

GAO

Report to the Chairman, Permanent
Subcommittee on Investigations,
Committee on Governmental Affairs,
U.S. Senate

April 1999

FOOD SAFETY

Experiences of Four Countries in Consolidating Their Food Safety Systems





United States
General Accounting Office
Washington, D.C. 20548

**Resources, Community, and
Economic Development Division**

B-281971

April 20, 1999

The Honorable Susan M. Collins
Chairman, Permanent Subcommittee
on Investigations
Committee on Governmental Affairs
United States Senate

Dear Madam Chairman:

Outbreaks of foodborne illnesses have raised questions about the safety of the U.S. food supply and the inherent weaknesses of the fragmented federal food safety system. The U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service has regulatory responsibility for ensuring the safety of meat, poultry, and some egg products, while the Department of Health and Human Services' Food and Drug Administration has regulatory responsibility for all other food products. Both these agencies inspect domestic and imported food. In addition, other federal agencies have food safety programs or responsibilities. As we have reported on many occasions, this fragmented system impedes the government's ability to efficiently and effectively oversee the safety of the food supply.¹ Consequently, we have recommended consolidating federal food safety activities. In August 1998, the National Academy of Sciences also recommended consolidating food safety functions and suggested a number of approaches that could be considered, including a single food safety agency. Shortly after the National Academy issued its report, the President established a Council on Food Safety, which was to review and report on the Academy's report in 1999.

To supplement the National Academy's study, you asked us to review the experiences of foreign countries that are consolidating their food safety responsibilities. Specifically, we (1) examined the reasons for and approaches taken to consolidation, the costs and savings, if any, associated with consolidation, and efforts to assess the effectiveness of the revised food safety systems and (2) identified the lessons that the United States might learn from these countries' experiences in consolidating their food safety functions. We visited three countries—Canada, Denmark, and Ireland—which have consolidated their food safety responsibilities, and one country—Great Britain—which is in the process of consolidating its food safety responsibilities. These four

¹See Related GAO Products.

countries' food safety systems are discussed in detail in appendixes I through IV.

Results in Brief

The reasons the four countries have consolidated, or are in the process of consolidating, their organizational responsibilities for food safety activities differed, as did the approaches they took. However, all four countries had similar views regarding the costs and benefits of consolidation and the need to evaluate their consolidation efforts. In deciding to consolidate food safety responsibilities, two of the countries—Great Britain and Ireland—were responding to public concerns about the safety of their food supplies and chose to consolidate responsibilities in the agencies that report to their ministers of health. The other two countries—Canada and Denmark—were more concerned about program effectiveness and cost savings and consolidated activities in agencies that report to their ministers of agriculture, who already control most of the food safety resources. All four countries are incurring short-term start-up costs in establishing their new agencies but are expecting long-term benefits in terms of money saved, more food safety for the money spent, and/or better assurance of food safety. None of the countries had developed performance measures and data early in the consolidation process to assess the effectiveness of its new system.

Foreign officials identified several common lessons from their experiences that they believe could be broadly applicable to any U.S. consolidation effort. In all four countries, a consensus had to be developed on the need to consolidate food safety responsibilities. Certain management initiatives, such as strong leadership and a dedicated start-up group to begin agency operations, were needed to establish any new agency. Adequate funding for start-up costs was also necessary. Furthermore, to help ensure the new agencies' early success, critical operational concerns, such as having the flexibility to shift program resources to the highest food safety priorities, establishing a common organizational culture, and ensuring openness in the decision-making process were important factors that had to be addressed. And finally, evaluation criteria and mechanisms need to be established early in the process in order to assess the new agency's performance.

Background

Foodborne illness in the United States is extensive and costly. Estimates of the incidence of foodborne illness range from 6.5 million to 81 million cases each year and result in 500 to 9,100 deaths. These illnesses cost the

nation between \$7 billion and \$37 billion annually in medical and productivity losses.²

Multiple agencies share the responsibility for regulating food safety in the United States—12 different federal agencies in six federal entities are involved. Our past reviews have shown inconsistencies and differences between agencies' approaches and enforcement authorities that undercut overall efforts to ensure a safe food supply.³ As such, we have recommended implementing a uniform, risk-based inspection system and a single food safety agency to help correct the problems created by this fragmented system.

Fragmentation is not unique to the United States. Food safety officials in each of the four countries we visited maintained that similar fragmentation existed in their systems prior to consolidation. For example, before consolidation, the Danish food-processing sector encompassed seven laws, about 125 regulations, and more than 30 federal agencies and local offices overseeing food safety activities. Prior to Ireland's consolidation, more than 50 agencies shared food safety responsibilities.

The four countries have recently completed or are still in the process of consolidating their activities. Specifically:

- Canada decided in 1996 to consolidate its food inspection activities into a single new agency. The new agency—the Canadian Food Inspection Agency—officially began operations in April 1997. However, the responsibility for setting health standards for food safety remained with Health Canada.
- Denmark phased in the consolidation of its food safety activities, beginning in 1995, by combining the Ministry of Agriculture and the Ministry of Fisheries into a single ministry—the Ministry of Agriculture and Fisheries. In December 1996, Denmark moved the food safety inspections conducted by its Health Ministry into the Ministry of Agriculture and Fisheries. The new consolidated agency is called the Ministry of Food, Agriculture, and Fisheries. The district and local inspection offices of the old ministries are being reorganized into 11 regional inspection offices within the new Ministry. Once this reorganization takes place, the consolidation will be complete.

²Food Safety: Information on Foodborne Illnesses (GAO/RCED-96-96, May 8, 1996).

³Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992), Food Safety: A Unified, Risk-Based System Needed to Enhance Food Safety (GAO/RCED-94-71, Nov. 4, 1993), and Food Safety: Fundamental Changes Needed to Improve Food Safety (GAO/RCED-97-249R, Sept. 9, 1997).

- Great Britain is in the process of consolidating its food safety activities. In September 1997, the Ministry of Agriculture, Fisheries and Food and the Department of Health set up a work group composed of staff from both agencies—known as the Joint Food Safety and Standards Group—to plan the consolidation. In January 1998, the government formally proposed consolidating all food safety responsibilities under a new agency to be known as the Food Standards Agency. Final legislation establishing this agency had not been enacted as of January 1999. However, the British government expects Parliament to act on the new agency this year.
- Ireland approved the consolidation all of its food safety responsibilities under the umbrella of the Food Safety Authority of Ireland in July 1998. This Authority officially assumed its responsibilities in January 1999.

The three European countries that we visited are members of the European Union and thus in some instances must follow Union directives.⁴ The European Commission, which is a regulatory body of the Union, recently made organizational changes that emphasized consumer protection in its food safety policy. The Commission has brought together certain responsibilities for consumer protection and public health for food into a single organization—Directorate General XXIV—which reports to the Commissioner for Consumer Policy and Health Protection. In addition, Directorate General XXIV is responsible for the relevant scientific committees in the food safety area. According to several of the European food safety officials with whom we met, these changes have made it easier for them to consolidate food safety responsibilities and to reorient newly consolidated agencies toward consumer protection.

Foreign Countries' Approaches To, and Preliminary Results Of, Consolidating Food Safety Activities

The four countries we visited had different reasons for consolidating their food safety activities, and therefore their approaches to reorganizing food safety responsibilities also differed. All four countries are incurring short-term costs while expecting long-term benefits. None had developed performance measures and data early in the process to assess the effectiveness of their new systems.

Reasons For, and Responsibilities Of, New Food Safety Agencies

The decisions to consolidate food safety responsibilities in the four countries we examined were based on each country's recent food safety history and economic considerations, among other things. Great Britain

⁴The European Union is a collection of 15 member nations, whose objectives are to promote European economic and social progress, assert the European identity, and introduce a European citizenship for the nationals of the member states.

and Ireland chose or plan to have their newly consolidated food safety activities report to their ministers for health. In Canada, the new agency reports directly to the Minister for Agriculture. Denmark combined food safety activities with agricultural and fisheries activities, creating a new ministry.

According to British food safety stakeholders,⁵ the British plan to consolidate food safety activities into a single agency—the Food Standards Agency in the Department of Health—was largely a result of the government’s perceived mishandling of the Bovine Spongiform Encephalopathy (BSE) outbreak.⁶ In Great Britain, as of February 1, 1999, the BSE outbreak has resulted in 35 human deaths from a new variant of Creutzfeldt-Jakob disease and has hurt the country’s cattle industry: 3.7 million of Britain’s 10 million cattle had to be destroyed. BSE has also had an adverse impact on the British beef export industry because the European Union banned the trading of British beef among member nations. Cattle producers have suffered large losses in the value of their animals because of depressed markets. Other industries affected by the BSE outbreak include slaughterhouses, auctioneers, truckers, and beef export firms. According to several food safety stakeholders, it was widely perceived that the fragmented and decentralized food safety system—divided between several central government departments, such as the Ministry of Agriculture, Fisheries and Food and the Department of Health, as well as local authorities—allowed this outbreak to occur. Some of the stakeholders were particularly concerned with the Ministry of Agriculture, Fisheries and Food’s dual responsibilities to promote agriculture and the food industry as well as to regulate food safety.

Consequently, during the 1997 election campaign for Parliament, the then candidate, and now prime minister, called for consolidating food safety responsibilities and for greater openness in the decision-making process about food safety. The public also demanded the consolidation of the food safety system as well as its removal from the Ministry of Agriculture, Fisheries and Food. As of January 1999, British food safety officials and other stakeholders remained committed to consolidating all activities related to food, including, among other things, the management of nutrition, food safety, chemical, and other additives, genetically modified

⁵Throughout this report we use the term “stakeholders” to mean the food industry (farmers and food processors), consumer groups, and affected government organizations and their employee unions.

⁶BSE, commonly known as “mad cow disease,” is one in a category of neurological disorders called transmissible spongiform encephalopathies. The human nervous system disorder Creutzfeldt-Jakob disease is among these transmissible spongiform diseases, and the crisis in Britain began when a new variant of Creutzfeldt-Jakob disease was discovered in association with mad cow disease.

organisms, and meat hygiene and dairy inspections. The consolidated agency will report to the Secretary of State for Health—the cabinet minister responsible for health. The enactment of the Food Standards Agency’s enabling legislation has been delayed while budgetary and other issues are being addressed. In the interim, the government established the Joint Food Safety and Standards Group, which is jointly managed by the Ministry of Agriculture, Fisheries and Food and the Department of Health.

Similarly in Ireland, outbreaks of foodborne illness and the potential economic consequences of real or perceived unsafe food products provided the impetus for the consolidation of food safety responsibilities into a single agency in July 1998—the Food Safety Authority of Ireland. Irish food safety officials said that a succession of high-profile outbreaks of foodborne illnesses throughout the world, such as the BSE outbreak in Great Britain and the E.coli outbreak in Scotland, shook consumer confidence in the safety of food and in the ability of regulatory agencies to protect the public. In 1998, roughly 80 head of Irish cattle—out of about 7 million head in total—were found to be infected with BSE. These developments signaled not only a public health concern but also a potentially devastating economic problem because Ireland exports about 90 percent of the meat it produces. According to Irish food safety officials, these developments also served to highlight the difficulties that the Department of Agriculture and Food faced in trying to carry out the dual mission of protecting consumers and promoting the food industry.

In July 1998, Ireland enacted legislation that (1) created the Food Safety Authority of Ireland, (2) made the Authority responsible for overseeing food safety activities, and (3) had the Authority report to the Minister of Health and Children. The legislation provided the Authority with the power to consolidate all food safety activities into a single agency. In exercising their new duties, as a first step, the Authority entered into service contracts with federal and local agencies to continue their food safety inspections and other activities. These contracts include mutually agreed-upon objectives and milestones. Preconsolidation funding arrangements were maintained. That is, the Parliament provides funds to agencies, which make resources available to fulfill their obligations with the Authority. According to Authority officials, if the service contracts are not satisfactorily performed, the Authority will initiate efforts to place all food safety activities under its direct control. The Authority received 6.5 million Irish pounds (\$10 million in U.S. dollars) in its first year budget—1.5 million Irish pounds for start-up costs and 5.0 million Irish pounds for coordinating inspection services and new educational

programs. The Authority took official charge of food safety on January 1, 1999.⁷

In contrast to Great Britain and Ireland, Canada initiated changes to its food safety activities to improve effectiveness and reduce costs. Canada did not face a loss of public confidence as did Great Britain and Ireland, but in the early 1990s, it faced a budgetary crisis and sought ways to reduce federal expenditures. By combining the various elements of its food inspection services, Canada expected to save about 13 percent of its food inspection budget, or \$44 million Canadian per year, (\$29 million in U.S. dollars) and improve the effectiveness of its inspection programs. In April 1997, the Canadian Food Inspection Agency began operations. While national food safety standards continue to be set by Health Canada—Canada’s Department of Health—all federal food inspections are the responsibility of the new food inspection agency, which is also responsible for animal and plant health inspections. The new agency has the status of a departmental corporation under the Financial Administration Act, which provides the agency with the authority to raise and retain funds from its activities. In addition, from the outset the agency has had “separate employer status,” which has enabled it to create its own personnel system. The new agency reports directly to the Minister of Agriculture and Agri-Food Canada—Canada’s department of agriculture.

Denmark also launched changes to its food safety system to achieve greater efficiency and effectiveness. In 1996, at the request of food safety stakeholders, Denmark sought to strengthen its efforts with respect to food safety and food quality by consolidating food safety activities in the newly created Ministry of Food, Agriculture, and Fisheries. Denmark’s aims were to simplify food safety administration, control, and legislation, believing that such reforms would lead to a more efficient and effective food safety system and provide assurances of the quality of Danish food products, many of which are exported. For example, prior to consolidation, three Danish ministries—Health, Agriculture, and Fisheries, each with its own local food safety structure—shared responsibilities for implementing food safety laws. According to the Permanent Secretary of the new ministry, the results of this fragmented approach included extensive overlapping responsibilities in some areas and gaps in coverage in other areas; inconsistent food safety inspections; and inefficient use of

⁷Under the Good Friday Agreement between Northern Ireland and the Republic of Ireland, there is to be an all-island food safety promotion body. Some functions of the Food Safety Authority of Ireland will be transferred to this promotion body and will be undertaken on an all-Ireland basis. These activities will include food safety promotion, food alerts, surveillance of food-related illnesses, and laboratory services.

food safety resources. The Permanent Secretary and all other stakeholders in Denmark believe that consolidating food safety responsibilities will address these concerns.

Countries Expect Long-Term Benefits but Are Incurring Start-Up Costs

Officials in the four countries we visited anticipated start-up costs with the consolidation of food safety activities. These costs are in addition to the ongoing operational costs. Specifically, the new, consolidated agencies require additional funding to establish a fully operational food safety system, including such overhead costs as computers and telephones. While the countries may have similar start-up activities, their costs cannot be compared because of differences in the size of the countries, the food safety activities that will be included in these new approaches, and the infrastructure already in place before these new efforts were launched. In Denmark, the start-up cost was about 120 million kroner (\$18 million in U.S. dollars, or about 3 percent of Denmark's food safety budget). Canadian officials estimated that their start-up costs were about \$25 million Canadian dollars (\$17 million in U.S. dollars, or about 7 percent of Canada's food safety budget). British food safety officials estimate that Great Britain will spend 30 million pounds (\$49 million in U.S. dollars, or about 25 percent of the British food safety budget) for start-up over a 3-year period. According to Irish food safety officials, the Food Safety Authority of Ireland's start-up costs were about 1.5 million Irish pounds (\$2 million in U.S. dollars). However, the start-up costs as a percentage of the total food safety budget could not be estimated. Canadian labor officials also noted less obvious costs, such as brief losses in productivity shortly before and immediately after consolidation.

Over the long term, however, food safety stakeholders in all four of the countries we visited believe that the benefits of consolidating food safety activities will outweigh the additional costs. Through a more effective, streamlined approach, these officials believe, consolidated food safety agencies offer opportunities to enhance consumer protection and to improve working relationships with the food industry. Specifically, these officials believe that consolidating food safety activities would

- improve service delivery by providing a single contact for consumer and industry clients;
- reduce overlap and the duplication of services;
- improve or reduce the need to coordinate food safety activities, thereby enhancing the efficiency and effectiveness of food safety regulation;

- provide more comprehensive oversight of food safety from “farm to table;” and
- enhance food safety, thereby providing continued access to international markets for producers and processors.⁸

None of the Four Countries Has Developed Data for Evaluating the Effectiveness of Consolidation

Food safety officials in all four countries said that their main priority to date has been to consolidate food safety activities. Nevertheless, they believe that evaluation is an important function. For example, in Canada, the legislation that created the Canadian Food Inspection Agency calls for performance measures. The Canadian inspection agency’s first business plan for 1999 acknowledges the need to establish measures to evaluate the agency’s performance. In Denmark, beginning in 1999, government officials said they plan to start using public health information, including foodborne illness data, to evaluate the effectiveness of the new organization. Great Britain has published a commitment to develop performance measures by the time the new agency begins operations. Ireland plans to introduce a system of monitoring its service contracts but has not yet determined when it would evaluate the Authority.

Lessons the Four Countries Learned From Their Experiences

Officials in the four countries identified several lessons that can be learned from their consolidation experiences. One of the most important is developing a consensus on the need to reform the food safety system. Other lessons learned include the importance of (1) strong leadership; (2) dedicated start-up groups; (3) additional start-up funding; (4) organizational flexibility; (5) personnel integration strategies; (6) open decision-making; and (7) evaluation criteria. These lessons are discussed below.

Consensus on the Need for Change. Officials believe that achieving consolidation requires strong support among stakeholders. This includes agreement not only on the need for a new system but also on its scope and configuration. Each of the four countries began with a highly fragmented and decentralized system. While food safety officials in these countries believe that these decentralized approaches were less than optimal, some stakeholders hesitated to embrace the new consolidated agencies.

In Great Britain and Ireland, the health and economic threats posed by outbreaks of foodborne illnesses served as strong incentives for change.

⁸All four of the countries we visited depend to some extent on food exports for their economic well-being. Officials believe that greater assurances of food safety should allow them to maintain current international markets and could actually improve their access to these markets.

Although Ireland has already begun functioning under its new food safety system, as of January 1999, Great Britain had not yet passed enabling legislation. Food safety officials anticipate parliamentary action during the current session. The delay in Great Britain is occurring not because consensus is lacking about the need for consolidation but because (1) it has been difficult for stakeholders to arrive at a consensus on how to fund the new system and (2) Parliament has been occupied with a full slate of other pressing matters, such as the reform of the House of Lords. Although the government favors imposing some forms of user fees on the food industry to help pay for the new system, industry and some consumer groups generally oppose such fees. Industry groups oppose them because of the additional costs they would add to production. The consumer groups with which we met oppose user fees because they fear such fees could lead to dependence on the food industry for funding and to a conflict of interest within the new food standards agency.

In Denmark and Canada, concerns about program effectiveness and budgetary savings drove the changes. In Denmark, food industry and consumer groups requested the government to reorganize the food safety system. In a letter to the Prime Minister, these groups called for consolidating the food safety system to improve the effectiveness of inspections. They believed that an efficient food safety system would help Denmark maintain its reputation for high-quality, safe foods—especially for export markets. In Canada, officials said that initial support for a consolidated food safety approach was considerable, but food safety inspector unions presented some opposition in the hearings before Parliament. However, even this opposition faded once the new inspection agency became operational and its advantages became apparent.

Strong leadership. Two of the four countries we visited relied upon strong leadership to get their new agencies started and to overcome initial bureaucratic opposition to change. In Ireland, a director was appointed early in the process to oversee the establishment of the Food Safety Authority of Ireland. The director has been able to work effectively with consumers, industry representatives, and government officials to establish the new agency's agenda. The Authority gained credibility and support with the early appointment of its director, a well-known and respected medical doctor and veterinarian. Even before the new agency became fully operational, its director became Ireland's spokesperson on food safety issues. In speaking out on these issues, the new director was viewed as advocating consumer protection while being fair to industry. In Denmark, the Permanent Secretary of the new ministry led the reorganization of its

food safety system. As of January 1999, Great Britain had not yet had a single individual in charge of the proposed new agency. Canadian officials noted that the Canadian Food Inspection Agency's first president was not appointed until late 1996, after many transition decisions had already been made. However, they also pointed out that each of the Canadian ministers involved in the transition provided strong leadership and support to the start-up group.

Dedicated start-up groups. In Canada and Ireland, dedicated start-up groups helped ensure that the new agencies began operations in a timely fashion. For example, Canada recruited seven key officials from agencies that would be affected by the consolidation to lay the groundwork for the food inspection agency. Throughout the period leading up to the creation of Canada's food inspection agency, the affected departments made a commitment to free these key officials from day-to-day operations so they could focus on creating the new agency. In addition, these key officials obtained the financial and human resources they needed because they had management's full support. In Great Britain, the Ministry of Agriculture, Fisheries and Food and the Department of Health established the Joint Food Safety and Standards Group, which brought together those parts of the two agencies likely to form the core of a consolidated food safety agency. As of January 1999, Great Britain had resolved many of the major issues regarding the creation of the Food Standards Agency, except the funding issue described earlier. Denmark did not rely on a start-up group because it consolidated food safety responsibilities in phases.

Additional start-up funding. Funding for start-up activities in the three countries that have consolidated their food safety activities was handled differently, but all three found that they needed additional funds. For example, these countries had to operate dual systems (while the new systems were being brought on line, the old system had to continue to operate); purchase new equipment and office space; and standardize procedures from the different agencies involved in the consolidation. Irish officials told us that one of the keys to their early success has been having adequate start-up funds available. By contrast, Canadian officials told us that they anticipated from the outset that they would have to request more start-up funds than the amount originally allocated. Indeed, they did request additional assistance from the Parliament. For example, the new inspection agency became legally responsible for its own staffing system on April 1, 1998, a year after the agency officially opened its doors. According to Canadian officials, the delay in creating the new personnel system occurred, at least in part, because they had underestimated the

funding and expertise required to develop and implement such a system. In Denmark, officials also noted the importance of additional funding for consolidation. They said they could more effectively manage additional start-up funds by phasing in food safety consolidation over several years.

Organizational flexibility. Food safety officials in all four countries said that the new agency should have sufficient organizational flexibility to shift resources to the areas of greatest risk. For example, the new Canadian and Danish agencies can move resources from one area to another, such as moving inspectors when risk assessments indicate such movements are needed. In Ireland, officials said that the service contract arrangement may impede the agencies' ability to move resources to respond to new or increasing risks. As such, Irish food safety officials told us that they plan to evaluate the service contract arrangement in about 3 years. If, at the end of that time, the Authority believes that the service contract system does not adequately ensure the safety of the food supply, it would then move to control all food safety resources. Currently, within its service agreement context, the Authority can only request that other agencies shift their resource allocations.

Personnel integration strategies. Integrating all of the new agency's personnel into a new organizational culture is important to ensuring its success, according to officials in two of the four countries we visited. For example, Canada recognized the need to integrate its inspection staff and to develop a new and distinct organizational culture and identity. As a result, the new agency's management devoted considerable time to obtain staff input on the agency's core mission and values. These consultations continue today to assist managers in charting the agency's future. In Denmark, the new agency was formed from three separate ministries—agriculture, health, and fisheries—each with its own culture and procedures and with staff located in different offices. In order to successfully blend these disparate groups, Denmark adopted an incremental approach in which existing agencies were consolidated over a 4-year period ending in 1999. According to Danish officials, this strategy for integrating personnel has made the new food safety agency much more cohesive, and therefore more effective, than their previous system.

Open decision-making. Openness in the new agencies' decisions and decision-making process is essential in order to maintain consensus and public confidence, according to officials in three of the four countries visited. To achieve openness, the new agencies will bring consumer protection groups into the decision-making process and will publicize food

safety concerns. This approach is significantly different from previous government practices. Historically, in Great Britain and Ireland, the public was not always informed about the bases for food safety decisions and the processes by which these decisions were reached. Denmark has a similar history regarding decisions on meat products. According to officials in these countries, this lack of openness has fueled public cynicism and mistrust, especially during outbreaks of foodborne illnesses. For example, during the BSE outbreak in Great Britain, consumer groups believed that the Ministry of Agriculture, Fisheries and Food withheld information from the public regarding the extent of the disease among the nation's cattle herds as well as information on the severity of the BSE threat to humans. All three European countries have made commitments to have open and transparent decision-making processes in their new food safety agencies.

Evaluation criteria. The ability to evaluate the new consolidated system should be built in as early as possible in a new agency's development. Officials in three of the four countries believe that a new agency's goals and the criteria for evaluating the agency's progress towards these goals should be defined. Some of the criteria suggested for measuring the effectiveness of a new agency include (1) downward trends in the incidence of foodborne illnesses, (2) increases in the level of confidence the public has in the new agency, and (3) an a reduction in bacterial levels on food products, such as meat and poultry. However, no single criterion should be relied upon exclusively to measure the effectiveness of a new agency's approaches; rather, a combination of measures should be used. In evaluating the Canadian Food Inspection Agency's first year of operations, the Canadian Auditor General found that agency lacked specific performance expectations and therefore concluded that it was difficult to determine what the Agency was trying to achieve. As discussed earlier, both Canada and Denmark plan to begin developing criteria for and measuring the effectiveness of their consolidation efforts in 1999.

Comments From the Four Countries Visited

We provided a draft of this report to the food safety agencies of Canada, Denmark, Great Britain, and Ireland. Overall, officials for these agencies commented that the draft report was accurate and useful. They also made a number of technical suggestions, which we incorporated as appropriate.

We conducted our review from May 1998 through March 1999 in accordance with generally accepted government auditing standards. To identify foreign countries that could be changing their food safety

responsibilities, we contacted the embassies of 16 foreign countries that officials in the Food and Drug Administration and the U.S. Department of Agriculture's the Food Safety and Inspection Service and the Foreign Agriculture Service identified as possibly making changes in their food safety structures.⁹ To (1) determine the reasons for and approaches taken to make changes; the costs and savings, if any, associated with the organizational change; and efforts to assess the effectiveness of the new systems and (2) identify the lessons that the United States might learn from these countries' experiences, we visited four countries that were making such changes—Canada, Denmark, Great Britain, and Ireland. We interviewed food safety officials as well as government officials in the ministries of health, agriculture, and treasury. We also interviewed representatives from the countries' food industry, consumer groups, farmers, and government employee unions. Additionally, we reviewed each nation's laws and regulations governing food safety, as well as documents concerning the consolidation of food safety responsibilities. See appendix V for a list of the organizations we met with in each country.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time we will send copies to congressional committees with jurisdiction over food safety issues; the Embassies of Canada, Denmark, Great Britain, and Ireland; Dan Glickman, the Secretary of Agriculture; Donna E. Shalala, the Secretary of Health and Human Services; and other interested parties. We will also make copies available to others on request.

⁹These 16 countries are Australia, Canada, Denmark, France, Germany, Great Britain, Hungary, Ireland, Japan, New Zealand, Norway, Poland, Portugal, Russia, Spain, and Sweden. None of these countries are decentralizing their food safety systems.

If you have any questions about this report please contact me at (202) 512-5138. Major contributors to this report are listed in appendix VI.

Sincerely yours,

A handwritten signature in black ink, reading "Lawrence J. Dyckman". The signature is written in a cursive style with a large, stylized "L" and "D".

Lawrence J. Dyckman
Director, Food and
Agriculture Issues

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Abbreviations

BSE	Bovine Spongiform Encephalopathy
GAO	U.S. General Accounting Office
USDA	U.S. Department of Agriculture

Canada's Food Safety System

Canada decided in 1996 to consolidate its food safety inspection functions. The Canadian Food Inspection Agency began operations in April 1997.

Reasons for Consolidating Food Safety Inspection Responsibilities

Canada consolidated its food inspection activities largely in response to budgetary pressures and calls from government and industry to operate more efficiently and effectively. Prior to the creation of the new agency, three separate departments performed activities related to food safety, which lead to duplication and overlap in many areas. According to a 1998 report by the Canadian Auditor General, in the early 1990s, the government reviewed programs to determine more efficient and effective approaches to delivering government service. These reviews were conducted in large part because of serious deficit and debt problems, as well as changing public perceptions and expectations about the role and performance of government. Following these reviews, the government initiated changes in at least four areas, including food inspection, and began to introduce alternative ways of providing services. All of the Canadian food safety stakeholders with whom we met agreed that this emphasis on alternative ways of doing business helped address budget problems, improved program efficiency and effectiveness, reduced duplication and overlap, and helped create the right environment in which to consolidate responsibilities for food safety inspections.

Responsibilities in the Old and New Food Safety Systems

Prior to the creation of the new Canadian Food Inspection Agency, three departments—Agriculture and Agri-Food Canada, Health Canada, and the Department of Fisheries and Oceans—provided inspection and related services for food safety, animal and plant health, and agricultural inputs, that is, animal feed, seed, and fertilizer. Generally, Health Canada was responsible for ensuring the health and safety of all food in Canada. Health Canada typically evaluated and set standards for food safety, managed crises caused by outbreaks of foodborne illnesses, issued recalls, conducted domestic product inspections, investigated consumer complaints, and audited Agriculture and Agri-Food Canada's and the Department of Fisheries and Oceans' efforts to ensure compliance with food safety standards. Agriculture and Agri-Food Canada and the Department of Fisheries had health and safety responsibilities for the food products under their jurisdiction. For example, Agriculture set meat and poultry standards for international trade and domestic commerce; registered feed, seed, and fertilizer products; inspected imported and domestic products, such as meat, poultry, dairy, fruits, and vegetables; and reviewed the labeling and processing of products. Fisheries registered

seafood establishments, which traded interprovincially and internationally (87 percent of fish products are exported), as well as these establishments' suppliers. Fisheries also inspected exports and vessels as well as all mollusk and shellfish. Agriculture and Fisheries also promoted the use of the food products whose safety they regulate. Table I.1 shows the responsibilities under Canada's previously decentralized food inspection system.

Table I.1: Canada's Food Inspection System Prior to Consolidation

Health Canada	Agriculture and Agri-Food Canada	Fisheries and Oceans Canada
Evaluation and standard setting for food safety	Evaluation and standard setting for trade and commerce	Evaluation and standard setting for trade and commerce
Research	Risk assessment and risk management	Development and application of quality management practices
Risk assessment and risk management	Registration of establishments that trade interprovincially and internationally and their suppliers; feed, seed, and fertilizer products	Risk assessment and risk management
Crisis management and product recalls		Registration
Compliance and enforcement including inspection of imports and domestic products, and nonfederally registered establishments	Compliance and enforcement including inspection of domestic and imported products and registered establishments	Compliance and enforcement including inspection of domestic and imported products, registered establishments and nonregistered fisherman packers
Complaints investigation	Export certification	Molluscan and shellfish inspection
Audits of Agriculture and Agri-Food Canada and the Department of Fisheries and Oceans	Animal and plant disease control	Export certification for fish products
	Laboratory support for commodities	Contaminant monitoring
Laboratory and diagnostic support	Labeling, process review	Vessel inspection
	Complaints investigation	Complaints investigations
		Laboratory analysis of fish and fish products

The new system consolidates food inspection activities into one agency, thus integrating the delivery of inspection and quarantine services currently provided by Agriculture and Agri-Food Canada, Health Canada, and the Department of Fisheries and Oceans. The new inspection agency provides all inspection services related to food safety, economic fraud, trade-related requirements, and animal and plant health programs. Its primary responsibility is to enforce standards pertaining to food safety and animal and plant health. To accomplish this task, it, among other things, registers processing plants, inspects domestic and imported foods,

certifies exports, and quarantines selected imported food products. The new agency's role also includes identifying and evaluating risk management options; conducting assessments for animal and plant health; setting standards for trade and commerce; developing risk-based inspection systems; investigating outbreaks of foodborne illness; conducting enforcement actions; and coordinating emergency responses. The responsibilities for setting food safety standards, risk assessment, and analytical testing research and audit have been reinforced but remain with Health Canada. Table I.2 shows each organization's new responsibilities in the current system.

Table I.2: Canada's Food Inspection System After Consolidation

Canadian Food Inspection Agency	Agriculture and Agri-Food Canada	Health Canada	Fisheries and Oceans Canada
Moved from Health: Inspect imports and domestic products, nonfederally registered establishments	No role.	Evaluation and standard setting for food safety	No role.
Laboratory and diagnostic support		Research	
Crisis management and product recalls		Risk assessment and risk management	
		Assess the effectiveness of the new agency's food safety programs	
Moved from Agriculture: Register establishments that trade interprovincially and internationally and their suppliers; feed, seed, and fertilizer products			
Compliance and enforcement including inspection of domestic and imported products, and registered establishments			
Animal and plant disease control			
Export certification			
Moved from Fisheries: Registration			
Compliance and enforcement including inspection of domestic and imported products, registered establishments and nonregistered fisherman packers			
Export certification for fish and fish products			
Vessel inspection			
Laboratory analyses for fish and fish products			

The Canadian Food Inspection Agency is a departmental corporation under the Financial Administration Act. The new agency is headed by a President, who reports to the Minister of Agriculture and Agri-Food. The minister, in turn, reports to Parliament on food safety inspection activities. The Minister of Health reports to Parliament on setting human food safety

standards and policies and assessing the effectiveness of the new agency's activities.

Funding and Personnel Under the New Agency

The new agency, although supported largely through general tax revenues, has the power to raise and retain funds from its activities. For fiscal year 1998, the new agency had a budget of about \$355 million Canadian dollars (\$238 million in U.S. dollars), which included about \$25 million in start-up funds and about \$330 million (\$221 million in U.S. dollars) in appropriations. Canadian officials expect the food safety agency's budgets to decline over the next 3 years, from about \$330 million this year to about \$311 million (\$208 million in U.S. dollars) in fiscal year 2000, about \$304 million (\$204 million in U.S. dollars) in fiscal year 2001, and about \$299 million (\$200 million in U.S. dollars) in fiscal year 2002. While most government departments are funded annually through parliamentary appropriations, the new agency has the authority to spend its annual appropriation over 24 months. According to officials of the new agency, this more flexible funding authority should allow the new agency to access funds over an extended period, providing for unplanned cash flows or other unforeseen expenses. Unlike most other federal departments, the new agency is allowed to raise a portion of its annual budget by assessing user fees. In 1998, the Canadian Auditor General estimated that in its first year of operation, the new agency raised about 12 percent of its budget through user fees.

With respect to personnel, the agency's enabling legislation created a management and accountability framework that provides the new agency with some flexibility to replace traditional departmental approaches. For example, the new agency received "separate employer status." That is, it has been delegated the authority to establish its own human resource management system, negotiate collective bargaining agreements with unions, and establish terms and conditions of employment. (Traditionally such authority is the responsibility of the Treasury Board—roughly equivalent to a combination of the U.S. Department of the Treasury, the Office of Personnel Management, and the Office of Management and Budget). Thus, the new agency can work with unions to create a more flexible work environment, such as changing inspectors' duty hours or work-site assignments. In its first year of operation, the agency reduced the number of union bargaining units from 19 to 4, thereby creating a more streamlined and efficient process.

Under the new system, existing departments provided the full-time equivalent of 4,500 staff years to the new agency. Of the total, Agriculture and Agri-Food Canada contributed over 86 percent; Health Canada, just over 3 percent; and the Department of Fisheries and Oceans, about 9 percent. The new agency operates programs in all 10 provinces and the Canadian territories. It has about 4,200 regional staff; 185 field offices; 408 third-party establishments, such as slaughterhouses; and 22 laboratories and research facilities. It will have a regional structure with four centers of operation and 18 regions.

Denmark's Food Safety System

Denmark phased in its operations over about 4 years, completing the consolidation in 1999. Its food safety system is housed in the new Ministry of Food, Agriculture, and Fisheries.

Reasons for Consolidating Food Safety Responsibilities

Denmark reorganized its food safety responsibilities to address problems in the coordination and integration of services. Prior to 1995, at the beginning of the consolidation process, three Danish ministries shared responsibilities for implementing food safety laws. According to the Permanent Secretary of the new ministry, this fragmented approach resulted in extensive overlaps of responsibilities in some areas and gaps in coverage in other areas; inconsistent food safety inspections; and inefficient utilization of food safety resources.

The chairman of the Danish National Academy of Sciences said that in 1995 the Academy reported that to improve the efficiency of food safety, Denmark's food safety system needed to be reorganized. The goal of the proposed reorganization was to simplify food safety legislation, administration, and control, with the belief that such reforms would lead to a more efficient and effective food safety system, and provide assurances that the high quality of Danish food products would continue. The Danish Academy recommended that a new consolidated agency include all of the activities related to food safety and adopt a consumer protection orientation. The Academy also noted that by consolidating food safety activities, the government could (1) take advantage of new risk-based inspection schemes, such as the Hazard Analysis and Critical Control Point system; (2) move resources to areas presenting greater risk; (3) improve international and European Union interactions; and (4) improve the uniformity and consistency of local inspections. Finally, the Academy's report concluded that the new agency should be based in the agriculture and fisheries ministry.

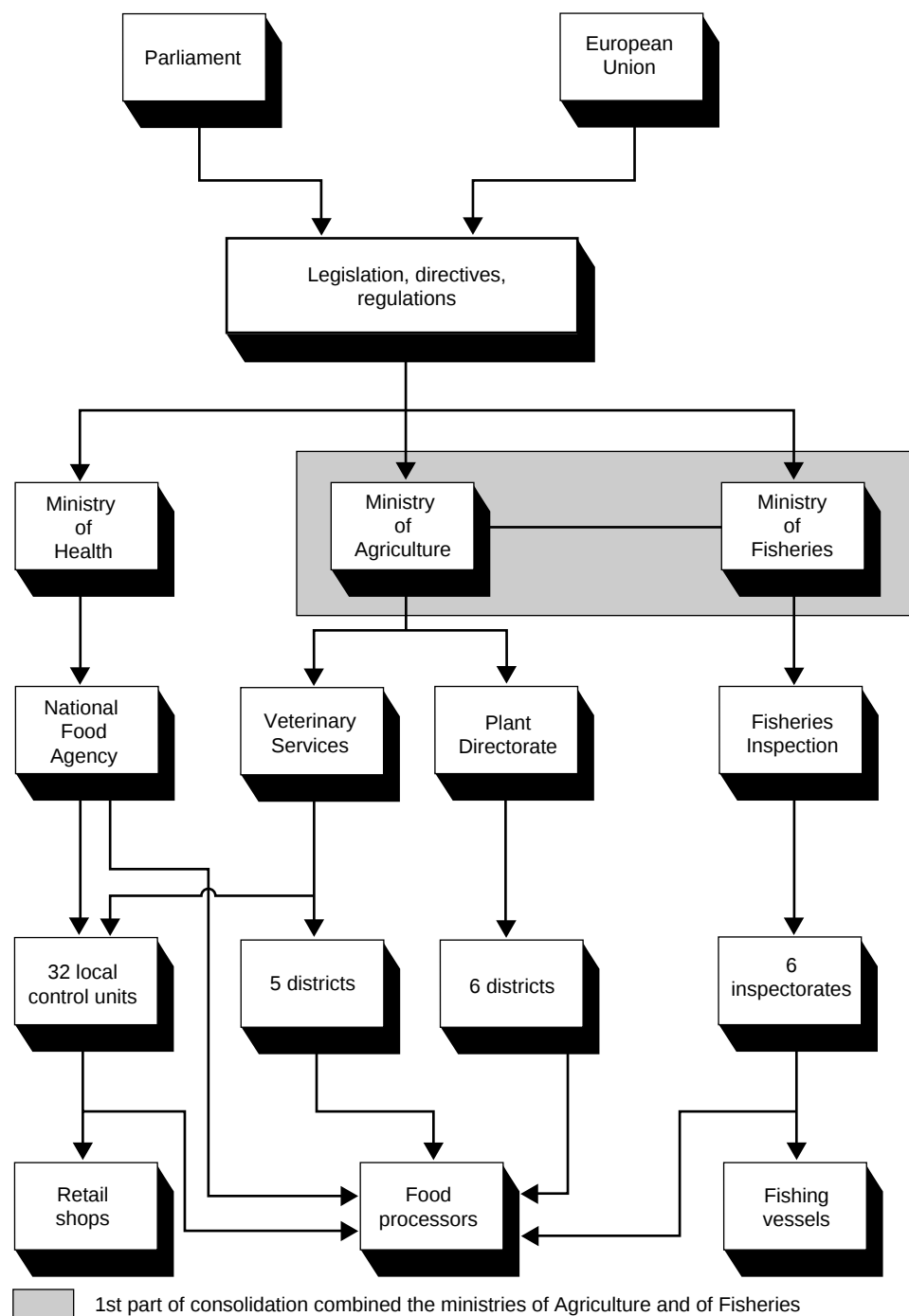
In a May 1996 letter to the Prime Minister, representatives of Denmark's consumers, farmers, and food industries also requested that the government reorganize the food safety system. In their letter, these stakeholders endorsed the concept of a consolidated food safety system to improve food inspections.

Responsibilities in the Old and New Food Safety Systems

Before consolidation, the three Danish ministries shared food safety responsibilities; each agency had its own headquarters and field staff. The Ministry of Health set food safety standards for local inspectors who inspected food processing plants, warehouses, and local retail stores. The

Ministry of Agriculture was responsible for, among other things, inspecting meat and poultry processing plants. The Ministry of Fisheries was responsible for the safety of all fish and seafood, including fishing vessels and processing plants. Figure II.1 shows Denmark's food safety system prior to consolidation.

Figure II.1: Denmark's Food Safety System Prior to Consolidation



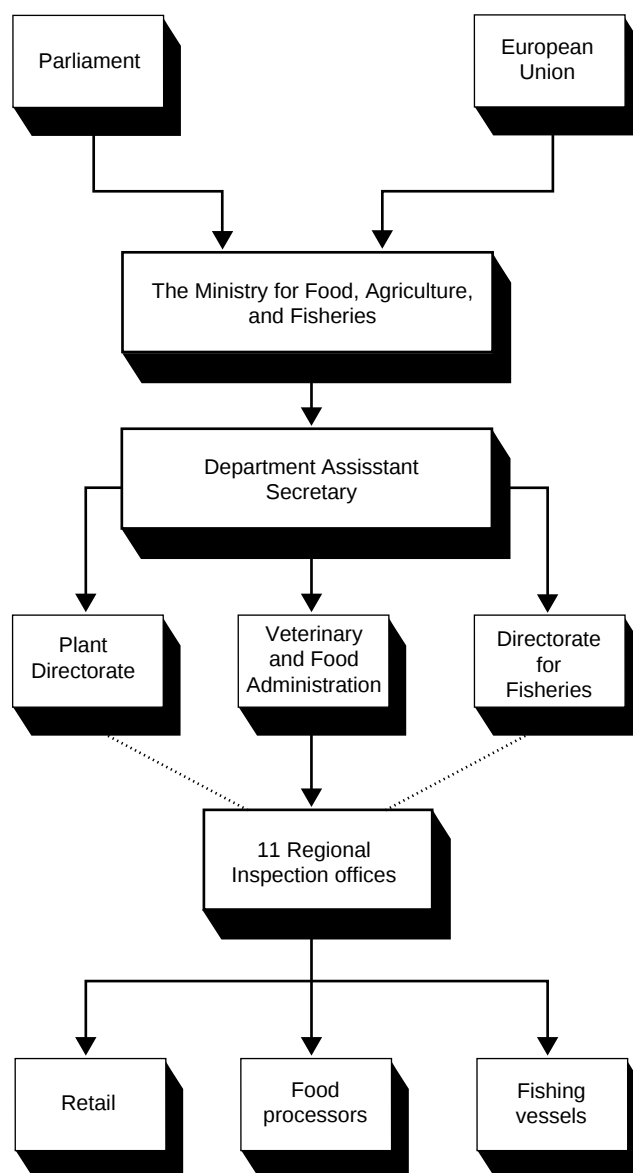
In 1995, the Danish government combined the Ministry of Agriculture and the Ministry of Fisheries and their respective responsibilities into a single ministry—the Ministry of Agriculture and Fisheries. In December 1996, the Danish government took a second step by moving the food safety activities of the Ministry of Health into the Ministry of Agriculture and Fisheries, and renamed the resulting organization the Ministry for Food, Agriculture, and Fisheries. The goal of this reorganization was to enhance the safety of food from its origins in the soil or sea to the table of the consumers. Danish food safety officials believe that with this approach there is a clear advantage for all sectors, including consumers, retailers, processors, farmers, and fishermen.

In July 1997, under the Ministry of Food, Agriculture, and Fisheries, the Danish government organized food safety into three subunits—the Danish Veterinary and Food Administration, the Danish Plant Directorate, and the Danish Directorate for Fisheries. The Danish Veterinary and Food Administration is responsible for (1) ensuring that consumers have healthy food, including meats as well as fruits and vegetables; (2) protecting consumers against misinformation; (3) monitoring and controlling animal diseases that can be transferred to humans; (4) inspecting meat at all the processing plants; (5) ensuring the safety and quality of fish imports and exports; and (6) coordinating the activities of other food safety agencies. The Administration is also the controlling authority for veterinarians, animal medicines, and compliance with animal protection rules. As of January 1999, the Administration was continuing the last phase of the consolidation by reorganizing the local and district offices.

The Danish Plant Directorate responsibilities include the quality of vegetable products, plant health, environmental regulations for agricultural production, and farmers' subsidies. It inspects seeds and cereals, feed and fertilizers, fruit and vegetables, and other plant and forestry seeds. It uses sampling and laboratory tests as well as farm visits to inspect processing plants and farms.

The Danish Directorate for Fisheries is responsible for, among other things, inspections of fresh waters and coastal areas, including fish farms. Figure II.2 shows Denmark's food safety system after consolidation.

Figure II.2: Denmark's Food Safety System After Consolidation



Funding and Personnel Under the New Agency

The total budget for the Ministry of Food, Agriculture, and Fisheries for calendar year 1999 is about 13.5 billion kroner (\$2 billion in U.S. dollars). This total represents around 4.75 billion kroner in appropriations and 8.7 billion kroner in European Union subsidies. The Ministry also received about 120 million kroner for start-up costs.

Altogether, the Ministry of Food, Agriculture, and Fisheries has 4,952 staff. The Ministry has a central administrative staff of 195. The Danish Veterinary and Food Administration has 1,400 employees—435 in central offices, 795 at slaughterhouses, and 170 in laboratories, border inspection posts, and in the food safety units. The Plant Directorate has a staff of 510 located throughout the country. The Fisheries Directorate has a staff of 325—75 in central offices, 150 in land-based inspection offices, and 100 on vessels. The remaining 2,522 staff are engaged in various agricultural promotion programs and research activities. The final phase of the consolidation will bring about 520 employees from local food inspection units into the Veterinary and Food Administration.

Danish food safety officials stated that they do not anticipate any savings in costs or personnel under the new organization. However, they believe that food safety inspections will be more consistent, resulting in a more efficient and effective food safety system.

Great Britain's Food Safety System

As of January 1999, the Food Standards Agency had not been formally established, but British food safety officials and other stakeholders said they remained committed to its creation. According to the Deputy Head of the Joint Food Safety and Standards Group, a draft bill to create the new agency was published for comment on January 27, 1999, and officials expect the Parliament to take action during the current legislative session.

Reasons for Consolidating Food Safety Responsibilities

Loss of public confidence in Great Britain's food safety system and acknowledged weaknesses that contributed to serious outbreaks of foodborne illnesses have made the creation of a new food safety system a government priority. Public confidence in the food safety system has eroded over the past 10 years in the face of several serious outbreaks of foodborne illnesses. Surveys of the British public in the mid-1990s showed that concern focused on four areas: the microbial safety of food,¹⁰ the chemical safety of food, the safety of genetically modified organisms and novel foods and processes, and the nutritional quality of the diet.

Many public interest groups and the chairs of expert scientific committees, as well as companies in the food processing, producing, and retailing fields, believe that the current system has real failings. According to these experts and government studies, Great Britain's food safety system is fragmented and lacks coordination among the different organizations involved in setting food policy and in monitoring and controlling food safety. That is, there are considerable overlaps and gaps between the Ministry of Agriculture, Fisheries and Food; the Department of Health; and the other departments dealing with food safety issues. Other concerns identified included (1) too many institutional barriers to promoting food safety at different points in the food chain; (2) a lack of a clear strategy and structure for monitoring the surveillance of chemical food safety, and (3) inconsistent enforcement of food safety laws throughout Great Britain.

The fact that the Ministry of Agriculture, Fisheries and Food promotes the economic interests of the food industry while being charged with protecting public health was also identified as a serious shortcoming of the system. Inevitably, there were perceived conflicts between concerns for food safety and the economic interests of some industry sectors. These conflicts have been handled within the Ministry of Agriculture, Fisheries and Food and are often perceived to be conducted in semi-secrecy. Many food safety decisions have been met with widespread skepticism, if not

¹⁰Microbial pathogens are harmful bacteria, viruses, and parasites that are transmitted by foods and foodborne outbreaks.

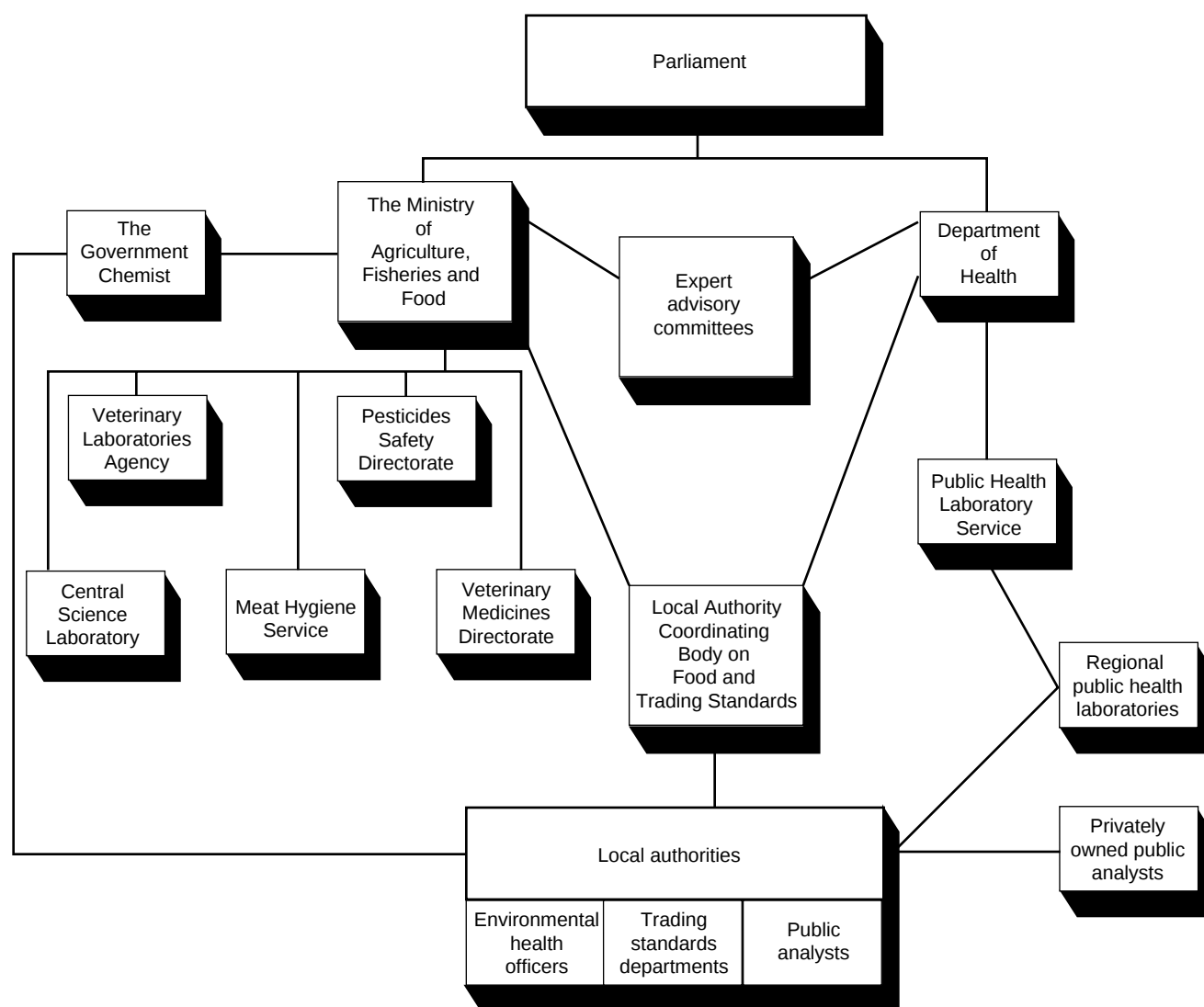
suspicion, because of a perceived conflict of interest and the relative secrecy of deliberations.

In September 1997, the Ministry of Agriculture, Fisheries and Food and the Department of Health set up the Joint Food Safety and Standards Group. This group brought together those parts of the two departments that are likely to form the operational core of a consolidated food safety agency. In January 1998, the government proposed consolidating food safety responsibilities in a new agency known as the Food Standards Agency. Despite widespread and continuing support for the proposed agency, Parliament did not enact enabling legislation for it during its 1997-98 session, because of, among other things, concerns over how to fund the new agency and difficulty in obtaining time on the legislative calendar. Nevertheless, the government has taken other steps to strengthen the handling of food safety issues, such as making a greater effort to ensure that information about food safety and human health is presented more clearly and more comprehensively to the public.

Responsibilities of the Current and Proposed Food Safety Systems

The framework for most food legislation in Great Britain derives from the 1990 Food Safety Act, which brought together and updated all food legislation into one comprehensive document and implemented some European Union legislative requirements. In Great Britain, responsibility for food standards and food safety is divided among several national government departments, the environmental health and trading standards departments of local authorities, and a number of other bodies. Figure III.1 displays the key features of the current food safety structure in Great Britain.

Figure III.1: Key Features of the Current Food Safety System in Great Britain



Prior to the creation of the Joint Food Safety and Standards Group in September 1997, the Ministry of Agriculture, Fisheries and Food was the lead department on food standards, the chemical safety of food, labeling, and food technology. Within the Ministry, various subunits at headquarters and in regional offices were responsible for specific aspects of food safety.

The Veterinary Laboratories Agency provided the Ministry with advice on how animal health can affect human health. The Pesticides Safety Directorate was responsible for evaluating and approving the use of pesticides and implementing post-approval controls. The Central Science Laboratory provided a wide range of scientific services and scientific support to policy work. The Meat Hygiene Service, established in 1995, provided meat inspection services to licensed meat premises and enforced hygiene and welfare laws in slaughterhouses. The Veterinary Medicines Directorate evaluated and approved veterinary medicines and maintained surveillance of, and monitored suspected adverse reactions to, residues in meat and animal products.

Furthermore, the Department of Health took the lead on issues of food hygiene, microbiological food safety, and nutrition. A number of subunits handled specific aspects of the Department's responsibilities. For example, the Public Health Laboratory Service, in partnership with its regional offices and local environmental health departments, was responsible for most laboratory analysis concerning the microbiological safety of food. The Department of Health also had some enforcement responsibilities, although enforcement is predominantly a local function. Most of the food safety activities previously performed by the Ministry of Agriculture, Fisheries and Food and the Department of Health are now being carried out by the joint group.

District and county councils are responsible for enforcing most food safety laws and regulations. Port health authorities and local environmental health departments have an enforcement responsibility with regard to enforcing food sanitation laws. The Trading Standards Departments—usually within County Councils—enforce food standards and labeling of food nutritional content. Coordination of local authorities' enforcement of food issues is the responsibility of the Local Authorities Coordination Body on Food and Trading Standards, which provides advice and guidance for enforcement authorities and advises the central government on enforcement issues. This body also acts as the nation's liaison for transborder food safety problems in the European Union.

Under the proposed new system, the new Food Standards Agency will assume most of Great Britain's food safety responsibilities and attempt to address past weaknesses. The Agency will be accountable to Parliament through the Secretary of State for Health.¹¹ According to the government's

¹¹The new safety agency will also report to the Health Ministers of Scotland, Wales, and Northern Ireland.

proposal, the new agency will be responsible for (1) formulating policy and advising the government on the need for legislation on all aspects of food safety and standards, as well as on certain aspects of nutrition; (2) providing information and educational material for the public on food matters; (3) working closely with government departments to protect the public, particularly in areas such as nutrition and farming practices; and (4) commissioning research and surveillance across the full range of its activities.

As envisioned, the Food Standards Agency will assume the responsibilities of the Ministry of Agriculture, Fisheries and Food and the Department of Health in ensuring the safety of the whole food chain, from "farm to table." The new Agency will have key roles at the farm level, with powers to prevent contaminated food from entering the food chain and to control animal diseases that could be passed through the food chain. At the processing level, the new agency will also have considerable authority because it will take over the Meat Hygiene Service and thus be responsible for inspecting and licensing fresh meat plants and for implementing measures to prevent the transmission of Bovine Spongiform Encephalopathy (BSE). At the consumer level, the Agency will have responsibility for all matters concerning food additives, chemical contaminants, and the labeling of food to ensure that consumers are not misled with regard to its content.

Although the Food Standards Agency will not take over the existing enforcement responsibilities of local authorities and local outbreaks will continue to be managed locally, it will set standards for enforcement and will have the power to take action directly to protect the public. In addition, it will take a leading role in coordinating responses with central and local authorities in the event of a national food emergency, such as the recent BSE crisis.

Funding and Personnel Under the New Agency

The Deputy Group Head of the Joint Group estimated the start-up cost for the new agency will be about 30 million pounds (\$49 million in U.S. dollars) spread over a 3-year period, and the operating cost for the new agency will be about 120 million pounds (\$196 million in U.S. dollars) annually. The local governments will spend 130 million pounds (\$212 million in U.S. dollars) annually on food safety.

While staffing levels have not yet been officially determined, the officials of the joint group estimate that about 500 staff will be employed at

headquarters and about 1,700 in the Meat Hygiene Service. A governing body composed of a chairperson and no more than 12 independent members will run the new agency. Governing members are to be appointed on the basis of their professional reputation and expertise, bringing a broad balance of relevant skills, experience, and independence to the new agency. In addition, members are to act collectively in the public interest; rather than to represent any particular sector or interest group. Current plans call for a majority of the members to be drawn from public interest backgrounds. The governing body will be empowered to publish any of the advice it gives the government.

Ireland's Food Safety System

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

Reasons for Consolidating Food Safety Responsibilities

For many years Irish consumers have been warned about the dangers of using unpasteurized milk, the need for proper hygiene in the home, and the necessity of proper cooking to ensure food safety. However, a succession of high-profile outbreaks of foodborne illnesses throughout the world, such as the Bovine Spongiform Encephalopathy outbreak in Great Britain, shook consumer confidence in the safety of food and in the ability of regulatory agencies to protect the public. In 1996, 21 elderly people died in a Scottish nursing home as a result of eating meat tainted with the E.coli O157 H:7 bacterium. Also in 1996, a European survey indicated that antibiotic residues in Irish pork were among the highest in Europe. These incidents undermined consumers' confidence in the Irish food industry and in the Irish regulatory agencies; the public began to respond to vague reassurances with skepticism. According to Irish officials, these outbreaks also helped to highlight the difficulties that the Department of Agriculture and Food faced in trying to carry out its dual mission of protecting consumers and promoting the food industry. Consumers seemed to regard the incidence of foodborne illnesses as equally the fault of the government and the food industry.

Avoiding serious outbreaks of foodborne illness and maintaining a strong food safety system are extremely important for Ireland's economy for two reasons. First, according to officials in the Irish Department of Agriculture and Food, roughly 90 percent of the country's food is produced for export. For example, Agriculture officials estimated that roughly 9 out of every 10 cows—worth about \$3.7 billion—are exported annually. Agriculture officials feared that any serious outbreak of a foodborne illness could effectively close many export markets, thereby depriving Ireland of foreign trade. Furthermore, Agriculture officials were concerned that Irish exports could decline, even without a major outbreak, if trading partners lost confidence in the Irish food safety system and thus in the safety of Irish food. Second, Ireland's economy also depends heavily on tourism. To the extent that outbreaks of foodborne illnesses, or the threat of outbreaks, dampen tourism, serious economic harm could follow.

By early 1997, the Irish government believed that addressing the country's food safety concerns could wait no longer. In addition to food related illnesses, other concerns, such as the availability of genetically modified

food and food irradiation, caused concern among much of the Irish population. Irish food safety officials believed that any threat to the food supply, whether real or potential, required a response that was sufficient to calm domestic and international markets. The Irish government established a start-up group—the Food Safety Authority—on January 1, 1998, and enacted legislation to create the Authority on July 2, 1998. The Authority assumed full control of the food safety system on January 1, 1999.

Responsibilities of the Old and New Food Safety Systems

Prior to the creation of the Authority, food safety was fragmented across more than 50 entities, including 6 major government departments, 33 local authorities, and 8 regional health boards. The Department of Agriculture and Food inspects farms, slaughterhouses, and deboning and trimming halls for compliance with food processing regulations. Local and county governments, as well as the Ministers of Environment; Public Enterprise; Marine; and Trade, Enterprise, and Employment, have various other food safety responsibilities. For example, Ireland has eight Health Boards that have local food safety authority, such as inspecting retail and catering outlets as well as butcher shops and some food processing plants.

According to Irish food safety officials, in 1996, the government established an interdepartmental committee to advise Parliament on how the various food safety agencies could be best coordinated. In early 1997, this committee recommended establishing the Food Safety Authority of Ireland as a “regulator of regulators.” That is, the responsibility for food safety would remain with existing agencies, but the Authority would audit these agencies and have a voice in setting and maintaining standards as well as in the promotion of good practices.

However, a new government—elected in mid-1997—came to office believing that the Authority should be directly accountable for all food safety functions. The new government envisioned an Authority that would take over all functions related to food safety and food hygiene from existing agencies, providing consumers with protection from illnesses related to unsafe food. The Authority was to be independent and science-based and provide for full “farm-to-fork” traceability. Original plans for creating the Authority included transferring all relevant staff to the new agency.

However, personnel issues precluded the wholesale transferring of staff to the new Authority. Roughly 2,000 staff, spread across the 50-plus agencies

deliver food safety services throughout the country. It is common for such staff to have other duties, in addition to food safety responsibilities. Officials found it impossible under these circumstances to transfer "food safety" personnel to the Authority without disrupting other, sometimes unrelated, programs. The solution was to have the Authority and existing agencies enter into contractual agreements, called "service contracts," which were to specify food safety activities.

In October 1998, the Authority began negotiating the terms and conditions of these contracts with the existing agencies. According to Authority officials, the first contracts took effect in March 1999. The contracts include objectives that the Authority wants the agencies to meet, as well as the time frame within which they should be met. Current plans call for existing funding arrangements to be maintained, that is, agencies will continue to receive appropriations from the Parliament. Agencies are then expected to make sufficient resources available to meet service contract obligations. The Authority is to publish the details of the service contracts and introduce a system to monitor agencies' compliance. If agencies do not satisfactorily perform their agreed-upon responsibilities, the Authority is to report to the Minister for Health and Children, which will arrange for such reports to be sent to Parliament.

Although the Authority will also have an enforcement role, its main function will be to foster, through education and promotion, a food safety culture at all stages of the food chain, from production to final use by the consumer. One of the Authority's key objectives is to bring about acceptance of the notion that the primary responsibility for food safety rests with the food industry and consumers, not the government. The Authority's enforcement responsibilities are also to be carried out through service contracts with the departments of Agriculture and Health and include the inspection, approval, licensing, and registration of food premises and equipment and laboratory analysis.

Funding and Personnel Under the New Agency

According to Authority officials, for fiscal year 1999, the Food Safety Authority of Ireland has a budget of about 6.5 million Irish pounds (\$9 million in U.S. dollars). Of this amount about 1.5 million pounds (\$2 million in U.S. dollars) was for start-up operations, and another 5.0 million pounds (\$7 million in U.S. dollars) is for the coordination of inspection services and new educational programs.

The Authority's organizational structure includes the Board, a Scientific Committee, a Consultative Council, and a Chief Executive. The 10-member Board provides strategic direction for the Authority, acting as a forum in which the work of its various structural elements is harmonized. To help ensure that the Authority maintains a consumer protection focus, food industry representatives are precluded from serving on the Board. The Scientific Committee has 15 members, all appointed by the Minister for Health and Children, and all with eminent scientific qualifications and experience to ensure the broadest possible range of expertise. As of January 1999, the Committee had the assistance of 85 scientists involved in 6 subcommittees and 10 working groups. The role of the Scientific Committee is to assist and advise the Board on matters pertaining to scientific or technical questions, food inspection and nutrition. The Board also receives advice from the Consultative Council—a body that includes consumers as well as food industry representatives. The Council has 24 members, 12 appointed by the Department of Health and Children and 12 by the Board.

The Chief Executive reports to the Board and is ultimately responsible for the implementation of policies and the achievement of the Authority's goals. According to Authority officials, there will be 60 staff to coordinate about 2,000 staff performing the food safety inspections and other activities through the service agreements. The Authority is divided into four divisions. The Technical and Scientific Division develops policy and sets standards, priorities, quality levels, and procedures for technical and scientific issues. It serves the research needs of the Scientific Committee and its subcommittees. In addition, it collects and assesses surveillance data on foodborne illnesses.

The Operations Division focuses on enforcement by overseeing the service contracts' implementation. The Operations Division coordinates, controls, and harmonizes all activities under these contracts. It also carries out an audit program throughout the food chain to help ensure compliance with the Authority's decisions on standards and processes.

The Communications, Education, and Information Division develops and implements policy on communications, education, and information for consumers, enforcement officers, public health professionals, and others in the food chain.

The Corporate Services Division develops and implements accounting, human resources, information technology, and legal services.

List of Stakeholders by Country

Canada

Agricultural Union
Agriculture and Agri-Food Canada
Canadian Food Inspection Agency
Canadian Meat Council
Consumers Association of Canada
Fisheries and Oceans Canada
Fisheries Council of Canada
Health Canada
Office of Auditor General of Canada
Treasury Board of Canada

Denmark

Agricultural Council of Denmark
Copenhagen Food Control Unit
Consumer Council
Danish Dairy Board
Danish Farmers Union
Danish Poultry Association
Danish Veterinary Association
Federation of Danish Pig Producers
and Slaughterhouses
Ministry of Food, Agriculture and Fisheries
Steff-Houlberg Processors

Great Britain

Consumers' Association
Department of Health
Department of the Treasury
Food, Drink, and Tobacco Federation;
Transport and General Workers Union
Federation of Fresh Meat Wholesalers
Joint Food Safety and Standards Group
Ministry of Agriculture, Fisheries and Food
National Consumer Council
National Farmers' Union
National Food Alliance

Appendix V
List of Stakeholders by Country

Northern Foods, plc
Sea Fish Industry Authority

Ireland

Avonmore Waterford Group, plc
Agriculture and Food Development Authority,
National Food Centre
Department of Agriculture and Food
Department of Health and Children
Food Safety Authority of Ireland
Food, Drink, and Tobacco Federation
RDS – Consumer Advocates
Super Quinn Supermarket

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Related GAO Products

Food Safety: Opportunities to Redirect Federal Resources and Funds Can Enhance Effectiveness (GAO/RCED-98-224, Aug. 6, 1998).

Food Safety: Fundamental Changes Needed to Improve Food Safety (GAO/RCED-97-249R, Sept. 9, 1997).

Food Safety: New Initiatives Would Fundamentally Alter the Existing System (GAO/RCED-96-81, Mar. 27, 1996).

Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992).

Food Safety and Quality: Who Does What in the Federal Government (GAO/RCED-90-19A & B, Dec. 21, 1990).

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