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Food Safety Assessment Program

Assessment Report of the Canadian Food Inspection Agency Activities Related to Domestic Ready-to-Eat Meat Products

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Executive Summary

In April 1997 the *Canadian Food Inspection Agency Act* established the Canadian Food Inspection Agency (CFIA), reporting to the Minister of Agriculture and Agri-food Canada. One of Health Canada's (HC) responsibilities is to assess the effectiveness of the Agency's activities related to food safety.

In Canada, food safety is an area of shared responsibility. Health Canada establishes standards and policies for the safety and nutritional quality of food sold in Canada. CFIA has the responsibility for enforcing those standards. In addition, provincial and municipal food agencies regulate food establishments such as food processors whose markets are local and whose products do not cross any borders. Some of these establishments may also produce domestic ready-to-eat meat products. CFIA works with these partners to enhance food safety.

The objective of this assessment was to assess the effectiveness of CFIA's programs and activities related to the safety of ready-to-eat meat products produced and sold in Canada. We examined inspection, laboratory and policy development activities relating to domestic ready-to-eat meat products. The roles and responsibilities of the various partners involved were also examined.

This report covers inspection and other related activities carried out by the CFIA pursuant to it's responsibilities under the *The Meat Inspection Act* and *The Food and Drugs Act*. *The Food and Drugs Act* applies to all food produced and sold in Canada, both in the registered and non-registered sectors (These terms are defined in the glossary). The registered sector is also regulated under the *Meat Inspection Act*.

Activities pursuant to *The Meat Inspection Act* are delivered primarily by the Meat Hygiene Program. Activities pursuant to The *Food and Drugs Act* (as it relates to food) are delivered primarily by the Food Safety Investigations program. It is important to note that the latter program was introduced in March 2000 following a program review. At this time, we had already completed the examination phase of this assessment.

The scope of this assessment includes the Agency's activities related to ensuring the safety of domestic ready-to-eat meat products since the creation of the Agency in April 1997, with emphasis on activities carried out between April 1, 1998 and March 31, 2000.

Background

Ready-to-eat meat products represent an important part of the diet of Canadians. According to Agriculture and Agri-food Canada, up to 65% of pork and 25% of beef wholesale cuts are sold by Canadian meat packers to Canadian meat processors to be transformed into a vast array of products including bacon, ham, sausages, delicatessen specialties and pâtés. Statistics Canada in its data on annual food expenditures estimates that cured, prepared and cooked meats represent 6% of the total retail food purchases per person and 30% of retail meat purchases. Unlike other meat products, they are generally consumed without further cooking. Therefore, they require that pathogens be rigorously controlled during processing.

Key Observations

CFIA is working with many partners to protect consumers. Since its creation on April 1st, 1997, CFIA has been working in partnership with HC to better define the respective responsibilities of the two organizations for different aspects of food safety, including those related to ready-to-eat meats.

Where responsibilities for inspecting ready-to-eat meat products are shared between federal and provincial jurisdictions, CFIA has begun to update its Memoranda of Understanding/Agreements with the provinces covering the management of these shared responsibilities. During the period covered by this assessment, one agreement has been signed with the province of Quebec. This agreement includes key elements to ensure proper accountability between partners and to prevent gaps and duplication in their respective inspection activities. However, some of these key elements, such as the requirement to exchange information related to RTE meat inspection activities, had not been fully implemented.

CFIA represents a strong government presence in federally registered establishments. Key risks are well identified, establishments are monitored closely, product sampling is done on a routine basis, compliance levels are high, and major deficiencies are corrected. Nevertheless, our assessment identified areas where the Agency could improve its inspection activities. We also noted that CFIA did not fully implement its product and environmental sampling work plans in some Areas (see Glossary), that sampling procedures for *Listeria monocytogenes* (see Glossary) had resulted in delays between the time when non-compliant samples were detected and when follow-up samples were taken. We also noted that controls for nitrite and nitrate levels may have been weakened when CFIA suspended analytical testing for this type of additive.

For historical and constitutional reasons, ready-to-eat meat products are subject to different inspection regimes. These regimes depend on how these products are traded and whether they fall under federal or provincial jurisdiction, and on the agreements between the two levels of government on the sharing of responsibilities for inspection. As could be expected, differences in the inspection regimes have led to differences in the type and quality of compliance information available. Our assessment has shown, for instance, that prior to March 2000, CFIA's inspections of non-federally registered establishments, although satisfactory in some respects, required important improvements, especially in terms of coverage of the establishments and timely follow-up inspections of non-compliant establishments. On April 1st, 2000 CFIA implemented a new program to address its responsibilities. The new Food Safety Investigations Program (FSIP) is responsible for program design and supporting activities related to foods under the *Food and Drugs Act* (FDA). The FSIP uses current risk analysis to establish its program priorities. It is designed to enable CFIA to allocate its resources more effectively (i.e., to concentrate its resources on areas where the risk is highest).

Conclusion

The inspection of ready-to-eat meat products is facing many challenges. Emerging microbiological hazards such as *E. coli* 0157:H7 and *Listeria monocytogenes* demand ever more vigilant and effective controls. Our assessment has shown that CFIA's key inspection activities are generally effective in promoting safe ready-to-eat meat products in Canada. However, we have identified some areas which would warrant the Agency's attention to increase food safety effectiveness.

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Introduction

The Ready-to-eat Meat Industry

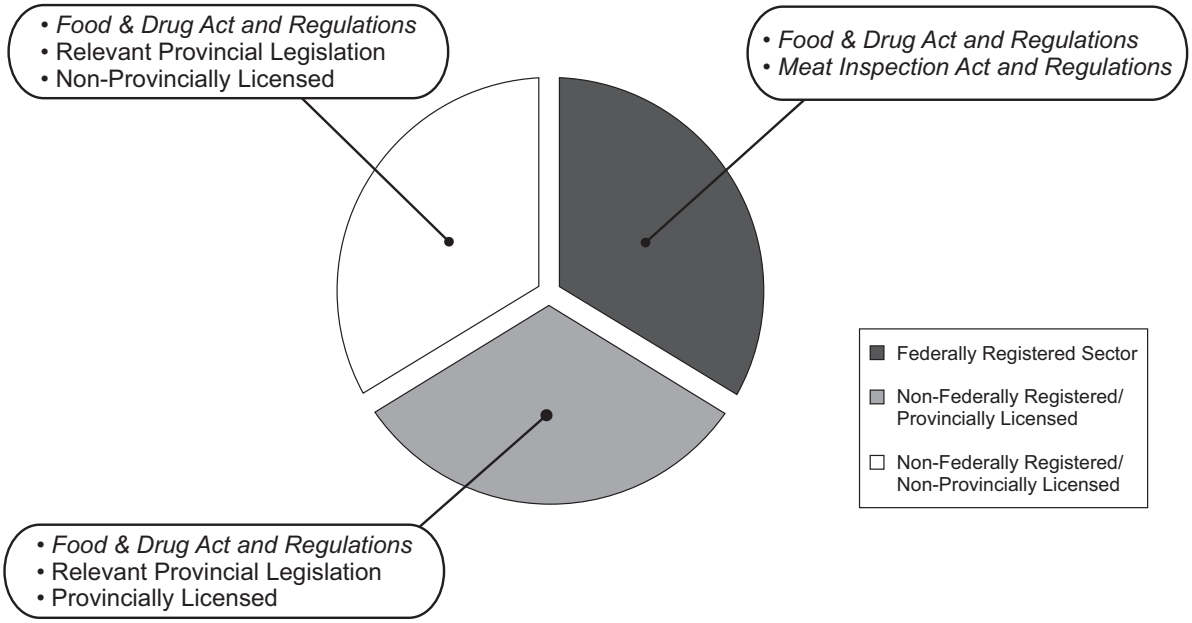
1. Ready-to-eat meat products represent an important part of the diet of Canadians. Unlike other meat products, they are generally consumed without further cooking. Therefore, they require that pathogens be rigorously controlled during processing.

2. The production and distribution of ready-to-eat (RTE) meats, like all foods, involve a complex chain of intermediaries including producers, manufacturers, transporters, distributors, wholesalers, and retailers. RTE meat establishments (e.g., processing/storage plants) that manufacture and/or distribute their products inter-provincially or internationally must be federally registered and therefore meet the Agency's requirements. Establishments, i.e., plants, whose products are sold or traded only within one province are not required to be federally registered and are mostly non-federally registered establishments. They could be registered provincially, although we have noted plants that are not registered—either federally or provincially. Some provinces require that their non-federally registered meat plants be provincially licensed in order to operate. ***Exhibit 1*** shows the different categories of establishments and the legislation that applies to each.

3. It is difficult to obtain an overall picture of the domestic ready-to-eat meat industry in Canada, i.e., the number of manufacturers and distributors, volume, and dollar value of domestic production. Within the limitations of the databases available, CFIA provided an approximate number of manufacturers for the commodities selected. This information is presented in ***Exhibit 2***. We could not obtain information on the volume and dollar value of production, although other sources provided some descriptive data on the industry. According to Agriculture and Agri-food Canada, up to 65% of pork and 25% of beef wholesale cuts produced are sold by Canadian meat packers to Canadian meat processing plants. There they are transformed into a vast array of products including bacon, ham, sausages, delicatessen specialties and pâtés. Statistics Canada in its data on annual food expenditures, estimates that cured, prepared and cooked meats represent 6% of total retail food purchases and 30% of retail meat purchases.

Exhibit 1

Domestic Ready-to-eat Meat Sectors Covered by Relevant Legislation*



** Note: This is not intended to be a quantitative representation of the relative importance of each sector since no reliable data is available for this purpose*

Exhibit 2

Approximate Numbers of Federally Registered & Non-Federally Registered Manufacturers of Domestic Ready-to-eat Meat Products*

	Atlantic (Nova-Scotia & New-Brunswick)	Quebec	Ontario
Federally Registered Manufacturers	11	80	64
Non-Federally Registered Manufacturers	50	120	145

** Excluding manufacturers of ready-to-eat meat can products.*

Note: Numbers for the non-federally registered sector were obtained from CFIA's FEL (Food Establishment List) which the Agency considers not entirely accurate. Nevertheless, it helped in establishing an approximate picture of the ready-to-eat meat industry covered by this assessment.

The Agency's Key Inspection Activities

Overview

4. The CFIA and HC are partners in food safety at the federal level. They both have responsibilities for ensuring the safety of the Canadian food supply. According to the *CFIA Act*, HC is responsible for establishing policies and standards relating to the safety and nutritional quality of food sold in Canada. Among Health Canada's responsibilities is developing policies and standards that may relate also to ready-to-eat meats. These include the Standards and Guidelines for Microbiological Safety and General Cleanliness of Food, and the Compliance Policy on Extraneous Matter, to name just two. These standards and policies provide direction to the Agency in carrying out its inspection and enforcement activities. With respect to ready-to-eat meats, the Agency fulfils its food safety mandate by enforcing the following Acts: the *Meat Inspection Act*, the *Consumer Packaging and Labelling Act*, and the *Food and Drugs Act* as it relates to food. A number of initiatives (such as a new Government of Canada *Listeria monocytogenes* policy) intended to improve inspection activities are in various phases of design and implementation within the Agency.

5. Several sectors of the Agency are involved in designing and delivering food inspection programs and activities aimed at enhancing the safety of ready-to-eat meats. The Agency carries out its monitoring and compliance activities primarily through staff working on two fronts within the organization: Programs and Operations. Programs Branch staff are mainly involved in developing inspection and compliance policies and guidelines; Operations Branch staff are responsible for conducting field activities in accordance with these policies and guidelines. Most Programs Branch staff are located in the Agency's national headquarters, and Area head offices, and Operations Branch staff are located primarily at the Area level (see Glossary). The four Areas are: Atlantic, Quebec, Ontario and Western. The Agency also works in conjunction with provincial food inspection authorities to enhancing the safety of foods through the chain of processing, distribution and sale.

Inspection Programs

6. The Meat Hygiene Program covers the inspection of ready-to-eat meat products manufactured in federally registered plants. It involves enforcing the *Meat Inspection Act* and *Regulations* and the *Food and Drugs Act and Regulations* for registered establishments. HQ Programs Branch staff are responsible for verifying and approving product formulations and recipes for ready-to-eat meats before they are manufactured; Operations Branch staff are responsible for carrying out inspection policies and guidelines, developing plant-inspection work plans, inspecting plants and products, and taking action to enforce compliance as necessary.

7. In past years, the Meat Hygiene Inspection has been involved with the design and implementation in federally registered establishments of the Food Safety Enhancement Program (FSEP)—see Glossary—which is an approach based on HACCP principles (Hazard Analysis of Critical Control Points)—see Glossary. FSEP represents a new inspection approach that puts more onus on the industry to develop and monitor its own food safety controls. Once the pilot project phase for FSEP has been completed the inspection approach for those FSEP approved plants will include the auditing of the establishments's HACCP food safety controls systems. Meanwhile, the traditional inspections continue.

8. The inspection priorities of the meat industry sector are categorized by the risk associated with a given product or type of processing operation. Ready-to-eat meat products such as fermented meats and cooked cured meats fall into the high risk category and are inspected accordingly. As would be expected, establishments that are registered by the CFIA are inspected more often than those that are not. There are a number of reasons for this difference, including:

The Law: All food sold in Canada is subject to the general provisions of the *Food and Drugs Act and Regulations*. This Act and regulations specifies requirements pertaining to products and manufacturing processes, but none related specifically to inspection frequency. The *Meat Inspection Act* and Regulations specify inspection requirements for federally registered establishments. Inspections frequencies are designed to meet these requirements.

Federal/Provincial Partnerships: Where federal/provincial agreements have been reached to reduce duplication or to increase co-operative work, those agreements influence food safety inspection or investigation activities.

Market Access Requirements: Federally registered meat establishments that produce food for export may be subject to requirements stipulated by other countries. These market access requirements can be in addition to federal health and safety standards.

9. The former Consumer Food Products Program (now redesigned as the Food Safety Investigations Program—see Glossary) covered the inspection of ready-to-eat meat products produced in non-federally registered establishments. This program involved enforcing the *Food and Drugs Act and Regulations* and the *Consumer Packaging and Labelling Act and Regulations* in the non-federally registered sector. It prioritized its inspection activities according to the following factors: risk category of a food commodity; processing operations (slicing, cooking, packaging); and the compliance status of the establishments or processing plants. A number of guidelines were developed under the program covering inspection and sampling activities.

10. On March 28, 2000, following a program review, the Agency established a new approach for the non-federally registered sector. It replaced the Consumer Food Products Program with the Food Safety Investigations Program. Agency officials indicated that the Program now has a focussed risk-based approach and should allow CFIA to be more effective.

Federal/Provincial/ Territorial Jurisdiction for Inspection of Ready-to-eat meat Manufacturers/ Distributors

11. The June 1997 document, prepared by the Canadian Food Inspection System Implementation Group (CFISIG), entitled Continuing Progress Towards a Canadian Food Inspection System: Recommendations and Report to Ministers, explains the jurisdictional aspects of food safety inspections:

Canada's Food inspection system operates in a complex jurisdictional context involving federal, provincial/territorial and in certain cases municipal authorities. Under the provisions of the Constitution, both federal and provincial governments have enacted food safety and quality legislation to achieve their respective policy objectives. Enforcement of the more than 70 existing provincial and federal food-related Acts is generally divided among agriculture, health, and fisheries agencies, but also includes environment and natural resource departments. The number of Acts and enforcement agencies have, as a consequence, created some legislative anomalies and through the duplication of inspection activities and layering of costs, have impeded the competitiveness of Canada's food industry.

12. In order for the food inspection system to function more effectively and efficiently across Canada, a number of formal agreements have been signed between provincial and federal governments. These agreements define how the two levels of government will co-operate to improve the food inspection system without formally relinquishing any of their rights. The Agency recognizes that all of the agreements that were signed before it was created will need to be reviewed and updated. For example, CFIA has signed agreements with the government of Quebec clarifying their respective roles and responsibilities in the province of Quebec. This has resulted in an agreement where the inspection of food products and food establishments in the non-federally registered sector would be inspected by MAPAQ staff (Ministère de l'Agriculture, des Pêcheries et de l'Alimentation du Québec) who have been designated by CFIA to enforce or administer any Act or provision that the Agency enforces or administers in accordance with section 13 (3) of the *CFIA Act*.

Objective and Scope

13. The objective of this assessment was to assess the effectiveness of the Canadian Food Inspection Agency's programs and activities related to the safety of ready-to-eat meat products produced and sold in Canada. The scope of this assessment included activities related to the safety of domestic ready-to-eat meat products. These activities mainly related to the Meat Hygiene Program for the federally registered sector and the Consumer Food Products Program for the non-federally registered sector. (As mentioned earlier, in March 2000, the latter program was re-designed and re-named the Food Safety Investigations Program.). Because we have not reviewed this new program, we will not comment on the Agency's new approach for the non-federally registered sector.

14. As appropriate, the involvement of other organizational units within the Agency in contributing to the health and safety of domestic ready-to-eat meat products has been considered and examined, e.g., Laboratories Directorate. Implementation and delivery of programs by the Agency's Operations Branch were also assessed. This assessment covered CFIA's inspection activities related to ensuring the safety of domestic ready-to-eat meat products since the creation of the Agency in April 1997, with emphasis on activities carried out between April 1, 1998 and March 31, 2000.

15. We carried out our assessment at CFIA Headquarters and in the Areas of Quebec, Ontario, and Atlantic. The examination phase included activities such as reviewing program plans and procedures and inspection and compliance reports, interviewing program staff and stakeholders; and analysing available audit reports and other documents. We did not examine the programs and activities associated with allergens, complaint investigations, or imported ready-to-eat meats. For more information, please refer to the *About the Assessment* section at the end of this report.

Observations and Recommendations

I. Roles, Responsibilities and Activities

16. CFIA is working with many partners to protect consumers. Since its creation on April 1st, 1997, the CFIA has been working with HC to better define the respective responsibilities of the two organizations for different aspects of food safety, including those related to ready-to-eat meats.

17. Where responsibilities for inspecting ready-to-eat meat products are shared between federal and provincial jurisdictions, CFIA has begun to update its Memoranda of Understanding (MOUs) with the provinces. During the period covered by this assessment, one agreement was signed with the province of Quebec. This agreement includes key provisions to ensure proper accountability between partners for inspections and prevent gaps and duplication in their respective activities in these areas. However, some of these provisions, such as the requirement to exchange information related to inspection coverage and compliance activities, had not been fully implemented for the non-federally registered RTE meat sector.

CFIA is working with Health Canada to ensure the safety of foods, including RTE meats

18. A Memorandum of Understanding (MOU) between HC and CFIA, entitled Framework for Federal Food Safety and Inspection Activities, outlines their respective roles and responsibilities, and establishes principles and mechanisms for an effective working relationship between the two organizations. A detailed grid of the respective roles and responsibilities of HC and CFIA accompanies the Framework. Also, in recognition of the need for better communication and information sharing between HC and the CFIA, a number of senior-level committees have been established. For example, Health Canada is working in co-operation with CFIA to update the current policy to better deal with the risk posed by *Listeria monocytogenes*. Finally, as explained in more detail in *paragraphs 96 to 98*, CFIA has worked in concert with HC to implement new controls for *E. coli* 0157:H7 with respect to ready-to-eat fermented sausages containing beef.

Generic HACCP model for beef jerky should be reviewed

19. While “beef jerky” products (see Glossary) represent only a small proportion of all the ready-to-eat products available on the market, Health Canada has a concern that these products could present certain

risks to public health if not manufactured under properly controlled conditions.

20. We note that CFIA has developed a detailed HACCP (Hazard Analysis of Critical Control Points) model for beef jerky as it has done for other RTE meat products. It highlights the different hazards associated with this product, identifies the critical control points in the production process and provides procedures for helping to ensure the safety of the product. Manufacturers who do not export to the United States can adopt the model on a voluntary basis. The entire industry is expected to adopt the Agency's Food Safety Enhancement Program (FSEP—see Glossary) when CFIA implements a mandatory requirement to institute HACCP in all federally registered establishments. Full implementation of this initiative is still pending, as consultations with industry continue.

21. At the request of CFIA, Health Canada provided a Request for Advisory Opinion (RAO) that led to the recall of a beef jerky product in May 1999. RAOs provide an opinion on the health and safety issues specific to a particular manufactured product. They involve a review of the manufacturing process, the physical and chemical characteristics of the end product, such as pH and water activity, and the conditions under which the products are usually sold. Although Health Canada's RAOs are meant to apply to specific manufactured products, they do provide some general recommendations applicable to similar manufactured products. In this case, the Health Canada RAO indicated the existence of potential risks associated with beef jerky products and made several recommendations. One was to monitor the raw product to ensure the initial bacterial load is low and that pathogens such as *E. coli* O157:H7 are not detected".

22. In March 2001 the assessment team more closely reviewed CFIA's Beef Jerky generic HACCP model and identified an area of concern in light of both the incidences of *E. coli* 0157:H7 associated with fermented meat products containing beef as an ingredient and the February 2000 Health Canada's interim guideline issued to address the potential risk associated with those specific fermented meat products. As a result the assessment team requested on April 11, 2001 a Health Canada Health Risk Assessment (HRA) on CFIA's Beef Jerky generic HACCP model.

23. On June 25, 2001 Health Canada's Health Risk Assessment (HRA) confirmed the food safety improvement needed with regard to the manufacturing practice outlined in that generic model and provided specific recommendations to address it. Specifically, the HRA indicated that the internal temperature of beef jerky products may not attain the temperature of the oven (smoke house) when heat dried for one

hour at 70°C to kill pathogens such as *Salmonella and E. coli* 0157:H7. The HRA was communicated to the Agency on June 27th, 2001.

Recommendation

The Canadian Food Inspection Agency should review and update its beef jerky generic HACCP model in light of the recommendations provided in the latest Health Canada Health Risk Assessment. The Agency should also ensure that all potential users of this model are made aware of these recent modifications.

CFIA has signed Memoranda of Agreements with provinces

24. As stated previously, federal and provincial governments share responsibility for food safety. Both jurisdictions have legislation pertaining to ready-to-eat meat products. HC and CFIA are members of the Canadian Food Inspection System Implementation Group, which is working to harmonize federal and provincial food safety regulations and standards. As part of a CFIA initiative, the Agency participated in the development of a Meat Inspection Code. Both Health Canada and CFIA participate actively in the Federal/Provincial/Territorial committee on Food Safety, which is dedicated to protect and improve health through developing policy related to food safety.

25. Co-operation between different levels of government also takes the form of a number of federal/provincial food inspection agreements which were signed more than 10 years ago. These agreements are fairly broad in scope, focussing primarily on the respective responsibilities for inspecting the manufacturing sector.

26. CFIA has begun to update these agreements with the provinces. For example, in September 1998, it signed an agreement for inspecting edible meat products with the province of Quebec. Another agreement with the province of Ontario is also being completed. These agreements call for sharing responsibility for inspections between CFIA and its provincial partners. Under these arrangements, CFIA would continue to share responsibility and accountability for ensuring that inspections are carried out as specified in the agreements.

27. The importance of maintaining accountability in such agreements is articulated in a 1998 joint paper of the OAG (Office of the Auditor General) and TBS (Treasury Board Secretariat) entitled: *Modernizing Accountability Practices in the Public Sector*. This paper discussed the issue of maintaining accountability when entering into public sector partnerships. It argued that: *In multi-partner situations, as frequently occur in alternative service delivery initiatives, effective accountability arrangements can be particularly challenging to put in place. And there is danger that without care,*

accountability will be dissipated among a variety of overlapping concerns and interests. The paper continued to explain that in multi-partner cases, each partner has dual accountabilities. On the one hand, the partnership creates accountability obligations among or between partners. On the other hand, each partner remains accountable to its own governing body.

28. The agreement between the federal government and Quebec recognizes the respective responsibilities of both parties for enhancing food safety and for which they will be accountable. In this agreement, CFIA clearly defined its responsibility for enforcing the *Food and Drugs Act*. To reduce overlap and duplication in the inspection of the edible meat sector, the Agency, in accordance with the *CFIA Act* section 13(3), designated MAPAQ (Ministère de l'Agriculture, des Pêcheries et de l'Alimentation du Québec) staff as inspectors/analysts/ veterinary inspectors or other officers to enforce or administer the Food and Drugs Act for non-federally registered meat products and in non-federally registered establishments that sell their products within Quebec.

29. According to the framework agreement signed between CFIA and MAPAQ, the Agency is responsible for ensuring that provincial inspectors are provided with adequate training to carry out inspection work in support of the *Food and Drugs Act*. Both parties also agreed to exchange information related to inspection, recalls and complaints as specified in the framework agreement. Finally, in recognition of its responsibility for enforcing the *Food and Drugs Act*, the Agency, according to the agreement, may carry out audits to determine whether the inspection work managed by MAPAQ complies with the pre-established provisions in the agreement, and whether these provisions have been effectively implemented. As part of this agreement which has taken the form of a Memorandum of Understanding (MOU) a Framework Agreement Management Committee was set up. Its role was to identify, among other things, what information, training and resources both organizations need, and to discuss their respective current and future responsibilities and any other issues concerning the Agreement.

Some commitments in the agreements with certain provinces have not been met

30. Signing an agreement constitutes an important step in the management of federal-provincial relations. Equally important is that all parties adhere to their commitments. In the case of the agreement with Quebec, the CFIA has fulfilled most aspects of the signed agreements. The Agency informed the assessment team that they did not conduct a "formal" evaluation of MAPAQ's inspection programs. However, based on a presentation of MAPAQ's "5M" risk based inspection approach, the Agency recognised the overall equivalency of MAPAQ's

inspection approach with theirs. Without a formal review of MAPAQ's implemented inspection programs, it may be difficult for CFIA to identify training needs, if any, that should be provided to MAPAQ's inspectors to enforce the *Food and Drugs Act and Regulations* in RTE meat inspection. In 1999-2000 CFIA did provide MAPAQ with training in retail labelling inspection. Although certain exchange of information is readily taking place such as complaints and recalls, there are other areas which require improvements. For example, the inspection activities carried out by MAPAQ on behalf of CFIA to enforce the *Food and Drugs Act* were not available at the Agency. It is therefore difficult for the Agency to identify if any inspection gaps exist. Lastly, although optional, CFIA did not conduct an audit of MAPAQ during the period covered by this assessment, to determine whether the inspection work managed by MAPAQ complies with the pre-established provisions and whether these provisions were effectively implemented.

31. The Framework Agreement Management Committee, consisting of members of CFIA and MAPAQ, has been meeting regularly to facilitate the management of those agreements. Discussions, up to now, did not include the delivery of the inspection programs for RTE meat manufacturers, distributors and transporters, carried out by MAPAQ.

32. We also reviewed how another federal/provincial agreement was implemented, this one signed in March 1992 with Ontario. Among other things, this federal/provincial agreement provided for federal and provincial inspectors to jointly inspect meat plants licensed by the Ontario Ministry of Agriculture, Food and Rural Affairs (OMAFRA). This provision was designed to improve the thoroughness of inspections and, consequently, improve the safety and reputation for excellence of products manufactured in Ontario's licensed meat processing plants. Though CFIA intended to utilize previous agreement until such time it is updated, no joint inspections had taken place in Ontario since the creation of the Agency in April 1997.

Recommendation

In the future, CFIA should ensure that key commitments in agreements with provincial partners, are fulfilled.

II. Federally Registered Establishments

33. In this section of our report, we will examine how the CFIA's inspection activities for ready-to-eat meats are designed, prioritized and carried out. We will also look at CFIA's enforcement and compliance activities.

34. CFIA represents a strong, continuous government presence in federally registered establishments. Accordingly, key risks are well identified, establishments are monitored closely, product sampling is done on a routine basis, compliance levels are high, and major deficiencies are corrected. Nevertheless, our assessment identified areas where the Agency could improve its inspection activities. We noted that CFIA did not fully implement its product and environmental sampling work plans in some Areas, that sampling procedures for *Listeria monocytogenes* resulted in delays between the time when non-compliant samples were detected and when follow-up samples were taken, and that controls for nitrite and nitrate levels may have been weakened by the suspension of analytical testing for this type of additives.

A. Design and Implementation of Programs and Activities

1) Design of Inspection Procedures

The Agency's inspection manuals cover most manufacturing controls needed to ensure the safety of food products

35. We reviewed CFIA's inspection guidelines to determine whether they covered important controls and practices that affect the safety of manufactured ready-to-eat meat products. Based on food science and discussions with Health Canada's experts, we selected seven such controls and practices relating to cooked cured meats and fermented meats. For each manufacturing control and practice, we identified corresponding benchmarks. The benchmarks were based upon generally recognized references such as: Good Manufacturing Practices Codex (1997 version), CFIA's generic HACCP (Hazard Analysis of Critical Control Points) models for various ready-to-eat meat products, and Draft Government of Canada Common Inspection Approach documents relating to RTE meat products.

36. We also reviewed another set of guidelines—CFIA's Food Safety Control Guidelines (HACCP generic models). These guidelines were generally detailed and clearly explained what food safety controls and practices are needed. In light of the evolving scientific literature, the assessment team identified an area which needs to be reviewed jointly by HC and CFIA (i.e., the cooking guidelines for products of less than 5.08 cm (2 inches) in diameter should specify a holding time when cooked at the minimum internal product temperature of 69°C). Specifying a minimum time and temperature internal cooking regime would provide a wider safety margin for the destruction of harmful bacteria.

37. We also examined whether CFIA provides sufficient guidance to inspectors on the procedures for inspecting those key food

manufacturing controls necessary to ensure a safe product. We did this by reviewing CFIA's national inspection guidelines and interviewing inspectors to assess the extent to which they understood these procedures. Generally, CFIA provides adequate guidance to its inspection staff. Interviewed inspectors demonstrated an awareness of key manufacturing controls and indicated how they inspected them.

Recommendation

CFIA should review its inspection guidelines and address the requirement for a specified holding time for sausages of less than 5.08 cm (2 inches) in diameter when cooked at a minimum internal temperature of 69ºC.

CFIA's guidelines for rating the compliance of plants are based on health and safety factors

38. We examined CFIA's inspection guidelines related to a rating system (see paragraphs 63 to 66). The key purpose of inspecting a plant is to assess the extent to which it follows manufacturing practices that are designed to ensure food safety. The compliance rating of a plant serves to indicate whether it is operating in a satisfactory manner, or whether further actions to ensure compliance are needed. CFIA's rating system is based on the inspection of food safety controls, facility construction and maintenance, pest control, sanitation, etc. In some cases it also incorporates other concerns such as detecting economic fraud or non-compliance with humane slaughter and handling regulations. The rating system allows CFIA inspectors to rate each individual food safety control, which in turn is linked to a plant's overall compliance rating.

39. As explained in paragraph 7, CFIA is implementing the Food Safety Enhancement Program (FSEP), an approach based on HACCP principles. As part of this new approach, CFIA has developed HACCP generic models. It has also trained inspectors on HACCP principles and is consulting the industry on the eventual implementation of the mandatory HACCP approach in federally registered establishments. The majority of federally registered meat and storage facilities have already implemented FSEP or are in the process of doing so.

40. We compared the national inspection guidelines that the Agency uses to rate establishments with the critical control points outlined in its HACCP generic models for ready-to-eat meats. The purpose in comparing the two was to determine the extent to which the guidelines called attention, or assigned appropriate rating, to the Critical Control Points (CCP) as part of rating a facility, i.e., a failure to meet the CCP should lead to a non-compliance rating. Critical control points are important to maintaining the safety of food. Therefore, the inspection guidelines should clearly identify them as such and their weight

on the overall rating should be adjusted accordingly. However, our comparison showed that this was not the case. We note that, unlike the FSEP, the CFIA's Dairy Program has emphasized the importance of scrutinizing CCPs carefully in arriving at compliance ratings.

Recommendation

Until HACCP is fully implemented in federally registered meat processing plants/ establishments, the assigned establishment inspection ratings should put due emphasis on important food safety controls.

The Agency recognizes key hazards associated with ready-to-eat meat products in its sampling guidelines and monitors them

41. We examined the Agency's product sampling guidelines to determine whether they identified and covered the key hazards (microbiological, chemical, and extraneous matter) associated with ready-to-eat meat products. We found that the guidelines did identify all key hazards. The laboratory methods that the Agency uses to determine the compliance of the sampled products are recognized by Health Canada.

42. In the federally registered sector, product sampling is done on a routine basis to monitor the more important health and safety concerns associated with ready-to-eat meat products. This activity includes end-product sampling for:

- microbiological analyses such as, total Aerobic counts, *E. coli, Staphylococcus aureus, Salmonella*;
- *E. coli* O157:H7 analysis of fermented meat products containing beef (initiated in January of 2000);
- nitrite/nitrate levels in ready-to-eat meat products; or
- environmental sampling for *Listeria monocytogenes*.

These sampling plans are summarized in ***Exhibit 3a*** and ***3b***.

43. Sampling can be done more often if the results are unsatisfactory or if consumer complaints arise. However, apart from prescheduled routine sampling, inspectors have no clear guidance on collecting more samples if, during an inspection, they observe that a facility is not following good manufacturing practices.

44. Most ready-to-eat meat products require refrigeration to maintain shelf-life and safety. We reviewed the sampling guidelines to determine whether they included taking samples at the distribution or retail levels, where temperature abuse problems can potentially occur. The Agency's

Exhibit 3a

Microbiological Ready-to-eat Meat Products Sampling Plans for Ontario, Quebec & Atlantic Federally Registered Sector

	Ontario (# establishments : 63*)		Quebec (# establishments : 80)		Atlantic (# establishments : 15)	
	M200	**M205**	**M200**	**M205**	**M200**	**M205**
97/98	72	102	117	164	24	30
98/99	72	102	117	164	24	30
99/00	160	160	174	174	30	30

Note: Based on NHQ Assigned Area Sampling.

* *From Ontario Area information it is estimated that there were 50, 63 and 77 RTE federally registered plants included in our assessment scope over the 3 fiscal years 97-98, 98-99 and 99-00 respectively.*

M200 (RTE Meat End Product Testing)

*M205 (*Listeria *Environmental Sampling)*

Exhibit 3b

Total National Nitrite/Nitrate Sampling Plans for Federally Registered Sector

Nitrite/Nitrate Sampling Work Specifications (All Areas)	**Total Number of Samples**		
	97/98	**98/99**	**99/00**
M-104 – Domestic Cured Meats	50	82	0
M-106 – Domestic Dry Fermented Sausage	150	115	0
M-109 – Domestic Cured Ham	150	128	0

product sampling guidelines cover sampling only at the manufacturing level, not at the distribution and/or retail level. We note that where provincial food inspection services exist they usually conduct inspection of retailers and often test products. This is an area that could be reviewed to ensure there are no gaps in the food safety coverage.

2) Prioritization and Planning of Inspection Activities

CFIA's planning for plant inspections is comprehensive

45. The existing regulations and trade requirements influence the planning, the nature, and the extent of inspections of federally registered plants (establishments). In effect, they provide the tools and the environment for comprehensive inspections of these facilities. For example, section 27 (1) and 29 (1) of the *Meat Inspection Regulations* require that all plants that process meat which will be exported or moving inter-provincially be federally registered. Furthermore, warehouses where products are stored must be federally registered. As a result, the CFIA has an up-to-date list of "federally registered" ready-to-eat meat manufacturing establishments and federally registered storage warehouses. The transport vehicles used to ship the finished products are inspected for appropriate protection against contamination and deterioration of the finished products.

46. Part of the registration process for meat manufacturers includes the requirement that the recipe, label, list of ingredients and manufacturing process for a given product be submitted for review and approval before that product is manufactured. Following approval, CFIA establishes inspection procedures for inspecting the product, which are included in the national inspection guideline.

47. The health and safety risks associated with individual products along with regulatory requirements and past compliance ratings are the basis for determining inspection procedures and the frequency of inspection. Inspections are carried out on a daily, weekly, monthly or yearly basis. We found that all Areas adhered to the national guideline and had adopted lists of inspection tasks customized for each federally registered ready-to-eat meat establishment and had assigned frequencies for each task.

3) Implementation of Inspection Activities

Inspections are conducted on a regular basis

48. Inspectors visit the plants and facilities in the federally registered sector regularly. According to CFIA's Resource Management System (see Glossary), the frequency of inspection varies with the degree of compliance of the manufacturing plant. Manufacturers that are compliant (i.e., that use proper production methods and follow accepted procedures) are theoretically inspected at least twice a week, at which time inspectors carry out a variety of tasks to ensure food safety. At the other end of the spectrum, an inspector could visit, almost every day, manufacturers that have been less compliant.

49. We reviewed 28 plant inspection files from the Quebec, Ontario and Atlantic areas (12, 12 and 4 respectively). We found that the overall inspection frequencies were satisfactory.

Inspections conducted in federally registered establishments generally cover the key food safety controls

50. As previously described in paragraph 35, we identified a number of health and safety controls and good manufacturing practices (GMPs) that are generally recognized as key to ensuring the safety of ready-to-eat meat products. With the help of the Agency, these health and safety controls and good manufacturing practices were translated into TIP ("The Inspection Program") (see Glossary) tasks.

51. We reviewed the relevant plant files, among the 28 mentioned above in paragraph 49, to determine whether the inspections had covered the key food safety controls for selected ready-to-eat meat products over the 12-month period. When required, the Agency provided clarifications which allowed us to conclude that all plants had consistently received complete inspection coverage.

In some Areas, CFIA's product and environmental sampling activity in the federally registered ready-to-eat meat sector falls short of the targets specified in its work plans

52. We reviewed the implementation of the federally registered sector's products and environmental sampling work plans for microbiological and nitrite/nitrate concerns. Our review covered the period between 1997 and 2000 for three areas: Ontario, Quebec and Atlantic. National Headquarters' sampling target for the M-200 work plan (microbiological testing of ready-to-eat meat end products) for the 1997-1999 period was approximately 1.5 samples per plant. That target increased to 2 samples per plant in 1999-2000. The M-205 work plan (*Listeria* environmental sampling of manufacturing areas such as the ready-to-eat meat packaging area) specifies that each plant is to be environmentally sampled twice a year.

53. It is important that CFIA fully implement its product sampling work plans if it is to adequately monitor the safety of RTE meat products manufactured in federally registered establishments. However, we found that the Agency did not meet its planned targets in the two work plans that we examined. We found that the percentage of implementation of M-200 and M-205 work plans (i.e., the sampling and testing actually done as a percentage of what was

planned) varied greatly across the three Areas. In some Areas, it was observed to be as low as about 50% of the target for the respective work plans. ***Exhibit 4*** summarizes the percentages (actual versus planned) for these work plans. ***Exhibit 5*** presents the percentage of accomplished Nitrites/Nitrates national sampling workplans in federally registered ready-to-eat meat sector. It indicates that the level dropped in all three areas in 1998-99. Paragraphs 74 to 77 discuss the nitrite/nitrate issue further.

Recommendation

To ensure that it can adequately monitor the safety of RTE meat products, CFIA should ensure that it carries out environmental and product sampling activities in accordance with its work plans.

CFIA carries out a range of quality assurance activities

54. The Agency carried out program audits and reviews during its early stages on a division-by-division basis for federally registered programs. These audits were intended to ensure that the programs were being implemented at the field level in accordance with nationally established priorities and policies. They were conducted in accordance with an audit protocol which can be found in the Meat Hygiene Manual of Procedures. For the non-federally registered programs, quality assurance consisted of supervisors reviewing inspection work.

Exhibit 4

Percentage of Accomplished Microbiological Sampling Workplans in Federally Registered Ready-to-eat Meat Sector

	Ontario		Quebec		Atlantic	
	M200	M205	M200	M205	M200	M205
97/98	73.6%	106%	84.6%	80.5%	117%	76.7%
98/99	62.5%	55.9%	89.7%	63.4%	112.5%	110%
99/00	51.9%*	49.4%*	96.0%	82.3%**	93.8%	100%**

Note: % of sampling completed based on NHQ assigned Area sampling.

M200 (RTE Meat End Product Testing)

*M205 (*Listeria *Environmental Sampling)*

** According to CFIA's data, approximately 60% of the Ontario's establishments were sampled at least once over the course of the 99-00 year for M-200 and M-205.*

*** It should be noted that 94% of Quebec establishments and 100% of the Atlantic establishments have been sampled at least once under M-205.*

55. In 1999, a new Program Audit function was created to carry out internal program audits of the federally registered and non-federally registered sectors programs. The programs to be audited by the Planning Performance and Program Review division (PPPR) are selected according to the Agency's priorities. The audit function works with the Programs Branch and with the Operations Branch to identify improvements that could be made in the food inspection programs. As well, it allows for a harmonized CFIA internal audit system across all commodities. Essentially, the purpose of CFIA's program audits is to determine whether its programs both conform to the written procedures (Acts, Regulations, manuals of procedures, inspection manuals and work plans) relating to the Agency, and are delivered in a consistent manner across Canada. Audits also contribute to ensuring that programs are designed in a way that enables them to meet their objectives. The PPPR division co-ordinates the performance management framework for the Programs Branch to facilitate consistent and effective work planning, reporting and performance measurement consistent with the corporate framework and Agency needs.

56. At the time of this assessment, the Agency had not done any audits pertaining to ready-to-eat meat products since the new audit division had been created.

57. Several other initiatives contribute to better quality assurance with respect to CFIA's inspection activities. These include training sessions, training manuals, videocassettes and

Exhibit 5

Percentage of Accomplished Nitrites/Nitrates Sampling Workplans in Federally Registered Ready-to-eat Meat Sector

National			
	Nitrite/Nitrate Work Plans		
Fiscal Year	**M-104**	**M-106**	**M-109**
97/98	96%	67%	77%
98/99	60%	39%	54%
99/00	–	–	–

M104 – Nitrite/Nitrate levels in domestic cured meats

M106 – Nitrite/Nitrate levels in domestic dry fermented sausage

M109 – Nitrite/Nitrate levels in domestic cured ham

management supervision reviews. Training priorities are based on corporate needs. CFIA has indicated to the assessment team that their management control framework operates to promote accountability, effectiveness and continuous management and program improvement. Key activities include both internal and external reviews. Internal review activities include those of management oversight of inspectors (Operations Branch), program audit, corporate audit, compliance and enforcement, and legal services. External reviews comprise largely of those carried out by such organizations as Health Canada, the Office of the Auditor General, Treasury Board, and foreign trading partners also contribute to CFIA's improvement.

B. Enforcement Actions

1) CFIA's Tools for Promoting Compliance

CFIA has an array of tools at its disposal to get the industry to comply

58. In its own documentation, CFIA emphasizes that a key objective is to get the industry to comply with CFIA and HC food safety standards and requirements. CFIA has at its disposal a comprehensive assortment of tools to achieve this objective.

59. First and foremost, Section 11.(3) of the Canadian Food Inspection Agency Act recognizes that the Agency is responsible for enforcing the Food and Drugs Act as it relates to food. It provides CFIA with authority to inspect and/or verify that food and food products for domestic consumption meet Canadian standards for safety, quality, identity, processing, packaging, and labelling. The Act also authorizes CFIA to take action as needed when food and food products do not meet these standards. These elements are highlighted in CFIA's Enforcement and Compliance Policy Manual.

60. Inspectors are required to carry out procedures aimed at both controlling and reducing risks to Canadian consumers, and getting food processing plants and other related facilities to comply with Canadian regulations. Compliance and enforcement actions at their disposal include:

- inspecting, monitoring and auditing to verify compliance;
- responding to complaints of non-compliance;
- investigating violations and offenses;
- issuing warnings;
- issuing mandatory recall orders;
- injunctions;
- refusing to issue or renew licences, registrations or permits;

- suspending, revoking or cancelling licences, registrations or permits;
- prosecutions; and
- administrative monetary penalties, where applicable.

61. Many compliance actions are applicable to either sector (i.e., both the federally registered and non-federally registered sectors) and are similar in their overall approach. However, an additional tool to promote compliance is available to inspectors assigned to federally registered establishments: a manufacturer may be "de-registered". De-registration provides a powerful incentive to "follow the rules" because, unless federally registered, a manufacturer is not allowed to export to other countries or provinces. De-registration is not an option for non-federally registered establishments.

2) Compliance and Enforcement Actions

Ninety nine percent of ready-to-eat meat products sampled in federally registered establishments are satisfactory in terms of the level of harmful pathogens

62. Ready-to-eat meat products sampled in 1998-1999 and 1999-2000 under the monitoring work specification M-200 exhibited a high level of microbiological compliance. Of the 405 RTE meat products sampled in the combined Ontario, Quebec and Atlantic areas only four samples were found to be unsatisfactory in terms of containing harmful microbiological pathogens such as *Staphylococcus aureus* and *E. coli*. The average compliance level was 99%.

Overall, plant compliance ratings are appropriate

63. CFIA summarizes the findings of inspections, classifies establishments according to those findings, and assigns them a qualitative rating based mainly on health and safety factors. Inspectors rate plants monthly. There are six rating categories (AAA, AA, A, B, C and F) see ***Exhibit 6***. Each category denotes a level of compliance. Plants receive ratings in a series of specific areas (sanitation, pest controls, etc.). Those which receive a lower compliance rating are inspected more often. Overall, as shown in ***Exhibit 7***, the aggregate ratings demonstrate that there is a high level of compliance, with a substantial majority of plants rated "A" or more.

64. The six rating categories mentioned above are defined in the Meat Hygiene Manual. Based on these definitions, inspectors use their professional judgement and experience to rate the establishments. CFIA informed us that there are no national rating guidelines for inspectors to consult when rating a plant. This was also confirmed in a training manual in use in Ontario in October 1998. The manual recognized that there is no national, formalized and prescriptive step-by-step rating

Exhibit 6

Classification System Used for Assessment of Federally Registered Establishments

AAA
"Rating received because the establishment is being operated in accordance with the appropriate Act and Regulations. The construction, sanitation and operation observed during the inspection are higher than the legislative requirements."

AA
"Rating received because the establishment is being operated in accordance with the appropriate Act and Regulations. The construction, sanitation and operation observed during the inspection are generally higher than the legislative requirements."

A
"Rating received because the establishment is being operated in accordance with the appropriate Act and Regulations. The construction, sanitation and operation observed during the inspection generally meet the minimum legislative requirements. Improvements are expected to be made on a short or long term basis according to their significance."

B
"Rating received because during the inspection, although the establishment was at the limit of acceptability, it met minimum legislative requirements. Immediate improvements were required. Measures to eliminate the hazard concerning the safety of the products produced were initiated immediately. An action plan is established between management and inspection staff outlining the time frames and actions to be taken to make the required improvements." An establishment is classified "B" when one or more of the reviewed parameters demonstrate a need for significant improvement, (e.g. construction, sanitation, etc.), and is, therefore, close to not meeting minimum legislative requirements.

C
"Rating received because the establishment is not being operated totally in accordance with the appropriate Act and Regulations. Operations are suspended in areas where products produced may be at risk. An action plan is developed to determine an acceptable time frame in which all improvements will be made. If the action plan is not implemented, the protocol for cancellation of licence shall be instituted."

F
"Rating received because the establishment is not being operated in accordance with the appropriate Act and Regulations. Deviations observed during the inspection may place the safety of the products in jeopardy. As a result, the establishment is not eligible to continue to operate as a federally registered establishment. Corrective action must be instituted immediately or the protocol for suspension of licence is implemented and products produced are being detained as necessary. This establishment falls into the category "fail".

Source: CFIA, Meat Hygiene – Manual of Procedures*, Section 1.77*

process, when it stated that there was a "need for greater uniformity in rating of establishments and how establishment inspections are done."

65. To determine whether the absence of a step-by-step documented process could result in plants being graded incorrectly, we reviewed a sample of 29 plant files over a 12-month period ranging from October 1998 to December 1999. We examined 327 establishment inspection reports to determine whether the health-and safety-related conditions that inspectors had reported had resulted in an appropriate rating. In particular, we focussed on a principle in the Meat Hygiene Manual which says that inspectors should assign a "B" rating to an establishment when one or more of the review parameters demonstrate that significant improvement is needed. When we reviewed the Establishment Inspection Reports, we considered only those conditions that were clearly related to health and safety when we made judgements in this respect. Because of our conservative approach, the number of establishment inspection reports incorrectly rated could be higher. Therefore, the proportions of incorrect ratings calculated are low-end estimates.

66. As shown in ***Exhibit 8***, in Quebec and Ontario, a small percentage of the examined establishment inspection reports was incorrectly rated. They were rated "A" even though one or more health and safety conditions would have warranted assigning a rating of "B" or lower. In the Atlantic Area, a more substantial proportion of forms were not rated appropriately (but for a lower number of establishments). Overall in the three Areas covered by this assessment the proportion of files incorrectly rated is at least 6%. These figures indicate that there is no clear evidence that the

Exhibit 7

Compliance Ratings in Federally Registered Establishments Producing Ready-to-eat meat products Fiscal Year 1998-1999

Rating	Ontario (63* Establishments)	Quebec (84* Establishments)	Atlantic (15* Establishments)
AA	12.7%	9.5%	26.7%
A	77.8%	83.3%	66.6%
B	7.9%	6%	6.7%
C	1.6%	1.2%	–

*Note: Tabulation of **minimum** compliance ratings obtained by establishments in monthly inspections during year examined.*

** Approximate number of establishments based on comprehension of available data.*

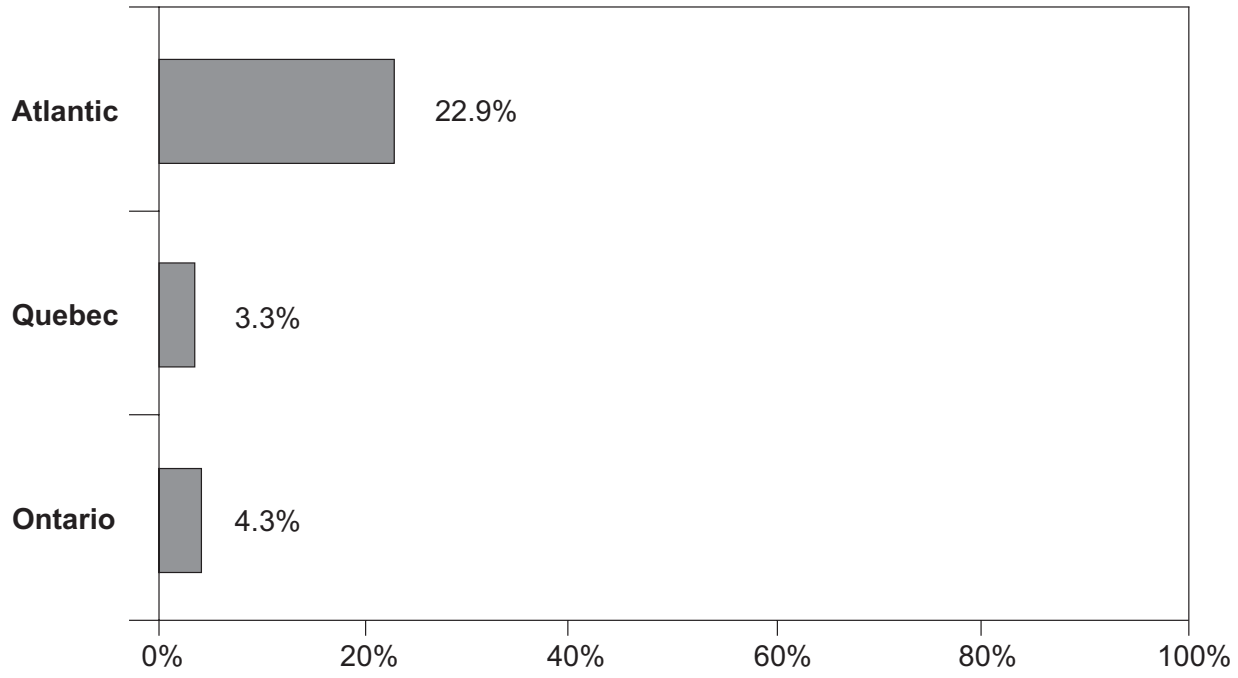
absence of a step-by-step process has a pervasive negative impact on the reliability of the ratings given by the inspectors. However it is worth noting that these errors have affected, at one point or another, an important proportion of plants, in all Areas.

The sampling procedure for *Listeria monocytogenes* results in excessive delays between the time when non-compliant samples are detected and when follow-up samples are taken

67. We also examined more specific compliance issues relevant to ready-to-eat meats. One these pertains to *Listeria monocytogenes*. This pathogen can cause listeriosis, an illness that is potentially life threatening especially to predisposed groups such as newborns, the elderly and those with weak immune systems. It can also cause miscarriage. The micro-organism also causes listerial gastroenteritis, a relatively mild flu-like disease. Foods susceptible to

Exhibit 8

Percentage of Monthly Inspection Files with an Inappropriate Health and Safety Overall Compliance Rating



Note: Ontario – 12 establishments (141 reports)
Quebec – 13 establishments (151 reports)
Atlantic – 4 establishments (35 reports)

Note: The inspection reports/files examined covered a continuous 12 month period between Oct 98 and Dec 99, as provided by the Agency.

contamination include different types of ready-to-eat meats that are eaten without further cooking.

68. CFIA has taken steps to address the risks posed by *Listeria monocytogenes*. According to the Agency's operational sampling program included in Meat Hygiene Manual, in an effort to reduce the prevalence of *Listeria monocytogenes* in RTE meat products, environmental sampling of post-processing product contact areas (e.g., slicing equipment, table surfaces, employees' aprons, packaging equipment) will be routinely done twice a year in each plant.

69. As shown in ***Exhibit 9***, CFIA's *Listeria monocytogenes* sampling model used in federally registered establishments contains more sampling steps than the procedure used in the non-federally registered establishments or the model proposed by the USDA (May 1999) to its food industry to address *Listeria monocytogenes*. That is, there are more environmental sampling steps before end products are tested for safety when the presence of *Listeria monocytogenes* on food contact surfaces is detected. Delays in end-product testing put off timely enforcement actions that may be necessary [if sampling reveals the presence of *Listeria monocytogenes*].

70. To assess the impact of the numerous sampling steps that the Agency follows, we calculated the time lapse between each of them and the cumulative time lapse before any problems had been resolved or the end product had been tested for safety. The results are presented in ***Exhibit 10***. They show that on average, in the three Areas covered by our assessment, it took two months between each environmental sampling, despite the fact that the Agency has indicated that a maximum time lapse of 30 days in between sampling would be reasonable. Ontario and Quebec fail to meet this standard by a wide margin, while the Atlantic Area essentially adheres to it. Only when the third environmental sampling is still positive for *Listeria monocytogenes*, do CFIA's procedures prescribe end-product testing.

71. Based on the information provided by CFIA, it was not possible to calculate the time lapse between the last (i.e., the third) environmental sampling and end-product sampling. Furthermore, it was not possible for us to either obtain the test results of samples, or even find out if the testing had been carried out. We also noted that in a few instances (three of the 37 samples found contaminated with *Listeria monocytogenes* – 8%) no follow-ups had been done, despite the fact that CFIA's inspectors had found positive samples in the first environmental sampling.

Exhibit 9

Comparison of *Listeria monocytogenes* Compliance Flowchart Guides

Figure a.
CFIA's operational Sampling Program for *Listeria monocytogenes* – Registered sector

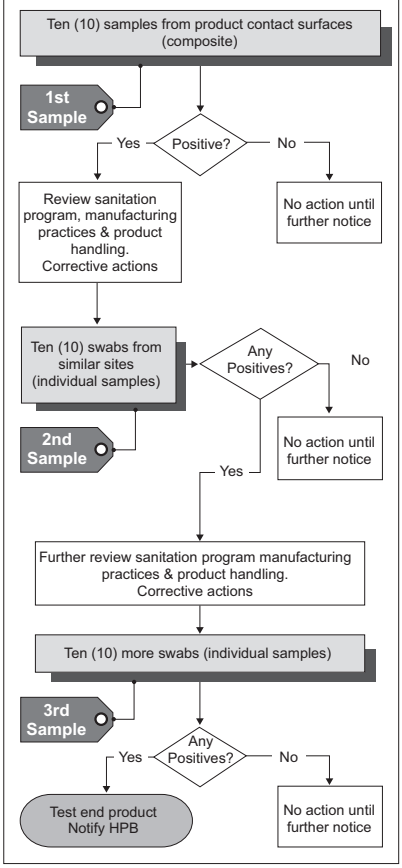


Figure b.
***Listeria* compliance flowchart used by CFIA for the non-registered sector**

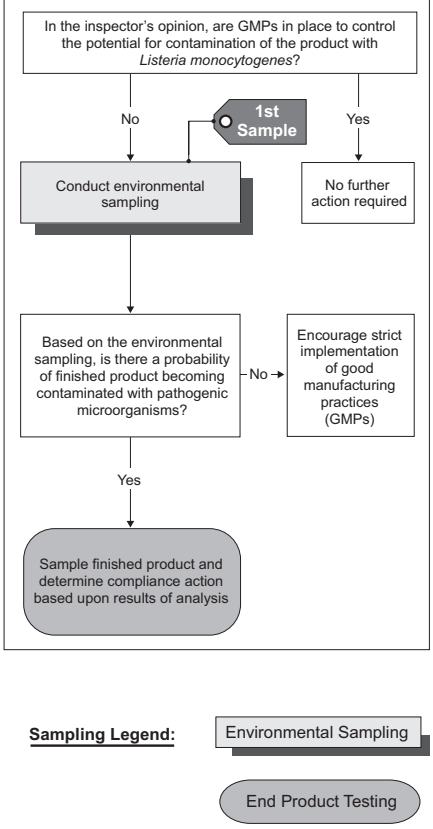
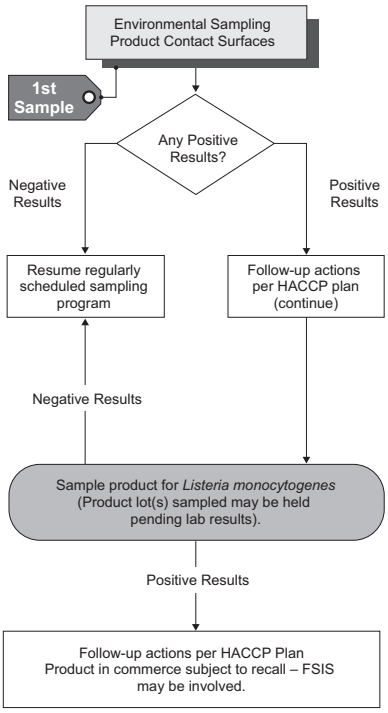


Figure c.
Excerpt from the FSIS USDA May 1999 Policy – *Listeria* Guidelines for Industry – Sampling flowchart (ready-to-eat product)



72. It is important to recognize that between each environmental sampling, a review of the sanitation program, manufacturing practices and product handling, can help identify the source of any contamination. As shown in ***Exhibit 11***, after three environmental samplings, the number of non-compliant samples decreased from 37 to 6. These figures indicate that processing plants do try to correct problems once they have been detected. However, in the case of the remaining positive samples, after four months on average (six months in the Quebec Area), the problem persisted, while end-product testing and possible enforcement actions had yet to be carried out.

73. The success of the Agency in meeting its objective of reducing the prevalence of *Listeria monocytogenes* in ready-to-eat meat products has been limited. ***Exhibit 12*** outlines the compliance levels for *Listeria monocytogenes* over the first three years since the Agency began operating. It shows that although the Atlantic Area still has the highest incidence of *Listeria monocytogenes*, it has made some progress in reducing it. In the Quebec Area, the prevalence levels have remained relatively stable. In Ontario, the prevalence of *Listeria monocytogenes* increased in 1999-2000, although it remains the Area with the lowest prevalence.

Recommendation

CFIA should modify its sampling procedure for Listeria monocytogenes by:

- *determining how it could reduce the time lapse between initial and follow-up samplings;*
- *ensuring that follow-up sampling is done when positive results for Listeria monocytogenes occur;*
- *tracking end-product safety testing to ensure that it is conducted as prescribed in the operational sampling program included in the Meat Hygiene Manual.*

Exhibit 10

Average Time Between *L. monocytogenes* Follow-up Samplings in Federally Registered Establishments – (1999 – 2000)

Atlantic Area (all 4 Provinces)	**Quebec Area**	**Ontario Area**	**National Average** (Based on Selected Areas)
38 days	84 days	54 days	58 days
24 days	106 days	59 days	63 days
Data Not Available	Data Not Available	Data Not Available	Data Not Available

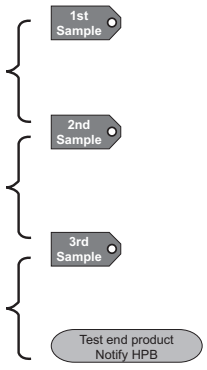


Exhibit 11

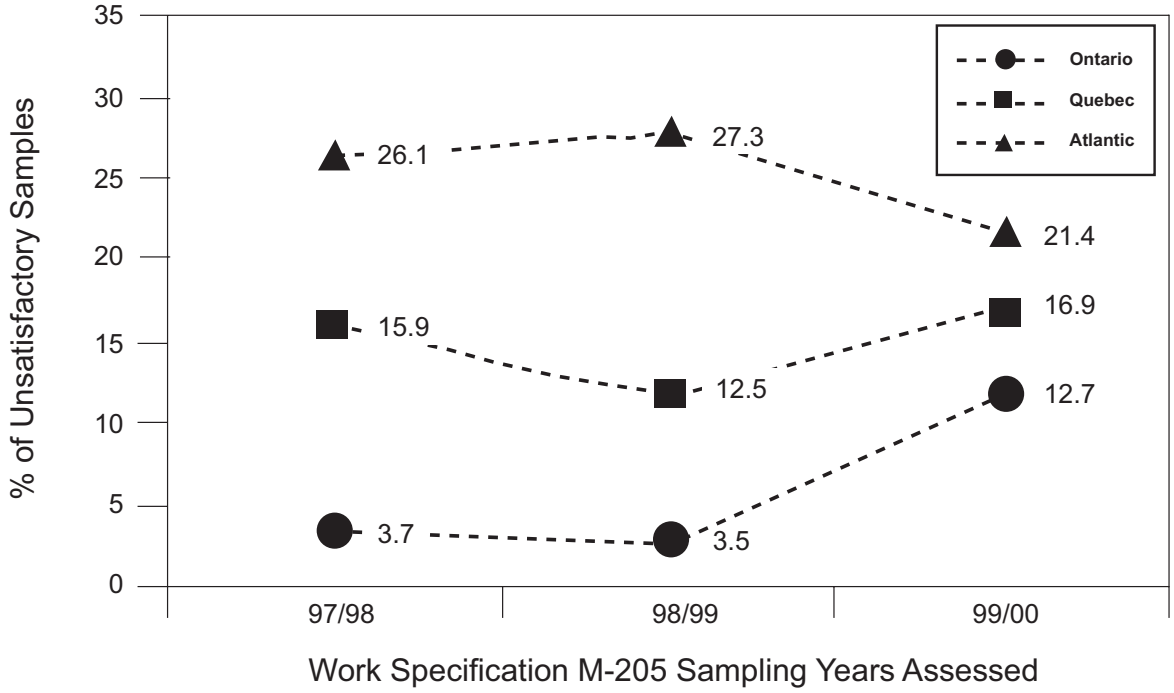
Number of *Listeria monocytogenes* Unsatisfactory Environmental Sample Results Obtained in Federally Registered Ready-to-eat Meat Manufacturers During 1999 – 2000

Area Assessed	Number of non-compliant environmental samples obtained in (99-00)	Number of non-compliant environmental samples that were not followed up	Number of non-compliant environmental samples found after 2nd sampling	Number of non-compliant environmental samples found after 3rd sampling
Ontario	10	0	2	1
Quebec	21	1	7	3
Atlantic (All 4 provinces)	6	2	2	2
Totals	**37**	**3**	**11**	**6**

Source: CFIA, Work specifications M205, M205S.

Exhibit 12

Prevalence of *L. monocytogenes* in the manufacturing environment of federally registered ready-to-eat meat establishments



CFIA has stopped routine testing for the levels of nitrites and nitrates in federally registered ready-to-eat meat products

74. Nitrites and nitrates are food additives used in curing meats. They stabilize red meat colour, inhibit some spoilage and food poisoning organisms, and contribute to flavour. However, nitrites themselves present some risks. If taken in very large doses, they are potentially lethal. Nitrites and nitrates are permitted in the Food and Drugs Regulations as preservatives in meat at combined levels not exceeding 200 ppm (parts per million) prior to processing.

75. The levels of nitrites and nitrates used in curing formulae are reviewed when new recipes are submitted for approval and when they are monitored annually. According to CFIA's inspection manual, the levels of these substances in curing formulae are also verified by the inspector during routine inspections. Moreover, CFIA indicated that inspectors can submit samples for laboratory testing at any time if they consider it necessary.

76. In 1997-1998 and 1998-1999, CFIA monitoring activities were to determine whether the levels of nitrites and nitrates used in federally registered ready-to-eat meat products complied with the regulations. ***Exhibit 5*** shows that percentage of accomplished sampling was lower in 1998-1999. According to CFIA's data, the percentage of accomplished Nitrites/Nitrates sampling workplans was 38 % lower nationally in 1998-1999 (from 264 to 163 submitted samples nationally). Routine analytical monitoring of products stopped entirely in 1999-2000.

77. In 1997-1998, the compliance level was 92% and in 1998-1999, it was 99%. Although the level of compliance has been very high, the few samples that were unsatisfactory contained high levels of nitrates/nitrites. Some results were in the order of 1300-1500 ppm of nitrates and, in another case, 325 ppm of nitrites. Repeated consumption of foods containing high doses may pose an acute risk to young children and susceptible populations. In 1997-1998, 8 out of 17 non-compliant results came from the same plant. The Agency was unable to provide the assessment team with comprehensive follow-up documentation to indicate how it had responded to the problem.

Recommendation

CFIA should resume sampling and testing for nitrite and nitrate levels in RTE products in federally registered establishments on a regular basis.

Major deficiencies in federally registered establishments are corrected within a reasonable period

78. In general, the average expected time to correct "major" deficiencies ranges from immediately to within one month. Major deficiencies include conditions that are likely to affect

health and safety. Inspectors determine the time within which an establishment is expected to correct a given problem. In doing so, inspectors take into consideration both the extent to which a problem or deficiency could affect health and safety, and what actions would be necessary to correct it.

79. To assess the corrective actions taken to correct deficiencies and bring plants into a compliance position, we selected a broad range of facilities in terms of size, the ready-to-eat meat products included in our scope, and their compliance ratings. Out of 28 plant files that we reviewed for the Quebec, Ontario and Atlantic areas, 22 plants had major deficiencies identified and reported at some point within the 12-month period examined. The average "actual" time to correct problems for 11 of those 22 plants (50%) exceeded the average expected corrective time. However, all problems had been corrected on average within three months. The steps that plants had taken were generally adequate to deal with the deficiencies.

III. Non-Federally Registered Establishments

80. The creation of CFIA in 1997 resulted in Health Canada and the CFIA sharing unique and complementary roles and responsibilities. Health Canada is responsible for establishing policies and standards relating to the safety and nutritional quality of food sold in Canada and assessing the effectiveness of the Agency's activities related to food safety while CFIA is responsible for federal food inspection program delivery. Health Canada transferred 150 inspector positions and 49 laboratory analysis positions to CFIA to undertake its role in delivering federal food inspection programs. Starting on April 1st, 1997, CFIA has been mainly responsible for the implementation of the Inspection Program as defined in the Roles and Responsibilities Framework for Federal Food Safety and Inspection Activities between Health Canada & Canadian Food Inspection Agency (Revised, June 30, 1999). On April 1st, 2000, CFIA implemented a new program to address its responsibilities. The new Food Safety Investigations Program (FSIP) is responsible for program design and supporting activities related to foods under the *Food and Drugs Act* (FDA). FSIP uses current risk analysis to establish its program priorities. It is designed to enable CFIA to allocate its resources more effectively (i.e., to concentrate its resources on areas where the risk is highest).

A. Inspection Approach in Use before March 2000

CFIA used a basic inspection model that performed well in some key respects

81. The Consumer Food Products Program (CFPP), as it was called before March 2000, was inherited from Health Canada and transferred

to the Agency when it was created in 1997. The inspection model previously used by Health Canada and then by CFIA recommended a predetermined frequency of inspection according to risks and, when necessary, inspectors collected samples and implemented corrective action. The CFPP used food inspection rating guidelines that were based on health and safety.

82. The key features of the CFPP, provided for inspection priorities and frequencies set according to the degree of risk. It identified manufacturing of ready-to-eat meats as a high risk area and identified the key hazards associated with those products.

83. Our review of the follow-up actions undertaken by CFPP to microbiologically non-compliant ready-to-eat meat products and environmental samples showed that they were appropriate. These actions implemented by CFPP entailed voluntary detention of products, voluntary disposal of products posing health and safety risks, recalls and investigations including environmental swabs and product sampling. The enforcement actions implemented were also appropriate. They were consistent with the level of risk observed and were conducted in a timely manner. We also noted key areas where the CFPP was not performing as well, as discussed in the following sections. Our observations focus largely on the period between April 1998 and March 2000. During that period, RTE meat products were included under the CFPP inspection programs.

84. It should be noted that the observations made in the following section were made under the CFPP which was in effect during this assessment coverage period. The CFPP was redesigned following a review by CFIA's Corporate Audit and Review to confirm the program mandates, designs and priorities for the Consumer Food Products and Retail Food programs and to draft work plans for fiscal year 2000-2001 that utilize resources in an effective and risk based manner. The assessment team seeks to provide the Agency with observations which may enhance the new Food Safety Investigations Program (FSIP).

The CFPP establishment inspection program was incomplete

85. We reviewed the inspection guidelines used by inspectors assigned to the non-federally registered meat sector under the Consumer Food Products Program (i.e., before the advent of the current Food Safety Investigations Program). The purpose of the review was to determine whether the CFPP inspector's guidelines addressed the necessary requirements to produce safe ready-to-eat meat products. We found that CFPP's national inspection guidelines for RTE meats need to be expanded to include the critical

control points of the other generic RTE meat commodities since the fermented Meat Sausage Good Manufacturing Practices Guideline was amongst the few commodity specific national inspection document available to inspectors.

86. Since the non-federally registered establishments are not required by federal legislation to register before they begin operation, it was difficult for CFIA to have a complete list of these plants, which is a useful tool for monitoring purposes. CFPP management recognizes the keeping of an up-to-date list of non-federally registered plants presents an on-going challenge. In some provinces the provincial legislation requires the manufacturers to be licensed or registered prior to operation and therefore subject to that inspection regime. In provinces where there are no provincial inspection services, it is possible that a non-federally registered ready-to-eat manufacturer may manufacture and sell its products without having previously informed government inspection agencies.

87. It is important that RTE meat products are kept at 4°C or below during transport and storage to maintain food safety. According to the Agency's inspection priorities and risk assessment, distributors and transporters were ranked lower priority. Distributors and transporters are inspected by CFIA when necessary.

The coverage of non-federally registered ready-to-eat meat manufacturers was incomplete

88. Ready-to-eat meat products were categorized as "high" in terms of health and safety risks. According to the Agency's work plans and work specifications, non-federally registered manufacturers of these high risk commodities were to be inspected every 12 to 18 months. According to the Agency's guidelines, all establishments should have been inspected at least twice in the three-year period which this assessment covered. The inspection results are summarized in ***Exhibit 13***. They show that CFIA was unable to meet its frequency of inspection guidelines. A third of non-federally registered ready-to-eat meat manufacturers producing these high-risk commodities had not been inspected in the past three years in the Ontario and Atlantic Areas. For the reasons discussed in paragraph 12, we did not include the Quebec Area in this exercise.

89. The design of the program focussed on regular inspection of the manufacturing controls rather than predetermined product sampling. Product sampling was conducted for example, when deficient good manufacturing practices had been identified during a regular plant inspection or when investigating a complaint. Therefore the potential number of investigative sampling is closely dependent upon the number of establishment inspections conducted.

In Ontario, microbiological sampling was not always carried out when required

90. According to the Agency's relevant work specification which was used under the CFPP before March 2000: "Finished product and environmental samples will only be submitted to the laboratories for analyses if it is found during an inspection that good manufacturing practices (GMPs) are not in place and/or previous inspections have indicated possible problems and/or environmental samples have been found positive."

91. In Atlantic, all 11 establishments that obtained a non compliance rating (compliance rating of "2" or lower) due to microbiological concerns between 1997 and 2000 were sampled. In Ontario, over the same period, only 53% (10 out of 19) of manufacturers that had been assigned an unsatisfactory rating for microbiological concerns were sampled as required.

Exhibit 13

Inspection Coverage in the Non-Federally Registered Ready-to-eat Meat Sector (1997-2000)

Inspection Coverage 1997-2000	Ontario*	Atlantic (NB & NS)	Combined Ont & Atl (NB & NS)
Percentage of manufacturers that had ***at least 2*** establishment inspections done in 3 years.	**30%** (31/104)	**22%** (11/50)	**27%** (42/154)
Percentage of manufacturers that had ***at least 1*** establishment inspection done in 3 years.	**72%** (75 /104)	**55%** (28/50)	**67%** (103/154)

** Note: The non-federally registered establishments that were reviewed for the Ontario area did not include the 41 establishments that are licensed with the province and that according to an M.O.U. between CFIA and OMAFRA require joint inspections. These joint inspections have not been conducted by CFIA during the period assessed.*

(_): Approximate Number of Establishments Involved

Note: In Quebec, since September 1998, the MAPAQ is conducting inspections in non-federally registered RTE meat establishments.

CFIA did not carry out follow-up inspections in the majority of non-compliant non-federally registered establishments within the established follow-up time frame

92. We reviewed CFIA's follow-ups of non-compliant, non-federally registered establishments inspected between April 1997 and March 2000. We focussed on the 32 establishments that received a compliance level or rating of "2" from CFIA. According to the Food Inspection Reference Manual, a "2" rating means that the problems identified in the inspections could have caused temporary adverse health consequences.

93. For the Ontario and Atlantic areas, we examined if CFIA had carried out follow-up inspections within three months as prescribed in CFPP's relevant work specifications for plants rated "2". The intent of follow-up inspections is to determine whether manufacturers had taken appropriate action to correct any problems. Again, as explained in paragraph 12, we did not include the Quebec area in this exercise.

94. Our review of follow-up actions demonstrated that 82% (26/32) of plants with a rating of "2" had not been reinspected within the prescribed three-month period:

- 41% (13/32) of follow-up inspections had not been done within the prescribed three-month period; the average follow-up time was 10 months, with a minimum of 5 months and a maximum of 26 months; and
- 41% (13/32) had no follow-up inspections.

95. The absence or delay of follow-up inspections before March 2000 could have allowed manufacturers to continue producing RTE meat products under unsanitary conditions. It is important to recognize that plants may have taken some follow-up actions. However CFIA had neither verified nor documented any such actions through follow-up inspections.

CFIA is working with Health Canada to address issues related to ready-to-eat fermented meat products containing beef as an ingredient

96. From 1994 to 1999, several outbreaks involving raw fermented sausages contaminated with *E. coli* 0157:H7 occurred. One of the most recent took place in November 1999 and was traced to a type of raw, fermented sausage manufactured in a federally registered establishment. More than 150 people became sick, and at least five developed hemolytic uremic syndrome. In February 2000, in response to the increasing potential health risk associated with ready-to-eat fermented meat sausages containing beef as an ingredient, Health Canada issued an interim guideline. This guideline describes the additional

interventions that are recommended for the production of ready-to-eat fermented sausages containing beef as an ingredient or where there is a risk of cross-contamination from beef. Following appropriate consultation with industry and consumers groups etc. these guidelines will be developed into a regulation to establish equivalent requirements for federally registered and non-federally registered establishments.

97. CFIA had already implemented equivalent control measures in December 1999 in all federally registered establishments. The implementation of mandatory process controls in the federally registered sector is facilitated by the fact that manufacturers depend upon their federal registration to pursue business. In response to Health Canada's interim guideline, the CFPP developed a nationwide work project, the objectives of which are to inform and to assess the fermented meat manufacturers of the non-federally registered sector. Implementation of this project began with presentations to industry in March 2001.

98. HC and CFIA are working together in implementing the mandatory controls for ready-to-eat fermented sausages containing beef as an ingredient in the non-federally registered sector, through the Federal/Provincial/ Territorial Committee on Food Safety.

B. New Approach Implemented by the Agency

99. In 2000, the CFIA's Corporate Audit and Review Directorate reviewed the former Consumer Food Product Program. It examined the challenges facing the Program with a view to clarifying its objectives, structures and management framework. The review was also intended to propose an approach for making the best use of resources in a strategic, risk-based manner. This review resulted in the creation of the Bureau of Food Safety and Consumer Protection with its component programs, the Food Safety Investigations Program (FSIP) and the Fair Labelling Practices Program (FLPP).

100. The new Bureau, through the FSIP, is responsible for operational policy, program design, coordination of annual work plans and supporting CFIA operations for all programs and activities under the CFIA provisions of the *Food and Drugs Act*. A systematic risk based approach is used to set program priorities. The process involves scanning all available intelligence (complaints, scientific and trade publications, public health risks posed by known hazards and emerging food safety hazards, etc.) and using this information to identify national priorities. Risk management options are then

identified and the option(s) likely to have the greatest impact on managing the risk are then selected and implemented. CFIA expects this approach to be more holistic, allowing them to better target their investigations and enforcement actions within the available resource base.

101. The Food Safety Investigations Program has identified the non-federally registered ready-to-eat fermented meat products sector as one of its high risk-high priority projects. This project, which is in progress, is focussed on achieving compliance with *Food and Drugs Act and Regulations* requirements while recognizing the shared legislative responsibility between the federal and provincial governments for this industry sector. It employs industry education, assessment of manufacturing controls, finished product sampling and analysis, and compliance and enforcement actions as necessary to achieve compliance with legal requirements.

Conclusion

102. The following points summarize our key conclusions with respect to the main topics addressed in the assessment.

Roles and Responsibilities

103. In areas where responsibilities for inspecting ready-to-eat meat products are shared between federal and provincial jurisdictions, CFIA has begun to update its Memoranda of Understanding / Agreement with the provinces. During the period covered by the assessment, one agreement had been signed with the province of Quebec. The agreement included provisions key to ensuring proper accountability between partners and to ascertain that there are no gaps or duplication were included in the agreement. However, some of these key elements, such as the requirement to exchange information related to inspection activities, had not been implemented.

Federally Registered Establishments

104. CFIA represents a strong presence in federally registered establishments. Key risks are well identified, establishments are monitored closely, product sampling is done on a routine basis, compliance levels are high, and major deficiencies are corrected. Our assessment also identified areas where inspection activities could be improved. We have noted that CFIA's product and environmental sampling work plans were not fully implemented in some Areas, that sampling procedures for *Listeria monocytogenes* resulted in delays between the time when non-compliant samples were detected and when follow-up samples were taken, and that controls for nitrite and nitrate levels may have been weakened by the suspension of analytical testing for this type of additives.

Non-federally Registered Establishments

105. Our assessment has shown that before March 2000, CFIA's inspections of non-federally registered establishments, although satisfactory in some respects, had several drawbacks, especially in terms of coverage of the RTE meat establishments and timely follow-ups of non-compliant establishments. On April 1st, 2000 CFIA implemented a new program to address its responsibilities. The new Food Safety Investigations Program (FSIP) is responsible for program design and supporting activities related to foods under the *Food and Drugs Act* (FDA). The FSIP uses current risk analysis to establish its program priorities. It is designed to enable CFIA to allocate its resources more effectively (i.e., to concentrate its resources on areas where the risk is highest).

Conclusion

106. The inspection of ready-to-eat meat products is facing many challenges. Emerging microbiological hazards such as *E. coli* 0157:H7 and *Listeria monocytogenes* demand ever more vigilant and effective controls. Our assessment has shown that CFIA's key inspection activities are generally effective in promoting safe ready-to-eat meat products in Canada. However, we have identified some areas which would warrant the Agency's attention to increase food safety effectiveness.

CFIA Management Response

The CFIA is pleased to have the opportunity to respond to the assessment of the Agency's food safety activities related to domestic ready-to-eat (RTE) meat products conducted by Health Canada. In many respects, this assessment report confirms and validates the program design and delivery activities of the Agency in this important field. The recommendations provided by Health Canada have been carefully considered and the Agency will take appropriate action and implement steps to enhance our food safety activities.

The CFIA delivers nine food safety programs, of which two involve activities related to domestic ready-to-eat meat products. The two programs, the Meat Hygiene Program and the Food Safety Investigations Program (FSIP), are based on different legislative mandates leading to different approaches to food safety outcomes. As noted in this report, the FSIP was implemented in March 2000 to enhance the effectiveness of the food safety programs pursuant the *Food and Drugs Act* delivered by Health Canada prior to the creation of the Agency. This assessment did not examine the activities of CFIA's current FSIP.

The FSIP uses science committees and risk analysis to establish program priorities and allocate resources to areas where risk is highest. For example, the FSIP has developed a multi-year project, beginning in April 2002, to be delivered in the ready-to-eat fermented meat sector. As this represents an area of shared jurisdiction, work sharing agreements are being negotiated to carry out this project in collaboration with the responsible provincial government agencies. The objective of the project is to assess the degree of process control in RTE fermented meat establishments and compliance with requirements for pathogen reduction. The project is designed to promote awareness of pathogens within the sector and to provide recommendations to improve compliance to individual firms.

CFIA and Health Canada share unique and complementary roles in the federal food safety system. Health Canada establishes standards for the safety and nutritional quality of food sold in Canada. The CFIA enforces those standards. This assessment has highlighted areas where food safety standards relative to RTE meat products need to be reviewed. The CFIA will support these initiatives and work actively with Health Canada to address standards when required. Should Health Canada introduce revised food safety standards, CFIA programs, procedures and inspection guidelines will be amended accordingly.

The assessment made several recommendations applicable to the activities carried out under the Meat Hygiene Program. Health Canada completed a Health Hazard Assessment (HHA) that identified new measures to enhance product safety. With respect to the recommendation to update the beef jerky generic HACCP model, the CFIA will promptly inform industry of the new requirements identified in the HHA and modify both program requirements and the appropriate HACCP Generic Models.

The assessment identified areas where the CFIA could improve inspection activities within federally registered RTE meat establishments and the Agency is implementing appropriate action. For example, the CFIA has resumed a monitoring program for nitrites and nitrates in RTE meat products to verify industry performance in this area and to confirm that compliance levels remain high. Plans are being developed to increase efforts to comply with national standards for product and environmental sampling plans in the Operational Areas where delivery is below 100%. The Agency will also increase our efforts to track end-product safety testing and conduct follow-up sampling as outlined in the *Listeria monocytogenes* operational sampling program in the Meat Hygiene Manual of Procedures. As documented in the assessment, the Program is currently conducting follow-up sampling within specifications 92% of the time.

To enhance program oversight the CFIA is in the process of staffing 15 new veterinary supervisors across the country. These officers will provide quality assurance of CFIA activities in federally registered establishments. They will be responsible for monitoring the delivery of CFIA activities (including sampling plans) and taking appropriate action if national objectives are not met.

As noted in the assessment, where responsibility for inspecting RTE meat products is shared between federal and provincial jurisdictions the CFIA has begun to update its agreements with the provinces covering the management of these shared responsibilities. Since this assessment, agreements have been signed with two provinces. The CFIA will continue to work with provinces and territories to update agreements and put in place mechanisms to allow for the key commitments in the agreements to be fulfilled.

Since the initiation of this assessment, the CFIA has moved towards implementing a mandatory HACCP regime for federally registered meat establishments and storages. The program is expected to be fully implemented in the spring of 2004 at which time establishment ratings will become obsolete and will be removed from the policy. In the interim, establishment ratings criteria address important food safety controls. Any food safety issue identified by a CFIA inspector impacts the establishment's rating.

In summary, the CFIA confirms its commitment to responding to the recommendations of the assessment and implementing improvements to the food safety activities related to domestic RTE meat products.

About the Assessment

Objective

The objective of this assessment was to determine the effectiveness of the Canadian Food Inspection Agency's programs and activities related to the safety of domestic ready-to-eat meat products produced and sold in Canada.

Criteria

The criteria against which the Agency's programs and activities were assessed are:

1. Does CFIA make reasonable efforts to ensure that the respective roles and responsibilities of itself with the provinces/territories, and Health Canada for the safety of domestic ready-to-eat meat products are clearly defined and understood to reduce health and safety gaps?

   1.1 Does CFIA make reasonable efforts to ensure that the respective responsibilities of the Canadian Food Inspection Agency and the provincial/territorial counterparts for the safety of domestic ready-to-eat meat products are clearly defined and understood to reduce health and safety gaps?

   1.2 Does CFIA make reasonable efforts to ensure that the respective responsibilities of Health Canada and CFIA with respect to hazard identification, risk assessment and food safety standard/policy setting are clearly defined and understood?

2. Does CFIA design and implement programs and activities which effectively monitor the food safety risks associated with domestic ready-to-eat meat products?

   2.1 Does CFIA design inspection procedures capable of determining whether domestic ready-to-eat meat products/establishments meet Canadian health and safety standards?

   2.2 Does CFIA prioritize and plan its inspection activities based upon risk to health?

   2.3 Does CFIA implement work plans in a way consistent with the level of risk?

   2.4 Does CFIA conduct health and safety inspections in accordance with established procedures?

3. Where non-compliance with Canadian health and safety standards is identified, does CFIA take appropriate enforcement action to control and reduce the risk to health?

   3.1 Does CFIA design clear and comprehensive enforcement procedures to address non-compliant domestic ready-to-eat meat products / establishments in accordance with the level of risk?

3.2 Does CFIA ensure that where non-compliance is determined, consistent enforcement action in accordance with the level of risk, is taken ?

Scope and Approach

The scope of this assessment covered activities related to the safety of domestic ready-to-eat meat products manufactured by the federally registered and non-federally registered sectors.

Activities related to some high risk domestically manufactured ready-to-eat meat products were examined. Examples of such products are:

- Fermented meat products
- Cooked cured meats
- Cooked non-cured meats
- Dried meats
- Multiple foods (such as sandwiches or modified atmosphere packaged sandwiches containing ready-to-eat meats)

This assessment covered activities related to the safety of domestic ready-to-eat meat products since the formation of the Agency in April 1997, with emphasis on activities delivered between April 1, 1998 and March 31, 2000.

The following Areas were assessed: Quebec, Ontario, and Atlantic. The assessment included activities such as: reviewing of program plans and procedures and inspection and compliance reports, interviewing program staff, and analysing available food safety results and trends. Programs and activities associated with allergens, complaint investigative procedures and imported ready-to-eat meats were not examined during this assessment.

This assessment was carried out according to the mandate defined in the *Canadian Food Inspection Agency Act*. Section 11 (4) of this Act specifies that: “The Minister of Health is responsible for establishing policies and standards relating to the safety and nutritional quality of food sold in Canada and assessing the effectiveness of the Agency’s activities related to food safety”. Therefore the assessment role of the Minister of Health, as defined in this Act covers exclusively the CFIA and does not include the assessment of any activities related to food safety undertaken by Health Canada or any other federal or provincial organizations. Our scope reflects this legislative provision.

Assessment Team:

Yves Genest / *Darren Goodyear*: Senior Project Managers, *Luciano Silicani*: Project Leader, *Michel Cloutier*: Auditor, *France Lacroix*: Auditor, *Brenda Redmond*: Auditor, *Freddy Wu*: Auditor.

Glossary

Area (also known as Operational Area):
With headquarters in the National Capital Region, the CFIA organization consists of four Operational Areas, (Western, Ontario, Quebec and Atlantic). These Areas are subdivided into 18 regional offices, 185 field offices (including border points of entry), and 408 offices in non-government establishments (such as processing facilities). The Agency also has 22 laboratories and research facilities that provide scientific advice, develop new technologies, provide testing services, and conduct research.

Beef Jerky:
Beef Jerky is made from sliced raw beef which has been spiced, salted, smoked and dried. It is considered a fully dry shelf-stable product.

***Canadian Food Inspection Agency Act* (*CFIA Act*):**
The *Canadian Food Inspection Agency Act* is an Act to establish the Canadian Food Inspection Agency and to repeal and amend other Acts as a consequence. Passed by the House of Commons on February 12, 1997.

Canadian Food Inspection System (CFIS):
The Canadian Food Inspection System is a collaborative initiative of all levels of government. Its aim: an integrated Canadian food inspection system which is responsive to both consumers and industry.

Codex Alimentarius:
The Codex Alimentarius Commission is a subsidiary body of the United Nations World Health Organization and the Food and Agriculture Organization of the United Nations.

Cooked meat product:
Health Canada's position when defining a cooked meat product is that the cooking process (product's internal time/temperature combination) must be sufficient to achieve a 5 log reduction of *Listeria monocytogenes* which is among the most heat resistant food bacteria.

***E. coli* O157:H7:**
E. coli is a normal inhabitant of the intestines of all animals, including humans. Normally *E. coli* serves a useful function in the body by suppressing the growth of harmful bacterial species and by synthesizing appreciable amounts of vitamins. A minority of *E. coli* strains are capable of causing human illness by several different mechanisms. *E. coli* serotype O157:H7 is a rare variety of *E. coli* that produces large quantities of one or more related, potent toxins that cause severe damage to the lining of the intestine. It is also responsible for Hemolytic Uremic Syndrome (HUS), commonly referred to as "Hamburger Disease", which is a disease that affects the kidneys and other organs. It poses a substantial threat to Canadian children as one of the leading causes of both acute and chronic kidney failure.

Environmental Samples:

In the context of our RTE report, it refers to microbiological samples (swabs) taken from food contact surfaces and non-food contact surfaces in critical post processing (i.e., post cooking) areas/environment where RTE meat products are handled. Samples are typically taken to detect *Listeria monocytogenes*.

Federally Registered Establishments (meat products):

For the purpose of this assessment when we refer to Federally Registered Establishments we mean meat processing/storage facilities that fall under the definition of "Registered Establishment" as defined under section 3 the *Meat Inspection Act*.

The *Meat Inspection Act* defines "Registered Establishments" as:

(1) It shall be a condition of the registration and operation of an establishment as a registered establishment that the establishment and all animals and meat products in it are subject to this Act and the regulations.

(2) No person shall operate a registered establishment unless that person has obtained a licence therefor in accordance with the regulations.

Fermented Meat Products:

Fermented meat products mainly refer to manufactured ready-to-eat raw meat sausages produced via a controlled fermentation process.

Food Inspection Reference Manual (FIRM):

The Food Inspection Reference Manual was developed by the previous Health Protection Branch of Health Canada to be used by its food safety inspectors when inspecting food-processing establishments. Although some inspection guidelines are dated 1977, the FIRM's guidelines are still used as an inspection reference tool by the Agency's inspectors when carrying out inspections in the non-registered food industry sector.

Food Safety Enhancement Program (FSEP)

FSEP is CFIA's program designed to encourage the development and maintenance of HACCP (see below) systems in federally registered agri-food processing establishments.

In order to qualify for the regulatory system audit under FSEP, the operator must develop and maintain an acceptable and effective HACCP system. The system must be fully documented and readily accessible for review and audit by the CFIA.

Hazard Analysis Critical Control Points (HACCP)

Hazard Analysis Critical Control Points (HACCP) represents a new system for approaching the management of chemical, physical and biological hazards which affect food production. HACCP identifies specific hazards and specifies measures to control them rather than relying mainly on end-product testing to ensure their safety.

Inspection Program

For the purpose of this assessment, an Inspection Program includes those activities that promote, assess and achieve compliance with legislation and policies with regards to food safety.

***Listeria monocytogenes* (*L. monocytogenes*):**

A food poisoning bacteria which is found virtually everywhere. It causes Listerioris, an illness that is potentially life threatening especially to predisposed groups such as newborns, the elderly and people with weak immune systems. It can also cause miscarriage. The micro-organism also causes listerial gastroenteritis, a relatively mild flu-like disease.

Meat Hygiene manual of Procedures (Also known as Meat Hygiene Manual):

The Meat Hygiene Manual of Procedures is the key reference document for inspectors in the Foods of Animal Origin Division. Chapter 4 of the Meat Hygiene Manual of Procedures deals with "Inspection Procedures, Monitoring, and Controls" and provides the inspectors with a descriptive guide on how to carry out inspection procedures. The Meat Hygiene Manual also provides some guidance to inspectors on what compliance actions to take if required.

Ministère de l'Agriculture, des Pêcheries et de l'Alimentation du Québec (MAPAQ)

Provincial food inspection in Quebec for the non-federally registered sector is delivered by the Ministry of Agriculture, Fisheries and Food (MAPAQ).

Nitrites/Nitrates

Nitrite and nitrate salts are food additives used in curing meats. They stabilize red meat colour, inhibit some spoilage and food-poisoning organisms, and contribute to flavour. Nitrates transform into nitrites in meat and have antimicrobial activity against *Clostridium botulinum* as well as for some other pathogens. It is this antimicrobial activity of nitrites in cured meats which is of greater pubic health importance compared to colour or flavour development and that warrants the continued use of nitrites in such products.

Non-Federally Registered Establishments (meat products):

For the purpose of this assessment, when we refer to non federally registered establishments we mean those meat processing/storage establishments and related facilities that are ***not*** under the jurisdiction of the *Meat Inspection Act*.

Ontario Ministry of Agriculture, Food & Rural Affairs (OMAFRA)

In Ontario, the non-federally registered slaughterhouses with or without meat processing and their retail outlets (on the same premises of a slaughter house) are under the jurisdiction of OMAFRA and inspected by the same. The non-federally registered, free standing meat processing plants which are not located on the same site as a slaughterhouse are inspected by the Ontario Ministry of Health.

Planning, Performance & Program Review Division (PPPR):

The Planning, Performance and Program Review Division of CFIA manages and coordinates activities associated with national commodity-related Program Audits, Work Planning, Performance Management and the Resource Management System (RMS). Branch consistency and coherence in these activities is the goal.

The Division develops and implements program audits, planning and performance measurement systems by working with the Program Divisions and with Operations Branch to allow for a harmonized CFIA internal audit system across all commodities through which needed improvements can be identified; working with internal and external groups to coordinate, facilitate and develop a consistent framework for foreign commodity related program audit activities; developing and implementing Programs Branch Business Priorities to conform to the Corporate Business Plans and Agency Priorities; adapting the Programs Branch planning framework to conform to the Agency planning framework; implementing the adapted Planning Process and establishing a reporting framework; and, managing the RMS.

Resource Management System (RMS):

The Resource Management System is a resource allocation system that the Canadian Food Inspection Agency uses to determine the resources required to carry out inspection activities in the federally registered sector.

***Staphylococcus aureus* (*S. aureus*)**

Staphylococcus aureus is the most common cause of foodborne illness. This bacterium produces a poison/ toxin that causes illness. Symptoms of staphylococcal food poisoning are usually rapid and in many cases serious, depending on individual response to the toxin, the amount of contaminated food eaten, the amount of toxin in the food ingested, and the general health of the victim. The most common symptoms are nausea, vomiting, abdominal cramping, and prostration often accompanied by diarrhea. Deaths are rare; duration of illness is commonly not more than a day or two.

The Inspection Guide (known as the TIP):

The inspection tasks to be carried out in federally registered establishments are determined with the help of the "Inspection Guide", commonly known as the TIP (The Inspection Program) guide.

Uncured meat products:

This term refers to meat products that do not contain added nitrites/nitrates.