories to implement preventive food safety control measures along the food chain.

Like the EU and Canada, Japan takes a farm-to-table approach (referred to there as a “food chain” approach) to food safety. According to the

Japanese Food Safety Commission, Japanese law stipulates that food safety be ensured at each stage of the food production process and apportions responsibility for food safety among the national government, the local governments, food operators, and consumers. (Consumers are responsible for improving their knowledge and understanding of food safety and expressing their opinions about policies to ensure food safety. One of the ways they can educate themselves about food safety is by paying close attention to food labels, and according to USDA's Foreign Agricultural Service, the Japanese government has recently introduced initiatives to strengthen food labeling requirements.) At the national level, the Ministry of Agriculture, Forestry, and Fisheries oversees primary production processes, including animal health and the use of agricultural chemicals, and the Ministry of Health, Labor, and Welfare oversees the processing and distribution stages. Moreover, with regard to imports, the ministry develops a monitoring plan each year for imports that prescribes measures for ensuring food safety in three stages: (1) in the exporting countries, (2) at entry into Japan, and (3) during internal distribution.

Producers in Most of the Selected Countries Are Responsible for Food Safety

The burden for ensuring food safety in most of the selected countries lies primarily with food producers, rather than with inspectors, although inspectors play an active role in overseeing compliance. This principle applies to both domestic and imported products. We were told that like the farm-to-table concept, producer accountability is a proactive approach that focuses on prevention.

According to EU sources, for example, food and feed operators have primary responsibility for food safety, while member states provide oversight over these operators at all stages of production. Business operators are responsible for the food and animal feed (such as cattle fodder or pet food) that they produce, transport, store, or sell. They must (1) be able to rapidly identify any supplier or consignee, (2) immediately inform the competent authorities if they have a reason to believe their food or feed is not safe, (3) immediately withdraw a product from the market if they have reason to believe the product is not safe, (4) apply HACCP principles in their processes and ensure that controls are applied at critical points,⁵ and (5) cooperate with the competent authorities in actions taken to reduce risk. The competent authority in each member

⁵Primary producers, that is, farmers, hunters, and fishermen, are not required to apply HACCP principles. However, guides to good practice encourage the use of appropriate hygiene practices at farm level.

Producer Responsibility: The Case of EU Feed Suppliers

Feed suppliers in the EU must apply HACCP principles, register with their national competent authorities to help ensure traceability, and comply with specific microbiological criteria, such as for levels of *Salmonella*, molds, and yeast. The competent authorities in each country approve certain feed operators (i.e., those manufacturing and/or selling certain feed additives) by visiting the facility before they start up any activity to ensure that the operators meet the requirements of the legislation, and once the operator is approved, the competent authority provides oversight and imposes penalties for noncompliance. The EU Food and Veterinary Office, in turn, inspects the competent authorities' oversight and provides recommendations when there are shortcomings. It also inspects countries aspiring to join the EU, and non-EU countries intending to export to the EU, to verify the effectiveness of their national control systems to implement EU standards in the areas of food safety, animal health and welfare, and plant health. As for imported feed, importers must ensure that their feed meets EU standards.

state is responsible for monitoring producers to ensure that they are meeting these obligations. The EU Food and Veterinary Office then assesses the performance of the member states' competent authorities, countries aspiring to join the EU, and non-EU countries intending to export to the EU to verify the effectiveness of national control systems for enforcing EU requirements in the areas of food safety, animal health and welfare, and plant health.

In Japan, business operators who produce, import, sell, or conduct other business for fertilizers, agricultural chemicals, feed, feed additives, veterinary medicines, and other agricultural products bear primary responsibility for ensuring food safety when conducting their business activities. These operators are also responsible for providing accurate and appropriate information on their products and for cooperating with policies implemented by the national and local governments. The national government is responsible for formulating and implementing policies to ensure food safety. With regard to imports, the burden of compliance with Japanese food safety regulation lies with importers, but the Japanese government (specifically, the Ministry of Health, Labor, and Welfare) further ensures compliance through a high level of import monitoring. In 2006, for example, Japan reported that its inspectors examined 11 percent of declared products coming into its ports.

Some producers in selected countries have commented that placing responsibility on them is generally positive. One industry representative, for example, told us that, "farmers and producers can no longer hide behind meat inspectors." An industry representative from another country said that, because producers are concerned with protecting their name brands, greater accountability makes them proactive. A consumer representative from a third country echoed this view, stating that importers are bearing more responsibility for ensuring the safety of their food imports because they are aware of the damages— financial and image-related—that violations cause to their business.

Some Countries Separate Risk Assessment from Risk Management

To create independent safeguards, some of the selected countries created separate agencies for (1) risk assessment—scientific evaluation of all known and potential adverse health effects resulting from foodborne hazards—and (2) risk management—the process for weighing policy alternatives to accept or minimize assessed risks and to select appropriate responses. The EU, for example, created the European Food Safety Agency to conduct risk assessment, while Japan created the Food Safety Commission for this purpose. Germany created the Federal Institute for

Risk Assessment to assess risks and the Federal Office of Consumer Protection and Food Safety to lead food safety risk management. This office also coordinates food safety surveillance at the federal level. (The 16 individual German states are responsible for food safety legislation and oversight of food inspections performed by local governments.) Canada consolidated public health policy and standard-setting responsibilities, including research, risk assessment, and setting limits on the amount of a substance allowed in a food product, in one agency, Health Canada. Table 2 provides the names of the risk assessment and risk management bodies in each of the selected countries.

Table 2. Risk Assessment and Risk Management Bodies in Selected Countries

Country	Risk assessment body	Risk management body
Canada	Health Canada	Canadian Food Inspection Agency
EU	European Food Safety Agency	Risks are managed by individual EU member states
Germany	Federal Institute for Risk Assessment	The Federal Office of Consumer Protection and Food Safety (coordinating body) ^a
Ireland	Science Committee of the Food Safety Authority of Ireland ^b	Food Safety Authority of Ireland
Japan	Food Safety Commission ^c	Ministry of Health, Labor, and Welfare and Ministry of Agriculture, Forestry, and Fisheries
The Netherlands	National Institute for Public Health and the Environment ^d	Food and Consumer Product Safety Authority
The UK	Food Standards Agency ^e	Food Standards Agency

Sources: Canada, EU, Germany, Ireland, Japan, the Netherlands, and the UK.

Notes:

^aGermany's 16 federal states are responsible for overseeing compliance with the law, and as such, they are in charge of food and feed safety, animal health and welfare, and plant health. The Federal Office of Consumer Protection and Food Safety coordinates—but does not oversee—the activities of the federal states in these areas.

^bIn Ireland, a Scientific Committee was established in 2000 to aid the Food Safety Authority of Ireland in risk assessment. The committee is made up of scientists from a variety of disciplines whose work for the authority is voluntary.

^cIn 2003, Japan established the Food Safety Commission as a Cabinet-level agency responsible for conducting neutral, scientific risk assessments related to food safety, including the use of food additives, pesticide residues, and the presence of illness-causing bacteria, and other issues. The commission became a fully functioning, independent agency in 2005. Previously, the two ministries responsible for managing food safety—the Ministry of Health, Labor, and Welfare and the Ministry of Agriculture, Forestry, and Fisheries—conducted their own scientific risk assessments. While the Food Safety Commission now assesses risks, the two ministries are responsible for managing these risks.

^dThe Food and Consumer Product Safety Authority's Office of Risk Assessment commissions the National Institute for Public Health and the Environment to conduct risk assessments on its behalf.

^eThe Food Standards Agency also receives advice from 10 scientific committees that provide input, as needed, on various food-related risks.

Some countries have also separated their risk management agencies from those that promote industry in order to ensure independence. For example, Ireland and the UK, as part of their restructuring several years ago, took risk management away from their ministries of agriculture, which consumers perceived as favoring the food industry over consumer protection. Similarly, prior to Japan's 2003 food safety system restructuring, the Food Agency within the Ministry of Agriculture, Forestry, and Fisheries, which was responsible for food safety, was managed in collaboration with industrial promotion bureaus within the ministry; the Food Agency was abolished when the Food Safety Commission was created.

Inspections of Imports Are Based on Risk, and in the EU and Japan, Importers Bear Some Costs

The selected countries base their inspections of imports on the degree of risk presented by particular food types, and the EU and Japan require that importers bear the cost of disposing of or reinspecting noncompliant food products. Live animals and animal products, such as meat, milk, and fish, are among those that present the highest level of risks because they can transmit serious human and animal diseases. In addition, certain plant products, such as nuts, wheat, corn, beans, rice, and certain spices can present high levels of risks because they may be contaminated by aflatoxins—toxins produced by mold that can damage the liver and may lead to liver cancer. Fruits and vegetables may also be considered high risk if they contain unacceptably high levels of pesticide residues. Risk may also be considered high if a product is traded in large quantities or if a product or the area it comes from is known to be susceptible to particular plant or animal diseases.

According to the EU, it has shifted its focus from regular, but random, sampling to paying attention to the sources of greatest risk. If the risk of a given food product is not known or quantified, the EU applies what it refers to as the “precautionary principle.” If there are reasonable grounds for suspecting a problem, the commission acts to limit the risk. The EU asserts that it does not necessarily need to wait for proof that there really is a risk.

The EU requires that all imports of live animals and products of animal origin enter the EU only through certain border inspection posts—airports, rail stations, and deepwater ports—of which there are about 300. The posts, which are under the authority of each member state's official veterinary services, must be notified in advance of the presentation of

such consignments; these consignments must undergo an official veterinary check at the post. A member state's customs service cannot release consignments unless they have passed through veterinary controls. When a consignment arrives at a border inspection post accompanied by the correct health certification, three types of checks will be carried out:

- Documentary—for all consignments, inspectors review the accompanying documents.
- Identity—for all consignments, inspectors verify that the identity of the goods corresponds fully with the veterinary documents supplied.
- Physical—for a percentage of consignments, depending on the type of animal product and the country of origin, inspectors physically inspect the consignments to ensure they do not pose a threat to public and animal health. According to EU officials, EU legislation also specifies a minimum number of physical checks to be carried out per product group (e.g., meat, fish, or dairy) by each member state. A physical inspection may also involve taking samples for laboratory tests.

When all tests and checks are satisfactory, the consignment is issued a Common Veterinary Entry Document and is placed on the EU market.

If a consignment does not comply with EU requirements, it may be rejected. In these cases, EU officials negotiate with the owner of the consignment and the country of dispatch, where appropriate, about whether to destroy the product, to retreat it for uses other than the human food chain, or to return it. Food or feed business operators or their representatives are responsible for the consignment and are liable for any costs incurred by the competent authorities to destroy or redispach it.

When consignments are not in compliance, all other border inspection posts are notified through the EU's Rapid Alert System for Food and Feed (rapid alert system), an electronic notification system managed by DG-SANCO in Brussels. The system alerts all EU member countries of a potential food problem, including either a direct or an indirect risk to human health from food or feed. The rapid alert network involves all member states, the European Community, and the European Food Safety Authority, as well as the non-EU countries of Iceland, Liechtenstein, and Norway. Each participating country has a rapid alert system contact point to collect information on national notifications and enter them into the database. The exchange of information allows participating states to immediately ascertain whether they are also affected by a problem and

take appropriate measures. Since all EU border posts are connected electronically, problems at any one border can quickly be announced to all other border posts via the rapid alert system. Future imports from the same exporting country are then scrutinized more closely.

The EU also maintains a list of food products of nonanimal origin that may represent a human health risk. Cereals and nuts, for example, may appear on the high risk list. Such products undergo control measures, such as health certificates and testing, similar to those required for food products of animal origin. For example, all consignments of pistachios from Iran are sampled and checked. The safeguard measures are lifted once the problem has been addressed.

Food products of nonanimal origin—including fruits, vegetables, cereals, tubers, nondairy drinks, food of mineral origin (such as salt), spices, and condiments—represent less of a risk and as such, do not need to come from approved countries or establishments. These products can come into any EU port of entry. However, they are still subject to certain EU requirements in order to verify that they comply with EU food standards. Among other things, food business operators in non-EU countries must monitor the safety of products and processes under their responsibility, follow general hygiene provisions for primary production, develop HACCP principles, and register establishments with the appropriate competent authorities. The EU member states' competent authorities are responsible for carrying out regular controls of goods imported into EU territory.

The EU requires that member states ensure that adequate financial resources are available for organizing official controls on imports. Member states may therefore collect fees to cover costs occasioned by these controls. However, they must collect fees for certain activities, including controls for products of animal origin, such as meat inspection, and controls of dairy establishments. Fees are also levied for certain import controls on these commodities. EU officials stated that the fees may not be higher than the costs borne by the competent authorities.

Japan takes a similarly risk-based approach to inspections. Each year, the Ministry of Health, Labor, and Welfare produces an imported foods monitoring and guidance plan that, among other things, spells out the quantity and category of inspections to be conducted each year. In fiscal year 2007, for example, the goal was approximately 79,000 random inspections for 124 food groups. If an imported food belongs to a food group that is known to be at an increased risk for contamination from a

pathogen, pesticide residue, or animal drug, the ministry issues an order requiring that products with a high violation probability are inspected every time they are imported (lot by lot). According to the imported foods monitoring and guidance plan, moreover, if the number of imported foods from a specific country, area, or business entity violating the law is above 5 percent of the overall number of foods inspected, and if it is likely that the importation of violating goods will continue, given conditions in the exporting country, the ministry may ban the importation of such goods altogether.

While there is no cost to importers for random inspections at Japanese quarantine stations, if products are required to undergo more intensive inspections as a result of past problems, the importer pays for additional inspections. Japan also imposes financial penalties for importers found to be in noncompliance. According to an expert on the Japanese import system, many Japanese importers therefore require testing certificates from exporters to reduce the potential for violation. In situations where import violations are severe, the Ministry of Health, Labor, and Welfare lists the names of violators on its Web site, which is updated every few weeks.

The Selected Countries Take Steps to Ensure Certain Food Imports Meet Equivalent Safety Standards

The selected countries take steps to ensure that certain food imports meet equivalent safety standards. In the EU, for example, food products of animal origin imported from non-EU countries must meet standards at least equivalent to those of the EU for food quality and hygiene. If such foods are found not to be as safe as those of the EU and do not meet the requirements of EU hygiene regulations, the overseas firm is not allowed to export to the EU. The EU maintains a list of non-EU countries for which it has recognized the capacity of the competent authorities, as well as its animal and public health system but does not maintain such a list for food of nonanimal origin. Among the requirements for approving the export of products of animal origin are the following:

- a country's formal submission of a written application to export to the EU;
- the EU's verification of the exporting country's animal and public health system, such as legislation, control systems, disease surveillance measures, and laboratory facilities;

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- the country's submission and approval of a monitoring plan for residues of banned or restricted substances in the EU, including veterinary medicines and growth-promoting hormones; and
 - the country's provision of sanitary certification that the products to be exported to the EU meet import requirements.

Inspectors from the EU's Food and Veterinary Office normally visit non-EU countries to verify compliance with these conditions. If compliance is satisfactory, the EU may approve countries and establishments for export to the EU. In addition, non-EU countries must certify and approve business establishments wishing to export to the EU, noting that they meet the relevant EU requirements. The EU maintains lists of these establishments online for all the major categories of animal products (e.g., beef, dairy, fish, or poultry), and compliance is verified during follow-up inspections.

In Canada, the Canadian Food Inspection Agency requires importers of meat and seafood products to meet Canadian standards. Determination of a foreign country's equivalency is based on the approval of a country's system of meat inspection, approval of establishments operating within that system, and review and registration of individual meat products prepared in these establishments. To approve the exporting country's inspection and certification system, the Canadian Food Inspection Agency follows a process of equivalency evaluation, based upon provisions in the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization. The agreement requires each member to accept as equivalent sanitary and phytosanitary measures of another member if the exporting member objectively demonstrates to the importing member that its measures achieve the importing member's appropriate level of protection.

Canada's Foreign Country Meat Inspection Systems Evaluation Program requires that imported meat products—unless specifically exempted by Canadian legislation—meet the same standards and requirements as if they were produced in registered establishments in Canada. It also requires that the exporting country's inspection and certification systems, along with the establishments operating under those systems, be approved by the Canadian Food Inspection Agency before meat products can be exported to Canada. The competent authority of the exporting country must issue an official meat inspection certificate for every shipment of meat products exported to Canada. The competent authority is also expected to take appropriate actions if the Canadian Food Inspection

Agency notifies it about meat products found to violate Canadian requirements and is to communicate any actions to the agency. The Canadian Food Inspection Agency may require additional examination of subsequent shipments to Canada, with additional certification, for a predetermined number of shipments and/or weight of the certified shipment. The majority of the agency's inspectors are focused on meat products because of the higher risk relative to most other foods. Canada currently allows importation of meat products from 40 countries.

In the case of seafood, Canada enters into agreements with other countries it believes have reliable inspection systems and uses these agreements in concentrating its inspection resources on products and countries representing increased risk. Under some agreements, the Canadian Food Inspection Agency agrees that products from specified processing facilities meet certain standards and therefore are subject to fewer inspections at the border. The agency normally assesses these plants before it adds them to a list. Other agreements represent recognition by the agency that the inspection system in another country is equivalent to the system in Canada. Under these agreements, the competent authority in the other country will inspect and maintain the list of establishments eligible for reduced inspection frequency upon export to Canada.

Canada has an equivalency agreement in place with the EU for meat products and is working toward bringing an equivalency agreement for fishery products into force. The Canada-EU Veterinary Agreement allows equivalency determination according to criteria set out in the agreement that specify gradual levels of equivalency. These levels allow work toward equivalency in products to be tracked over time. The agreement is aimed at recognizing the equivalence of Canadian and EU inspection and certification requirements for trade between the EU and Canada in live animals and animal products.

Japan also requires importers to meet its food safety standards. For example, officials from the Japanese Ministry of Health, Labor, and Welfare or the Ministry of Agriculture, Forestry, and Fisheries engage in bilateral talks with their counterparts in the exporting country to explain Japanese food safety regulations. If a country has no prior record of exporting food to Japan, ministry officials may conduct field surveys to determine whether a country's food safety system can comply with Japanese food sanitary regulations and whether the exporting country's food safety regulations are comparable with Japan's. If Japan has already approved an exporting country and a new facility in that country seeks to export, ministry officials may conduct a pre-export inspection of that

facility; if the review is satisfactory, the ministry will issue a certificate to the exporter, copies of which must accompany every shipment of goods to Japan.

Japan also has arrangements with some governments to certify exports of certain high-risk products. According to Japanese officials, under a Japanese-Chinese agreement, for example, the Chinese government certifies Chinese spinach processors, who in turn oversee the practices of local farmers and test the product at three stages of production. Chinese authorities then conduct preshipment tests on the spinach before exporting, confirming that the exporter has observed the proper procedures on pesticide management. The spinach may be inspected again once it arrives in a Japanese port.

Selected Countries and the EU Cite Key Elements of Food Systems as Critical to Effectively Responding to Outbreaks of Foodborne Illness

The selected countries reported that three elements of their food safety systems are critical in helping them respond to outbreaks of foodborne illness. These elements include traceback procedures, cooperative arrangements between government veterinarians and public health officials, and mandatory recall authority. Officials in most of the selected countries told us that with respect to public health, their procedures for tracking the source of foodborne illness outbreaks are generally similar to U.S. procedures.

In general, the selected countries follow the same key steps in addressing outbreaks of foodborne illnesses. These steps include the following;

- *Identification of the outbreak.* In most of the selected countries, this is the responsibility of local medical practitioners, who, after treating victims, also notify the national authorities when there is a suspected outbreak of foodborne illness. The first tests are often conducted at local laboratories. In cases where more sophisticated testing is needed to identify the pathogen and its source, the local laboratories send samples to specialized laboratories—called reference laboratories—that can conduct

more sophisticated tests.⁶ Usually, the national public health monitoring institutes also collect data and confirm the number of illnesses in the outbreak.

- *Coordinated action to manage the outbreak.* In most of the selected countries, local public health authorities manage the outbreak as long as it is confined to a local region. However, if the outbreak crosses provincial or state borders or if the outbreak is very large, the national surveillance institute or health ministry may take over control activities.

The most common foodborne illnesses in the selected countries, listed in alphabetical order, are *Campylobacter*, *E. coli*, *Listeria*, norovirus, and *Salmonella*. (Noroviruses are a highly contagious virus transmitted by consumption of contaminated food or water or by direct person-to-person contact).

EU Requirement That All Foods Be Traceable May Accelerate the Identification of an Outbreak Source

All food must be traceable “one step forward and one step back” in EU member states, allowing industry and national governments to quickly track any questionable food products to minimize harm to public health and reduce the economic impact on industry. Food and feed business operators must be able to document where a particular food product came from and where it is going next. Specifically, they must be able to document the names and addresses of suppliers and customers, as well as the nature of the product and date of delivery. They are also encouraged to keep information on the volume and quantity of a product; the batch number, if one exists; and a more detailed description of the product, such as whether it is raw or processed. Food and feed business operators must also have systems and procedures that allow them to provide this information to the competent authorities on demand. (As described in EU guidance, exporters in trading partner countries are not legally required to fulfill the EU’s traceability requirement, except in circumstances where there are special bilateral agreements for certain sensitive sectors or where there are specific EU requirements, such as in the veterinary sector.

⁶Reference laboratories are specialized laboratories that assist in surveillance for, and investigation of, foodborne illness outbreaks. They use standardized equipment and methods to analyze samples isolated from humans, animals, and suspected foods. These laboratories generally have expertise in specialized areas in which there is a need for precise analytical methods and definitive diagnostic results. For example, a reference laboratory may conduct DNA “fingerprinting” of a pathogen such as *Salmonella* or *E. coli* to identify the precise strain of the pathogen. Networks of reference laboratories allow public and animal health scientists to identify patterns and determine whether a foodborne outbreak is occurring even if the affected persons are geographically far apart.

Tracing Dioxin in Milk in the EU

According to EU sources, the EU's traceability system proved useful during an incident that took place in 2004. During standard random monitoring of dioxin levels in milk at a Dutch farm, the national competent authorities found a high level of dioxin. The EU sources noted that the competent authorities immediately barred the farm from trade and began tracing the product through the food chain. They found that the source of contamination was clay, used in food processing to separate higher-quality potatoes from lower-quality ones. The dioxin-tainted clay had contaminated potato peels used for feeding animals. The EU's electronic Rapid Alert System for Food and Feed was used to trigger an exchange of information among national authorities about the problem. EU sources stated that the authorities quickly established that the clay had also been supplied to several food-processing companies located in Belgium, France, Germany, and the Netherlands. The authorities rapidly identified these businesses and barred from trade over 200 farms that had received the potentially contaminated potato peels. According to the EU, because of the traceability system, the contaminated products never reached consumers.

However, these traceability requirements pertain to EU importers, who should be able to identify their direct supplier in the non-EU country.)

Canada, Japan, and the EU also have mandatory animal identification programs for certain livestock species. In the EU, for example, in addition to farm registration obligations, producers must tag livestock with details of their origin, and when the animals are taken for slaughter, stamp them with the traceability code of the slaughterhouse. The tools used (ear tags, "passports," or bar codes) may vary from country to country but must carry the same information. In addition, to ensure the traceability of animals across borders, the EU established the Trade Control and Expert System, a central database for tracking the movement of animals both within the EU and from non-EU countries. In the event of a disease outbreak, the database ensures that all potentially affected animals can be quickly identified and that authorities can take appropriate measures.⁷

Although Canada does not have mandatory traceability for food, it does have mandatory cattle identification, which it is expanding to include all livestock. Beginning on January 1, 2001, Canadian farmers were required to tag all cattle with a bar-coded ear tag before the cattle left their farm of origin. The Canadian Food Inspection Agency began to fully enforce the program in 2002, with monetary penalties for noncompliance. In 2006, Canada initiated the transition to Radio-Frequency Identification (also known as RFID) tags on all cattle leaving their herds of origin. This tagging system is designed to facilitate the tracing of movement and identification of animals at various stages of the animal production chain, thereby helping to contain and eradicate animal disease.

Japan has a mandatory system in which all beef and dairy cattle must be identified using an ear tag. Information is maintained on an animal's identification number, breed, gender, and production history from the farm of origin through distribution to consumers.

⁷For information on the U.S. animal identification system, see GAO, *National Animal Identification System: USDA Needs to Resolve Several Key Implementation Issues to Achieve Rapid and Effective Disease Traceback*, [GAO-07-592](#) (Washington, D.C.: July 6, 2007).

Government Veterinarians and Public Health Officials in Some Countries Cooperate Closely to Trace the Source of Animal-to-Human Diseases

In light of concerns about highly pathogenic avian influenza and BSE, and in recognition of the connection between animal and human diseases, cooperation between public health officials and veterinarians has been critical in tracking the source of zoonotic (animal-to-human) diseases in some countries. For example, according to UK officials, the Veterinary Laboratories Agency, a regional network of 16 laboratories under the Department for Environment, Food, and Rural Affairs is responsible for veterinary research, disease surveillance, and diagnostic service. It has several memorandums of understanding with the Health Protection Agency—the UK agency that monitors outbreaks of infectious diseases—to conduct research. According to Health Protection Agency officials, the staff of these two agencies meets approximately once a month. In addition, staff from these agencies and the Food Standards Agency meets regularly to review trends in human and animal health. In particular, the Veterinary Laboratories Agency can assist in cases where a direct or indirect animal source is suspected in outbreaks of zoonotic diseases and where veterinary investigation or intervention could help reduce risks to the public. The agency may (1) conduct animal sampling for laboratory cultures, (2) help in identifying management and animal care factors that may have a bearing on human health risks, and (3) provide veterinary epidemiological input, such as data reports of *Salmonella* strains from farm animal surveillance. Strains of animal origin can also be selected for further identification and comparison with human strains.

According to UK officials, the UK's Health Protection Agency and the Veterinary Laboratories Agency work closely in the investigation of outbreaks of food poisoning related to food production animals and have in place standardized laboratory and epidemiological methods for disease strain characterization and outbreak investigation. In addition, the Health Protection Agency, the Veterinary Laboratories Agency, and another body, the Centre for Infections (a large research institute) support a joint position to further standardize laboratory methods and harmonize databases.

Health Protection Agency officials told us that communication between public health and veterinary officials has been useful during various outbreaks in the UK. For example, during the investigation of a 2004 outbreak of an antibiotic-resistant strain of *Salmonella* among cattle on an English farm, rapid communication of test results and epidemiological information between the Health Protection Agency and the Veterinary Laboratories Agency led to the containment of the outbreak before it could spread to humans. Officials from the Health Protection Agency likewise said that there are numerous examples of similar collaborative

activities between the Health Protection Agency and the Veterinary Laboratories Agency involving both *Salmonella* and a form of *E. coli* known as Verocytotoxin-producing *E. coli*. They also said that the agencies exchange strain typing and epidemiological data on an almost daily basis. They stated that the centralized nature of the UK government facilitates this close cooperation.

Similarly, in the Netherlands and Ireland, officials told us that public health officials and veterinarians cooperate closely. In the Netherlands, for example, the Dutch National Institute for Public Health, a government research institute that conducts research projects on public health issues, among other things, collaborates closely with the Dutch Central Veterinary Institute on issues related to zoonotic diseases and animal food products. In Ireland, veterinarians participate in a national zoonoses committee made up of medical experts, public health officials, regional veterinarians, and environmental officers that convenes in the event of a foodborne illness outbreak. Irish officials told us that during an outbreak of *Salmonella* Agona in Ireland in 2006, collaboration between the veterinary and medical doctors made it easier to trace the pathogen to its source, which was poultry. Moreover, the Irish Department of Agriculture, Fisheries, and Food operates the Central Veterinary Research Laboratory, which is the national reference laboratory for *Salmonella*. The laboratory also carries out typing (identification) of *Salmonella* samples.

All of the Selected Countries Have Mandatory Recall Authority

All of the selected countries have mandatory recall authority—the legal authority to remove, or require another party to remove, a product from the market. This authority enables them to force food producers to take a product off the market if there is a problem with it, such as microbial contamination, or the presence of allergens or non-permitted ingredients.⁸

The EU distinguishes between withdrawals and recalls and has authority for both. Withdrawals occur when the product is still under the control of the producer, and measures are intended to prevent the distribution or display of a dangerous product. Recalls occur when the product is already available to consumers, and measures are intended to have the unsafe

⁸For information on recall authority in the United States, see GAO, *Federal Oversight of Food Safety: High-Risk Designation Can Bring Needed Attention to Limitations in the Government's Food Recall Programs*, [GAO-07-785T](#) (Washington, D.C.: Apr. 24, 2007) and GAO, *Food Safety: USDA and FDA Need to Better Ensure Prompt and Complete Recalls of Potentially Unsafe Food*, [GAO-05-51](#) (Washington, D.C.: Oct. 6, 2004).

product returned. All member states must notify the EU when there is a serious risk to human health.

According to Irish and UK sources, one of the largest mandatory food recalls in the EU took place in February 2005, when the UK's Food Standards Agency discovered that a UK company had used spice contaminated with Sudan Red 1 dye in a variety of processed foods. Sudan Red 1 is an industrial dye used for coloring solvents, oils, waxes, and shoe and floor polishes. It entered EU countries in ground or crushed chili imported from India. Responding to the UK's rapid alert system notifications, other EU countries also recalled products contaminated with the dye.

The Canadian Food Inspection Agency also has mandatory recall authority for unsafe food products, but, according to an agency official, it has only used this authority a total of seven times. Although rarely used, this authority is effective "because it is there," according to a Canadian Food Inspection Agency official, who also said that recall authority has contributed to more effective industry cooperation. According to Canadian officials, one of the most significant outbreaks of foodborne illness in Canada occurred in December 2004, when *Salmonella* linked to mung bean sprouts from a single company sickened 300 people in Ontario. The Canadian Food Inspection Agency made preparations for a mandatory order to be issued because the company was not conducting a "proper" recall on its own. In the end, however, the company agreed to conduct a "proper" voluntary recall.

The Japanese government has mandatory recall authority, but according to Japanese officials, it has rarely used this authority. Typically, the local health centers run by the Ministry of Health, Labor, and Welfare that test food suspected to be the source of an outbreak will "suggest" to a company that it recall its tainted product. According to a Japanese official, if the government communicates in this way to a company, the company feels obliged to recall its products.

The Selected Countries Have Not Evaluated Their Reorganized Food Safety Systems, but Proxy Measures Indicate Improvements

None of the countries we reviewed had comprehensively evaluated the effectiveness of its reorganized food safety system, but most of the selected countries track certain indicators, such as the number of inspections conducted, enforcement actions taken, and foodborne illness outbreaks. Most of these countries had also assessed specific aspects of the country's food safety system. Furthermore, most of these countries use proxy measures, such as public opinion surveys, to assess effectiveness. In addition, industry stakeholders we interviewed cited the benefits of the reorganized food safety system.

None of the Selected Countries Has Comprehensively Evaluated the Effectiveness of Its Reorganized Food Safety System, but They Do Track Certain Indicators

None of the selected countries has comprehensively evaluated the effectiveness of its reorganized food safety systems. One food safety expert noted that it is difficult to determine the effectiveness of a food safety system because it involves proving that something did not happen, i.e., that exporters did not try to ship unsafe food to a country, a shipment of unsafe food did not get past inspectors, and consumers did not eat or drink unsafe food that entered the national food distribution system. An agency official also said that it is difficult to find quantitative data to measure change and performance. In addition, another official said that when the number of foodborne illnesses changes from year to year, it is difficult to know with certainty the cause of the change.

The food safety agencies in the countries we visited track key indicators, such as the number of inspections they conducted and the number of enforcement actions taken. Activities tracked by the Netherlands, for example, include the number of inspections conducted, the number of samples inspected, the number of approvals issued in the livestock and meat sector, international notifications of potential risk, and the number of written warnings issued. The EU also tracks the number of notifications and recalls member states issue under the EU's rapid alert system. Canada likewise tracks recalls. The public health or surveillance institutes of the selected countries monitor the number of foodborne illness outbreaks each year.

Most of the Selected Countries Formally Audit Certain Aspects of Their Food Safety Systems

Although none of the selected countries had comprehensively evaluated the effectiveness of its reorganized food safety system, some of the selected countries had assessed certain aspects of it. For example, Canada's Office of the Auditor General, GAO's Canadian counterpart, has conducted four reviews of certain Canadian Food Inspection Agency activities, including (1) a 2004 study on regulation of plants developed using biotechnology, (2) a 2000 report on the agency's Food Inspection Program, (3) a 1999 report on the agency's management of a particular foodborne illness outbreak, and (4) a 1998 report on the agency's creation. In March 2008, the Auditor General also reviewed selected Health Canada activities, including progress made by Health Canada's Pest Management Regulatory Agency in applying its procedures for evaluating and registering new pesticides and reevaluating older, registered pesticides; it also reviewed the amount of time it takes to get new, possibly safer pesticides to market. (This assessment also evaluated the Canadian Food Inspection Agency's progress in increasing the scope of its program that tests for residues in fresh fruits and vegetables.) The Auditor General found that since an audit conducted in 2003, the national government had made satisfactory progress in selected aspects of managing the safety and accessibility of pesticides, and it had shortened the time it takes to evaluate new pesticides. The Auditor General also reviewed Health Canada's progress in conducting national health surveillance in 2002. It found that Health Canada had made some progress toward resolving some of the weaknesses the auditors identified in a 1999 audit. However, it also found that national surveillance was still weak; many systems still lacked timely, accurate, and complete disease information; and gaps in surveillance continued.

Health Canada is responsible for assessing the Canadian Food Inspection Agency's activities and has completed 10 assessment reports, 9 of which have been published online. The most recent assessments found that the agency was fulfilling its mission, although minor improvements are needed. For example, in 2005, Health Canada reviewed the agency's Fish, Seafood and Production Program's Quality Management Program, a mandatory inspection program for federally registered fish and seafood establishments. The evaluation found that the program was generally effective in enhancing the safety of fish and seafood products. However, Health Canada recommended, among other things, that Canadian Food Inspection Agency managers responsible for the program should conduct trend analysis of complaints and incident data, an action that would enhance the management of emergencies and incidents. The agency agreed with the recommendation.

In the UK, the National Audit Office (GAO's UK counterpart) conducted an audit of the Food Standards Agency in 2003 and found that the agency had made progress in its stated objective of improving public confidence in food safety and standards. For example, according to the audit office, in 2001 and 2002 the Food Standards Agency investigated about 500 incidents with the potential to affect food safety. The agency issued 47 food hazard warnings to local authorities, alerting them to potential health dangers or requiring them to recall food from sale. More recently, the National Audit Office reviewed the agency's interaction with business and rated it highly on adopting innovative alternatives to classic regulation and on having an evidence-based culture. The auditors found that the Food Standards Agency was undertaking many positive initiatives in its risk assessment system. Areas needing further attention included developing a more strategic partnership with local authorities and providing better advice and guidance to small businesses. Overall, the auditors found that the agency was continuing to improve its performance from an already strong base.

Certain agencies within some countries have also conducted self-assessments. For example, the Canadian Food Inspection Agency has assessed its own performance using criteria developed in collaboration with the Canadian Treasury Board and measuring progress on four strategic outcomes: (1) protecting Canadians from preventable health risks related to food safety or the transmission of animal diseases to humans; (2) protecting consumers through a fair and effective food, animal, and plant regulatory regime; (3) sustaining the plant and animal resource base; and (4) securing Canada's food supply and agricultural resource base from deliberate threats. For each strategic outcome, the agency identified a number of specific targets. According to the agency's 2007 annual performance plan, the agency met or exceeded 31 of its 40 targets. In the UK, the Food Standards Agency conducted an internal review of lessons learned from the 2005 Sudan 1 incident, in which illegal dye was found in food, and the agency's board subsequently conducted a separate review of the incident. The board noted that the agency should take a central role in ensuring more coordinated attention to intelligence gathering and implementing early warning systems, as well as proactively sharing this information with the food industry.

In the EU, the Food and Veterinary Office develops an annual audit plan every year that identifies priority areas and countries it will audit that year. For example, in 2008, the office stated that it intended to conduct 256 audits and inspections, including 65 general audits in six member states. (General audits verify the extent to which countries comply with the multiyear control plans they have prepared.) As part of their audits, the

Food and Veterinary Office inspectors may visit producers or processing plants to establish that enforcement mechanisms are effective in practice. If necessary, the Food and Veterinary Office can send out inspectors in response to disease outbreaks both within and outside the EU.

During an audit, the Food and Veterinary Office assesses a member state's compliance with EU requirements for certain aspects of the member state's food safety system. For example, in its June 2005 assessment of Germany's import control system and four operating border inspection posts, the office found that import controls were generally applied correctly in the posts visited, with only minor shortcomings. However, the office also found that (1) supervision of imports that do not comply with EU regulations was inadequate, (2) traceability was not reliable, (3) exit of these noncompliant products from the EU was not ensured, and (4) some of the border inspection facilities had significant deficiencies. If the Food and Veterinary Office finds any shortcomings during its inspection, it makes recommendations to, and requires an action plan from, the member's competent authority for addressing the shortcomings. Together with other EU bodies, the Food and Veterinary Office evaluates this action plan and monitors its implementation and could take legal action to ensure that member states meet their obligations. In response to the Food and Veterinary Office audit of its border inspection posts, for example, Germany said that it had already taken some steps to address the shortcomings identified and would work to address the others.

Most of the Selected Countries Use Proxy Measures to Assess Their Systems, and Stakeholders Generally See Benefits of Reorganization

Among the proxy measures in the selected countries were consumer surveys. Several of the countries, including Canada, Japan, the Netherlands, and the UK, have surveyed their consumers on their views of the food safety system. This emphasis on public confidence in the food safety system comes in the wake of concerns about food agencies' ability to respond to outbreaks of BSE and other potential food contamination problems. For example, in 2003, the UK's Food Standards Agency noted that its effectiveness depended in part on the extent to which the public trusts it to provide reliable and impartial advice—trust that it earns principally by identifying and responding to food safety concerns. Indeed, public confidence in the UK's system for food safety and standards was the agency's first aim, followed by reducing foodborne illness and protecting consumers through improved food safety standards. In 2007, the public's confidence in the agency's ability to protect against foodborne illnesses was an estimated 60 percent, compared with about 44 percent in 2001.

Similarly, in 2005, the EU surveyed consumers to understand how they view risk, particularly food safety risks, in order to inform policy and communicate with the public on risk issues.⁹ It found that the public in all 25 EU member states was divided on whether food safety had improved in the past 10 years, with an estimated 38 percent believing it had, 29 percent believing it had stayed about the same, and 28 percent believing it had gotten worse. In some countries, however, views were more favorable. For example, the EU reported that an estimated 67 percent of people in Ireland believed that, overall, food safety had improved over the past 10 years.

Surveys can also be used to understand where the food safety system needs to be improved. For example, according to an official with Japan's Food Safety Commission, part of the commission's risk communication strategy is to survey consumers in order to find out how effectively the government communicates risk—how clearly, accurately, and convincingly. From these surveys, the commission learned that the public generally does not understand the concept of assessing risk. Consequently, one of the commission's current goals is to better communicate its role to the public and in general improve the clarity of its risk communications.

Germany has taken another approach to gauging public opinion. According to officials with the Federal Office of Consumer Protection and Food Safety, this agency convened stakeholders in November 2007 to discuss the effectiveness the Federal Office of Consumer Protection and Food Safety and the German food safety system in general. About 80 people from federal and state governments and trade associations attended. Comments on the agency's performance were generally positive. In particular, participants approved of the efforts of the national contact point for the EU's rapid alert system. However, they suggested some improvements in the system, and also suggested that the agency provide training to help prepare for Food and Veterinary Office audits. Participants also liked the *Journal of Consumer Protection and Food Safety* that the agency launched in 2006 to provide information, in both German and English, on basic and applied research and on official oversight of current developments in the areas of food and feed, veterinary

⁹This information comes from the EU's Eurobarometer—a series of surveys regularly performed on behalf of the European Commission since 1973. Eurobarometer produces reports of public opinion across the member states on a variety of EU-related topics, including social conditions, health, culture, and environment.

medicine, and genetic technology. Participants suggested that the agency establish a greater presence at conferences, fairs, and schools and that it be more visible to consumers as a partner.

The views of stakeholders, such as industry organizations and consumer advocacy groups, can also provide insight, albeit anecdotal, on the success of a country's food safety system. We spoke with representatives of stakeholder groups in each of the countries we visited and were told that, in most of the selected countries, the reorganization of the food safety system has been beneficial. In particular, stakeholders said reorganization has improved transparency. For example, one industry stakeholder in Canada said that consolidation greatly sped up the government's decision-making process and provided increased transparency, clarity, and accountability. In Japan, representatives of two consumer groups told us that the creation of the Food Safety Commission as an independent body responsible for risk assessments was a positive step, especially for increasing government transparency. A representative of an industry group in the UK also said that consolidation improved the functioning of the Food Standards Agency. This person believes the agency is now more transparent to industry, and it is easier to consult with agency staff on issues of concern.

Industry stakeholders told us that another benefit of reorganization was having a single point of contact. In the UK, for example, according to a representative of an industry group, the group provides its views to the Food Standards Agency through one-on-one or committee meetings, and has seen changes as a result of these contacts. Because of industry concerns about the way the Food Standards Agency managed a product recall, the agency agreed to notify industry before publishing a mandatory recall and changed preparation instructions for this product. Similarly, Canadian industry representatives told us that the reorganized and consolidated food safety system has had benefits. For example, representatives from two industry groups generally agreed that, with the consolidation, the Canadian Food Inspection Agency now has staff dedicated to food safety issues, a fact that has allowed a working relationship between industry and government to evolve. In addition, a representative from a third Canadian industry group told us that consolidation also helped strengthen the Canadian Food Inspection Agency's expertise and capability by combining staff from different agencies, although this representative was concerned about how the agency managed recalls.

Food Safety Officials in Other Countries Identified Issues of Future Concern

Experts in the six countries and the EU identified a number of challenges related to food safety that they expect to face over the next decade, with climate change the most frequently identified challenge. Table 3 summarizes the challenges identified.

Table 3: Emerging Food Safety Challenges Identified by Various Foreign Food Safety Officials

Challenges	Description
Climate change	Climate change may result in new pathogens, such as foodborne viruses, mycotoxins (molds), zoonoses, and changes in biodiversity that can lead to threats to the food chain. Climate change may enable pathogens to thrive and spread under new climatic conditions. For example, Listeriosis, especially in older people, seems to be increasing, perhaps because the climate is getting warmer, enabling <i>Listeria</i> to thrive. Climate change (warmer sea temperatures) may lead to outbreaks of the <i>Vibrio</i> bacterium in oysters. Climate change might also bring about changes in new pathogens as the temperature changes, along with crops and associated pests.
Demographic change	Countries are seeing increases in elderly populations, which tend to be more vulnerable than others to foodborne illness. Countries are seeing an increase in immigration; many immigrants bring home-prepared foods from overseas. If improperly prepared or preserved, these foods may cause illness.
Foodborne illness and zoonotic diseases	Foodborne illness from <i>Campylobacter</i> has increased significantly in the last several years, and it is one of the most frequent sources of food contamination. Scientists' understanding of <i>Campylobacter</i> is still limited because it generally occurs in isolated incidents and it is therefore more difficult to study. Incomplete knowledge of the nature and transmission of emerging zoonotic diseases (e.g., avian influenza and West Nile virus) is a growing concern, and inadequate veterinary care and public health infrastructure in some countries add to the complexity of managing these diseases. In addition, human and animal interactions are changing, with the potential for disease transmission, including <i>E. coli</i> and prions (which are involved in BSE). New fungi, pathogens, and diseases will continue to emerge and evolve.
New types of food and preparation	Popular new types of foods (e.g., ready-to-eat bagged salads) pose new risks. For example, a small amount of contaminated produce that is chopped and placed in multiple bags can affect a large number of people in disparate locations. More people are consuming foods that are raw or that do not involve a terminal kill step, such as cooking. Countries are seeing changes in production and processing based on new technologies, such as nanotechnology, genetic modification, and decontamination technologies (e.g., radiation).
Industry and trade development	The consolidation of the food industry, with fewer and fewer major corporations dominating entire food sectors, means that the potential impact of outbreaks and/or recalls is greater. The food supply is becoming increasingly global and the volume of international food trade is growing, which means it is increasingly difficult to control all elements of the food chain.

Challenges	Description
Regulatory and management issues	Assessing the risks of chemical and food additives, which are often imported as nonfood items, is a priority, and the number of contaminants is increasing.
	To focus more on risk, countries need to develop more data, which takes time and money.
	In spite of recent improvements in regulatory regimes, there is still potential for fraud in the system; it is difficult to develop a perfect system.
	Resources are sometimes mismatched with problems.
	The current regulatory system is not well suited at present to address certain new innovations, such as genetically modified organisms and nanotechnology.
	There are some differences between EU member countries in how they report information (e.g., zoonoses are reported by some countries as foodborne pathogens and by others as animal illnesses), which makes it difficult compare national statistics.
	Conducting risk assessments is getting more difficult.

Sources: Food safety officials in Canada, the EU, Germany, Ireland, Japan, the Netherlands, and the UK, and documents from these countries' food safety agencies.

As agreed with your offices, unless you publicly announce the contents earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees, the Secretaries of Agriculture and State, the Commissioner of the Food and Drug Administration, the Office of the U.S. Trade Representative, and other interested parties. We will also make copies available to others upon request. In addition, the report will be available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staffs have any questions about this report, please contact me at (202) 512-3841 or shamesl@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributors to this report are listed in appendix II.



Lisa Shames
Director, Natural Resources
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Appendix I: Country and EU Profiles

Canada's Food Safety System

Population and per capita gross domestic product (GDP). In 2007, Canada had an estimated population of 33.4 million, and in 2006 its estimated per capita GDP was US \$35,700.

Organization. The Canadian Food Inspection Agency (CFIA), created in 1997, is an independent agency that reports to the Minister of Agriculture and Agri-Food. It is responsible for inspection and quarantine programs for foods, plants, and animals. According to agency officials, Canada consolidated the food safety function in order to reduce overlap and duplication, improve effectiveness and efficiency, save money, and separate risk management from risk assessment.

Canada takes a “gate-to-plate” approach to food safety to safeguard not just the food supply but also the plants and animals upon which safe food depends. Products subject to CFIA’s inspection range from agricultural inputs, such as seeds, feeds, and fertilizers; to fresh foods, including meat, fish, eggs, grains, dairy products, fruit and vegetables; and prepared and packaged foods. The government also works with commodity sectors to develop and review food safety plans. CFIA is responsible for all food safety inspections, including inspections of imported and domestic products, export certifications, laboratory and diagnostic support, crisis management, and product recalls. It also inspects foods for quality assurance and is responsible for animal health and plant disease control. At the consumer end of the spectrum, CFIA educates Canadians about safe food-handling practices and various food safety risks through its Web site, food safety fact sheets, and the *Canadian Partnership for Consumer Food Safety Education*, a group of industry, consumer, and government organizations that jointly develop and implement a national program to educate consumers on how to safely handle food. CFIA employs over 6,000 people, including approximately 3,000 inspectors across all business lines. Approximately 10 percent of CFIA’s budget comes from user fees.

While CFIA is responsible for risk management, another government organization, Health Canada, under the Minister of Health, is responsible for risk assessment. Health Canada sets the policies and standards that govern the safety and nutritional quality of all food sold in Canada, and CFIA enforces these policies. Health Canada is also responsible for evaluating CFIA’s food program effectiveness. Another organization, the Public Health Agency of Canada, a separate body under the Minister of Health, also conducts national food- and waterborne disease surveillance activities and helps respond to infectious disease outbreaks.

CFIA verifies industry compliance with federal acts and regulations by registering and inspecting slaughterhouses and food-processing plants and testing products. If a food safety emergency occurs, CFIA works with Health Canada, the Public Health Agency of Canada, provincial agencies, and the food industry in implementing an emergency response system.

In 2005, CFIA's border inspection function was shifted to the Canadian Border Services Agency. This agency is responsible for initial inspections of food and agriculture products arriving in Canada. It refers any questionable shipments to CFIA for follow-up action. According to CFIA officials, border guards open and inspect about 2 percent of imports. A CFIA veterinarian inspects most imports of live animals upon entry.

According to Canadian officials, in December 2007, Canada's Prime Minister announced the new Food and Consumer Product Safety Action Plan, which aims to strengthen and modernize Canada's safety system for health, consumer, and food products and to protect the health of Canadians. The Action Plan responds to changes in trade, industry supply chains, and consumer buying patterns, which require a different approach to food safety assurance. Programs focused on prevention, targeting highest risks, rapid response, and regulatory and legislative modernization will be implemented with the (Canadian) \$113 million announced in Budget 2008. According to Canadian officials, proposed legislative amendments to Canada's Food and Drugs Act, along with a (Canadian) \$62.2 million investment from Budget 2008, will enable CFIA to undertake a series of food safety initiatives, including the following:

- working with industries, provinces, and territories to implement preventive food safety control measures along the food chain;
- putting in place tools to better identify importers, track imports, and work with foreign authorities to verify the safety of foods at their country of origin; and
- increasing authority to monitor risks to Canadians and prevent unsafe products from entering the Canadian marketplace.

Oversight of Imported Food

Certification programs and equivalency agreements. CFIA requires importers of meat and seafood products to meet Canadian standards. Determination of a foreign country's equivalency is based on the approval of a country's system of meat inspection, approval of establishments operating within that system, and review and registration of individual meat products prepared in these establishments. To approve the

exporting country's inspection and certification system, CFIA follows a process of equivalency evaluation, based upon provisions in the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization. The agreement requires each member to accept as equivalent sanitary and phytosanitary measures of another member if the exporting member objectively demonstrates to the importing member that its measures achieve the importing member's appropriate level of protection.

Canada's Foreign Country Meat Inspection Systems Evaluation Program requires that imported meat products—unless specifically exempted by Canadian legislation—meet the same standards and requirements as if they were produced in registered establishments in Canada. It also requires that the exporting country's inspection and certification systems, along with the establishments operating under that system, be approved by CFIA before meat products can be exported to Canada. The competent authority of the exporting country must issue an official meat inspection certificate for every shipment of meat products exported to Canada. The competent authority is also expected to take appropriate actions if CFIA notifies it about meat products found to violate Canadian requirements and is to communicate any actions taken to CFIA. CFIA may require additional examination of subsequent shipments to Canada, with additional certification, for a predetermined number of shipments and/or weight of the certified shipment. The majority of CFIA's inspectors are focused on meat products because of the higher risk relative to most other foods. Canada currently allows importation of meat products from 40 countries.

In the case of seafood, Canada enters into agreements with other countries it believes have reliable inspection systems and uses these agreements in concentrating its inspection resources on products and countries representing increased risk. Under some agreements, CFIA agrees that products from specified processing facilities meet certain standards and therefore are subject to fewer inspections at the border. CFIA normally assesses these plants before it adds them to a list. Other agreements represent recognition by CFIA that the inspection system in another country is equivalent to the system in Canada. Under these agreements, the competent authority in the other country will inspect and maintain the list of establishments eligible for reduced inspection frequency upon import to Canada.

Canada has an equivalency agreement in place with the European Union (EU) for meat products and is working toward bringing an equivalency

agreement for fishery products into force. The Canada-EU Veterinary Agreement allows equivalency determination according to criteria set out in the agreement that specify gradual levels of equivalency. These levels allow work toward equivalency in products to be tracked over time. The agreement is aimed at recognizing the equivalence of Canadian and EU inspection and certification requirements for trade between the EU and Canada in live animals and animal products.

Because of recent problems with Chinese and Vietnamese seafood imports, Canada has established more rigorous testing for specific seafood products from these countries. For example, from 2003 to 2005, Canada imposed a countrywide alert and instituted 100 percent testing of aquacultured fish products from Vietnam after repeatedly finding seafood products tainted with the antibiotic chloramphenicol, according to CFIA officials. The competent authority in Vietnam subsequently agreed to inspect and certify these products for the presence of certain antibiotics.

Foodborne Illness Outbreaks

According to data from the Public Health Agency of Canada, the most prevalent intestinal pathogen in Canada is *Campylobacter*, followed by *Salmonella* and parasitic infections (*Cryptosporidium*, *Cyclospora*, *Giardia*, and *Entamoeba*). *E. coli* ranks fourth in prevalence.

Response. If a foodborne illness outbreak occurs, CFIA, in partnership with Health Canada, provincial agencies, and the food industry, operates an emergency response system. This response system can be triggered by a consumer complaint, information from industry or trading partners, or the results of inspection and monitoring activities of CFIA or provincial food inspection agencies. In the event of an outbreak, CFIA investigates to pinpoint the source of the contamination. Health Canada gets involved in food safety emergencies when health risk assessments on food products are required, from either CFIA or the provinces or territories. The Public Health Agency of Canada gets involved in outbreak investigations when outbreaks involve more than one province or have international implications; if an outbreak involves only one province, the agency does not get involved unless its help is requested by the province.

Once a food is identified as a source, CFIA conducts the food safety investigation. On the basis of the results of the outbreak investigation and the food safety investigation, Health Canada (HC) conducts a health risk assessment for the implicated food and CFIA coordinates the risk management actions, one option of which might be to issue a recall. (For provincial outbreaks, the same process applies, except that the provincial health ministries have the lead in the outbreak investigation.) The Public

Health Agency serves as an adviser to CFIA and Health Canada in these situations. Health Canada provides risk assessments for all provincial emergency situations except for the province of Quebec. (For products produced and sold only in Quebec, the provincial authorities may conduct their own outbreak investigation and risk assessment and decide on recalls.)

Canadian officials told us that in many ways, their procedures for addressing the public health aspects of foodborne illness outbreaks are similar to those followed by the U.S. Centers for Disease Control and Prevention (CDC).

In 2006 and 2007, according to CFIA data, CFIA conducted 2,915 food safety investigations, of which 246 resulted in voluntary recalls. CFIA has mandatory recall authority for food, which it has used a total of seven times. Though infrequently used, according to a CFIA official, this authority has contributed to more effective industry cooperation. This official also said that mandatory recall is rarely used precisely “because it is there.” According to a Canadian industry representative, the mandatory food recall process is an important part of the food safety system because it is the last stop in the supply chain.

International coordination. CFIA has a memorandum of understanding with the U.S. Food and Drug Administration to cooperate on food recalls and exchange information. In addition, Canada participates in the CDC’s PulseNet, a network of public health and food regulatory agency laboratories.

Recent incidents. According to food safety officials, one of the most significant outbreaks of foodborne illness to occur in Canada was a 2004 outbreak of *Salmonella* in mung bean sprouts from a single company. Health Canada conducted the health risk assessment for this incident, and the Public Health Agency got involved at the request of the Ontario government. The outbreak affected 300 people in the province of Ontario. CFIA made preparations for a mandatory order to be issued because the company was not conducting a “proper” recall on its own. In the end, however, the company agreed to conduct a “proper” voluntary recall. CFIA put a hold on other products by the same company.

In 2006, moreover, Canada was affected by the same *E. coli* in spinach incident that occurred in the United States. One person in Canada was sickened by the tainted product. CFIA and Health Canada collaborated with the U.S. Food and Drug Administration (FDA) and the state of

California to assess and reduce the risk to Canadian consumers, and Health Canada assisted with tracing the product back to the source of contamination. U.S. spinach was recalled from Canadian store shelves, and Canada subsequently required U.S. spinach producers exporting to Canada to participate in an on-farm quality assurance program.

Although Canada does not have mandatory traceability for food, it does have mandatory cattle identification, which it is expanding to include all livestock. Beginning on January 1, 2001, Canadian cattle producers were required to tag all cattle with a bar-coded ear tag before the cattle left their farm of origin. The Canadian Food Inspection Agency began to fully enforce the program in 2002, with monetary penalties for noncompliance. In 2006, Canada began the transition to Radio-Frequency Identification (also known as RFID) tags on all cattle leaving their herds of origin. This tagging system is designed to facilitate the tracing of movement and identification of animals at various stages of the animal production chain, thereby helping to contain and eradicate animal disease.

Efforts to Measure
Effectiveness of the Food
Safety System

Performance measures. The Canadian government has not comprehensively evaluated the results of its 1997 reorganization. A CFIA official told us that it is difficult to find quantitative data to measure systemwide change and performance.

Evaluations and audits. Although there have been no comprehensive assessments of the Canadian food safety system, certain aspects have been formally reviewed. For example, Canada's Office of the Auditor General, GAO's Canadian counterpart, has conducted four reviews of certain CFIA activities, including (1) a 2004 study on regulation of plants developed using biotechnology, (2) a 2000 report on CFIA's Food Inspection Program, (3) a 1999 report on CFIA's management of a particular foodborne illness outbreak, and (4) a 1998 report on CFIA's creation. The Auditor General has also reviewed selected Health Canada activities, including progress made by Health Canada's Pest Management Regulatory Agency in applying its procedures for evaluating and registering new pesticides and reevaluating older registered pesticides and the amount of time it takes to get new, possibly safer, pesticides to market. (This assessment also evaluated CFIA's progress in increasing the scope of its program testing for residues in fresh fruits and vegetables.) The Auditor General found that since an audit conducted in 2003, the federal government had made satisfactory progress in selected aspects of managing the safety and accessibility of pesticides, and it had shortened the time it takes to evaluate new pesticides. The Auditor General also reviewed Health Canada's progress in conducting national health

surveillance in 2002. It found that Health Canada had made some progress toward resolving some of the weaknesses the auditors identified in a 1999 audit. However, it also found that national surveillance was still weak; many systems still lacked timely, accurate, and complete disease information; and gaps in surveillance continued.

Health Canada is responsible for assessing CFIA's activities and has completed 10 assessment reports, 9 of which have been published online. The most recent assessments found that CFIA was fulfilling its mission, although minor improvements were needed. For example, in 2005, Health Canada reviewed CFIA's Fish, Seafood, and Production Program's Quality Management Program, a mandatory inspection program for federally registered fish and seafood establishments. The evaluation found that the program was generally effective in enhancing the safety of fish and seafood products. However, Health Canada recommended, among other things, that CFIA managers responsible for the program should conduct trend analysis of complaints and incident data, which would enhance the management of emergencies and incidents. CFIA agreed with the recommendation.

CFIA has also assessed its own performance using criteria developed in collaboration with the Canadian Treasury Board and measuring progress on four strategic outcomes: (1) protecting Canadians from preventable health risks related to food safety or the transmission of animal diseases to humans; (2) protecting consumers through a fair and effective food, animal, and plant regulatory regime; (3) sustaining the plant and animal resource base; and (4) securing Canada's food supply and agricultural resource base from deliberate threats. For each strategic outcome, CFIA identified a number of specific targets. According to CFIA's 2007 annual performance plan, the agency met or exceeded 31 of its 40 targets.

Public opinion surveys. According to a CFIA report, public opinion research conducted in October 2006 and March 2007 suggested that CFIA was meeting its objective of ensuring that the public is aware of food safety risks. In the survey, 82 percent of Canadians said that they had heard about a food recall in the last year. According to CFIA, the research also indicated a positive link between Canadians' awareness of food recalls and their confidence in the food supply. In addition, in a September 2007 survey conducted by a third party on 29 federal departments using 11 indicators, CFIA and Health Canada were among those departments with the most public confidence.

Stakeholder perspectives. The views of industry stakeholders who interact frequently with CFIA can also provide insight, albeit anecdotal, on the effectiveness of a country's food safety system. Industry representatives we spoke to in Canada generally believed that CFIA was effective and that consolidation of the food safety system had been beneficial. For example, one industry stakeholder stated that his organization was glad there was a single government body responsible for enforcing food safety policy and regulations. This individual further told us that as a result of consolidation, there were now CFIA staff dedicated to food safety issues, a fact that has allowed a working relationship between industry and government to evolve, a point echoed by a second industry group. His group also supported CFIA's focus on risk-based inspections. A third industry group representative said that consolidation also helped strengthen agency expertise and capability by combining staff from different agencies. However, this person also expressed concern about CFIA's management of recalls.

Other Relevant Issues

Emerging trends and challenges. Officials identified the following concerns:

- The consolidation of the food industry, with fewer and fewer major corporations dominating entire food sectors, means that the potential impact of outbreaks and/or recalls is greater.
- The popularity of new types of foods (e.g., ready-to-eat bagged salads) poses new risks.
- Imported foods and processes are a concern, especially those, such as produce, that do not involve cooking to kill pathogens.
- Climate change, and the warmer sea temperatures that result, may lead to outbreaks of the *Vibrio* bacterium in oysters. Climate change might also result in new pathogens, new crops, and associated pests.
- Incomplete knowledge of the nature and transmission of emerging zoonotic diseases (e.g., bovine spongiform encephalopathy (BSE, otherwise known as mad cow disease), avian influenza, West Nile virus, new strains of rabies), is a growing concern, and inadequate veterinary care and public health infrastructure in some countries add to the complexity of managing these diseases.

The EU's Food Safety System

Population and per capita GDP. The European Union (EU) consists of the following 27 member countries: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom. Together, the countries have a population of about 490 million people. The EU's 2007 estimated average per capita gross GDP was US \$32,900.

Organization. Since January 2006, the EU food safety system has been fully integrated and is regulated by EU legislation that applies to all EU member countries and importers. However, food safety in Europe was historically part of agriculture policy under the EU's Directorate General for Agriculture. Two events in the late 1990s—the crisis with BSE and the discovery of dioxin in chicken products—drove the EU to comprehensively reform its food safety legislation. The EU created a separate body, the Directorate General for Public Health and Consumer Protection (referred to as DG-SANCO), focused on food safety and consumer protection. DG-SANCO, headquartered in Brussels, Belgium, is independent of the EU's agricultural policy.

DG-SANCO oversees three key areas: food safety, public health, and consumer affairs. The food safety mandate is broad, covering, among other things, animal health and welfare, veterinary inspections, plant health, food labeling, contaminants, and pesticide residues. DG-SANCO is divided into six directorates spread over three locations: Brussels; Luxembourg; and Grange, County Meath, Ireland. The Brussels office is involved in risk management. This includes the development of the EU policy on food safety, animal health and welfare, and plant health, and the daily management of food safety legislation. Luxembourg is home to a DG-SANCO group on public health and risk assessment. The Grange office houses the Food and Veterinary Office (FVO), which, through audits, inspections, and related activities, oversees member states' compliance with EU requirements for food safety and quality, animal health and welfare, plant health legislation, and imports from non-EU countries exporting to the EU. FVO also contributes to the development of EU policy on food safety, animal health and welfare, and plant health, and the development of effective control systems for food safety, animal health and welfare, and plant health.

Other entities playing important roles in the EU's food safety system include the following:

- The European Centre for Disease Prevention and Control (ECDC), based in Stockholm, Sweden, was established in 2005 and is the EU agency responsible for strengthening Europe's defenses against infectious diseases. Its mission is to identify, assess, and communicate current and emerging threats to human health posed by infectious diseases. The Center works with national health protection bodies across Europe to strengthen and develop continentwide disease surveillance and early warning systems. Its mission is centered on transmissible diseases to humans, and it collaborates with the European Food Safety Authority (EFSA), in particular in the field of zoonoses (ECDC transmits to EFSA the data it collects on foodborne diseases; EFSA includes these data in its annual report on zoonoses). ECDC also cooperates with the U.S. Centers for Disease Control.
- EFSA is the main scientific agency for food and feed safety. Based in Parma, Italy, EFSA provides independent scientific advice on all matters with a direct or indirect impact on food safety—including animal health and welfare, plant protection, genetically modified organisms, and nutrition. Its work falls into two major areas: risk assessments and risk communication, but its tasks also include data collection (for example, the annual zoonoses report). At the request of the European Commission as well as member states and the European Parliament, EFSA assesses the risks associated with the food chain, including, for example, risk assessment related to food or feed additives submitted for premarket approvals, microbiological risk, contaminants, animal health and welfare, and plant health. These risk assessments inform the policies and decisions of EU risk managers, who establish limits on these substances. EFSA also communicates to the public the results of its scientific work. Because its mission is independent risk assessment, EFSA is separate from the DG-SANCO structure. EFSA cooperates closely with the scientific bodies responsible for risk assessment in the various member states and with the U.S. Food and Drug Administration. The EFSA Advisory Forum is composed of a representative from each of the member states' national bodies responsible for risk assessment. The forum facilitates the sharing of scientific information between the national authorities and EFSA and ensures close cooperation with the national scientific bodies to avoid duplication and to promote common scientific views on risk assessment and risk communication.

At the national level, each EU member state has one or more agencies charged with implementing EU regulations, referred to as the “central competent authority” or “competent authority.” For example, in the UK, the Food Standards Agency is the competent authority for food and feed safety, while the Department of Environment, Food, and Rural Affairs is

the competent authority for animal health and welfare and plant health issues. Each member state is expected to prepare a multiyear control plan that contains general information on the structure and organization of the systems for feed and food control. This plan includes the designation of competent authorities and their tasks at the central, regional, and local level. The member states are required to provide the European Commission, the executive branch, or governing body, of the EU, with an up-to-date copy of their multiyear control plans on request.

Regulatory Framework

The EU has adopted an integrated farm-to-fork approach to food safety that aims to protect human life and health while also taking into account the protection of animal health and welfare, plant health, and the environment. Under this framework, food law and feed law cover all stages of production, processing and distribution.¹ Food and feed operators have primary responsibility for food safety; member states ensure surveillance and control of these operators, and the EC tests the performance of member states' control capacities and capabilities through audits and inspections.

In the EU, food and feed business operators have primary responsibility for food safety, while member states provide oversight over these operators at all stages of production. Business operators are responsible for the food and feed (such as cattle fodder or pet food) that they produce, transport, store, or sell. They must (1) be able to rapidly identify any supplier or consignee, (2) immediately inform the competent authorities if they have reason to believe their food or feed is not safe, (3) immediately withdraw a product from the market if they have reason to believe the product is not safe, (4) apply HACCP principles² in their processes and ensure that controls are applied at critical points,³ and (5) cooperate with the competent authorities in actions taken to reduce risk. The competent

¹Stages of production, processing, and distribution mean any stage, including import, from and including the primary production of a food through storage, transport, sale, or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed.

²Hazard Analysis and Critical Control Point (HACCP) is a science-based safety system for certain food products designed to improve the safety of food by having industry identify and control biological, chemical, and physical hazards in products before they enter the market.

³Primary producers, that is, farmers, hunters, and fishermen, are not required to apply HACCP principles. However, guides to good practice should encourage the use of appropriate hygiene practices at the farm level.

authority in each member state is responsible for monitoring producers to ensure that they are meeting these obligations. The EU's FVO then assesses the performance of the member states' competent authorities, countries aspiring to join the EU (referred to as candidate countries), and non-EU countries intending to export to the EU (referred to as third countries), to verify the effectiveness of national control systems for meeting EU standards in the areas of food safety, animal health and welfare, and plant health. Feed suppliers, for example, must apply HACCP principles, register with their national competent authorities to help ensure traceability, and comply with specific microbiological criteria, such as for levels of *Salmonella*, molds, and yeast. The competent authorities in each country approve certain feed operators (i.e., those manufacturing and/or selling certain feed additives) by visiting the facility before they start up any activity to ensure that the operators meet EU standards, and once the operator is approved, the competent authority provides oversight and imposes penalties for noncompliance. In turn, FVO inspects the competent authorities' oversight and provides recommendations when there are shortcomings. It also inspects countries aspiring to join the EU, and non-EU countries intending to export to the EU, to verify the effectiveness of national control systems to implement EU standards in the areas of food safety, animal health and welfare, and plant health. As for imported feed, importers must ensure that the feed meets EU standards.

According to EU sources, the primary law laying out the regulatory framework for food safety in the EU is the General Food Law of 2002. Subsequent legislation merged, harmonized, and simplified detailed and complex hygiene requirements previously contained in 17 directives covering the hygiene of foodstuffs and the production and marketing of products of animal origin. According to these sources, the EU's food legislation framework includes the major regulations and directives described in table 4.

Table 4: Major EU Laws, Regulations, and Directives

Regulation	Major provisions
General Food Law (Regulation [EC] 178/2002)	Covers the general principles and requirements of food law and procedures in matters of food safety and includes the following key provisions: (1) Safety: Business operators shall not place on the market unsafe food or feed; (2) Responsibility: Business operators at all stages of production shall ensure that food or feed satisfy the food law; (3) Traceability: Business operators shall be able to identify anyone from whom they have been supplied a food or food component; and (4) Emergency: Business operators shall immediately initiate withdrawals of food or feed from the market if they have a reason to believe that it is not in compliance with food safety requirements.
Hygiene I (Regulation [EC] 852/2004)	Covers the general rules for food business operators on the hygiene of all foodstuffs, noting that primary responsibility lies with business operators, food safety starts with primary production, and implementation of HACCP should reinforce business operator responsibility.
Hygiene II (Regulation [EC] 853/2004)	Covers specific rules for food business operators for foods of animal origin, including processed and unprocessed foods, and covers rules for importers of foods of animal origin.
Hygiene III (Regulation [EC] 854/2004)	Covers specific rules for the organization of specific controls for products of animal origin intended for human consumption, in particular for businesses producing meat, raw milk, eggs, or fishery products, and includes detailed inspection tasks.
Hygiene IV Directive [EC] 2002/99	Covers the general animal health rules governing all stages of production, processing, and distribution within the European Community and the introduction from non-EU countries of products of animal origin intended for human consumption. The stated aim is to prevent the spread of animal diseases as a result of placing animal produce on the market.
Council Directive [EC] 97/78	Covers the principles governing the organization of veterinary checks on products of animal origin entering the EU from third countries.
Regulation [EC] 882/2004	Covers official controls performed to ensure the verification of compliance with feed and food laws, animal health, and animal welfare rules.

Source: EU documents.

DG-SANCO provides training to member states to harmonize their food safety regimes and to ensure uniform application. The implementation of EU legislation in member states is reviewed by other EU members and by FVO. EU legislation is mostly in the form of regulations or decisions that are directly applicable in the member states. In other cases, the EU legislation takes the form of directives, which the member states must translate into national law. Directives establish the target objective(s) and allow member states to decide on the most appropriate measures and adapt them to their situations in order to reach the defined objective(s).

EU member states may also institute their own country-specific food safety regulations, as appropriate for their particular situations, provided that the level of protection defined at the EU level is not jeopardized and that the additional measures proposed do not impede the free circulation of goods among the member states.

The EU also emphasizes the importance of being able to trace food “one step forward and one step back” to quickly track any questionable food products. Each food and feed business operator must be able to identify its suppliers and which businesses it supplied. Specifically, the operator must be able to document the names and addresses of the suppliers and customers, as well as the nature of the product and date of delivery. The operators are also encouraged to keep information on the volume and quantity of a product; the batch number, if there is one; and a more detailed description of the product, such as whether it is raw or processed. Food and feed business operators must also have systems and procedures that allow them to provide this information to the competent authorities on demand. (Exporters in trading partner countries are not required to fulfill the EU’s traceability requirement, except in circumstances where there are special bilateral agreements for certain sensitive sectors or where there are specific EU requirements, such as in the veterinary sector. However, these traceability requirements pertain to EU importers, who should be able to identify their direct supplier in the non-EU country.)

According to EU sources, the EU’s traceability system proved useful during an incident that took place in 2004. During standard random monitoring of dioxin levels in milk at a Dutch farm, the national competent authorities found a high level of dioxin. EU sources noted that the competent authorities immediately barred the farm from trade and began tracing the product through the food chain. They found that the source of contamination was clay, used in food processing to separate higher-quality potatoes from lower-quality ones. The dioxin-tainted clay had contaminated potato peels used for feeding dairy animals. The EU’s electronic Rapid Alert System for Food and Feed was used to trigger an exchange of information among national authorities about the problem. According to EU sources, the authorities quickly established that the clay had also been supplied to several food-processing companies located in Belgium, France, Germany, and the Netherlands. The authorities rapidly identified these businesses and barred from trade over 200 farms that had received the potentially contaminated potato peels. EU sources noted that because of the traceability system, the contaminated products never reached consumers.

EU producers must also tag livestock with details of their origin, and when the animals are taken for slaughter, stamp them with the traceability code of the slaughterhouse. The tools used (ear tags, “passports,” or bar codes) may vary from country to country but must carry the same information. In addition, to ensure the traceability of animals across the EU, the EU established the Trade Control and Expert System (TRACES), a central

database for tracking the movement of animals both within the EU and from third countries. In the event of a disease outbreak, TRACES ensures that all potentially affected animals can be quickly identified and that authorities can take appropriate measures.

Oversight of Imported Food

Import controls. The EU's guiding principle is that all food products in the EU should be safe, regardless of origin. However, imported products require specific controls, owing to different animal, public, and plant health situations in countries of origin. Animal products such as meat, milk, fish, and honey, as well as live animals, present the highest level of risks because they can transmit serious human and animal diseases. Certain plant products, such as cereals and nuts, also present higher levels of risks because they may be contaminated by aflatoxins. "Shelf-stable" products, such as canned, processed, and dried foods present lesser risks; control requirements are thus tailored accordingly.

Equivalency agreement/certification programs. One of the key features of EU regulations is that products of animal origin imported from non-EU countries (referred to as third countries) must meet safety standards at least equivalent to those of the EU. If such food is found not to be as safe as that of the EU, the overseas firm is not allowed to export to the EU. For example, the EU maintains a list of third countries in which the capacity of the competent authority has been recognized, along with the country's animal and public health system and status, but the EU does not maintain such a list for food of nonanimal origin. On the basis of this recognition, third countries' competent authorities propose establishments to be approved for export of products of animal origin to the EU. Among the requirements for approving the export of products of animal origin are the following:

- formal submission of a written application to export to the EU;
- verification of the exporting country's animal and public health system, such as legislation, control systems, disease surveillance measures, and laboratory facilities;
- submission and approval of a monitoring plan for residues of banned or restricted substances in the EU, including veterinary medicines and growth-promoting hormones; and
- provision of sanitary certification that the products to be exported to the EU meet import requirements.

FVO normally visits countries to verify compliance with these conditions. If compliance is satisfactory, the EC may formally decide to approve countries and establishments for export to the EU. In addition, third countries must certify and approve business establishments wishing to export products of animal origin to the EU, noting that they meet the relevant EU standards. Lists of these establishments are maintained online by the European Community for all the main categories of animal products (e.g., beef, poultry, fish, or dairy), and compliance is verified during follow-up FVO missions. To help reduce problematic imports, DG-SANCO provides technical assistance to developing countries. In particular, DG-SANCO trains people overseas on hygiene and HACCP.

Inspections. The EU bases its inspections of imports on the degree of risk presented by particular food types. According to the EU, it has shifted its focus from regular, but random, sampling to paying attention to the sources of greatest risk. Risk may be high because a particular product is traded in large quantities, or because a product or the area it comes from is known to be susceptible to a particular plant or animal disease. If the risk of a given food product is not known or quantified, the EU applies what it refers to as the “precautionary principle.” If there are reasonable grounds for suspecting a problem, the commission acts to limit the risk. The EU asserts it does not necessarily need to wait for proof that there really is a risk.

Because of countries’ differing risk profiles, the EU has different inspection methods for food products of (1) animal origin, (2) nonanimal origin, and (3) high-risk foods of nonanimal origin.

First, all imports of live animals and animal products must enter the EU through its roughly 300 approved border inspection posts, which include airports, rail stations, and deepwater ports. The posts are under the authority of each member state’s official veterinary services. A member state’s customs service cannot release consignments unless they have passed through veterinary controls. The system thus requires the cooperation of veterinary authorities and customs officials. The border inspection posts must be notified in advance of the presentation of such consignments, which must undergo an official veterinary check at the inspection post. When a consignment arrives at a post, three types of checks are carried out:

- **Documentary:** A documentary check is carried out on all consignments.

- **Identity:** An identity check is carried out on all consignments to verify that the identity of the goods corresponds fully with the veterinary documents supplied.
- **Physical:** A physical check is carried out on a percentage of consignments on the basis of the type of animal or animal product and the country of origin to ensure it does not pose a threat to public and animal health. According to EU officials, EU legislation also specifies a minimum number of physical checks to be carried out for each product group (e.g., meat, fish, or dairy) by each member state. A physical inspection may also involve taking samples for laboratory tests.

When all tests and checks are satisfactory, the consignment is issued a Common Veterinary Entry Document and is placed on the EU market. In cases where testing is carried out because of unfavorable results of previous tests on the animal product or when a problem is suspected, the consignment will not be cleared or allowed to leave the border inspection post until the border authorities receive the results of the new tests.

If a consignment does not comply with EU requirements, it may be rejected. In these cases, EU officials negotiate with the owner of the consignment and the country of dispatch, where appropriate, about whether to destroy the product, to retreat it for uses other than the human food chain, or to redispach it. Food or feed business operators or their representatives are responsible for the consignment and are liable for any costs incurred by the competent authorities to destroy or redispach it. In addition, if consignments are not in compliance, all other border inspection posts are notified through the Rapid Alert System for Food and Feed. This electronic notification system, managed by DG-SANCO, alerts all EU member countries to a potential food problem, including either a direct or an indirect risk to human health from food or feed. The rapid alert system involves all member states, the EC, and EFSA, as well as Iceland, Liechtenstein, and Norway (non-EU countries). Each participating country has a rapid alert contact point to collect information on national notifications and enter them into the database. The exchange of information allows participating states to immediately ascertain whether they are also affected by a problem and take appropriate measures. Since all EU border posts are connected electronically, problems at any one border can quickly be announced via the rapid alert system to all other border posts. Future imports from the same exporting country are then scrutinized more closely.

Second, food products of nonanimal origin—including fruits, vegetables, cereals, tubers, nondairy drinks, food of mineral origin (such as salt), spices, and condiments—do not need to come from approved countries or establishments and can come into any EU port of entry. However, they are still subject to certain EU control requirements in order to verify that they comply with EU food safety standards. Among other things, food business operators in third countries must monitor the safety of products and processes under their responsibility, follow general hygiene provisions for primary production, develop HACCP principles, and register establishments with the appropriate competent authorities. In the EU, the competent authorities of the member states are responsible for carrying out regular controls of the goods imported into EU territory. Controls are determined based on potential risks.

Finally, the EU maintains a list of food products of nonanimal origin that may represent a health risk to humans. As noted above, cereals and nuts, for example, may appear on the high-risk list. Such products undergo control measures, such as health certificates and testing, similar to those required for food products of animal origin. For example, all consignments of pistachios from Iran are sampled and checked. The safeguard measures are lifted once the problem has been addressed.

Problems with imports are normally brought to light by inspections carried out by the FVO, checks at border inspection posts, checks carried out during the course of "market surveillance" by member states,⁴ business or consumer groups, or media reports. The following actions are available to address these problems:

- circulate information through the rapid alert system to all member states, especially their border inspection posts, to enable a higher level of surveillance;
- request that the exporting country take corrective action, such as deleting the exporting establishment from the authorized list for export to the EU;
- introduce additional requirements, such as a higher level of testing at border inspection posts, retention of consignments awaiting laboratory confirmation of noncontamination, and additional certification requirements through "safeguard decisions"; and

⁴Market surveillance refers to the routine monitoring of the rapid alert system's Web site and other sources to see if any products are being recalled.

- ban exports to the EU outright.

These measures are normally introduced in full consultation with the member states. In recent years, safeguard decisions have been taken in relation to products from a wide range of third countries, including China (all animal products banned in 2002) and Brazil (100 percent testing of poultry and meat products for veterinary residues). In urgent cases, the EU can also take safeguard measures on its own initiative, pending confirmation by the member states.

With respect to actions that can be taken domestically in response to an import problem, the EU distinguishes between withdrawals and recalls under the rapid alert system and has authority for both. Withdrawals occur when the product is still under the control of the producer and consist of measures aimed at preventing the distribution or display of a product that is dangerous to the consumer. Recalls occur when the product is already available to consumers and consist of measures aimed at achieving the return of an unsafe product. All member states must notify the EU when there is a serious risk to human health.

The EU requires that member states ensure that adequate financial resources are available for organizing official controls on imports. For that purpose, member states may collect fees or charges to cover the costs of these controls. However, they must collect fees for certain activities, including controls of products of animal origin, such as meat inspection, and controls of dairy establishments. Fees are also levied for certain import controls on these commodities. EU officials said that fees may not be higher than the costs borne by the competent authorities.

Foodborne Illness Outbreaks

According to EFSA, in 2005 the most frequently reported zoonotic pathogen in humans within the EU was *Campylobacter*, followed by

Salmonella. Other common zoonotic pathogens include Verotoxigenic *E. coli*,⁵ *Yersinia*,⁶ *Listeria*, and *Brucella*.⁷ *Salmonella*, *Campylobacter*, and

⁵Some forms of *E. coli* bacteria can produce toxins capable of killing a special type of cell called a Vero cell. These *E. coli* have thus become known as verotoxin or verocytotoxin *E. coli* (VTEC). VTEC O157 is the type most frequently associated with human disease.

⁶*Yersinia* is a bacterium that causes an infectious disease called Yersiniosis. Infection is most often acquired by eating contaminated food, especially raw or undercooked pork products. Drinking contaminated unpasteurized milk or untreated water can also transmit the infection. Occasionally, infection occurs after contact with infected animals.

foodborne viruses—especially calicivirus—were the most prevalent causes of foodborne outbreaks in the EU in 2005.

Response. Responsibility for investigating and controlling outbreaks of foodborne illness rests with local or regional authorities in most of the EU member states. National epidemiologists collect and analyze outbreak data and cooperate with other responsible bodies, such as the environmental health office or the regional veterinarian, to implement control measures. For larger outbreaks, or for those that cover more than one region, the member state's national surveillance institute, which monitors and investigates public health issues, often assists. The ECDC is not involved in outbreaks confined to one member state, except for providing training, guidelines, and possible expertise when requested. However, the country investigating an outbreak informs the ECDC if it finds that the contamination may affect other EU citizens because, for example, the food product is distributed in EU countries, or if the outbreak is likely to spread to other EU countries. The investigating country informs the ECDC through the Early Warning Response System—a computer database that deals with communicable diseases. ECDC assesses risk at the EU level to confirm a threat and then (1) works with other entities to ensure a coordinated approach to investigation and control; (2) cooperates closely with other EU agencies, particularly EFSA; (3) ensures proper communication with the EU and the public; and (4) assists the member states involved.

Data from all foodborne illness outbreaks are reported to EFSA and published annually. Cross-border outbreaks are not reported separately. In case of a foodborne illness outbreak, the member states must carry out epidemiological investigations. EFSA also provides guidance on what information should be reported in case of a foodborne illness outbreak.

ECDC manages a computerized database—Enter-net—an international surveillance network for human gastrointestinal infections. It involves all 27 EU countries, as well as Australia, Canada, Japan, South Africa, Switzerland, and Norway. Network participants include the microbiologists in charge of each country's national reference laboratory

⁷Bacteria of the *Brucella* family can cause an infectious disease called Brucellosis. Various *Brucella* species affect sheep, goats, cattle, deer, elk, pigs, dogs, and several other animals. Humans are generally infected by eating or drinking something that is contaminated with *Brucella*, breathing in the organism, or having the bacteria enter the body through skin wounds. The most common way to be infected is by eating or drinking contaminated milk products.

for *Salmonella* and *E. coli* infections, and each country's epidemiologist is responsible for the national surveillance of these diseases. The network conducts international surveillance of salmonellosis and *E. coli*, including antimicrobial resistance. Limited data on each laboratory-confirmed case of *Salmonella* or *E. coli* infection identified by the national reference laboratories are transferred to the central databases at the Enter-net hub. These records include microbiological and epidemiological data, which are analyzed on a regular basis and reported to all participants. The central database allows Enter-net to monitor trends in infection and recognize unusual events that can be seen only when the data are pooled internationally. The Enter-net database has led to a number of recalls, including, for example, peanuts from China.

When more than one EU member state is involved in an outbreak, human data are communicated to other member states through the Early Warning and Response System, a database managed by the European Commission with the support of the ECDC and used by public health authorities in member states and in European Economic Area (EEA) countries.⁸ The system is a forum for exchanging information on the details of specific events caused by communicable diseases and the public health measures planned or undertaken at national level to respond to those events. The database is confidential and can be accessed only by the officially nominated public health authority in member states, the commission, and the ECDC.

Information on any food involved in an illness outbreak is immediately communicated through the rapid alert system. There are also networks of EU reference laboratories linking national reference laboratories for each of the major foodborne pathogens. These networks provide support to member states' competent authorities in analyzing suspect food and exchanging information on the molecular typing of isolates (samples). The epidemiological investigation of foodborne outbreaks is an important tool for identifying the major causes of foodborne infections in humans. It is a major source of information used when deciding on priorities for the control of foodborne infections in the EU.

⁸The European Economic Area consists of the EU member states, the European Community, and Iceland, Liechtenstein, and Norway. Switzerland is not part of the EEA.

Efforts to Measure the
Effectiveness of Food Safety
Systems

Recent incidents. According to EU officials, the EU has had some recent problems with dye and chemical contamination of food, but there have not been any EU-wide incidents of foodborne illness outbreaks to date.

Performance measures. According to EU officials, performance measures for the EU include annual reports from EFSA on trends in foodborne illness, reports by individual member states on their effectiveness, and an EU health indicators database.

Evaluations and audits. FVO audits are the key EU instruments to ensure that member states and non-EU countries are complying with regulations. Under the EU's farm-to-fork approach, FVO must examine the entire chain. Each year FVO develops an inspection program that identifies priority areas and countries it will audit that year. During the audit, it assesses a member state's competent authorities and compliance with EU requirements. Competent authorities must have their own audit authorities, which FVO also audits. As part of their reviews, the FVO inspectors may visit producers or processing plants to establish that enforcement mechanisms are effective in practice. If necessary, FVO can send out inspectors in response to disease outbreaks both within and outside the EU. FVO makes recommendations to the country's competent authority to address any shortcomings found during the inspections. The competent authority in each member state is then asked to present an action plan to the FVO on how it intends to deal with any identified shortcomings. Together with other EU bodies, the FVO evaluates this action plan and monitors its implementation. According to FVO staff, if an audit turns up deficiencies, the commission could put in place safeguard measures that, for example, block trade from a particular country if the audit finds there is immediate harm to public, animal, or plant health. The commission can also issue an alert to all member states through the rapid alert system. As a last resort, the commission could take legal action to ensure that member states meet their obligations.

In 2006, FVO carried out 255 inspections, of which 68 percent were related to food safety, 14 percent to animal health, 13 percent to animal welfare, and 5 percent to plant health. Sixty-three percent of the audits were in EU member countries, 26 percent were in non-EU countries, and 11 percent were in EU candidate countries.

Public opinion surveys. The EU periodically surveys citizens in its member countries on a variety of issues as part of the Eurobarometer series.⁹ According to a 2005 Eurobarometer survey published in 2006, an estimated 38 percent of people in the EU stated that, overall, food safety had improved, 29 percent that it had stayed about the same, 28 percent that it had worsened, and 5 percent did not know. In addition, 47 percent of those surveyed stated that public authorities' actions in the EU with regard to food safety risks are usually appropriate, 33 percent that the actions are insufficient, 8 percent that the actions go beyond what is needed, and 12 percent did not know. Finally, according to the Eurobarometer survey, an estimated 59 percent of people in the EU agreed that food produced in the EU is safer than food imported from elsewhere, 27 percent disagreed, and 13 percent did not know.

Other Relevant Issues

Officials we spoke with at the DG-SANCO and FVO identified the following ongoing and future challenges to the EU's food safety system:

- The EU is looking to develop a more risk-based veterinary imports control program to identify the greatest risks associated with imported food, so that it can focus more on problem areas. Officials believe that it is possible to have a more flexible approach to veterinary controls in some areas without diminishing the overall approach. However, in order to focus more on risk, the EU needs to develop more data, and EU officials currently are looking to improve data availability. The development of data takes time and money.
- Despite regulatory improvements, there is still potential for fraud in the system.
- Resources are sometimes mismatched with problems.
- The food supply is becoming increasingly global, which means it is more difficult to control all elements of the food chain.
- The current regulatory system is also not well suited to address certain innovations, such as genetically modified organisms, certain agricultural crops, and nanotechnology.

⁹Eurobarometer is a series of surveys regularly performed on behalf of the European Commission since 1973. It produces reports of public opinion across the member states on a variety of EU-related topics, including social conditions, health, culture, and environment.

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- Some items, such as dyes, which are chemicals, are imported as nonfood items but can be used as additives in certain processed foods.
 - There are also differences between the EU member countries in how they report information. For example, zoonoses are reported by some countries as foodborne pathogens and by others as animal illnesses.
 - The number of contaminants, such as mycotoxins, as well as unauthorized additives, is increasing.
 - Conducting risk assessments is also getting more difficult. New legislation has moved to risk-based approaches. Member states have more leeway on how they define risk.

Germany's Food Safety System

Population and per capita GDP. In 2007, Germany had a population of approximately 82.4 million, and in 2006 it had an estimated per capita GDP of US \$31,900.

Organization. In 2002, the Federal Office of Consumer Protection and Food Safety (BVL) and the Federal Institute for Risk Assessment were established within the portfolio of the Federal Ministry of Consumer Protection, Food, and Agriculture. The German government took this action in response to numerous crises, including dioxin-contaminated chicken feed, misuse of antibiotics in pig feed, and the emergence of BSE in Germany in the late 1990s. The reorganization separated risk assessment from risk management. Prior to the reorganization, three federal ministries—for public health, agriculture, and environmental protection, overseeing a total of 18 agencies—were responsible for food safety.

Germany's 16 federal states are responsible for overseeing compliance with laws, and as such, they are in charge of food and feed safety, animal health and welfare, and plant health. Local authorities in each state are in charge of control and enforcement, and the federal states oversee inspections performed by local governments. To harmonize food safety activities among the states, the German government and federal states have established a set of standard operating procedures for the control of food establishments and the sampling of food products, among other things. As a result of this decentralized structure, BVL coordinates—but does not oversee—the activities of the federal states in these areas. BVL conducts surveillance (not audits) to ensure the states adhere to the EU regulations for food safety.

BVL's main focus is risk management. Other responsibilities include cooperating with the Federal Ministry of Consumer Protection, Food, and Agriculture in the areas of food safety, veterinary affairs, and consumer protection by providing data and support. BVL also provides logistical and organizational support to the states on food safety-related matters and houses the national and EU reference laboratories for residues, including veterinary medicines, for contaminants, and the National Reference Laboratory for Genetically Modified Organisms. The agency is also Germany's central contact point for the EU's Rapid Alert System for Food and Feed and for the EU's Food and Veterinary Office. BVL has approximately 430 employees.

The Federal Institute for Risk Assessment is in charge of risk assessment and risk communication. It provides scientific opinions on food and feed safety and animal health, as well as assessments of the health effects of chemicals, and risk assessments on genetically modified animals, plants, and feedstuffs. Its research results and recommendations are an important decision-making aid for a number of public agencies, including the Federal Ministry of Consumer Protection, Food, and Agriculture and BVL. The Federal Institute for Risk Assessment is also the primary German point of contact for the European Food Safety Authority. The institute houses 14 national reference laboratories related to food safety and hygiene.

The Robert Koch Institute is responsible for disease prevention and control. It is also responsible for scientific investigation, epidemiological and medical investigation, and analysis of dangerous diseases. It also collects, maintains, and reports epidemiological data at the federal level.

Each German state also has a ministry that oversees the control, planning, and coordination in all areas of food, feed, and veterinary matters in the state. Each state also has one or more authorities that oversee food safety and/or veterinary matters at the district or municipal level. In addition, five German states have provincial governments that supervise food-related matters at the provincial level—between the state and local level—and provide oversight over local authorities.

Although the Federal Ministry of Consumer Protection, Food, and Agriculture is the national-level competent authority for import controls on animals and food of animal origin, the individual states implement the veterinary import controls, and local authorities oversee Germany's 22 border inspection posts.

Oversight of Imported Food

According to BVL, Germany imports about 47 million tons of food per year, 19 percent of which comes from developing countries.

Import controls. Germany's regulations are fully harmonized with the EU's. For a more detailed summary of the EU food safety requirements, see the EU profile.

Inspections. See the EU profile for more detail.

Equivalency agreements/certification programs. See the EU profile for more detail.

According to German officials, Germany has some of its own laws overseeing food safety matters, including the Law on Food and Feed and certain other legislative acts pertaining to foods of animal origin and certain other specific products. According to these officials, some of Germany's most important food safety regulations include the following:

- a regulation for the execution of provisions of community food hygiene laws as a national executive order requiring implementation of EU regulations on food safety and other directives on adapting and consolidating national provisions concerning food import and market regulations, labeling and sanitary rules, and distribution;
- an import regulation for foodstuff of animal origin;
- product-specific regulations, such as those for wine, honey, and milk; and
- general administrative procedures.

The 16 federal states do not have their own food safety laws, but their regulations and administrative rules apply to their responsibility for enforcing food safety legislation.

The federal states also do not impose fees for regular controls—only for controls detecting infringements.

Foodborne Illness Outbreaks

According to data from the Robert Koch Institute, the most commonly reported intestinal pathogen in Germany in 2006 was norovirus, with 75,766 reported cases, followed by *Salmonella*, with 52,267 reported cases. *Campylobacter* was the next most common pathogen in Germany, with 52,035 reported cases. In addition, there were 6,470 cases of *E. coli* and 508 cases of *Listeria* infection.

Response. Multiple agencies in Germany are involved in managing an outbreak of foodborne illness. Local health agencies are the primary points of contact when an outbreak occurs. These agencies identify, treat, and report the illness to the Robert Koch Institute. The institute's epidemiological department collects data and identifies and confirms the number of illnesses. The institute is also the primary conduit for communication to the public throughout an outbreak. If the outbreak does not spread to a neighboring county or federal state, the local county health official retains responsibility for managing it. However, if the outbreak does spread, the Robert Koch Institute manages it, in collaboration with the local authority. The Federal Institute for Risk Assessment collaborates with the Robert Koch Institute to determine what the illness is, including the strain of the pathogen and the source of the outbreak. Local laboratories send any samples to the Federal Institute for Risk Assessment's reference laboratories for more sophisticated testing. The institute also has food and veterinary experts who assist in the investigation. (In the context of foodborne illness outbreaks, most of the food scientists are veterinarians specializing in food microbiology.) BVL helps track the source of the outbreak, provides information to other national agencies and the states, coordinates activities at the federal level, conducts tracking and tracing, and coordinates a recall if necessary. However, in Germany, it is the federal states that have the recall authority; BVL does not issue recalls. German officials told us that their procedures for addressing the public health aspects of foodborne illness outbreaks—in terms of identifying pathogens and tracking diseases—are generally similar to those followed in the United States by the Centers for Disease Control and Prevention.

International coordination. During an investigation of an outbreak of foodborne illness, BVL is responsible for notifying the EU's rapid alert system and for sending information received from other EU member states via the rapid alert system to competent authorities in the states. In 2006, Germany issued 425 rapid alert notifications, including 2 related to microbial contamination and 20 related to potentially pathogenic organisms. The Robert Koch Institute is the competent German body providing scientific advice to European Centre for Disease Control. A scientific officer from the Robert Koch Institute is member of the Center's Advisory Forum, where information on health threats is exchanged.

Recent incidents. According to a report by the Robert Koch Institute, on August 15, 2007, the institute detected an outbreak of *Salmonella* Panama in several German states during its routine computerized analysis of state-reported monitoring data. In all, 10 states reported *Salmonella* Panama

cases. On the same day that they identified the outbreak, Robert Koch Institute officials asked the states to investigate the issue at the local level, including having the local health officials ask the victims' parents to participate in a telephone interview so the institute could learn more about the child's illness and the food the family had eaten. Laboratories were asked to send *Salmonella* Panama samples to the national *Salmonella* reference laboratory in the state of Saxony-Anhalt.

A month earlier, the Robert Koch Institute had learned that during the course of semi-annual monitoring, a worker at a meat-processing plant had been diagnosed with asymptomatic *Salmonella* Panama. The plant produced, among other things, minisalami sticks, a snack popular with children. The institute then included consumption of minisalami sticks in questions about what had been eaten by the children who became ill. In several instances, parents separately told interviewers that their children had eaten minisalami sticks. To confirm the connection between the minisalami and the *Salmonella* Panama infection, institute staff conducted a case-control study, using 22 victims of the July outbreak as the "cases" and people from 20 affected communities as the controls. To identify the control cases, the institute asked certain local offices in the affected regions to select from their databases up to 30 families with children in three different age groups. Local officials used a statistical procedure called frequency matching to select 62 control cases. As part of a telephone survey, officials asked the parents of both the "case" (i.e., victim) and control subjects about their shopping and eating activities in the week prior to the outbreak. The institute then included consumption of minisalami sticks in questions about what the sick children had eaten. The experts found that in the 7 days before the outbreak, there was a high statistical correlation in the cases between consumption of minisalami and *Salmonella* Panama infection.

While the Robert Koch Institute was conducting the surveys, the reference laboratory identified the specific strain of *Salmonella* involved in the outbreak and confirmed that all 11 samples from the cases belonged to the same strain, as did the sample from the asymptomatic worker at the salami plant and a coworker's 10-month-old grandchild, who had become ill. BVL also queried the EU's rapid alert system to see if there had been any case of *Salmonella* Panama between January 1, 2006 and August 2007, and found none. The local competent authorities also examined minisalami samples from the processing plant thought responsible for the outbreak for *Salmonella* but found none and did not find any in minisalami products taken from shops in two states where the firm's products were sold.

In early September, staff from the local food safety authority and the Federal Institute for Risk Assessment again inspected the salami manufacturer. The competent authorities also conducted a thorough review of the firm's records. No shortcomings were found in hygiene procedures. Officials nonetheless concluded that the minisalami sticks were the most likely cause of the outbreak, even though the pathogen was not found in tests of the product.

In summarizing the incident, the Robert Koch Institute pointed out that this outbreak was discovered only through the nationwide aggregation of institute-collected data and computerized analysis, because the number of victims in any one state was too low to signal an outbreak. Furthermore, the case-control telephone survey enabled officials to conduct an almost real-time epidemiological analysis. In addition, according to the institute, close cooperation among the Federal Institute for Risk Assessment, BVL, the Robert Koch Institute, the national reference laboratory, and local authorities contributed to rapid investigation and management of the outbreak.

Efforts to Measure the
Effectiveness of Food Safety
Systems

Although Germany had not conducted a formal review of its reorganized food safety system at the time of our review, BVL met with relevant stakeholders in November 2007 to discuss how the German food safety system and BVL are working. Participants included consumers, politicians, administrators, nonprofit organizations, industries, scientists, and representatives from the EU, who discussed how BVL had performed over the 5 years since it was created. Among the themes discussed were data management and analysis, cooperation between the federal government and the states, international cooperation, and research and scientific work. Overall, participants believed that BVL had been meeting its objectives, and views were generally positive. In particular, participants approved of the efforts of the national contact point for the EU's rapid alert system. However, they suggested some improvements in the system, and also suggested that BVL provide training to help prepare for FVO audits. Participants also had positive things to say about the BVL press office, and suggested that BVL allow its home page to be reviewed by users and by external media experts. Participants furthermore spoke highly of BVL's *Journal of Consumer Protection and Food Safety*, which was launched in 2006 to provide information, in both German and English, on basic and applied research and on official oversight of current developments in the areas of food and feed, veterinary medicine, and genetic technology. Finally, participants suggested that BVL establish a greater presence at conferences, fairs, and schools and that it be more visible to consumers as a partner for information and questions.

Performance measures. According to BVL officials, measures used to evaluate performance include quality management systems within competent authorities, targets set through control and monitoring plans, data found in annual reports on food safety, and evaluation of rapid alert system notifications. BVL's performance is evaluated by the German Federal Court of Auditors, GAO's German counterpart.

Evaluations and audits. BVL cannot audit or evaluate the state-level food safety systems. However, some states audit other states' local and regional food safety systems upon request.

Moreover, between 2001 and 2007, FVO conducted 53 performance audits of certain aspects of Germany's food safety system and most made recommendations to German officials. In June 2005, for example, the office assessed the import control system and four operating border inspection posts in Germany. It found that import controls were generally applied correctly in the border inspection posts visited, with only minor shortcomings. However, it also found that supervision of imports that do not comply with EU regulations was inadequate, traceability was not reliable, and the exit of these noncompliant products from the EU was not ensured. Furthermore, it found significant deficiencies at some of the border inspection post facilities. FVO audits have been conducted on such topics as BSE, food hygiene, and animal welfare. The office discusses any problems it detects at the state level with BVL and the states.

Public opinion surveys. Officials from BVL stated that the agency is in constant dialogue with stakeholders and evaluates daily consumer mails and queries related to food safety and consumer protection (including on economic issues).

According to a 2005 Eurobarometer survey published in 2006, an estimated 37 percent of people in Germany stated that overall, food safety had improved over the past decade, 37 percent that it had stayed about the same, 21 percent that it had worsened, and 5 percent did not have an opinion. In addition, an estimated 56 percent of the Germans surveyed stated that usually public authorities' actions in the EU with regard to food safety risks were appropriate, 28 percent that actions were insufficient, 8 percent that the actions went beyond what is needed, and 8 percent did not have an opinion. Finally, an estimated 60 percent of the Germans surveyed agreed that food produced in the EU was safer than food imported from elsewhere, 30 percent disagreed, and 10 percent did not know.

Stakeholder perspectives. The views of stakeholders who interact frequently with BVL can also provide insight, albeit anecdotal, on the effectiveness of a country's food safety system. In Germany, a representative of an industry group told us that overall the consolidated food safety system represented an improvement over the previous system. This person also said that the EU's rapid warning system was working well, although there was room for improvement in some areas. Furthermore, one of the positive outcomes of the consolidation, in this person's view, was the establishment of a working group of representatives from the 16 states who meet to discuss problems of food law interpretation. According to this person, one of the challenges of the German food safety system was the different interpretations of law at the state and local levels. For example, public warnings and information can vary among the state governments during food crises, and some states took different views on whether a product should be recalled. Finally, this industry representative noted that the EU's traceability requirements made firms more proactive in protecting their brand names.

Other Relevant Issues

Emerging trends and challenges. Officials we spoke with identified the following areas of concern with regard to ongoing and future challenges to the country's food safety system:

- Climate change may affect foodborne illness, in that illness can spread under new climatic conditions.
- New fungi, pathogens, and diseases will continue to emerge.
- Genetically modified organisms will continue to be developed, but there is zero tolerance for them in Germany.

Ireland's Food Safety System

Population and per capita GDP. In 2007, Ireland had a population of approximately 4.1 million, and in 2006 its estimated per capita GDP was US \$44,500.

Organization. Before Ireland reorganized its food safety system, about 50 different public agencies were in charge of food control, with little coordination among their activities. Responsibilities were shared between the Department of Agriculture and Food (now known as the Department of Agriculture, Fisheries, and Food—DAFF), the Department of Health and Children, 33 local authorities, 8 health boards, the Department for the Marine and the Department of Trade. With no central system of coordinating food safety control activities, there were overlaps and gaps in the functions of the different agencies. Some of the government

departments had dual roles of promoting the industry and overseeing food controls, raising conflict-of-interest concerns.

The Food Safety Authority of Ireland (FSAI) was created in 1998 to oversee the enforcement of food safety regulations. An independent, science-based body under the jurisdiction of the Minister for Health and Children, FSAI coordinates the enforcement of food regulations among various state agencies; sets food standards that are based on science and risk assessment; manages risk in association with other agencies and the Irish food sector; and communicates risks to consumers, public health professionals, and the food industry. It is the central competent authority for Ireland under EU legislation. FSAI has 87 employees who oversee a total of about 2,500 people working in 39 other government agencies as part of the integrated national system. (About 1,200 members of this workforce focus exclusively on food safety issues, while others, such as veterinarians, work only a few days per week on food safety matters.) Twenty-five staff work at the three Irish border inspection posts. In all, FSAI and its partner agencies oversee food safety in nearly 45,000 food establishments.

FSAI has service contracts with the 39 entities—such as DAFF, the Sea Fishery Protection Agency, the Health Service Executive, the National Standards Authority—to oversee specific elements of the system. For example, DAFF enforces food safety legislation for meat, milk, and egg products, and inspects live animals and products of animal origin coming through Ireland's three border inspection posts from non-EU countries, while the Health Service Executive inspect imports of food of nonanimal origin. Only specific products of nonanimal origin known to present a risk are restricted to specific points of entry. FSAI does not provide money to these government agencies for their work but instead establishes the terms of work, such as conducting a set number of inspections annually on the basis of the risk level of the food product. Each agency is audited to make sure it is carrying out its contractual obligations. FSAI's authority extends from the farm gate to the final consumer; its jurisdiction is only food safety, not on-farm hygiene or feed control. (The latter is overseen by DAFF, separately from the FSAI contract.)

FSAI is charged with investigating and managing food-related incidents in Ireland and is the country's point of contact for the EU's rapid alert system. In 2006, FSAI conducted 76 investigations related to food safety, 16 percent of which were related to microbial contamination.

One of the largest food recalls in Irish history took place in 2005, when FSAI oversaw the recall of 67 products contaminated with a chili powder containing carcinogenic industrial dye called Sudan Red 1 that was used as an ingredient in a variety of processed foods. The dye entered EU countries in ground or crushed chili imported from India; Ireland was notified by its counterpart in the UK, the Food Standards Agency, about the discovery in a primary ingredient used in the manufacture of other foods. FSAI then worked with official agencies and the food industry to ensure that all contaminated products were traced and removed from Irish retail stores. It advised consumers to either dispose of the product or return it to the store where it was purchased. FSAI also posted a list of the affected food products on its Web site.

Two other entities are of particular importance to the food safety system:

- The Health Service Executive, created in 2005, runs the health services in Ireland. It is also responsible for import controls on foods of nonanimal origin. Within the executive is the Health Protection Surveillance Centre (HPSC), which was established in 1998 to collect, interpret, and disseminate data on infectious disease and to provide data on foodborne illness to the relevant authorities.
- A Scientific Committee was established in 2000 to assist FSAI in assessing risk. The committee is made up of scientists from a variety of disciplines whose work for FSAI is voluntary. Among other things, the committee clarifies scientific and technical issues relating to food safety and hygiene. FSAI then manages risk on the basis of the committee's assessments.

Regulatory Framework

According to Irish officials, most of Ireland's food safety legislation comes from EU legislation, but some flexibility is allowed on how member states apply the food safety requirements within their national territory (in particular, for producers supplying small quantities of foods within their local areas). Ireland is examining the areas for which "national rules" can be applied to determine what national legislation should be introduced. Under consideration is the reintroduction of a national ban on the sale of raw milk in Ireland. In the area of labeling, Ireland has introduced national legislation that, according to Irish officials, requires all beef sold in Irish restaurants and catering outlets to include information on the country of origin. This would apply in addition to the EU beef labeling regulations.

Oversight of Imported Food

Import controls. Ireland's regulations are fully coordinated with the EU's. For a more detailed summary of the EU food safety requirements, see the EU profile.

Inspections. Ireland's regulations are fully coordinated with the EU's. See the EU profile.

Equivalency agreements/certification programs. Ireland's regulations are fully coordinated with the EU's. See the EU profile.

Foodborne Illness Outbreaks

Ireland applies veterinary inspection fees to importers. Fees currently charged contribute a small proportion of the total import control budget. According to an Irish official, as of April 2008, the fee structure was being reviewed to ensure that it aligns with the EU Food Hygiene legislation.

According to Irish sources, the most common gastroenteric pathogen in Ireland is *Campylobacter*, of which there were 1,815 cases in 2006—more than four times the number of *Salmonella* infections (422). Other sources of foodborne illness in Ireland in 2006 were *E. coli* (158 cases), *Listeria* (7 cases), and norovirus (1,639 cases).

Response. Outbreaks in Ireland are generally managed at the local level, but HPSC gets involved if there is a large national outbreak or an international outbreak affecting Ireland. If someone becomes ill with 1 of 67 diseases that must be reported to public health officials, the local public health authority is immediately notified, and a local environmental or public health officer interviews the patient about where he or she had been and what was eaten and forwards the information to HPSC.

To determine the cause of an outbreak, HPSC examines a sample of the pathogen to ascertain whether it is normally associated with food (microbiological evidence); determines whether other people have been afflicted by the same strain (epidemiological evidence); and looks at the hygiene of the food institution that produced the food (environmental evidence) if the source is thought to be food. If the foodborne illness appears to be an isolated case, no additional work is conducted. However, if a similar case occurs, samples of the bacteria are sent to reference laboratories for more precise typing.

HPSC uses a surveillance database, called the Computerized Infectious Diseases Reporting System, to combine and link epidemiological data from laboratories and hospitals so that all notifiable diseases can be tracked. The Health Service Executive (HPSC's parent organization)

notifies FSAI in the case of an outbreak and provides FSAI with information on the outcome of any investigations. It also shares these data with the European Centre for Disease Control in Stockholm. Irish officials told us the procedures they follow are generally similar to those followed by the U.S. Centers for Disease Control and Prevention for monitoring foodborne illness.

DAFF's Veterinary Research Laboratory Service also provides a range of services in relation to identifying and addressing zoonotic diseases. As part of this, the DAFF Central Veterinary Research Laboratory is the national reference laboratory for *Salmonella* and carries out typing of *Salmonella* samples from official control samples and from samples taken by food business operators of their own products.

International coordination. In the case of an outbreak, FSAI, as Ireland's competent authority, sends out the necessary data alerts to the public and follows up after the outbreak.

Recent incidents. Detailed information on recent outbreaks was not provided.

Efforts to Measure the Effectiveness of Food Safety Systems

An FSAI official told us that FSAI was working on a consolidated report on overall performance of the food safety system, but as of April 2008, the report was not available.

Performance measures. According to an Irish official, FSAI's service contracts require that inspection frequencies be risk-based, so FSAI can measure performance against these requirements.

Evaluations and audits. FSAI's audit and compliance unit periodically audits the work of all the contracted agencies to make sure they are meeting the terms of their contracts in such areas as the number of inspections and tests conducted, number of staff, and corrective actions to address previous audit findings (e.g., of food businesses or by the EU Food and Veterinary Office). Together, FSAI and the audited agency work to resolve any identified problems. If FSAI uncovers a problem with how an agency fulfills the terms of its contract, the two agencies meet to discuss it to prevent future occurrences. FSAI also monitors the contracts through regular reporting on inspection frequencies and outcomes and through food sampling and analysis.

If noncompliance with a service contract is found to be particularly egregious, FSAI could also report it to the head of an agency, but this has

not yet happened. In addition to FSAI audits, all of the agencies with service contracts to FSAI either have established—or will be establishing—internal audit systems, according to an Irish official.

If FSAI finds breaches in food businesses' implementation of the EU and Irish food law, FSAI and the official agencies can take legal action against the food business, which may result in fines, and in extreme cases, prison sentences, but issuing enforcement orders and subsequently “naming and shaming” on the FSAI Web site is FSAI's main compliance tool.

The EU's Food and Veterinary Office has also conducted a number of audits of various aspects of the Irish food safety system. Between 2001 and 2006, the office conducted 31 audits in Ireland on such topics as on-farm animal welfare, import controls and border inspection posts, and traceability of beef and beef products, among others. As part of its evaluations, the Food and Veterinary Office provided some recommendations for improvement in areas where it identified gaps. In 2005, for example, the office audited Irish import controls and border inspection posts. Auditors found that the import control system was well defined and generally applied in a uniform way in all the Irish border inspection posts, but on two occasions, implementation of certain EU legislation had been delayed. Major deficiencies identified in a 2003 audit had been for the most part corrected, with a few exceptions, according to the Food and Veterinary Office report. However, the office noted that Irish border inspection posts used a simplified customs clearance procedure for all consignments handled by customs agents that did not flag the need for veterinary checks required for products of animal origin. The Irish central competent authority for food safety follows up on any recommendations in Food and Veterinary Office reports to make sure that the corrective actions are taken.

Public opinion surveys. According to a 2005 Eurobarometer survey published in 2006, an estimated 67 percent of people in Ireland stated that overall, food safety had improved over the past decade, 14 percent that it had stayed about the same, 11 percent that it had worsened, and 8 percent did not know. In addition, an estimated 52 percent stated that usually public authorities' actions in the EU with regard to food safety risks are appropriate; 23 percent, that the actions are insufficient; 7 percent, that the actions go beyond what is needed; and 18 percent did not know. Finally, an estimated 65 percent agreed that food produced in the EU is safer than food imported from elsewhere, 13 percent disagreed, and 22 percent did not know.

Stakeholder perspectives. The views of stakeholders who interact frequently with FSAI and the agencies it oversees can also provide insight, albeit anecdotal, on the food safety system's effectiveness. In Ireland, we spoke with representatives of one industry and one consumer group. Representatives of the industry group said that the reorganization that created FSAI had a positive impact and that its new umbrella structure is working well. In particular, they believed that this structure opened lines of communication between government and industry. They also approved of the approach FSAI took a few years ago concerning a major recall of a chocolate product. Nonetheless, they expressed concern that FSAI has little authority over local inspectors and needs more control over the service contracts with the agencies it oversees. A representative of the consumer group stated that, overall, consumers have great respect for FSAI and that the hygiene of food production had improved with consolidation of the system a few years ago. However, this representative believes the government could do more to educate the public on food safety issues.

Other Relevant Issues

Emerging trends and challenges. Irish officials identified the following issues as areas of concern:

- Resources for the number of inspections required were limited, and inspectors were concerned that they must rely to a certain extent on statements by importers, which means there is potential for fraud in the system.
- The possible increased risk of botulism among migrant workers from Eastern Europe, who may import home-produced foods that are not transported under refrigerated conditions, is a concern.

Japan's Food Safety System

Population and per capita GDP. In 2007, Japan had an estimated population of 127.4 million, and in 2006 its per capita GDP was estimated to be US \$33,100.

Organization. Several food safety-related crises in the past decade, including outbreaks of *E. coli* and concern over the BSE crisis, drove Japan to comprehensively reform its food safety system. In 2003, Japan established the Food Safety Commission (FSC) as a cabinet-level agency responsible for conducting objective, neutral, scientific risk assessments related to food safety, including the use of food additives, pesticide residues, the presence of illness-causing bacteria, and other issues. FSC became a fully functioning, independent agency in 2005. Previously, the

two ministries primarily responsible for managing food safety—the Ministry of Agriculture, Forestry and Fisheries (MAFF) and the Ministry of Health, Labor and Welfare (MHLW)—conducted their own scientific risk assessments. FSC, MAFF, and MHLW are the three agencies responsible for food safety at the national level.

While FSC assesses risks, MHLW and MAFF are responsible for managing these risks. MHLW is responsible for setting standards for food processing and manufacturing and monitoring imported and domestic food throughout the supply chain. It also operates quarantine stations throughout Japan, which are responsible for ensuring the safety of food entering the country, as well as regional health centers, which are responsible for dealing with cases of foodborne illness. In 2007, MHLW employed 334 inspectors, up from 314 the previous year. MAFF is the ministry primarily responsible for setting regulations for food labeling, setting nutritional standards for food produced in Japan, establishing nutritional guidelines for the Japanese public, and ensuring Japanese agricultural products comply with the World Trade Organization's (WTO) Sanitary and Phytosanitary (SPS) Measures.

The National Institute of Infectious Diseases conducts research on contagious diseases. It serves as Japan's reference laboratory for infectious diseases and is responsible for collecting information on such diseases from the local public health centers. It also monitors incidents of infectious diseases around the country. In the event of an outbreak, the institute performs epidemiological investigations.

Oversight of Imported Food

Import controls. Japan imports about 60 percent of its food. It uses a risk-based approach in inspecting imported food entering the country and also emphasizes the role of the exporting country in ensuring the safety of the food it exports. MHLW produces an Annual Imported Foods Monitoring and Guidance Plan intended to promote intensive, effective, and efficient inspections of imported foods at the border and also provides guidance to importers. The plan also spells out the quantity and category of inspections to be conducted each year. In fiscal year 2007, for example, the goal was approximately 79,000 random inspections for 124 food groups. According to the plan, food safety should be secured by appropriate measures in every stage of the domestic and overseas food supply chain. On the basis of this principle, the plan lays out measures for ensuring the sanitation of food imports in three stages: (1) in the exporting countries, (2) at entry into Japan, and (3) through internal distribution.

Inspections. Thirty-one quarantine stations at ports of entry throughout Japan are responsible for inspecting food imports. They are primarily responsible for reviewing import notifications and certificates. Some quarantine stations house Imported Food Inspection Offices, which are responsible for conducting more advanced technical tests, such as microbiological sampling. In addition, two specialized stations are responsible for conducting the most technically complicated tests. Quarantine stations randomly select shipments for monitoring on a daily basis; such tests are paid for by the Japanese government. In fiscal year 2006, MHLW conducted nearly 80,000 random inspections and found 360 violations.

Port of entry inspections beyond routine document checks depend on a variety of factors: companies' past violations; whether Japan has certified the exporting companies; and information on exporting countries, including the types of agreements they have with Japan, resource materials, and manufacturing methods. Japan maintains this information in a national database. Additionally, Japan has specific concerns related to certain contaminants, such as aflatoxin and agro-chemicals. If an imported food belongs to a food group that is known to be at a higher risk for contamination (e.g., from a pathogen, pesticide residue, or animal drug), MHLW issues a Ministerial Inspection Order, which, according to Japanese sources, requires that products with a high violation probability be inspected at every time of importation (lot by lot). Japan prohibits the importation and distribution of products that fail to pass inspection; importers bear the cost of that inspection, and future inspections from that country are strengthened. In 2006, for example, Japan required compulsory testing of 100 percent of Vietnamese shrimp imports after inspectors repeatedly found chloramphenicol, a banned antibiotic, in shipments of Vietnamese shrimp. Moreover, according to the Imported Foods Monitoring and Guidance Plan for fiscal year 2007, if the number of imported foods from a specific country, area, or business entity violating the law is above 5 percent of the overall number of those inspected, and if it is likely that the importation of violating goods will continue, given conditions in the exporting country, MHLW may ban the importation of such goods altogether.

Testing under the Ministerial Inspection Order includes laboratory testing for pathogens, which the importing company pays for. Violation information is entered into the database the quarantine stations use in making future inspection decisions. If a violation is found under a Ministerial Inspection Order, the shipment may be recalled, disposed of, or shipped back to the exporter (at the expense of the importer in Japan).

The importing company is asked to investigate the cause of the violation, and before resuming importation must test a sample of the product. Companies with repeat violations will not be allowed to export to Japan, and the Japanese government publishes violations on its Web site. In fiscal year 2006, there were over 100,000 inspections conducted under the MHLW Ministerial Inspection Order, uncovering 681 violations. Overall, in 2006, Japan inspected 11 percent of declared products coming into its ports. (This figure includes both random inspections and Ministerial Inspection Order examinations.)

If MHLW believes that certain foods represent a particularly significant hazard, it can issue a comprehensive prohibition on the importation of those foods, which means that these high-risk items can be barred from Japan without even undergoing an inspection. According to an MHLW official, this type of prohibition has never been issued.

Japan also provides the option for first-time exporters to submit their products to voluntary inspections, giving these exporters an opportunity to demonstrate that their products pose a low health risk. Before sending the first shipment to Japan, these exporters send samples of their products to private Japanese companies approved by MHLW for testing and analysis. On the basis of the outcome of these preliminary tests, the exporter is either rejected or approved to proceed with the first shipment. If an exporter is approved and subsequently exports to Japan, the first shipment will be subject to routine random monitoring; if the exporter did not go through with voluntary inspection, the first shipment would be subject to a Ministerial Inspection Order.

Japan has also created a “Positive List” of substances that must be controlled in all imported foods stuffs.¹⁰ If an importer violates the positive list, MHLW will subsequently test 30 percent of all products coming to Japan from the violating country for 1 year. For a second violation, Japan imposes 100 percent “hold-and-test,” meaning that all goods from the violating country will be held and tested for 2 years and a minimum of 300 imports.

¹⁰The allowable residue of any chemical in a food commodity entering or produced in a country is known as the Maximum Residue Level (MRL) and is expressed in parts per million (ppm); in Japan, these MRLs are compiled into a master list called the Positive List. This is the list of allowable substances eligible for marketing in Japan. Foods containing residues exceeding the MRL levels on the positive list are prohibited from being sold or used as food in Japan.

In addition to government programs, there are Japanese private sector initiatives to help ensure food safety. For example, according to an official from the umbrella organization for the many private food cooperatives in Japan, all growers that supply products to co-ops are required to prove that they adhere to “Good Agricultural Practices,” as well as specific regulations of the co-op, such as those for pesticide usage. Co-ops have their own specifications—separate from the government—for acceptable materials, additives, and labeling requirements, including detailed nutritional information. Some growers also provide the co-ops with information about their products (e.g., location of farm, names of the farmers, types of pesticides used, dates of planting, dates of cultivation, dates of packaging and shipping). Consumers can then access this information using a cell phone to scan the barcode on the product packaging. The Japanese Consumers Cooperative Union also has its own programs to ensure the safety of imported foods that are independent of the government. For example, it conducts its own inspections of overseas firms from which it imports foods and tests incoming products twice a year.

As a result of a food safety scare in early 2008, when frozen dumplings imported from China were found to be contaminated with a dangerous level of pesticides, the Japanese government announced its plans to implement various new food safety measures in several areas, including (1) establishing a new consumer agency to oversee work currently being handled by multiple ministries, and (2) establishing a director-general position in the MHLW, MAFF, and other government bodies to oversee the distribution of information related to foodborne illness. In addition, public health centers will be required to be open 24 hours a day, and prefectural governments will be required to notify the health minister when there is a case of poisoning,¹¹ (3) increasing testing for all imported foods, with special attention to agriculture residues in processed foods, and (4) requiring stricter labeling requirements. At the time of our review, these measures had not yet become law.

Bilateral agreements/certification programs. According to Japanese sources, Japanese officials from MAFF and/or MHLW engage in bilateral talks with their counterparts in the exporting country to explain Japanese food sanitary regulations. If a country has no prior record of exporting

¹¹A prefecture in Japan is a subnational jurisdiction, a governmental body larger than a city, town, or village. Japan has 47 prefectures.

food to Japan, MHLW officials may conduct field surveys to determine whether a country's food safety system can meet Japanese food sanitary regulations and whether the exporting country's food safety regulations are comparable to Japan's. If Japan has found an exporting country's food safety system and food safety regulations satisfactory, and a new facility in that country seeks to export to Japan, MHLW officials may conduct a pre-export inspection of that facility. If the review is satisfactory, MHLW will issue a certificate to the exporter, copies of which must accompany every shipment of goods to Japan.

According to Japanese officials, under Japan's bilateral agreement with China to screen spinach imports, the Chinese government certifies Chinese spinach processors (exporters), who in turn oversee the practices of local farmers (including requiring them to, among other things, keep records on pesticide purchase and usage) and test the product at three stages of production. Chinese government authorities then conduct preshipment tests on the spinach before exporting, confirming that the exporter has observed the proper procedures on pesticide management. The spinach may be randomly inspected again once it arrives in Japanese ports. Chinese exporters of 19 other products, including tea leaves and frozen vegetables, are likewise required to register with the Chinese government, and blowfish and meat from China also require certification of processing. Japan has certification programs in place with other countries as well. For example, after concerns about high levels of antibiotics in Thai shrimp came to light, MHLW worked with the Thai government to identify shrimp exporters that were subsequently included on a "safe list" as being reliably able to comply with Japanese requirements for antibiotic levels.

Foodborne Illness Outbreaks

Response. MHLW operates a network of regional health centers in partnership with local governments, which are responsible for the day-to-day operation of the centers. In cases of foodborne illness, these centers work with hospitals to identify the cause and the source of contamination. They will notify MHLW only if the number of patients with the same symptoms exceeds 50. According to MHLW officials, the most recent outbreaks over the past 2 years have been confined to single prefectures. In these cases, MHLW coordinates the work of the participating groups (e.g., hospitals, health centers, and food manufacturers), oversees data collection, and communicates with the public. The Japanese government has mandatory recall authority for unsafe food products, but according to a Japanese official, it has rarely exercised this authority. Typically, the government (specifically, MHLW-run local health centers responsible for testing food that is suspected to be the source of an outbreak) will

Efforts to Measure the Effectiveness of the Food Safety System

“suggest” to companies that they recall their product. According to this official, if the government communicates in this way to a company, the company feels obliged to recall its products.

With regard to animal tracking, Japan has a mandatory system in which all beef and dairy cattle must be identified using an ear tag. Information is maintained on an animal’s ID number, breed, gender, and production history from the farm of origin through distribution to consumers.

Recent incidents. Japanese officials did not identify any major outbreaks of foodborne illness.

Performance measures. Japan does not have a systematic assessment mechanism in place to measure the effectiveness of its food safety system, and officials we contacted from the Board of Audit of Japan, GAO’s counterpart organization, told us that they had not referred to the Japanese food safety system in the annual audit report or other reports. (Each year the Board of Audit prepares an audit report showing the results of all audits conducted that year and sends it to the Cabinet with the audited final accounts of revenues and expenditures of the state. The Cabinet then submits both of them to the Diet. The Audit Report is used in the Diet (legislative) session for deliberation on the state’s final accounts and for future administration by the financial authorities.) However, Japanese officials indicated that some components of the system are subject to review under certain conditions.

Evaluations and audits. The FSC conducts investigations to ascertain whether its assessment results have been appropriately reflected in the food safety policies implemented by the risk management agencies (MHLW and MAFF). Also, according to FSC and MHLW officials, if there is a food safety-related emergency, such as a natural disaster that affects the food supply, bioterrorism, or an outbreak of foodborne illness, FSC is responsible for monitoring and reporting on how effectively MHLW handles the crisis. However, Japanese officials noted that such a scenario has not occurred, so no assessments had been conducted to date.

Public opinion survey. MAFF and FSC conduct public opinion surveys. A staff member from a Japanese nongovernmental organization told us that the August 2007 and February and March 2006 surveys conducted by MAFF indicate that consumers perceive imported foods in general to be unreliable and untrustworthy. A private organization, the Japanese Consumers Cooperative Union, also conducted some consumer surveys and noted that surveys from 2005 to the present have shown that the most

important consumer concerns are country of origin (for imported foods), the trustworthiness of all suppliers (domestic and foreign), and the overall quality of the product. Food additives are a major concern for consumers, as is pesticide residue on food. The surveys generally indicate that Japanese consumers are more concerned about food additives and chemicals than about microorganisms.

Stakeholder views. The perspectives of stakeholders can be useful in providing some insight into the effectiveness of a country's food safety system. In Japan, we spoke to representatives of two consumer organizations about their perceptions of the Japanese food safety system. Both individuals told us that the creation of the FSC has been a positive step, increasing transparency between government and stakeholders. One of these people told us that, previously, expert committee meetings within ministries were closed, but now they are open to the public, a change that is viewed as positive. A representative of the other consumer group stated that the government needs to improve its risk communication to the public; for example, many Japanese consumers are still highly suspicious of imported beef and do not fully understand the safety measures in place for beef.

Other Relevant Issues

Officials in Japan identified the following areas of concern with regard to ongoing and future challenges to the country's food safety system:

- Assessing the risks of chemical and food additives is a priority. At the time of our review, FSC was reviewing the potential public health risks of approximately 800 chemicals.
- Foodborne illness from *Campylobacter* has increased significantly in the last several years and is one of the most frequent sources of food contamination. In response to this, FSC has initiated risk assessments relating to microorganism contamination of food, starting with *Campylobacter*.
- The volume of international food trade is growing, and imported food is increasingly harder to track.
- Human/animal interactions are changing, with potential for disease transmission, including *E. coli* and prions (which are involved in BSE).

The Netherlands Food Safety System

Population and per capita GDP. In 2007, the Netherlands had a population of approximately 16.6 million, and in 2006 its estimated per capita GDP was US \$32,100.

Organization. In response to public concern about food safety stemming from the dioxin contamination of animal feed, the BSE crisis, and other animal diseases, as well as the EU's proposed food safety legislation, the Netherlands created the Food and Consumer Product Safety Authority (VWA) in July 2002. Consumers, parliament, and interest groups had demanded a single powerful organization to investigate and monitor food and product safety. Two organizations, the Inspectorate for Health Protection and Veterinary Public Health and the National Inspection Service for Livestock and Meat were combined into one agency under VWA as of January 1, 2006.

VWA, an independent agency in the Ministry of Agriculture, Nature, and Food Quality, is responsible for assessing and communicating risk and managing food safety incidents. It monitors food and consumer products to safeguard public health and animal health and welfare. It also enforces food-related legislation, coordinates inspection activities throughout the country, and conducts research; each of VWA's five regional divisions has its own laboratory to carry out routine microbiological and chemical analyses for food safety controls. One of VWA's regional departments (southwest) is in charge of managing the Netherlands' seven border inspection posts and overseeing imports of foods of animal origin. VWA inspectors work with Dutch customs agents, who carry out documentary checks on imports. VWA is also the contact point for the EU's Rapid Alert System for Food and Feed and for the EU Food and Veterinary Office. In 2006, VWA had a total of 1,750 employees. (The previous year, it had transferred its meat inspectors to private bodies.)

The National Institute for Public Health and the Environment (RIVM) is a government research institute that conducts research on public health (infectious diseases, care, prevention, and food safety), medicines, nutrition, and the environment for VWA, as well as for a number of other inspection services and Dutch ministries. RIVM assists VWA and the Dutch government in developing food safety policy and conducts formal risk assessments for VWA. The formal risk assessments are commissioned through VWA's Office of Risk Assessment, to which the results are reported. VWA then advises the inspectorate and/or the ministries. RIVM houses several of the Dutch national reference laboratories as well as both the Dutch and EU community reference laboratories (on *Salmonella* and on residues). The institute also collaborates closely with the Dutch

Central Veterinary Institute (part of Wageningen University and Research Centre) on issues related to zoonotic diseases and animal food products. RIVM's Centre for Infectious Disease Control, established in 2005, conducts surveillance on infectious diseases; collects data on health, illness, and disease; and provides early warnings on threats to public health.

The RIKILT Institute for Food Safety (RIKILT), part of Wageningen University and Research Center, is a private research organization that also performs research for the Dutch government on food and feed. It is a reference laboratory for pesticide and veterinary residues, feedstuffs, and genetically modified organism analyses. RIVM is responsible for conducting risk analysis for food (fork), while RIKILT is responsible for assessing feed and food quality (farm). RIVM, RIKILT, and the Central Veterinary Institute are "house institutes" of VWA. They all assist VWA and the Dutch government in developing food safety policy and conduct formal risk assessments commissioned by VWA's Office of Risk Assessment.

Meat inspection in the Netherlands is conducted by official veterinarians, who are employed by VWA either as permanent staff or as staff hired on a temporary basis. In the past, their assistants were employed by VWA as well, but these posts were privatized a few years ago. However, because these assistants work under the oversight of official veterinarians, meat inspection in the Netherlands is still in public hands.

Oversight of Imported Food

Import controls. The Netherlands' regulations are fully harmonized with the EU's. For a more detailed summary of the EU food safety requirements, see the EU profile.

Inspections. See the EU profile.

VWA's annual budget is about 165 million euros, with 40 million to 43 million euros paid by producing companies and 5 to 6 million euros from import control fees based on usage. The port of Rotterdam is the largest port in Europe and one of the largest in the world. The money Dutch customs officials receive from the EU's import tax is sent to the EU treasurer in Brussels after the Netherlands deducts 10 percent, which is the fee for administering the Dutch ports. (EU member states are required to give a certain percentage of their GDP to the EU, so any additional costs on import controls not covered by fees can be deducted from their annual payment to the EU).

Equivalency agreements/certification programs. See the EU profile.

In addition to government initiatives, a Dutch official told us that some private companies have programs in place to promote food safety. KLM airlines, for example, has a program called “OK to Forward” to conduct document checks before a company ships certain live animal products and before KLM accepts these products on its airplanes. This is an additional quality control and assurance procedure put in place to prevent problems at the port of entry.

Foodborne Illness Outbreaks

Campylobacter is the most frequent cause of gastroenteritis in the Netherlands. In 2006, there were 3,401 confirmed cases. In 2006, there were 1,667 confirmed cases of *Salmonella*. (Dutch epidemiological studies indicate that if unconfirmed cases were included, the number would likely be much higher). There were 69 reported cases of *Listeria*. According to Dutch sources, *E. coli* has been comparatively rare in the Netherlands, with 78 cases reported in 2004.

Response. Any instance of foodborne illness is first reported to VWA through local public health services, which are responsible for controlling the illness. If more than one local public health service is involved, RIVM’s Preparedness and Response Unit, a branch of the Centre for Infectious Disease Control, takes charge of control activities. VWA and the regional public health laboratories may become involved in investigating samples. Moreover, at VWA’s request, RIVM provides epidemiological resources to assist in tracing the illness. A committee for managing the crisis, called the outbreak management team, is also set up to bring all knowledge together to get the best possible advice. The Ministry of Agriculture takes the lead during a crisis related to contaminated food or animal products, but if a person is infected with a pathogen, the Dutch Ministry of Public Health takes over because it is then considered a public health issue. (Two persons infected with the same strain of a pathogen is considered an outbreak in the Netherlands). However, if there is a large and widespread epidemic, the Ministry of Internal Affairs will take over.

Dutch officials told us that on the public health side, their procedures for addressing foodborne illness outbreaks are similar to those followed in the United States by the Centers for Disease Control and Prevention for identifying pathogens and tracking diseases. However, they noted that there is greater integration of veterinary and public health in the Netherlands.

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VWA has mandatory recall authority under EU legislation, but it has not used this authority very often. According to Dutch officials, when a recall is needed, VWA will first ask the affected company to recall the product by putting information in the newspaper, and the company is subsequently held accountable if there are any further issues with its product.

International coordination. In the event of an outbreak, VWA would send out notifications to other EU member states using the Rapid Alert System for Food and Feed. In 2006, the Netherlands issued 55 rapid alert notifications, including 1 related to microbial contamination and 3 related to potentially pathogenic microorganisms. RIVM is very involved in the networks of the European Food Safety Authority and the European Centre for Disease Control. In addition, RIVM reports results of the Dutch human laboratory surveillance for *Salmonella*, *Campylobacter*, and *E. coli* on a monthly basis to the EU network, Enter-net.

Recent incidents. No information on recent outbreaks was provided.

At the time of our review, the Dutch government had not formally evaluated its reorganized food safety system.

Performance measures. Indicators tracked by VWA include the number of inspections conducted, samples inspected, EU approvals in the livestock and meat sector, international notifications of potential risk, and written warnings issued. Of the approximately 145,000 inspections conducted in 2005, the greatest number were in the area of meat and fish.

Evaluations and audits. Although there had been no formal evaluations of the impact of consolidation on the Dutch food safety system at the time of our review, the EU Food and Veterinary Office had conducted 45 audits of certain aspects of the Dutch food safety system between 2001 and 2007. For example, in March 2006, the office audited the Netherlands' import control system for products of animal origin and live animals and the application of import requirements in two border inspection posts. It found that overall the Netherlands has a well-organized system that complies with EU requirements, as well as good cooperation between veterinary services and customs. However, the Food and Veterinary Office also found that the EU requirement that the border inspection post and its inspection centers be in the same customs-designated area was not applied at the Rotterdam post, and that even though the movement of consignments to the inspection centers is controlled using a customs transit procedure, this procedure was not in conformance with EU legislation or consistent with practices at other large EU border inspection

posts. Furthermore, the Food and Veterinary Office noted some shortcomings with respect to supervising the destruction of confiscated illegal imports of certain products of animal origin.

Public opinion surveys. According to VWA, public confidence in food safety is the highest in Europe, at 80 percent. Moreover, according to a 2005 Eurobarometer survey published in 2006, an estimated 52 percent of people in the Netherlands stated that overall, food safety had improved over the past decade, 33 percent that it had stayed about the same, and 12 percent that it had worsened; 4 percent did not know. In addition, an estimated 53 percent stated that usually public authorities' actions in the EU with regard to food safety risks were appropriate, 22 percent that the actions were insufficient, and 17 percent that the actions went beyond what is needed; 7 percent did not know. Finally, an estimated 57 percent agreed that food produced in the EU was safer than food imported from elsewhere, 34 percent disagreed, and 10 percent did not know.

Stakeholder perspectives. The views of stakeholders who interact frequently with government food safety bodies can also provide qualitative insight, albeit anecdotal, on the effectiveness of a country's food safety system. In the Netherlands, we spoke to representatives of one consumer organization and one product board, which is a government-authorized trade association. A representative of the consumer organization stated that VWA and RIVM responded well in 2005 to the Sudan Red 1 incident, in which an industrial dye was found in certain imported food products. During the outbreak, communication to the public, facilitated by VWA, was quite good. However, this person also said that it is sometimes difficult to know who takes the lead for communicating with the public during a food safety crisis—it can be VWA, RIVM, the Ministry of Agriculture, or the Ministry of Public Health. In this person's view, government communication during a crisis could be improved, and there should be a designated point of contact for providing information during a crisis. The industry representative told us that a 2006 reorganization of VWA that moved meat inspectors out of VWA and into private, accredited inspection firms that VWA audits has been successful, in that "people with the right qualifications are doing their job well."

Other Relevant Issues

According to VWA documents, the agency is concerned with the following ongoing and future challenges to the country's food safety system:

- climate change, including the potential for new foodborne viruses, mycotoxins (molds), new pathogens, and new plants and insects that can lead to threats to the food chain;

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- demographic change, such as immigration, and the impact of age on risks (children and the elderly tend to be more susceptible to illness than others);
 - sociocultural trends, including changes in lifestyle and behavior and the segmentation of society;
 - globalization (large-scale movements of humans, animals, and goods increase the risk of the introduction and rapid spread of pathogens); and
 - changes in production and processing based on new technologies, such as nanotechnology, genetically modified organisms, and decontamination technologies.

The UK's Food Safety System

Population and per capita GDP. In 2007, the United Kingdom (UK), consisting of England, Northern Ireland, Scotland, and Wales, had an estimated population of about 61 million, and its estimated per capita GDP in 2006 was US \$31,800.

Organization. The Food Standards Agency (FSA) was created in 1999 as the lead food safety body. Prior to this, food safety responsibilities were divided among several central government departments, such as the Ministry of Agriculture, Fisheries, and Food and the Ministry of Health, as well as local authorities. FSA was founded in response to (1) the loss of public confidence in the government's handling of food safety issues, such as BSE and *Salmonella* in egg products; and (2) perceived conflict of interest in the Ministry of Agriculture, Fisheries, and Food, which also promoted UK agriculture. FSA is responsible for developing and implementing food laws in the UK and is the UK's competent authority for EU food and feed legislation. FSA also conducts scientific research to guide the implementation of its key responsibilities and conducts surveys on nutrition and diet to document changes in eating habits. It is the main UK body in charge of assessing the risk of food. The agency employs about 2,350 staff, including 1,600 inspectors in the Meat Hygiene Service, an executive agency within FSA that inspects premises where fresh meat is processed. According to FSA officials, the focus of the agency's inspections is on processes. For example, farmers are to employ HACCP measures to ensure food safety.

Another independent government agency, the Health Protection Agency (HPA) was established in 2005 following reorganization of the UK's public health laboratory system. HPA is an "arm's length body," independent of

government. It is responsible for managing infectious diseases, disease outbreaks, radiological health, and emergency planning. If a foodborne illness outbreak covers a wide area, HPA initiates investigations to determine the contaminant and identify the source and provides information to FSA to manage risk. HPA has a network of approximately 3,000 staff at three major centers and smaller regional and local centers throughout England and works with locally based colleagues in Northern Ireland, Scotland, and Wales. It also has a central office based in London. The infectious disease side of HPA is divided into three areas of responsibility: the Centre for Infections, based at Colindale, in north London, the laboratory and epidemiological center for characterizing disease strains and for coordinating national epidemiological investigations; Local and Regional Services, which coordinates outbreak investigations at the local level; and the Regional Microbiology Network, which is the laboratory equivalent of Local and Regional Service and is the frontline service for identifying the causes of disease.

Other key agencies in the UK's food safety system include the following:

- Department for Environment, Food, and Rural Affairs, which manages animal health and welfare and plant issues, including imports from non-EU countries for products of animal origin.
- Veterinary Laboratories Agency, a regional network of 16 laboratories under the Department of Environment, Food, and Rural Affairs that are responsible for veterinary research, disease surveillance, and diagnostic services.
- Animal Health, which is responsible for operating the UK's 23 border inspection posts for products of animal origin and live animals. Animal Health is responsible for ensuring that these posts meet the required standards and that veterinary checks are correctly and consistently implemented across the UK.
- Her Majesty's Revenue and Customs oversees customs procedures to import goods and releases consignments after Animal Health and other requirements have been met.
- Local authorities (district and county authorities) that enforce legislation on imported food. There are a total of 468 local authorities in the UK.

Some private sector industry organizations in the UK also participate in voluntary food safety efforts. For example, according to a UK industry representative, the Assured Food Standards Association sets voluntary standards for industry on agricultural products. That is, it provides guidance for primary producers growing vegetables or raising animals for meat. The British Retail Consortium, a trade association, offers HACCP-based certification for processed foods. In addition, an association for smaller producers, called SALSA (Safe Food for Local Suppliers Association), is a membership organization made up of the National Farmers Union and other agriculture-related nongovernmental organizations that tries to improve small-scale production processes.

Oversight of Imported Food

Import controls. The UK's regulations are fully coordinated with the EU's. For a more detailed summary of the EU food safety requirements, see the EU profile.

Inspections. The UK's procedures for inspections are fully coordinated with the EU's. See the EU profile for more detail.

Equivalency agreements/certification programs. See the EU profile for more detail.

According to a UK official, EU legislation is implemented through the UK's food safety laws, for example, by implementing additional EU import control measures where there is a serious risk to public or animal health.

Foodborne Illness Outbreaks

According to HPA data, *Campylobacter* is the most commonly reported bacterial cause of infectious intestinal disease in England and Wales. In 2006, there were 46,603 reports of *Campylobacter*, 12,633 reports of *Salmonella*, and 1,003 reports of *E. coli* O157.¹²

Response. An outbreak of foodborne illness is defined in the UK as either two or more linked cases of the same disease or when the observed number of cases unaccountably exceeds the expected number. General medical practitioners are required to notify the local authority—usually the Consultant in Communicable Disease Control, who is now a member of the Local and Regional Services Directorate of the HPA—of cases or

¹²This paragraph refers to *reports* rather than *cases* because, according to UK officials, for every case of *Salmonella* reported nationally, there are about three other cases in the community. For *Campylobacter*, the multiplier is about 10, and for *E. coli* O157, it is about 2.

suspected cases of food poisoning. These consultants are asked to report outbreaks through HPA's central reporting system. In cases of an outbreak extending beyond a local area, or in the event of serious localized outbreaks, the environmental health officers of the local authority are required to inform the FSA.

Routine surveillance can help detect outbreaks, and the HPA has established a baseline for the expected number of cases of infection that generally occur at any given time. (All reports for a current week are compared with reports from the past 5 years to see if there are any exceedances of the baseline.) If HPA's reference laboratories determine that the total numbers of laboratory-confirmed cases have exceeded this baseline, they notify FSA. The Veterinary Laboratories Agency may provide assistance to outbreak control teams if a direct or indirect animal source is implicated in outbreaks of intestinal (or other zoonotic) diseases and where veterinary investigation or intervention could help reduce risks to the public. The agency may (1) conduct animal sampling for laboratory cultures, (2) help in identifying management and animal care factors that may have a bearing on human health risks, and (3) provide veterinary epidemiological input, such as data reports of *Salmonella* strains from farm animal surveillance. Strains of animal origin can also be selected for further identification and comparison with human strains. The HPA and the Veterinary Laboratories Agency work very closely in the investigation of outbreaks of food poisoning related to food production animals and have in place standardized laboratory and epidemiological methods for strain characterization and outbreak investigation. In addition, the HPA's Centre for Infections and the Veterinary Laboratories Agency support a joint post targeted at the further standardization of laboratory methods and the harmonization of databases.

UK officials told us that in many ways, their procedures for addressing the public health aspects of foodborne illness outbreaks are similar to those followed by the U.S. Centers for Disease Control and Prevention, except that the UK reference and veterinary laboratory systems are more centralized than in the U.S. system. The UK officials also believed that the particularly close working relationship between the HPA and the Veterinary Laboratories Agency is different from the U.S. system and has proven useful in addressing foodborne illness outbreaks. Moreover, the close working relationship between the HPA's gastroenteric and epidemiological teams has also been beneficial during outbreaks.

When an outbreak occurs in the UK, an outbreak control team investigates the incident. The team consists of a consultant on communicable disease

control, an environmental health officer, and a consulting microbiologist. Depending on the size and nature of the incident, other individuals, such as representatives of the FSA, the Meat Hygiene Service, the Veterinary Laboratories Agency, a consultant in infectious diseases, a toxicologist, a food examiner/microbiologist, and others, may also become involved. The team follows an outbreak control plan that describes, among other things, the roles and responsibilities of each team member and information on arrangements for care of patients and for media liaison.

During an outbreak, FSA works with the local authority in charge of the affected food producers, industry, and other government agencies and departments to determine an appropriate risk management strategy. FSA can also issue a food alert to local authorities who enforce the law, and it publishes these alerts on its Web site. It can force the producer to recall the product, although FSA officials said they have rarely used their recall authority, because it is the food business operator's responsibility to ensure the safety of the food the operator places on the market, and it is usually the operator who takes action to recall unsafe food. In 2006, FSA dealt with a total of 1,342 food safety-related incidents, including 146 related to microbial contamination. Ten (about 1 percent) of the incidents addressed in 2006 were classified as high risk, that is, they had the potential to cause death or serious illness; they were complex (affecting a large number of products or required a high level of resources to manage); and/or they were widespread and likely to generate a high level of public concern.

International coordination. As the designated UK point of contact for the EU's rapid alert system, FSA notifies other EU member nations about food problems it has identified. HPA coordinates with its European counterparts using an EU database called Enter-net; this database makes it possible for scientists to track pathogen strains throughout Europe.

Recent incidents. In 2006, there was a major outbreak of *Salmonella* in chocolate products produced by Cadbury Schweppes, a large British candy manufacturer. Although no one died from the outbreak, over 130 people—mainly children—became ill. According to HPA officials, the incident came to light when, during routine surveillance, HPA discovered an increase in exceedances of the baseline level of *Salmonella* and determined that it was witnessing a major outbreak of *Salmonella* Montevideo, a rare strain of the *Salmonella* bacterium. A private food laboratory sent the HPA some *Salmonella* samples for identification. According to HPA sources, HPA scientists used a range of analytical techniques to trace the bacteria to Cadbury's chocolate products. They

then notified FSA, and an outbreak control team was assembled, consisting of representatives from HPA, FSA, other government departments, and local authorities. To determine whether the outbreak had extended beyond the UK, HPA electronically transmitted a molecular profile of the outbreak strain to over 50 countries 2 days after recognition of the outbreak. (This electronic transmission was done through the EU-funded Enter-net network for the surveillance of *Salmonella*, Verocytotoxin-producing *E. coli*,¹³ and *Campylobacter*.¹⁴) For its part, FSA used the EU's rapid alert system to communicate the distribution information of affected products outside the UK. HPA scientists also communicated with their Veterinary Laboratories Agency counterparts, who found the same *Salmonella* strains in poultry. Local authorities determined that a leaking pipe had dripped *Salmonella*-contaminated water into the candy manufacturer's products. No direct connection to poultry was found, but the laboratory findings strongly suggested that the animal source of the contaminating strain was poultry. Following identification of the outbreak in children, the time between the initiation of laboratory studies and withdrawal of the product was 8 or 9 days. In all, the bacteria had contaminated 30 different Cadbury products; over 1 million chocolate bars were removed from the market at a cost of over £30 million (about \$60 million).

According to HPA officials, the established interactions between the HPA and the Veterinary Laboratories Agency, including standardized methods of strain typing and rapid communication of epidemiological findings (such as those described above) facilitated investigations to determine the animal source of the contaminating strain. HPA officials told us that such communications have been useful in several other outbreaks, including, for example, the investigation and containment of a 2004 outbreak of multiple antibiotic-resistant *Salmonella* Paratyphi B variant Java among cattle on an English farm. Rapid communication of typing results and epidemiological information between the HPA and the Veterinary

¹³Some forms of *E. coli* bacteria can produce toxins capable of killing a special type of cell called a Vero cell. These *E. coli* have thus become known as verotoxin or verocytotoxin-producing *E. coli* (VTEC).

¹⁴At the time of the outbreak the epidemiological and laboratory hub of Enter-net was based in the Department of Gastrointestinal Infections of the HPA, at the Centre for Infections, Colindale. In September 2007, Enter-net was subsumed into the newly formed European Centre for Disease Control, based in Stockholm, Sweden. Although not a member of Enter-net, the United States is party to all Enter-net communications regarding outbreaks and strain typing.

Efforts to Measure the Effectiveness of the Food Safety System

Laboratories Agency resulted in containment of the outbreak before it could spread to humans. According to HPA, there are numerous examples of similar collaborative activities between the HPA and the Veterinary Laboratories Agency involving both *Salmonella* and Verocytotoxin-producing *E. coli*, with typing and epidemiological data being exchanged on an almost daily basis. The reporting of outbreaks to the HPA is done on a voluntary basis. There is no lower size limit on the number of cases affected for a report to be generated; HPA would follow up on single cases of severe diseases, such as botulism or listeriosis.

At the time of our review, the UK had not conducted a review of its reorganized food safety system. However, FSA, the UK's National Audit Office (the UK equivalent of GAO), and the EU's Food and Veterinary Office have reviewed individual aspects of the system.

Performance measures. Performance measures for FSA include the number of illness reported and consumer surveys on food safety issues. For example, FSA reported in 2006 that incidents of foodborne illness declined by 19.2 percent between 2001 and 2006. According to FSA statistics, this reduction equates to 1.5 million fewer people suffering from foodborne illness, 10,000 fewer in the hospital as a result of this illness, and an estimated total cost savings of more than \$750 million (nearly U.S. \$1.5 billion). FSA staff attributed this decline to, among other things, (1) an ongoing decline in *Salmonella* incidences as a result of efforts in the farming industry to reduce contamination of eggs, including improved biosecurity measures and vaccination of laying hens, and (2) measures undertaken to keep slaughterhouses clean and reduce cross-contamination. For example, HACCP measures were introduced in slaughterhouses, and new, clean henhouses were being used on many farms; and (3) FSA made efforts to educate the public on preventing *Campylobacter* contamination.

Evaluations and audits. The UK's National Audit Office, GAO's counterpart in the UK, conducted an audit of FSA in 2003 and found that the agency had made progress in its stated objective of improving public confidence in food safety and standards. For example, according to the office, in 2001 and 2002 the FSA investigated about 500 incidents with the potential to affect food safety. FSA issued 47 Food Hazard Warnings to local authorities, alerting them to potential health dangers or requiring them to recall food from sale. The audit office also made some recommendations for further progress.

More recently, the National Audit Office assessed the extent to which FSA implemented a set of principles, referred to as the Hampton principles, that include the following:

- Regulators, and the regulatory system as a whole, should use comprehensive risk assessment to concentrate resources on the areas that need them most.
- No inspection should take place without a reason.
- Regulators should provide authoritative, accessible advice easily and cheaply.
- All regulations should be written so that they are easily understood, easily implemented, and easily enforced, and all interested parties should be consulted when they are being drafted.

The National Audit Office review team concluded that, in many respects, FSA regulated in accordance with the Hampton principles. The office rated FSA highly on adopting innovative alternatives to classic regulation and on having an evidence-based culture. Many positive initiatives were being undertaken by FSA in its risk assessment system. Areas to develop further included developing more of a strategic partnership with local authorities and providing better advice and guidance to small businesses. Overall, the National Audit Office found that FSA was continuing to improve its performance from an already strong base.

After the 2005 Sudan Red 1 incident in which illegal dye was found in food, FSA conducted an internal review of the lessons learned. In January 2007 the FSA Board established an independent panel to review the lessons learned following the incident, what changes had been introduced as a result, and how well different parts of the food chain, including manufacturers, retailers, enforcement authorities, and FSA, are able to identify emerging issues and prevent them from developing into food incidents in future. The board made recommendations to both FSA and industry. Among other things, it recommended that FSA take a central role in ensuring more coordinated attention to intelligence gathering and implementing early warning systems, as well as proactively sharing this information with the food industry.

In addition to reviews conducted by UK agencies, the EU's Food and Veterinary Office conducted 71 audits in the UK between 2001 and 2007 and provided recommendations for corrective measures in certain areas.

For example, a 2006 report on import controls and border inspections found a largely functioning import control system in place, but also found that there were some weaknesses, such as in implementing a training program for contract/part-time officials. In addition, it found some general shortcomings related to implementation of the border control system, such as not all live animals arriving at the border inspection posts were checked as required, and veterinary checks on some species were being carried out by technical staff instead of by official veterinarians. Other Food and Veterinary Office audits have included reviews of import controls on food of animal origin, animal welfare on farms, and foot-and-mouth disease.

Public opinion surveys. FSA annual consumer surveys between 2001 and 2007 show a marked decline in the public's concerns about foodborne illness, from 71 percent to 57 percent. FSA surveys also indicated that public trust in FSA was an estimated 60 percent in 2007, compared with 44 percent in 2001. The survey likewise found that FSA was seen as a reliable source of information for both food safety and healthy eating by the majority of those who use it, although it was used and considered reliable more for food safety than for healthy eating.

According to a 2005 Eurobarometer survey published in 2006, an estimated 47 percent of people in the UK stated that overall, food safety had improved over the past decade, 30 percent that it had stayed about the same, 17 percent that it had worsened, and 6 percent did not know. In addition, an estimated 50 percent stated that usually public authorities' actions in the EU with regard to food safety risks were appropriate, 24 percent stated that the actions were insufficient, 12 percent stated that the actions went beyond what is needed, and 13 percent did not know. Finally, an estimated 47 percent agreed that food produced in the EU is safer than food imported from elsewhere, 32 percent disagreed, and 21 percent did not know.

Stakeholder perspectives. The views of industry and consumer groups can serve as an informal indicator of the effectiveness of a country's food safety system. In the UK, we spoke to representatives of two industry organizations. A representative of one such organization stated that he thought consolidation of the UK's food safety system had resulted in improvements; a representative from another organization said that FSA listens more to industry concerns now. According to one representative, FSA is now more transparent to industry, and it is easier to consult with the agency on issues of concern. Nevertheless, this person believed that

Other Relevant Issues

FSA could do a better job of sharing information. Another industry stakeholder noted that FSA acted “disproportionately” to a recent recall.

Emerging trends and challenges. Officials we spoke with identified the following areas of concern with regard to ongoing and future challenges to the country’s food safety system:

- Pathogens continue to evolve.
- People are changing the types of foods they eat and the ways they prepare them.
- More people are eating out, and food preparation in small restaurants and by caterers carries more risk.
- Demographic changes mean that there are and will continue to be more elderly people in the UK, and these people tend to be more vulnerable to foodborne illness than others.
- There is an ever-increasing international market for foods, particularly produce. Although only a very small proportion of such foods is contaminated with an organism capable of causing disease, the scale of food importation, particularly from countries where standards are not as stringent as in the UK, has resulted in an increasing number of international outbreaks. Such outbreaks have been regularly identified by the Enter-net network, and international intervention measures have been introduced on numerous occasions.
- Incidences of foodborne illness caused by *E.coli* or *Campylobacter* have continued to increase at a steady rate in 2006. Scientists’ understanding of *Campylobacter* is still limited because it generally occurs in isolated incidents (i.e., it is not an “outbreak” bacterium) and is therefore more difficult to study.
- Listeriosis, especially in older people, seems to be increasing, not just in the UK but around the world. The reason for this increase is unclear and is likely to reflect multiple factors, including perhaps the fact that a warmer climate enables *Listeria* to thrive.
- Many immigrants, both from other EU member states and from non-EU countries, bring home-prepared foods into the UK from overseas. If improperly prepared or preserved, these foods may cause illness.

Appendix II: GAO Contact and Staff Acknowledgments

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Staff Acknowledgments

In addition to the individual named above, José Alfredo Gómez, Assistant Director; Anne Johnson, Analyst-in-Charge; Bart Fischer; Jeremy Rothgerber; Carol Herrnsstadt Shulman; and Rebecca Yurman made key contributions to this report. Important contributions were also made by Kevin Bray and Michele Fejfar.

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