



United States Department of Agriculture

Food Safety and
Inspection Service

APR 11 2016

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Mr. Greg Read
First Assistant Secretary, Exports Division
Department of Agriculture and Water Resources
18 Marcus Clarke Street Canberra City GPO Box 858
Canberra ACT 2601, Australia

Dear Mr. Read,

The USDA, Food Safety and Inspection Service (FSIS) conducted an on-site audit of Australia's meat and poultry inspection system from November 17 through December 8, 2014. The comments received from the Government of Australia are included as an attachment to the enclosed copy of the final audit report.

If you have any questions, please feel free to contact me directly.

Sincerely,

A handwritten signature in blue ink that reads "Jane H. Doherty". The signature is fluid and cursive, with the first letters of each word being capitalized and prominent.

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN
AUSTRALIA

NOVEMBER 17 – DECEMBER 8, 2014

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING MEAT
PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

March 23, 2016
Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an ongoing equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from November 17 – December 8, 2014, to determine whether Australia's food safety system governing the production of meat continues to be equivalent to that of the United States. Australia is eligible to export meat and poultry products (ratites only) to the United States, however, this audit concentrated only on the meat inspection system.

The audit was designed to verify equivalence of Australia's meat inspection system and focused on the six main system components: (1) Government Oversight (Organization & Administration); (2) Statutory Authority and Food Safety Regulations (Inspection System Operations and Product Standards); (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Government Chemical Residue Control Programs; and (6) Government Microbiological Testing Programs. FSIS reviewed information provided by the Central Competent Authority (CCA) in FSIS' self-reporting tool (SRT), reports of corrective actions instituted by the CCA to address the 2013 FSIS audit observations, and reports of corrective actions implemented to address point of entry (POE) violations reported by FSIS from January 2013 to September 2014. FSIS also verified the ongoing implementation of Australia's equivalent post-mortem inspection system.

FSIS observations of inspection program activities, interviews of inspection personnel, and reviews of official inspection records during the on-site audit confirm that the components of Australia's meat inspection system continue to meet United States core requirements. However, FSIS identified the following finding related to the HACCP systems component of the Australian meat inspection system:

- Repeated POE violations in which meat products from Australia have been rejected for public health reasons involving zero tolerance (ZT) and ingesta violations, indicate that greater effort is required on the part of the CCA to ensure the adequacy of HACCP systems implemented by establishments

FSIS expects that the CCA will implement prompt corrective actions to address the above reported finding and provide to FSIS a report on the adequacy of their implementation within the next 60 calendar days. FSIS will evaluate the adequacy of the CCA's proposed corrective actions once received.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) conducted an ongoing equivalence verification of Australia's meat inspection system that included an on-site audit of the performance of the system that took place from November 17 through December 8, 2014. Although Australia is eligible to export meat and poultry products to the United States (U.S.), this audit only included the meat inspection system of Australia (MISA).

During the period between January 1, 2013 and June 23, 2014, Australia exported to the United States 1,005,212,356 pounds of meat products derived from bovine, ovine and caprine species. From that volume, 1,002,908,654 pounds of products were accepted and approximately 2,300,000 pounds were refused at United States Points of Entry (POE). Approximately, 525,000 pounds were refused because of food safety violations related to zero tolerance for contamination of meat products with fecal matter, ingesta, milk, pathological issues, and failed laboratory analysis. The remaining 1,775,000 pounds were refused because of shipping damage and labeling or certificate issues.

The audit standards applied to evaluate the MISA included applicable legislation determined by FSIS to be equivalent as part of the initial equivalence process, as well as any subsequent equivalence determinations that have been made under provisions of the Sanitary/Phytosanitary Agreement. This audit was conducted pursuant to the specific provisions of the United States laws and regulations, in particular:

1. The Federal Meat Inspection Act (21 U.S.C. 601 et seq.),
2. The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901-1906), and
3. The Food Safety and Inspection Service Regulations (Title 9 Code of Federal Regulations (CFR), Chapter III, Part 327).

II. AUDIT GOAL AND OBJECTIVES

FSIS' overall goal for the audit was to verify that Australia's food safety system governing meat production continues to be equivalent to that of the United States, with the ability to produce and export meat products that are unadulterated, safe, wholesome, and properly labeled. To achieve this goal, the audit focused on the six components of the program to determine if they are equivalent and can maintain the system's equivalence. The six equivalence components are the following: (1) Government Oversight (Organization & Administration); (2) Statutory Authority and Food Safety Regulations (Inspection System Operations and Product Standards); (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Government Chemical Residue Control Programs; and (6) Government Microbiological Testing Programs. FSIS also verified the adequacy of implementation of the corrective actions implemented by the CCA to address the findings reported by FSIS during the 2013 audit and the measures implemented to prevent the recurrence of POE violations.

III. AUDIT METHODOLOGY

For this on-going equivalence verification audit, FSIS utilized its established four-phase process: planning, execution (on-site), evaluation, and feedback. Each phase is described below.

The first phase involved document and data analysis of previous audit findings and corrective actions. The FSIS auditor examined the six equivalence components of the MISA, FSIS data on exported product types and volumes from Australia, as well as POE testing results, and other data collected by FSIS since the last on-site audit. The FSIS auditor also reviewed documents that describe the design of AEMIS, which, as indicated by CCA officials, includes the inspection methods and procedures currently in place at establishments certified to produce meat products for the United States market, and those in place at establishments that produce meat products for other markets. Furthermore, FSIS assessed the corrective actions proffered by the CCA to address the findings of the 2013 audit. The auditor also examined reports provided by the CCA on the verification of corrective actions that occurred in 2013 to address POE violations reported by FSIS.

The analysis of available information served as the basis to prepare the on-site audit itinerary that included visits to the CCA headquarters office, seven local inspection offices, and seven establishments currently certified to export meat products to the United States. The seven selected establishments included three ovine and four bovine slaughter/fabrication facilities whose raw meat products failed to meet FSIS food safety standards during re-inspection at a United States POE. The audit also included on-site audits of one private microbiological and residue laboratory that analyzes product samples from the audited establishments. Additional information reviewed by the FSIS auditor included the responses provided by the CCA via the self-reporting tool (SRT), outlining the current structure of the inspection system, and identifying significant changes that have occurred since the last FSIS audit.

The second phase was the on-site verification. The FSIS auditor verified the CCA's oversight activities through on-site document reviews, interviews, observations, and site visits. The auditor reviewed management, supervision, and administrative functions at the CCA headquarters and at the seven inspection offices located at the audited establishments. FSIS also verified that the national system of inspection, verification, and enforcement was being implemented in accordance with equivalent Australian statutes and regulations. This ongoing equivalence verification audit also assessed the corrective measures implemented by the CCA to address the findings of the 2013 audit and the POE violations reported by FSIS. Additionally, FSIS assessed the adequacy of the CCA's oversight of its technical support by reviewing documentation related to the functions maintained at one private microbiological and residue laboratory.

The FSIS auditor observed how government officials, establishments, and laboratories interact to control hazards and prevent non-compliances. The review placed emphasis on the CCA's ability to provide oversight through supervisory reviews, which ensure that the meat inspection system continues to operate in accordance with the regulations of the government of Australia and meets requirements specified in United States 9 CFR 327.2.

The third phase of the audit is evaluation. FSIS conducted evaluation activities throughout the entire audit process. Before and during the on-site verification and upon return to the United States, the FSIS auditor determined that the CCA's performance was consistent with the information provided to FSIS and supported the conclusion that the performance of the CCA was equivalent to the United States' meat inspection system. The results of the evaluation are discussed in the corresponding sections of this report for each of the system's components.

The final phase of the audit process is feedback, which begins with FSIS providing a draft audit report to the CCA and giving them an opportunity for comment. After reviewing the CCA's comments and responses to all observations, FSIS finalizes the report. The CCA develops an action plan to address any issues raised by the audit, and FSIS will monitor resolution of all issues.

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT

The first of the six equivalence components that the FSIS auditor reviewed was Government Oversight. FSIS' import eligibility requirements state that a foreign inspection system must be designed and administered by the national government of the foreign country with standards equivalent to those of the United States' system of meat inspection. The FSIS auditor evaluated this component by conducting a review and analysis of documentation submitted by the CCA as support for the responses provided in the SRT, as well as on-site record reviews, interviews, and observations made by the FSIS auditor at government offices, establishments, and laboratories of the inspection system.

FSIS assessed the organization and administration of the MISA and confirmed that the Food Division of Australia's Department of Agriculture (DA) continues to serve as the CCA responsible for the full spectrum of production of safe food for domestic consumption and for export. Additionally, the Exports Division (ED) is headed by a First Assistant Secretary who oversees the functions of three Assistant Secretaries in charge of developing and maintaining export standards and ensuring food safety. The Assistant Secretary for Food Exports manages delivery of regulatory oversight of the MISA with the assistance of three Field Operations Managers (FOMs), who supervise the Area Technical Managers (ATMs), and the government On-Plant Veterinarians (OPVs) stationed at the establishments. At the in-plant level, the OPVs in turn, supervise:

- The in-plant government inspectors that are classified as Food Safety Meat Assessors (FSMAs) who perform post-mortem meat inspection at export registered meat establishments. According to the Australian government, meat inspection for the United States can only be undertaken by government employed FSMAs (see Appendix B, letter from Greg Read to Dr. Shaukat H. Syed, 23 December 2015; letter from Greg Read to Dr. Shaukat H. Syed, February 2016).
- The Australian Government Authorized Officers (AAOs) are non-government officials, who are authorized by the Australian government to conduct post-mortem examination duties at certified establishments.

FSIS reviewed procedures that the CCA uses to describe the protocol followed by meat producing establishments to obtain approval and certification to export meat products to the United States. The information provided shows that eligible establishments must first register with the CCA, maintain consistent regulatory compliance, and be free from debt to the commonwealth. In addition, establishments file an application for certification with the ED and develop an Approved Arrangement (AA).

An AA is a series of documents evaluated and approved by CCA officials that describe the processes and practices establishments follow to implement quality systems and food safety program to meet regulatory and certification requirements. The FSIS auditor verified that the Non-Interference Clause (NIC) for AAOs was implemented during the establishment visits. In accordance with the NIC, AAOs specifically assigned to perform post-mortem examination duties on behalf of the Australian government must be supported in their functions by establishments' staff, and establishments must not interfere with the performance of their post-mortem duties.

As part of the mandated requirements for establishments certified to export to the United States, the AAs must include a HACCP program that establishes a Critical Control Point (CCP) to ensure that there is ZT for visible fecal matter, ingesta, or milk material on carcasses, as required by the CCA.

The CCA also requires that establishments and in-plant FSMAs conduct visual Meat Hygiene Assessments (MHA) to verify the adequacy of hygienic conditions of meat products before shipping and to determine the Product Hygiene Index (PHI) for establishments. The MHA examines the macroscopic carcass data, including hair, bruises, or blood clots; hide pieces; smears or stains; specks; rail dust; seed; foreign objects; feces; ingesta; milk; urine; and pathology. Microbiological data is collected for Aerobic Plate Count (APC), for generic *E. coli*, and *Salmonella*. Results of the MHA conducted by in-plant OPVs and FSMAs and by establishment personnel are collected and submitted to a centrally located data processing site on a monthly basis. The data from all certified establishments is analyzed and packaged as a nationwide comparative analysis of the PHI standing of each establishment, which is sent by the CCA to establishments and in-plant government officials. As indicated by the CCA officials, this monitoring mechanism permits the MISA to detect rapidly issues and developing trends that are corrected early to maintain market access.

In addition, the CCA describes in its Meat Hygiene Assessment Objective Methods for the Monitoring of Processes and Product, 2nd edition, that MHAs are additional activities that will assist in the implementation of HACCP plans. FSIS verified this feature of the Australian meat inspection system by observing government officials collect samples in accordance with established protocol. Such data includes findings related to carcass contamination at the CCP for zero tolerance that are identified by the FSMA that conducts carcass-by-carcass verification at the end of the line.

In-plant government officials, consisting of full time government OPVs, supported by FSMAs, provide inspection of production facilities; and verify the performance of the AAOs who conduct post-mortem examination of the head and viscera in bovine.

At least one FSMA is required to be present on each inspection chain at plants exporting to the United States. The OPV has a veterinary degree and qualification in food safety competencies and is present full time in the plant, performing ante-mortem inspection, post-mortem inspection dispositions, post-mortem inspection verification; and monitoring, verification, and reporting establishment's regulatory compliance.

FSIS reviewed documentation that demonstrates that the CCA has published regulations and manages their enforcement at slaughter/fabrication establishments certified to export raw meat products to the United States. The CCA ensures that all animals intended for slaughter receive ante-mortem and post-mortem inspection. During the on-site audit, the FSIS auditor verified that the CCA maintains a regulatory presence at establishments certified to export meat products to the United States. The OPV or a FSMA performs ante-mortem inspection. Post-mortem inspection is conducted in one of the following two approaches: a traditional approach in which FSMAs conduct all phases of post-mortem inspection and an equivalent in which post-mortem inspection of the carcasses is accomplished by FSMAs and AAOs examine the heads and viscera.

As indicated previously, AAOs are non-government plant employees that have been authorized by the Australian government to specifically conduct post-mortem examination duties. The AAOs' responsibilities include: taking action when carcasses are presented for post-mortem examination; taking action when carcasses are not appropriately presented for post-mortem inspection; conducting post-mortem examination and making dispositions as they relate to non-food safety carcass conditions; notifying the FSMA or the OPV when assistance is needed for making dispositions; performing post-mortem examination of all suspect animals and emergency slaughter animals under the supervision of the OPV; and following directions of the OPV for further duties related to post-mortem inspection such as collection of residue samples.

The delivery of post-mortem inspection is overseen by OPVs who remain the highest regulatory authority at certified establishments. The FSIS auditor verified by records review and observations at slaughter establishments that government officials ensure that post-mortem inspection of slaughtered livestock is conducted in accordance with uniform instructions and performance standards developed by the CCA and consistent with the United States' import requirements that call for the examination of all carcasses and parts of slaughtered livestock. OPVs and FSMAs stationed at establishments monitor the adequacy of dressing procedures, collect official verification samples of tissues to be analyzed by chemical and microbiological laboratories, and verify that establishments collect and analyze samples of their products to verify efficacy of sanitary controls. In addition, the government inspectors report post-mortem non-compliances and results of verification activities to the CCA by entering establishment performance information into the national databank maintained by the Australian meat inspection system. FSMAs are also stationed on the slaughter line to conduct carcass-by-carcass inspection, in accordance with the design for equivalence determination conducted by FSIS.

The FSIS auditor verified that the CCA exercises ultimate control and supervision over the official inspection activities of all employees or licensees of the system by conducting regular evaluations of their performance and by promptly correcting deficiencies. The CCA ensures that OPVs and FSMAs verify that meat production activities conducted at certified establishments

comply with regulatory requirements that apply to safe production of meat products for human consumption, sanitary product handling practices and controls, and construction and maintenance of facilities. The uniform enforcement of its regulations is accomplished by disseminating regulatory issuances that provide instructions or clarification on how to enforce the system's regulations and how to ensure compliance with export standards via automated information distribution networks.

The FSIS auditor observed that the Australian Government Regulatory Team via the Department of Agriculture uses the FSMAs to deliver post-mortem examination. The FSMAs are employees of the Australia government.

The FSIS auditor verified that in-plant government officials receive copies of Standard Procedures (SP) and Work Instructions (WI) issued by the CCA at their stations. Additionally, the auditor verified during the on-site audit interviews that CCA officials demonstrated that they were knowledgeable of the technical and administrative instructions contained in the WI, which are issued by the CCA based on its export standards and the United States' requirements. The WIs provide methods, references, and itemized instructions to in-plant FSMAs and AAOs to verify the establishments' compliance with the United States' requirements. Carcass Zero Tolerance (ZT) Verification, WI 2.02.09, is used to verify that slaughter establishments that export meat to the United States effectively implement a HACCP plan that includes a CCP to prevent the presence of fecal matter, ingesta and milk contamination (ZT) on carcasses.

During the on-site audit, the FSIS auditor confirmed that OPVs assigned at certified slaughter/fabrication establishments earned a veterinary degree. Veterinarians also complete induction training to develop and master technical, regulatory, and supervisory skills needed to perform their duties. The ultimate responsibility for delivery of inspection and verification services at the certified establishments remains with the office of the OPV. Government OPVs are off-line veterinary inspectors who conduct ante-mortem inspection, disposition, and reporting; verify adequacy of post-mortem inspection and examination conducted by FSMAs and AAOs, respectively; make post-mortem dispositions of retained carcasses; monitor, verify and audit an establishment's compliance with their AAs; and supervise and manage inspection personnel.

The in-plant FSMAs and AAOs assigned to conduct post-mortem inspection or, in the case of AAOs, examination, must earn a national qualification in meat safety, namely Meat Safety (MS) IV certificate, issued by a registered training organization, and obtain food safety auditor competencies for officers undertaking verification. Additionally, they must demonstrate a satisfactory level of proficiency in the performance of assigned meat inspection or examination duties. They carry out dispositions, carcass-by-carcass assessments to identify pathology and contamination, and assist the government veterinarian with post-mortem inspection duties. The CCA also grants authorization to AAOs who have obtained an MS III certificate, to perform post-mortem examination, but as a temporary 12-month appointment. This acceptance allows the candidates the opportunity to gain additional experience to obtain a MS IV certificate.

The FSIS auditor observed the regulatory activities performed by FSMAs and OPVs at seven slaughter establishments in which post-mortem inspection is conducted with the participation of

FSMAs and AAOs. FSIS observed the presence of one FSMA at the end of each slaughter line (EOL). The EOL-FSMA verifies that each carcass is free of visual contamination and pathological lesions of food safety significance after AAOs post-mortem examination and the CCP for ZT monitoring station. Accordingly, as per CCA instructions, when the EOL-FSMAs find ZT contamination on the carcasses, they notify the establishments, require corrective actions as per the establishments' HACCP plans, and document the occurrences in the post-mortem inspection record kept at their stations. The review of records conducted by FSIS showed that in-plant officials identify non-compliances, take official control actions, document all actions, and require corrective actions.

During the previous FSIS audit, FSIS reviewed post-mortem inspection records, noted that EOL-FSMAs regularly identified ZT contamination on carcasses, and documented such occurrences, but CCA officials did not use that data to evaluate the adequacy of implementation of the establishments' HACCP plans. Rather, they used it as an indicator of the adequacy of post-mortem examination delivery on the part of AAOs. This non-compliance was corrected by the CCA issuing a new guidance for government in-plant personnel to formally discuss CCP-ZT deviations with the establishments and to investigate the root cause of the non-compliance. Additionally, establishments' quality assurance staff is accountable for CCP-ZT deviation and the implementation of response measures.

The FSIS auditor verified that establishments that are unable to meet the standards of the export program are delisted, and their certifications are suspended as part of the CCA's administrative actions. Records presented by in-plant officials demonstrate that, in response to FSIS reports of POE violations from 2013 through 2014, officials in the CCA carried out proper action to verify that establishments implemented appropriate corrective actions. Furthermore, the CCA has instituted a POE response policy (RP) that frames delivery of regulatory verification to be implemented to respond to POE violations. The RP provides measures to be followed when Australian meat products are involved in POE violations. Depending on the frequency of violations of FSIS requirements from the United States exporting establishments at the United States POE, the CCA will take regulatory actions that progress from verification activities to denial of access to the United States market when an establishment is involved in three violations taking place in one year.

The FSIS auditor verified that the CCA provides oversight to its technical support by auditing the adequacy of the performance of laboratories. The FSIS auditor observed the establishments' collection, handling, and shipping of product samples, for *Salmonella* and generic *E. coli* analyses, to private laboratories overseen by in-plant government officials in accordance with procedures that FSIS previously determined to be equivalent. The laboratories of the Australian meat inspection system gain and maintain accreditation granted by the International Laboratory Accreditation Cooperation (ILAC) and the National Association of Testing Authorities (NATA). NATA is an Australian agency and a member of ILAC that provides assurances to the CCA that analytical services provided by accredited laboratories are in line with government regulations and meet market access requirements. NATA provided laboratory accreditation for International Organization for Standardization (ISO) 17025 to government approved laboratories. These requirements pertain to all government-approved laboratories. In addition, CCA representatives and scientists conduct audits of both chemical residue and microbiological laboratories.

During the 2013 audit, FSIS reported that government oversight of slaughter establishments required the attention of the CCA to ensure that establishments fully met the regulatory HACCP requirements of the Australian meat inspection system. Specifically, the CCA's instructions to in-plant inspection personnel did not direct inspectors to document deviations from the critical control point for zero tolerance contamination (CCP-ZT) as evidence of inadequate implementation of establishments' HACCP plans. Additionally, inspection officials collected data that showed frequent occurrence of CCP for ZT deviations, but the CCA did not use that information as an indicator of inadequate implementation of establishments' HACCP plans. The FSIS auditor verified that this problem has since been corrected.

An additional 2013 audit finding was related to establishments not conducting a re-assessment of their HACCP plans as they underwent modification of post-mortem inspection. The CCA responded that in their view, transitioning from FSMAs conducting post-mortem inspection to a combination of AAOs and FSMAs did not require a reassessment of the establishments' HACCP plan. The reason that the CCA gives is that meat examiners continue to be trained at the same level, interventions relating to CCPs are the same under the new system, and the new system only affects who will conduct meat inspection and thus does not affect the effectiveness of the slaughter HACCP plans. The CCA has also indicated that establishments are required to conduct a reassessment of their HACCP systems when the incidence of deviations at CCP-ZT exceeds the established level of confidence, thus indicating an inadequate control of the slaughter process.

FSIS observations of inspection program activities, interviews of inspection personnel, and reviews of official inspection records during the on-site audit confirm that the CCA has administrative controls to support its inspection system, and that the CCA is enforcing applicable regulatory requirements.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. This component pertains to the legal authority and the regulatory framework utilized by the CCA to impose upon producers' requirements equivalent to those governing the United States' system of meat inspection. An equivalent inspection system operates an appropriate regulatory framework that demonstrates equivalence with FSIS requirements, including, but not limited to, humane handling, slaughter, ante-mortem inspection, post-mortem inspection, establishment construction, facilities, equipment, daily inspection, direct and continuous official supervision of slaughter activities, and periodic supervisory visits to establishments eligible to export meat products to the United States.

The evaluation of this component included an analysis of information provided by the CCA in the SRT and observations of the functions of government offices, establishments, and laboratories gathered during the on-site verification phase of the audit of the system. The FSIS auditor verified that the meat inspection system of Australia has statutory authority to deliver inspection to all certified establishments, and that the official inspection and verification activities were in accordance with the responses provided in the SRT and supporting

documentation. There are no other regulatory changes associated with the export of meat products to the United States since the last audit that would have required changes by the CCA.

Furthermore, the CCA has rules that require that official inspection personnel, laboratories, and establishments ensure that meat products meet United States requirements. In addition, the system has regulatory requirements for continuous inspection of slaughter and processing activities at establishments that produce meat products for the United States market, control of inedible and condemned materials, and periodic supervisory reviews of certified establishments.

On-site observations, and government and establishments records reviews conducted by the FSIS auditor demonstrate that, from the point of arrival to the establishments, all cattle are identified and inspected in accordance with established procedures to ensure that only animals that pass ante-mortem inspection continue to slaughter. All animals presented for slaughter undergo ante-mortem inspection, which is conducted by the OPV at small establishments and with the assistance of FSMAs at large establishments. CCA officials verify that livestock arrive at the slaughter establishments accompanied by required documentation that allows the system to trace products back to primary centers of production. During ante-mortem inspection, officials detect abnormalities in livestock presented for slaughter and input inspection results into a data bank managed by the CCA. The FSIS auditor verified the adequacy of ante-mortem facilities as well as the compliance of the establishments in meeting the humane handling requirements imposed by the CCA and the United States.

Post-mortem inspection can be delivered following two configurations of inspection stations. In one configuration, the EOL-FSMA performs carcass-by-carcass inspection at a station located on the line, after the AAO head, viscera, and carcass examination stations. In the other configuration, the AAO head and viscera examination stations remain on the line, and the AAO carcass examination station is eliminated. In that arrangement, the EOL-FSMA alone performs carcass-by-carcass inspection on each slaughter line.

During this on-site audit, FSIS observed that the post-mortem inspection, where the EOL-FSMA is stationed at the end of the line beyond the AAO carcass inspection station, was instituted at three out of the seven certified establishments audited. The remaining four establishments utilized the services of FSMAs. The certified establishments present and correlate proper presentation of heads, viscera, and carcasses and maintained proper synchronization for the post-mortem inspection. Each establishment has a retain carcass line and disposition of suspects and verification of acceptability of the final product was conducted by the OPV. The establishments present heads, viscera, and carcasses properly identified for inspection. The design of the inspection stations meets equivalent requirements, and the EOL-FSMAs demonstrated an acceptable level of proficiency to perform their inspection duties. FSIS also verified the functions of the OPVs as they verified the adequacy of post-mortem inspection.

The OPVs report to plant management results of daily verification of post-mortem inspection and ensure that the establishments promptly address deficiencies in the performance of AAOs. Records reviewed by FSIS showed that OPVs or their designees assess the technical competency of the AAOs daily by monitoring the accuracy and consistency of their post-mortem inspection decisions. The DA inspection personnel follow instructions provided by the CCA in WI 3.03.01,

which describes the verification procedure, responsibilities, and actions to be taken when non-conformances are identified.

The FSIS auditor verified that the CCA requires establishment operators to adhere to their AAs and ensure that their premises are properly built and maintained in good repair to prevent the creation of insanitary conditions. FSIS conducted observations of supervisory officials as they evaluated design and maintenance of the facilities, sanitary conditions, monitoring of food safety systems, official verification activities, and competence of in-plant officials. The observations made by the FSIS auditor indicate that supervisory government officials periodically assess the functions of FSMAs and AAOs, establishments, document non-compliances, verify adequacy of corrective actions, and provide guidance to officials and establishments. Documents reviewed by FSIS during the audit indicate that operators of the establishments and government officials interact to ensure that noncompliances related to maintenance of the facilities are identified and addressed to comply with the regulations of the program.

FSIS determined that, in accordance with the rules of the Australian meat inspection system, there are the following operational verification levels:

1. Establishment verification of their approved arrangements such as internal audits
 - Quality assurance team, and
 - Establishments have primary responsibility for food safety and legislative compliance.
2. Monitoring, verification, and audit establishment compliance with the AAs and legislation
 - The Australian Government Regulatory Team.
3. Periodic supervisory audits of in-plant system
 - Area Technical Managers (ATMs), Food Safety Auditors (meat products, minced meat, meat preparations, casings).
4. Performance management
 - Field Operations Managers.
5. System audits
 - DA certification integrity unit and DA compliance unit.
6. External audits
 - Australian National Audit Office, importing country authorities.

OPVs conduct regular on-site reviews of the performance of the food safety systems of the establishment compliance with the AAs, and the DA performs audit and verification activities such as post-mortem under veterinary supervision, operational and system verification, microbiological data and ongoing monitoring, residue data and ongoing monitoring, and objective data analysis such as product hygiene index. ATMs also conduct periodic (quarterly) evaluations of the performance of in-plant officials and verify the level of regulatory compliance maintained by certified establishments. The FSIS auditor reviewed ATMs' reports and found that they regularly assess the progress of corrective actions.

Periodic evaluations are also conducted by FOMs who assess establishments' performance. FOMs verify corrective actions addressing deficiencies identified by foreign auditors and to FSIS' reports of POE violations. The FSIS auditor reviewed records and reports generated by

the OPVs to document assessments of the establishments' AAs and verified that deficiencies are identified, documented, and corrected by the establishments. These observations made by FSIS indicate that government officials periodically assess the functions of inspection personnel and establishment operators, document non-compliances, verify adequacy of corrective actions, and provide guidance to officials and establishments.

The ATMs' inspection officials assessed the food safety systems of certified establishments by conducting evaluations of production areas and reviewing documentation generated and maintained by establishment personnel and in-plant government inspection personnel. The ATMs' performance of the oversight of the establishment reviews demonstrated that the CCA maintained adequate regulatory oversight over the production functions of establishments in accordance with Australian regulations.

The FSIS auditor verified that OPVs and ATMs input data into the system as they complete reports of audit outcomes. At the end of each month, OPVs compile results of daily verification activities conducted by the establishment and inspection personnel and send a report to CCA headquarters. The system then processes the data and generates output that reaches the OPVs and establishments approximately one month after submission. Government officials at several levels can access and analyze the data to determine compliance levels maintained by establishments and performance trends developing at local and national levels. Furthermore, the collected data allows the CCA to identify establishments that require greater official oversight. FSIS observed that the resident veterinarians and ATMs could access the data bank from the government offices at the establishment and were proficient at gathering and filtering data to generate examples of work instructions, post-mortem inspection summaries, and daily inspection reports.

FSIS observations of inspection program activities, interviews of inspection personnel, and reviews of official inspection records during the on-site audit confirms that the CCA's meat inspection system continues to have both legal authority and a regulatory framework to implement requirements equivalent to those governing the United States' system of meat inspection.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. The inspection system must provide requirements for sanitation, sanitary handling of products, and development and implementation of sanitation standard operating procedures.

The evaluation of this component included a desk review and analysis of the information provided by the CCA in the sanitation component portions of the SRT, covering Sanitation Standard Operating Procedures (SSOP) and Sanitation Performance Standard (SPS) observations gathered during the on-site verification audit of seven slaughter establishments and their corresponding DA local offices. FSIS reviewed legislation, regulations, and official instructions such as the National Establishment Verification System (NEVS) to verify that the CCA has and exercises legal authority in verification of the establishment structure and maintenance,

sanitation and pest control to require establishments to develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions.

The information reviewed indicates that the CCA has legal authority to require that establishments operate in a manner that prevents the creation of insanitary conditions, and that establishments develop written sanitation programs that they are to follow to prevent direct product contamination and that in-plant official inspection personnel perform duties to verify the adequacy of implementation of plant sanitation programs. The OPVs and FSMAs who regularly assess the conditions perform official verification of compliance with that requirement and maintenance of the facilities at all certified establishments, review of their written sanitation procedures, and evaluate their implementation.

Establishments are also required to monitor the adequacy of their facilities, conduct analysis of product and personnel flow, develop maintenance programs for equipment and structures, and develop methodology to classify the severity of the deficiencies. During the on-site audit, the FSIS auditor verified the adequacy of verification and inspection functions of CCA officials. The auditor reviewed monitoring records for pre-operational and operational sanitation. The auditor verified that the written sanitation programs prepared by the establishments describe the procedures are being followed to ensure that all product contact surfaces will be cleaned and sanitized prior to the beginning of production, along with what measures that they will implement to prevent direct product contamination throughout the production day.

Additionally, during the on-site audit, the FSIS auditor verified on-site the functions of the ATMs and OPVs as they evaluated the sanitary conditions of the plants and reviewed electronic and hard copy documents, as well as monitoring and verification records such as in-plant DA verification forms. The FSIS verification activities also included an assessment of the sanitary dressing procedures that the CCA reported to FSIS as part of the corrective actions implemented by the establishments to address POE violations involving ZT contamination on raw beef products reported by FSIS in fiscal years 2013 and 2014.

The FSIS auditor observed that, as proffered in the corrective actions presented by the CCA, the sanitary issues were addressed at individual establishments and a checklist was developed based on sanitary observations for all United States-certified establishments. The DA verifies compliance with the implementation requirements for the National Establishment Verification System in order to allow in-plant government staff more time to assess high priority areas. Additionally, in-plant officials assess the level of cleanliness of arriving livestock and require that the establishments adjust slaughter line speeds accordingly. Inspection records also demonstrated that in-plant government officials regularly inspect the facilities and document deficiencies that are corrected and verified as part of the procedure prescribed by the CCA.

FSIS observed government officials as they assessed the pre-operational and operational sanitation monitoring and confirmed CCA evaluation of the sanitation procedures of the establishments. However, a number of sanitation minor deficiencies were identified by the FSIS auditor and immediately corrected by the CCA and industry. These deficiencies, although addressed by prompt corrective measures by the establishments and the CCA, indicate that establishments and the CCA need to monitor and better verify the sanitary conditions of their

equipment and facilities. In addition, in-plant officials need to assess in a more critical manner the implementation of sanitation programs to identify and require correction of potential sources of product contamination.

The FSIS analysis and on-site verification activities indicate that the CCA requires operators of official establishments to develop, implement, and maintain sanitation programs.

VII. COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. This component requires that an inspection system must have regulatory requirements for certified establishments to develop, implement, and maintain HACCP plans.

The evaluation of this component included a desk review and analysis of the information provided by the CCA in its SRT and by auditing on-site the performance of establishments, and government sectors of the system.

The evaluation of this component included a document review of regulatory standards such as Australian Standards for Hygienic Production and Transportation of Meat and Meat Products for Human Consumption (AS4696) that includes HACCP implementation and Australian guidelines, and training materials, issued by the CCA. FSIS also assessed the adequacy of HACCP program verification activities conducted by government officials and establishment operators at the establishment level by observing on-site verification activities and by reviewing electronic and hard copy versions of monitoring and verification records generated by operators and in-plant government officials.

The documents reviewed also included reports presented by the CCA in response to multiple POE violations related to the United States' requirement for ZT for fecal matter, ingesta, and milk contamination on meat products. The observations, review of documents, and analysis of information conducted by FSIS revealed that the Australian meat inspection system imposes regulatory requirements for the development, implementation, and maintenance of HACCP programs in certified establishments that include the slaughter HACCP plan and a CCP to control ZT contamination. Furthermore, the FSIS auditor verified that in-plant officials and ATMs periodically assess the adequacy of the establishments' HACCP programs.

FSIS' on-site evaluation of the design and execution of HACCP programs as well as records and documents review indicate that CCA officials assess the adequacy of the hazard analysis, monitoring of CCPs, corrective actions, record keeping, and verification activities at seven audited establishments comply with the HACCP system rules. CCA officials also conducted HACCP program reviews in response to POE violations.

The FSIS auditor verified that establishments and government offices have responded to the six POE violations reported by FSIS from November 2013 through July 2014 that included five instances of ZT deviations related to fecal matter and ingesta on meat products. The CCA and the establishments involved have responded to FSIS reports by conducting investigations, re-

training operators on their kill floors to prevent carcass contamination, and assessing the adequacy of the establishments' HACCP plans. However, repeated POE violations in which meat products from Australia have been rejected for public health reasons involving ZT and ingesta violations indicate that greater effort is required to ensure the adequacy of HACCP systems implemented by establishments.

In conclusion, the CCA addressed the findings above by requiring that establishments monitor the CCPs in their HACCP plans at an appropriate frequency and ensure that the establishments adequately identify the root causes of CCP deviations to initiate corrective actions to effectively prevent recurrence. However, because of the number of reported POE violations in which meat products from Australia were rejected for public health reasons, FSIS expects that the CCA will ensure that United States-eligible establishments do better at assessing the adequacy of their HACCP systems.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUES CONTROL PROGRAM

The fifth of six equivalence components that FSIS reviewed was Chemical Residues. The inspection system is to have a written chemical residue control program that is organized and administered by the national government and that includes random sampling of the internal organs, fat, and muscle of carcasses for chemical residues as identified by the exporting country's relevant authorities or by FSIS as potential contaminants.

FSIS assessed Australia's residue control program by analyzing information provided through the SRT, as well as provided by the CCA during the audit of the central offices and by observing operations at the official chemical residue laboratory, and seven certified slaughter establishments.

Agriculture chemical control in Australia involves Federal and State governments. The Federal Government has policy-setting roles and responsibilities. The Australian Pesticides and Veterinary Medicines Authority (APVMA) sets maximum residue limits (MRLs) and registers pesticides and veterinary drugs. The Food Standards Australia and New Zealand adopts MRLs into the Food Codes.

State/Territory governments have regulatory roles and responsibilities including establishing legislation that sets out how pesticides and veterinary drugs should be used, and conducting investigations and regulatory action if residues above the Australian MRL are detected.

The FSIS auditor verified that the CCA has delegated the responsibility to maintain monitoring and surveillance of animals and animal products to detect evidence of chemical residues in edible tissues to the National Residue Survey (NRS). The auditor also established that the NRS is an operational unit of the FD that manages food safety and residue controls. In accordance with the statute that governs food safety in Australia, the NRS identifies potential problems and provides guidance to other organizations where there is a need for control or follow up to address violations or emerging issues related to the presence of chemical residues and contaminants in food.

Additionally, the NRS is monitoring chemical residues and other contaminants and manages national random and targeted testing programs for chemical residues in agricultural food commodities. The NRS is operated by the Australian government's DA and is funded by levies on primary production by those industries that choose to participate in the Survey. The NRS laboratory performance evaluation (PE) system has been developed to provide assurance of reliability using a range of proficiency tests (PT) and other PE techniques in the selection of laboratories for NRS work.

- The NRS is a NATA accredited provider of proficiency tests and is recognized as complying with ISO/IEC 17043:2010 General requirements for proficiency testing,
- All NRS programs are industry funded through levies (transaction, slaughter or value) or direct contract payments,
- Laboratories performing tests are contracted by NRS,
- NRS has an Memorandum of Understanding (MOU) with the state/territory government to follow up actions, and
- NRS certified to AS/NZS ISO 9001:2008 for its quality management system.

Official documents reviewed by FSIS indicate that the NRS operates within a statutory framework that permits its functions to be financed on a full-cost recovery basis. Industries pay for the analytical services provided by the NRS, which in turn, pays the laboratories when they receive an invoice, and when the analysis of the results is conducted. Results of the analyses provide the CCA with indicators of the adequacy of chemical residue controls at primary centers of production. The database that laboratory analyses generate is managed and packaged by the NRS, which distributes quarterly and annual reports of analytical results to stakeholders and trading partners.

Additional information provided by the CCA to FSIS indicates that factors considered when determining the annual monitoring residue program include: registered use of a particular chemical, likely occurrence of residues, extent and pattern of use, incentives for misuse, persistence of the compound in the environment, past monitoring results, availability of suitable analytical methods, testing capacity and laboratory proficiency, testing arrangements, specific overseas requirements, and perceptions of the residue as a possible public health hazard.

FSIS verified that the NRS manages national random and targeted testing programs for chemical residues in agricultural commodities in consultation with industry and the sectors of the CCA that participate in the testing of food products. The NRS also manages the design of the testing programs and operational processes that include sample collection, shipping to laboratories, management, and analysis of data and initiation of trace-back activities. However, analysis of samples is delegated to laboratories that the NRS contracts with through a competitive bidding process.

All NRS meat-testing programs are designed, operated, and reviewed within agreed budgets by the NRS in consultation with the DA and industry.

Random monitoring programs:

- Risk-based approach to program design, and

- Sample collection rates based on production levels, or are requirements set by export markets.

Targeted testing programs

- Designed to meet particular management objectives relating to potential chemical residues that could pose a risk for access to export or domestic markets.

Sample collection at export registered slaughterhouses

- Frequency as requested by the NRS (also on the professional opinion of the OPV), and
- Collected by the OPV or regulatory team under OPV supervision.

The type of oversight the CCA provides to the functions of chemical laboratories was also assessed by FSIS. Before a laboratory is contracted it must be accredited by NATA to ISO 17025 for relevant analytical method and satisfy pre-tender proficiency testing (PT). Once the lab is contracted by NRS, it is being awarded a three to five year contract to analyze samples. Additionally, the contracted laboratories continue using the methods of analysis evaluated at the time of their assessment and participate in proficiency testing via inter-laboratory and intra-laboratory check sample programs. The NRS audits the laboratories periodically to evaluate their performance, assessing their technical and managerial competence in accordance with ISO 17025 standards, NATA standards, CCA and United States requirements. The system provides a pool of capable laboratories (emergency response) providing consistent laboratory performance.

FSIS' ongoing equivalence audit included review of documents provided by the CCA and records of NRS past evaluations that document that the laboratories are being adequately overseen by the Australian government. The program includes random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified as potential contaminants. Furthermore, FSIS verified that the OPV collects samples in accordance with standard operating procedures, as instructed by the NRS, and when, in the professional judgment of the OPV, sampling of animal tissues is deemed necessary to establish their acceptability as a source of human food. Collected samples are sent to the laboratories for analyses via a Central Receiving and Dispatch site in Canberra. FSIS also verified that provisions of the regulatory controls managed by the CCA confer legal authority upon in-plant officials to condemn food products when laboratory analysis indicates the presence of chemical residues at a level that exceeds Australian standards.

The NRS report for the random monitoring program results of 2013-14 showed that 6,000 samples of cattle meat have 99.96% compliance. Goat meat commodity was sampled 255 times with 99.61% compliance, while in sheep 5,494 samples were analyzed with 99.76% compliance.

The CCA has a chemical residue control program that is organized and administered by the national government in accordance with the United States' requirements.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs. This component pertains to the microbiological analysis programs that the

CCA organizes and administers to verify that meat products destined for export to the United States are unadulterated, safe, and wholesome.

To determine ongoing equivalence of this component, FSIS reviewed the responses provided by the CCA in the Pathogen Reduction Standards section of its SRT that describe generic *E. coli* and *Salmonella* sampling, as well as *E. coli* O157:H7 and non-O157 Shiga toxin producing *Escherichia coli* (STEC) control program. During the on-site audit, FSIS assessed the daily implementation of the microbiological sampling of generic *E. coli*, *Salmonella*, and *E. coli* O157:H7 and testing of raw meat product activities conducted by establishments and laboratories. The documents reviewed during this ongoing equivalence audit demonstrate that the CCA administers a national regulatory microbiological monitoring program for establishments producing meat products for export to the United States. The program provides indicators of the adequacy of sanitary dressing procedures and production practices and verification of effectiveness of establishments' food safety controls designed to address microbiological pathogens.

The Australian laboratory system operates under ILAC and NATA, which provide laboratory accreditation of ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories" to government and commercial/private laboratories. FSIS confirmed that laboratories conducting microbiological analysis of meat samples are participants of the Approved Laboratory Program (ALP) of the DA. General requirements contain annual review of laboratory compliance to the requirements of ISO/IEC 17025 by the DA or NATA, 6-monthly proficiency for all organisms, report results directly to the DA, both private (in-plant) and commercial laboratories, DA approved methods (FSIS equivalence determination). Laboratories participating in the ALP conduct microbiological analyses of edible meat products from certified establishments. Prior to testing the products, the laboratories successfully complete an evaluation of their performance conducted by NATA. Laboratories also submit their scope of accreditation, an agreement to participate in proficiency testing programs, and the details of the approved laboratory methods they intend to use to analyse products.

The DA approved laboratory program uses approved methods that must be internationally recognized by Association of Official Analytical Chemists (AOAC), must be appropriately validated for meat or meat product. Currently, DA approved methods are for aerobic plate count (APC), generic *E. coli*, Coliforms, *Salmonella*, *Listeria*, and *E. coli* O157:H7.

FSIS audited one approved private microbiological laboratory, Symbio Alliance in Brisbane, during the on-site verification portion of this audit and reviewed official documents including reports and records generated by DA and NATA experts that contained results of evaluations, proficiency tests, and verification of corrective actions. The FSIS auditor verified that NATA and DA audits of this laboratory had assessed acceptability of laboratory conditions, scope of accreditation, adequacy of records generated, and corrective actions taken to address results of past audits in accordance with the guidance provided by ISO 17025. FSIS established that the CCA maintains oversight of this laboratory to ensure that it follows official protocols and performs its functions adequately.

Documents reviewed by FSIS and observations made at certified slaughter establishments demonstrate that testing of raw products for generic *E. coli* and *Salmonella* are conducted at slaughter facilities. Collection of random samples, along with the shipping and handling of the samples, is done by the establishment employees under the supervision of in-plant Australian inspection officials and in accordance with instructions issued by the CCA in the *E. coli* and *Salmonella* monitoring program for export-slaughter establishments. Cattle will be sampled after 12 hours of active chilling. Small stock carcasses are sampled after minimum of 4 hours of active chilling. Sampling was carried out by sponging the approved site on the randomly selected carcass. Generic *E. coli* samples are taken at a frequency proportional to a slaughter establishment's volume of production at the rate of one test in 300 carcasses in cows/bulls with sampling area of 300 cm². In sheep, the sampling frequency was one (1) in 1,000 carcasses with sampling area of 75 cm². The *Salmonella* samples are taken at frequency proportional to a slaughter establishment's volume of production at the minimum rates of one test per 1,500 carcasses with 300 cm² in cattle, while one test per 5,000 carcasses with 75 cm² is required as a sampling area in sheep. The samples must be sent to the laboratory on the day of collection and analysed no later than the day following collection. The *E. coli* and *Salmonella* samples must be transported to the laboratory at the sample temperature between 0° to 10° C.

The samples are analyzed at CCA-approved, NATA-accredited laboratories that participate in six months of external proficiency testing and report results of the analyses to CCA officials and establishments at the same time. Generic *E. coli* results are quantified and reported in colony forming units per square centimeter (cfu/cm²). The results of this organism in the ESAM program are assessed on a moving window of 15 samples for continuous evaluation. The audited laboratory was using Petri film or ISO methods for detection of this organism. *Salmonella* results are qualitatively assessed, i.e. detected or not detected, and reported as pass or fail based on the test result being positive or negative. The visited laboratory was using ISO/PCR/ELISA testing methods for this pathogen on beef carcasses. The DA verifies microbiological sampling, testing and results. Establishments also test contact surfaces and equipment to verify the effectiveness of their sanitation process.

The FSIS auditor assessed the implementation of the microbiological verification activities overseen by the CCA in-plant and verified that certified slaughter establishments conduct microbiological sampling of carcasses and parts in accordance with official protocols. In addition, in-plant officials verify the adequacy of implementation of sampling and analysis protocols, and track and evaluate sampling results. Furthermore, government officials enter reported results into the national ESAM program Meat Tech Database, which is managed by the CCA to track establishments' performance and to analyze the national status of microbial control strategies.

The regulations imposed by the CCA upon producers to control *Salmonella* in raw meat products require that three consecutive failures to meet the *Salmonella* control standards is deemed by the Australian authorities as a failure to maintain the minimum standard for slaughter hygiene and sanitation. Such a failure brings into question the adequacy of the HACCP plan of the establishment. Accordingly, the CCA would impose regulatory sanctions consistent with the statutory framework of the Australian meat inspection system and exclude such operators from the export program.

FSIS also assessed the *E. coli* O157:H7 control program managed by the CCA. Documents reviewed included the results of testing of raw ground beef components for the *E. coli* O157:H7 program provided by the CCA and records maintained by the establishments. The CCA requires test and hold for all lots of raw ground beef components destined for the United States and verification of the testing programs used by the establishments to determine that they meet the requirements of the MISA. In addition, the CCA tests raw ground beef components destined for the United States at least monthly. The CCA revised this protocol to include the additional STECs of concern and presented it to FSIS in July 2013 in the SRT for determination of continued equivalence. It was found to be equivalent in January 2014. Samples collected by the establishment and government officials are analysed in CCA-approved laboratories.

FSIS evaluated the ability of government officials to provide oversight over the collection and handling of samples for *E. coli* O157:H7 analysis and verified that plant employees adhere to proper aseptic protocols. They also confirmed that the officials conducted identification and handling of samples in an adequate manner. Government officials adequately verified that identification of collected samples was consistent with CCA requirements. The O157 Shiga toxin(s) samples for beef are tested by the PCR, MLG/GDS method.

The microbiological testing programs component of the MISA is organized and administered by the national government to verify that meat products destined for export to the United States are unadulterated, safe, and wholesome in accordance with the United States' requirements.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on December 8, 2014, in Canberra with representatives of the DA, FSIS, and Foreign Agriculture Service AS. At this meeting, the preliminary observations from the audit were presented by the FSIS auditor.

In conclusion, FSIS observations of inspection program activities, interviews of inspection personnel, and reviews of official inspection records during the on-site audit confirm that the components of Australia's meat inspection system continue to meet US core requirements. However, FSIS identified the following finding related to the HACCP systems component of the Australian meat inspection system:

- Repeated POE violations in which meat products from Australia have been rejected for public health reasons involving ZT and ingesta violations indicate that greater effort is required on the part of the CCA to ensure the adequacy of HACCP systems implemented by establishments.

FSIS expects that the CCA will implement prompt corrective actions to address the above reported finding and provide to FSIS a report on the adequacy of their implementation within the next 60 calendar days. FSIS will evaluate the adequacy of the CCA's proposed corrective actions once received.

APPENDICES

APPENDIX A: Australia's Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|---|---|----------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION JBS Australia PTY LTD 490 Meat works Road Bordertown South Australia | 2. AUDIT DATE 12/03/2014 | 3. ESTABLISHMENT NO. 90 | 4. NAME OF COUNTRY Australia |
| | 5. NAME OF AUDITOR(S) Oto Urban, DVM | | 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT |

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

| Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements | Audit Results | Part D - Continued Economic Sampling | Audit Results |
|--|---------------|---|---------------|
| 7. Written SSOP | | 33. Scheduled Sample | |
| 8. Records documenting implementation. | | 34. Specks Testing | |
| 9. Signed and dated SSOP, by on-site or overall authority. | | 35. Residue | |
| Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements | | Part E - Other Requirements | |
| 10. Implementation of SSOP's, including monitoring of implementation. | X | 36. Export | |
| 11. Maintenance and evaluation of the effectiveness of SSOP's. | | 37. Import | |
| 12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration. | | 38. Establishment Grounds and Pest Control | |
| 13. Daily records document item 10, 11 and 12 above. | | 39. Establishment Construction/Maintenance | |
| Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements | | 40. Light | |
| 14. Developed and implemented a written HACCP plan. | | 41. Ventilation | |
| 15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions. | | 42. Plumbing and Sewage | |
| 16. Records documenting implementation and monitoring of the HACCP plan. | | 43. Water Supply | |
| 17. The HACCP plan is signed and dated by the responsible establishment individual. | | 44. Dressing Rooms/Lavatories | |
| Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements | | 45. Equipment and Utensils | |
| 18. Monitoring of HACCP plan. | | 46. Sanitary Operations | X |
| 19. Verification and validation of HACCP plan. | | 47. Employee Hygiene | |
| 20. Corrective action written in HACCP plan. | | 48. Condemned Product Control | |
| 21. Reassessed adequacy of the HACCP plan. | | Part F - Inspection Requirements | |
| 22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. | | 49. Government Staffing | |
| Part C - Economic / Wholesomeness | | 50. Daily Inspection Coverage | |
| 23. Labeling - Product Standards | | 51. Enforcement | X |
| 24. Labeling - Net Weights | | 52. Humane Handling | |
| 25. General Labeling | | 53. Animal Identification | |
| 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture) | | 54. Ante Mortem Inspection | |
| Part D - Sampling Generic E. coli Testing | | 55. Post Mortem Inspection | X |
| 27. Written Procedures | | Part G - Other Regulatory Oversight Requirements | |
| 28. Sample Collection/Analysis | | 56. European Community Directives | O |
| 29. Records | | 57. Monthly Review | |
| Salmonella Performance Standards - Basic Requirements | | 58. SRM | |
| 30. Corrective Actions | | 59. | |
| 31. Reassessment | | | |
| 32. Written Assurance | | | |

60. Observation of the Establishment

Date: 12/03/2014 Est #:90 [S/B] (Australia)

10/51 The FSIS auditor observed that moving viscera plates were not properly washed with remaining blood and other unidentified matter covering several plates. The DA ATM manager stopped the operation and requested the total wash and sanitation of the viscera metal plates. This corrective action was corrected by the establishment management 9 CFR 416.13 (c).

46/51 The establishment employee performing sanitary dressing procedure by pooling the lamb skin off was observed to have his knife sharpener contacting his boots and legs and was not sanitizing his knife after this non-compliance. The employee was instructed by the establishment management to sanitize his knife 9 CFR 416.4 (a).

55/51 The Australian Government approved establishment paid AAO was not properly designated such as with assigned identification and was performed the retained carcass inspection. This retained carcass checking is done by the AAO since AAO requested retain carcass inspection. The FSIS auditor checked the written HACCP and sanitary procedures which indicated the requirement for AAO's identification which was not observed on the lamb slaughter floor. This non-compliance was scheduled for the corrective action 9 CFR 310.1 b (1).

- This establishment performing post-mortem inspection in lamb, the viscera and carcasses are inspected by the one (1) Australian Government authorized (AAO) officer at the viscera and one (1) AAOs at the carcass inspection. One AAO is scheduled for retain carcass and floor duties. One (1) FSMA is inspecting carcasses for pathology and ZT tolerance contamination in this establishment.
- Daily assessment of Inspectors by the OPV:
 - 1) OPV looks 1% of carcasses with MSFA
 - 2) OPV looks 2.5% of carcasses with OOAS

61. NAME OF AUDITOR
Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|---|---|-----------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION PO Box 412 Warrnambool 3280 Victoria Australia | 2. AUDIT DATE 11/21/2014 | 3. ESTABLISHMENT NO. 180 | 4. NAME OF COUNTRY Australia |
| | 5. NAME OF AUDITOR(S) Oto Urban, DVM | | 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT |

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

| Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements | Audit Results | Part D - Continued Economic Sampling | Audit Results |
|--|---------------|---|---------------|
| 7. Written SSOP | | 33. Scheduled Sample | |
| 8. Records documenting implementation. | | 34. Species Testing | |
| 9. Signed and dated SSOP, by on-site or overall authority. | | 35. Residue | |
| Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements | | Part E - Other Requirements | |
| 10. Implementation of SSOP's, including monitoring of implementation. | X | 36. Export | |
| 11. Maintenance and evaluation of the effectiveness of SSOP's. | | 37. Import | |
| 12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration. | | 38. Establishment Grounds and Pest Control | |
| 13. Daily records document item 10, 11 and 12 above. | X | 39. Establishment Construction/Maintenance | |
| Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements | | 40. Light | |
| 14. Developed and implemented a written HACCP plan. | | 41. Ventilation | |
| 15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions. | | 42. Plumbing and Sewage | |
| 16. Records documenting implementation and monitoring of the HACCP plan. | | 43. Water Supply | |
| 17. The HACCP plan is signed and dated by the responsible establishment individual. | | 44. Dressing Rooms/Lavatories | |
| Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements | | 45. Equipment and Utensils | X |
| 18. Monitoring of HACCP plan. | | 46. Sanitary Operations | |
| 19. Verification and validation of HACCP plan. | | 47. Employee Hygiene | |
| 20. Corrective action written in HACCP plan. | | 48. Condemned Product Control | |
| 21. Reassessed adequacy of the HACCP plan. | | Part F - Inspection Requirements | |
| 22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. | | 49. Government Staffing | |
| Part C - Economic / Wholesomeness | | 50. Daily Inspection Coverage | |
| 23. Labeling - Product Standards | | 51. Enforcement | X |
| 24. Labeling - Net Weights | | 52. Humane Handling | |
| 25. General Labeling | | 53. Animal Identification | |
| 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture) | | 54. Ante Mortem Inspection | |
| Part D - Sampling Generic E. coli Testing | | 55. Post Mortem Inspection | |
| 27. Written Procedures | | Part G - Other Regulatory Oversight Requirements | |
| 28. Sample Collection/Analysis | | 56. European Community Directives | O |
| 29. Records | | 57. Monthly Review | |
| Salmonella Performance Standards - Basic Requirements | | 58. SRM | |
| 30. Corrective Actions | | 59. | |
| 31. Reassessment | | | |
| 32. Written Assurance | | | |

10 The FSIS auditor observed the ZT fecal/ingesta/milk monitoring/verification stand's electric cord contacting the passing carcasses during the CCA verification procedure. The immediate and appropriate corrective action of this non-compliance was performed by the establishment management. The electric cord was moved out of the way of moving carcasses 9 CFR 416.13 (c).

10/51 Passing carcasses were contacting and leaning against the stand's railing in the boning room. This non-compliance was corrected immediately by the establishment management by moving the railings from the carcass way 9 CFR 416.13 (c).

13 The verification of the sanitary non-compliance by the OPV did not record the corrective action accomplishment in the weekly verification form. This non-compliance was promised to be corrected by the Field Operation Manager and OPV 9 CFR 416.17 (c).

45/51 Broken and missing conveyor modules in boning room were posing a potential source for product contamination. This non-compliance was observed during of the sheep boning room sanitation and it was scheduled to be corrected by the establishment management 9 CFR 416.3 (a).

- This establishment is performing post-mortem inspection in beef/calves and sheep. The head, viscera and carcasses are inspected in bovine, while viscera and carcasses are inspected in ovine by the DA, Food Safety Meat Assessors (FSMA). There is no inspection performed by the Government Approved establishment paid AAOs in this establishment.

61. NAME OF AUDITOR
Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|--|---|------------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION G&K O'Connor Pty Ltd Kooweerup Road Pakenham Victoria 3810 Australia, PO Box 140 Pakenham | 2. AUDIT DATE 11/24/2014 | 3. ESTABLISHMENT NO. 1265 | 4. NAME OF COUNTRY Australia |
| | 5. NAME OF AUDITOR(S) Oto Urban, DVM | | 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT |

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

| Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements | Audit Results | Part D - Continued Economic Sampling | Audit Results |
|--|---------------|---|---------------|
| 7. Written SSOP | | 33. Scheduled Sample | |
| 8. Records documenting implementation. | | 34. Species Testing | |
| 9. Signed and dated SSOP, by on-site or overall authority. | | 35. Residue | |
| Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements | | Part E - Other Requirements | |
| 10. Implementation of SSOP's, including monitoring of implementation. | | 36. Export | |
| 11. Maintenance and evaluation of the effectiveness of SSOP's. | | 37. Import | |
| 12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration. | | 38. Establishment Grounds and Pest Control | |
| 13. Daily records document item 10, 11 and 12 above. | X | 39. Establishment Construction/Maintenance | |
| Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements | | 40. Light | |
| 14. Developed and implemented a written HACCP plan. | | 41. Ventilation | |
| 15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions. | | 42. Plumbing and Sewage | |
| 16. Records documenting implementation and monitoring of the HACCP plan. | | 43. Water Supply | |
| 17. The HACCP plan is signed and dated by the responsible establishment individual. | | 44. Dressing Rooms/Lavatories | |
| Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements | | 45. Equipment and Utensils | |
| 18. Monitoring of HACCP plan. | | 46. Sanitary Operations | |
| 19. Verification and validation of HACCP plan. | | 47. Employee Hygiene | |
| 20. Corrective action written in HACCP plan. | | 48. Condemned Product Control | |
| 21. Reassessed adequacy of the HACCP plan. | | Part F - Inspection Requirements | |
| 22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. | | 49. Government Staffing | |
| Part C - Economic / Wholesomeness | | 50. Daily Inspection Coverage | |
| 23. Labeling - Product Standards | | 51. Enforcement | X |
| 24. Labeling - Net Weights | | 52. Humane Handling | |
| 25. General Labeling | | 53. Animal Identification | |
| 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture) | | 54. Ante Mortem Inspection | |
| Part D - Sampling Generic E. coli Testing | | 55. Post Mortem Inspection | |
| 27. Written Procedures | | Part G - Other Regulatory Oversight Requirements | |
| 28. Sample Collection/Analysis | | 56. European Community Directives | O |
| 29. Records | | 57. Monthly Review | |
| Salmonella Performance Standards - Basic Requirements | | 58. SRM | |
| 30. Corrective Actions | | 59. | |
| 31. Reassessment | | | |
| 32. Written Assurance | | | |

60. Observation of the Establishment

Date: 11/24/2014 Est #:1265 5 [S/B] (Australia)

13 The OPV (IIC) did not indicate the non-compliance (condensation) extent and location in the Weekly Verification Form. This observation was promised to be changed in the future description of non-compliances 9 CFR 416.17 (c).

13/51 Observed sanitary non-compliance in the establishment's daily records were not properly and sufficiently described by the establishment QA employee. The establishment QA management committed itself to the change of non-compliance recording 9 CFR 416.16 (a).

- This establishment is performing post-mortem inspection in beef, only. The head, viscera and carcasses are inspected by the DA, Food Safety Meat Assessors (FSMA). There is no inspection performed by the Government Approved establishment paid AAOs in this establishment and no end of chain inspection.

61. NAME OF AUDITOR

Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|---|---|------------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION JBS Australia PTY LTD 490 Meat works Road Bordertown South Australia | 2. AUDIT DATE 11/19/2014 | 3. ESTABLISHMENT NO. 1614 | 4. NAME OF COUNTRY Australia |
| | 5. NAME OF AUDITOR(S) Oto Urban, DVM | | 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT |

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

| Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements | Audit Results | Part D - Continued Economic Sampling | Audit Results |
|--|---------------|---|---------------|
| 7. Written SSOP | | 33. Scheduled Sample | |
| 8. Records documenting implementation. | | 34. Species Testing | |
| 9. Signed and dated SSOP, by on-site or overall authority. | | 35. Residue | |
| Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements | | Part E - Other Requirements | |
| 10. Implementation of SSOP's, including monitoring of implementation. | | 36. Export | |
| 11. Maintenance and evaluation of the effectiveness of SSOP's. | | 37. Import | |
| 12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration. | | 38. Establishment Grounds and Pest Control | |
| 13. Daily records document item 10, 11 and 12 above. | | 39. Establishment Construction/Maintenance | |
| Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements | | 40. Light | |
| 14. Developed and implemented a written HACCP plan. | | 41. Ventilation | |
| 15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions. | | 42. Plumbing and Sewage | |
| 16. Records documenting implementation and monitoring of the HACCP plan. | | 43. Water Supply | |
| 17. The HACCP plan is signed and dated by the responsible establishment individual. | | 44. Dressing Rooms/Lavatories | |
| Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements | | 45. Equipment and Utensils | |
| 18. Monitoring of HACCP plan. | | 46. Sanitary Operations | |
| 19. Verification and validation of HACCP plan. | | 47. Employee Hygiene | |
| 20. Corrective action written in HACCP plan. | | 48. Condemned Product Control | |
| 21. Reassessed adequacy of the HACCP plan. | | Part F - Inspection Requirements | |
| 22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. | | 49. Government Staffing | |
| Part C - Economic / Wholesomeness | | 50. Daily Inspection Coverage | |
| 23. Labeling - Product Standards | | 51. Enforcement | |
| 24. Labeling - Net Weights | | 52. Humane Handling | |
| 25. General Labeling | | 53. Animal Identification | |
| 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture) | | 54. Ante Mortem Inspection | |
| Part D - Sampling Generic E. coli Testing | | 55. Post Mortem Inspection | |
| 27. Written Procedures | | Part G - Other Regulatory Oversight Requirements | |
| 28. Sample Collection/Analysis | | 56. European Community Directives | O |
| 29. Records | | 57. Monthly Review | |
| Salmonella Performance Standards - Basic Requirements | | 58. SRM | |
| 30. Corrective Actions | | 59. | |
| 31. Reassessment | | | |
| 32. Written Assurance | | | |

60. Observation of the Establishment

Date: 11/19/2014 Est #:1614 5 [S/B] (Australia)

There are no significant findings to report concerning this establishment and the government oversight verification.

- This establishment performing post-mortem inspection in sheep, only. The viscera and carcasses are inspected by the DA, Food Safety Meat Assessors (FSMA).

61. NAME OF AUDITOR
Oto Urban. DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|---|---|-----------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION JBS Australia Est. 235 2 Locke Way Riverview QLD 4303 | 2. AUDIT DATE 12/01/2014 | 3. ESTABLISHMENT NO. 235 | 4. NAME OF COUNTRY Australia |
| | 5. NAME OF AUDITOR(S) Oto Urban, DVM | | 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT |

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

| Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements | Audit Results | Part D - Continued Economic Sampling | Audit Results |
|--|---------------|---|---------------|
| 7. Written SSOP | | 33. Scheduled Sample | |
| 8. Records documenting implementation. | | 34. Specics Testing | |
| 9. Signed and dated SSOP, by on-site or overall authority. | | 35. Residue | |
| Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements | | Part E - Other Requirements | |
| 10. Implementation of SSOP's, including monitoring of implementation. | X | 36. Export | |
| 11. Maintenance and evaluation of the effectiveness of SSOP's. | | 37. Import | |
| 12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration. | | 38. Establishment Grounds and Pest Control | |
| 13. Daily records document item 10, 11 and 12 above. | | 39. Establishment Construction/Maintenance | |
| Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements | | 40. Light | |
| 14. Developed and implemented a written HACCP plan . | | 41. Ventilation | |
| 15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions. | | 42. Plumbing and Sewage | |
| 16. Records documenting implementation and monitoring of the HACCP plan. | | 43. Water Supply | |
| 17. The HACCP plan is signed and dated by the responsible establishment individual. | | 44. Dressing Rooms/Lavatories | |
| Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements | | 45. Equipment and Utensils | |
| 18. Monitoring of HACCP plan. | X | 46. Sanitary Operations | X |
| 19. Verification and validation of HACCP plan. | | 47. Employee Hygiene | |
| 20. Corrective action written in HACCP plan. | | 48. Condemned Product Control | |
| 21. Reassessed adequacy of the HACCP plan. | | Part F - Inspection Requirements | |
| 22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. | | 49. Government Staffing | |
| Part C - Economic / Wholesomeness | | 50. Daily Inspection Coverage | |
| 23. Labeling - Product Standards | | 51. Enforcement | X |
| 24. Labeling - Net Weights | | 52. Humane Handling | |
| 25. General Labeling | | 53. Animal Identification | |
| 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture) | | 54. Ante Mortem Inspection | |
| Part D - Sampling Generic E. coli Testing | | 55. Post Mortem Inspection | |
| 27. Written Procedures | | Part G - Other Regulatory Oversight Requirements | |
| 28. Sample Collection/Analysis | | 56. European Community Directives | O |
| 29. Records | | 57. Monthly Review | |
| Salmonella Performance Standards - Basic Requirements | | 58. SRM | |
| 30. Corrective Actions | | 59. | |
| 31. Reassessment | | | |
| 32. Written Assurance | | | |

60. Observation of the Establishment

Date: 12/01/2014 Est # 235: [S/B] (Australia)

10/51 Establishment operator did not properly sanitized his knife after removing tip of the tail during the sanitary dressing procedure. This non-compliance was immediately corrected by the OPV and establishment management by instructing the operator to sanitize his knife 9 CFR 416.13(c).

18/51 The leakage from the operator ruptured esophagus was observed during the audit of the slaughter line operation 417.4(2)(ii). The DA OPV and the establishment management corrected this non-compliance by instructing the operator to change of handling this procedure/esophagus.

46/51 The establishment slaughter area (structure over the carcass verification stand) and overhead structures in the boning room were observed with rusty bolts. Additionally, the flaking paint was noted over the boning tables ceiling in the boning room. This non-compliance was scheduled for corrective action by the establishment management 9 CFR 416.4(b).

- All inspection service performing ante and post-mortem inspection in this establishment are employees of DA, Food Safety Meat Assessors (FSMA). There are no Australian Government authorized (AAO) officers in this establishment.
- Daily assessment of Inspectors by the OPV:
 - 1) OPV looks 1% of carcasses with MSFA
 - 2) OPV looks 2.5% of carcasses with OOAS

61. NAME OF AUDITOR

Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|--|---|-----------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION Northern Co-operative, Meat Company LTD, 10615 Summerland Way Casino, NSW 2470; Australia. | 2. AUDIT DATE 12/02/2014 | 3. ESTABLISHMENT NO. 239 | 4. NAME OF COUNTRY Australia |
| | 5. NAME OF AUDITOR(S) Oto Urban, DVM | | 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT |

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

| Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements | Audit Results | Part D - Continued Economic Sampling | Audit Results |
|--|---------------|---|---------------|
| 7. Written SSOP | | 33. Scheduled Sample | |
| 8. Records documenting implementation. | | 34. Species Testing | |
| 9. Signed and dated SSOP, by on-site or overall authority. | | 35. Residue | |
| Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements | | Part E - Other Requirements | |
| 10. Implementation of SSOP's, including monitoring of implementation. | | 36. Export | |
| 11. Maintenance and evaluation of the effectiveness of SSOP's. | | 37. Import | |
| 12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration. | | 38. Establishment Grounds and Pest Control | |
| 13. Daily records document item 10, 11 and 12 above. | | 39. Establishment Construction/Maintenance | |
| Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements | | 40. Light | |
| 14. Developed and implemented a written HACCP plan. | | 41. Ventilation | |
| 15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions. | | 42. Plumbing and Sewage | |
| 16. Records documenting implementation and monitoring of the HACCP plan. | | 43. Water Supply | |
| 17. The HACCP plan is signed and dated by the responsible establishment individual. | | 44. Dressing Rooms/Lavatories | |
| Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements | | 45. Equipment and Utensils | |
| 18. Monitoring of HACCP plan. | | 46. Sanitary Operations | X |
| 19. Verification and validation of HACCP plan. | | 47. Employee Hygiene | |
| 20. Corrective action written in HACCP plan. | | 48. Condemned Product Control | |
| 21. Reassessed adequacy of the HACCP plan. | | Part F - Inspection Requirements | |
| 22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. | | 49. Government Staffing | |
| Part C - Economic / Wholesomeness | | 50. Daily Inspection Coverage | |
| 23. Labeling - Product Standards | | 51. Enforcement | |
| 24. Labeling - Net Weights | | 52. Humane Handling | |
| 25. General Labeling | | 53. Animal Identification | |
| 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture) | | 54. Ante Mortem Inspection | |
| Part D - Sampling Generic E. coli Testing | | 55. Post Mortem Inspection | |
| 27. Written Procedures | | Part G - Other Regulatory Oversight Requirements | |
| 28. Sample Collection/Analysis | | 56. European Community Directives | O |
| 29. Records | | 57. Monthly Review | |
| Salmonella Performance Standards - Basic Requirements | | 58. SRM | |
| 30. Corrective Actions | | 59. | |
| 31. Reassessment | | | |
| 32. Written Assurance | | | |

60. Observation of the Establishment

Date: 12/02/2014 Est # 239: [S/B] (Australia)

46 The FSIS auditor observed that carcasses stored in the chiller were clumped together, no spacing was provided among carcasses and they were located very close to the floor exposing them to the contamination by the contact with the floor and by the employee's boots. This non-compliance was scheduled for corrective action by the establishment management 9 CFR 416.4(d).

- This establishment performing post-mortem inspection in two species; beef and veal. In beef, the head, viscera and carcasses are inspected by the DA, Food Safety Meat Assessors (FSMA). In veal, there is one (1) Australian Government authorized (AAO) officer at the head and one (1) or two (2) AAOs at the viscera inspection. One (1) FSMA is inspecting carcasses in this establishment.
- Daily assessment of Inspectors by the OPV:
 - 1) OPV looks 1% of carcasses with MSFA
 - 2) OPV looks 2.5% of carcasses with OOAS

61. NAME OF AUDITOR

Oto Urban. DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|---|---|-----------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION Thomas Foods International, Tamworth 51-89 Phoenix Street Tamworth, NSW, 2340 | 2. AUDIT DATE 11/26/2014 | 3. ESTABLISHMENT NO. 394 | 4. NAME OF COUNTRY Australia |
| | 5. NAME OF AUDITOR(S) Oto Urban, DVM | | 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT |

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

| Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements | Audit Results | Part D - Continued Economic Sampling | Audit Results |
|--|---------------|---|---------------|
| 7. Written SSOP | X | 33. Scheduled Sample | |
| 8. Records documenting implementation. | | 34. Species Testing | |
| 9. Signed and dated SSOP, by on-site or overall authority. | | 35. Residue | |
| Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements | | Part E - Other Requirements | |
| 10. Implementation of SSOP's, including monitoring of implementation. | | 36. Export | |
| 11. Maintenance and evaluation of the effectiveness of SSOP's. | | 37. Import | |
| 12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration. | | 38. Establishment Grounds and Pest Control | |
| 13. Daily records document item 10, 11 and 12 above. | X | 39. Establishment Construction/Maintenance | |
| Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements | | 40. Light | |
| 14. Developed and implemented a written HACCP plan. | | 41. Ventilation | |
| 15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions. | | 42. Plumbing and Sewage | |
| 16. Records documenting implementation and monitoring of the HACCP plan. | | 43. Water Supply | |
| 17. The HACCP plan is signed and dated by the responsible establishment individual. | | 44. Dressing Rooms/Lavatories | |
| Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements | | 45. Equipment and Utensils | X |
| 18. Monitoring of HACCP plan. | | 46. Sanitary Operations | X |
| 19. Verification and validation of HACCP plan. | | 47. Employee Hygiene | |
| 20. Corrective action written in HACCP plan. | | 48. Condemned Product Control | |
| 21. Reassessed adequacy of the HACCP plan. | | Part F - Inspection Requirements | |
| 22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. | | 49. Government Staffing | |
| Part C - Economic / Wholesomeness | | 50. Daily Inspection Coverage | |
| 23. Labeling - Product Standards | | 51. Enforcement | X |
| 24. Labeling - Net Weights | | 52. Humane Handling | |
| 25. General Labeling | | 53. Animal Identification | |
| 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture) | | 54. Ante Mortem Inspection | |
| Part D - Sampling Generic E. coli Testing | | 55. Post Mortem Inspection | |
| 27. Written Procedures | | Part G - Other Regulatory Oversight Requirements | |
| 28. Sample Collection/Analysis | | 56. European Community Directives | O |
| 29. Records | | 57. Monthly Review | |
| Salmonella Performance Standards - Basic Requirements | | 58. SRM | |
| 30. Corrective Actions | | 59. | |
| 31. Reassessment | | | |
| 32. Written Assurance | | | |

60. Observation of the Establishment

Date: 11/26/2014 Est # 394: [S/B] (Australia)

7/51 The written SSOP program is missing the preventive action section. The establishment included preventive action in their daily records but preventive action was not written in their sanitary procedures, since the sanitary cleaning has been performed by the contracted company. The establishment agreed to include preventive action to their sanitary procedures 9 CFR 416.15(b).

13/51 Description of sanitary non-compliance during the CCA's In-plant Inspection Service oversight performance was missing to indicate the precise location of the observed sanitary deficiency-condensation 9 CFR 416.17(c). The DA IIC agreed to include the precise location of the non-compliance during the future oversight of non-compliances.

45/51 Broken and missing conveyor modules in boning room were posing a potential source for product contamination. This non-compliance was observed during the pre-operational sanitation in the boning room and it was scheduled to be corrected by the establishment management 9 CFR 416.3 (a).

46 The establishment operator was observed to wipe out the overhead located structures such as pipes which were present directly over the boning tables used for processing of the edible product. This non-compliance was corrected by the establishment management 9 CFR 416.4(a).

- This establishment employs two (2) AAOs, one (1) at the viscera the other at the carcass. The FSMA of DA is performing pathology and contamination inspection at the end of the line.
- Daily assessment of Inspectors by the OPV;
 - 1) OPV looks 1% of carcasses with MSFA
 - 2) OPV looks 2.5% of carcasses with OOAS

61. NAME OF AUDITOR

Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE

APPENDIX B: Australia's Response to Draft Final Audit Report



Australian Government
**Department of Agriculture
and Water Resources**

Dr Shaukat H. Syed
Director, International Audit Staff
Office of Investigation, Enforcement and Audit
Food Safety and Inspection Service
United States Department of Agriculture
Washington, DC 20250-3700

Dear Dr Syed

Australian Export Meat Inspection System 2014 Audit – Draft Final Audit Report

Thank you for forwarding the Draft Final Audit Report, following the audit of the Australian Export Meat Inspection System (AEMIS) conducted by the United States Food Safety and Inspection System (FSIS) from 17 November to 8 December 2014.

Given my strong concerns about the inaccuracy of the report, particularly the Executive Summary, I felt it necessary to write a preliminary response to you. I will write separately in regard to a number of errors and contextual settings that are contained in the body of the report.

The department would like to strongly refute the two main findings in the report. The first finding was that there has been a change in AEMIS in which recruitment agencies or 'providers' are able to source Food Safety Meat Assessors (FSMAs) for the conduct of post-mortem inspection. This finding is not correct.

Under AEMIS, meat inspection for the US can be undertaken by government employed FSMAs or department-approved Australian Government Authorised Officers (AAOs). AAOs can be employed by establishments or by independent providers. Where the establishment employs AAOs, an FSMA is still required to undertake carcass inspection at the final carcass inspection point or at the end of the chain. The department has never engaged FSMAs through 'providers' and I can assure you that all FSMAs are government employees.

To further support my claims, the department over the last two years has explored the option of engaging official meat inspectors through alternate employment arrangements. In this regard a possible alternate model was presented to Dr Urban at an entry meeting on 17 November 2014. It was made very clear during the entry meeting that Australia would not implement this or any alternate employment arrangement unless it has full support from FSIS. In this regard I have had a number of meetings with FSIS since this audit on the latter subject. These discussions have always been exploratory in nature around "what is possible". At no time have I suggested that such a model has been implemented and again I have subscribed strongly to the position that Australia would not change any element of its meat inspection employment arrangements unless agreed by FSIS. I therefore find it incomprehensible how such an unsubstantiated and non-factual finding and conclusion could be reflected in the official report.

The second finding was in relation to port-of-entry (POE) rejections that occurred at the end of calendar year 2013 and the first part of 2014, particularly with reference to beef shipments. Our records show that there were two notifications for Shiga toxin-producing *E. coli* (STEC) in beef in the last half of 2013. There have been no notifications for STEC since this time. In addition, there were two notifications for ingesta contamination in 2013 (beef and lamb), and three faeces/ingesta notifications in 2014 (all lamb). FSIS requested that the department implement corrective actions in response to this finding. As FSIS is aware, upon notification of a POE rejection, the department undertakes an investigation and provides a report to FSIS in accordance with agreed protocols which have been in place between FSIS and the department for several years. The department also implemented system improvements in July 2013 in response to detections of faeces/ingesta by making improvements to Meat Hygiene Assessment at all US-listed small stock establishments. Further refinements were made in 2015¹. I do not believe, therefore, that this should be a finding of this audit, nor should there be a particular focus on beef. This 'finding' simply reflects the longstanding agreed response protocol, the effectiveness of which FSIS has not questioned.

The department considers that publication of the report in its current form is not an accurate reflection of Australia's meat inspection system. As such, the department respectfully requests that FSIS considers these comments and amends the report before it is finalised.

It is my view that it is critical that we take the time to resolve these matters. I would be pleased to provide any further information, should you require it, either at future meetings with you in the US or to FSIS delegates attending the Codex Committee on Food Import and Export Certification and Inspection Systems in Australia in February 2016.

Please do not hesitate to contact me if you require further information.

Yours sincerely,



Greg Read
First Assistant Secretary
Food Division

23 December 2015

¹ <http://www.agriculture.gov.au/export/controlled-goods/meat/elmer-3/notices/2015/mn15-05>



Australian Government
**Department of Agriculture
and Water Resources**

Alfred V. Almanza
Deputy Under Secretary
Food Safety and Inspection Service
Office of Food Safety
1400 Independence Ave, SW
Washington, D.C.

Dear Mr Almanza

Thank you for your letter of 19 November 2015 regarding the FSIS definition of “government inspector”. Please accept my apologies for the delayed response. The Department of Agriculture and Water Resources (the department) has been considering your letter in conjunction with the draft final audit report from FSIS’ 2014 audit, which also raises the matter of employment of official inspectors.

You would be aware that Australia was granted equivalency of the Australian Export Meat Inspection System (AEMIS) in March 2011. The modification of AEMIS to allow a government Food Safety Meat Assessor (FSMA) at the carcass inspection point was approved in October 2012. What essentially this agreement requires, as verified by your auditors, is that every US chain has a federal government inspector at the end of the chain in any alternate inspection arrangement. What constitutes a “federal inspector” I take as being clarified by your correspondence to me of 19 November 2015.

I can confirm that, consistent with the language of your letter, all official inspection personnel in US listed plants, including On-Plant Veterinarians (OPVs) and FSMAs, are employees of the department and are paid directly by the government. Official personnel are not employed through a third party such as a recruitment agency on a “contract” basis. We do not use any contractors on any of our export plants for official duties, including those US listed.

The information to this effect was recorded in our recent self-reporting tool questionnaire under question D4 where the department confirmed OPVs and FSMAs are authorised officers employed by the department. This was provided to you in July 2015.

You would be aware that information was provided to a US auditor during the 2014 audit advising that the department was exploring the option of sourcing government inspectors through a recruitment agency or similar provider. However, I assure you that the department has not pursued this option and would not do so without first raising it with FSIS and gaining agreement.

The department has ultimate control and supervision over the official government activities of all employees of the system and meet the criteria outlined in your letter. Therefore, Australia’s inspection personnel meet the definition of government inspector under the Federal Meat Inspection Act (21 U.S.C 603(a)).

Please do not hesitate to contact me if you require further information.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Greg Read', with a stylized flourish at the end.

Greg Read
First Assistant Secretary
Exports Division
8 March 2016



Australian Government
**Department of Agriculture
and Water Resources**

Ms Jane Doherty
International Coordination Executive
Office of International Coordination
Food Safety and Inspection Service
United States Department of Agriculture
Washington, DC 20250-3700

Dear Ms Doherty

Australian Export Meat Inspection System 2014 Audit - Draft Final Audit Report

Thank you for forwarding the updated Draft Final Audit Report, following the audit of the Australian Export Meat Inspection System (AEMIS) conducted by the United States Food Safety and Inspection System (FSIS) from 17 November to 8 December 2014.

The department acknowledges the audit finding that the Australian food safety inspection scheme meets the core criteria for all six equivalence components. However, I have concerns with the finding noted in the Executive Summary (Pg. i) and Section X, Conclusions and Next Steps (Pg. 21). I have also addressed additional issues which are noted individually in a table attached to this letter (Attachment 1).

To provide additional information and context for all of the issues I have noted in the attached table, I am providing the information which follows.

The Draft Final Audit Report lists one finding on Hazard Analysis and Critical Control Point (HACCP) systems related to port-of-entry (POE) rejections from the end of 2013 to the first half of 2014. I note in the report that you request the department implement prompt corrective actions to address this (Pgs. i, 21). I believe this was done at the time the incidents occurred and reported to FSIS in accordance with our agreed protocol, as outlined in Meat Notice 2013/05. During the audit, FSIS verified that the corrective actions that were implemented in response to each POE detection were adequate. I do not believe this should be a finding of this audit. The 'finding' simply notes POE detections which have been effectively dealt with under the protocol and is not within the scope of this audit.

I am pleased to note that the Draft Final Audit Report confirms that systems governing the oversight of sanitation are adequate, and that the department reviews the HACCP systems of meat establishments in response to POE detections. The auditor also verified additional measures Australian establishments are taking to reduce food safety risks (Pg. 12, para 5). These measures include assessing cleanliness of incoming animals to set slaughter line speeds,

implementing processes that allow in-plant government officials to focus on high priority areas, and systems to ensure strong government oversight.

However, there are also some comments of concern in the Draft Final Audit Report.

The report references trade statistics quoted in the introduction of the report which are incorrect surrounding the volume of product rejected at POE due to ZT and STEC defects according to Australian records. The report states a volume of 525,000 pounds of meat derived from bovine, ovine and caprine species was rejected between 1 January 2013 and 23 June 2014. The correct figure, based on notifications from FSIS for individual violations during the time referenced was 186 647 pounds of meat for ZT and 52 260 pounds for STEC presence, totalling 238 907 pounds. This is a significant difference of 286 093 pounds. The total rejected volume percentage is 0.02% rather than the 0.05% stated in the report. The department takes POE violations seriously, investigates all notifications and takes necessary action to ensure Australia's high food safety standards are maintained.

The audit report states that in-plant officials need to assess in a more critical manner the implementation of sanitation programs (Pg. 13, para 1). In November 2014, the department implemented improved processes whereby the departmental on-plant veterinarian (OPV) more actively reviews post-mortem verification data, as well as Product Hygiene Indicator data, to identify any trends which may indicate systemic problems on plant. This is now discussed as part of the standard agenda for the OPV's weekly meeting with establishment management as described in the new work instruction *Conducting a Meat Establishment Verification System Weekly Meeting*. Additionally, the department released Meat Notice 2015/05 in October 2015 titled *Amended Performance Criteria for the Assessment of the effectiveness of Sheep/lamb and goat slaughter floor processes (HACCP)*. This notice was an update to a version that establishments were being transitioned to during FSIS' 2014 audit and continues to be implemented at all small-stock slaughter plants. The arrangement was discussed in detail with the auditor at the time of the audit.

The report states "the FSIS auditor verified that the CCA exercises ultimate control and supervision over the official inspection activities of all employees or licensees of the system by conducting regular evaluations of their performance and by promptly correcting deficiencies" (Pg. 5, para 5). The report later states that "the CCA need to monitor and better verify the sanitary conditions of their equipment and facilities" (Pg. 12, para 6). These statements are contradictory. I therefore ask for this latter statement to be deleted from the report.

Finally, I note in Section IV, Government Oversight, that you reference and attach previous correspondence on a draft audit report that I now view as updated and replaced. I have assessed the draft report you have provided on 31 March 2016 as the only report and therefore limited my comments to this document. Therefore, I believe attaching official and draft correspondence which references a separate, now irrelevant and unofficial draft report, is misleading. I ask that the letter Read to Syed on 23 December 2015 and draft correspondence Read to Syed February 2016 be removed from the text and the Appendix B of the report. I support the inclusion of my letter Read to Almanza dated 8 March 2016 if you feel it is relevant along with this response. The draft in Appendix B should be replaced with a copy of the official letter provided to you.

Given that the Final Audit Report will be published, I believe it is essential that we work together to ensure publicly available information accurately reflects the features of Australia's meat production system. I therefore trust you will consider the department's response and amend the final report accordingly. The department considers the publication of the report in its current form an inaccurate reflection of the performance of Australia's meat inspection system.

Please do not hesitate to contact me if you require further information.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Greg Read', with a large, stylized flourish extending upwards and to the right.

Greg Read
First Assistant Secretary
Food Division

5 April 2016

Attachment 1 – Draft Final Audit Report review table



Australian Government
Department of Agriculture
and Water Resources

Attachment 1

1. Government oversight

| Report Page Reference | Report Comment | Departmental Response | Department Request |
|------------------------------|--|--|--|
| Pg.(i) & Pg. 19 | <p>FSIS identified the following finding related to the HACCP systems component of the Australian meat inspection system:</p> <ul style="list-style-type: none">• Repeated POE violations in which meat products from Australia have been rejected for public health reasons involving zero tolerance (ZT) and ingesta violations, indicate that greater effort is required on the part of the CCA to ensure the adequacy of HACCP systems implemented by establishments | <p>The process regarding POEs is that FSIS reports POE violations in response to findings during reinspection. The department investigates and responds as per the agreed protocol. While the audit verified investigations and actions undertaken as part of the protocol arrangements, the finding, as worded in the report, is not relevant to the audit.</p> | Delete from the report. |
| | <p>FSIS expects that the CCA will implement prompt corrective actions to address the above reported findings.</p> | <p>The department provided a swift and appropriate response to these actions and the report confirms this (Pg. 13, para 6).</p> | <p>The statement in the report is incorrect and should be deleted.</p> |

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| Pg. 1, para 2 | During the period between January 1, 2013 and June 23, 2014, Australia exported to the United States 1,005,212,356 pounds of meat products derived from bovine, ovine and caprine species. From that volume, 1,002,908,654 pounds of products were accepted and approximately 2,300,000 pounds were refused at United States Points of Entry (POE). Approximately, 525,000 pounds were refused because of food safety violations related to zero tolerance for contamination of meat products with fecal matter, ingesta, milk, pathological issues, and failed laboratory analysis. | The department does not agree with these statistics. The department accepts the overall volume as being approximately correct but strongly disagrees with the volume refused entry at POE due to food safety violations for zero tolerance/STEC contamination on meat products. The total rejected product, as notified by FSIS in rejection notices, totals 186,647 lbs for ZT and 52,260 lbs for STEC resulting in a total of 238,902 lbs. | Delete from report or amend with correct statistics and provide context for the rejections. Australia had a rejection percentage of approximately 0.02% between 1 January 2013 and 23 June 2014 based on FSIS' data for ZT and STEC incidences. |
| Pg. 2, para 3 | The seven selected establishments included three ovine and four bovine slaughter/fabrication facilities whose raw meat products failed to meet FSIS food safety standards during re-inspection at a United States' POE. | Each of the seven establishments has a successful history of export to the US. The POE detections were isolated incidents that were corrected according to the agreed POE response protocol outlined in Meat Notice 2013/05. Each establishment maintained eligibility to export to the US throughout each investigation. | Delete from the report or provide further context surrounding the choice of establishments. |

2. Sanitation

| Report Page Reference | Report Comment | Departmental Response | Department Request |
|-----------------------------------|--|--|---|
| Pg. 12, para 6 and Pg. 13, para 1 | However, a number of sanitation minor deficiencies were identified by the FSIS auditor and immediately corrected by the CCA and industry. These deficiencies, although addressed by prompt | The department is aware from the auditors closing presentation that several isolated deficiencies were identified during the on- | Audit comment noted. However the department requests that the procedure implemented in November |

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| | corrective measures by the establishments and CCA, indicate that establishments and CCA need to monitor and better verify the sanitary conditions of their equipment and facilities. | site visits. These were immediately corrected per the auditor's comments. | 2014 is noted in the report to improve the report's accuracy. |
| | In addition, in-plant officials need to assess in a more critical manner the implementation of sanitation programs to identify and require correction of potential sources of product contamination. | In November 2014 the department implemented improved processes whereby the departmental on-plant veterinarian (OPV) more actively reviews post-mortem verification data, as well as Product Hygiene Indicator data, to identify any trends which may indicate systemic problems on plant. This is now discussed as part of the standard agenda for the OPV's weekly meeting with establishment management and is captured in a departmental work instruction. | Audit comment noted. However the department requests that the procedure implemented in November 2014 is noted in the report to improve the report's accuracy. |

3. HACCP

| Report Page Reference | Report Comment | Departmental Response | Department Request |
|-----------------------|---|---|--|
| Pg. 14, para 1 | However, repeated POE violations in which meat products from Australia have been rejected for public health reasons involving ZT and ingesta violations indicate that greater effort is required to ensure the adequacy of HACCP systems implemented by establishments. | In response to all POE notifications by FSIS the department conducts a full investigation into the matter in accordance with the agreed protocol. This includes a review of the adequacy of the HACCP system. Results of the investigation are provided to FSIS and FSIS accepted their responses and closed each case file respectively. | This comment is misleading – delete from the report or provide further evidence. |

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| Pg. 14, para 2 | However, because of the number of reported POE violations in which meat products from Australia were rejected for public health reasons, FSIS expects that the CCA will ensure that United States-eligible establishments do better at assessing the adequacy of their HACCP systems. | As above. | As above. |
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4. Appendix A

| Report Page Reference | Report Comment | Departmental Response | Department Request |
|---|---|--|---|
| Pg. 27 – Comments for regarding EST 1265 | There is no inspection performed by the Government Approved establishment paid AAOs in this establishment and no end of chain inspection. | There is no inspection performed by the Government Approved establishment paid AAOs in this establishment. | This comment is incorrect. Replace with text provided by the department. |