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Northeast Region

Audit Report

Animal and Plant Health Inspection Service Oversight of the Importation of Beef Products from Canada

Report No. 33601-01-Hy
February 2005

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

DATE: February 14, 2005

REPLY TO
ATTN OF: 33601-01-Hy

SUBJECT: Oversight of the Importation of Beef Products from Canada

TO: W. Ron DeHaven
Administrator
Animal and Plant Health Inspection Service

Barbara J. Masters
Acting Administrator
Food Safety and Inspection Service

ATTN: William J. Hudnall
Deputy Administrator
Marketing and Regulatory Programs – Business Services

Ronald F. Hicks
Assistant Administrator
Office of Program Evaluation, Enforcement and Review

This report presents the results of our audit of oversight of the importation of beef products from Canada. Your response to the draft, dated February 9, 2005, is included as exhibit A. Excerpts of your response and the Office of Inspector General's (OIG) position are incorporated into the Findings and Recommendations section of the report. Based on your response, management decision has been reached on all recommendations except No. 3. Please follow your agency's internal procedures in forwarding documentation for final action to the Office of the Chief Financial Officer. Management decisions for the remaining recommendation can be reached once you have provided the additional information outlined in the report section OIG Position.

In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the corrective actions taken or planned, and the timeframes for implementation of the remaining recommendation. Please note that the regulation requires management decision to be reached on all recommendations within 6 months of report issuance

/s/

ROBERT W. YOUNG
Assistant Inspector General
for Audit

Executive Summary

Animal and Plant Health Inspection Service's Oversight of the Importation of Beef Products from Canada (Audit Report No. 33601-01-Hy)

Results in Brief

This report presents the results of the Office of Inspector General's (OIG) audit of the Animal and Plant Health Inspection Service's (APHIS) oversight of the importation of beef products from Canada following the detection of a Canadian cow with bovine spongiform encephalopathy (BSE) in May 2003. In June 2004, we initiated several actions in response to concerns raised by four U.S. Senators that the U.S. Department of Agriculture (USDA) did not follow appropriate safety measures, beginning sometime in the fall of 2003, in allowing expanded Canadian beef imports into the United States. We reviewed USDA's actions pertaining to the importation of Canadian products, including the use of risk mitigation[1] measures.

On May 20, 2003, the 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 BSE. Prior to this time, there was a free flow of trade between the United States and Canada for live cattle and beef. Due to the serious impact on trade, USDA officials sought a method to allow limited imports from Canada and determined to use the APHIS permit process as a vehicle to facilitate trade. At that time, APHIS did not have a history of issuing permits for the importation of edible meat and meat products. Veterinary import permits were generally issued for items derived from animals, such as blood, cells or cell lines, hormones, and microorganisms including bacteria, viruses, protozoa, and fungi.

On August 8, 2003, the Secretary of Agriculture (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 under 30 months of age to resume. This rule for live animals and processed meat products was issued January 4, 2005.

The Secretary's announcement on August 8, 2003, regarding low-risk products followed USDA's review of the results of Canada's epidemiological investigation into the detection of BSE in that country. Based on the results

[1] Risk mitigations include such actions as certificates indicating the product is pure liver, Canadian Food Inspection Agency (CFIA) verification that calves were 36 weeks of age or less when slaughtered, and CFIA verification that animals are not known to have been fed prohibited products during their lifetime.

of the investigation, as well as international guidelines[2] that indicated that products derived from young animals do not pose a risk to human health, USDA issued permits to allow these low-risk products into the United States.

Subsequent to the Secretary's announcement, APHIS issued 1,155 permits[3] allowing the import of a variety of products from Canada, to include many items that had been included in the Secretary's announcement as well as other items that were not initially identified as allowable low-risk products. In April 2004, a lawsuit was filed in U.S. District Court in Montana, which resulted in a temporary restraining order that identified the specific low-risk Canadian products that were eligible for import into the United States. The list of low-risk products was the same as the list posted on August 15, 2003, by APHIS on its website as a clarification of the Secretary's August 8, 2003, announcement. On May 5, 2004, the District Court converted the temporary restraining order into a preliminary injunction. Among other things, the preliminary injunction included an exhibit listing the specific Canadian products that would be considered low-risk and details of required risk mitigations.

To accomplish our review of USDA's actions pertaining to the importation of Canadian products, we interviewed officials from APHIS, the Food Safety and Inspection Service (FSIS), and the Office of the General Counsel (OGC). We analyzed APHIS records relating to the oversight of imported Canadian product, to include a review of the 1,155 import permits and associated documentation. We met with personnel from the U.S. Department of Homeland Security's Customs and Border Protection (CBP) in Detroit, Michigan and Sweetgrass, Montana to understand their actions to enforce restrictions on the importation of ruminant products from Canada. We also visited FSIS import reinspection facilities located in Buffalo, New York; Detroit, Michigan; and Sweetgrass, Montana. At these facilities, we analyzed documentation on file for 12,427 shipments of ruminant products to determine whether the product imported from Canada met APHIS requirements. These facilities reinspected more than 646 million of the 802 million pounds of Canadian product presented for entry into the United States between September 2003 and September 2004.

From August 2003 to April 2004, APHIS officials allowed a gradual expansion in the types of Canadian beef products approved for import into the United States. The expansions in product type included processed products, bone-in product, and edible bovine tongues, hearts, kidneys, and lips. In October 2003, APHIS allowed bovine tongues despite the APHIS Transmissible Spongiform Encephalopathy (TSE) Working Group[4]

[2] The International Office of Epizootics, the international standard-setting organization for animal health, established these guidelines.
[3] As of September 16, 2004.
[4] Created by APHIS to analyze risks of BSE to the United States, disseminate accurate information about TSEs, and act as a reference source for responding to questions about TSEs.

conclusion in June 2003 that fresh or frozen bovine tongues were "moderate risk" products,[5] even when the required risk mitigations were in place. Thus, bovine tongues, one of the items for which APHIS approved import permits, were deemed as posing a "moderate risk," and not a "low risk" by the APHIS TSE Working Group.

The Chairperson of the TSE Working Group explained that the risk status for bovine tongues changed from moderate to low some time between June and November 2003, although the change was not documented prior to the November 2003 issuance of APHIS' "Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States." The risk analysis categorized bovine tongues as eligible product when Canadian inspection officials verify the risk mitigation, which is that tonsils are removed.

Additionally, APHIS allowed an expansion in the type of Canadian facilities that would be allowed to produce items for export to the United States. The gradual expansion occurred because the agency employees tasked with administering the permit process did not consider the initial announcement made by the Secretary to exclude products similar to those on the published list of low-risk products, if APHIS had concluded that the products posed similar risk levels. However, APHIS did not develop documentation to support the agency's conclusions that the additional products were low-risk products. APHIS also did not have a review structure or other monitoring process in place to identify discrepancies between publicly stated policy and agency practice. According to APHIS officials, they considered the initial announcement made by the Secretary to be part of an effort to demonstrate to the world that such trade with Canada was safe and appropriate. Accordingly, they allowed the import of products they considered low risk in an attempt to further that greater effort. However, APHIS did not document the process it used to determine the additional products were low risk.

As a result of the "permit creep" that occurred between August 2003 and April 2004, APHIS issued permits for the import of beef tongue as well as other permits for products with questionable eligibility. Further, the agency allowed the import of products from Canadian facilities that produced both eligible and ineligible products, thus increasing the possibility that higher-risk product could be inadvertently exported to the United States. This practice contrasted with APHIS' publicly stated policy that only Canadian facilities that limited production to eligible products would be allowed to ship to the United States. In addition, APHIS did not

[5] "Recommendations of APHIS TSE Working Group for allowing certain commodities from Canada to be imported into the United States," dated June 16, 2003. When required risk mitigation measures are in place, to include various CFIA verifications, removal of tonsils, and random sample analysis by USDA of any suspicious tissue to confirm absence of specified risk materials, fresh and frozen bovine tongues have a "moderate" risk.

communicate its decisions to all interested parties and USDA was criticized by segments of the public, the cattle industry, and the U.S. Congress.

APHIS issued permits to allow the import of beef cheek meat with questionable eligibility because the agency did not establish a clear working definition for the general term "boneless beef." Instead of coordinating with FSIS, APHIS reviewers relied upon their own understanding of the term. Some APHIS reviewers considered the term "boneless beef" broadly, to mean any bovine meat that did not contain a bone. Thus, some applicants who requested permits to import beef cheek meat and other products received permits allowing the import of "boneless beef or boneless beef trim." As a result, over 63,000 pounds of beef cheek meat with questionable eligibility entered U.S. commerce from Canada.

Further, we found that FSIS did not always communicate effectively about the eligibility status of beef cheek meat. FSIS distributed information to its import inspectors by way of a series of numbered memoranda, titled Part 4, Canada, BSE Restrictions, Revision 2 through Revision 11. Some of the issuances were supplemented by additional guidance, in the form of supplemental memoranda. However, in our opinion, FSIS managers did not ensure consistent interpretation of the provisions of the various memoranda, a factor that contributed to the entry of the previously mentioned 63,000 pounds of beef cheek meat with questionable eligibility. Because APHIS changed its instructions to FSIS frequently and did not document the direction provided to FSIS,[6] it was even more difficult for FSIS to keep its field staff fully apprised of the status of product eligibility.

FSIS officials did not agree that the import inspectors misinterpreted the instructions in the numbered memoranda. Furthermore, FSIS officials asserted that the 63,000 pounds of beef cheek meat was eligible for import when it was imported from April to June 2004. However, they agreed that controls should be strengthened to better communicate the eligibility of product that frequently changed as beef cheeks did from August 2003 to July 2004. Two FSIS import inspectors we interviewed advised us that beef cheeks had been "going back and forth" regarding eligibility. APHIS notified FSIS that effective July 20, 2004, beef cheek meat was not an eligible product for import into the United States. According to APHIS direction, beef cheek meat has not been eligible for import since July 20, 2004. As of the date of this report, it is still not eligible for import. Some FSIS officials assert that the beef cheek meat was eligible product. In contrast, the APHIS National Incident Commander for BSE Enhanced Surveillance stated in an August 18, 2004 interview, that further discussion was still required with respect to the import of cheek meat and that no new

[6] We found that APHIS did not document its direction to FSIS prior to April 2004 when the Ranchers-Cattlemen Action Legal Fund (R-CALF) filed a lawsuit against USDA in U.S. District Court in Montana.

scientific information on this topic had been considered by APHIS. Given the importance of the issues, ongoing litigation, and differences in scientific opinion, it would have been prudent for APHIS to write down its decisions about the eligibility status of beef cheek meat at points in time. However, the agency did not do so; or did not retain such documentation for our review.

In January 2005, FSIS assessed the shipments of beef check meat and concluded, "FSIS has no reason to believe that these four shipments[7] of beef cheek meat are injurious to health." In its assessment, FSIS explained that in January 2004, the agency implemented interim final rules that prohibited the use of specified risk materials for human food. On the matter of beef cheek meat, the FSIS rule maintained that beef cheeks are not part of the skull, which is a specified risk material. The FSIS rule continued to allow the use of beef cheek meat for human food, provided that the meat is not contaminated with specified risk materials. FSIS further supported its conclusion on the basis that Canada had a pre-existing equivalent specified risk material system in place. However, as previously noted, beef cheek meat is not a product that is currently eligible to be imported into the United States.

APHIS issued 1,155 permits for the importation of ruminant products from Canada without ensuring that the agency had an appropriate system of internal controls to manage the process. The APHIS permit system was originally designed to allow for the import of research quantities (generally small amounts) of material into the United States. According to APHIS officials, this permit system handled approximately 400 permit requests annually. The procedures that APHIS had developed for handling permit requests for small amounts of product were not adequate to deal with the high volume of requests for large quantities of commercial use beef. The agency did not implement or finalize standard operating procedures for processing the large volume of permits. For example, APHIS did not establish controls to ensure that risk mitigation measures were consistently applied. We found that 8 of the 83 permits issued for bovine liver did not include the risk mitigation measure that the livers be from animals slaughtered after August 8, 2003.[8] We also found that APHIS did not implement requirements to perform onsite monitoring of permit holders, Canadian facilities, or inspection personnel[9] at U.S. ports of entry. As a result, there was reduced assurance that Canadian beef entering the United States was low-risk. Some product with questionable eligibility, as described above, entered U.S. commerce.

[7] The four shipments included one shipment identified by FSIS that entered U.S. commerce in April 2004 and three shipments that we identified that entered U.S. commerce in May and June 2004.
[8] The date the Secretary of Agriculture announced that USDA would begin to accept applications for import permits for certain low-risk products from Canada.
[9] The inspection personnel include CBP agriculture inspectors and FSIS import inspectors.

We analyzed data for 9,953 shipments, a 100 percent review of all shipping documents from May 2004 through September 2004, at the 4 FSIS inspection houses that we visited. We also analyzed 11 shipments reinspected in October 2004 by the 2 FSIS inspection houses in Sweetgrass, Montana when we were performing onsite fieldwork. This analysis, a total of 9,964 shipments, was based on the preliminary injunction filed on May 5, 2004, that described the ruminant products eligible to be imported from Canada. As part of that review, we identified over 42,000 pounds of product with questionable eligibility.

Recommendations In Brief

APHIS needs to institute procedures for communicating changes in policy to all interested parties, e.g., importers and the public, and monitoring the consistency between agency practice and publicly stated policy. APHIS also needs to strengthen its controls and finalize its procedures for issuing and monitoring permits for commercial quantities of products.

We recommend that FSIS implement controls to communicate the specific eligibility of product when its eligibility status changes. FSIS should also implement an edit check in its import information system to identify ineligible product presented for entry into the United States.

Agency Response

APHIS and FSIS agreed with the report's recommendations. We have incorporated excerpts from the agencies' 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 all of the recommendations except No. 3.

Abbreviations Used in This Report

AIIS	Automated Import Information System
APHIS	Animal and Plant Health Inspection Service
AVIC	Area Veterinarian in Charge
BSE	Bovine Spongiform Encephalopathy
CBP	U.S. Customs and Border Protection
CFIA	Canadian Food Inspection Agency
C.F.R.	Code of Federal Regulations
DHS	U.S. Department of Homeland Security
FSIS	Food Safety and Inspection Service
HCRA	Harvard Center for Risk Analysis
NCIE	National Center for Import-Export
OCFO	Office of the Chief Financial Officer
OGC	Office of the General Counsel
OIG	Office of Inspector General
PPQ	Plant Protection and Quarantine
R-CALF	Ranchers-Cattlemen Action Legal Fund
Secretary	Secretary of Agriculture
SOPs	Standard Operating Procedures
SRM	Specified Risk Material
TSE	Transmissible Spongiform Encephalopathy
USDA	United States Department of Agriculture
VRS	Veterinary Regulatory Services
VS	Veterinary Services

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Background and Objectives

Background

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) is responsible for protecting and promoting U.S. agricultural health. The APHIS mission is an integral part of USDA's efforts to provide the Nation with safe and affordable food.

Since 1989, APHIS has led an interagency effort to monitor bovine spongiform encephalopathy (BSE), widely known as "mad cow disease." BSE is a chronic, degenerative 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. BSE belongs to the family of diseases known as transmissible spongiform encephalopathy (TSE), the causes of which are not fully known. TSE diseases have a prolonged incubation period of months or years and result in a progressive, debilitating neurological illness, which is always fatal. Affected animals may display changes in temperament, such as nervousness or aggression, abnormal posture, decreased milk production, or loss of body weight despite continued appetite. There is no test to detect BSE in a live animal.

After Canada discovered a BSE-infected cow on May 20, 2003, Canada was added to the Code of Federal Regulations (C.F.R.) listing of regions where BSE exists. This action was consistent with APHIS program regulations[10] that prohibit importation of beef products from regions in which BSE is known to exist. However, USDA and APHIS officials were interested in restoring some level of trade with Canada. Accordingly, the APHIS Administrator requested the agency's TSE Working Group to determine what low-risk products from Canada could enter the United States. On June 16, 2003, the TSE Working Group made its recommendations for allowing certain commodities from Canada to be imported into the United States to the APHIS Deputy Administrator for Veterinary Services. The TSE Working Group categorized each commodity as low, moderate, or high risk based on both the inherent risk of the product and the effectiveness of potential risk mitigation. The Chairperson of the TSE Working Group stated that their recommendations were based on research into BSE that has occurred since 1990.

On August 8, 2003, the Secretary of Agriculture (Secretary) announced that USDA would begin to accept applications for import permits for certain low-risk products from Canada. The Secretary's announcement followed USDA's review of the results of Canada's epidemiological investigation into the detection of BSE in that country. Based on the results of the

[10] 9 C.F.R. § 94.18(a)(1), January 1, 2003

investigation, as well as international guidelines[11] that indicate that products derived from young animals do not pose a risk to human health, USDA issued permits to allow these products to be imported into the United States. The regulation[12] allows the APHIS Administrator to prescribe the conditions under which beef products can be brought into or through the United States under permit. The Secretary's announcement included the following Canadian products:

- Boneless sheep or goat meat from animals under 12 months of age;
- Boneless bovine meat from cattle under 30 months of age;
- Boneless veal (meat) from calves that were 36 weeks of age or younger at slaughter;
- Fresh or frozen bovine liver;
- Vaccines for veterinary medicine for non-ruminant use; and
- Pet products and feed ingredients that contain processed animal protein and tallow of non-ruminant sources when produced in facilities with dedicated manufacturing lines.

The list of low-risk Canadian products associated with the August 8, 2003, announcement specifically excluded manufacturing trim derived from bone, advanced meat recovery, mechanically separated meat, ground meat, or low-temperature rendered product. On August 15, 2003, USDA amended the list of allowable products as a clarification of the August 8, 2003, announcement. The clarification was in response to questions that came up after the first list was issued. The list was amended to include "trim" from boneless beef from cattle less than 30 months of age and veal (including carcasses) from calves 36 weeks of age or under. This type of "trim" was part of the boneless product determined to be low-risk by the APHIS TSE Working Group.

APHIS officials examined the requests for these import permits, taking into account steps Canada had taken, such as mandating the removal of specified risk materials (SRM's), e.g., brain, skull, and spinal cord, from certain cattle at slaughter, to further reduce any risks associated with the meat products. The import permits issued by APHIS required that risk-reducing steps be taken in order for the permit to be valid. APHIS relied on Canadian inspection officials to certify that the required risk mitigation measures were in place and operating.

In September 2003, APHIS revised the requirement that Canadian facilities would not be allowed to export beef or other bovine products to the United States, under permit, if they handled any products not included on the list of low-risk materials. On September 4, 2003, APHIS allowed facilities that

[11] The International Office of Epizootics, the international standard-setting organization for animal health, established these guidelines.
[12] 9 C.F.R. § 93.401(a), January 1, 2003

slaughter cattle over 30 months of age to produce beef for export to the United States, as long as the facilities had an approved product segregation plan. On September 25, 2003, APHIS allowed facilities that process cattle over 30 months of age to export beef product to the United States, as long as the facilities had an approved product segregation plan.

On October 3, 2003, APHIS decided to expand the list of low-risk products to include processed products containing beef, e.g., roast beef, ground beef, lasagna, and frozen hamburger patties. On October 22, 2003, APHIS also decided to expand the list of low-risk products to include edible bovine tongues, hearts, kidneys, and lips.

On October 31, 2003, USDA released the findings of a second assessment conducted by the Harvard Center for Risk Analysis (HCRA) that confirmed the findings of the initial study released in 2001. The study evaluated the potential for BSE to spread if it were introduced from Canada prior to May 20, 2003, when USDA banned products from Canada due to the discovery of a BSE-infected cow. The assessment specifically examined scenarios for the likely introduction of BSE from Canada into the United States. The scenarios used for this assessment included hypothetical introductions at various times of both infected animals and contaminated animal feed. The study found that even if infected animals or ruminant feed material entered the U.S. animal agriculture system from Canada, the risk of it spreading extensively within the U.S. herd was low, that any possible spread would now have been reversed by controls put in place in the late 1990's, and that eventually, the disease would be eliminated from the United States.

On November 4, 2003, APHIS issued a proposed rule in the *Federal Register* to amend the regulations regarding the importation of animals and animal products. The rule proposed to recognize a category of regions that present a minimal risk of introducing BSE into the United States, via live ruminants and ruminant products. The proposed minimal risk regions would include regions in which an animal has been diagnosed with BSE but in which specific preventative measures have been in place for an appropriate period of time to reduce the risk of BSE being introduced to the United States. The preventative measures included: (1) restrictions on the importation of animals and animal products sufficient to minimize the possibility that infected animals or animal products from regions at higher risk for BSE would be imported into the proposed minimal risk region; (2) surveillance for BSE at levels that meet or exceed recommendations by the International Office of Epizootics, the international organization of animal health; and (3) a ban on feeding of ruminant protein to ruminants. In the proposed rule, APHIS explained that it intended to add Canada to the list of minimal risk regions.

In the November 4, 2003, proposed rule, APHIS proposed to allow the importation of certain live ruminants and ruminant products and byproducts from minimal risk regions. The ruminant and ruminant products included such items as: (1) bovine animals less than 30 months of age for immediate slaughter; (2) bovine animals for feeding to be moved to a designated feedlot and then to slaughter at less than 30 months of age; (3) fresh meats from bovines less than 30 months of age; (4) fresh whole or half carcasses of bovines less than 30 months of age; (5) bovine liver; and (6) certain types of gelatin and tallow.

On November 25, 2003, APHIS decided to allow Canadian facilities that receive and process bone-in beef product from the United States, New Zealand, or Australia to export bone-in beef product to the United States.

On January 12, 2004, the Food Safety and Inspection Service (FSIS) issued an interim final rule in the *Federal Register* to amend the Federal meat inspection regulations to designate certain material as SRM's, declare these SRM's as inedible, and prohibit their use for human food. The items listed as SRM's were: the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the traverse 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.

On March 8, 2004, APHIS reopened in the *Federal Register* the comment period on the proposed rule that the agency issued on November 4, 2003. On December 23, 2003, USDA had announced a presumptive positive case of BSE in a Holstein cow in Washington State. An international reference laboratory in England verified the diagnosis on December 25, 2003. Detection of BSE in the imported cow in Washington State occurred after APHIS conducted its analysis of the risk of importing ruminants and ruminant products and byproducts under the conditions of the November 4, 2003, proposed rule. APHIS asserted that it was important for the agency to explain the extent to which it believed that detection might affect the conclusions of the risk analysis, and, consequently, the validity of the proposed rule. Based on APHIS' original risk analysis, along with risk mitigation measures currently in place and those that would be added by the proposed rule, the agency concluded that a BSE case in a second cow of Canadian origin did not alter its risk estimate. On January 4, 2005, the rule proposed by APHIS on November 4, 2003, was published in the *Federal Register*. The rule is scheduled to become effective on March 7, 2005.

The March 8, 2004, *Federal Register* notice explained that FSIS had designated certain SRM's and prohibited the SRM's from the human food supply. Accordingly, APHIS did not continue to believe that it was necessary to require that beef imported from BSE minimal risk regions be

derived only from cattle less than 30 months of age, provided equivalent measures are in place to ensure that SRM's are removed when the animals are slaughtered, and that such measures as are necessary are in place. APHIS had concluded that such measures had already been put in place in Canada.

On April 19, 2004, APHIS announced that beef products eligible for import into the United States included bone-in, boneless, ground meat, and further processed beef products. This action led to a lawsuit filed by the Ranchers-Cattlemen Action Legal Fund (R-CALF) in U.S. District Court in Montana, which resulted in a preliminary injunction that identified the low-risk Canadian products that were eligible for import into the United States. The list of low-risk products was the same as the list posted on August 15, 2003, by APHIS on its website as a clarification of the Secretary's August 8, 2003, announcement.

On May 20, 2004, and June 23, 2004, the Inspector General received letters from four U.S. Senators expressing concerns about USDA's actions regarding the importation of Canadian beef products into the United States. The Senators expressed concern that USDA did not follow appropriate safety measures in allowing expanded Canadian beef imports into the United States.

Objectives

Our audit objective was to evaluate APHIS' oversight of the importation of products from Canada. Specifically, we determined whether (1) APHIS met existing regulatory requirements and established policies and procedures when it issued permits allowing the importation of Canadian beef products, (2) actions taken by APHIS to expand the scope of approved permits to import Canadian beef products met existing requirements and procedures, (3) APHIS properly considered and implemented risk mitigation measures, and (4) APHIS kept other Federal agencies (e.g., USDA's FSIS and the U.S. Department of Homeland Security's (DHS) Customs and Border Protection (CBP)) adequately apprised of matters regarding the importation of Canadian beef products.

To accomplish our objectives, we performed fieldwork at APHIS headquarters in Riverdale, Maryland. We analyzed the 1,155 import permits issued by APHIS from August 2003 to September 2004 and evaluated the controls under which they were processed. We visited four FSIS import reinspection houses and two ports of entry to test the adequacy of controls implemented to ensure that only eligible Canadian product entered the United States. We also met with officials from USDA's FSIS and DHS' CBP in Washington, D.C. to understand how APHIS informed them about matters regarding the importation of Canadian beef products. (See Scope and Methodology for details.)

Findings and Recommendations

Section 1. Agency Decisions to Expand Canadian Imports

Finding 1 APHIS Expanded the Types of Products and Types of Facilities

From August 2003 to April 2004, APHIS allowed the expansion of the types of Canadian beef products approved for import into the United States. The expansions in product type included processed products, bone-in product, and edible bovine tongues, hearts, kidneys, and lips. During this period, APHIS also allowed expansions of the types of Canadian facilities approved to produce items for export to the United States. These expansions conflicted with public announcements by USDA, and APHIS did not seek public comments on these changes. According to APHIS officials, this occurred because APHIS officials believed that the list of low-risk products included in the initial August 8, 2003, announcement was not intended to exclude similar products that posed similar risk levels. Agency officials asserted that they believed that they could add products to the list if the risk factors and risk levels associated with such products were consistent with the products listed in the initial announcement. APHIS officials considered the initial announcement made by the Secretary to be part of an effort to demonstrate to the world that such trade with Canada was safe and appropriate. Accordingly, they allowed the import of products they considered low risk in an attempt to further that greater effort. As a result, APHIS did not communicate these actions and explain them to all interested parties, products with questionable eligibility entered U.S. commerce, and segments of the public, the cattle industry, and the U.S. Congress criticized USDA.

- Allowing the import of processed products. The initial August 8, 2003, announcement of the beef products allowed as imports from Canada did not include processed products. However, APHIS employees almost immediately began issuing permits for a variety of processed items, which was not consistent with the APHIS published listing of low-risk products. On August 27, 2003, APHIS issued the first permit that allowed the importation of processed products containing beef, e.g., roast beef, beef pastrami, corned beef, and pizza with beef topping. APHIS did not announce or otherwise publicize the decision to allow the importation of Canadian processed beef product. According to APHIS officials, announcing this decision was not necessary because the processed products were no different than any other low-risk product that was already permitted to enter. An APHIS official explained that they communicated the decisions to importers on a case-by-case basis, as APHIS received requests to import processed product. The agency did not have a review structure or other monitoring process in place to

identify the discrepancy between publicly stated policy and agency practice.

In October 2003, after the issuance of multiple permits for processed products, the APHIS Administrator formally decided to allow Canadian processed beef products to be imported into the United States. This decision allowed ground beef to enter when included in processed products but continued to prohibit the direct import of ground beef. The decision also allowed the import of processed beef products (ground beef, low temperature rendered products, and other processed products that lose their identity) when coupled with specified risk mitigation measures. In the decision memorandum documenting his decision, the APHIS Administrator noted that this allowed the use of certain ground products and demonstrated acceptance of the Canadian Food Inspection Agency's (CFIA) control of process verification steps. The APHIS Administrator also noted that this decision would appear to be inconsistent by allowing ground beef to be imported in certain processed products while continuing to prohibit the direct import of ground beef.

The APHIS Administrator further expanded the decision on processed product on October 23, 2003, to allow the direct import of ground meat. The memorandum documenting the APHIS Administrator's decision noted that this decision addressed industry concerns that permit policies were too restrictive for trade and maintained consistency by allowing the entry of meat from animals less than 30 months of age regardless of processing. The decision memorandum also noted that this decision constituted a significant change in policy without opportunity for public comment. Further, the decision noted that this change increased the possibility that higher-risk product – mechanically separated product or product from animals more than 30 months of age – may be imported into the United States due to possibilities of a breakdown in the segregation process in the facility or of mislabeling. Nevertheless, the Administrator decided to allow the direct import of ground meat.

The APHIS Administrator's memorandum documenting the decision to allow the import of processed meat, either in processed product or directly, included the requirement that the product would be "processed in a CFIA inspected processing facility that has a CFIA approved segregation plan … that has undergone review and approval by the National Center for Import and Export (NCIE)." APHIS officials explained that this requirement only applies if the processing facility receives meat from animals less than 30 months of age and meat from animals more than 30 months of age. In our opinion, this requirement, as documented in the decision memorandum, applied to all facilities that processed meat. However, when we attempted to review the segregation plans that were required by the decision memorandum, the Director of the

APHIS NCIE advised us that only one such plan had been received and that plan had not been considered to be acceptable. That is, not a single Canadian facility met the minimum requirement, set forth in the Administrator's decision memorandum, of having a product segregation plan that had been reviewed and approved by APHIS NCIE. Nevertheless, our review disclosed that APHIS issued at least 55 permits allowing the import of such processed beef products as ground beef, frozen hamburger patties, lasagna, meatballs, pot roasts, potpies, casseroles, pepperoni, jerky, sausage, and frankfurters. According to data maintained by FSIS, over 5.6 million pounds of processed products entered U.S. commerce from September 1, 2003 to April 30, 2004.

- Allowing imports from Canadian facilities that handle higher-risk products. One of the requirements put in place on August 8, 2003, was that Canadian facilities would not be allowed to export beef or other bovine products to the United States, under permit, if they handled any products not included on the list of low-risk materials. That is, for a slaughter facility to prepare beef for export, the facility would be required to limit its slaughter of cattle to those under 30 months of age that had not been fed prohibited products. The purpose of this condition was to reduce the chance that higher-risk product (mechanically separated product or product from animals more than 30 months of age) would be accidentally co-mingled with the low-risk product and exported to the United States. In less than a month, on September 4, 2003, APHIS decided to allow facilities that slaughter older cattle to produce beef for export to the United States, as long as the facility had an approved product segregation plan. APHIS officials did not announce or otherwise publicize this change in practice. APHIS relied on CFIA to certify that required risk mitigation measures were in place.

  Another expansion of the types of facilities eligible to export products to the United States occurred after the National Food Processors Association requested permission to import otherwise eligible products that were further processed at Canadian facilities that also processed ineligible products. On September 25, 2003, APHIS agreed to allow this practice, but did not make any public announcement. A decision memorandum approved by the APHIS Administrator on October 23, 2003, documented the various options considered.

  According to the decision memorandum, the change in practice addressed industry concerns that permit policies were too restrictive for trade. Additionally, APHIS considered that allowing the entry of meat from animals less than 30 months of age, regardless of processing, provided more consistency than previous policy. The memorandum notes that disadvantages of this decision included enacting a change in policy without opportunity for public comment and an increased possibility that

higher-risk product (mechanically separated product or product from animals more than 30 months of age) may be imported into the United States due to possibilities of mislabeling. Nevertheless, the policy change was enacted.

If an interested person had consulted the APHIS website in October 2003, they would have been led to believe that APHIS policy allowed Canadian beef to be imported only from facilities that dealt solely in eligible product. The decision made by APHIS to expand the number and type of facilities eligible to export product to the United States was not communicated to the public, although APHIS officials considered the absence of an opportunity for public comment to be a disadvantage of the policy adopted.

The policies expanding eligibility to Canadian facilities handling both eligible and ineligible product had a major effect on the ability of importers to bring in Canadian beef. That is, of 300 boneless beef permits issued between August 28, 2003 and April 5, 2004, only one permit was issued for product that would enter the United States from a facility dedicated solely to producing eligible product. The other 299 permits allowed beef produced "in compliance with a CFIA approved segregation plan for animals greater than 30 months of age." If APHIS had continued to require compliance with the provisions as originally set forth in the August 8, 2003, announcement, only 1 of the 300 permits would have been issued. Because neither FSIS nor APHIS tracks the amount of product imported under a specific permit, we were unable to determine how much of the more than 480 million pounds of boneless beef and boneless beef trim reported as imported between September 1, 2003 and April 30, 2004, came in under the single permit.

Allowing the import of product from facilities that produce both eligible and ineligible products increases the possibility that higher-risk product could be inadvertently exported to the United States. Initially, facilities producing both eligible and ineligible products were not allowed to export to the United States. The APHIS Administrator's October 3, 2003, decision to change this practice, stated that the requirement had been modified to allow segregation at slaughter facilities with appropriate company controls and oversight and verification by the CFIA. This was the option recommended by the Deputy Administrator. An incident that occurred in July 2004, illustrates the risk associated with making that change. The assigned Canadian meat inspector had gone on vacation and a substitute inspector accidentally approved mislabeled product. About 41,000 pounds of finely textured beef trim, meat scavenged from beef taken off the bone at high pressure and considered to be a higher-risk product by APHIS officials and thus ineligible for import, was mislabeled to indicate that it was an eligible product. The mislabeled ineligible

product was shipped to the United States. A Pennsylvania firm used the mislabeled product to make frozen hamburger patties, which were then distributed to retail establishments in 10 states. When the regular Canadian inspector returned from vacation, he became aware of the mislabeling, notified USDA and FSIS officials, and a recall of the ineligible hamburger ensued. The recall of the beef patties subsequently resulted in recovery of over 93 percent of the ineligible product.

In an April 26, 2004, temporary restraining order issued by the District Court in Montana, USDA was enjoined from allowing the import of any bovine meat other than the products allowed under the August 8, 2003, announcement. However, APHIS did not immediately address the issue of ensuring that bovine meat that enters the United States under permit comes from slaughter facilities that kill only animals less than 30 months of age. While APHIS officials took some action to cancel certain types of permits, no effort was made to review or cancel permits that had been issued allowing the import of meat from facilities that slaughter cattle older than 30 months. Based on our review, this would have included, at a minimum, the 299 boneless beef permits previously discussed.

The subsequent preliminary injunction, issued on May 5, 2004, reinforced the requirement that limited imported Canadian beef to product slaughtered in facilities that did not kill animals over 30 months. APHIS officials considered that there was not a need to cancel or amend the previously issued permits that allowed beef slaughtered in facilities that slaughter cattle older than 30 months. In the view of the APHIS officials, it was appropriate to rely on Canada's assertion that only establishments that limited slaughter to cattle less than 30 months were eligible to export to the United States. Effective May 28, 2004, the CFIA issued written guidance[13] to its inspectors, stating "Only establishments that slaughter only cattle under 30 months of age are eligible to export to the U.S." In our opinion, the permit language, which was developed specifically to allow imports from facilities slaughtering older cattle, could mislead a Canadian facility or importer to believe that product slaughtered in violation of the temporary restraining order and subsequent injunction was eligible for import.

- Allowing the import of edible bovine tongues, hearts, kidneys, and lips. The Secretary's August 8, 2003, announcement did not include these products as low-risk items eligible for import from Canada. On October 22, 2003, APHIS posted a revised chart of eligible low-risk Canadian product on the APHIS website. The revised chart included edible bovine tongues, hearts, kidneys, and lips. In the information

[13] CFIA Meat Hygiene Manual of Procedures, Chapter 11, Export, Annex Z, Conditions Applicable to the Exportation of Ruminant Meat/Meat Products.

posted to the web, APHIS did not explain why these products were considered to be low-risk. This represented an additional expansion of the types of products that could be imported from Canada.

The APHIS TSE Working Group did not specifically address bovine hearts, kidneys, and lips in June 2003 in the "Canadian Commodities Preliminary Risk Assessment for BSE," the document that set forth the working group's conclusions about the risk levels of various products, required risk mitigations, and an evaluation of the current situation. However, the working group reached the conclusion that fresh or frozen bovine tongues were "moderate risk" products, even when the required risk mitigations were in place. Thus, bovine tongues, one of the items posted on the revised chart of eligible low-risk products, had actually been deemed as posing a "moderate risk" by the APHIS TSE working group.

We interviewed the Chairperson of the TSE Working Group in December 2004 in an attempt to understand how bovine tongues had been listed as a "low-risk" product on the APHIS web site, when the TSE Working Group had deemed bovine tongues to pose a moderate risk, even when specified risk mitigation measures, such as removal of the tonsils, were in place. The Chairperson explained that the listing was not intended to be authoritative and was based on the TSE Working Group's understanding of the issue in June 2003. Further, the Chairperson explained that bovine tongues had been listed separately because different members of the scientific community had differing opinions about the risk level. According to the Chairperson, there were many discussions of this issue, both in the APHIS chain of command and with colleagues in FSIS. The discussions included the APHIS Deputy Administrator and the Administrator, who made the final decision to list bovine tongues as "low-risk" and allow their entry into the United States.

When we interviewed the former APHIS Administrator, he explained that, in his opinion, edible bovine tongues, hearts, kidneys, and lips could have been listed as part of the Secretary's original announcement. However, the products were not listed, because APHIS did not initially anticipate the demand for these products. The current APHIS Administrator, who was the Deputy Administrator at the time of the decision to allow the import of bovine tongues, hearts, kidneys and lips, stated that the decision was made after careful consideration of all risks, although this risk assessment may not have been documented. According to data maintained by FSIS, over 1.5 million pounds of this type of product entered U.S. commerce from September 1, 2003 to April 30, 2004.

In an interview in February 2005, the Chairperson of the TSE Working Group explained that she agreed with the decision to add bovine tongues to the list of "low-risk" products published on October 22, 2003, although her agreement was not documented. She explained the decision to add tongues to the "low-risk" list was consistent with APHIS' "Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States." This risk analysis was made available to the public in November 2003, when APHIS issued the proposed rule "BSE; Minimal-Risk Regions and Importation of Commodities." The risk analysis noted that tongues are low-risk products; however, they may be contaminated with adjacent tonsils, a specified risk material that is prohibited from use in human food. The risk analysis categorized tongues as eligible product when Canadian inspection officials verify the risk mitigation, which is that tonsils are removed. The 26 bovine tongue permits that we reviewed required CFIA to certify, "the tonsils and retropharyngeal lymph nodes were removed."

- Allowing the import of bone-in beef product. On November 25, 2003, APHIS allowed Canadian facilities that receive and process bone-in beef product from the United States, New Zealand, or Australia to export bone-in beef product to the United States. However, APHIS did not announce or otherwise publicize this change or provide any documentation to explain why these products were considered low-risk. According to data maintained by FSIS, over 3,000 pounds of bone-in product entered U.S. commerce from December 1, 2003 to January 21, 2004.

  In an additional expansion of the types of items for which APHIS would issue import permits, on April 19, 2004, the agency announced that beef products eligible for import into the United States included bone-in, boneless, ground meat, and further processed beef products. According to data maintained by FSIS, over 139,000 pounds of bone-in product entered U.S. commerce from April 19, 2004 to April 30, 2004. This announcement, in part, lead to the preliminary injunction filed on May 5, 2004, imposed by the U.S. District Court in Montana.

In summary, from August 2003 to April 2004, APHIS allowed the expansion of the types of Canadian beef products approved for import into the United States. During this period, APHIS also allowed expansions of the types of Canadian facilities approved to produce items for export to the United States. APHIS did not believe the Secretary's August 2003 announcement to issue permits for low-risk products limited its discretion in determining additional products that could be allowed for import. Decision memoranda signed by the Administrator noted that enacting a change in policy without opportunity for public comment constituted a "disadvantage" of APHIS' decision to expand the types of product eligible for import. The agency also did not have

a review structure or other monitoring process in place to identify discrepancies between publicly stated policy and agency practice.

Recommendation No. 1

Develop and implement procedures for communicating changes in policy to all interested parties, including importers, the U.S. Congress, and the public.

Agency Response.

APHIS agrees with this recommendation and will work to ensure that all import policy changes are immediately posted on the web site and efficiently distributed.

Several mechanisms are currently in place for communicating policy changes to interested parties, including importers, Congress, and the public. First, APHIS posts "Dear Importer" letters on its web page to notify interested parties, including importers and the public, of changes to import policy. Moreover, APHIS provides copies of these letters to APHIS' Plant Protection and Quarantine's (PPQ) Veterinary Regulatory Services (VRS) staff. The VRS staff modifies those documents into "Alerts" which they forward to their port personnel and DHS' Customs and Border Protection personnel. Port personnel provide copies of APHIS information (PPQ and DHS Alerts) to brokers, importers, exporters, agents, and other interested parties.

APHIS, Veterinary Services' (VS) Regional Directors also provide information on import policy changes to each Area Veterinarian in Charge (AVIC). Each AVIC forwards this information to VS field personnel and border and port personnel in their area. APHIS also provides the information to any interested party who contacts the office and requests information regarding import changes. Additionally, National Center for Import-Export (NCIE) personnel provide frequent policy updates to FSIS colleagues through e-mail and facsimile transmissions. Finally, VS personnel work with their colleagues in APHIS' Legislative and Public Affairs staff to ensure that Congress is aware of import policy changes.

APHIS recognizes that it did not timely post all updates during the immensely busy period following the August 8, 2003, announcement. The Agency will continue to move information through the established channels described above and work to identify new and more efficient ways to ensure all interested parties receive all necessary information regarding changes in import policy. As we determine specific improvements regarding the internal communication channels we can use to ensure all web-based notifications are posted in a timely fashion, we will document and implement those procedures. We anticipate refined procedures will be in place by the end of March 2005.

OIG Position.

We accept APHIS' management decision. However, we noted that the response does not directly address the situation described in this report, which was a conscious decision by the Administrator not to publicly announce certain changes in policy. For final action, APHIS needs to provide the Office of the Chief Financial Officer (OCFO) the refined procedures to include details of how the agency will ensure retention of the emails and faxes used to provide policy updates to FSIS.

Recommendation No. 2

Develop and implement procedures to monitor APHIS actions with regard to permit issuance and to confirm that agency practice is consistent with publicly stated policy.

Agency Response.

APHIS agrees with this recommendation and has taken action to implement changes in addition to existing procedures. VS maintains standard operating procedures (SOPs) and standardized permit language for drafting permits to ensure consistency. We provide all permitting staff with a copy of the SOP manual and train staff accordingly. The permitting staff holds frequent meetings where experts discuss and establish procedures for any emerging issues concerning importation of animal origin material (i.e., Organisms and Vectors, By-products and or meat products). While these mechanisms have been successful in the past, our systems were clearly strained under the unprecedented volume of permit requests after the Secretary's announcement.

NCIE is developing a refined tracking system and enacting protocols to ensure that the NCIE Import Animal Products Team leaders and the NCIE Director will update the database whenever changes are made to policies, product certifications statements, and permit guidelines.

We expect to revise the tracking system, including adding a new mail-in database to document policy changes, product certifications, and permit guidelines, by the end of February 2005. Also, we will add a NCIE Quickplace site, so staff can communicate about all changes; we expect the new server for this site to be in place by March 2005.

OIG Position.

We accept APHIS' management decision. For final action, APHIS needs to provide OCFO with documentation with how the tracking system was revised and with evidence that the new server has been put in place.

Finding 2 APHIS Allowed Beef Cheek Meat With Questionable Eligibility to be Imported as Boneless Beef

APHIS issued permits to allow the import of products with questionable eligibility because the agency did not establish a clear working definition for the general term "boneless beef." Instead of coordinating with FSIS, APHIS reviewers relied upon their own understanding of the term. Some APHIS reviewers considered the term "boneless beef" broadly, to mean any bovine meat that did not contain a bone. Thus, some applicants who requested permits to import beef cheek meat and other products received permits allowing the import of "boneless beef or boneless beef trim." As a result, over 63,000 pounds of beef cheek meat with questionable eligibility entered U.S. commerce from Canada. As of the date of this report, beef cheek meat is not eligible for import from Canada.

The following illustrates how APHIS issued permits to import beef cheek meat, a product deemed ineligible for most of the time period covered by this report. In November 2003, a California meat company applied for a permit to import boxed beef, top sirloins, flapmeat, inside skirts, inside rounds, tongues, beef tonguetips, beef cheek meat, beef lips, and other items. The firm planned to import an estimated 390 tons of product annually. Instead of preparing separate permits for the various items requested and advising the importer that beef cheek meat was not eligible for import, APHIS issued the importer a permit with the language "as requested in your application you are authorized to import or transport the following materials – Boneless Beef or Boneless Beef Trim." Thus, neither the importer nor the Canadian shipper was on notice that the beef cheek meat was ineligible to enter the United States.

The Harvard risk assessment,[14] dated November 26, 2001, identifies the potential for contamination of cheek meat by brain or other tissues when the head is split and from the use of captive bolt stunning that uses air injection. The Update of the Opinion on TSE Infectivity Distribution in Ruminant Tissues, adopted by the Scientific Steering Committee of the European Commission, Health and Consumer Directorate-General cautions, "cheek meat of animals certified safe for human consumption…does not pose a risk if a wide range of precautions to avoid cross-contamination is taken. The feasibility of implementation of the precautions under field conditions may however be questioned and in any case require to be previously verified."[15] An FSIS message to import inspection personnel, dated October 7, 2003,

[14] USDA commissioned this assessment for a comprehensive investigation of BSE risk in the United States.
[15] Adopted at the Scientific Steering Committee meeting of 10-11 January 2002 and amended at its meeting of 7-8 November 2002.

states, in part, "Head meat and cheek meat, which must be declared as such on the label, are restricted by APHIS and thus, are not eligible." According to FSIS data, over 21,000 pounds of cheek meat entered the U.S. between September 1, 2003 and April 30, 2004.

As part of our review at FSIS' import reinspection houses, we identified over 42,000 pounds of beef cheek meat that entered the United States between May 19, 2004 and June 9, 2004. Information noted on the health certificates clearly identified the product as beef cheeks even though the import permit called the product "boneless beef." The same exporter and same importer were involved with all 3 shipments of the more than 42,000 pounds of beef cheeks. Based on a review of the documentation available at the import house, the three shipments were among those noted as "skipped" by FSIS.[16]

Although FSIS procedures generally call for a review of the shipping documentation for all shipments, to include a review for consistency between the health certificate and other shipping records, there was no indication in the records that FSIS inspectors had noted the inconsistencies in documentation for two of the three shipments. While each of the three shipments was shown to be "beef cheeks" on the health certificate, FSIS had coded the three shipments differently in its automated import information system. The three Import Inspection reports referred to the product variously as "beef wholesale trim," "beef trim cheek meat" and "beef wholesale cuts."

One shipment of beef cheeks imported into the United States on June 1, 2004, was noted to be released based on a June 1, 2004 conversation at 9:00 pm with the Director of FSIS' Import Inspection Division. No explanation was documented on the FSIS inspection report to show why the shipment was released. An email sent by the Director of the FSIS Import Inspection Division, subsequent to the phone call, stated in part "… beef cheek meat from Canada is permitted under the current permitted products from Canada (assuming it has an APHIS permit issued), since cheek meat is considered skeletal muscle." In our opinion, the FSIS Director's conclusion was incorrect, in part because the decision did not incorporate the clarifying information issued, as supplemental guidance, by the FSIS Import Inspection Division. However, FSIS officials did not consider the supplemental guidance issued October 7, 2003, to be in effect and asserted the beef cheeks were eligible for import. Two FSIS import inspectors we interviewed advised us that beef cheeks had been "going back and forth" regarding eligibility.

As shown by the previous example, FSIS did not always communicate effectively with its managers and import inspectors about the eligibility status

[16] FSIS examines paperwork on all shipments arriving for reinspection and performs a physical reinspection of imported product on a sample basis, so some shipments are not physically inspected prior to release by FSIS.

of beef cheek meat. FSIS distributed information to its import inspectors by way of a series of numbered memoranda, titled Part 4, Canada, BSE Restrictions, Revision 2 through Revision 11. Some of the issuances were supplemented by additional guidance, in the form of supplemental memoranda. However, in our opinion, FSIS managers did not ensure consistent interpretation of the provisions of the various memoranda, a task that was made more difficult by the changing instructions provided by APHIS to FSIS. According to the FSIS Acting Deputy Assistant Administrator, each numbered Revision cancelled and replaced the previous Revision. Thus, in his opinion, if the Revision in force at a particular time did not specifically mention a particular product, then import inspectors were to interpret this as allowing the product to be imported. However, in contrast to the explanation provided by the FSIS manager, documentation showed that numbered Revisions were sometimes clarified by supplemental guidance that enumerated products that were specifically ineligible, but not mentioned in the numbered Revision memorandum itself. For example, in the memorandum dated August 27, 2003, "Revision 2," FSIS advised agency import inspectors that boneless bovine meat was an eligible low-risk Canadian ruminant product. The memorandum did not specifically mention head and cheek meat. However, supplemental guidance to Revision 2, dated October 7, 2003, clarified that "Head and cheek meat, which must be declared as such on the label, are restricted by APHIS and thus, are not eligible."

FSIS management advised us that the agency did not consider the more than 42,000 pounds of beef cheeks that we identified as imported between May 19, 2004 and June 9, 2004, to be ineligible. According to the FSIS Acting Deputy Assistant Administrator, the April 26, 2004, temporary restraining order prohibited APHIS from issuing import permits for products other than those included as part of the August 15, 2003, list. That is, the restraining order had the effect of limiting the list of eligible products to those contained in the August 27, 2003, FSIS Import Notice. We noted that the products listed in the April 27, 2004, Revision 7 memorandum are the same as those listed in the August 27, 2003, Revision 2 memorandum; the wording of the entry for boneless bovine meat is identical. However, because cheek meat was not specifically mentioned in Revision 7, cheek meat was considered to be eligible for import by the FSIS manager we interviewed. In our opinion, this conclusion is inconsistent with FSIS' earlier guidance to its import inspectors that clarified Revision 2 to state, "head and cheek meat, which must be declared as such on the label, are restricted by APHIS and thus, are not eligible." We believe that since FSIS intended Revision 7 to mirror the listing of eligible products in Revision 2, and since Revision 2 did not allow head and cheek meat (per Supplemental Guidance #2), in our opinion, head and cheek meat were not allowed by Revision 7 and the 42,000 pounds that were subsequently imported had questionable eligibility. However, FSIS officials did not consider the supplemental guidance issued

October 7, 2003, to be part of Revision 7 and asserted the beef cheeks were eligible for import at the time they were imported.

In January 2005, FSIS assessed the shipments of beef check meat and concluded, "FSIS has no reason to believe that these four shipments[17] of beef cheek meat are injurious to health." In its assessment, FSIS explained that in January 2004, the agency implemented interim final rules that prohibited the use of specified risk materials for human food. This rule instituted requirements for the removal, segregation, and disposition of the specified risk material. On the matter of beef cheek meat, the FSIS rule maintained that beef cheeks are not part of the skull, which is a specified risk material. The FSIS rule continued to allow the use of beef cheek meat for human food, provided that the meat is not contaminated with specified risk materials. FSIS further supported its conclusion on the basis that Canada had a pre-existing equivalent specified risk material system in place[18] and that FSIS has judged the Canadian meat inspection system to be equivalent to the U.S. meat inspection system for many years. An FSIS review performed in December 2004 found no deficiencies in the Canadian system related to BSE controls. The BSE controls tested by FSIS personnel included such controls as whether the Canadian establishment routinely evaluated the effectiveness of their procedures for the removal, segregation, and disposition of specified risk material and whether the CFIA veterinarian took appropriate action when noncompliance was found regarding controls over specified risk materials. FSIS personnel also tested whether the CFIA veterinarian verified that captive bolt stunners were not used to stun cattle.

We requested the Director of the FSIS Import Inspection Division to provide any additional information on the issue of beef cheeks that FSIS had received from APHIS. None of the information provided by FSIS or APHIS supported the position that APHIS had concluded that beef cheeks would be eligible for import. FSIS considered that beef cheeks would be eligible because beef cheeks are considered boneless beef according to FSIS' technical definition of this term. However, as described above, APHIS did not use FSIS' definition of boneless beef. As of February 14, 2005, beef cheeks are not eligible for import from Canada.

Further, in an August 18, 2004 interview, the APHIS National Incident Commander for BSE Enhanced Surveillance confirmed that further discussion was still required with respect to the import of head and cheek meat and that no new scientific information on this topic had been considered by APHIS.

[17] The four shipments included one shipment identified by FSIS that entered U.S. commerce in April 2004 and three shipments that we identified that entered U.S. commerce in May and June 2004.
[18] Canada's policy on specified risk materials became effective July 2003.

FSIS officials explained that import inspectors assume all products presented for reinspection are eligible unless they receive direction from FSIS management or the import information system that certain product is not eligible. Regarding beef products from Canada, FSIS officials explained they were trying to timely communicate the complex matter of which products were eligible in a frequently changing environment. FSIS officials advised that the Import Inspection Division's established controls are generally effective for rapidly notifying import inspectors of new or changed policy in a constant environment. However, they agreed the controls should be strengthened to better communicate the eligibility of product that frequently changed eligibility status, as beef cheeks did between August 2003 and July 2004. We believe that the communication about product with frequently changing eligibility should specify whether or not the product is eligible to be imported into the United States. As an additional safeguard, FSIS should establish an edit check in the agency's automated system to flag ineligible product when it is presented for entry into the United States.

APHIS issued permits that allowed the importation of 63,000 pounds of beef cheek meat with questionable eligibility because the agency did not establish a clear working definition for the general term "boneless beef." APHIS needs to immediately cancel all permits that allow beef cheek meat to be imported. FSIS should implement controls to communicate to import inspectors the specific eligibility of product when its eligibility status changes. FSIS should also establish an edit check in its import information system to flag ineligible product presented for entry.

Recommendation No. 3

Immediately cancel all permits that allow the importation of beef cheek meat.

Agency Response.

To address this recommendation, APHIS will immediately notify by letter holders of permits for "boneless beef" that such permits do not allow the importation of cheek meat.

OIG Position.

We cannot accept APHIS' management decision. The actions taken by APHIS are a good first step, but the actions are not sufficient to prevent beef cheek meat from being imported into the United States. APHIS needs to notify FSIS and DHS' CBP that permit holders are not allowed to import this product. APHIS also needs to develop a plan to address the outstanding permits that could allow the importation of beef cheek meat.

Recommendation No. 4

FSIS should implement controls to communicate the specific eligibility of product when its eligibility status changes.

Agency Response.

FSIS agrees with this recommendation and will implement controls to communicate the specific eligibility of product when the eligibility status changes. FSIS will complete the review and update of the controls by July 2005.

OIG Position.

We accept FSIS' management decision. For final action, FSIS needs to provide OCFO with the documentation that implements the agreed upon controls.

Recommendation No. 5

FSIS should implement an edit check in its import information system to identify ineligible product presented for entry into the United States.

Agency Response.

FSIS currently performs quarterly verification of its import information system while monitoring and overseeing the system and import inspection program performance. In addition, the import inspection system has a limited set of edit checks that are presently incorporated in its current configuration. FSIS will enhance this feature of the system by reprogramming the Automated Import Information System (AIIS) to include drop-down menus containing a specific set of eligible products. The reprogrammed system will eliminate product description from being entered into a text field and thereby mitigate or restrict the possibility of ineligible product being entered in the system.

FSIS expects to complete the AIIS reprogramming by January 2006.

OIG Position.

We accept FSIS' management decision. For final action, FSIS needs to provide OCFO with documentation to support that AIIS has been reprogrammed to include drop-down menus containing a specific set of eligible products.

Finding 3 APHIS Did Not Establish Adequate Controls to Manage the Permit Process

APHIS issued 1,155 permits for the importation of ruminant products from Canada without ensuring that the agency had an appropriate system of internal controls to manage the process. These permits were issued from August 20, 2003 to September 16, 2004. Due to the serious impact on trade, USDA officials sought a method to allow limited imports from Canada and determined to use the APHIS permit process as a vehicle to facilitate trade. The APHIS permit system was originally designed to allow for the import of research quantities (generally small amounts) of material into the United States. The procedures that APHIS had developed for handling permit requests for small amounts of product were not adequate to deal with the high volume of requests for large quantities of commercial use beef. The agency did not implement or finalize standard operating procedures for processing the large volume of permits. APHIS also did not implement requirements to perform onsite monitoring of permit holders, Canadian facilities, or inspection personnel[19] at U.S. ports of entry. As a result, there was reduced assurance that Canadian beef entering the United States was low-risk, and some product with questionable eligibility, as described in an earlier finding, entered U.S. commerce.

Departmental regulation[20] holds agency program managers responsible for the integrity and quality of program performance. To achieve this, an agency should establish policies and procedures to reasonably ensure that programs achieve their intended results and that reliable information is obtained, maintained, reported, and used for decision making.

On May 20, 2003, the Secretary halted imports of live cattle and other ruminants from Canada after a cow in Alberta was found to have BSE. At that time, APHIS did not have a history of issuing permits for the importation of edible meat and meat products. Veterinary import permits were generally issued for items derived from animals, such as blood, cells or cell lines, hormones, and microorganisms including bacteria, viruses, protozoa, and fungi.

APHIS officials acknowledged that the agency did not have the best possible processes in place to handle the volume of permit requests that ensued after the August 8, 2003, announcement that certain products could enter from

[19] The inspection personnel include agriculture inspectors with the U.S. Customs and Border Patrol and import inspectors with the Food Safety and Inspection Service.
[20] Departmental Regulation No. 1110-2, Management Accountability and Controls, February 23, 1999

Canada with a permit. Agency officials tried to adapt the permit system, which in the past had handled approximately 400 requests annually for research quantities of products, to handle a greater number of large commercial product requests. Given USDA's goal of beginning to issue permits by the end of August 2003 and not knowing the volume of requests that might arrive, APHIS officials believed that they did not have time to carefully design a better system. APHIS issued 1,155 permits in a little more than one year following the August 2003 announcement, and the processes designed to deal with a much lower volume proved inadequate to ensure the desired level of compliance.

Representatives of the Office of the General Counsel (OGC) told us that the APHIS Administrator had existing regulatory authority[21] to implement a permit process allowing low-risk ruminant products to be imported from Canada. However, OGC also told us that they advised APHIS to issue permits on an exception basis rather than as a general practice. The Secretary of Agriculture announced on August 8, 2003, that USDA would accept applications for permits to import certain beef products from Canada.

APHIS officials developed undated draft documentation that purported to describe the agency's controls for issuing and monitoring permits for commercial quantities of ruminant products. Our analysis of this draft documentation disclosed that it did not implement an appropriate system of controls to manage the process. We found that the draft documentation did not address such control areas as: (1) ensuring the permit contains an accurate description of permitted products, (2) notifying applicants when requested items are not approved for import, (3) canceling permits issued in error, (4) consistently applying risk mitigation measures, and (5) performing onsite monitoring of permit holders, Canadian facilities, or inspection personnel at U.S. ports of entry. We also found that these controls were not finalized during the period of our review.

We analyzed the 1,155 import permits to identify permits issued for ineligible product, to determine whether risk mitigation measures were consistently applied or amended, and to determine whether permits were appropriately cancelled following the preliminary injunction filed on May 5, 2004. Finally, we visited four FSIS import reinspection houses and two ports of entry to understand how the requirements to import ruminant products from Canada were implemented. At these locations, we reviewed the shipping documents for 12,427 shipments of imported product, which generally included the Canadian health certificate, the APHIS permit, and FSIS reinspection documentation. The four FSIS import reinspection houses we reviewed reinspected over 80 percent of the Canadian product presented for entry into the United States between September 2003 and September 2004.

[21] 9 C.F.R. § 93.401(a), January 1, 2003

We identified five major areas where APHIS management controls were not adequate to ensure that the permit process operated effectively.

- Ensuring accurate description of permitted products. APHIS officials did not establish controls to ensure that permits accurately described the material to be imported based on the permit holder's application. For example, we reviewed the permits and supporting applications for 300 "boneless beef" permits issued from August 2003 through April 2004. Permits for the import of "boneless beef and boneless beef trim" were issued when applicants requested diverse items such as "boneless beef," "beef and beef by-products" and "boneless scalded beef scalps."

- Notifying applicants when requested items are not approved for import. APHIS did not have a policy or practice to notify applicants when APHIS did not approve products the applicant requested to import. In one instance, an applicant requested 48 different items, to include ground beef, spiced beef salami, and bulk meat loaf paprikash. Nevertheless, the applicant was issued a permit stating, "As requested in your application, you are authorized to import…boneless beef or boneless beef trim." There was no mention of the various processed items the applicant had requested.

- Canceling permits issued in error. Because APHIS did not use consistent terminology in the issuance of permits, the agency was not able to ensure that permits were appropriately cancelled in response to the temporary restraining order issued on April 26, 2004, and the subsequent preliminary injunction filed on May 5, 2004. APHIS issued 50 permits that allowed edible bovine tongues, hearts, kidneys, and lips to enter or transit the United States. The preliminary injunction required that these permits be cancelled. APHIS used an automated "word search" feature to attempt to identify permits that should be cancelled pursuant to the judge's order. However, the items for which the reviewers searched were described in a variety of ways and a search for "beef lips" would not necessarily return "beef-lips," "headmeat/lips" or "bovine lips." Thus, some permits that should have been cancelled were not. Through our review, we identified 11 permits for edible bovine tongues, hearts, kidneys, and lips that were not cancelled following the preliminary injunction. We also identified four that were not amended to remove these products from permits for product transiting the United States. Although we did not identify any instances where the permits were used to import ineligible product after the date of the preliminary injunction, APHIS failure to cancel or amend the permits represents a serious weakness in internal control.

- Consistently Applying Risk Mitigation Measures. APHIS officials did not establish controls to ensure that risk mitigation measures were applied consistently. For example, APHIS officials established the general policy that the risk mitigation measures for importing fresh or frozen bovine liver would include provisions that: (1) the material only be pure bovine liver, (2) the cattle from which the liver was obtained were not slaughtered at a facility that uses air-injection stunning, and (3) the livers be from animals slaughtered after August 8, 2003.[22] APHIS issued 83 permits for bovine liver from August 2003 to March 2004. Our review of these permits disclosed that APHIS did not consistently ensure that permits included all required risk mitigation measures. For example, we identified that 8 of the 83 permits for bovine liver did not include the requirement that the livers be from animals slaughtered after August 8, 2003. Without this mitigation measure, there is reduced assurance that Canadian bovine liver entering the United States was low-risk. According to data maintained by FSIS, almost 4.9 million pounds of bovine liver was imported into the United States from September 1, 2003 to April 30, 2004. Our audit also disclosed additional permits that lacked required mitigations to include boneless beef permits and processed product permits.

- Onsite Monitoring. We found that APHIS performed no onsite validations to assess whether permit holders, Canadian facilities, or inspection personnel at U.S. ports of entry properly implemented APHIS restrictions. The inspection personnel at U.S. ports of entry include agriculture inspectors with U.S. Customs and Border Protection (CBP) and import inspectors with Food Safety and Inspection Service (FSIS).

  APHIS officials recognized the economic impact of closing the border in May 2003 to trade in ruminant products as well as the importance of restoring trade without a risk to food safety or public health. Accordingly, APHIS worked with Canadian food safety officials to require that Canadian officials certify that agreed-upon risk mitigations, as listed on the APHIS import permit, were met prior to low-risk ruminant product being exported to the United States. These certifications regarding risk mitigation measures were recorded on an annex to the Canadian health certificate. These two documents, i.e., the health certificate and the annex, accompanied each shipment of product exported to the United States. APHIS required the permit number to be recorded on these documents so that the product described on the health certificate could be reconciled with the product described on the permit. According to APHIS officials, due to their confidence in the Canadian

[22] This is the date the Secretary of Agriculture announced that USDA would begin to accept applications for import permits for certain low-risk products from Canada. It was important that a "beginning date" for slaughter be established, to ensure that frozen beef liver from cattle slaughtered before the feed ban had been enacted could not be exported to the United States.

inspection system, they did not perform onsite reviews to determine whether APHIS restrictions were adequately implemented in Canada.

APHIS relies on CBP and FSIS to ensure product presented for entry is accompanied by required certifications that APHIS restrictions were implemented. In addition, APHIS officials worked with CBP officials to implement extra measures for ensuring that only eligible Canadian product was allowed to enter U.S. commerce. The measures required CBP to verify that each shipment included the Canadian health certificate and annex and the APHIS permit. CBP officials in Detroit, Michigan and Sweetgrass, Montana, informed us that they only released shipments after verifying the required documentation.

Once released by CBP, FSIS reinspected the product in accordance with its import inspection requirements. FSIS import inspectors first check the documents to assure the CFIA properly certifies the shipment. Inspection may be delayed or refused if the documents contain irregularities or errors. Inspectors next examine each shipment for general condition and labeling and then conduct the inspection assignments. Reinspection of products is done on a sample basis, and is intended to be performance based, in that better performing foreign establishments have their products reinspected less frequently. Reinspection tasks include product examination, in which an inspector examines all sample units for defects, such as blood clots, bruises, and bone fragments. During the product examination, the inspector verifies the accuracy of the label; for example, he determines whether or not a product labeled "boneless beef" is actually boneless beef and not some other product.

During the course of our review at the four FSIS Inspection Houses, we did not identify any ineligible Canadian product that entered the United States, other than the beef cheeks with questionable eligibility that are described in Finding No. 2.

APHIS needs to strengthen its controls and finalize its procedures dealing with permits issued for commercial quantities of products. Procedures need to be implemented to ensure that consistent terminology is used to identify the type of product to be imported. This may require coordination with other USDA agencies. The procedures to be established should ensure that: (1) applicants are notified of the reasons APHIS removes or revises material requested, (2) permits are timely cancelled or amended as necessary, and (3) the correct risk mitigation measures are consistently included on the permits. APHIS should perform onsite reviews of permit holders, foreign facilities, and inspection personnel at U.S. ports of entry to confirm that processes are effectively implemented.

Recommendation No. 6

Develop and implement procedures that require consistent terminology to be used when identifying the type of product to be imported.

Agency Response.

APHIS agrees with this recommendation and will continue efforts underway since the summer of 2004 to ensure that APHIS and FSIS use consistent terminology by May 31, 2005. To do this, APHIS and FSIS will make this issue the top priority on the agenda of the regular weekly conference calls the Agencies staffs conduct. In those cases where FSIS has an established definition in a published regulation, APHIS will adopt that definition if at all possible. In a case where the FSIS definition is not appropriate, APHIS will ensure that both agencies understand the different terminology and will publish an explanation of the difference so the general public can understand the difference and how it might be applied. After May 31, 2005, the agencies will continue to use the weekly conference call to ensure that any new terms or issues involving current terminology are discussed and settled quickly.

An example in the report that highlights the need for consistent terminology relates to the OIG questions surrounding the eligibility of beef cheeks that entered the U.S. from Canada. The beef cheeks that entered from Canada from April 21 through June 9, 2004, were in full compliance with the requirements at the time and were eligible for entry. However, differences in terminology made this a difficult situation to sort through and without significant detailed conversations with both Agencies, one could have determined that ineligible product entered due to differences in terminology. This clearly demonstrates the need for better communication between the Agencies as well as the use of consistent terminology.

OIG Position.

We accept APHIS' management decision. For final action, APHIS needs to provide OCFO with documentation of the agreement between APHIS and FSIS to use consistent terminology. APHIS needs to also provide a copy of the controls implemented to verify that the agreed upon terminology is used by APHIS personnel.

In the response to this recommendation, FSIS continues to assert that the 63,000 pounds of beef cheek meat was eligible at the time of import. However, neither FSIS nor APHIS has provided any documentary evidence to support the eligibility of beef cheek meat between April and June 2004. APHIS officials advise that beef cheek meat is not eligible for import from Canada.

Recommendation No. 7

Develop and implement procedures for notifying applicants of APHIS' decision to remove or revise material requested and require this notification to explain the reasons for APHIS decision.

Agency Response.

APHIS agrees with this recommendation and has begun developing such procedures. APHIS will develop a series of "form" letters personnel can easily use to explain why permits are denied. Using these letters should be an effective means of supporting NCIE's goal of transparency. APHIS will begin using these new form letters by March 15, 2005.

OIG Position.

We accept APHIS' management decision. For final action, APHIS needs to provide OCFO with a copy of the implemented procedures and copies of the form letters used to explain to applicants why permits were denied or why requested material was revised or removed.

Recommendation No. 8

Develop and implement procedures to ensure that permits are timely cancelled or amended as necessary. Implement a monitoring process to validate that such actions occur timely and accurately.

Agency Response.

APHIS agrees with this recommendation and will implement an automated system that can generate specific tracking reports. Although NCIE does have an electronic system for tracking permit requests and permits in the Permit Information Tracking System, the process of identifying permits to be cancelled is cumbersome.

APHIS is working to develop a new, sophisticated E-permits system for use Agencywide. We anticipate placing the system in use on January 1, 2006. Because this is an agencywide system and is a very intensive effort, it will take that long to complete it. In the meantime, NCIE is already working with the Information Technology Staff to improve the Permit Information Tracking System. As a result NCIE can now query the system by shipper to identity permits to be cancelled.

OIG Position.

We accept APHIS' management decision. For final action, APHIS needs to provide OCFO with a copy of the interim procedures that were implemented to query the system by shipper to identify permits to be cancelled. APHIS also needs to provide OCFO with a copy of the procedures, once developed and implemented, with the upcoming E-permit system that allow the agency to identify permits that need to be cancelled.

Recommendation No. 9

Develop and implement procedures that validate that all required risk mitigation measures are consistently included on the permits.

Agency Response.

APHIS agrees with this recommendation and has begun taking action to address these points. NCIE will hire additional staff as funding allows to handle in any future situations where such a large number of permits are received in a limited amount of time. The recently published final rule on Minimal Risk Regions will allow the entry of the Canadian products for which APHIS has been issuing permits, so the volume should decrease substantially. Meanwhile the NCIE staff will examine protocols to refine quality control measures and will document and implement these measures by the end of March 2005.

Since risk mitigations are linked to products, we note that OIG's recommendation here is inherently related to the evolving definition of boneless beef. Different products require different mitigations – as such, since the boneless beef encompassed different products as its definition was refined, mitigations from permit to permit reflected this evolution.

While APHIS is pleased that only 2 percent of the over 1,000 permits issued after the August 8 announcement contained incorrect or missing mitigations, we understand OIG's concern and share the desire to correct the problem. APHIS did examine all permits and determined that the missing or incorrect mitigations were not consequential for ensuring safe product. Mitigations missed included issues of documentation, and while these requirements are indeed important within our regulatory framework, NCIE staff did not permit product that was not subjected to the mitigations necessary to deem it safe.

OIG Position.

Our report does not attempt to quantify the number of permits issued with incorrect or missing mitigations, in part because APHIS had not established definitive policies, which specified what mitigations were required. Thus, APHIS' assertion that only 2 percent of the permits contained incorrect or missing mitigations is erroneous. Our report provided examples of the types

of missing mitigation and should not be construed as a list of all permits with incorrect or missing mitigations.

We accept APHIS' management decision. For final action, APHIS needs to provide OCFO with a copy of the procedures implemented to validate that all required risk mitigation measures are consistently included on the permits.

Recommendation No. 10

Development and implement a monitoring process that includes onsite reviews of permit holders, foreign facilities, and inspection personnel at U.S. ports of entry to confirm that restrictions are adequately implemented.

Agency Response.

APHIS agrees that we should have a monitoring process that includes onsite reviews of permit holders, foreign facilities, and inspection personnel at U.S. ports of entry. However, we believe that given limited resources the process should provide APHIS with the authority to do the monitoring as deemed necessary given all factors. It is important to note that nearly all permits issued indicate that exporting facilities are always subject to APHIS inspection. Therefore, we often reserve the option for on-site monitoring – in any country or regions – if it becomes necessary. We do not believe it is necessary, nor do we believe it is feasible, to conduct inspections of all permit holders or foreign facilities. The process should focus on permit holders and foreign facilities, which do not have an established record of compliance. For example APHIS enjoys a close and transparent working relationship with Canada. Canadian officials routinely advise VS personnel of issues, investigate issues of concern that we raise, and solve problems that we note. Canada has a veterinary infrastructure that is at least equivalent to our infrastructure. Imposing any measures on Canada that undermine our mutual trust would only harm our efforts to establish equivalency in our trading relationship, thus leading to barriers to U.S. exports. Imposing mandatory and regular monitoring measures on Canada would waste valuable resources.

APHIS' Plant Protection and Quarantine unit is the Agency's official liaison with the DHS-CBP border inspection personnel. As part of the transfer agreement between USDA and DHS, the two agencies will establish a quality control program to ensure that CBP border inspection personnel are effectively carrying out the agriculture inspection mission. Negotiations to establish the quality control program have been ongoing for several months, but are complicated by the sensitive homeland security issues involved in granting USDA officials access to ports of entry. We expect to finalize the quality control program by July 31, 2005, but must emphasize that this is not totally within APHIS' ability to effectuate.

OIG Position.

We accept APHIS' management decision. For final action, APHIS needs to provide OCFO with documentation of the monitoring process implemented that includes onsite reviews of permit holders, foreign facilities, and inspection personnel at U.S. ports of entry.

Scope and Methodology

We performed our audit at APHIS Headquarters located in Riverdale, Maryland; FSIS import reinspection houses in Buffalo, New York; Detroit Michigan; and Sweetgrass, Montana and ports of entry in Detroit and Sweetgrass. We performed our audit fieldwork from June through December 2004.

We interviewed responsible APHIS and OGC Headquarters officials. We also held discussions with responsible APHIS, OGC, FSIS, and CBP personnel. We held a discussion with CBP Headquarters officials to obtain an understanding of their inspection process.

We analyzed the information APHIS disseminated to the public after Canada discovered a BSE-infected cow on May 20, 2003 and the information used to expand the list of eligible ruminant products. We also analyzed the permit process for the importation of ruminant products from Canada implemented after trade was re-established on August 8, 2003. In order to evaluate APHIS' controls, we analyzed the 1,155 permits issued by APHIS from August 2003 to September 2004 that allowed ruminant products to be imported from Canada. We analyzed this information to determine such things as whether APHIS ensured the permit contained an accurate description of the permitted products, notified applicants when requested items were not approved for import, cancelled permits issued in error, and consistently applied risk mitigation measures.

We visited a total of four FSIS import reinspection houses, including two in Sweetgrass, Montana; one in Buffalo, New York; and one in Detroit, Michigan. We selected the locations based on the level of beef products imported from Canada that were presented for FSIS re-inspection. The four facilities we reviewed reinspected more than 646 million of the 802 million pounds of Canadian product presented for entry into the United States between September 2003 and September 2004. At the inspection houses, we interviewed the import inspectors to obtain an understanding of their reinspection process and implementation of APHIS restrictions on Canadian products. We examined the documents accompanying shipments into the United States, to include international health certificates and the associated annexes.

At the FSIS import reinspection houses, we reviewed documents for 12,427 shipments as part of four different analyses to determine whether any ineligible products entered U.S. commerce. Our first analysis comprised a random selection of at least three shipments per month from September 2003 through April 2004. In this sample, we examined data for 98 shipments. Next, we performed a 100 percent review of all shipping documents from

April 19, 2004 through April 26, 2004. This more intensive review was based on the APHIS decision to expand eligible low-risk Canadian product to include bone-in beef products. A temporary restraining order filed by R-CALF cancelled APHIS' announcement on April 26, 2004. As part of this stage of our review, we examined data for 1,145 shipments. Our third analysis comprised a 100 percent review of all shipping documents from May 2004 through September 2004 at the 4 FSIS inspection houses we visited. This analysis was based on the preliminary injunction filed on May 5, 2004, that described the eligible ruminant products from Canada. As part of the third analysis, we examined data for 9,953 shipments. We also analyzed 11 shipments reinspected in October 2004 by the 2 FSIS inspection houses in Sweetgrass, Montana when were performing onsite fieldwork. Our third analysis included a total of 9,964 shipments. Our final analysis included a random selection of shipments from September 2003 to October 2003 to determine whether edible bovine tongues, hearts, kidneys, and lips entered U.S. commerce before APHIS announced that these products were eligible. As part of this stage of our review, we examined data for 1,220 shipments.

We selected two ports of entry for review based on their proximity to the FSIS import reinspection houses. We interviewed CBP agriculture inspectors at the ports and observed their inspection procedures for implementing APHIS' restrictions on Canadian products.

We conducted the audit in accordance with Government Auditing Standards established by the Comptroller General of the United States.

To accomplish our audit objectives, we:

- Reviewed laws, regulations, policies, procedures, and USDA and agency announcements as well as the regulatory functions associated with importing or transporting controlled materials;

- Interviewed responsible APHIS and OGC officials at their Headquarters offices;

- Conducted meetings with responsible APHIS, OGC, and FSIS officials. We conducted a meeting at the CBP Headquarters office to obtain an understanding of their inspection process at the ports of entry;

- Analyzed information used by APHIS to determine eligible ruminant products to be imported from Canada;

- Visited FSIS import reinspection houses in Buffalo, New York; Detroit Michigan; and Sweetgrass, Montana to review shipping documents accompanying ruminant products imported from Canada; and

- Visited ports of entry to interview responsible CBP agriculture inspectors and observe procedures for allowing ruminant products imported from Canada.

USDA

United States Department of Agriculture

Animal and Plant Health Inspection Service

Washington, DC 20250

FEB 0 9 2005

SUBJECT: Oversight of the Importation of Beef Products from Canada, Report No. 33601-1-HY

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

The enclosed information contains our comments for each recommendation identified in OIG's report 33601-HY. The Animal and Plant Health Inspection Service and Food Safety and Inspection Service are committed to keeping both U.S. agriculture and the nation's food supply safe and appreciate your recommendations.

Thank you for the opportunity to review the report. We look forward to receiving the final version of your report pending publication and release.

Kevin Shea /for

W. Ron DeHaven
Administrator
Animal and Plant Health Inspection Service

Barbara Masters

Barbara Masters
Acting Administrator
Food Safety and Inspection Service

Enclosure

Animal and Plant Health Inspection Service (APHIS)
Food Safety and Inspection Service (FSIS)

Response to Office of the Inspector General (OIG) report:
Animal and Plant Health Inspection Service Oversight of the Importation of Beef Products from Canada, Report No. 33601-01-Hy

General Comments

The Food Safety and Inspection Service (FSIS) has reviewed the report. We will further strengthen controls for communicating to import inspectors the specific eligibility of product when the eligibility status changes. In addition, FSIS will include an edit check function in the automated import information system.

Second, the OIG report notes that the Harvard risk assessment stated that beef cheek meat presents a higher risk when heads are split during slaughter or air injection stunning is employed. It is important to note that this statement, which is in the Harvard risk assessment, was simply a statement taken from the EU Scientific Steering Committee (SSC) updated opinion on TSE infectivity distribution in ruminant tissues (http://europa.eu.int/comm/food/fs/sc/ssc/out296_en.pdf). The Harvard risk assessment did not quantitatively evaluate the human health risk associated with beef cheek meat. There is only a small risk (based on qualitative assessment by experts) if the beef cheek meat is cross-contaminated with specified risk materials. This, as the EU points out, would likely occur when heads are split or air-injection stunning is used. This is unlikely the case for beef cheek meat from Canada since that country does not split heads or use air-injection stunning. Canada also has further requirements to prevent cross-contamination during dressing and salvage equivalent to those in the U.S. interim final rules that were published on January 12, 2004. FSIS does not consider cheek meat produced under the equivalent system from Canada to be a threat to human health.

Responses to Recommendations

Recommendation No. 1

Develop and implement procedure for communicating changes in policy to all interested parties, including importers, the U.S. Congress and the public:

APHIS agrees with this recommendation and will work to ensure that all import policy changes are immediately posted on the web site and efficiently distributed.

Several mechanisms are currently in place for communicating policy changes to interested parties, including importers, Congress, and the public. First, APHIS posts "Dear Importer" letters on its web page to notify interested parties, including importers and the public, of changes to import policy. Moreover, APHIS provides copies of these letters to APHIS' Plant Protection and Quarantine's Veterinary Regulatory Services (VRS) staff. The VRS staff modifies those documents into "Alerts" which they forward to their port personnel and DHS' Customs and Border Protection personnel. Port

personnel provide copies of APHIS information (PPQ and DHS Alerts) to brokers, importers, exporters, agents, and other interested parties.

APHIS, Veterinary Services' (VS) Regional Directors also provide information on import policy changes to each Area Veterinarian in Charge (AVIC). Each AVIC forwards this information to VS field personnel and border and port personnel in their area. APHIS also provides the information to any interested party who contacts the office and requests information regarding import changes. Additionally, National Center for Import-Export (NCIE) personnel provide frequent policy updates to Food Safety and Inspection Service (FSIS) colleagues through e-mail and facsimile transmissions. Finally, VS personnel work with their colleagues in APHIS' Legislative and Public Affairs staff to ensure that Congress is aware of import policy changes

APHIS recognizes that it did not timely post all updates during the immensely busy period following the August 8, 2003, announcement. The Agency will continue to move information through the established channels described above and work to identify new and more efficient ways to ensure all interested parties receive all necessary information regarding changes in import policy. As we determine specific improvements regarding the internal communication channels we can use to ensure all web based notifications are posted in a timely fashion, we will document and implement those procedures**.** We anticipate refined procedures will be in place by the end of March 2005.

Recommendation 2:

Develop and implement procedures to monitor APHIS actions with regard to permit issuance and to confirm that agency practice is consistent with publicly stated policy.

APHIS agrees with this recommendation and has taken action to implement changes in addition to existing procedures. VS maintains standard operating procedures (SOPs) and standardized permit language for drafting permits to ensure consistency. We provide all permitting staff with a copy of the SOP manual and train staff accordingly. The permitting staff holds frequent meetings where experts discuss and establish procedures for any emerging issues concerning importation of animal origin material (i.e., Organisms and Vectors, By-products and or meat products). While these mechanisms have been successful in the past, our systems were clearly strained under the unprecedented volume of permit requests after the Secretary's announcement.

NCIE is developing a refined tracking system and enacting protocols to ensure that the NCIE Import Animal Products Team leaders and the NCIE Director will update the database whenever changes are made to policies, product certifications statements, and permit guidelines.

We expect to revise the tracking system, including adding a new mail-in database to document policy changes, product certifications, and permit guidelines, by the end of February 2005. Also, we will add a NCIE Quickplace site, so staff can communicate about all changes; we expect the new server for this site to be in place by March 2005.

Recommendation No. 3

Immediately cancel all permits that allow the importation of beef cheek meat.

To address this recommendation, APHIS will immediately notify by letter holders of permits for "boneless beef" that such permits do not allow the importation of cheek meat.

Recommendation No. 4

FSIS should implement controls to communicate the specific eligibility of product when the eligibility status changes.

FSIS agrees with this recommendation and will implement controls to communicate the specific eligibility of product when the eligibility status changes. FSIS will complete the review and update of the controls by July 2005.

Recommendation No. 5

FSIS should implement an edit check in its import information system to identify ineligible product, e.g., beef cheek meat, presented for entry into the United States.

FSIS currently performs quarterly verification of its import information system while monitoring and overseeing the system and import inspection program performance. In addition, the import inspection system has a limited set of edit checks that are presently incorporated in its current configuration. FSIS will enhance this feature of the system by reprogramming the Automated Import Information System (AIIS) to include drop-down menus containing a specific set of eligible products. The reprogrammed system will eliminate product description from being entered into a text field and thereby mitigate or restrict the possibility of ineligible product being entered in the system.

FSIS expects to complete the AIIS reprogramming by January 2006.

Recommendation No. 6

Develop and implement procedures that require consistent terminology when identifying products

APHIS agrees with this recommendation and will continue efforts underway since the summer of 2004 to ensure that APHIS and FSIS use consistent terminology by May, 31, 2005. To do this, APHIS and FSIS will make this issue the top priority on the agenda of the regular weekly conference calls the Agencies staffs conduct. In those cases where FSIS has an established definition in a published regulation, APHIS will adopt that definition if at all possible. In a case where the FSIS definition is not appropriate, APHIS will ensure that both agencies understand the different terminology and will publish an explanation of the difference so the general public can understand the difference and how it might be applied. After May 31, 2005, the agencies will continue to use the weekly conference call to ensure that any new terms or issues involving current terminology are discussed and settled quickly.

An example in the report that highlights the need for consistent terminology relates to the OIG questions surrounding the eligibility of beef cheeks that entered the U.S. from Canada. The beef cheeks that entered from Canada from April 21 through June 9, 2004, were in full compliance with the requirements at the time and were eligible for entry. However, differences in terminology made this a difficult situation to sort through and without significant detailed conversations with both Agencies, one could have determined that ineligible product entered due to differences in terminology. This clearly demonstrates the need for better communication between the Agencies as well as the use of consistent terminology.

Recommendation No. 7

Develop and implement procedures for notifying applicants of APHIS decision to remove or revise material requested and required this notification to explain the reasons for APHIS decision.

APHIS agrees with this recommendation and has begun developing such procedures. APHIS will develop a series of "form" letters personnel can easily use to explain why permits are denied. Using these letters should be an effective means of supporting NCIE's goal of transparency. APHIS will begin using these new form letters by March 15, 2005.

Recommendation No. 8

Develop and implement procedures to ensure that permits are timely cancelled or amended as necessary. Implement a monitoring process to validate that such actions occur timely and accurately.

APHIS agrees with this recommendation and will implement an automated system that can generate specific tracking reports. Although NCIE does have an electronic system for tracking permit requests and permits in the Permit Information Tracking System, the process of identifying permits to be cancelled is cumbersome.

APHIS is working to develop a new, sophisticated E-permits system for use Agencywide. We anticipate placing the system in use on January 1, 2006. Because this is an agencywide system and is a very intensive effort, it will take that long to complete it. In the meantime, NCIE is already working with the Information Technology Staff to improve the Permit Information Tracking System. As a result NCIE can now query the system by shipper to identity permits to be cancelled.

Recommendation No. 9

Develop and implement procedures that validate all required risk mitigation measures are consistently included on the permits.

APHIS agrees with this recommendation and has begun taking action to address these points. NCIE will hire additional staff as funding allows to handle in any future situations where such a large number of permits are received in a limited amount of time. The recently published final rule on Minimal Risk Regions will allow the entry of the Canadian products for which APHIS has been issuing permits, so

the volume should decrease substantially. Meanwhile the NCIE staff will examine protocols to refine quality control measures and will document and implement these measures by the end of March 2005.

Since risk mitigations are linked to products, we note that OIG's recommendation here is inherently related to the evolving definition of boneless beef. Different products require different mitigations – as such, since the boneless beef encompassed different products as its definition was refined, mitigations from permit to permit reflected this evolution.

While APHIS is pleased that only 2 percent of the over 1,000 permits issued after the August 8 announcement contained incorrect or missing mitigations, we understand OIG's concern and share the desire to correct the problem. APHIS did examine all permits and determined that the missing or incorrect mitigations were not consequential for ensuring safe product. Mitigations missed included issues of documentation, and while these requirements are indeed important within our regulatory framework, NCIE staff did not permit product that was not subjected to the mitigations necessary to deem it safe.

Recommendation No. 10

Develop and implement a monitoring process that includes onsite reviews of permit holders, foreign facilities, and inspection personnel at U.S. ports of entry to confirm that restrictions are adequately implemented.

APHIS agrees that we should have a monitoring process that includes onsite reviews of permit holders, foreign facilities, and inspection personnel at U.S. ports of entry. However, we believe that given limited resources the process should provide APHIS with the authority to do the monitoring as deemed necessary given all factors. It is important to note that nearly all permits issued indicate that exporting facilities are always subject to APHIS inspection. Therefore, we often reserve the option for on-site monitoring – in any country or regions – if it becomes necessary. We do not believe it is necessary, nor do we believe it is feasible, to conduct inspections of all permit holders or foreign facilities. The process should focus on permit holders and foreign facilities which do not have an established record of compliance. For example APHIS enjoys a close and transparent working relationship with Canada. Canadian officials routinely advise VS personnel of issues, investigate issues of concern that we raise, and solve problems that we note. Canada has a veterinary infrastructure that is at least equivalent to our infrastructure. Imposing any measures on Canada that undermine our mutual trust would only harm our efforts to establish equivalency in our trading relationship, thus leading to barriers to U.S. exports. Imposing mandatory and regular monitoring measures on Canada would waste valuable resources.

APHIS' Plant Protection and Quarantine unit is the Agency's official liaison with the DHS-CBP border inspection personnel. As part of the transfer agreement between USDA and DHS, the two agencies will establish a quality control program to ensure that CBP border inspection personnel are effectively carrying out the agriculture inspection mission. Negotiations to establish the quality control program have been ongoing for several months, but are complicated by the sensitive homeland security issues involved in granting USDA officials access to ports of entry. We expect to finalize the quality control program by July 31, 2005, but must emphasize that this is not totally within APHIS' ability to effectuate.

Informational copies of this report have been distributed to:

Administrator, APHIS
ATTN: Agency Liaison Officer (9)
Administrator, FSIS
ATTN: Agency Liaison Officer (10)
General Accountability Office (1)
Office of the Chief Financial Officer
Director, Planning and Accountability Division (1)