



U.S. Department of Agriculture



Office of Inspector General
Northeast Region

Audit Report

Food Safety and Inspection Service Assessment of the Equivalence of the Canadian Inspection System

Report No. 24601-05-Hy
December 2005



UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250



December 20, 2005

REPLY TO

ATTN OF: 24601-05-Hy

TO: Barbara Masters
Administrator
Food Safety and Inspection Service

ATTN: Jane Roth
Acting Assistant Administrator
Office of Program Evaluation, Enforcement, and Review

FROM: Robert W. Young /s/
Assistant Inspector General
for Audit

SUBJECT: Food Safety and Inspection Service Assessment of the Equivalence of the
Canadian Inspection System

This report presents the results of our audit of the Food Safety and Inspection Service's assessment of the equivalence of the Canadian inspection system. Your response to the official draft, dated December 9, 2005, is included as exhibit A. Excerpts of your response and the OIG's position are incorporated into the Findings and Recommendations section of the report. Based on your response, we were able to reach management decision on the report's five recommendations. Please follow your agency's internal procedures in forwarding documentation for final action to the Office of the Chief Financial Officer.

We appreciate the courtesies and cooperation extended to us by members of your staff during this audit.

Executive Summary

Food Safety and Inspection Service Assessment of the Equivalence of the Canadian Inspection System (Audit Report No. 24601-05-Hy)

Results in Brief

We evaluated the Food Safety and Inspection Service's (FSIS) assessment of the equivalence of the Canadian inspection system for meat and poultry products. In a November 6, 2003, memorandum, the FSIS Administrator and the Under Secretary for Food Safety identified serious concerns with the Canadian inspection system. They noted in the memorandum that these concerns had the potential for compromising public health. We found FSIS did not timely address these serious concerns. For example, in July 2003, FSIS identified that Canadian inspection officials were not enforcing certain pathogen reduction and Hazard Analysis and Critical Control Point (HACCP) system regulations. These same types of concerns were identified again in June 2005, almost 2 years later.

Timely actions were not taken because FSIS does not have protocols or guidelines for evaluating deficiencies in a country's inspection system that could jeopardize a country's overall equivalence determination. In addition, FSIS did not institute compensating controls (e.g., increased port-of-entry testing) to ensure that public health was not compromised while deficiencies were present. Over 4.4 billion pounds of Canadian processed product entered U.S. commerce from January 1, 2003 through May 31, 2005. In FSIS' information system, the products were categorized as cuts and trimmings of raw product as well as products with additional processing from pork, veal, beef, poultry, and lamb. These products were produced and allowed to be exported to the United States even though FSIS officials questioned the equivalence of the Canadian inspection system.

FSIS regulations¹ require foreign inspection systems to provide standards equivalent to those of the United States. These requirements include the implementation of sanitation controls and HACCP requirements. Sanitation controls cover all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene practices, and good product handling and storage practices. All plants must develop, adopt, and implement a HACCP plan for each of their processes. Under HACCP, plants identify critical control points during their processes where hazards such as microbial contamination can occur, establish controls to prevent or reduce those hazards, and maintain records documenting that controls are working as intended.

In July 2003, as part of an onsite review, FSIS identified serious concerns with the Canadian inspection system. These concerns included the

¹ Title 9, Code of Federal Regulations (C.F.R.) § 327.2 (a) (2) and 9 C.F.R. § 381.196 (a) (2), January 1, 2005 edition.

insufficient implementation of sanitation controls and HACCP requirements by establishments and the lack of enforcement in these areas by Canadian inspection officials. Based on these concerns, FSIS proposed an enforcement review in 2004. (Enforcement reviews can lead to a determination that a country's system is not equivalent to U.S. standards and, thus, not eligible to export to the United States). The proposed 2004 enforcement review was not conducted and FSIS officials did not reassess Canada's implementation and enforcement of sanitation controls and HACCP requirements until almost 2 years later. When FSIS officials finally returned to Canada in May 2005, they continued to find the same types of deficiencies they had found in 2003. FSIS should analyze the deficiencies identified in the 2003 and 2005 reviews to determine whether immediate actions are needed to address concerns regarding public health and if additional enforcement measures are needed.

FSIS' analysis of the regulations governing the Canadian inspection system identified two areas which may not be equivalent to the United States inspection system. FSIS found that Canadian policy allowed less than daily inspection coverage in processing establishments. By contrast, FSIS has a long established history of requiring the presence of an inspector in a U.S. processing establishment at least once per shift per day. FSIS also identified differences in the testing performed for *Listeria monocytogenes*. Canadian inspection officials require establishments to perform risk-based environmental sampling, as opposed to the finished product sampling required by FSIS.

In a management alert to the FSIS Administrator in July 2005, we reported that FSIS had not taken timely action to resolve the agency's June 2003 finding that Canada does not require daily inspection coverage at processing establishments that export product to the United States. In addition, FSIS' actions regarding Canadian processing establishments were not consistent with how the agency treated similarly situated countries. When FSIS identified less than daily inspection in establishments in Australia in June 2004, and in Belgium in July 2003, the establishments were immediately delisted and no longer allowed to export product to the United States. According to FSIS officials, Australia and Belgium did not pursue an equivalence determination, which was pursued by Canada. In response to our recommendations, FSIS agreed to initiate a number of actions to ensure that an equivalence determination was made regarding daily inspection coverage. However, FSIS asserted that a final decision could not be made until 2007. In the interim, FSIS agreed to implement measures that the agency believes will ensure there is no increased risk to the public health in the United States. These measures included doubling the sampling of Canadian shipments and increasing the presence of Canadian inspection officials in processing establishments exporting to the United States.

**Recommendation
In Brief**

FSIS needs to develop and implement protocols for postponing or canceling a scheduled enforcement review and for determining which equivalence deficiencies would call into question a country's overall equivalence to U.S. standards. In addition, FSIS should analyze the deficiencies identified in the 2003 and 2005 reviews of the Canadian inspection system to determine whether additional actions are needed to address concerns regarding public health. Finally, FSIS needs to develop an action plan for determining whether the Canadian inspection system control for *Listeria monocytogenes* in ready-to-eat products is equivalent to that of the United States.

Agency Response

FSIS agreed with the report's recommendations. We have incorporated the agency's response in the Findings and Recommendations section of this report, along with the OIG position. The response is included as Exhibit A.

OIG Position

Based on the response, we were able to reach management decision on the report's five recommendations.

Abbreviations Used in This Report

BSE	Bovine Spongiform Encephalopathy
C.F.R.	Code of Federal Regulations
FSIS	Food Safety and Inspection Service
HACCP	Hazard Analysis and Critical Control Point
OCFO	Office of the Chief Financial Officer
Secretary	Secretary of Agriculture
USDA	U.S. Department of Agriculture

Table of Contents

Executive Summary	i
Abbreviations Used in This Report	iv
Background and Objectives	1
Findings and Recommendations.....	4
Section 1. Equivalency of the Canadian Inspection System.....	4
Finding 1 FSIS Did Not Timely Address Concerns With the Canadian Inspection System	4
Recommendation 1	11
Recommendation 2	12
Recommendation 3	13
Recommendation 4	14
Recommendation 5	14
Scope and Methodology.....	15
Exhibit A – Agency Response	16

Background and Objectives

Background

U.S. food safety legislation² requires foreign countries that export meat and poultry products to the United States to establish and maintain systems that are equivalent to the U.S. inspection system. Meat and poultry products must originate in countries and establishments approved to export to the United States. The U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) is responsible for monitoring foreign countries and exporters to ensure the countries' food safety systems are equivalent to U.S. standards and that exporters are certified as meeting those standards.

FSIS administers its imported meat and poultry inspection program primarily through the Office of International Affairs and the Office of Program Evaluation, Enforcement, and Review. The Office of International Affairs is responsible for formulating policies, determining a foreign country's eligibility to export meat and poultry products to the United States, reviewing food safety requirements imposed by foreign governments, and reinspecting imported meat and poultry products. The Office of Program Evaluation, Enforcement, and Review conducts system audits, which include a review of a sample of exporting establishments, to ensure that products are produced under requirements equivalent to U.S. inspection requirements. These review and inspection activities form the basis of FSIS' determinations of whether a country's inspection system is equivalent to U.S. standards.

Food safety equivalence evaluations are based on provisions of the Agreement on the Application of Sanitary and Phytosanitary Measures, which became effective in January 1995. Prior to this agreement, FSIS focused on individual establishments and evaluated whether foreign food safety systems were "at least equal to" the U.S. system. The principle underlying FSIS' current import inspection activities is the "systems approach," which evaluates the equivalence of the inspection system controls of each country. Regulations³ codify FSIS' responsibilities for evaluating foreign meat and poultry inspection systems. The burden for demonstrating equivalence rests with the exporting country and the importing country is free to set any level of protection it deems appropriate to control or eliminate a food safety hazard.

FSIS evaluates the equivalency of foreign meat and poultry inspection systems through a process that consists of (1) document analysis, (2) onsite review, and (3) port-of-entry product reinspection. Judgments of system equivalence are necessary for FSIS and the American public to develop and maintain trust in imported meat and poultry products.

² The Federal Meat Inspection Act and Poultry Products Inspection Act.

³ Title 9, Code of Federal Regulations (C.F.R.) § 327, Imported Products, and 9 C.F.R. § 381, Subpart T, Imported Poultry Products.

A foreign country must apply for and receive a determination of equivalency before it can export meat and poultry products to the United States. To make this determination, FSIS performs a document review and an onsite equivalency verification. After a country is determined to have an equivalent system and is eligible to export to the United States, FSIS relies on the country to provide effective oversight of food inspection activities and enforcement of U.S. requirements. However, FSIS continues to monitor the country's activities. In addition to randomly sampling imported meat and poultry products, FSIS conducts onsite reviews of the country's inspection system to ensure that its procedures and standards remain equivalent. Reviewers visit certified establishments and focus on five areas of risk (i.e., animal disease, sanitation, enforcement, residue, and slaughter/processing). These reviews are generally conducted annually. If the monitoring reviews identify critical weaknesses in the implementation and enforcement of key provisions, FSIS generally conducts an enforcement review, with the objective of determining whether exports to the United States should continue. Unsatisfactory enforcement review findings may prompt FSIS to suspend exports to the United States from the country until the identified problems are corrected.

In July 2003, a routine monitoring review of Canada's inspection system was conducted to ensure that its procedures and standards remained equivalent. The objective of this review was to evaluate the performance of the Canadian inspection system with respect to controls over slaughter and processing establishments certified as eligible to export product to the United States. This review disclosed that Canadian inspection officials were not enforcing requirements as necessary to ensure equivalence with FSIS pathogen reduction and Hazard Analysis and Critical Control Point (HACCP) system regulations. FSIS also found that some processing establishments were allowed to export products to the United States, even though they did not receive daily inspection, as required by U.S. standards. As noted in FSIS' report to the U.S. Congress, in March 2004:

“A foreign plant can be delisted if it were found to have any serious deficiency that shows it is not meeting standards equal to those achieved in U.S. domestic plants. Examples include instances of direct product contamination; poor environmental sanitation that could lead to direct product contamination; lack of a sanitation standard operating procedure or failure to implement an existing procedure; no HACCP plan or an inadequate plan or not following an existing plan; no testing for generic *E. coli*; **less than continuous inspection coverage** (emphasis added); humane slaughter violations; and any other fundamental requirement of equivalence.”

On May 20, 2003, the Secretary of Agriculture (Secretary) halted imports of live cattle, other live ruminants, beef, and other ruminant products from

Canada after a cow in Alberta was found to have bovine spongiform encephalopathy (BSE), widely known as “mad cow disease.”⁴ Prior to this time, live cattle and beef were traded freely between the United States and Canada. Due to the serious impact on trade, USDA officials sought a method to allow limited imports from Canada. On August 8, 2003, the Secretary announced a list of low-risk products, including boneless beef from cattle less than 30 months of age and veal meat from calves less than 36 weeks of age, which would be allowed into the United States from Canada, under certain predetermined conditions. In November 2003, USDA published a proposed rule in the *Federal Register* to create a low-risk category for countries with BSE, to place Canada on that list, and to allow imports of, among other things, low-risk beef products and live cattle less than 30 months of age to resume.

On March 2, 2005, a temporary injunction was issued by a U.S. district court regarding USDA’s minimal risk rule. This ruling temporarily delayed the implementation of the rule, which would have re-established trade with Canada for live cattle less than 30 months of age and certain meat products. On July 14, 2005, however, the Ninth Circuit Court of Appeals lifted the preliminary injunction that blocked implementation of the BSE minimal risk rule and allowed the importing of live cattle less than 30 months of age from Canada to the United States for processing.

Objectives

The objective of our review was to evaluate FSIS’ assessment of the equivalence of the Canadian inspection system. This evaluation included determining whether FSIS took appropriate and timely actions on identified concerns and whether FSIS ensured that Canadian processing plants exporting meat and poultry products to the United States received daily inspection.

To accomplish the objective, we performed fieldwork at FSIS Headquarters. Our audit work primarily covered FSIS’ assessments of the Canadian inspection system from July 2003 through July 2005. (See Scope and Methodology for details.)

⁴ Since 1989, USDA’s Animal and Plant Health Inspection Service has led an interagency effort to monitor BSE. BSE is a chronic disease affecting the central nervous system of cattle. Worldwide there have been more than 180,000 cases in cattle since the disease was first diagnosed in 1986 in Great Britain.

Findings and Recommendations

Section 1. Equivalency of the Canadian Inspection System

Finding 1

FSIS Did Not Timely Address Concerns With the Canadian Inspection System

The FSIS did not timely address serious concerns with the Canadian inspection system even though high-level agency officials documented the potential for compromising public health. In July 2003, FSIS found that Canadian inspection officials were not enforcing pathogen reduction and HACCP system regulations. These same types of concerns were identified again in June 2005, almost 2 years later. However, as of September 2005, FSIS has not made a determination whether the identified concerns are serious enough to limit the import of Canadian products. As a result, FSIS has allowed the importation of almost 700 million pounds of meat and poultry from plants that did not receive daily inspection, a requirement for all U.S. meat and poultry plants. Additionally, FSIS allowed the import of over 261 million pounds of ready-to-eat meat and poultry that had not been subjected to finished product testing for *Listeria monocytogenes*, as is required of U.S. plants.

Timely actions have not been taken because FSIS does not have protocols or guidelines for evaluating deficiencies in a country's inspection system that could jeopardize a country's overall equivalence determination. In addition, FSIS did not institute compensating controls to ensure that public health was not compromised while deficiencies were present. Over 4.4 billion pounds of Canadian processed product entered U.S. commerce from January 1, 2003 through May 31, 2005. In FSIS' information system, the products were categorized as cuts and trimmings of raw product as well as products with additional processing from pork, veal, beef, poultry, and lamb. These products were produced and allowed to be exported to the United States even though FSIS officials questioned the equivalence of the Canadian inspection system.

FSIS regulations⁵ require foreign inspection systems to provide standards equivalent to those of the United States. These requirements include the implementation of sanitation controls and HACCP requirements. Sanitation controls cover all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene practices, and good product handling and storage practices. All plants must develop, adopt, and implement a HACCP plan for each of their processes. Under HACCP, plants identify critical control points during their

⁵ 9 C.F.R. § 327.2 (a) (2) and 9 C.F.R. § 381.196 (a) (2), both effective January 1, 2005.

processes where hazards such as microbial contamination can occur, establish controls to prevent or reduce those hazards, and maintain records documenting that controls are working as intended.

Our audit tests disclosed that in July 2003, as part of an onsite review, FSIS identified serious concerns with the Canadian inspection system. These concerns included the insufficient implementation of sanitation controls and HACCP requirements by establishments and the lack of enforcement in these areas by Canadian inspection officials. Based on these concerns, FSIS proposed, but did not conduct, an enforcement review in 2004. This review was initially postponed due to resource constraints, but was subsequently cancelled when the Secretary directed FSIS to work with Canadian inspection officials to resolve the outstanding differences. The enforcement review could have led to the determination that meat and poultry products produced under the Canadian inspection system were not eligible to be imported into the United States. When FSIS officials returned to Canada in May 2005, they continued to find the same types of deficiencies they found in 2003.

We also found that FSIS' analysis of the regulations governing the Canadian inspection system identified two areas which may not be equivalent to the U.S. inspection system. FSIS found that Canadian policy allowed less than daily inspection coverage in processing establishments. By contrast, FSIS has a long established history of requiring the presence of an inspector in a U.S. processing establishment at least once per shift per day. FSIS also identified differences in the testing performed for *Listeria monocytogenes*. Canadian inspection officials require establishments to perform risk-based environmental sampling instead of risk-based finished product sampling required by FSIS.

- **Serious Concerns Identified in 2003.** In July 2003, FSIS completed an onsite review of the Canadian inspection system and concluded that Canada's meat and poultry inspection system had serious deficiencies in enforcing U.S. inspection requirements, particularly those of the pathogen reduction and HACCP system regulations. The findings of the 2003 review disclosed continuing problems with the implementation of U.S. inspection requirements in all Canadian establishments certified to export product to the United States.

On November 6, 2003, the FSIS Administrator and the Under Secretary for Food Safety informed the Secretary of their concerns with the Canadian inspection system. In this memorandum to the Secretary, agency officials concluded that the Canadian inspection system had failed to implement adequate corrective actions in response to FSIS reviews in 2002 and 2003. These reviews found that Canada was not maintaining inspection requirements equivalent to those of the United States. In the 2003 review, FSIS officials visited 37 Canadian

establishments to evaluate their inspection program. FSIS officials found a number of deficiencies that call into question the equivalence of the Canadian inspection system. Examples included the insufficient implementation of sanitation controls and HACCP requirements by establishments as well as the lack of enforcement in these areas and less than daily inspection at processing establishments by Canadian inspection officials.

- In 22 of the 37 establishments, FSIS officials found that the Canadian inspection system did not have adequate sanitation controls. FSIS officials found that Canadian establishments did not ensure sanitation controls were adequately implemented or evaluated for effectiveness. FSIS also found that the establishments did not take corrective actions when sanitation controls failed to prevent direct product contamination or adulteration and did not maintain daily records of these activities.
- FSIS officials found that Canadian inspection officials did not implement certain HACCP requirements in 27 of the 37 establishments. FSIS found that Canadian establishments were deficient in validating their HACCP plans, documenting corrective actions, and reassessing the adequacy of the plans.
- As part of the review of specific establishments, FSIS evaluated whether Canadian inspection officials adequately enforced FSIS requirements. FSIS officials found that the Canadian inspection system did not have adequate controls to ensure FSIS requirements were enforced. FSIS officials identified deficiencies in the areas of sanitation controls and HACCP requirements that had not been previously noted by Canadian inspection officials. This condition occurred in 32 of the 37 establishments visited by FSIS officials.
- Of the 37 establishments visited, 28 were establishments that produced processed products. FSIS officials found that Canadian inspection officials provided less than daily inspection at 10 of the 28 processing establishments visited. Foreign establishments should be delisted when FSIS finds a serious deficiency such as this that shows standards equivalent to U.S. standards are not met. However, FSIS did not require the 10 Canadian establishments to be delisted even though FSIS was aware that Canadian policy allowed processing establishments to receive less than daily inspection coverage.⁶

⁶ None of these 10 establishments were slaughter establishments.

In the November 6, 2003, memorandum to the Secretary, FSIS reported that it believed that public health may be compromised if the agency did not immediately take strong enforcement actions in response to the deficiencies noted in the Canadian inspection system. FSIS planned an enforcement review for fiscal year 2004. According to the memorandum to the Secretary, “if the results of the enforcement review are unsatisfactory, FSIS will consider suspending inspection operations in all certified establishments.”

- **No Enforcement Review in 2004**. Despite planning for an enforcement review in 2004, FSIS performed no onsite reviews in Canada in response to the deficiencies noted in 2003. The enforcement review planned for June 2004 was postponed until October 2004 due to resource constraints. On October 8, 2004, FSIS officials notified Canadian inspection officials that the review was indefinitely postponed to give FSIS more time to prepare for the review. However, on October 6, 2004, an email from the Assistant Administrator for International Affairs explained that the Secretary had directed the agency to work with Canadian inspection officials to resolve outstanding differences identified in 2003, which included less than daily inspection in processing establishments.

In 2003, FSIS identified concerns which caused the agency to question the equivalence of the Canadian inspection system and to express concern about U.S. public health. These concerns were not resolved when FSIS implemented the Secretary’s direction and compensating controls (e.g., increased port-of-entry testing) were not instituted to alleviate their concerns. FSIS should implement a protocol for determining when a scheduled enforcement review can be postponed or cancelled. This protocol should provide guidance on the criteria to use for making this decision, the documentation to be completed, and the compensating controls that will be implemented in the interim until the concerns are resolved.

FSIS did perform onsite reviews in December 2004 and February 2005; however, these reviews did not focus on the differences identified in 2003. These two reviews primarily evaluated the implementation of FSIS’ requirements related to BSE. In December 2004, FSIS officials performed a review of 15 Canadian establishments that slaughtered cattle and calves for export to the United States. This review found that Canadian establishments implemented FSIS’ requirements for BSE and controlled the use of hormone implants in calves. In February 2005, FSIS officials visited two Canadian beef slaughter establishments and three establishments that processed this product. This review found that

Canadian inspection officials adequately implemented FSIS' rules regarding BSE and specified risk materials.⁷

- **Serious Concerns Continue in 2005.** In May 2005, FSIS initiated a more thorough examination of the Canadian inspection system. FSIS visited 35 establishments, which included 3 meat slaughter establishments, 21 meat and poultry processing establishments, and 11 meat and poultry establishments that had both slaughter and processing operations. FSIS also evaluated operations for residue and microbiological testing at 12 laboratories. The review was completed in June 2005, and FSIS officials continued to find a number of deficiencies that call into question the equivalence of the Canadian inspection system. As in 2003, the deficiencies included the insufficient implementation of sanitation controls and HACCP requirements by establishments and the lack of enforcement in these areas by Canadian inspection officials. FSIS officials noted, but did not report, less than daily inspection at 17 processing establishments.
 - In 21 of the 35 establishments, FSIS officials found that the Canadian inspection system did not have adequate sanitation controls. FSIS continued to find that Canadian establishments did not ensure sanitation controls were adequately implemented or evaluated for effectiveness. In addition, the establishments did not take corrective actions when sanitation controls failed to prevent direct product contamination or adulteration and did not maintain daily records of these activities.
 - FSIS officials found that Canadian inspection officials did not implement certain HACCP requirements in 19 of the 35 establishments. FSIS again found that Canadian establishments were deficient in validating their HACCP plans, documenting corrective actions, and reassessing the adequacy of the plans.
 - As part of the review of specific establishments, FSIS again evaluated whether Canadian inspection officials adequately enforced FSIS requirements. FSIS officials found that the Canadian inspection system did not have adequate controls to ensure FSIS requirements were enforced. FSIS officials identified deficiencies in the areas of sanitation controls and HACCP requirements that had not been previously noted by Canadian inspection officials. This condition occurred in 29 of the 35 establishments visited by FSIS officials.

⁷ Specified risk materials are prohibited from use for human food. The materials include the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), dorsal root ganglia of cattle 30 months of age and older, tonsils, and distal ileum of the small intestine of all cattle.

In 2003, FSIS identified concerns which caused the agency to question the equivalence of the Canadian inspection system and to express concern about U.S. public health. The same types of concerns were identified in the review completed in June 2005. FSIS should analyze the deficiencies identified in the 2003 and 2005 reviews to determine whether immediate actions are needed to address concerns regarding public health and if additional enforcement measures are needed.

- **Less Than Daily Inspection in Processing Establishments.** On July 29, 2005, we issued a management alert to FSIS which identified a condition that warranted the agency's immediate attention. We reported that FSIS had not taken timely action to resolve the agency's July 2003 finding that Canada does not require daily inspection coverage at processing establishments that export product to the United States. Specifically, the agency identified 10 processing establishments that received less than daily inspection and subsequently Canada reported 252 of its processing establishments did not receive daily inspection coverage during all processing shifts. Almost 700 million pounds of product entered U.S. commerce from these 252 establishments from January 1, 2003 through May 31, 2005. In FSIS' information system, the products were categorized as cuts and trimmings of raw product as well as products with additional processing from pork, veal, beef, poultry, and lamb.

According to established FSIS policy, foreign establishments are required to receive daily inspection coverage in order to be eligible to export to the United States. In the United States, FSIS has a long established history of requiring the presence of an inspector in an establishment at least once per shift per day. In addition, FSIS' actions regarding Canadian processing establishments were not consistent with how the agency treated similarly situated countries. When FSIS identified less than daily inspection in establishments in Australia in June 2004, and Belgium in July 2003, the establishments were immediately delisted and no longer allowed to export product to the United States.

As part of our management alert in July 2005, we recommended that FSIS specify a date by which Canada must provide documentation to demonstrate that its policy of less than daily inspection coverage in processing establishments provides the same level of protection as FSIS' requirement of daily inspection coverage. We also recommended that FSIS establish a time period for the agency to evaluate the equivalency of Canada's submission and implement the results of the equivalence determination.

In response to our recommendations, FSIS agreed to take a number of steps to ensure that the equivalence evaluation and determination is completed in a timely manner and that there is no increased risk to the public health in the United States during that process. Canadian inspection officials agreed to provide documentation and data by June 30, 2007, to demonstrate that its policy of less than daily inspection coverage in processing establishments provide the same level of protection as FSIS' requirement of daily inspection. This amount of time was considered necessary by the FSIS Administrator to develop the plan, collect and analyze the data, and have the results peer reviewed. FSIS agreed to complete its analysis of this documentation and data and make its decision by November 1, 2007. In the interim, FSIS stated that it doubled the sampling of shipments from these processing establishments at the U.S. ports of entry on August 22, 2005. According to FSIS' sampling plan for Canadian product, FSIS would double its sampling of shipments of products imported into the United States, except for shipments of products imported in extremely low volumes. No change was made for the sampling of these shipments because FSIS currently samples all or 50 percent of the shipments imported.

In response to our recommendations, FSIS explained that Canadian inspection officials agreed to increase inspection presence in processing establishments exporting to the United States. In a memorandum dated August 12, 2005, FSIS officials confirmed their understanding regarding the increase in inspection presence. FSIS officials confirmed that Canadian inspection officials "will assure that a government inspector will visit all Canadian processing establishments that are certified for export to the United States at least once during the critical phases of production (for example, verification of critical control points) of products that will be exported to this country." According to FSIS officials, Canadian inspection officials initiated these revisions on August 22, 2005, and completed them on September 12, 2005.

- **No Sampling of Ready-to-Eat Product for *Listeria monocytogenes*.** In April 2004, FSIS initiated a comparison of the United States and Canadian inspection systems. Through this analysis, FSIS identified that Canadian inspection officials did not routinely sample ready-to-eat product for the presence of *Listeria monocytogenes*. FSIS found that Canadian inspection officials require establishments to perform risk-based environmental sampling as a substitute for the United States requirement for risk-based finished product sampling. FSIS needs to establish a definite time period for determining whether the Canadian inspection system control for *Listeria monocytogenes* in ready-to-eat meat and poultry product is equivalent to that of the United States. In addition, FSIS needs to increase port-of-entry reinspection testing in an effort to institute a compensating control. According to FSIS data, over

261 million pounds of ready-to-eat product was exported to the United States from Canada from January 1, 2003 through May 31, 2005.

In March 2005, Canada presented data on environmental testing for *Listeria monocytogenes* and how it relates to the presence of *Listeria monocytogenes* in finished ready-to-eat products. In subsequent meetings, Canadian inspection officials provided FSIS officials with a proposed program to be considered for equivalence with FSIS sampling and monitoring programs. As a result of the discussions of the proposed program, Canadian inspection officials indicated that Canada would consider the development of a study protocol that would be designed to result in data that would demonstrate the comparable value of environmental testing and finished product testing in verifying the absence of *Listeria monocytogenes* in ready-to-eat foods. In August 2005, FSIS requested a status report on this issue.

In July 2003, FSIS identified that Canadian inspection officials were not enforcing requirements equivalent to FSIS' pathogen reduction and HACCP system regulations. In a memorandum to the Secretary in November 2003, FSIS officials stated that the deficiencies in the Canadian inspection system may compromise U.S. public health. The agency did not take timely action to address the serious concerns with the Canadian inspection system. For example, FSIS postponed and ultimately cancelled an enforcement review of the Canadian inspection system. When an enforcement review is recommended by the agency, there should be a documented justification for not performing the scheduled review. The protocol for postponing or canceling a scheduled enforcement review should specify such things as what criteria must be met, what documentation must be completed, and what compensating controls will be implemented in the interim. FSIS also needs to implement protocols for evaluating deficiencies that call into question the equivalence of a foreign country inspection system. For Canada, the deficiencies dealt with the insufficient implementation of sanitation controls and HACCP requirements by establishments and the lack of enforcement in these areas by Canadian inspection officials. The protocols should specify which deficiencies are public health concerns, the timeframes for making an equivalence decision and acting on the decision made, and the compensating controls to be implemented while decisions are being made.

Recommendation 1

Develop and implement a protocol for postponing or canceling a scheduled enforcement review. The protocol should specify what criteria must be met, what documentation must be completed, and what compensating controls should be implemented to address concerns in the interim.

Agency Response.

FSIS concurs with this recommendation and has begun developing a process for evaluating when a scheduled enforcement audit should be postponed or cancelled. This will be completed by March 31, 2006, and implementation will begin immediately thereafter.

OIG Position.

We accept FSIS' management decision. For final action, FSIS needs to provide the Office of the Chief Financial Officer (OCFO) with documentation that describes the process developed for evaluating when a scheduled enforcement review should be postponed or cancelled.

Recommendation 2

Analyze the deficiencies identified in the 2003 and 2005 reviews of the Canadian inspection system to determine whether immediate actions are needed to address concerns regarding public health and if additional enforcement measures are needed to resolve any outstanding concerns. If the deficiencies no longer potentially compromise public health, document the rationale for this conclusion.

Agency Response.

During and immediately following the 2003 and 2005 audits, FSIS addressed audit deficiencies with Canadian Food Inspection Agency officials. For those deficiencies that had potential impact on public health such as product contamination, FSIS auditors required the establishments to take immediate corrective actions. In some instances, FSIS also required enforcement action be taken by Canadian authorities. These enforcement actions included immediate delisting of the establishment or the issuance of a warning letter that required the establishment to take specific corrective actions within 30 days or be delisted.

FSIS believes the analyses we have already conducted of the 2003 and 2005 reviews have identified and resolved all potential public health concerns. In light of this recommendation, FSIS will again review the 2003 and 2005 audit findings to determine if any additional measures are necessary to verify that public health is not being compromised. This review will be completed by December 31, 2005.

Additionally, during the 2003 audit FSIS found that some Canadian processing plants received less than daily inspection, a current requirement for establishments that export meat and poultry products to the United States. Since then, Canada has increased its inspection presence in processing plants

exporting to the United States. Canada has agreed to provide documentation to demonstrate that its policy of less than daily inspection coverage in processing establishments provides the same level of protection as FSIS' requirement of daily inspection. The plan for demonstrating that this inspection system is equivalent must be agreed upon by both countries and peer reviewed. After Canada has collected sufficient data and submits its documentation, FSIS will analyze the documentation and make a determination.

OIG Position.

We accept FSIS' management decision. For final action, FSIS needs to provide OCFO with a copy of the report of FSIS' review to determine if additional enforcement measures are needed to address any outstanding concerns. If FSIS concludes that the deficiencies no longer potentially compromise public health, the FSIS review report should document the rationale for this conclusion.

Recommendation 3

Develop and implement protocols for determining which equivalence deficiencies would question a country's overall equivalence determination. The protocols should specify which deficiencies are public health concerns, the timeframes for making an equivalence decision and acting on the decision made, and the compensating controls to be implemented while decisions are being made.

Agency Response.

FSIS concurs with this recommendation and has begun to develop a process for determining when a country's overall equivalence is questionable and what measures should then be taken by FSIS. This will be completed by March 31, 2006, and implementation will begin immediately thereafter.

OIG Position.

We accept FSIS' management decision. For final action, FSIS needs to provide OCFO with documentation that describes the process developed for determining that a country's overall equivalence is questionable and what measures should then be taken by FSIS.

Recommendation 4

Specify a date by which Canada must provide documentation to demonstrate that its inspection system control for *Listeria monocytogenes* in ready-to-eat meat and poultry products is equivalent to that of the United States. Establish a time period for the agency to evaluate the equivalency of Canada's submission and implement the results of the equivalence determination.

Agency Response.

On November 14, 2005, the Canadian Food Inspection Agency implemented a *Listeria monocytogenes* testing program for ready-to-eat meat and poultry products exported to the United States. This *Listeria monocytogenes* testing program parallels what is currently being done by FSIS for ready-to-eat meat and poultry products in the United States.

OIG Position.

We accept FSIS' management decision. For final action, FSIS needs to provide OCFO with documentation that describes the process for evaluating the *Listeria monocytogenes* testing program implemented by Canadian inspection officials and documentation to support that Canada's *Listeria monocytogenes* testing is equivalent to that of the United States.

Recommendation 5

As a compensating control while the equivalence determination is being made, increase port-of-entry testing of ready-to-eat product for *Listeria monocytogenes*.

Agency Response.

As a compensating control, in each year since 2003, FSIS has doubled port-of-entry testing of Canadian ready-to-eat meat and poultry products for *Listeria monocytogenes*.

OIG Position.

We accept FSIS' management decision. For final action, FSIS needs to provide OCFO with documentation to support that FSIS has doubled port-of-entry testing for *Listeria monocytogenes*.

Scope and Methodology

Our audit focused on evaluating FSIS' assessment of the equivalence of the Canadian inspection system. To do this, we primarily examined FSIS' assessments of the Canadian inspection system from July 2003 through June 2005. In addition, we reviewed the reports of FSIS' onsite reviews since July 2001.

To determine the adequacy FSIS' assessment of the equivalence of the Canadian inspection system, we concentrated our fieldwork at FSIS Headquarters in Washington D.C. We held discussions with officials and reviewed supporting documentation from the Office of International Affairs, the Office of Policy, Program, and Employee Development, and the Office of Field Operations. We also held discussions with staff from the Office of Program Evaluation, Enforcement, and Review and from the Office of Public Health Science, who participated in the most recent onsite review of Canada's inspection system in June 2005.

Our review included analyzing FSIS' overall procedures for reviewing a country's inspection system, as well as those specifically related to Canada's inspection system. We reviewed procedures for conducting annual equivalence reviews, conducting enforcement reviews, and determining which deficiencies would call into question the equivalence of a foreign country's food safety system. We also analyzed FSIS' side-by-side comparison of the inspection systems of the United States and Canada, which was completed in February 2005. Finally, we discussed FSIS' policy for U.S. slaughter and processing establishments to have daily inspection coverage once per day per shift with representatives from FSIS' Office of Policy, Program, and Employee Development, FSIS' Office of Field Operations, and the Office of the General Counsel.

We conducted our audit between May 2005 and September 2005, in accordance with Generally Accepted Government Auditing Standards.

Exhibit A – Agency Response

Exhibit A – Page 1 of 4



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

DEC - 9 2005

TO: Robert W. Young
Assistant Inspector General for Audit
Office of Inspector General

FROM: *Barbara J. Masters*
Barbara J. Masters, D.V.M.
Administrator

SUBJECT: Office of Inspector General (OIG) Official Draft Audit Report – FSIS Assessment of the Equivalence of the Canadian Inspection System, Report No. 24601-5-Hy

We appreciate the opportunity to review and comment on this report. The Food Safety and Inspection Service (FSIS) has reviewed the draft report with great interest and has responded to each of the five audit recommendations. In addition to these responses, we provide the following comments:

In its examination of the actions taken by FSIS to address concerns regarding Canada's inspection system identified during the 2003 and 2005 audits, the draft report focuses on on-site system audits, which are only a single part of the FSIS process for determining and verifying equivalence for some processing establishments in Canada. It's important to note that the equivalence process includes three interrelated and comprehensive activities which, taken together, provide the basis for FSIS equivalence determinations. These are: on-site system audits, port-of-entry reinspection (POE), and recurring document analyses.

The on-site system audits are a combination of establishment reviews, laboratory reviews, and government oversight. Establishment reviews provide FSIS with "real time" observations of how a foreign food regulatory program is demonstrating compliance with FSIS inspection requirements and its own inspection regulations. When deficiencies are identified, FSIS immediately evaluates the findings, including how a foreign government addresses them, which collectively provide FSIS a benchmark to evaluate whether a foreign food regulatory system is maintaining equivalence. POE reinspections by FSIS of product from exporting countries provide additional evidence of how a foreign inspection system is functioning. Each imported lot is inspected and representative samples of product are examined, which provides FSIS further indicators of foreign inspection system equivalence. The third component, recurring document analyses, is the process whereby FSIS reviews the laws, regulations and implementing policies of a foreign food regulatory system to ensure its inspection infrastructure remains in place and to identify any changes that may differ from previous document analyses.

The equivalence evaluation FSIS is conducting of Canada's processing inspection system is an example of this three-part process. First, FSIS conducted on-site system audits of Canada's inspection system in 2003, 2004, and 2005. Second, FSIS reinspected millions of pounds of

product from Canada, providing hands-on daily confirmation that product entering the U.S. from Canada's inspection system is safe and wholesome. And third, during the 2003 to 2005 time period, FSIS conducted extensive document reviews of Canada's inspection requirements including a thorough side-by-side assessment of Canadian and U.S. inspection regulations. Together, these three components have provided FSIS confidence that Canada's meat and poultry food regulatory system continues to be equivalent.

Notably, during and immediately following the 2003 and 2005 audits, FSIS addressed audit deficiencies with Canadian Food Inspection Agency (CFIA) officials. For those deficiencies that had potential impact on public health such as product contamination, FSIS auditors required the establishments to take immediate corrective actions. In some instances, FSIS also required enforcement action be taken by Canadian authorities. These enforcement actions included immediate delisting of the establishment or the issuance of a warning letter that required the establishment to take specific corrective actions within 30 days or be delisted.

Section 1. Equivalency of the Canadian Inspection System

1. Recommendation 1

Develop and implement a protocol for postponing or canceling a scheduled enforcement review. The protocol should specify what criteria must be met, what documentation must be completed, and what compensating controls should be implemented to address concerns in the interim.

Agency Response

FSIS concurs with this recommendation and has begun developing a process for evaluating when a scheduled enforcement audit should be postponed or cancelled. This will be completed by March 31, 2006, and implementation will begin immediately thereafter.

2. Recommendation 2

Analyze the deficiencies identified in the 2003 and 2005 reviews of the Canadian inspection system to determine whether immediate actions are needed to address concerns regarding public health and if additional enforcement measures are needed to address any outstanding concerns. If the deficiencies no longer potentially compromise public health, document the rationale for this conclusion.

Agency Response

During and immediately following the 2003 and 2005 audits, FSIS addressed audit deficiencies with Canadian Food Inspection Agency (CFIA) officials. For those deficiencies that had potential impact on public health such as product contamination, FSIS auditors required the establishments to take immediate corrective actions. In some instances, FSIS also required enforcement action be taken by Canadian authorities. These enforcement actions included immediate delisting of the establishment or the issuance of a warning letter that required the establishment to take specific corrective actions within 30 days or be delisted.

FSIS believes the analyses we have already conducted of the 2003 and 2005 reviews have identified and resolved all potential public health concerns. In light of this recommendation, FSIS will again review the 2003 and 2005 audit findings to determine if any additional measures are necessary to verify that public health is not being compromised. This review will be completed by December 31, 2005.

Additionally, during the 2003 audit FSIS found that some Canadian processing plants received less than daily inspection, a current requirement for establishments that export meat and poultry products to the U.S. Since then, Canada has increased its inspection presence in processing plants exporting to the U.S. Canada has agreed to provide documentation to demonstrate that its policy of less than daily inspection coverage in processing establishments provides the same level of protection as FSIS' requirement of daily inspection. The plan for demonstrating that this inspection system is equivalent must be agreed upon by both countries and peer reviewed. After Canada has collected sufficient data and submits its documentation, FSIS will analyze the documentation and make a determination.

3. Recommendation 3

Develop and implement protocols for determining which equivalence deficiencies would question a country's overall equivalence determination. The protocols should specify which deficiencies are public health concerns, the timeframes for making an equivalence decision and acting on the decision made, and the compensating controls to be implemented while decisions are being made.

Agency Response

FSIS concurs with this recommendation and has begun to develop a process for determining when a country's overall equivalence is questionable and what measures should then be taken by FSIS. This will be completed by March 31, 2006, and implementation will begin immediately thereafter.

4. Recommendation 4

Specify a date by which Canada must provide documentation to demonstrate that its inspection control for *Listeria monocytogenes* (*Lm*) in ready-to-eat (RTE) meat and poultry products is equivalent to that of the U.S. Establish a time period for the agency to evaluate the equivalency of Canada's submission and implement the results of the equivalence determination.

Agency Response

On November 14, 2005, the CFIA implemented an *Lm* testing program for RTE meat and poultry products exported to the U.S. This *Lm* testing program parallels what is currently being done by FSIS for RTE meat and poultry products in the U.S.

5. Recommendation 5

As a compensating control while the equivalence determination is being made, increase port-of-entry testing for RTE product for *Lm*.

Agency Response

As a compensating control, in each year since 2003, FSIS has doubled port-of-entry testing of Canadian RTE meat and poultry products for *Lm*.

If you have any questions, please call Jane Roth, Acting Assistant Administrator, Office of Program Evaluation, Enforcement and Review on (202) 720-8609.