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Report of the Auditor General of Canada

CHAPTER 4

Canada's Food Recall System

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CHAPTER 4

Canada's Food Recall System

Performance audit reports

This report presents the results of a performance audit conducted by the Office of the Auditor General of Canada under the authority of the *Auditor General Act*.

A performance audit is an independent, objective, and systematic assessment of how well government is managing its activities, responsibilities, and resources. Audit topics are selected based on their significance. While the Office may comment on policy implementation in a performance audit, it does not comment on the merits of a policy.

Performance audits are planned, performed, and reported in accordance with professional auditing standards and Office policies. They are conducted by qualified auditors who

- establish audit objectives and criteria for the assessment of performance,
- gather the evidence necessary to assess performance against the criteria,
- report both positive and negative findings,
- conclude against the established audit objectives, and
- make recommendations for improvement when there are significant differences between criteria and assessed performance.

Performance audits contribute to a public service that is ethical and effective and a government that is accountable to Parliament and Canadians.

Table of Contents

Canada's Food Recall System

Main Points

What we examined

The Canadian food safety system is made up of many players working together to protect consumers from potentially unsafe foods. In addition to food producers, manufacturers, distributors, importers, and retailers, who use many controls to maintain the safety of their products, the system relies on legislation, policies, and inspection programs put in place by government.

The Canadian Food Inspection Agency (CFIA) works in collaboration with its federal partners in food safety—Health Canada and the Public Health Agency of Canada (PHAC)—and with provincial and territorial authorities to administer and enforce the laws and regulations that govern the safety and quality of food sold in Canada.

The CFIA manages the food recall process on behalf of the federal government and makes sure that industry takes appropriate action when a voluntary recall is implemented.

Canada has recently experienced some large and high-profile food recalls, including the 2008 recall of almost 200 ready-to-eat meat products produced in Ontario and the September 2012 recall of over 7 million kilograms of beef products in Canada and the United States. This 2012 recall was the largest meat recall in Canada's history.

We examined whether the CFIA, with the support of Health Canada and the PHAC, adequately manages the food recall system. We examined each main step of the food recall process, from when a food safety concern is first brought to the Agency's attention to follow-up actions taken to identify and correct the underlying cause of the recall.

Our audit did not include the CFIA's food inspection system, which aims to prevent food safety problems, nor did it examine the government's response to outbreaks of food-borne illness.

Audit work for this chapter was completed on 24 July 2013. More details on the conduct of the audit are in **About the Audit** at the end of this chapter.

Why it's important

The ability to prevent or contain food safety incidents in a timely and appropriate manner is a critical component of the CFIA's mandate to protect Canadians from preventable food safety risks. Timely action at each stage of the recall process helps ensure that potentially unsafe food is identified quickly, removed from the marketplace, and disposed of or corrected. Timely action must then be taken to identify how the contamination occurred and the corrective measures that need to be implemented to prevent a reoccurrence. Emergency procedures need to be well established, understood, and tested so that the CFIA is prepared to act quickly when managing large and complex food recalls.

What we found

- The first three steps of the Canadian Food Inspection Agency's food recall process—from when a food safety issue is first identified to conducting the investigation and making recall decisions—are generally working well, particularly when recalls are not managed using emergency procedures. In the 59 recalls we examined, the CFIA initiated a food safety investigation promptly and issued its recall decision within 8 days in all but 10 cases. In those cases, the response was delayed by more complex investigative work. Also, when required, the Agency issued public warnings within 24 hours. The CFIA also verified that the recalled products had been removed from the marketplace.
- Health Canada provides timely health risk assessments of food concerns to the CFIA, to support the Agency's decision-making process. For example, it assesses urgent concerns within eight hours. When needed, the PHAC helps the CFIA by providing information on the types of food consumed by people who have fallen ill.
- There are weaknesses in the CFIA's follow-up activities after a product has been removed from the marketplace. The CFIA did not have the documentation it is required to collect to verify that recalling firms had appropriately disposed of recalled products or taken timely actions to identify and correct the underlying cause of the recall to reduce the likelihood of a food safety issue reoccurring.
- Our review of three large-scale recalls that occurred in 2012, which the CFIA managed under its emergency procedures, showed that these procedures have not been finalized or tested regularly. Changes in governance structures and decision-making processes that are triggered when an emergency response plan is activated are not well understood by officials, leading to confusion, particularly for those who are normally responsible for leading and managing food safety investigations and recalls.

- In the high-profile recalls in which emergency procedures were activated, the CFIA did not adequately document the considerations, analysis, and rationale for important food safety decisions or communicate this information to key stakeholders. Despite these shortcomings, there were no further illnesses associated with these recalls.
- The weaknesses identified in this audit relate partly to some long-standing issues. For example, the Agency's guidance for managing food safety investigations and recalls is incomplete, unclear, and not finalized on a timely basis. This can lead to confusion about responsibilities and the actions that must be taken at all stages in the investigation and recall process. We noted many examples of incomplete documentation of important decisions and key steps in the recall process. As a result, the Agency does not know that its recall activities are carried out across the country consistently and according to policies, procedures, and requirements.

The Agency has responded. The Canadian Food Inspection Agency agrees with all of the recommendations. Its detailed responses follow the recommendations throughout the chapter.

Introduction

4.1 The Canadian food safety system consists of many players working together to protect consumers from potentially unsafe foods. Food producers, manufacturers, distributors, importers, and retailers use many controls to maintain the safety of their products. Government legislation, policies, and inspection programs are designed to provide additional protection. Despite these measures, however, food products sometimes pose health risks, and **food recalls** may be required to minimize the risks to consumers. The Canadian Food Inspection Agency (CFIA) is responsible for making sure that industry takes appropriate action during a food recall.

Food recall—An action taken by a firm to remove unsafe food products from the marketplace.

4.2 Since 2004, all food recalls in Canada have been voluntary, which means that the recalls were voluntarily carried out by the responsible firm. Should a firm choose not to issue a voluntary recall for a product that poses a health risk, the Minister of Agriculture and Agri-Food Canada can order a mandatory recall under the *Canadian Food Inspection Agency Act*. In addition, the CFIA may seize and detain the product if the firm is unwilling to remove the product from the marketplace and appropriately dispose of it.

4.3 Recently, Canada has experienced some large and high-profile food recalls. In 2008, an outbreak of listeriosis, a bacterial infection, resulted in the recall of almost 200 products. The outbreak was related to ready-to-eat meats produced at a facility in Ontario and was linked to 57 cases of illness and 23 deaths. Subsequently, several federally commissioned reviews were undertaken. Foremost among these was the *Report of the Independent Investigator into the 2008 Listeriosis Outbreak* (more commonly known as the Weatherill Report). This report contained 57 recommendations, some of which were aimed at improving the food recall system.

4.4 The largest meat recall in Canadian history occurred in September 2012. The presence of the E. coli bacterium in beef products from a meat processing plant in Alberta (owned by XL Foods Inc.) led to a recall of over 7 million kilograms of beef products across Canada and the United States. There were 18 confirmed cases of illness linked to the recalled meat. The Government of Canada appointed an expert advisory panel to review the events and circumstances related to this recall.

4.5 In June 2013, the expert panel issued its report, which found weaknesses in the food safety control systems at the XL Foods Inc. facility. The panel concluded that the CFIA and the firm could have

detected the contamination before the beef products were distributed, which would have prevented the recall. The panel issued 30 recommendations, which were aimed at improving prevention strategies and regulatory oversight; surveillance and trend analysis; incident management and recall response; and communications with the public and stakeholders. The government accepted all of the panel's recommendations.

Roles and responsibilities

4.6 The firm that has produced, distributed, or imported the unsafe food (the recalling firm) has the primary responsibility for implementing the food recall. This includes distributing a list of the affected products to its customers and notifying them of the need to remove the products from further distribution or sale. The recalling firm must then collect and dispose of or correct the recalled product so that unsafe food does not re-enter the marketplace. The recalling firm is also responsible for identifying the potential cause of the contamination that led to the recall, to prevent a reoccurrence. As part of this process, the recalling firm may be required to conduct internal reviews of its food safety control systems to make sure that they are designed appropriately and are operating effectively.

4.7 The Canadian Food Inspection Agency (CFIA) is responsible for administering and enforcing legislation and regulations for assuring the safety and quality of food sold in Canada. All food produced in or imported into Canada is covered by the *Food and Drugs Act*, which prohibits the manufacture or sale of food that is unfit for human consumption. Many foods are also covered by other acts. These include dairy, eggs, beef, pork, poultry, fish, seafood, fruits, vegetables, honey, and maple syrup. Canadian firms that produce, process, or distribute these commodities between provinces and territories, or internationally, must register with the Agency in order to operate. As such, the firms that trade in these commodities are referred to as "federally registered."

4.8 Firms that produce products such as infant foods, alcoholic beverages, and bakery and cereal products do not need to be registered by the CFIA. These commodities, which still must meet the food safety requirements of the *Food and Drugs Act*, are often referred to as "non-federally registered" products. About 70 percent of the food sold in Canada is in this category.

4.9 In November 2012, the Government of Canada passed the *Safe Food for Canadians Act*, which consolidates the food provisions of four separate statutes. The *Food and Drugs Act* continues to exist separately, providing overarching protection for consumers from any foods that are unsuitable for consumption, including those marketed exclusively within provinces.

4.10 The ability to prevent food safety incidents, or contain them in a timely and appropriate manner, is a critical component of the CFIA's mandate to protect Canadians from preventable food safety risks. This part of its mandate requires the Agency to investigate food safety concerns and determine whether a food recall is needed. When a recall occurs, the Agency's role is to monitor the firm's implementation of each step of the process to confirm that the recall has been effectively implemented.

4.11 The Public Health Agency of Canada and Health Canada are the CFIA's two primary federal partners in the food safety investigation and recall process. Their analyses of food safety issues provide critical information that the CFIA considers when determining whether a firm should proceed with a recall. A memorandum of understanding signed in 2008 governs the relationships among these three entities in regard to food safety.

4.12 Provincial and territorial public health and agriculture agencies are also part of the food safety system. They establish rules that govern the food producers, processors, and distributors operating within their provincial and territorial boundaries. These agencies also handle food contamination issues, including outbreaks of food-borne illnesses and product recalls within their own jurisdictions. They may support federal food safety investigations and recalls by providing information on food-borne illnesses and by conducting sampling and other activities requested by the CFIA.

4.13 Organizations outside Canada—namely, national food safety authorities and firms that export products to Canada—may also be involved in Canadian recalls. In addition to the recalling firm and government organizations, everyone along the distribution chain, from farmer to consumer, plays a role in reducing the risk of food contamination.

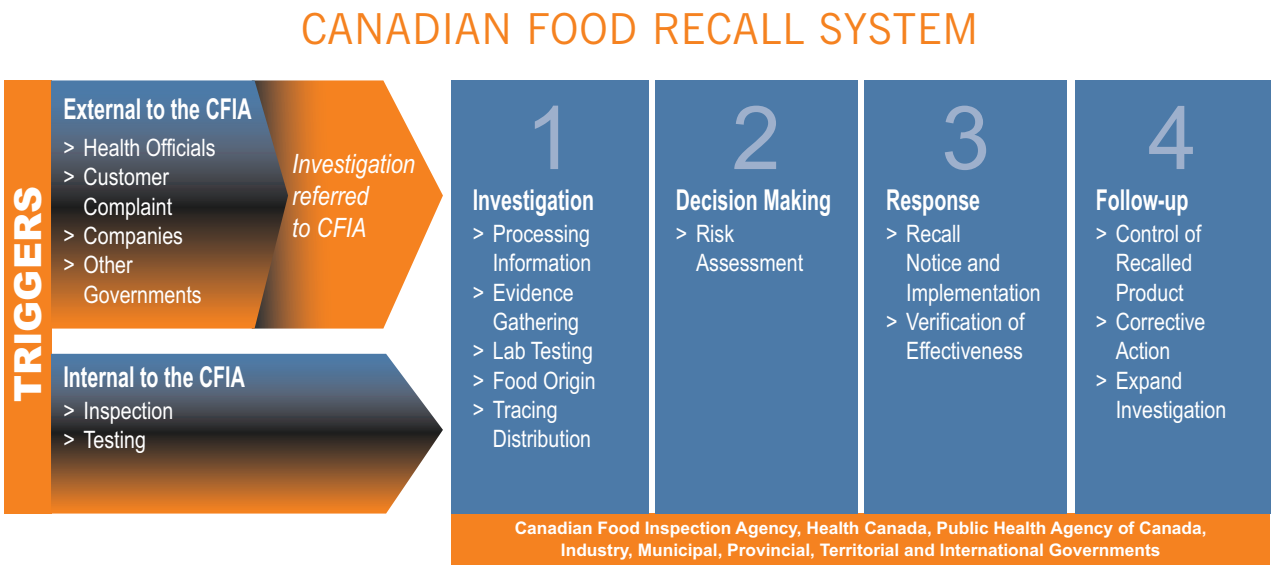
Food recall system

4.14 Canada's food recall system has four key steps (Exhibit 4.1). The first step is a food safety investigation to determine the nature, extent, and source of the problem. The Canadian Food Inspection Agency (CFIA) conducts about 3,000 food safety investigations a year. Incidents that can trigger a food safety investigation and recall include food-borne illness, consumer complaints, concerns raised by the firm after routine product sampling, and inspections by the CFIA.

4.15 During a food safety investigation, the CFIA works with the recalling firm to find the source of the problem, tracing the food product back through the distribution chain to the production or processing facilities. The CFIA also investigates to determine the extent to which potentially contaminated products might have been distributed to Canadian and foreign markets. When an investigation confirms a food safety risk, the investigation is referred to the CFIA's Office of Food Safety and Recall in Ottawa.

4.16 The second step in the food recall process is decision making. Using the information obtained during the food safety investigation, the CFIA may ask Health Canada to assess the health risks posed by the potentially contaminated food product. Based on this assessment, the CFIA determines the strategy needed to manage these health risks and decides whether to recommend that the firm issue a voluntary recall.

Exhibit 4.1 **Canada's food recall system**



Source: Canadian Food Inspection Agency

Food recalls are assigned to one of three classes, according to the risk they pose to human health (Exhibit 4.2). Other options to manage the health risks include detaining or seizing the product, cancelling or suspending the firm's registration or licence, and prosecuting the firm. There have been approximately 200 to 300 food recalls each year since 2006.

4.17 The third step in the process occurs once a decision is made by the responsible firm to issue a recall. The CFIA oversees the recalling firm's implementation of the recall, which includes verifying that the firm has notified its clients of the recall and that the affected product has been recovered and removed from the marketplace. The Agency may also issue a public warning to inform consumers of the food safety hazard and the products involved. In the fourth and final step of the recall process, the Agency verifies that the firm has either corrected or disposed of the affected product, and it oversees the firm's actions to identify and correct the source of the contamination.

Exhibit 4.2 Food recall classes

- **Class I (High risk):** There is a high risk that eating or drinking the food product will lead to serious health problems or death.
- **Class II (Moderate risk):** Eating or drinking the food product will most likely lead to short-term or non–life-threatening health problems. The chance of any serious health symptoms is low in healthy populations.
- **Class III (Low and no risk):** Eating or drinking the food product will not likely result in any undesirable health effects. This category can include food products that pose no health and safety risk but do not comply with relevant laws (for example, a product has more than the allowed level of an additive or preservative).

Source: Canadian Food Inspection Agency

Focus of the audit

4.18 Our audit objective was to determine whether the Canadian Food Inspection Agency (CFIA), with the support of Health Canada and the Public Health Agency of Canada, adequately manages the food recall system.

4.19 Our audit focused primarily on the CFIA and its management of each key step of the food recall process as identified in Exhibit 4.1. Specifically, we examined

- whether the Agency followed its own policies and procedures,

- whether the Agency was prepared to handle large-scale food recalls and managed them effectively when it activated its emergency procedures, and
- whether Health Canada and the Public Health Agency of Canada adequately supported the CFIA in fulfilling its responsibilities for food recalls.

4.20 Our audit work focused on federal actions; we did not audit the actions of provinces, territories, or industry. We did not audit the findings of the Government of Canada's appointed panel that reported on the 2012 beef recall at XL Foods Inc.

4.21 Audit work for this chapter covers the period from 1 January 2010 to 31 December 2012. More details about the audit objective, scope, approach, and criteria are in **About the Audit** at the end of this chapter.

Observations and Recommendations

Investigations and recall decisions

4.22 A food safety investigation is the first step in the recall process, as set out in the Canadian Food Inspection Agency's (CFIA) procedures manual for food investigations. The manual states that when a food safety concern is brought to the CFIA's attention, the Agency investigates to determine whether a potential hazard to human health exists, and to define the nature and extent of the problem. Investigative work includes determining whether additional affected products remain on the market and discovering the source or sources of the contamination. During the investigation, the Agency works closely with the recalling firm to obtain information on the product and its distribution, including the product's destinations, shipping dates, labels, and lot codes.

4.23 The CFIA's guidance states that food safety investigations are to be done in a thorough, consistent, and timely manner. It does not define time standards, but states that investigations are to begin immediately when a food safety concern is identified. In addition, the Agency's guiding principles, as outlined in an internal framework, state that the depth and breadth of the investigation and response must be proportional to the nature of the hazard and likelihood of occurrence.

The Canadian Food Inspection Agency investigated food safety issues promptly

4.24 We examined whether the CFIA had conducted its food safety investigations consistently, without undue delay, and in a manner that was proportional to the scope and scale of the food safety issue. We found that the Agency's management of food safety concerns was consistent with its policy of immediately investigating issues that pose the highest risk to Canadians. In 55 of the 59 food recalls we examined (93 percent), we found that investigations were initiated within 24 hours after the initial problem was identified. We also found that in 49 of the 59 recalls (83 percent), the decision to issue a recall was made within eight days of the initial trigger, with 31 of these 49 recalls (63 percent) being determined within three days. The CFIA conducts many activities during this decision-making period, which may include sampling the suspected product to confirm the presence of contamination, interviewing complainants, consulting with the Public Health Agency of Canada if illness is involved, and asking Health Canada to conduct a risk assessment. We did not observe any undue delays attributed directly to the CFIA's efforts.

4.25 We then looked at the 10 recalls that took longer than eight days to make a recall decision, and we observed that the additional time resulted from more complex investigative work rather than from a delayed response on the Agency's part. We also found that the depth of the CFIA's food safety investigation was proportional to the risk posed, with more investigative work being conducted for issues of higher risk.

4.26 Registered meat establishments are required to maintain product distribution records to facilitate the timely location of products during a food safety investigation. We noted that in two large meat recalls in 2012, timely access to distribution records was a challenge. During the early stages of the XL Foods investigation in September, CFIA officials told us that the firm was slow in providing distribution records, and when the CFIA investigators initially received the information, it was in an unusable format. The investigators spent several days interpreting the information and putting it into a usable format, which delayed the investigation. The March 2012 recall by New Food Classics had also involved delays in obtaining distribution records. The CFIA indicated that the delay in their receiving information from this firm was due to the firm's entering into receivership during the recall.

4.27 We note that such delays are not a recent problem. Failure to provide distribution records on a timely basis was also cited in the Report of the *Independent Investigator into the 2008 Listeriosis Outbreak* (Weatherill Report), which recommended that the CFIA should

encourage federally regulated meat processors to make their records more accessible. We found that the CFIA has since encouraged industry to improve access to distribution records. However, given that the Agency continues to experience difficulties in obtaining timely and usable information, stronger measures are needed.

4.28 **Recommendation.** To facilitate its food safety investigations, the Canadian Food Inspection Agency (CFIA) should clarify the information it needs and should require industry to maintain this information in a complete, accessible, and immediately usable format. For registered establishments, inspectors should regularly validate that the information maintained by the establishment is complete and accessible.

The Agency's response. Agreed. The CFIA is implementing this recommendation.

As of 15 May 2013, it is a regulatory requirement that federally registered meat establishments maintain product distribution records in a usable and accessible format that can be produced for the CFIA in a timely manner during an investigation or recall.

By 31 December 2013, the Agency's inspectors will have verified that all registered meat establishments have updated their food safety protocols according to these new requirements. Where companies have not complied with this new regulatory requirement, corrective measures will be taken by the Agency.

The *Safe Food for Canadians Act* will further strengthen regulatory requirements for traceability and the provision of documents to the CFIA by regulated parties by extending this requirement to all food commodities. We anticipate that this Act will come into force in January 2015.

Health Canada and the Public Health Agency of Canada adequately supported food safety investigations

4.29 If the food safety investigation indicates a potential health risk, the CFIA may ask Health Canada to complete an independent **health risk assessment** (HRA) to help determine whether a recall is needed and to appropriately classify the recall. This arrangement provides an independent assessment of risks, which is in keeping with international risk assessment principles. If a firm has already initiated a recall, the CFIA may request an HRA to validate the firm's decision and to confirm that the classification and extent of the recall are proportional to the risk level. Health Canada has standard operating procedures for

Health risk assessment—A scientifically based process to determine the likelihood of harm to an individual or a population after exposure to a hazardous agent.

completing HRAs. If the health risk associated with a product is high, the HRA must be completed within eight hours.

4.30 Under a memorandum of understanding, the Public Health Agency of Canada (PHAC) supports the CFIA's investigations and Health Canada's HRA process by sharing important information. For example, through its own research and working with the provinces, the PHAC identifies vulnerable human populations and investigates the links between food-borne illnesses and their suspected sources.

4.31 We examined whether Health Canada supported the CFIA's food safety investigations by conducting timely HRAs that were consistent with international risk assessment principles set out by the World Health Organization and the Food and Agriculture Organization of the United Nations. An HRA that is consistent with international principles demonstrates scientific rigour and is therefore important for the CFIA to consider before it asks a firm to implement a recall. We also examined whether the CFIA had received adequate support from the PHAC so that information critical to food safety investigations was provided when needed.

4.32 We found that Health Canada and the PHAC adequately supported the CFIA's food safety investigations by providing the Agency with the information it needed on a timely basis. We found that Health Canada had established and followed standard operating procedures for its HRAs, which were conducted according to international principles. Health Canada conducts an HRA whenever the CFIA issues a request, including during evenings and weekends. We found that Health Canada met its time standards by assessing urgent concerns within eight hours. We also found that the PHAC adequately supported the CFIA's investigations by providing timely information, such as the number of people who have fallen ill and the types of food they consumed. Our findings are consistent with those of the expert panel that reviewed the XL Foods recall. In its report, the panel noted that the communication among the CFIA, Health Canada, and the PHAC was open and constructive.

Product recalls

4.33 Once the recalling firm has decided to issue a voluntary recall, it is required to implement the recall, which includes notifying its clients to remove the product from sale. The Canadian Food Inspection Agency (CFIA) is then responsible for verifying that the recalling firm has effectively carried out the recall and that unsafe products have been removed from the marketplace. Depending on the nature of the food

safety hazard, the Agency may also issue a public warning to inform consumers of the recall.

The CFIA verified that the recalled product had been removed from the marketplace

4.34 The CFIA uses a process called an "effectiveness check" to verify that the recalling firm has effectively carried out the recall. To determine the number of effectiveness checks required, the Agency uses a statistical sampling plan, in which the number of samples examined depends on the number of distributors and retailers that have received the recalled product. According to a CFIA procedures manual, effectiveness checks for all Class I recalls must be completed within 13 days of the date the recall was authorized, and checks for Class II recalls must be completed within 17 days. We examined whether the CFIA conducted its effectiveness checks according to its sampling plan and within the established timelines.

4.35 We found that the CFIA conducted the appropriate number of effectiveness checks required by its sampling plan. We also found that these checks were completed within the Agency's time standard in 84 percent of files we examined. Our analysis was based on information obtained from multiple sources, including the CFIA's **Issues Management System** (IMS), paper files, and follow-up questions with Agency officials. We observed that the CFIA does not consistently record information on effectiveness checks and does not itself verify whether it is completing the required number of checks and meeting its timelines. Our recommendation in paragraph 4.86 addresses the need for the CFIA to improve the information that it collects and records to verify that it has adequately carried out its oversight responsibilities for food safety investigations and recalls.

Issues Management System—A database tool used by the Canadian Food Inspection Agency to record the actions it takes during an investigation and recall.

The Agency issued public warnings to consumers within 24 hours of the decision to recall the product

4.36 Some recalls require a public warning. The CFIA's decision-making guidelines indicate that a public warning may be issued when a food safety issue is linked to one or more specific products that are likely to be in the consumer's home. The Agency has committed to inform consumers within 24 hours of Class I recalls that extend to the consumer level. Timely notification of consumers is important to allow them to become aware of potential health risks posed by food that may be in their homes and to provide time for them to take appropriate action.

4.37 We examined whether the Agency was applying its decision-making guidelines for issuing public warnings and whether it met its time standards when a warning was required. We found that the CFIA applied its guidelines when deciding whether to issue a public warning. Of the 59 recalls we examined, the CFIA determined that 28 required a public warning, and all of these warnings were issued within the required 24 hours.

Follow-up after a recall

4.38 The Canadian Food Inspection Agency's (CFIA) policies require officials to conduct follow-up activities with the recalling firm once the product has been removed from the marketplace. For example, the Agency must verify that the product has been disposed of appropriately. It must also evaluate the corrective actions taken by the firm to prevent a reoccurrence of the problem that triggered the recall.

The CFIA did not have assurance that disposition of the recalled product is consistently verified

4.39 As part of the recall follow-up actions, the recalling firm must correct or dispose of the recalled product. A firm may relabel a product to identify an allergen, cook the recalled product to eliminate the bacteria, or dispose of the product (for example, through landfill or incineration). The CFIA is responsible for making sure that the option the firm selects is appropriate and implemented. Appropriate disposal or correction (referred to as disposition) of recalled products prevents contaminated products from re-entering the marketplace.

4.40 We examined whether the Agency had developed and implemented procedures to monitor the firm's disposition of the recalled product. We found that the Agency has not developed clear guidance to support its officials in carrying out their responsibilities for monitoring product disposition. Officials we met with informed us that they determined the extent of their verification actions based on their experience and knowledge of the recalling firm. We observed that different approaches were used during the same recalls. For example, during a meat recall, some inspectors asked to witness the disposal, while other inspectors asked for documentation to support the recalling firm's claim that the product was disposed of or corrected.

4.41 The CFIA's policies require its officials to document the decisions and actions taken to verify that the recalling firm has appropriately corrected or disposed of the affected product. This documentation would include such items as the date of disposal, the amount disposed of, and the name of the person who validated the

disposal. We found that the Agency did not adequately document its verification of product disposition. For most of the recalls we examined, the incomplete documentation prevented us from being able to verify that the CFIA had adequate assurance that foods posing serious safety risks to Canadians did not re-enter the marketplace.

4.42 We note that two large meat recalls that occurred in 2012 (XL Foods Inc. and Cardinal Meat Specialists Ltd.) were an exception to this general finding. For these recalls, we found that the CFIA verified the firm's disposition of the recalled product and clearly documented its oversight activities. The Agency demonstrated that it had adequate assurance that the recalled products associated with these recalls did not re-enter the marketplace.

4.43 **Recommendation.** The Canadian Food Inspection Agency (CFIA) should review and update its guidance for monitoring and documenting the correction or disposal of recalled products. This should include the steps necessary to provide the Agency with assurance that the appropriate disposal or corrective activities have been identified and carried out.

The Agency's response. Agreed. The CFIA is implementing this recommendation.

The CFIA is developing comprehensive operational guidance in order to provide inspection staff with greater clarity on the disposition of non-compliant food products, including products subject to recall. This guidance, which will be completed by 31 December 2013, will assist inspectors in the assessment of the regulated party's activities and documentation related to

- the reprocessing or further processing within or outside the establishment, as per applicable regulatory requirements, to ensure that the hazard is eliminated or reduced to acceptable levels; or
- the product's destruction or disposal as waste.

Through this guidance, we will ensure that these activities are applied consistently across the CFIA. This will be reinforced by using improved documentation, clearly communicating procedures nationally, and providing training to staff by 31 January 2014.

The Agency did not adequately follow up to verify that recalling firms had corrected the underlying cause of the recall on a timely basis

4.44 We looked at whether the Agency had developed and adhered to procedures for following up on the responsible firm's actions to identify and correct the underlying cause of the recall. We also examined whether the Agency's established timelines had been met.

4.45 Almost 70 percent of our 2010 and 2011 audit sample of recalls involved firms that were not registered with the CFIA. We noted that while the Agency has broad authority under the *Food and Drugs Act* to make sure that non-registered firms recall contaminated food from the marketplace, these firms are not required to inform the CFIA of the actions they take after a recall to fix the underlying cause. Despite this lack of authority to require corrective action after a recall, we found that the CFIA asked non-registered firms to provide information on how they would correct the issue that caused the recall.

4.46 We also examined follow-up actions undertaken at registered establishments. We focused on registered meat establishments because they represented the majority of the registered establishments in our audit.

4.47 Follow-up actions in registered meat establishments include verifying that the firm has corrected any deficiencies identified by the CFIA during its investigation. Inspectors use corrective action requests (CARs) to follow up on non-compliance. The Agency's procedures manual for meat products states that when issuing a CAR, inspectors should base the required date for completing the corrective action on the seriousness of the non-compliance, not exceeding 60 calendar days after the CAR is issued. We examined CARs directly associated with the food recalls to determine whether the Agency was verifying that the corrective actions were completed within the established time frame. CARs were issued in 14 of the 20 meat recalls we examined. They were aimed at improving food safety precautions through such measures as enhanced sanitary controls and safer cooking procedures.

4.48 We found that corrective actions were not being completed on a timely basis. For 10 of the 14 meat recalls that required corrective actions, the corrective action was completed after the 60-day time frame. Our findings are consistent with a recent internal audit conducted by the Agency, which found that CARs were not being adequately monitored or resolved on a timely basis.

4.49 **Recommendation.** The Canadian Food Inspection Agency (CFIA) should clarify its policies and procedures for following up on the underlying causes of a recall in the non-registered sector.

The Agency's response. Agreed. The CFIA is implementing this recommendation.

The CFIA is reviewing its procedures for following up on the underlying causes of a recall in the non-registered sector. The Agency will implement revised operational guidance by 30 April 2014, including thorough documentation of the implementation of corrective measures by firms, in order to address the underlying causes of a recall.

The CFIA is modernizing its legislative and regulatory framework with the passage of the *Safe Food for Canadians Act* and the development of new regulations to support the Act. These initiatives will align the Agency's regulatory tools across all food commodities, including those in the non-registered sector.

4.50 **Recommendation.** The Canadian Food Inspection Agency (CFIA) should monitor its corrective action requests in registered meat establishments to confirm that they are completed within the required 60-day period.

The Agency's response. Agreed. The CFIA has implemented this recommendation.

In March 2013, the CFIA enhanced its monitoring and oversight of open corrective action requests (CARs) in response to recommendations from an internal audit related to the management of CARs that remain open past the scheduled date of closure. Weekly reports are submitted to responsible managers to enable appropriate action to be taken to ensure that past due CARs are closed, or for CARs that remain open, that the rationale for the extension and the interim measures to mitigate food safety risks are implemented and documented. Through quarterly reporting, senior Agency officials are also made aware of the status of CARs.

The Agency did not complete other required follow-up activities in registered meat establishments on a timely basis

4.51 For registered meat establishments, the Agency has additional follow-up requirements. After a recall, the recalling firm must review its food safety system and make any necessary improvements to food safety controls to help prevent future problems. To facilitate a timely and effective response in the case of another recall, the firm must also

review and update its recall plan to incorporate lessons learned. The Agency's procedures manual on meat products requires CFIA inspectors to verify the firm's revised food safety system and recall plan within 30 calendar days of the recall file's closure in the Issues Management System (IMS).

4.52 We examined whether the CFIA conducted its review of the firm's revised food safety system and recall plan within the specified 30-day period. We found that the CFIA did not complete the required reviews on a timely basis. Of the 20 files we examined, 4 establishments were closed and 16 required follow-up. For 7 of these 16 files, the CFIA could not provide evidence that this work was carried out. We found that the CFIA completed the follow-up work within 30 days of the closure of the recall in 2 of the 9 remaining files.

4.53 We also found that using the closure of the IMS file as the basis to complete this work does not allow for timely follow-up. For the 20 meat recalls we looked at, the Agency's files remained open for 81 to 984 calendar days after closure of the recall, and 7 of the 20 files were still open as of May 2013. As such, the Agency's time standard does not provide adequate assurance that the recalling firm has completed its follow-up activities on a timely basis.

4.54 Recommendation. The Canadian Food Inspection Agency (CFIA) should reassess its time standards for verifying that registered meat establishments have reviewed and updated their food safety systems and recall plans after a recall. The CFIA should verify that the firm has completed this work on a timely basis and should document the results of this review.

The Agency's response. Agreed. The Agency is implementing this recommendation.

The CFIA is reviewing operational guidance for implementation by 31 March 2014 to ensure that inspectors have clear instructions on the closure of a recall. The Agency will ensure that the process and associated timelines to be followed by inspectors on the closure of a recall are clear and feasible.

The CFIA has reviewed the delivery of its quality management system (QMS) and identified a number of areas for improvement. This has led to the development of a QMS enhancement plan. The enhanced QMS will allow targeting of high-risk inspection activities, such as those related to food recall and follow-up activities, and verification that inspectors have delivered the operational guidance as intended.

Recalls managed with emergency procedures

4.55 The Canadian Food Inspection Agency (CFIA) has an obligation under the *Emergency Management Act* to have emergency preparedness plans. In addition to having an approved emergency response plan that applies to all areas under its mandate, the Agency has a draft emergency response plan that it uses to manage food safety emergencies. The Food Safety Emergency Response Functional Plan has been in draft form for several years.

4.56 The CFIA distinguishes among food safety emergencies, high-profile issues, and food investigations and recalls that it conducts routinely. In its emergency response plans, the CFIA uses the definition of an emergency found in the Emergency Management Framework for Canada: "A present or imminent event that requires prompt coordination of actions concerning persons or property to protect the health, safety or welfare of people, or to limit damage to property or the environment." The CFIA defines a high-profile issue as "an incident that requires immediate assessment as it has the potential to become an emergency." In such a situation, the CFIA may activate its emergency response procedures for managing high-profile issues. When emergency procedures are activated, the Agency uses a standardized management structure called the Incident Command System (ICS) to control and coordinate the response. Depending on how extensive the issue is, officials may choose to activate emergency procedures at the regional, area, or national levels, or all of these levels.

4.57 The Weatherill Report found that the CFIA's senior management was not adequately engaged at the early stages of the 2008 listeriosis outbreak and recommended improved governance structures, including use of the ICS, to manage such events. In response, the Agency has started using the system to manage incidents related to food safety.

4.58 In 2012, the CFIA activated its emergency procedures to manage three investigations. The Agency considered the following to be high-profile issues: a recall of frozen beef burgers from New Food Classics in March 2012, linked to 1 case of illness; a recall of beef products from XL Foods Inc. in September 2012, linked to 18 cases of illness; and a recall of frozen beef burgers from Cardinal Meat Specialists Ltd. in December 2012, linked to 8 cases of illness.

4.59 These high-profile meat recalls were part of our audit sample of 59 recalls, for which we presented general findings earlier in this chapter. Given that the Agency used its emergency procedures to manage these high-profile cases, we also examined whether the use of these procedures facilitated the Agency's response.

Implementation of emergency response plans created confusion

4.60 As stated in the CFIA's draft plan for food safety emergencies, the principal objective of the plan is to "provide better coordination, more efficient use of resources, and enhanced communication throughout a response." The Agency identifies the necessary elements for successful emergency management. One of these is ensuring that emergency plans and response efforts are an extension of the day-to-day roles and responsibilities of CFIA staff. The Agency further notes that in an emergency, any significant deviation from these roles may cause miscommunication and confusion.

4.61 We found that the activation of the ICS at the national level was effective in engaging the CFIA's senior management. We also observed, after the XL Foods recall, that the CFIA implemented improvements to its emergency procedures, including changing the ICS structure to better integrate food safety specialists. The improved procedures were used in the Cardinal Meat Specialists recall.

4.62 In contrast, we found that activating the ICS also created confusion, particularly for those staff members at headquarters and in the regions who are normally responsible for managing food safety investigations and recalls, and who usually make key decisions themselves. When the ICS is established, decision making for all steps in the investigation and recall process shifts from the food safety specialists in the regions and from staff at headquarters in the Office of Food Safety and Recall to the incident commander of the emergency operations centre. Many of these officials informed us that they were not aware that decision-making responsibilities shifted when the ICS was activated. They stated that they did not know who was making the decisions and that they were not provided with the rationale for important decisions. These officials were the main contacts with the establishments involved in the recall, so not having this information meant that they were unable to answer important questions posed by the recalling firms.

4.63 We also found that important stakeholders were confused during the three recalls in which the ICS was used. For example, during the XL Foods recall, firms that had received the recalled products were provided with conflicting information on the scope of the recall, such as the dates and products involved. Also, officials from the recalling firms received multiple information requests from a number of CFIA officials. The CFIA's challenge in obtaining distribution information from the establishments (described in paragraph 4.26) was in part due to the nature of its own information requests. Officials from Cardinal

Meat Specialists and XL Foods informed us that they received multiple requests for information from different CFIA staff members, which created confusion and increased the workload. They emphasized the need for the CFIA to provide clear requests for information, preferably in writing, with a relative level of priority indicated for each request. In addition, the recalling firms' officials suggested that designating a single point of contact at the CFIA would improve efficiency. Similar information appears in the expert panel's report on the XL Foods beef recall, which notes the CFIA's delayed receipt of distribution records and the firm's confusion concerning the Agency's information requests. The panel recommended improvements in these areas.

4.64 We identified two main factors that contributed to the confusion among CFIA officials and stakeholders. First, the governance structures outlined in the draft emergency plan for food products did not meet the Agency's own definition of the elements necessary for successful emergency management—namely, that response efforts should be an extension of the day-to-day roles and responsibilities. Instead, we found that establishing the emergency response process created new governance mechanisms and decision-making authorities, and that these changes were not well understood by Agency officials or key stakeholders.

4.65 Second, we found that many CFIA officials were not familiar with the Agency's draft emergency management plan related to food safety. The *Emergency Management Act* requires federal organizations to develop emergency management plans and to test them regularly. The CFIA's plan (the Food Safety Emergency Response Functional Plan) states that having emergency plans that are regularly tested helps develop trust and mutual agreement within the Agency and with its partners. However, this plan has been in draft form since 2004 and has not been tested. Internal reviews conducted by the Agency have also noted the need to finalize the plan and to clearly delineate roles and responsibilities of all key staff.

4.66 **Recommendation.** The Canadian Food Inspection Agency (CFIA) should evaluate its emergency processes for food safety and finalize its procedures. This should include clearly defining roles and responsibilities and the communications channels required to keep all key stakeholders informed when emergency procedures are activated. In particular, the roles of those parties responsible for investigations and recalls that are conducted through non-emergency procedures should be clarified. The approved procedures should be communicated, tested, and updated on a regular basis.

The Agency's response. Agreed. The CFIA is implementing this recommendation.

The Food Safety Emergency Response Functional Plan (FSERFP) was finalized on 30 September 2013. The plan describes how the Incident Command System supersedes day-to-day roles and how it is used in conjunction with existing guidance materials to enhance coordination and management of an event.

Orientation and training will be completed by 31 December 2013, and exercises will be conducted by 31 May 2014, for staff identified as potential members of the National Emergency Response Team. This will enable the CFIA to implement and test the FSERFP. Ongoing updates will be made to the FSERFP, as required.

Documentation of the analysis and rationale for important food safety decisions was limited

4.67 Food safety investigations and recalls are constantly evolving processes, and risk management decisions must be made in this context. The CFIA's guiding principles state that the CFIA will "document information, evidence and decisions taken to support the response, ensuring transparency with partners and stakeholders." The Agency has noted that such documentation is particularly important in more complex food safety investigations and recalls.

4.68 In the high-profile recalls in which emergency procedures were activated, the CFIA did not adequately document the considerations, analysis, and rationale for important food safety decisions or communicate this information to key stakeholders. Despite these shortcomings, however, we noted that there were no additional illnesses associated with these recalls.

4.69 In our review of the recall files for XL Foods, we noted that there was considerable confusion among officials at both the CFIA and the recalling firms regarding the products and dates involved in the recall. We noted that during one point in the investigation, CFIA officials had recommended that products from six production dates be recalled. In addition, a presentation to senior management reported that products from an additional date (8 September 2012) had been recalled by the firm. We also noted that CFIA officials had instructed one food distribution company to recall products from a date that was not subject to the recall. Ultimately, the recall included products from five production dates (24, 27–29 August, and 5 September 2012).

4.70 We found that the rationale for selecting the five recall dates and excluding other dates was not adequately documented. We could not find adequate evidence demonstrating the Agency's analysis and considerations of this and other key decisions. We also found that important food safety decisions were not communicated to key stakeholders, including many food safety experts within the Agency. Our recommendation in paragraph 4.86 is aimed at improving the documentation and communication of key decisions.

4.71 Identifying the root cause of the contamination is often one of the most challenging parts of a food safety investigation. We found that the CFIA conducted a detailed food safety review at the Cardinal Meat Specialists and XL Foods establishments to determine the source of the contamination.

4.72 New Food Classics was under receivership and not operating, so an in-depth investigation at the establishment was not possible. As part of the Agency's efforts to identify the origin of the contaminated meat, the Office of Food Safety and Recall identified three slaughter facilities as potential sources (XL Foods and two Cargill plants located in Alberta and Ontario) and started collecting information from those firms.

4.73 We found that the CFIA did not adequately document the work it conducted to determine the root cause of the New Food Classics recall that occurred in March 2012. During this investigation, the Agency's Food Safety Investigation and Review Committee transferred responsibility for the investigation to the CFIA's Western Area office. Staff members at that office were directed to conduct a review of documents from the three firms to determine whether any significant deviations had occurred during key slaughter and production dates associated with the products provided to New Food Classics.

4.74 We found that the work that was done consisted of summarizing the information collected before the Committee's decision and before the Agency had obtained all of the information that it had requested during its initial investigation. The Western Area office concluded in the summary reports that no deviations had occurred at the three slaughter facilities. However, the reports did not explain the methodology or analysis used to arrive at this conclusion. The reports were not reviewed and approved by management, nor were they communicated to key officials within the Agency. (Our recommendation is found at paragraph 4.86.)

Lessons learned reviews were not comprehensive

4.75 The CFIA's internal guidance recommends that the incident commander at each emergency operations centre conduct a post-incident review to identify problems that occurred during the emergency response and to document processes that worked well.

4.76 During our audit, the Agency drafted a directive that elaborated on the structure and format of these post-incident reviews. Agency staff applied this approach to the three recalls that had been managed through emergency procedures in 2012. The directive requires a structured evaluation and reporting process to be completed after any emergency, high-profile issue, or exercise. We found that the Agency's new directive provided greater clarity to guide its officials in carrying out post-incident reviews. The previous guidance had indicated only that post-incident reviews were required; they had not described the content and scope of the reviews.

4.77 We found that the CFIA conducted a post-incident review for each of the three high-profile recalls of 2012. However, we also found that the completed reviews did not fully meet the requirements of the new directive. For example, the directive requires that a detailed report be produced for each incident and outlines what the report should contain (such as descriptions of the scope, methodology, organizational structure, and stakeholder engagement). The CFIA completed a detailed review for the New Food Classics recall, but not for the XL Foods or Cardinal Meat Specialists recalls.

4.78 We also noted a lack of information regarding who participated in the post-incident reviews. For example, while the New Food Classics post-incident review listed those who participated in the review, the XL Foods and Cardinal Meat Specialists post-incident reviews did not. As important stakeholders responsible for implementing food recalls, industry officials informed us that they would like to be included in lessons learned exercises that the CFIA conducts following large recalls. For high-profile situations such as the three large recalls we looked at, sharing the perspectives of key participants may be beneficial to improving the recall process. In our view, the CFIA should consider whether these reviews should be made public. The need for inclusiveness and transparency is a long-standing issue—one that we reported, for example, after examining post-outbreak reviews in the 1999 September Report of the Auditor General, Chapter 15, Management of a Food-Borne Disease Outbreak.

4.79 **Recommendation.** The Canadian Food Inspection Agency (CFIA) should finalize its directive for post-incident reviews and

implement it after any food recall that activates emergency response procedures. These reviews should include the perspectives of key stakeholders and should examine the strengths and weaknesses of the investigation, the recall process, and the emergency management process.

The Agency's response. Agreed. The CFIA agrees with and is implementing this recommendation.

The Food Safety Emergency Response Functional Plan (FSERFP), finalized on 30 September 2013, includes the process for post-incident reviews. The CFIA has developed operational guidance related to this process, which will be finalized by 31 December 2013.

The CFIA will develop a post-incident process to include the perspectives of the key stakeholders in a recall by 31 March 2014.

Guidance and supporting systems

4.80 During this audit, we identified some contributing factors for some of the weaknesses we identified. These are long-standing issues that were previously identified in internal or external audits and evaluations.

The CFIA's guidance for managing food safety investigations and recalls is not finalized on a timely basis

4.81 Having clear policies and guidance is important so that officials are aware of their responsibilities and of the actions that must be taken at all stages of the investigation and recall. During the course of our audit, we noted that the Canadian Food Inspection Agency (CFIA) has many documents that outline policies and procedures. These include core documents, such as the CFIA Framework for Food Safety Investigation and Response (finalized in July 2012) and the Food Investigation Response Manual (finalized in August 2011). Supporting guidance includes a consumer complaints manual, training manuals, and manuals for registered establishments.

4.82 We found that terminology and expectations are not always consistent. For example, the roles and responsibilities outlined in the Food Investigation Response Manual were not always consistent with established practice. We also found that manuals and guidance are not finalized on a timely basis. For example, the Food Safety Emergency Response Functional Plan has been in draft form since 2004, and the consumer complaints manual has been in draft form for several years. In the 2010 Fall Report of the Auditor General of Canada, Chapter 9, Animal Diseases—Canadian Food Inspection Agency, we noted that

the Agency applied draft procedures to manage animal disease emergencies. Delays in updating, finalizing, and approving manuals and guidance are also noted in the Agency's internal audits and reviews.

4.83 **Recommendation.** The Canadian Food Inspection Agency (CFIA) should regularly review, update, and approve its policies and procedures for food safety investigations and recalls. This review should include determining the needs of staff implementing the policies and the information that the Agency requires to provide it with assurance that key steps in the recall process have been carried out by the recalling firms. These documents should clearly indicate how the policies and procedures apply when the emergency response process is activated.

The Agency's response. Agreed. The CFIA is implementing this recommendation.

The CFIA has four manuals to guide inspection activities related to food safety investigations and recalls. Three of these manuals are finalized: the Food Safety Emergency Response Functional Plan, the CFIA Framework for Food Safety Investigation and Response, and the Food Investigation Response Manual. The fourth, the Food Complaint Manual, will be finalized by 31 March 2014.

The CFIA is committed to reviewing these manuals every two years, with the aim of continuously reflecting the current operating environment.

Incomplete record keeping limited the Agency's ability to track investigations and recalls

4.84 The Agency's officials are required to use the Issues Management System (IMS) to document their oversight activities and important decisions. Supervisors must review the IMS file to verify that the activities have been carried out and are appropriately documented before they close the file.

4.85 Throughout our audit, we found many examples of incomplete documentation. For each recall we examined, we reviewed information in the IMS file to determine whether each step in the process was carried out according to established policies, and whether it was documented in the IMS as required. We found that many of the IMS files were not complete, particularly for steps in the follow-up stage of the recall. As we report in paragraphs 4.67 to 4.74, important food safety decisions were not adequately documented. Having critical information consolidated in a central location would provide assurance

to the CFIA that key steps in the food recall process are implemented and that important decisions—and the considerations leading to them—are documented.

4.86 **Recommendation.** The Canadian Food Inspection Agency (CFIA) should identify the information it needs to provide assurance that it has adequately carried out its oversight responsibilities for food safety investigations and recalls. To ensure transparency with partners and stakeholders, the Agency should determine which information and evidence it needs to include in recording its key decisions. It should then ensure that this information is collected, recorded, and communicated on a timely basis.

The Agency's response. Agreed. The CFIA is implementing this recommendation.

The CFIA is undertaking a comprehensive review of how it documents information, including decisions related to recalls. Specifically, this review will improve access to documentation and enhance its thoroughness. By 31 December 2013, this initiative will result in the development of operational policy and procedures to be applied to key operational decisions, including those associated with routine and non-routine food safety investigations and recalls.

The Agency did not adequately verify that inspectors were conducting investigations and recalls according to its policies

4.87 According to the CFIA, continuous improvement in program design is one of the principles that guide its activities related to food safety investigation and response. The CFIA has a quality management system (QMS) to support its continuous improvement efforts. Inspection supervisors conduct QMS evaluations to make sure that inspectors are following policies and procedures, and to identify areas where improvements are needed. For example, the QMS may identify that an inspector needs additional training or that the CFIA's policies and procedures need to be clarified. As part of its QMS, the CFIA assesses three components of the recall system: complaints and investigations, recall management, and effectiveness checks. Each year, the CFIA determines how many quality verifications must be conducted.

4.88 We examined whether the CFIA completed the required quality verifications for the three tasks related to food safety investigations and recalls. We also examined whether improvements in policies and processes that had been identified by the QMS had been made.

4.89 We found that the CFIA did not conduct all of the quality assessments it had planned in 2010, 2011, and 2012. During that period, the Agency completed 72 percent of planned verifications of its recall management activities and 69 percent of planned verifications for effectiveness checks. We also found considerable regional variation in the delivery rates of completed assessments. For example, in 2010 and 2011, 15 of the 16 completed assessments for the recall management task were from western Canada. Only one assessment of recall management was conducted in Ontario; none were conducted in Quebec or Atlantic Canada. The lack of complete information from all areas limits the Agency's ability to develop a national picture of how well it is delivering its recall activities and areas for improvement. A recent internal audit conducted by the Agency also found that it is not doing all of its planned quality verifications.

4.90 CFIA officials reported that not enough time is available to allow them to deliver all of the quality verifications that are planned. The supervisors who carry out these activities are also responsible for overseeing food safety investigations and recalls, which take priority. Officials also commented that the quality verifications have indicated that policies and procedures could be improved or clarified, but that improvements are not made on a timely basis. For example, the CFIA has not defined the mandatory training required to conduct investigations and recalls, and the consumer complaints manual has been in draft form for several years.

4.91 **Recommendation.** The Canadian Food Inspection Agency (CFIA) should investigate the reasons that quality verifications for food investigations and recalls are not being delivered as planned and should identify options to improve the delivery rates. When quality verifications have identified policies and procedures that could be improved or clarified, these issues should be resolved on a timely basis.

The Agency's response. Agreed. The CFIA is implementing this recommendation.

The CFIA has reviewed the delivery of the quality management system (QMS) and identified a number of areas for improvement. This has led to the development of a QMS enhancement plan. The enhanced QMS will allow targeting of high-risk inspection activities, such as those related to food recall and follow-up activities. By 31 March 2015, these verifications will be conducted by specialized staff. This enhanced process will strengthen the quality management, including

the establishment of a systematic reporting and performance tracking process.

Assessment of information needs

4.92 Effective communications throughout the recall process help provide assurance that all key stakeholders are aware of the food safety issue and of the actions they need to take. For recalling firms, this awareness includes understanding what is expected of them during an investigation and recall. Consumers need to be aware of the food recall so that they do not consume the recalled product. According to the Communications Policy of the Government of Canada, federal entities are required to assess the information needs of Canadians and to provide the public with timely, accurate, clear, objective, and complete information about their policies, programs, services, and initiatives. The Canadian Food Inspection Agency's (CFIA) policies and guidance state the need for transparency with partners, stakeholders, and the public.

4.93 We assessed whether the CFIA has determined what information stakeholders need about recalls, and whether it has communicated this information in a consistent and timely manner.

The CFIA has not assessed the information needs of stakeholders

4.94 We observed that the CFIA has ongoing communications with recalling firms during the investigation and recall process, and that it communicates with key stakeholders, such as food distributors and retailers, particularly when conducting effectiveness checks to ensure that the product has been removed from the marketplace. We also found that the Agency communicates information about food recalls to the public in a number of ways, including issuing timely public warnings of the recalls and providing information on its website, and through email and social media. In response to a recommendation in the Weatherill Report, the Agency now discloses the results of its investigation of the implicated facility and describes the corrective actions taken when the events that led to the recall are linked to serious illness or death.

4.95 Although the Agency disseminates information about recalls to stakeholders, it has not assessed whether it is meeting their needs. As noted in paragraph 4.63, industry officials indicated that the information the CFIA provides during an investigation and recall could be improved. The expert panel had also stated in its report that improvements were needed to the information provided to industry, and that the public was confused by the information communicated during the XL Foods recall. The panel recommended that the CFIA

improve communications with industry and improve the readability of the alerts to consumers. It also recommended that the Agency use the opportunity to educate the public on how recalls are carried out.

4.96 **Recommendation.** The Canadian Food Inspection Agency (CFIA) should determine what information is needed by key stakeholders to allow them to take appropriate action during a recall. Based on this determination, the Agency should adapt the information it currently provides.

The Agency's response. Agreed. The CFIA is implementing this recommendation.

In response to recommendations of the Independent Review of XL Foods Inc. Beef Recall 2012, the Agency has revised its warnings to the public and has tested them with focus groups and the Consumer Association Roundtable. These templates, written in a clearer manner, are being finalized and will be implemented by 31 December 2013.

The CFIA is committed to the timely exchange of important information with key stakeholders during emergency and routine food safety events. This commitment is subject to the provisions of the *Privacy Act* and takes into account confidential business information.

Also in response to the recommendations of the expert panel that reviewed the XL Foods recall, the CFIA has enhanced its communication with industry during national emergency responses by ensuring that appropriate technical expertise is available.

Conclusion

4.97 We concluded that the Canadian Food Inspection Agency (CFIA) did not adequately manage the food recall system. Although the Agency acted promptly to investigate food safety concerns and verified that recalled products were removed from the marketplace, significant improvements to the food recall system were needed.

4.98 The first three steps in the food recall process were generally working well, from the point of identifying a food safety issue to conducting the investigation and making recall decisions—particularly when recalls were not managed using emergency procedures. Health Canada and the Public Health Agency of Canada provided the CFIA with adequate and timely support during food safety investigations.

4.99 There were weaknesses in the CFIA's follow-up activities after a product had been removed from the marketplace. The Agency did not

have adequate assurance that it consistently verified that the recalled product was disposed of appropriately or that the underlying cause of the recall was identified and corrected on a timely basis.

4.100 The CFIA's emergency response plan for food safety issues, used to manage three high-profile recalls in 2012, has been in draft form since 2004. It has not been finalized or tested. The activation of emergency processes created new governance structures that were not well understood by some officials, which contributed to confusion among staff and key stakeholders.

4.101 For high-profile recalls managed under emergency procedures, we found that the CFIA did not adequately document the considerations, analysis, and rationale for important food safety decisions, or communicate this information to key stakeholders. Despite these shortcomings, there were no further illnesses associated with these recalls.

4.102 The weaknesses identified in this audit were partly related to some long-standing issues. For example, the Agency's guidance for managing food safety investigations and recalls was incomplete, unclear, and not finalized on a timely basis. We noted many examples of incomplete documentation of important decisions and key steps in the recall process. As a result, the Agency did not know whether its recall activities were carried out across the country consistently and according to policies, procedures, and requirements.

About the Audit

All of the audit work in this chapter was conducted in accordance with the standards for assurance engagements set out in The Canadian Institute of Chartered Accountants Handbook—Assurance. While the Office adopts these standards as the minimum requirement for our audits, we also draw upon the standards and practices of other disciplines.

As part of our regular audit process, we obtained management's confirmation that the findings reported in this chapter are factually based.

Objective

The overall audit objective was to determine whether the Canadian Food Inspection Agency (CFIA), with the support of Health Canada and the Public Health Agency of Canada, adequately manages the food recall system.

Scope and approach

Our audit examined the Government of Canada's management of food safety investigations and recalls. We examined each main step in the food recall process, from when a food safety concern is first brought to the attention of the CFIA to follow-up actions taken at the end of a recall. Our audit work focused primarily on the CFIA because it is the federal lead for food safety investigations and recalls. Given that the Agency relies on Health Canada and the Public Health Agency of Canada for support in identifying and assessing the health risks posed by potentially unsafe food, we examined how well these entities supported the CFIA in fulfilling its responsibilities for food recalls.

We looked at actions taken from the start of a food safety investigation through to the end of the process, including follow-up activities that are conducted to identify and correct the underlying cause of the recall. To do this, we examined a random sample of Class I and Class II recalls from 2010 and 2011 (the most serious types). Our sample size was 45 recalls out of a population of 344. Given that there were three high-profile beef recalls in 2012, we also examined all 14 Class I meat recalls in 2012. All recalls during our audit period were voluntarily initiated by industry.

This audit did not examine the CFIA's food inspection process or compliance and enforcement actions, except for those activities directly related to food recalls. We did not audit the science behind decisions made during a recall, but we assessed whether key decisions were documented along with the rationale. We did not assess the food-borne illness surveillance systems of the Public Health Agency of Canada, nor how that Agency manages the public health response to the outbreak of food-borne illness. We also did not look at Health Canada's responsibilities for setting food safety standards or its responsibilities for assessing the effectiveness of the CFIA's activities related to food safety. We did not examine Health Canada's responsibilities for food safety on conveyances (such as cruise ships, trains, or ferries) or in First Nations communities.

Our audit work focused on federal actions; we did not audit the actions of provinces, territories, or industry. We did not audit the findings of the Government of Canada's appointed panel that reported on the 2012 beef recall at XL Foods Inc.

We reviewed policy and guidance documents and the electronic and paper files associated with the investigations and recalls included in our sample. We also collected evidence through interviews with officials from the CFIA, Health Canada, and the Public Health Agency of Canada, and we met with representatives from the food industry.

Criteria

Criteria	Sources
To determine whether the Canadian Food Inspection Agency, with the support of Health Canada and the Public Health Agency of Canada, adequately manages the food recall system, we used the following criteria:	
The Canadian Food Inspection Agency has developed and implemented mechanisms to coordinate its food safety investigations, including with Health Canada and the Public Health Agency of Canada, so that these investigations are conducted consistently, without undue delay, and in a manner that is proportional to the scope and scale of the food safety issue.	• *Canadian Food Inspection Agency Act* • Food Investigation Response Manual, Canadian Food Inspection Agency • Quality Management System Manual, Canadian Food Inspection Agency
Health Canada supports the Canadian Food Inspection Agency's food safety investigations by conducting timely health risk assessments that are consistent with international risk assessment principles.	• *Food and Drugs Act* • Codex Alimentarius: Working Principles for Risk Analysis for Food Safety for Application by Governments, World Health Organization and the Food and Agriculture Organization of the United Nations • Food Directorate Standard Operating Procedures for Providing Health Risk Assessments to the CFIA in the Context of Food Safety Investigations, Health Canada • 2008 Memorandum of Understanding between Health Canada, the Public Health Agency of Canada and the Canadian Food Inspection Agency
The Canadian Food Inspection Agency has determined what information related to recalls is needed by stakeholders and has communicated this information in a consistent and timely manner.	• *Canadian Food Inspection Agency Act* • Communications Policy of the Government of Canada, Treasury Board
The Canadian Food Inspection Agency verifies in a consistent and timely manner that recalls are effectively implemented by recalling firms.	• Food Investigation Response Manual, Canadian Food Inspection Agency • Quality Management System Manual, Canadian Food Inspection Agency
The Canadian Food Inspection Agency follows up in a consistent and timely manner with regulated parties to ensure that underlying causes of food safety issues are addressed.	• Food Investigation Response Manual, Canadian Food Inspection Agency • Quality Management System Manual, Canadian Food Inspection Agency
The Canadian Food Inspection Agency assesses the completeness of recall plans for registered meat establishments.	• Food Safety Enhancement Program Manual, Canadian Food Inspection Agency • Meat Hygiene Manual of Procedures, Canadian Food Inspection Agency

Management reviewed and accepted the suitability of the criteria used in the audit.

Period covered by the audit

The audit covered the period between 1 January 2010 and 31 December 2012. Audit work for this chapter was completed on 24 July 2013.

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Appendix List of recommendations

The following is a list of recommendations found in Chapter 4. The number in front of the recommendation indicates the paragraph where it appears in the chapter. The numbers in parentheses indicate the paragraphs where the topic is discussed.

Recommendation	Response
Investigations and recall decisions	
4.28 To facilitate its food safety investigations, the Canadian Food Inspection Agency (CFIA) should clarify the information it needs and should require industry to maintain this information in a complete, accessible, and immediately usable format. For registered establishments, inspectors should regularly validate that the information maintained by the establishment is complete and accessible. **(4.24–4.27)**	Agreed. The CFIA is implementing this recommendation. As of 15 May 2013, it is a regulatory requirement that federally registered meat establishments maintain product distribution records in a usable and accessible format that can be produced for the CFIA in a timely manner during an investigation or recall. By 31 December 2013, the Agency's inspectors will have verified that all registered meat establishments have updated their food safety protocols according to these new requirements. Where companies have not complied with this new regulatory requirement, corrective measures will be taken by the Agency. The *Safe Food for Canadians Act* will further strengthen regulatory requirements for traceability and the provision of documents to the CFIA by regulated parties by extending this requirement to all food commodities. We anticipate that this Act will come into force in January 2015.

Recommendation	Response
Follow-up after a recall	
4.43 The Canadian Food Inspection Agency (CFIA) should review and update its guidance for monitoring and documenting the correction or disposal of recalled products. This should include the steps necessary to provide the Agency with assurance that the appropriate disposal or corrective activities have been identified and carried out. **(4.39–4.42)**	Agreed. The CFIA is implementing this recommendation. The CFIA is developing comprehensive operational guidance in order to provide inspection staff with greater clarity on the disposition of non-compliant food products, including products subject to recall. This guidance, which will be completed by 31 December 2013, will assist inspectors in the assessment of the regulated party's activities and documentation related to • the reprocessing or further processing within or outside the establishment, as per applicable regulatory requirements, to ensure that the hazard is eliminated or reduced to acceptable levels; or • the product's destruction or disposal as waste. Through this guidance, we will ensure that these activities are applied consistently across the CFIA. This will be reinforced by using improved documentation, clearly communicating procedures nationally, and providing training to staff by 31 January 2014.
4.49 The Canadian Food Inspection Agency (CFIA) should clarify its policies and procedures for following up on the underlying causes of a recall in the non-registered sector. **(4.44–4.48)**	Agreed. The CFIA is implementing this recommendation. The CFIA is reviewing its procedures for following up on the underlying causes of a recall in the non-registered sector. The Agency will implement revised operational guidance by 30 April 2014, including thorough documentation of the implementation of corrective measures by firms, in order to address the underlying causes of a recall. The CFIA is modernizing its legislative and regulatory framework with the passage of the *Safe Food for Canadians Act* and the development of new regulations to support the Act. These initiatives will align the Agency's regulatory tools across all food commodities, including those in the non-registered sector.

Recommendation	Response
4.50 The Canadian Food Inspection Agency (CFIA) should monitor its corrective action requests in registered meat establishments to confirm that they are completed within the required 60-day period. **(4.44–4.48)**	Agreed. The CFIA has implemented this recommendation. In March 2013, the CFIA enhanced its monitoring and oversight of open corrective action requests (CARs) in response to recommendations from an internal audit related to the management of CARs that remain open past the scheduled date of closure. Weekly reports are submitted to responsible managers to enable appropriate action to be taken to ensure that past due CARs are closed, or for CARs that remain open, that the rationale for the extension and the interim measures to mitigate food safety risks are implemented and documented. Through quarterly reporting, senior Agency officials are also made aware of the status of CARs.
4.54 The Canadian Food Inspection Agency (CFIA) should reassess its time standards for verifying that registered meat establishments have reviewed and updated their food safety systems and recall plans after a recall. The CFIA should verify that the firm has completed this work on a timely basis and should document the results of this review. **(4.51–4.53)**	Agreed. The Agency is implementing this recommendation. The CFIA is reviewing operational guidance for implementation by 31 March 2014 to ensure that inspectors have clear instructions on the closure of a recall. The Agency will ensure that the process and associated timelines to be followed by inspectors on the closure of a recall are clear and feasible. The CFIA has reviewed the delivery of its quality management system (QMS) and identified a number of areas for improvement. This has led to the development of a QMS enhancement plan. The enhanced QMS will allow targeting of high-risk inspection activities, such as those related to food recall and follow-up activities, and verification that inspectors have delivered the operational guidance as intended.

Recommendation	Response
Recalls managed with emergency procedures	
4.66 The Canadian Food Inspection Agency (CFIA) should evaluate its emergency processes for food safety and finalize its procedures. This should include clearly defining roles and responsibilities and the communications channels required to keep all key stakeholders informed when emergency procedures are activated. In particular, the roles of those parties responsible for investigations and recalls that are conducted through non-emergency procedures should be clarified. The approved procedures should be communicated, tested, and updated on a regular basis. **(4.60–4.65)**	Agreed. The CFIA is implementing this recommendation. The Food Safety Emergency Response Functional Plan (FSERFP) was finalized on 30 September 2013. The plan describes how the Incident Command System supersedes day-to-day roles and how it is used in conjunction with existing guidance materials to enhance coordination and management of an event. Orientation and training will be completed by 31 December 2013, and exercises will be conducted by 31 May 2014, for staff identified as potential members of the National Emergency Response Team. This will enable the CFIA to implement and test the FSERFP. Ongoing updates will be made to the FSERFP, as required.
4.79 The Canadian Food Inspection Agency (CFIA) should finalize its directive for post-incident reviews and implement it after any food recall that activates emergency response procedures. These reviews should include the perspectives of key stakeholders and should examine the strengths and weaknesses of the investigation, the recall process, and the emergency management process. **(4.75–4.78)**	Agreed. The CFIA agrees with and is implementing this recommendation. The Food Safety Emergency Response Functional Plan (FSERFP), finalized on 30 September 2013, includes the process for post-incident reviews. The CFIA has developed operational guidance related to this process, which will be finalized by 31 December 2013. The CFIA will develop a post-incident process to include the perspectives of the key stakeholders in a recall by 31 March 2014.

Recommendation	Response
Guidance and supporting systems	
4.83 The Canadian Food Inspection Agency (CFIA) should regularly review, update, and approve its policies and procedures for food safety investigations and recalls. This review should include determining the needs of staff implementing the policies and the information that the Agency requires to provide it with assurance that key steps in the recall process have been carried out by the recalling firms. These documents should clearly indicate how the policies and procedures apply when the emergency response process is activated. **(4.81–4.82)**	Agreed. The CFIA is implementing this recommendation. The CFIA has four manuals to guide inspection activities related to food safety investigations and recalls. Three of these manuals are finalized: the Food Safety Emergency Response Functional Plan, the CFIA Framework for Food Safety Investigation and Response, and the Food Investigation Response Manual. The fourth, the Food Complaint Manual, will be finalized by 31 March 2014. The CFIA is committed to reviewing these manuals every two years, with the aim of continuously reflecting the current operating environment.
4.86 The Canadian Food Inspection Agency (CFIA) should identify the information it needs to provide assurance that it has adequately carried out its oversight responsibilities for food safety investigations and recalls. To ensure transparency with partners and stakeholders, the Agency should determine which information and evidence it needs to include in recording its key decisions. It should then ensure that this information is collected, recorded, and communicated on a timely basis. **(4.67–4.74, 4.84–4.85)**	Agreed. The CFIA is implementing this recommendation. The CFIA is undertaking a comprehensive review of how it documents information, including decisions related to recalls. Specifically, this review will improve access to documentation and enhance its thoroughness. By 31 December 2013, this initiative will result in the development of operational policy and procedures to be applied to key operational decisions, including those associated with routine and non-routine food safety investigations and recalls.

Recommendation	Response
4.91 The Canadian Food Inspection Agency (CFIA) should investigate the reasons that quality verifications for food investigations and recalls are not being delivered as planned and should identify options to improve the delivery rates. When quality verifications have identified policies and procedures that could be improved or clarified, these issues should be resolved on a timely basis. **(4.87–4.90)**	Agreed. The CFIA is implementing this recommendation. The CFIA has reviewed the delivery of the quality management system (QMS) and identified a number of areas for improvement. This has led to the development of a QMS enhancement plan. The enhanced QMS will allow targeting of high-risk inspection activities, such as those related to food recall and follow-up activities. By 31 March 2015, these verifications will be conducted by specialized staff. This enhanced process will strengthen the quality management, including the establishment of a systematic reporting and performance tracking process.
Assessment of information needs	
4.96 The Canadian Food Inspection Agency (CFIA) should determine what information is needed by key stakeholders to allow them to take appropriate action during a recall. Based on this determination, the Agency should adapt the information it currently provides. **(4.94–4.95)**	Agreed. The CFIA is implementing this recommendation. In response to recommendations of the Independent Review of XL Foods Inc. Beef Recall 2012, the Agency has revised its warnings to the public and has tested them with focus groups and the Consumer Association Roundtable. These templates, written in a clearer manner, are being finalized and will be implemented by 31 December 2013. The CFIA is committed to the timely exchange of important information with key stakeholders during emergency and routine food safety events. This commitment is subject to the provisions of the *Privacy Act* and takes into account confidential business information. Also in response to the recommendations of the expert panel that reviewed the XL Foods recall, the CFIA has enhanced its communication with industry during national emergency responses by ensuring that appropriate technical expertise is available.