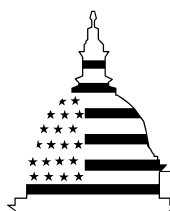


February 2005

FOOD SAFETY

Experiences of Seven Countries in Consolidating Their Food Safety Systems



G A O

Accountability ★ Integrity ★ Reliability



Highlights of [GAO-05-212](#), a report to congressional requesters

Why GAO Did This Study

The safety and quality of the U.S. food supply are governed by a complex system that is administered by 15 agencies. The U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA), within the Department of Health and Human Services (HHS), have primary responsibility for food safety. Many legislative proposals have been made to consolidate the U.S. food safety system, but to date no other action has been taken. Several countries have taken steps to streamline and consolidate their food safety systems. In 1999, we reported on the initial experiences of four of these countries—Canada, Denmark, Ireland, and the United Kingdom. Since then, additional countries, including Germany, the Netherlands, and New Zealand, have undertaken consolidations.

This report describes the approaches and challenges these countries faced in consolidating food safety functions, including the benefits and costs cited by government officials and other stakeholders. In commenting on a draft of this report, HHS and USDA said that the countries' consolidation experiences have limited applicability to the U.S. food safety system because the countries are much smaller than the United States. The two agencies believe that they are working together effectively to ensure the safety of the food supply.

www.gao.gov/cgi-bin/getrpt?GAO-05-212.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Robert A. Robinson at (202) 512-3841 or robinsonr@gao.gov.

FOOD SAFETY

Experiences of Seven Countries in Consolidating Their Food Safety Systems

What GAO Found

In consolidating their food safety systems, the seven countries we examined—Canada, Denmark, Germany, Ireland, the Netherlands, New Zealand, and the United Kingdom—varied in their approaches and the extent to which they consolidated. However, the countries' approaches were similar in one respect—each established a single agency to lead food safety management or enforcement of food safety legislation. These countries had two primary reasons for consolidating their food safety systems—public concern about the safety of the food supply and the need to improve program effectiveness and efficiency. Countries faced challenges in (1) deciding whether to place the agency within the existing health or agriculture ministry or establish it as a stand-alone agency while also determining what responsibilities the new agency would have and (2) helping employees adjust to the new agency's culture and support its priorities.

Although none of the countries has analyzed the results of its consolidation, government officials consistently stated that the net effect of their country's consolidation has been or will likely be beneficial. Officials in most countries stated their new food safety agencies incurred consolidation start-up costs. However, in each country, government officials believe that consolidation costs have been or will likely be exceeded by the benefits. These officials and food industry and consumer stakeholders cited significant qualitative improvements in the effectiveness or efficiency of their food safety systems. These improvements include less overlap in inspections, greater clarity in responsibilities, and more consistent or timely enforcement of food safety laws and regulations. In addition to these qualitative benefits, officials from three countries, Canada, Denmark, and the Netherlands, identified areas where they believe financial savings may be achieved as a result of consolidation. For example, in the Netherlands officials said that reduced duplication in food safety inspections would likely result in decreased food safety spending and that they anticipate savings from an expected 25 percent reduction in administrative and management personnel.

Although the seven countries we reviewed are much smaller than the United States, they are also high-income countries where consumers have very high expectations for food safety. Consequently, we believe that the countries' experiences in consolidating food safety systems can offer useful information to U.S. policymakers.

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Abbreviations

AMS	Agricultural Marketing Service
APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
BSE	bovine spongiform encephalopathy
CDC	Centers for Disease Control and Prevention
CFIA	Canadian Food Inspection Agency
DVFA	Danish Veterinary and Food Administration
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
EU	European Union
FDA	Food and Drug Administration
FSA	Food Standards Agency
FSAI	Food Safety Authority of Ireland
FSIS	Food Safety and Inspection Service
GDP	gross domestic product
HHS	U.S. Department of Health and Human Services
KvW	Inspectorate for Health Protection and Veterinary Public Health
NMFS	National Marine Fisheries Service
NZFSA	New Zealand Food Safety Agency
RVV	National Inspection Service for Livestock and Meat
USDA	U.S. Department of Agriculture
VWA	The Food and Consumer Product Safety Authority

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United States Government Accountability Office
Washington, D.C. 20548

February 22, 2005

The Honorable George V. Voinovich
Chairman
The Honorable Daniel K. Akaka
Ranking Member
Subcommittee on Oversight of Government Management,
the Federal Workforce and the District of Columbia
Committee on Homeland Security and Governmental
Affairs
United States Senate

The Honorable Richard Durbin
United States Senate

As we have previously reported, the federal food safety system in the United States emerged piecemeal, over many decades, typically in response to particular health threats or economic crises. The result is a fragmented legal and organizational structure that gives responsibility for specific food commodities to different agencies and provides them with significantly different authorities to enforce food safety laws. In fiscal year 2003, the principal federal agencies with food safety responsibilities spent nearly \$1.7 billion to ensure the safety and quality of the U.S. food supply.

Many legislative proposals have been made to reform existing laws and consolidate the U.S. food safety system, but to date no action has been taken. Most recently, in 2004, parallel Senate and House bills proposed combining the food safety regulatory programs of the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA), within the Department of Health and Human Services (HHS), and the voluntary seafood inspection program operated by the Department of Commerce.

Several countries have taken steps to streamline and consolidate food safety functions. In 1999, we reported on the experiences of four countries—Canada, Denmark, Ireland, and the United Kingdom—that were consolidating their food safety systems.¹ In response to your interest in learning about these and other countries' experiences with consolidation, we updated information on the countries covered in the 1999 report and

¹GAO, *Food Safety: Experiences of Four Countries in Consolidating Their Food Safety Systems*, [GAO/RCED-99-80](#) (Washington, D.C.: Apr. 20, 1999).

included information on three other countries that have also undertaken consolidation efforts—Germany, the Netherlands, and New Zealand. This report describes the approaches these seven countries have taken in consolidating food safety functions, the challenges they faced, and the results of the countries’ efforts, including benefits and costs cited by government officials and industry or consumer stakeholders.

To develop this information, we examined the seven countries’ efforts to streamline and consolidate their food safety systems,² including the benefits and costs that resulted, as cited by government officials.³ We conducted structured interviews with senior government officials from food safety, agriculture, and health agencies and with representatives of food industry and consumer organizations, reviewed and analyzed the documents they provided, and reviewed World Health Organization and GAO reports. We also met with European Union (EU) food safety officials to discuss how the EU’s food legislation is affecting its member countries’ decisions to consolidate, as well as how the EU interacts with food safety agencies in member countries.⁴ The information on countries’ food safety systems in this report, including descriptions of laws, is based almost exclusively on interviews with and documentation provided by high-level food safety officials as well as food industry or consumer stakeholders from the seven countries we examined. Most of the information we obtained was qualitative. To the extent possible, we corroborated the qualitative information provided by government officials by interviewing food industry and consumer organization stakeholders. We obtained very limited quantitative information. We asked government officials questions intended to help us assess the reliability of the quantitative information they provided, but we could not determine the reliability of most of this information because of constraints on the amount of time the countries’ food safety officials could devote to our study. Although we could not assess the quantitative information’s reliability, we are reporting it in order to provide descriptive information that will inform policymakers in the

²For the purposes of this report, we defined consolidation as the transfer of responsibility and resources for performing a food safety function from two or more agencies to a single agency.

³ In examining countries’ food safety systems, we did not obtain information on agencies that are responsible for foodborne illness surveillance for each of the seven countries.

⁴Five of the countries whose systems we studied, Denmark, Germany, Ireland, the Netherlands, and the United Kingdom, are members of the European Union.

United States about the various approaches, challenges, and benefits that countries' officials identified to us regarding their consolidation efforts.

Appendix I provides more information on our scope and methodology. We conducted our work from April 2004 through December 2004 in accordance with generally accepted government auditing standards.

Results in Brief

The seven countries we examined have taken various approaches to consolidate their food safety systems. Each of the seven countries we reviewed established a single agency to lead food safety management or enforcement of food safety legislation and modified existing food safety laws, although their approaches and the extent to which they consolidated differed. For example, Denmark centralized its system by creating a new federal agency in which it consolidated almost all the food safety functions and activities, including inspections, which were previously distributed among several government agencies. In contrast, Germany's new agency functions as a coordinating body to lead food safety management and formulate general administrative rules to guide the implementation of national food safety laws by the German federal states.⁵ The German federal states continue to be responsible for overseeing food inspections performed by local governments. The two major factors motivating countries to consolidate their food safety systems were public concern about food safety and a need to improve program effectiveness and efficiency. For example, in the United Kingdom, consolidation occurred primarily in response to a loss of consumer confidence resulting from the outbreak of mad cow disease, and in Canada, consolidation was intended to achieve greater program effectiveness and reduce expenditures. A third important motivating factor for the EU countries has been the need to comply with recently adopted EU legislation. These EU changes aim to harmonize and simplify its food safety legislation and to create a single, transparent set of food safety rules that is applicable to all EU member countries.

In reorganizing their food safety systems, several countries cited challenges in two areas. First, many countries had to consider whether to place the new agency within the existing health or agriculture ministry or

⁵The Federal Republic of Germany consists of 16 federal states, known as *länder*. Under Germany's federal structure, the federal states have responsibilities that include the implementation of food safety laws.

establish it as a stand-alone agency while also determining what responsibilities the new agency would have. For example, Ireland chose to place its new food safety agency in its existing Department of Health and Children, in part, to separate food safety responsibility from the promotion of the food industry, which is the responsibility of the Department of Agriculture and Food. On the other hand, to separate food safety regulation from political pressures, New Zealand established a semi-autonomous food safety agency. A second challenge, cited by officials in several countries, was helping employees assimilate into the new agency's culture and support its priorities. To foster the development of a common organizational culture, food agency officials in Denmark moved employees to centralized locations and held monthly meetings to familiarize them with the mission and culture of the organization.

Although none of the countries has formally analyzed its consolidation results, the government officials and stakeholders we interviewed in each of the seven countries stated that the overall effect of consolidation has been or will likely be positive. None of the countries has conducted an analysis to compare the effectiveness and efficiency of its consolidated food safety system with that of the previous system. For example, officials stated they could not determine whether their country's consolidation had reduced foodborne illness because consolidation was only one of many factors that could influence the frequency of foodborne illness. Furthermore, it may be too early to fully assess the benefits of consolidation for several of the countries because their new food safety structures have been functioning for 3 years or less. Although limited, some information on costs and benefits was available. As expected, most countries incurred start-up costs in reorganizing. These expenditures were used for purposes such as acquiring buildings and purchasing laboratory equipment. Some countries experienced a temporary reduction in the quantity of food safety activities performed due to consolidation-related disruptions. However, government officials in each of the seven countries believe that these consolidation costs have been or will likely be exceeded by the benefits. Specifically, these officials, as well as stakeholders in each country, consistently stated that consolidation of their food safety systems has led to significant qualitative improvements in food safety operations that enhance effectiveness or efficiency. For example, government officials and stakeholders cited such benefits as reduced overlap in inspections, more targeted inspections based on food safety risk, more consistent or timely enforcement of food safety laws and regulations, and greater clarity in responsibilities. Government officials in Canada, the Netherlands, and Denmark stated that some cost savings may be achieved as a result of

changes that have already taken place or are expected from planned changes needed to complete their consolidation efforts. For example, in the Netherlands officials said that reduced duplication in food safety inspections would likely result in decreased food safety spending. Dutch officials also said that they anticipate savings to be derived from an expected 25 percent reduction in administrative and management personnel and from selling excess property.

In commenting on a draft of this report, HHS and USDA stated that they are working together effectively to ensure food safety and pointed out limitations related to the information available for our study. For example, both agencies said the report does not contain cost-benefit analyses of countries' consolidations, and USDA said the report does not have information on causal relationships between consolidation and quantifiable public health benefits, such as changes in the incidence of foodborne illness. They also said that these countries' consolidation experiences have or may have limited applicability to the U.S. food safety system because the countries have smaller food and agriculture industries than the United States. Our report clearly acknowledges that the countries provided limited quantitative data on the costs and benefits of consolidation and points out that the information presented is based on structured interviews with high-level officials, documentation they provided, and interviews with food industry or consumer stakeholders from each of the seven countries we reviewed. As our report states, government officials, as well as food industry and consumer stakeholders, consistently stated that consolidation of their food safety systems has led to significant improvements in food safety operations that enhance effectiveness and efficiency. In addition, our report clearly states that the countries we reviewed are smaller than the United States, but it also notes that, similar to the United States, they are high-income countries where consumers have high expectations for food safety. Consequently, we believe this report provides useful information on countries' experiences, particularly with regard to the qualitative improvements in food safety operations cited by government officials.

Background

While the U.S. food supply is generally safe, each year, according to a Centers for Disease Control and Prevention (CDC) estimate, tens of millions of Americans become ill and thousands die from eating unsafe food. Furthermore, USDA's Economic Research Service has estimated that the costs associated with foodborne illnesses are about \$7 billion, including medical costs and productivity losses from missed work.

The safety and quality of the U.S. food supply is governed by a complex system that is administered by 15 agencies. The principal federal agencies with food safety responsibilities operate under numerous statutes underpinning the federal framework for ensuring the safety and quality of the food supply in the United States. These laws give the agencies different regulatory and enforcement authorities, and about 70 interagency agreements aim to coordinate the combined food safety oversight responsibilities of the various agencies. The federal system is supplemented by the states, which have their own statutes, regulations, and agencies for regulating and inspecting the safety and quality of food products.

USDA and FDA have primary responsibility for ensuring the safety of foods. USDA's Food Safety and Inspection Service regulates meat, poultry, and certain egg products, and FDA regulates the safety of all other foods, including milk, seafood, and fruits and vegetables. The Environmental Protection Agency (EPA) sets limits on the amount of pesticide residues that are allowed in food, and the National Marine Fisheries Service within the Department of Commerce provides fee-for-service inspections to ensure the safety and/or quality of commercial seafood. Similarly, USDA's Agricultural Marketing Service (AMS) performs food quality assurance inspections that include food safety elements. In addition to their established food safety responsibilities, USDA, FDA, and EPA, along with the Department of Homeland Security, have begun to address food security.⁶ Figure 1 summarizes the 15 agencies and their food safety responsibilities.

⁶For the purposes of this report, we defined food security as distinct from food safety in that food security refers to the vulnerability of a nation's food supply to deliberate actions that contaminate food or reduce the available quantity of food.

Figure 1: U.S. Federal Agencies' Food Safety Responsibilities

Agency		Responsible for
U.S. Department of Agriculture	Food Safety and Inspection Service	All domestic and imported meat, poultry, and processed egg products
	Animal and Plant Health Inspection Service	Protecting the health and value of U.S. agricultural resources (e.g., animals and plants)
	Grain Inspection, Packers and Stockyards Administration	Establishing quality standards, inspection procedures, and marketing of grain and other related products
	Agricultural Marketing Service ^a	Establishing quality and condition standards for dairy, fruit, vegetable, livestock, meat, poultry, and egg products
	Agricultural Research Service	Conducting food safety research
	Economic Research Service	Providing analyses of the economic issues affecting the safety of the U.S. food supply
	National Agricultural Statistics Service	Providing statistical data, including agricultural chemical usage data, related to the safety of the food supply
	Cooperative State Research, Education, and Extension Service	Supporting food safety research, education, and extension programs in the land-grant university system and other partner organizations
Department of Health and Human Services	Food and Drug Administration	All domestic and imported food products except meat, poultry, and processed egg products
	Centers for Disease Control and Prevention	Protecting the nation's public health, including foodborne illness surveillance
Department of Commerce	National Marine Fisheries Service	Voluntary, fee-for-service examinations of seafood for safety and quality
Environmental Protection Agency		Regulating the use of pesticides and maximum allowable residue levels on food commodities and animal feed
Department of the Treasury	Alcohol and Tobacco Tax and Trade Bureau	Enforcing laws covering the production, use, and distribution of alcoholic beverages
Department of Homeland Security ^b		Coordinating agencies' food security activities
Federal Trade Commission		Prohibiting false advertisements for food

Source: GAO.

^aAccording to USDA, AMS has no statutory authority in the area of food safety. However, AMS performs some functions related to food safety for several foods. For example, AMS graders monitor a

shell egg surveillance program that identifies cracked and dirty eggs. In addition, AMS performs functions related to food safety for the National School Lunch Program.

^bIn 2001, by Executive Order, the President stated that the then Office of Homeland Security, as part of its efforts to protect critical infrastructures, should coordinate efforts to protect livestock, agriculture, and food systems from terrorist attack. In 2002, Congress enacted the Homeland Security Act of 2002, Pub. L. No. 107-296, 116 Stat. 2135 (2002), setting out the department's responsibility to protect and secure critical infrastructures and transferring several food safety related responsibilities to the Department of Homeland Security. As a result of the Executive Order, the Homeland Security Act of 2002 establishing the Department of Homeland Security, and subsequent Presidential Directives, the Department of Homeland Security provides overall direction on how to protect the U.S. food supply from deliberate contamination.

Many proposals have been made to consolidate the U.S. food safety system, but to date no action has been taken. Several bills introduced in the Congress, reports by the National Academy of Sciences and the National Commission on the Public Service, and several of our reports and testimonies have proposed consolidation of the U.S. food safety system. For example, in 2001, parallel Senate and House bills proposed consolidating inspections and other food safety responsibilities in a single independent agency. In 2004, legislation was again introduced in the Senate and the House to establish a single food safety agency to protect public health, ensure food safety, and improve research and food security. This proposed legislation would combine the two food safety regulatory programs of USDA and FDA, along with a voluntary seafood inspection program operated by the Department of Commerce. The proposed new food safety program would have been based on a comprehensive analysis of the hazards associated with different foods and their processing and would require, among other things, the enforcement of the adoption of process controls in food establishments as well as the establishment and enforcement of science-based standards.

In 1998, the National Academy of Sciences recommended integrating the U.S. food safety system and suggested several options, including a single food safety agency.⁷ More recently, the National Commission on the Public Service recommended that government programs that are designed to achieve similar outcomes be combined into one agency and that agencies with similar or related missions be combined into large departments.⁸ The Commission chairman testified before a House subcommittee that important health and safety protections fail when responsibility for

⁷*Ensuring Safe Food From Production to Consumption*, Institute of Medicine, National Research Council (Washington, D.C.: National Academy Press, 1998).

⁸*Urgent Business For America: Revitalizing the Federal Government For the 21st Century*, Report of the National Commission on the Public Service (Washington, D.C., 2003).

regulation is dispersed among several departments, as is the case with the U.S. food safety system.

The division of responsibility among several government agencies responsible for food safety is not unique to the United States. Food safety officials in the countries we selected for this review said they faced similar divisions of responsibilities and that their countries' reorganizations were intended to address this problem.

Although the seven countries whose food safety systems we reviewed are much smaller in population than the United States, they, like the United States, are high-income countries⁹ where consumers have very high expectations for food safety. Table 1 presents data on population, size of economy, food expenditures, and consumer spending for food as a percentage of total consumer spending for the seven countries and the United States. The table shows that U.S. consumers' spending on food as a percentage of their total spending is somewhat similar to that of the other seven countries, ranging from about 10 percent in the United States to over 16 percent in Ireland and the United Kingdom. In general, high-income countries tend to spend a smaller percentage of their income on food than low-income countries. For instance, in low-income countries consumers' spending for food often exceeds 50 percent of their total spending.¹⁰

⁹All seven countries, as well as the United States, are in the World Bank's high-income category.

¹⁰For all of the 114 countries analyzed in a recent USDA Economic Research Service study, consumer spending on food as a percentage of total spending ranged from nearly 74 percent of the total budget in Azerbaijan to just below 10 percent in the United States. James Seale, Jr., Anita Regmi, and Jason Bernstein, "International Evidence on Food Consumption Patterns," Technical Bulletin Number 1904, Economic Research Service, USDA, October 2003.

Table 1: Comparison of Selected Countries' Population, Gross Domestic Product (GDP), Total Food Consumption, per Capita GDP, and Spending for Food as a Percentage of Total Spending

Country	Population ^a (2004)	Size of economy (2003 GDP ^b) (dollars in millions)	Total food consumption ^c (2003) (dollars in millions)	Per capita GDP ^d (2003)	Spending for food as a percentage of total spending ^e
Canada	32,507,874	\$834,390	\$45,375	\$27,097	11.68
Denmark	5,413,392	212,404	12,430	39,497	14.02
Germany	82,424,609	2,400,655	162,251	29,137	13.09
Ireland	3,969,558	148,553	5,018	38,864	16.59
Netherlands	16,318,199	511,556	27,659	31,759	13.29
New Zealand	3,993,817	76,256	5,525	19,350	15.19
United Kingdom	60,270,708	1,794,858	104,550	30,355	16.37
United States	293,027,571	10,881,609	\$564,040	36,924	9.73

Source: GAO using various sources cited below.

Note: For each data source, the table shows most recent year available from the source.

^aCentral Intelligence Agency, *The World Factbook*, Field Listing—Population, July 2004 estimates, (<http://www.cia.gov/cia/publications/factbook/fields/2119.html>).

^bWorld Development Indicators database, World Bank, September 2004 World Bank, (<http://www.worldbank.org/data/datatopic/GDP.pdf>). Gross Domestic Product is the market value of the goods and services produced by labor and property located in a particular country.

^cConsumer expenditure amounts, except for the United States, are from national statistical offices/OECD/Eurostat/Euromonitor for 2003. The amount for 2003 for the United States is from the Economic Research Service, USDA. All amounts are for expenditures of food and nonalcoholic beverages brought into the home.

^dUnited Nations, Department of Economics and Statistics Division, Indicators on Income and Economic Activity. All amounts are for 2003 and were last updated in December 2004.

^eERS/USDA Data – International Food Consumption Patterns, (<http://www.ers.usda.gov/data/InternationalFoodDemand>). Food budget shares are estimated across 114 countries using 1996 data for nine major consumption groups and eight food subgroups including bread and cereals; meat; fish; dairy products; fats and oils; fruit and vegetables; beverages and tobacco; and other food products.

Most of the countries we selected for this review are members of the EU¹¹ and, as such, must abide by EU food safety legislation. The development and implementation of EU food safety legislation is the responsibility of the Health and Consumer Protection Directorate General. In 2002, to respond to consumer concerns about the safety of the food supply, the EU created a

¹¹The EU is a treaty-based institutional framework that defines and manages economic and political cooperation among its 25 member countries. EU member countries have reached EU-wide agreement in certain policy areas, including food safety, and operate as a single economic market.

new independent food safety institution, the European Food Safety Authority (EFSA), which is responsible for providing independent, scientific advice on all matters linked to food and animal feed safety. The tasks performed by EFSA include communicating with the public on food safety matters and providing risk assessments to the European Commission, the European Parliament, and the EU Member States.

In addition to creating EFSA in April 2004, the EU adopted additional, comprehensive food safety legislation¹² that becomes effective, in large part, on January 1, 2006. Together with the earlier regulation establishing EFSA, the legislation is intended to create a single, transparent set of EU food safety rules applicable to all food, including animal and nonanimal products. The legislation covers the entire food supply chain from production to consumption and places more requirements on EU member nations. It identifies specific food safety objectives and, unlike much of the EU's previous food safety legislation, specifies the methods by which those objectives must be achieved. For example, it requires food business operators to adopt specific hygiene measures and a permanent procedure or procedures based on Hazard Analysis and Critical Control Point principles.¹³ Moreover, the legislation requires that each EU country establish and implement an official food and animal feed control plan by January 1, 2007. Thereafter, an annual report on the implementation of this national control plan must be submitted. To carry out its official controls over food and animal feed, a country must designate responsible entities. If a country has more than one responsible entity, it must ensure effective coordination between these entities. According to a paper presented at a

¹²According to EU officials, the legislative package includes Regulation (EC) No. 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs; Regulation (EC) No. 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law and animal health and animal welfare rules; Regulation (EC) No. 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin; Regulation (EC) No. 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organization of official controls on products of animal origin intended for human consumption; and Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC.

¹³Hazard Analysis and Critical Control Point principles are risk-based and make industry, rather than government inspectors, responsible for identifying steps in food production where food safety hazards are most likely to occur and for establishing controls that prevent or reduce such hazards.

2004 international forum for food safety regulators, in recent years many EU countries have chosen to establish a national food safety authority, but the establishment of such an authority is not obligatory.¹⁴

Countries Have Taken Various Consolidation Approaches, and Officials and Stakeholders Cited Challenges and Costs but Believe Food Safety Systems Are Now More Effective

The seven countries we examined had two primary reasons for reorganizing and consolidating their food safety systems, took various approaches, and often faced similar challenges. While the extent to which countries consolidated their food safety systems varied considerably, each country established a single agency to lead food safety management or enforcement of food safety legislation.¹⁵ Although most countries incurred some consolidation start-up costs, government officials, as well as food industry and consumer stakeholders, generally agree that consolidation has led to significant qualitative improvements in the effectiveness or efficiency of their food safety systems. Our ability to evaluate these improvements and other information officials provided was limited because none of the countries has conducted an analysis to measure the effectiveness and efficiency of its consolidated food safety system relative to that of the previous system. In some cases, it may be too early to fully assess the benefits of the countries' consolidations.

The seven countries whose reorganizations we reviewed consolidated their food safety systems primarily to improve program effectiveness and efficiency or to respond to public concern about food safety.

¹⁴"European Food Safety Control Systems: New Perspectives on a Harmonized Legal Basis" (paper presented at the Second Food and Agriculture Organization of the United Nations/World Health Organization Global Forum for Food Safety Regulators, October 2004).

¹⁵The Netherlands established a lead agency to enforce food safety legislation. The other six countries established a lead agency for risk management. Risk management is the process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options. However, some countries, such as Germany, have separated responsibility for risk assessment—the scientifically based process consisting of hazard identification, hazard characterization, exposure assessment, and risk characterization—from risk management by placing risk management and risk assessment responsibilities in separate entities.

According to a 1998 National Research Council report,¹⁶ an effective food safety system protects and improves the public health by ensuring that foods meet science-based safety standards through the integrated activities of the public and private sectors. This report also addresses efficiency, stating the greatest strides in ensuring food safety from production to consumption can be made through a scientific risk-based system that ensures that surveillance, regulatory, and research resources are allocated to maximize effectiveness. Public concern about food safety became an important issue in several industrialized countries during the 1990s when bovine spongiform encephalopathy (BSE), commonly known as mad cow disease, was confirmed in large numbers of cattle.¹⁷ In addition to improving effectiveness and efficiency and responding to public concern about food safety, some EU countries were further prompted to consolidate by the need to comply with recently approved EU food safety legislation that becomes effective, in large part, January 1, 2006. The new legislation places more requirements on EU member countries. For example, each EU member country will be required to submit and annually update a plan for the implementation of the new law and to report annually on the implementation of that plan.

Regarding consolidation approaches, each country established a single agency to lead food safety management or enforcement of food safety legislation. Each country modified its existing legal framework to give legal authority and responsibility to the new food safety agency. However, countries' approaches in consolidating their food safety systems varied, particularly with respect to how comprehensively food safety functions were consolidated. For example, Denmark centralized its system by creating a new federal agency in which it consolidated almost all its food safety functions and activities, including food inspections, which were previously distributed among several federal and local government agencies. On the other hand, in Germany, which established a new lead food safety agency, the 16 federal states continue to be responsible for oversight of food inspections performed by local governments. Germany's

¹⁶*Ensuring Safe Food From Production to Consumption*, National Research Council (Washington, D.C.: 1998).

¹⁷BSE is an always fatal, neurodegenerative disease that has been found in cattle in numerous countries. Cattle contract the disease through animal feed that contains protein derived from the remains of diseased animals. Scientists generally believe an equally fatal disease in humans—known as variant Creutzfeldt-Jacob Disease (vCJD)—is linked to eating beef from cattle infected with BSE.

new food safety agency functions as a coordinating body to lead food safety management, including formulation of general administrative rules to guide the federal states' implementation of national food safety laws.

In reorganizing their food safety systems, officials from several countries cited challenges in two areas. First, many countries faced a similar decision regarding whether to place the new agency within the existing health or agriculture ministry or establish it as a stand-alone agency while also determining what responsibilities the new agency would have. A second challenge, cited by officials in several countries, was helping employees assimilate into the new agency's culture and support its priorities.

Although countries have not formally analyzed consolidation results, the government officials and stakeholders we interviewed in each of the seven countries cited improvements in food safety system operations and stated that the net effect of consolidation has been or will likely be positive. None of the countries has conducted an analysis to measure the effectiveness and efficiency of its consolidated food safety system relative to that of the previous system. For example, officials stated that they could not determine whether their country's consolidation had resulted in public health benefits, such as reduced foodborne illness, because consolidation was only one of many factors that could affect the frequency of foodborne illness. Furthermore, it may be too early to fully assess the benefits of consolidation for several of the countries, as their countries' new food safety structures have been functioning for 3 years or less. Although limited, some information on costs and benefits was available. As expected, most countries incurred start-up costs, which included, for example, the acquisition of buildings and purchases of laboratory equipment. Some countries experienced a temporary reduction in the quantity of food safety activities performed due to consolidation-related disruptions. However, government officials in each of the seven countries believe the benefits of their consolidations have exceeded or will likely exceed the costs. In particular, these officials, as well as food industry and consumer stakeholders in each country, consistently stated that consolidation of their food safety systems has led to significant qualitative improvements in food safety operations that enhance effectiveness or efficiency. These improvements include the reduction of overlapping food safety activities, such as inspections of food establishments by various agencies. (Figure 2 summarizes each country's improvements in food safety operations as cited by government officials, food industry stakeholders, or consumer stakeholders.) Moreover, government officials in Canada, the Netherlands, and Denmark stated that some cost savings

may be achieved as a result of changes that have already taken place or are expected from planned changes needed to complete their consolidation efforts.

Figure 2: Improvements in Food Safety Operations Cited by Government Officials or Stakeholders

	Countries						
	Canada	Denmark	Germany	Ireland	Netherlands	New Zealand	United Kingdom
Improved service delivery by providing a single contact for consumer and industry clients	GS	S	S	GS	GS	S	G
More consistent or timely enforcement of food safety laws and regulations	GS	GS	S	G		GS	G
Reduced overlap in inspections	GS	GS			G		
Clearer responsibilities and reduced gaps in oversight	GS	GS	GS	G	S	GS	G
Streamlined communications	GS	GS	GS	G		GS	G
Increase coordination among entities involved in food safety activities	GS	GS	GS	GS	G	G	G
Frequency of inspections based on risk		G		G		S	
Improve accountability and transparency	G	GS	G	GS	G	GS	GS
Unified position when dealing with international organizations or trade partners	G	G					G
Improved information systems		GS		G	G		
Expenditures for food safety based on the volume of foods regulated, consumed, or risk of foodborne illness		G					

G = Government official
 S = Industry or consumer stakeholder
 GS = Both government official and stakeholder
 Source: GAO analysis of information from officials and stakeholders.

Note: The improvements listed are based on structured interviews with food safety officials and food industry and consumer stakeholders.

Figures 3 through 9 show summary information on each country's reasons for consolidation, entities responsible for food safety before and after

consolidation, challenges, and start-up¹⁸ and other consolidation-related costs, as well as examples of consolidation benefits. This information was provided by government officials and food industry or consumer stakeholders. For more detailed information on each country, see appendixes II through VIII.

¹⁸In consolidating their food safety systems, six of the seven countries incurred start-up costs in addition to ongoing operational costs. In these countries, the newly created consolidated food safety agencies needed additional funding to establish a fully operational food safety system. Although some countries provided documentation regarding these start-up costs, we were not able to determine the reliability of this information.

Figure 3: Summary of Canada's Food Safety System Consolidation

Reasons for consolidation	Improve effectiveness (e.g., consistency of inspections and clarification of responsibilities). Improve efficiency by reducing duplication and overlap in food safety activities. Reduce federal spending.
Entities responsible for food safety before consolidation	Inspections: (1) Health Canada; (2) Agriculture and Agri-Food Canada; and (3) Fisheries and Oceans Canada. Food policy and risk assessment: (1) Health Canada; (2) Agriculture and Agri-Food Canada; and (3) Fisheries and Oceans Canada.
Entities responsible for food safety after consolidation	In 1997, Canada reorganized its food safety system. Inspections: Canadian Food Inspection Agency (CFIA), a separate regulatory agency (departmental corporation) whose president reports directly to the Minister of Agriculture and Agri-Food Canada. Public health policy and standard setting: Health Canada.
Responsibilities of food safety agency(ies) after consolidation	CFIA: All inspection/compliance activities, including inspections of imported/domestic products, laboratory and diagnostic support, crisis management and product recalls, and export certification. ^a Health Canada: Public health policy and standard setting, including research, risk assessment, and setting limits on the amount of a substance allowed in a food product. ^b
Challenges	(1) Assignment of specific food safety roles and responsibilities: To address this challenge, the CFIA and Health Canada jointly developed a food safety functions matrix to clearly define responsibilities. (2) Assimilating employees into a new agency's culture and priorities and a high retirement rate among former employees of the health, agriculture, and fisheries departments: Officials said it is important to plan for the merging of organizational cultures and bring the workforce into a dialogue on the new organization's vision and objectives.
Start-up and other consolidation-related costs cited by officials and stakeholders	(1) According to Canadian officials, in fiscal year 1998 Canada spent \$25 million Canadian (\$18 million U.S.) in start-up funds to consolidate food safety inspections within the CFIA. This amount was about 7 percent of the agency's fiscal year 1998 budget. (2) According to labor officials, productivity briefly declined shortly before and immediately after consolidation. In addition, according to government officials, retirements resulted in a temporary loss of experience.
Examples of benefits cited by officials and stakeholders	(1) Financial savings: A senior CFIA official stated that during the agency's first 2 years, fiscal year 1997 and fiscal year 1998, the consolidation reduced food safety operating expenditures 10 percent relative to preconsolidation food safety spending. Noting that no comprehensive analysis has been performed to determine the net impact of the consolidation on food safety expenditures, the official based this statement on his knowledge of food safety operating expenditures before and after consolidation. (2) Reduced overlap in inspections: Inspectors have been trained to perform more than one type of food safety inspection. This cross-utilization of inspectors enables one inspector to complete inspections of a food-processing facility that were previously performed by two or more inspectors. As a result, the number of visits made to the same food-processing facility has been reduced. (3) Clearer responsibilities, better coordination, and reduced gaps in oversight: Officials said consolidation has clarified food safety responsibilities, and, as a result, the food safety system's ability to mitigate risk and to respond to a potential crisis has improved. They cited the response to managing the 2003 BSE crisis as an effective reaction to a problem, stating that food safety personnel knew their specific responsibilities and responded in a timely, thorough manner. Officials said the effectiveness of this response can, in part, be attributed to the universal coordination of animal health and food safety that has resulted from the consolidation.^c

Source: GAO analysis of information from Canadian officials and stakeholders.

^aThe Canadian Food Inspection Agency is also responsible for food quality assurance inspections and animal and plant disease control.

^bHealth Canada's responsibilities include research, risk assessment and standard setting in relation to the nutritional quality of foods marketed in Canada.

^cAn international review supported this assessment, stating the investigation was comprehensive, thorough, and timely. In addition, food industry stakeholders said the government's response to BSE was very effective.

Figure 4: Summary of Denmark’s Food Safety System Consolidation

Reasons for consolidation	Improve effectiveness (e.g., communications with consumers and consistency of inspections). Improve efficiency (e.g., move resources to high-risk areas and reduce overlaps in responsibilities).
Entities responsible for food safety before consolidation	Inspections: (1) Ministry of Agriculture; (2) Ministry of Fisheries; and (3) municipalities. Standard setting: (1) Ministry of Health; (2) Ministry of Agriculture; and (3) Ministry of Fisheries.
Entities responsible for food safety after consolidation	In 1997, the Danish government created the Danish Veterinary and Food Administration (DVFA) as an agency of the Ministry of Food, Agriculture, and Fisheries. Inspections were consolidated within DVFA in 1999 and 2000. The organization was fully in place by January 2000. In an August 2004 governmental reorganization, DVFA was moved to the Ministry of Family and Consumer Affairs.
Responsibilities of food safety agency(ies) after consolidation	The DVFA is responsible for almost all food safety responsibilities. Exceptions are the Plant Directorate, which is responsible for animal feed inspections, and the Directorate for Fisheries, which is responsible for inspection of fish on ships. These two agencies are in the Ministry of Food, Agriculture, and Fisheries.
Challenges	(1) Municipal inspectors, who were accustomed to being part of much smaller systems, were transferred into the DVFA. To foster the development of a common culture and reinforce the new agency’s mission, DVFA moved employees to centralized locations and held monthly meetings. (2) Having adequate funding for start-up costs, which were originally underestimated.
Start-up and other consolidation-related costs cited by officials and stakeholders	(1) According to officials, start-up costs associated with Denmark’s consolidation were about 204.5 million Danish kroner (about \$26 million U.S.), or approximately 21 percent of DVFA’s fiscal year 2000 budget. The start-up funds were spent for new data processing systems, laboratory equipment, staff compensation, and buildings. (2) Officials said the number of inspections performed declined from 1999 to 2000 while DVFA was being formed, but began to increase after 2000.
Examples of benefits cited by officials and stakeholders	(1) Reduced overlap in inspections: Inspectors have been trained to perform more than one type of food safety inspection. This cross-utilization of inspectors enables one inspector to complete the inspection of a single food processing facility, which previously might have been performed by two or more inspectors, and reduces the number of visits made to the same food processing facility. (2) Frequency of inspections based on risk: Officials stated consolidation and accompanying reform of food safety laws facilitated risk-based inspections. The frequency of most inspections is now based on an individual food product’s safety risk and on an individual company’s food safety record, not on agencies’ jurisdiction, as was the case before consolidation. As a result, the frequency of inspections at some food processing plants and of lower risk food products has been reduced, making more resources available for inspections of higher risk companies and foods. (3) More consistent or timely enforcement of food safety laws and regulations: Reducing inconsistency in inspections resulting from the sharing of food safety responsibilities among three ministries and local authorities was one of the chief reasons Denmark decided to consolidate its food safety system. According to officials, moving nearly all food inspection responsibilities to the DVFA, establishing uniform guidelines, and training inspectors greatly reduced these inconsistencies in enforcement. Officials added that they expect this increased consistency in inspections will make it easier for them to comply with new EU food safety legislation. (4) Possible financial savings: Officials said consolidation enabled a reduction in the number of microbiological laboratories from 11 to 6. As a result, they estimate the annual operating costs of microbiological laboratories have been reduced considerably. In addition, a senior official stated that consolidation of regional and local offices has reduced administrative expenses.

Source: GAO analysis of information from Danish officials and stakeholders.

Figure 5: Summary of Germany’s Food Safety System Consolidation

Reasons for consolidation	Address public concerns about food safety stemming from the discovery of BSE in Germany in 2000 and earlier food safety problems. Improve compliance with EU food safety legislation.
Entities responsible for food safety <i>before</i> consolidation	Research, risk assessment, and communication: (1) Federal Ministry of Health and (2) Federal Ministry of Food, Agriculture and Forestry. Implementation of federal legislation and oversight of inspections: Sixteen federal states. Inspections: Municipalities and other local governments.
Entities responsible for food safety <i>after</i> consolidation	Federal Ministry of Consumer Protection, Food, and Agriculture. This ministry has two new agencies. In 2002, Germany established a coordinating body, the Federal Office of Consumer Protection and Food Safety, to lead food safety management. In addition, the Federal Institute for Risk Assessment was established in 2002 to separate scientific risk assessments from decision making.
Responsibilities of food safety agency(ies) <i>after</i> consolidation	The Federal Office of Consumer Protection and Food Safety interacts with the EU, coordinates food safety activities, and develops general rules to guide the implementation of national food safety laws by the German federal states. The Federal Institute for Risk Assessment performs risk assessments and provides scientific advice. The German federal states continue to be responsible for enforcement and oversight of municipalities’ inspections.
Challenges	According to officials, negotiations between the federal government and the federal states concerning reform of food safety law have been complicated, as some reforms that would give the federal government increased authority would require constitutional changes, according to officials.
Start-up and other consolidation-related costs cited by officials and stakeholders	Germany’s consolidation did not require significant start-up spending.
Examples of benefits cited by officials and stakeholders	Streamlined communications and improved crisis management: Officials said that the consolidation has resulted in enhanced communication between the federal government and the federal states, as well as providing more complete food safety information to consumers. As an example, they cited the response of the Federal Ministry of Consumer Protection, Food, and Agriculture and its two new agencies to the emergence of acrylamide ^a in food as a major public concern. In responding to the acrylamide issue, the federal government established a food risk forum to enable state food safety agencies, the food industry, and consumer organizations to more easily communicate with each other. In addition, acrylamide questions and answers were put on the Internet to address consumer concerns. According to officials, before the consolidation, coordinated communication happened only sporadically, and at times the federal agencies and the federal states disseminated conflicting information. Officials believe these streamlined communications are beginning to restore consumers’ confidence in the food safety system. A consumer organization representative agreed that the consolidation had improved communication during food crises.

Source: GAO analysis of information from German officials and stakeholders.

^aResearch has found that acrylamide, a carcinogen, may be formed in starch-containing foods when they are baked or fried.

Figure 6: Summary of Ireland’s Food Safety System Consolidation

Reasons for consolidation	Address public concern about food safety stemming from food scares and the detection of BSE. Consumers perceived the Ministry of Agriculture and Food, which was responsible for inspecting farms and meatpacking plants, to favor the interests of the food industry over consumer protection. Address agricultural and food industry concerns about reductions in beef exports resulting from the BSE detection.
Entities responsible for food safety before consolidation	(1) Department of Agriculture and Food; (2) Department of Environment; (3) Department of Public Enterprise; (4) Marine Department; (5) Department of Enterprise, Trade and Employment; (6) Department of Health and Children. Eight regional health boards. Thirty-three local authorities. According to officials, these entities’ activities were not coordinated and, no independent accountability system existed to provide assurance of enforcement of food safety laws.
Entities responsible for food safety after consolidation	(1) Food Safety Authority of Ireland (FSAI). In 1998, to coordinate and oversee the activities of the existing food safety entities, Ireland established the FSAI. FSAI is an independent food safety agency that reports to the Minister of Health and Children. (Ministries, health boards, and local authorities continue to perform inspections.)
Responsibilities of food safety agency(ies) after consolidation	The FSAI has risk assessment, management, and communication responsibilities. In addition, it is responsible for the enforcement of food safety legislation. It carries out this responsibility by establishing and overseeing service contracts with some of the previous food safety entities. Under these contracts, the previous food safety entities continue to perform functions such as inspections.
Challenges	(1) In deciding where to place the new agency, FSAI, within the government, Ireland chose to place the agency under its existing Ministry of Health and Children specifically to separate food safety responsibilities from food and agriculture promotion efforts, which is the responsibility of the Department of Agriculture and Food. (2) FSAI also had to bring about the clear understanding that the food industry has the primary responsibility for food safety.
Start-up and other consolidation-related costs cited by officials and stakeholders	Officials stated Ireland spent approximately 1.5 million Irish pounds (\$2 million U.S.) for start-up costs in fiscal year 1999. ^a The start-up funds were used for temporary staff, renting office space, and operational expenses.
Examples of benefits cited by officials and stakeholders	(1) Single contact for consumer and industry clients: Officials cited improved relations with stakeholders as a result of providing consumers with a single agency contact and forming a council group that encompassed both industry and consumers to discuss the concerns faced by each group. According to the officials, this level of communication between the government, industry, and consumers had not existed prior to the consolidation when no single agency had food safety as its central mission. (2) Improved accountability and transparency: According to officials, the establishment of Ireland’s lead food safety agency, the FSAI, has made the many entities that have food safety responsibilities more accountable for the performance of those responsibilities. Before consolidation, food safety functions, most notably inspections, were the responsibility of over 50 entities across the government with no central government authority to coordinate or monitor the performance of these entities. Consolidation made the FSAI responsible for enforcing food safety legislation and tracking the many entities’ food safety activities. FSAI uses service contracts with each of the government departments, local authorities, and regional health boards to reach agreement with the entities on performance standards, including methods of inspection and the number of inspections to be conducted. FSAI officials meet formally at least three times a year with each entity’s liaison to facilitate monitoring of the service contracts. Separate audits are conducted to verify compliance with their contract requirements.

Source: GAO analysis of information from Irish officials and stakeholders.

^aIreland’s start-up costs as a percentage of its total food safety budget could not be estimated.

Figure 7: Summary of the Netherlands' Food Safety System Consolidation

Reasons for consolidation	Address public concern about food safety resulting from BSE and other food safety crises. Improve effectiveness and/or efficiency by reducing overlap and improving coordination within the food safety system. Facilitate compliance with EU food safety legislation.
Entities responsible for food safety <i>before</i> consolidation	(1) Inspectorate for Health Protection and Veterinary Public Health within the Ministry of Public Health, Welfare and Sports. (2) National Inspectorate Service for Livestock and Meat within the Ministry of Agriculture, Nature, and Food Quality.
Entities responsible for food safety <i>after</i> consolidation	Food and Consumer Product Safety Authority. In 2002, the Netherlands established the Food and Consumer Product Safety Authority, an independent agency within the Ministry of Public Health, Welfare and Sports. In 2003, the new agency was moved to the Ministry of Agriculture, Nature and Food Quality. The new agency includes both inspection offices, which are to be consolidated by January 1, 2006.
Responsibilities of food safety agency(ies) <i>after</i> consolidation	According to officials, the Food and Consumer Product Safety Authority's core responsibilities cover three areas: (1) risk assessment and research – to identify and analyze potential threats to the safety of food and consumer products; (2) enforcement – to ensure compliance with legislation for meat, food, and consumer products, which may include non-food items; and (3) risk communication – to provide information concerning risk and risk reduction, based on accurate and reliable data.
Challenges	(1) Determining the responsibilities and authorities the new food safety agency would have and the ministry in which to place the new agency. (2) Increased employee attrition.
Start-up and other consolidation-related costs cited by officials and stakeholders	Officials estimate the Netherlands' Food and Consumer Product Safety Authority will spend approximately 5 million euros (\$6 million U.S.) on its ongoing consolidation process, or about 3 percent of its 2004 budget.
Examples of benefits cited by officials and stakeholders	(1) Reduced overlap in inspections: Before the consolidation, two inspection offices from separate ministries had responsibility for inspecting slaughterhouses. After consolidation, both inspection offices were placed under the new food safety agency, and now only one inspection office inspects slaughterhouses. In addition, inspectors are being trained to perform more than one type of food safety inspection. This cross-utilization of inspectors will enable one inspector to complete the inspection of a single food-processing facility which was previously conducted by two or more inspectors and reduce the number of visits made to the same food-processing facility. (2) Possible financial savings: Officials anticipate consolidation of inspections ^a will result in financial savings derived from an expected 25 percent reduction in administrative and management personnel and from selling excess property. The Netherlands has also begun to cross-utilize inspectors, training them to perform more than one type of inspection, and has eliminated duplication of food safety inspections by placing its two inspection offices under one agency. Together, these changes are expected to reduce food safety expenditures. A senior Dutch official stated that having one agency be responsible for the entire food supply chain will result in potential savings. (3) Single contact for consumer and industry clients: Industry stakeholders said that before the creation of the Food and Consumer Product Safety Authority, it was unclear to consumers which agency had responsibility for various food safety activities, stakeholders said it is now very clear that the new agency has responsibility for all food safety functions.

Source: GAO analysis of information from Dutch officials and stakeholders.

^aThe Netherlands plans to merge its two inspection offices into one national inspection office within its food safety agency, the Food and Consumer Product Safety Authority.

Figure 8: Summary of New Zealand's Food Safety System Consolidation

Reasons for consolidation	Improve effectiveness in several areas, including coordination within the food safety system and eliminate inconsistencies in the country's oversight of domestic food, imports, and exports.
Entities responsible for food safety before consolidation	(1) Ministry of Health. (2) Ministry of Agriculture and Forestry. In addition, Food Standards Australia New Zealand, a trans-Tasman ^a independent statutory authority established under Australian law, sets standards for composition, labeling, and contaminants for all foods produced or imported for sale in New Zealand and Australia.
Entities responsible for food safety after consolidation	New Zealand Food Standards Authority (NZFSA). In 2002, New Zealand established NZFSA, a single, independent food safety agency. The new agency is a semi-autonomous body attached to the Ministry of Agriculture and Forestry. In addition, Food Standards Australia New Zealand continues to set standards for composition, labeling, and contaminants.
Responsibilities of food safety agency(ies) after consolidation	NZFSA has farm-to-table responsibilities. It develops policy advice for the government and performs public outreach, surveillance, standards setting, enforcement, research, and risk assessments.
Challenges	(1) Where to place the new agency within the government: According to officials, the NZFSA's semi-autonomous status is intended to provide a level of separation from producers sought by the New Zealand public. (2) Adjustment to new organizational culture: Officials stated that reassigning employees to the new food safety agency was moderately challenging because some employees from the larger organizations, particularly those from the Ministry of Health, had difficulty assimilating into the culture of the new agency. Approximately 100 employees moved from the Ministry of Agriculture and Forestry and 12 staff moved from the Ministry of Health into the new food safety agency.
Start-up and other consolidation-related costs cited by officials and stakeholders	New Zealand officials stated that during 2002 New Zealand spent about \$2 million New Zealand (about \$1 million U.S.) on consolidation start-up costs. ^b The start-up funds were primarily used for moving expenses, development of new communication and branding materials, temporary personnel, and rented office space.
Examples of benefits cited by officials and stakeholders	Streamlined communication: According to industry stakeholders, the consolidation has increased and streamlined communication between the food industry and the new food safety agency. They said that before the creation of NZFSA, such communication was not as good as it could have been because two ministries had food safety responsibilities, neither placed food safety as a top priority, and coordination between the two ministries was weak. As a result of the increased and streamlined communication offered by the consolidated food safety system, stakeholders said that the new food safety agency is more responsive to food safety crises. They said the new agency established a network that quickly delivers information to notify the public of food safety issues. This increased interaction has made industry more confident in how the government handles food safety matters. New Zealand's consumer stakeholders told us that streamlined communication is a result of the consolidation and added that this improved communication has improved consumer confidence.

Source: GAO analysis of information from New Zealand officials and stakeholders.

^aThe Trans-Tasman Mutual Recognition Arrangement is an arrangement between the Commonwealth, State and Territory Governments of Australia and the Government of New Zealand. According to its 1998 guide, the Arrangement allows goods to be traded freely between New Zealand and Australia.

^bNew Zealand has not compiled information on its total 2002 food safety spending because several entities had food safety responsibilities. According to officials, NZFSA's fiscal year 2004-2005 budget is about \$78 million New Zealand (about \$53 million U.S.).

Figure 9: Summary of the United Kingdom's Food Safety System Consolidation

Reasons for Consolidation	Address public concerns about food safety stemming from (1) the discovery of BSE and other food safety crises and (2) a perception that food safety regulators favored the food industry at the expense of consumer protection.
Entities responsible for food safety <i>before</i> consolidation	(1) Ministry of Agriculture, Fisheries, and Food. Within this ministry, the Meat Hygiene Service performed meat inspections. (2) Department of Health. (No link existed between the central government and local entities that conducted food safety inspections.)
Entities responsible for food safety <i>after</i> consolidation	Food Standards Agency (FSA). In 2000, the United Kingdom established FSA as its lead food safety agency. FSA is independent of other government departments. The Meat Hygiene Service was moved from the Ministry of Agriculture, Fisheries, and Food to FSA. In addition, some employees were moved from the Ministry of Agriculture, Fisheries, and Food and the Department of Health to FSA. Local entities continue to be responsible for inspections of nonmeat products.
Responsibilities of food safety agency(ies) <i>after</i> consolidation	According to officials, FSA is responsible for scientific risk assessments, research, risk management, policy development, including negotiation in the EU on behalf of the United Kingdom, standard setting, education, and public outreach. It has audit authority and reserve powers ^a over local entities' inspections. Before the creation of FSA, the central government performed only very limited education and public outreach and did not perform oversight of local entities.
Challenges	Deciding which responsibilities to place in the new food safety agency.
Start-up and other consolidation-related costs cited by officials and stakeholders	In 2000, FSA had start-up costs totaling approximately 9 million pounds sterling (about \$14 million U.S.), or about 8 percent of the agency's budget for that year, according to British food safety officials.
Examples of benefits cited by officials and stakeholders	Improved accountability and transparency: According to British officials, establishing a lead food safety agency to consolidate food safety functions in the central government has made local authorities more accountable for food safety inspections, and the results of food safety inspections are more transparent to the public and the central government. Officials stated that before the establishment of FSA, no criteria existed for how local food safety inspections were to be performed, and there was no requirement to report the results of those inspections to the central government. Inspection records were kept at the local level. FSA has authority to audit food safety inspections conducted by local entities, and these entities must provide FSA with statistical information on their food safety inspections. According to officials, this information is made available to the public on a quarterly basis.

Source: GAO analysis of information from British officials and stakeholders.

^aAccording to an FSA official, reserve powers range from providing help and guidance by directing the way in which the local authority operates to performing the local authority's services.

Concluding Observations

Although different in many respects, the seven countries' experiences provide information on the reform and consolidation of food safety systems that can be useful to U.S. policymakers. While the seven countries had to overcome challenges, their experiences show that reforming and streamlining food safety systems is possible when a consensus exists among government agencies, the food industry, and consumer organizations. As we learned from food safety officials and industry and consumer stakeholders in each country we reviewed, such reforms may

result in benefits such as reducing overlaps in food safety inspections and basing the frequency of inspections on the risks posed by specific products. We have reported in the past that the federal food safety system in the United States could benefit from statutory and organizational reforms. As Congress and other policymakers consider the advantages and disadvantages of streamlining multiple existing food safety statutes into a uniform and risk-based framework and whether to consolidate federal food safety functions under a single agency, these countries' lessons may offer useful information.

Comments from the Seven Countries Examined

We provided relevant excerpts from a draft of this report to officials of food safety agencies in Canada, Denmark, Germany, Ireland, the Netherlands, New Zealand, and the United Kingdom for their review. The officials either replied that they had no technical comments or provided technical corrections, which we incorporated into the report as appropriate.

Agency Comments and Our Evaluation

Although this report does not evaluate HHS's or USDA's food safety programs and, therefore, makes no recommendations to the agencies, we provided a draft copy to HHS and USDA for review and comment. In commenting on this report, both HHS and USDA stated that U.S. food safety agencies are working together effectively.

HHS noted that our report provides limited quantitative data on the results of each country's consolidation. The report clearly states that the information presented was obtained primarily through structured interviews with high-level government officials and food industry and consumer stakeholders from each of the seven countries we reviewed. In addition, our report acknowledges that these officials provided limited quantitative data; when it was provided to us, we included it in the report. Our report also acknowledges that none of the countries has conducted a formal analysis to compare the effectiveness and efficiency of its consolidated food safety system with that of the previous system. HHS also commented that the countries included in our report have smaller food and agriculture industries than the United States. We agree, and our report highlights such differences in table 1, which shows that the seven countries have smaller economies and less total food consumption than the United States. Our report also points out, however, that these countries are similar to the United States in that they are high-income countries where consumers have high expectations for food safety. Finally, HHS

commented that the report does not identify the agencies that are responsible for foodborne illness surveillance in each of the countries we reviewed. We have added a footnote to indicate that the report does not contain that information. HHS also provided technical comments, which we have incorporated in the report as appropriate. HHS's comments are presented in appendix IX.

In its comments, USDA stated that the report does not contain rigorous cost-benefit analyses or quantitative data on the public health effects of the countries' consolidations, such as changes in foodborne illness rates. Our report clearly acknowledges that we obtained limited quantitative information and that none of the countries has conducted an analysis to compare the effectiveness and efficiency of its consolidated food safety system with that of the previous system. Specifically, with regard to the effect of consolidation on public health benefits, the report states that officials told us they could not determine whether their country's consolidation had reduced foodborne illness because consolidation was one of many factors that could influence the frequency of foodborne illness. USDA also stated that the report does not contain quantitative data on reorganization costs. This statement is incorrect. All but one of the seven countries provided information on the costs of reorganization, which the report presents in figures 3 through 9. Similar to HHS, USDA commented that the countries we reviewed have much smaller populations and also differ from the United States in climate and agricultural production. Our report identifies differences of this type in table 1. The report points out, however, that these countries and the United States have at least one important similarity: they are high-income countries where consumers have high expectations for food safety. As a result, we believe the consolidation experiences of the countries reviewed have applicability to the United States. USDA also provided technical comments, which we incorporated into the report as appropriate. USDA's comments are included in appendix X.

We are sending copies of this report to the appropriate congressional committees, the Secretaries of Agriculture and of Health and Human Services, and other interested parties. We will also make copies available to others upon request. In addition, this 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 call me at (202) 512-3841. Key contributors to this report are listed in appendix XI.

A handwritten signature in black ink, reading "Robert A. Robinson". The signature is fluid and cursive, with the first name "Robert" being the most prominent.

Robert A. Robinson
Managing Director, Natural Resources
and Environment

Scope and Methodology

This report describes the approaches the seven countries have taken in consolidating food safety functions, the challenges they faced, and the results of the countries' efforts, including benefits and costs cited by government officials and industry or consumer stakeholders.

For the purposes of this report, we defined consolidation as the transfer of responsibility and resources for performing a food safety function from two or more agencies to a single agency.

To identify countries that have consolidated their food safety systems, we interviewed USDA and FDA officials, reviewed a 2001 World Health Organization report on how countries have organized their food safety systems,¹ and reviewed the Internet sites of countries' food safety agencies. We selected a judgmental sample of seven countries for our review based on the following criteria: USDA and FDA officials agreed that these countries have consolidated, the countries have high per capita income, and the countries have consolidated functions of their food safety system within the last 10 years.

To address our objective, we examined the seven countries' efforts to streamline and consolidate their food safety systems, including the benefits and costs that resulted, as cited by government officials. We conducted structured interviews with senior government officials from food safety agencies and with representatives of food industry or consumer organizations in each country, reviewed and analyzed the documents they provided, and reviewed World Health Organization and GAO reports. We also met with European Union (EU) food safety officials to discuss how the EU's food legislation is affecting its member countries' decisions to consolidate, as well as how the EU interacts with food safety agencies in member countries.

The information on countries' food safety systems in this report, including descriptions of laws,² is based almost exclusively on interviews with and documentation provided by high-level food safety officials as well as food industry or consumer stakeholders from the seven countries we examined.

¹World Health Organization, *Improved Coordination and Harmonization of National Food Safety Control Services* (World Health Organization Regional Office for Europe, Copenhagen, Denmark, 2001).

²We did not perform independent analysis of those laws or attempt to independently assess their intent.

Most of the information we obtained was qualitative. To the extent possible, we corroborated the qualitative information provided by government officials by interviewing food industry and consumer organization stakeholders. We obtained very limited quantitative information. We asked government officials questions intended to help us assess the reliability of the quantitative information they provided, but we could not determine the reliability of most of this information because of constraints on the amount of time the countries' food safety officials could devote to our study. Although we could not assess the quantitative information's reliability, we are reporting it in order to provide descriptive information to inform policymakers in the United States about the various approaches, challenges, and benefits that countries' officials identified to us regarding their consolidation efforts.

The data in table 2 on selected countries' population, gross domestic product, food consumption, income, and consumer spending were used for background purposes and were not verified.

We conducted our work from April 2004 through December 2004 in accordance with generally accepted government auditing standards.

Canada's Food Safety System Consolidation

In 1997, Canada consolidated its food inspection activities with the creation of the Canadian Food Inspection Agency. Food safety standard setting, research, and risk assessment were consolidated within Health Canada.

Reasons for Consolidating Food Safety Responsibilities

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.

Responsibilities and Structure Before and After Consolidation

Before Canada consolidated its food safety system, its food safety inspection, food policy, and risk assessment responsibilities were shared by three separate entities—Health Canada, Agriculture and Agri-Food Canada, and Fisheries and Oceans Canada.

In 1997, the Canadian parliament approved the Canadian Food Inspection Agency (CFIA) Act. All food safety inspection activities were assigned to CFIA, a separate regulatory agency whose president reports to the Minister of Agriculture and Agri-Food Canada. CFIA is responsible for all food safety inspections and related activities, including inspections of imported and domestic products, export certifications, laboratory and diagnostic support, crisis management, and product recalls. CFIA is also responsible for food quality assurance inspections and animal health and plant disease control. Canada has adopted a comprehensive farm-to-table approach to food safety responsibilities.

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, were consolidated within Health Canada.¹ With the placement of food safety inspections and related activities in CFIA and risk assessment in Health Canada, inspection responsibilities were separated from risk assessment to allow for an independent scientific risk assessment process.

¹Health Canada's responsibilities include research, risk assessment and standard setting in relation to the nutritional quality of foods marketed in Canada. For example, Health Canada is responsible for nutrition labeling, health claims, and nutrient content claims.

Legislation

In 1997, the Canadian Food Inspection Agency Act created the agency and gave it authority to implement existing food safety laws. Additional legislative reform intended to increase the food safety system's effectiveness and efficiency beyond the gains already achieved was introduced in the Canadian parliament in November 2004.² According to CFIA, under this proposed legislation, the authorities for CFIA inspectors contained in eight commodity-specific laws would be strengthened and made consistent. In addition, the law would give CFIA additional inspection and enforcement authorities to protect the food supply, such as the authority to hold products while awaiting test results.

Challenges

CFIA faced a challenge in helping staff adjust to a new organization as its work force combined former employees from the health, agriculture, and fisheries departments. According to officials, several senior officials retired when CFIA was being formed. As a result, the agency temporarily had less experience at the management level than would have been optimal. Canadian officials told us it is important to plan for the merging of organizational cultures and to bring the new work force into a dialogue on the new organization's vision and objectives.

Employee unions were initially concerned that the consolidation would lead to privatization of the food safety work force. According to a CFIA official, these concerns decreased substantially when the work force realized privatization was not planned. In addition, the official stated that labor relations have improved because unions now only have to interact with one food safety inspection agency instead of three.

In addition, assignment of responsibilities was a major obstacle during the implementation phase of Canada's consolidation. To address this challenge, Health Canada and CFIA jointly developed a food safety functions matrix to clearly define responsibilities.

Annual Expenditures and Number of Employees

According to a senior official, CFIA's fiscal year 2003 food safety spending was \$360 million Canadian (\$232 million U.S.). Spending for all of its activities—food safety, animal health, and plant protection—was \$517

²The CFIA Enforcement Act was introduced in the Canadian Parliament on November 26, 2004.

million Canadian (\$334 million U.S.). User fees assessed on food establishments financed a portion of this spending. These user fees for food inspections have been frozen at about \$40 million Canadian (about \$26 million U.S.) since 1997 and in fiscal year 2003 accounted for about 11 percent of CFIA's food safety spending.

According to a Health Canada official, the fiscal year 2004 budget for Health Canada's food program was about \$42 million Canadian (\$31 million U.S.).

Reducing spending was one of Canada's objectives in consolidating its food safety system. A senior CFIA official stated that during the agency's first two years, fiscal years 1997 and 1998, the consolidation reduced food safety operating expenditures by 10 percent relative to preconsolidation food safety spending.³ The official based this statement on his knowledge of food safety operating expenditures before and after the consolidation. The official noted that Canada has not performed an analysis on the effect of its consolidation on food safety expenditures. According to the official, such an analysis would be difficult because (1) the last audited preconsolidation quantification of food safety expenditures was published in a 1994 report by Canada's Office of the Auditor General and (2) in fiscal year 1997, when the CFIA was formed, food safety, animal health, and plant health expenditures were not separated in financial reports. The agency began separating these expenditures in financial reports beginning in fiscal year 2000.

According to the CFIA official, CFIA's work force consisted of about 5,300 employees in fiscal year 2003. According to a Health Canada official, the Health Canada food program had approximately 400 staff in fiscal year 2004.

³The official also noted that since fiscal year 1998, CFIA's total expenditures for all of its activities—food safety, animal health, and plant protection—have increased, but said this increased spending was not related to the consolidation and attributed the increase to higher food production, exports, and consumption, as well as increased spending in response to threats from new animal and plant diseases and pests. While some of these new plant pests and animal diseases, such as BSE, are food safety issues, others, such as foot-and-mouth disease, an animal disease, and the Asian long-horned beetle, an insect that harms trees, are not related to food safety.

Stakeholder Reaction

The food industry stakeholders we interviewed were consistently supportive of Canada's consolidation. Among the consolidation-related benefits they cited were improved communications, particularly with respect to food recalls; easier interaction with regulators through having a single contact for enforcement and compliance; fewer inspectors visiting processing plants; clarification of responsibilities; and increased consistency in the enforcement of food safety laws.

While expressing overall support for the consolidation, representatives of some food industry organizations cited a need for more timely decision making. For example, representatives of one organization said their member companies, which, they said, often have more technical expertise than the government authorities on specific matters, sometimes have to wait too long for a decision on a food safety question and lose commercial opportunities as a result. In addition, some industry representatives said Health Canada's setting of standards should better reflect CFIA's ability to enforce the standards.

Denmark's Food Safety System Consolidation

In 1997, Denmark consolidated its food safety system with the creation of the Danish Veterinary and Food Administration.

Reasons for Consolidating Food Safety Responsibilities

Denmark consolidated its food safety system to (1) improve effectiveness in several areas, including communications with consumers and consistency of inspections and (2) improve efficiency in numerous ways, such as by moving resources to areas that present higher risks and reducing overlaps in responsibilities.

Responsibilities and Structure Before and After Consolidation

Before Denmark consolidated its food safety system, responsibilities for inspections were shared by multiple entities, including the Ministry of Agriculture, the Ministry of Fisheries, and a large number of municipalities. Standard-setting responsibilities were shared by the Ministry of Health, the Ministry of Agriculture, and the Ministry of Fisheries.

In 1997, the Danish government consolidated the multiple agencies' activities into the Danish Veterinary and Food Administration (DVFA), an agency of the newly formed Ministry of Food, Agriculture, and Fisheries. Inspections were consolidated within the DVFA in 1999 and 2000. In August 2004, as part of a governmental reorganization, the Danish Veterinary and Food Administration was moved to the newly created Ministry of Family and Consumer Affairs.

The DVFA is responsible for almost all food safety responsibilities. For logistical reasons, a few duties were not moved to the new agency in 1999 and 2000. These remaining duties are with the Plant Directorate, which is responsible for animal feed inspections, and the Directorate for Fisheries, which is responsible for inspections of fish on ships. These two agencies are in the Ministry of Food, Agriculture, and Fisheries. According to officials, the DVFA has farm-to-table food safety responsibilities.

Denmark has separated risk management and risk assessment. The Danish Institute for Food and Veterinary Research, a separate institute within the DVFA, is responsible for research and risk assessment.

Legislation

The Danish Food Act, adopted in 1998, reformed Danish food safety law by replacing seven existing food laws with this single law. The legislation

harmonizes the regulation of food of animal origin and other food, and, according to Danish officials, it is very similar to EU food legislation.

Challenges

Officials said when bringing employees from several agencies into a new organization, it is important to establish a common culture. The consolidation involved over 2,000 employees, including about 500 municipal inspectors who were moved to the DVFA. To foster the development of a common organizational culture, food agency officials moved employees to centralized locations and established online discussion groups to familiarize employees with the mission and culture of the organization. In addition, the division heads in the regional offices held monthly meetings with employees.

Moreover, officials stressed the need to have adequate funding for start-up costs.

Annual Budget and Number of Employees

According to officials, DVFA's budget for 2004 was 856 million Danish kroner (about \$142 million U.S.). About 61 percent of this planned spending was to be financed by user fees assessed on food establishments. User fees finance nearly all meat inspections.

Officials stated that DVFA had about 2,000 employees (1,820 full-time equivalents) in 2004.

Stakeholder Reaction

The food industry and consumer organization representatives we interviewed told us their organizations supported the proposed consolidation and continue to support it. They stated that the consolidation has improved the food safety system's effectiveness. Improvements cited include more consistent enforcement of food safety regulations, reduced overlap in inspections, streamlined communications, clearer responsibilities, and improved service delivery as a result of having a single contact. For example, a food industry representative stated that having a single contact leaves no doubt about which authority to approach when a problem or question arises. In addition, the representative said Denmark's *salmonella* control program is an example of a situation where the

consolidation's clearer responsibilities have been beneficial.¹ Without the consolidation, said the representative, this program probably would have experienced conflicts between the health and agriculture ministries and would not have been as successful.

User fees are also an important consideration for the Danish food industry. As noted earlier, Danish food companies finance a significant portion of DVFA's spending through payment of user fees. According to industry officials, the payment of these fees motivated the food industry to support reforms in the Danish food safety system that would hold down inspection costs.

According to a consumer organization representative, the consolidation made food safety inspections and enforcement of laws and regulations more consistent. Before the consolidation, the representative said, many municipal food safety entities had insufficient expertise and resources and the central government's oversight of municipal food safety entities was uneven. In addition, the representative stated that the consolidation had facilitated the development of DVFA's online system to report the results of inspections. The representative believes having access to inspection reports has contributed to Danish consumers' continued high confidence in the safety of their food.

¹*Salmonella* bacteria, sometimes present in meat, are a source of foodborne illness in humans.

Germany's Food Safety System Consolidation

The German parliament approved the creation of the Federal Office of Consumer Protection and Food Safety and the Federal Institute for Risk Assessment in 2002.

Reasons for Consolidating Food Safety Responsibilities

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.

Responsibilities and Structure Before and After Consolidation

Before Germany consolidated its food safety system, responsibilities for research, risk assessment, and communication were shared by the Federal Ministry of Health and the Federal Ministry of Food, Agriculture and Forestry.¹ Responsibilities for implementation of federal legislation and oversight of inspections were shared by the sixteen federal German states, and inspections were performed by municipalities and other local governments.

In 2002, the creation of two new food safety agencies was approved by the German Parliament. Both of the new agencies are in the Federal Ministry of Consumer Protection, Food, and Agriculture.

The Federal Office of Consumer Protection and Food Safety, a coordinating body, is responsible for leading food safety risk management. It serves as Germany's contact point with the European Commission, including (1) acting as a coordinator for Food and Veterinary Office audits of compliance with EU food safety legislation and (2) implementing in Germany the European rapid alert system for consumer health protection and food safety. In addition, this agency's responsibilities include coordinating food safety surveillance at the federal level and formulating general administrative rules to guide the implementation of national food safety laws by the German federal states. The federal states continue to be responsible for implementation of food safety legislation and oversight of food inspections performed by local governments.

¹The Federal Environment Ministry had responsibility for industrial contaminants, such as dioxin, in food. It continues to have this responsibility.

The other new food safety agency is the Federal Institute for Risk Assessment, whose responsibilities include providing impartial scientific advice and support for the law-making activities and policies of the federal government in all fields concerning food safety and consumer health protection, except for animal diseases. The Federal Institute for Risk Assessment performs risk assessments and communicates risk assessment results to the general public. According to officials, this agency was created to separate risk assessments from decision making. The purpose of this separation was to increase public confidence in risk assessments by distancing these assessments from possible political interference.

A chronology of the consolidation of Germany's food safety system follows:

- November 2000—The detection of BSE in German cattle and other food safety issues undermined consumer confidence in the food safety system.
- July 2001—The Federal Performance Commissioner's Report, a study of the German food safety system, was produced by a German national audit office task force. The report's three main recommendations were to (1) reorganize the Federal Ministry of Consumer Protection, Food, and Agriculture, (2) establish a coordinating body within the federal government, and (3) establish a scientific unit to perform risk assessments.
- December 2001—In response to the task force report's second and third recommendations, administrative guidance issued by the Federal Ministry of Consumer Protection, Food, and Agriculture established the Federal Office of Consumer Protection and Food Safety and the Federal Institute for Risk Assessment as "institutes."
- August 2002—The German parliament approved the Consumer Health Protection and Food Safety Restructuring Act, authorizing the creation of these two new food safety agencies.
- November 2002—The Consumer Health Protection and Food Safety Restructuring Act took effect.
- December 2003—The Federal Office of Consumer Protection and Food Safety presented the federal states with a draft general administrative regulation that would harmonize their food safety controls. As of

October 2004, German officials expected these regulations to take effect in January 2005.

Legislation

The Consumer Health Protection and Food Safety Restructuring Act, which took effect in November 2002, separated the fields of risk management and risk assessment by authorizing the creation of Germany's two new food safety agencies.

Challenges

According to officials, negotiations between the federal government and the federal states concerning reform of food safety law have been complicated, as some reforms that would give the federal government increased authority would require constitutional changes.

Annual Budget and Number of Employees

According to officials, the Federal Office of Consumer Protection and Food Safety's budgeted spending for 2004 was 25 million euros (about \$31 million U.S.), and the budgeted 2004 spending for the Federal Institute for Risk Assessment was 47 million euros (about \$58 million U.S.).

In 2004, according to officials, the Federal Office of Consumer Protection and Food Safety had about 350 employees, and the Federal Institute for Risk Assessment had about 540 staff.

Stakeholder Reaction

The German food industry and consumer organization stakeholders we contacted support the consolidation.

According to a representative of a major food industry organization, the German food industry supports the creation of the Federal Office of Consumer Protection and Food Safety because it has increased coordination of the federal states' food safety activities and has improved Germany's ability to respond to potential food safety crises. In addition, to further improve Germany's ability to prevent potential food safety crises and in view of impending EU legislation, the food industry advocates increasing the Federal Office of Consumer Protection and Food Safety's authority to coordinate the federal states' food safety activities, thus enabling increased harmonization of food safety standards and control procedures across states. Moreover, the food industry representative stated

that the separation of risk assessment and risk management has given the food safety system more credibility in the view of the public and industry.

A representative of the consumer organization we contacted stated that the consolidation has made the food safety system more effective. In addition, the representative stated that the consolidation has increased German consumers' confidence, but added that German consumers continue to have less confidence than consumers in other European countries. The consumer organization favors giving the Federal Office of Consumer Protection and Food Safety increased authority.

Ireland's Food Safety System Consolidation

In 1998, the Irish government enacted legislation creating the Food Safety Authority of Ireland. The Authority assumed all responsibility for food safety in July 1999.

Reasons for Consolidating Food Safety Responsibilities

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. Maintaining a strong food safety system is also extremely important for Ireland's economy for several reasons. According to senior food safety officials, roughly 90 percent of the country's meat and 75 percent of food is produced for export. If trading partners lost confidence in the food safety system, thus losing confidence in the food, exports could decline—even without a major outbreak. In addition, Ireland's economy depends heavily on tourism, and outbreaks of foodborne illnesses could affect tourism and cause serious harm to the economy. Furthermore, when BSE was found in Irish cattle in the 1990's, Irish consumption of meat declined as consumers questioned the effectiveness of the Department of Agriculture and Food, which was responsible for inspections of abattoirs, meatpacking plants, and farms. Also, some consumers perceived that the Department favored the interests of the food industry over consumer protection.

Responsibilities and Structures Before and After Consolidation

According to officials, before the consolidation of Ireland's food safety system, food safety functions were the responsibility of over 50 entities across the government, including six government departments, 33 local authorities, and eight regional health boards, with no central government authority to coordinate all of these entities. The Department of Agriculture and Food, inspected farms, slaughterhouses, and meat processing facilities for compliance with food safety regulations and was also responsible for the promotion of the agriculture industry. Local governments and regional authorities (e.g., health boards) had various other food safety responsibilities, such as inspecting meat plants producing for the home market, production and processing of food of nonanimal origin and the retail and catering sectors. In addition, multiple agencies were tasked with enforcing food safety legislation with no central accountability system in place to ensure that food safety legislation was being properly enforced or to coordinate food safety functions and activities across the food supply chain.

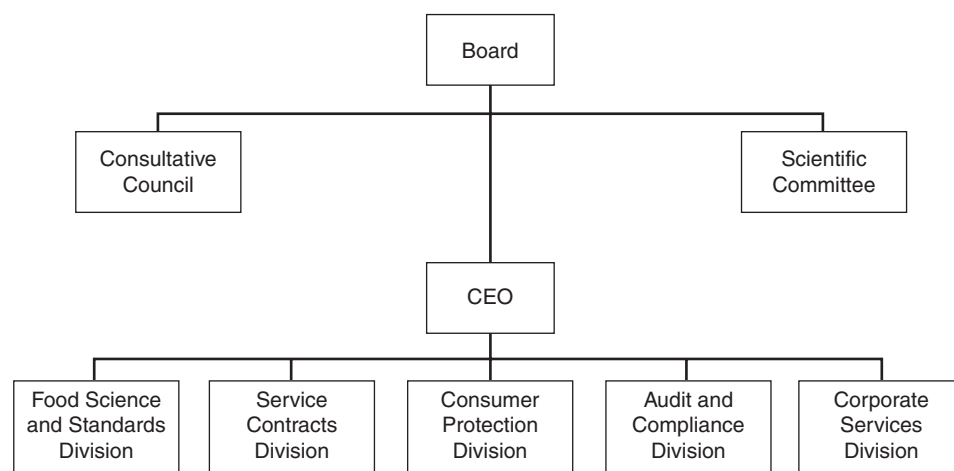
As a result of a series of food scares in the 1990s, the Irish government undertook a review of its food safety system in 1996 to assure the safety and quality of their food products. The government's review eventually led to the establishment of a lead food safety agency. The government established an interdepartmental committee to advise the Irish parliament on how the various food safety entities could best be coordinated. In early 1997, this committee recommended establishing a Food Safety Authority of Ireland. Under this recommendation, the responsibility for implementation of food safety laws would have remained with the existing agencies. The Authority would have audited these agencies and had a voice in setting and maintaining standards as well as in promoting good practices. Before this recommendation was enacted, a new government took office after an election in mid-1997. The new government believed that the Authority should be directly accountable for all food safety functions, including enforcement of food legislation. This proposal led to the establishment of the Food Safety Authority of Ireland (FSAI), formally established in law under the Food Safety Authority of Ireland Act, 1998, and beginning its official operation in January 1999. The legislation which established the FSAI provides for the transfer of all relevant staff to the new agency. Alternatively it provides that the FSAI can enter into a service contract with existing agencies for the enforcement of food legislation. As the likely personnel issues surrounding the smooth transfer of staff would have delayed commencement of FSAI's food safety enforcement role, the service contract mechanism was used. At the time, roughly 2,000 staff, spread across more than 50 agencies, delivered food safety services throughout the country. Many staff had duties in addition to food safety responsibilities and therefore officials found it difficult to transfer "food safety" personnel to the Authority without disrupting other programs.

FSAI is an independent, science-based body that reports to the Department of Health and Children.¹ According to officials, the government deliberately placed the FSAI under the auspices of the Department of Health and Children rather than the Department of Agriculture and Food, as the former's focus is on consumer health and protection, whereas the latter is associated with industry and trade development and promotion.

¹According to officials, FSAI maintains independence due to its clear separation from the food industry. Section 10 of the Food Safety Authority of Ireland Act, 1998 states: "The Authority shall, subject to this Act, be independent in the exercise of its functions."

A Board of 10 members, appointed by the Minister of Health and Children, governs FSAI although a chief executive officer leads day-to-day operations.² In addition, the agency has a 15 member scientific committee that assists and advises the Board. See figure 10.

Figure 10: Food Safety Authority of Ireland's Organization



Source: GAO analysis of information from Irish officials.

FSAI is the single regulatory authority with responsibility for enforcing food safety legislation in Ireland. This responsibility is managed through service contracts with agencies performing food safety activities. FSAI has the responsibility to monitor and audit these agencies to determine how well they fulfill the tasks laid out in their service contracts. FSAI meets formally at least three times a year with each agency's liaison to facilitate monitoring of the service contracts, and began auditing the agencies on their performance in fulfilling their service contracts, in the second half of 2004.³

FSAI has risk assessment, risk management, and risk communication responsibilities, including setting standards according to the scientific

²Members of the Board are primarily from academia or public health fields.

³Each service contract is valid for 3 years, at the conclusion of which it is revised and renewed.

advice (put forth by the scientific committee), making risk management decisions with the agencies that are responsible for conducting food safety inspection and enforcement, and communicating risks to consumers, the food industry, and public health professionals. According to officials, FSAI's responsibility for food law enforcement begins when food or animals are transported from the farm. In the fisheries and aquaculture sector, it has responsibility for food law at the level of primary production. However, feed safety and animal welfare are outside its jurisdiction.

Procedures are in place to deal with food scares and food crises, should they emerge. Such crisis measures include a 24-hour emergency number, where local authorities can contact FSAI, as well as a memorandum of understanding between FSAI and all the agencies with food safety functions on how to coordinate during a crisis. In addition, FSAI is the national contact for the EU's rapid alert food safety system.

Legislation

According to senior food safety officials, legislative reform of Ireland's food safety laws was minor. The Food Safety Authority of Ireland Act, 1998, as well as establishing FSAI, also transferred authority for enforcement of existing food legislation and setting food safety and hygiene standards to FSAI. Although food law in Ireland dates back to the 1800's, most of Ireland's national food legislation today is derived from Ireland's EU membership.

Challenges

According to officials, in deciding where to place the new food safety agency within the government, Ireland chose to place it under its existing Department of Health and Children specifically to separate food safety responsibilities from food and agriculture promotion efforts, which is the responsibility of the Department of Agriculture and Food.

In addition, food safety agency officials had the overall role of bringing about the general understanding that the primary responsibility for food safety rests with the food industry. According to senior officials, FSAI works with all stakeholders towards this end. Industry stakeholders we spoke with stated they are now aware that they have such a responsibility. This change was, in part, due to the FSAI holding open forums with shellfish farmers, caterers, industry groups, and other stakeholders. The forums discussed problems and solutions, as well as advocated partnerships.

Annual expenditures and number of employees

FSAI officials estimated that FSAI spends 9.4 million euros (about \$11.6 million U.S.) on food safety activities annually. Government departments, such as the Department of Agriculture and Food, still retain responsibility for policy and legislation and have separate budgets.

In 2004, FSAI had 82 employees.

Stakeholder Reaction

According to industry stakeholders, FSAI has been successful in making the concerns and desires of consumers and retailers on food safety matters a higher priority than they were before the consolidation and making food safety a higher priority for industry by fostering open communication. Industry representatives stated these changes have been positive for industry. For example, stakeholders also stated that their positive relationship with FSAI has allowed industry organizations to be informed about discussions at the EU level and subsequently voice their position to FSAI on issues discussed at this level. A report published in October 2003 on industry attitudes toward food safety stated that 910 of 1,300 industry representatives surveyed (70 percent) considered food safer than it had been 10 years earlier.⁴

A consumer organization stakeholder cited several examples of why consumers support Ireland's consolidation of its food safety system. For example, the official stated that FSAI is a single contact point for consumers when food safety concerns or questions arise. Moreover, the official said, the consolidation and creation of FSAI added accountability to food safety in Ireland, which did not exist before. As a result, said the official, consumers are more confident in the safety of the food supply, as well as more aware and knowledgeable about food safety. A report published in October 2003 on consumers attitudes toward food safety stated that more than half of 800 adult consumers (53 percent) surveyed considered food safer than it had been 10 years earlier.⁵

⁴FSAI's Food Safety Consultative Council conducted the survey. The results were published in October 2003 in a report entitled "Industry Attitudes to Food Safety in Ireland."

⁵"Consumer Attitudes to Food Safety in Ireland," based on a survey by FSAI's Food Safety Consultative Council, was published in October 2003.

The Netherlands' Food Safety System Consolidation

In 2002, the Netherlands moved an inspection office from the health ministry and an inspection office from the agriculture ministry to its new food safety agency, the Food and Consumer Product Safety Authority. According to Dutch officials, further consolidation is to occur by January 1, 2006, when the merger of the two inspection offices is to be completed.

Reasons for Consolidating Food Safety Responsibilities

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,¹ BSE, and other animal diseases triggered the Netherlands' decision to restructure its food safety system. Officials noted that the need to comply with recently adopted EU legislation also motivated the Netherlands' consolidation.

Responsibilities and Structure Before and After Consolidation

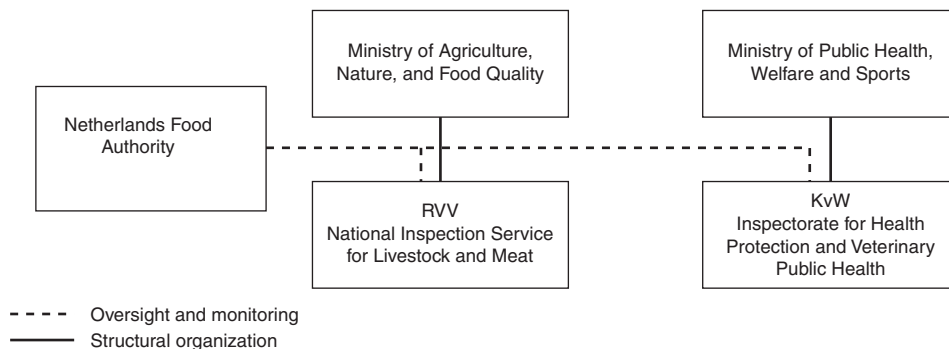
Before the Netherlands consolidated its food safety agencies in 2002, the country maintained two food safety inspection offices, each located in a different ministry. The Inspectorate for Health Protection and Veterinary Public Health (KvW) was in the Ministry of Public Health, Welfare and Sports. The National Inspection Service for Livestock and Meat (RVV) was in the Ministry of Agriculture, Nature and Food Quality. According to a senior food safety official, having food safety responsibilities divided between two different ministries caused overlap within the Netherlands' food safety system. For example, both ministries had responsibilities for inspecting slaughterhouse facilities. Officials stated that communications between the two inspection agencies needed to be streamlined and duplication of inspection efforts needed to be reduced.

In 2001, before beginning its 2002 consolidation, the Netherlands tried to address the problems associated with having two inspection offices by creating the Netherlands Food Authority, a small team of scientists who monitored the work of the two inspection offices, KvW and RVV. (See fig. 11 below.) However, according to officials, by 2002, both the Dutch parliament and consumer organizations wanted more guarantees for food safety inspections than could be offered by the Netherlands Food Authority. Therefore, in July 2002, the Netherlands converted the

¹In 1999, dioxin, a potential carcinogen, was found in animal feed in Europe. To protect consumer health, the European Commission adopted measures to remove poultry, pigs, and cattle suspected of having eaten contaminated feed from the food supply chain.

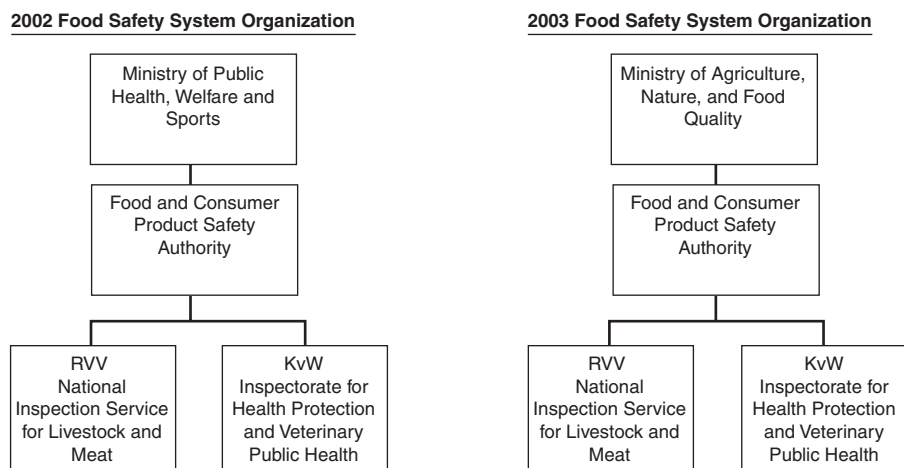
Netherlands Food Authority into a new food safety agency, the Food and Consumer Product Safety Authority, and placed both the RVV and KvW within the new agency. Initially, the Food and Consumer Product Safety Authority was housed under the Ministry of Public Health, Welfare and Sports, but in 2003 it was moved to the Ministry of Agriculture, Nature and Food Quality. (See fig. 12 below.) According to officials, moving the new food safety agency to the agricultural ministry increased its prominence.

Figure 11: The Netherlands' 2001 Food Safety System Organization



Source: GAO analysis of information from Dutch officials.

Figure 12: The Netherlands' 2002 and 2003 Food Safety System Organization



Source: GAO analysis of information from Dutch officials.

According to officials, the Food and Consumer Product Safety Authority's core responsibilities cover three areas: (1) risk assessment and research—to identify and analyze potential threats to the safety of food and consumer products; (2) enforcement—to ensure compliance with legislation for meat, food, and consumer products, which may include nonfood items; and (3) risk communication—to provide information concerning risk and risk reduction, based on accurate and reliable data. The agency's enforcement responsibilities include food, animal health, and animal welfare inspections.²

Senior food safety officials stated that the Netherlands' consolidation efforts are not complete. According to officials, the two inspection offices will be merged into one by 2006. This single inspection office will consist of inspectors responsible for inspecting several types of food products. The Food and Consumer Product Safety Authority has begun training current inspectors in anticipation of this merger.

Legislation

According to an agency document, the Food and Consumer Product Safety Authority derives its responsibilities from various sources, including the Food and Consumer Product Safety Authority Organization Decree, dated July 10, 2002. To accomplish the move of inspection offices, the RVV and the KvW, within the Netherlands food safety system, officials stated that no major legal changes or new laws were needed. Only minor revisions in some laws, such as changing the name of the organization responsible, were necessary.

Challenges

Officials in the Netherlands faced three challenges in changing the country's food safety system. First, the government had to decide what responsibilities and authorities the new food safety agency would have. Second, as discussed above, the government had to decide which ministry the new food safety agency would be placed in. The third challenge was an increase in employee attrition. For example, an official stated that attrition increased when the Food and Consumer Product Safety Authority was moved from the Ministry of Public Health, Welfare and Sports to the Ministry of Agriculture, Nature and Food Quality.

²According to officials, producers have the primary responsibility for product quality.

Annual Budget and Number
of Employees

According to officials, in 2004, the Food and Consumer Product Safety Authority's budget was 188 million euros (about \$232 million U.S.), and the agency's workforce consisted of about 2,700 full-time equivalents. Officials also told us that the workforce would decrease to about 1,800 full-time equivalents by January 2006. Among the factors causing this reduction are the partial privatization of meat inspections and the reorganization and reduction of administrative and management personnel.

Stakeholder Reaction

Representatives of the fruit and vegetable, dairy, and livestock and meat industries all stated that their operations were not affected by the consolidation in the Netherlands' food safety system. However, they all stated that the change was beneficial for consumers in that it clarified that the Food and Consumer Product Safety Authority was the responsible agency for food safety functions. The Food and Consumer Product Safety Authority performed a study of Dutch consumers' confidence in the safety of food in 2002 and 2003. The study results show that consumers in both years had high confidence in food safety. In addition, one industry representative explained that as a result of moving the two inspection offices into a single agency, the two offices now have common goals.

New Zealand's Food Safety System Consolidation

The New Zealand Food Safety Authority was established in July 2002.

Reasons for Consolidating Food Safety Responsibilities

According to officials, the New Zealand Food Safety Authority (NZFSA) was established in July 2002 to improve the effectiveness of New Zealand's food safety system by coordinating and harmonizing food safety efforts. Specifically, New Zealand wanted to address inconsistencies between the methods used in the Ministry of Agriculture and Forestry's export food safety program and the Ministry of Health's domestic food safety program.

Responsibilities and Structure Before and After Consolidation

Before the consolidation, the Ministry of Agriculture and Forestry had food safety responsibilities for agricultural production, meat and dairy processing, food exports, and registration of agricultural compounds and veterinary medicines. The Ministry of Health was responsible for addressing health issues, as well as ensuring the safety of food sold on the domestic market, including imported food. According to officials, to address inconsistencies between the two ministries' food programs, New Zealand's government consolidated food safety responsibilities of the two ministries into one semi-autonomous body attached to the Ministry of Agriculture and Forestry.

NZFSA is now New Zealand's controlling authority for domestic food safety and imports and exports of food and food-related products. It is responsible for administering legislation covering food for sale on the domestic market; primary processing of animal products and official assurances related to their export; exports of plant products; food imports; and the regulation of agricultural compounds, such as pesticides and fertilizers, as well as veterinary medicines. NZFSA has farm-to-table responsibilities—from primary production through processing to retailers, importing, and exporting, as well as responsibility for consumer education. According to officials, the export program's purposes are to maintain and increase exports while providing assurances of food safety and keeping compliance costs under control. NZFSA's organization includes a verification agency, which audits animal product facilities to verify that exporters are following agreed processes. According to officials, about 280 of NZFSA's approximately 480 employees are in the verification agency.

In addition, New Zealand and Australia share a trans-Tasman independent agency established under Australian law, the Food Standards Australia New Zealand, that develops food standards for composition, labeling, and

contaminants that apply to all foods produced or imported for sale in New Zealand.¹

Legislation

Officials stated that existing food safety legislation required only very minor modification to create the New Zealand Food Safety Authority and authorize it to regulate food safety. However, officials stated that the total domestic food regulatory program is currently under review, and it was expected that quite extensive change would be needed as an outcome of this review. Legislative change is expected in late fiscal year 2005-2006.

Challenges

According to officials, adjustment to a new organizational culture was somewhat challenging for some employees. They said some employees from the larger organizations, particularly employees from the Ministry of Health, had difficulty assimilating into the culture of the new agency. Approximately 100 employees moved from the Ministry of Agriculture and Forestry, and 12 staff moved from the Ministry of Health into the new food safety agency. A second challenge for officials was deciding where within the government the agency would be located. NZFSA was established as a semi-autonomous body attached to the Ministry of Agriculture and Forestry. According to officials, its semi-autonomous status is intended to provide a level of separation from producers sought by the New Zealand public. In addition, the government had to decide whether to move certain food-related responsibilities to the new agency. For example, responsibility for human nutrition was kept at the Ministry of Health.

Annual Budget and Number of Employees

According to officials, NZFSA's budget for the fiscal year that ended June 30, 2004, was approximately \$78 million New Zealand (about \$53 million U.S.). A portion of NZFSA's spending is financed by user fees assessed on industry for a range of regulator-provided services, including export certification, export audit arrangements, and market access efforts. Officials stated that NZFSA had approximately 480 employees in 2004.

¹Food Standards Australia New Zealand was established by the Australian Food Standards Australia New Zealand Act 1991.

Stakeholder Reaction

According to a consumer organization representative, before the creation of NZFSA, consumers were dissatisfied with the low priority both ministries placed on food safety. According to this representative, consumer organizations advocated changes in the food safety system, including the creation of a single agency dedicated to food safety.

In 2003, about one year after its creation, NZFSA commissioned a study conducted by an independent research organization to provide benchmark information on food safety issues among New Zealand's general public. The study revealed that a majority of respondents considered food safety standards to be improving, although concerns remain about specific foods, such as chicken; food outlets; and other food-related issues, including salmonella. Only one-third of the survey's respondents stated that they were confident in the level of monitoring and enforcement of food safety standards. Despite these concerns, officials of a consumer organization stated that the creation of NZFSA was a very positive step that was strongly supported by consumers, and that the agency was too new for consumer confidence levels to have significantly increased at the time of the survey.

An official representing a food industry organization in New Zealand stated that the organization, along with others, had advocated the establishment of a single food safety agency for years. The official stated the previous system was piecemeal and inefficient, due to coordination problems associated with two ministries having food safety responsibilities and neither ministry placing a high priority on food safety. As a result of the establishment of NZFSA, the industry is more confident in how the nation handles food safety. One official stated that as a result of the consolidation, the use of available resources for food safety activities is more efficient because food safety resources are located in one agency instead of fragmented between two ministries. In addition, the official stated that consumer confidence levels have improved due to an increase in the government's responsiveness to food safety crises. According to the official, NZFSA has a responsive network that quickly delivers information to notify the public of food safety issues. Finally, the official stated that NZFSA has significantly improved transparency and remains committed to ongoing discussions with its many stakeholder groups. For example, in responding to reports of increased iodine levels in children, NZFSA began discussions immediately with endocrinologists, other doctors, and with food industry representatives to address the issue.

The United Kingdom's Food Safety System Consolidation

In 1999, the Queen, by and with the consent of Parliament, enacted legislation to establish the independent Food Standards Agency, which went into effect on April 1, 2000.

Reasons for Consolidating Food Safety Responsibilities

Officials stated that the United Kingdom 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 BSE. 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.

Responsibilities and Structure Before and After Consolidation

Before the reorganization of the United Kingdom's food safety system in 2000, food safety responsibilities were divided among several central government departments, such as the Ministry of Agriculture, Fisheries, and Food and the Department of Health, as well as local authorities. The Meat Hygiene Service, a subunit of the Ministry of Agriculture, Fisheries, and Food was responsible for meat inspections, including enforcing hygiene in slaughterhouses. Other food inspections, conducted by local authorities, received no oversight from the central government.

In 1999, to address public concerns, the Parliament passed the Food Standards Act of 1999 to establish the independent Food Standards Agency (FSA) as the country's lead food safety agency. Officials stated that the core groups of employees that started with FSA were from the Ministry of Agriculture, Fisheries, and Food and the Department of Health. The Meat Hygiene Service was moved out of the Ministry of Agriculture, Fisheries, and Food and placed within FSA.¹ In addition, FSA was granted audit authority over local enforcement.

¹In June 2001, the Department for Environment, Food, and Rural Affairs (DEFRA) was created. Its responsibilities include on-farm issues, such as animal welfare and the safety of animal feed, as well as promotion of agriculture and the food industry. According to officials, elements of the Ministry of Agriculture, Fisheries, and Food, which no longer exists, were moved to FSA (1999 to 2000) and DEFRA (2001).

According to officials, FSA is responsible for scientific risk assessments, risk management, standard setting, education, and public outreach. In addition, its subunit, the Meat Hygiene Service, is responsible for meat inspections. For other foods, FSA forms inspection policy and audits local inspection authorities. Fruit, crops, and animal feed are also within its jurisdiction. FSA has no agricultural or food promotion responsibilities.

FSA has the powers of an agency in a ministry, but is not part of a ministry. However, according to officials, the agency is held accountable to the Westminster Parliament and devolved administrations in Scotland, Wales, and Northern Ireland through Health Ministers.

An independent Board that consists of a Chairman, a Deputy Chair, and up to 12 other members appointed to act collectively in the public interest, manage the FSA. The Board's Chairman, who is appointed by the Secretary of State for Health; Scottish Ministers; the National Assembly for Wales; and the Department of Health, Social Services and Public Safety in Northern Ireland, determines food policy and holds discussions on policy issues in public meetings.

Legislation

The Food Standards Act of 1999 established the FSA. It classifies the FSA as an independent nonministerial government department and defines the agency's functions and powers, including its function to monitor and audit the performance of local authorities and where necessary to exercise reserve powers² over local authorities.

Challenges

The United Kingdom's main challenge in consolidating was deciding which responsibilities to place in the new food safety agency. The government had to decide whether to (1) separate or combine food safety and nutrition, (2) include the Meat Hygiene Service within the new agency, and (3) include nonmeat inspections as a responsibility of the new agency or to sustain that authority with the local governments. Decisions on these issues were made after several debates in Parliament and considerable discussion among government officials and stakeholders from the food industry and consumer organizations.

²According to an FSA official, reserve powers range from providing help and guidance by directing the way in which the local authority operates to performing the local authority's services.

An additional challenge cited by FSA officials was to avoid duplication of efforts during the establishment of FSA and the termination of the Ministry of Agriculture, Fisheries, and Food. To address this challenge, a joint interim group was created to help reduce such duplication of efforts.

Annual Budget and Number of Employees

According to officials, FSA's annual budget is approximately 130 million pounds sterling (about \$220 million U.S.); most of that amount is allocated for meat inspections. The food industry pays FSA about 30 million pounds sterling (about \$51 million U.S.) annually in user fees for inspections.

Officials stated that FSA's workforce consists of approximately 3,000 employees.³

Stakeholder Reaction

A consumer stakeholder stated that the establishment of FSA was an improvement to the food safety system because the agency has made the system more open and transparent than it was before the consolidation. Surveys of consumer attitudes on particular areas of the food safety system have been conducted, but no survey has been conducted to measure the confidence level of consumers for the entire food safety system. For example, this stakeholder stated that surveys conducted by a consumer association concluded that meat is still a concern for consumers, but the association has not conducted a survey to determine confidence levels over the entire food chain. The same consumer stakeholder also stated that FSA has increased public education about food safety.

Industry stakeholders agreed that the establishment of a single, independent food safety agency has increased consumer confidence. A stakeholder stated that the most significant result of the consolidation was a shift from an industry focus to a consumer focus on food safety matters. Stakeholders also said transparency regarding the government's oversight of food safety matters has greatly increased. In addition, one stakeholder noted that the consolidation resulted in increased accountability within the food safety system. However, industry stakeholders cited dissatisfaction with the new agency's reporting on the testing of food products. One stakeholder stated that FSA collects product samples, tests them, and reports results without consulting companies. Another stated that the

³According to officials, about 2,500 of these employees are with the Meat Hygiene Service.

agency comments on food product studies before they are actually completed.

Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

FEB - 1 2005

Mr. Robert A. Robinson
Managing Director, Natural Resources and Environment
U.S. Government Accountability Office
Washington, DC 20548

Dear Mr. Robinson:

Enclosed are the Department's comments on the U.S. Government Accountability Office's (GAO's) draft report entitled, "Food Safety—Experiences of Seven Countries in Consolidating Their Food Safety Systems" (GAO-05-212). The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department provided several technical comments directly to your staff.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

A handwritten signature in cursive script that reads "Daniel R. Levinson".

Daniel R. Levinson
Acting Inspector General

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for U.S. Government Accountability Office reports. OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

**COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
ON THE U.S. GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT
REPORT, "FOOD SAFETY—EXPERIENCES OF SEVEN COUNTRIES IN
CONSOLIDATING THEIR FOOD SAFETY SYSTEMS" (GAO-05-212)**

We appreciate the opportunity to review and comment on the U.S. Government Accountability Office's (GAO) draft report.

The GAO draft report states that the decision and results by each country for such consolidation and/or reorganization are not well substantiated by quantitative data or evidence. The report does cite some anecdotal or qualitative remarks on "perceived" benefits. For example, a statement is given that the reorganization achieved more timely response but no data to show how much the time of response changed or improved. However, it would have been instructive to know the cost/benefit rationale to undertake such reorganization and all of the necessary steps to complete the transition, over what period of time, total cost and number of personnel to accomplish.

In using these countries as a reference point for consolidation of food safety programs, it should also be pointed out that each of the countries studied represent a much smaller food and agriculture industry than we have here in the U.S. Therefore, the scalability of any conclusions, based on these experiences, would need to be assessed with that in mind.

In 2002, the Bush Administration looked into the issue of consolidating food safety agencies, particularly Department of Health and Human Services, Food and Drug Administration and the U.S. Department of Agriculture/Food Safety and Inspection Service, and concluded that the goals of the Administration are better advanced through enhanced interagency coordination rather than through the development of legislation to create a single food agency. The current and recent Administrations have strived to develop a central framework without reorganizing many different organizations, agencies, and departments. Largely, this has been accomplished through interagency councils, workgroups, scientific partnerships, and coordinated budget activities.

HHS believes that the current food safety system is working. Federal agencies with food safety authorities are working together effectively. The American food supply continues to be among the safest in the world.

Appendix IX
Comments from the Department of Health
and Human Services

The term “surveillance” needs to be clarified. The Centers for Disease Control is described on page 9 (Figure 1: U.S. Federal Agencies’ Food Safety Responsibilities) as being responsible for “Protecting the nation’s public health, including foodborne illness surveillance.” However, the report focuses on surveillance of the food supply, not of people and illness. Identifying where surveillance and investigation of foodborne illnesses reside in the seven countries will help avoid the misinterpretation that ALL food-related activities were shifted into the consolidated agencies described. For example, human disease surveillance for foodborne diseases, such as Salmonella or E. coli O157, is conducted by the Health Department, not the Food Safety Authority, in Denmark, Germany, and the Netherlands. If GAO did not collect information on which agency is responsible for human foodborne disease surveillance after consolidation, a special note should be made in the report.

Comments from the U.S. Department of Agriculture



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

FEB 4 2005

Robert A. Robinson
Managing Director, Natural Resources and Environment Team
United States Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Robinson,

Please find the enclosed specific comments from the U.S. Department of Agriculture (USDA) on the Government Accountability Office (GAO) draft report entitled, "FOOD SAFETY: Experiences of Seven Countries in Consolidating Their Food Safety Systems." The Department appreciates the opportunity to comment on this draft report.

From a public health regulatory standpoint, we are primarily interested in whether consolidation of food safety systems resulted in a measurable benefit to public health. Unfortunately your study did not determine whether consolidation or reorganization in these foreign countries had reduced foodborne illness rates for any of the countries included in the study. The report does not contain rigorous cost-benefit analyses to support the claimed or implied benefits. We had hoped that the report would contain quantitative data including foodborne illness rates, pathogen levels in regulatory samples, operating efficiencies obtained from consolidation, and reorganization costs. Additionally, the report does not contain an analysis to compare the effectiveness and efficiency of the consolidated food safety systems with those of the previous systems.

During the course of the audit, we noted differences between the U.S. and the countries identified in this report. The seven countries whose food safety systems you reviewed are much smaller in population than the United States. Because of differences in climate and agricultural production, it may not be possible to compare food safety systems of these other countries to our own. Because of these issues we believe that the report's observations have limited applicability to the U.S. food safety agencies.

USDA plays an integral role in ensuring the safety of the nation's food supply. For example, as a partner in the U.S. food safety effort, the Food Safety and Inspection Service maintains a strong working relationship and open communication with other public health agencies. Our agencies continue to demonstrate the active cooperation, communication, and coordination on public health issues to effectively and seamlessly ensure the safety of the nation's food supply.

Appendix X
Comments from the U.S. Department of
Agriculture

Robert A. Robinson

Effective communication and coordination is the best way to ensure that the safety and security of all food products are being considered in the farm to table continuum. The USDA believes the existing system is working. The American food supply continues to be among the safest in the world.

Sincerely,



Dr. Barbara J. Masters
Acting Administrator

Enclosure

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In addition to those named above, major contributors to this report were Lawrence J. Dyckman and Kelli Ann Walther. Nancy Crothers, Barbara El Osta, Michele Fejfar, and Amy Webbink also made key contributions to this report.

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