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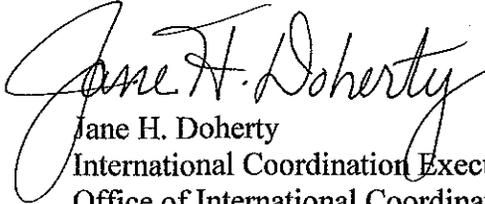
JUN 20 2017

Dear Narelle Clegg,

The FSIS onsite audit conducted from September 12 through September 30, 2016, supports that Australia's inspection system continues to remain equivalent to that of the United States. Enclosed is a copy of the final audit report. The comments received from the Government of Australia are included as an attachment to the report.

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

Sincerely,



Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN
AUSTRALIA

SEPTEMBER 12 - 30, 2016

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING
MEAT PRODUCTS
EXPORTED TO THE UNITED STATES OF AMERICA

June 7, 2017

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from September 12 - 30, 2016. The purpose of the audit was to determine whether Australia's food safety inspection system governing meat (i.e., raw beef, mutton, lamb, and goat) products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and accurately labeled and packaged. An additional objective was to assess the regulatory oversight that the Central Competent Authority (CCA) provides to swine slaughter and processing establishments, to determine if equivalence of that aspect of Australia's meat inspection system could be reinstated.

The audit focused on six system equivalence components: Government Oversight (e.g., Organization and Administration); Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); Government Sanitation; Government Hazard Analysis and Critical Control Points (HACCP) Systems; Government Chemical Residues Testing Programs; and Government Microbiological Testing Programs.

An analysis of each component did not identify any systemic findings representing an immediate threat to public health. However, the FSIS auditors identified the following finding:

Government Microbiological Testing Programs

- The CCA has not verified that laboratories have internal procedures to ensure that only approved methods are used to analyze samples of meat (i.e., raw beef, lamb, mutton, and goat) product destined for export to the United States.

During the audit exit meeting, the CCA committed to address the preliminary finding as presented. FSIS will further assess the equivalence of Australia's meat inspection system upon receiving the CCA's proposed corrective actions for the reported finding.

In reference to reinstatement of equivalence of Australia's pork inspection system, the FSIS auditors were unable to see the traditional inspection for swine slaughter since those operations were not being conducted at the time. The CCA informed FSIS that Australia would be operating under traditional inspection at swine slaughter establishments that produce pork products for export to the United States. A follow-up onsite audit will be conducted to complete the swine slaughter inspection equivalence reinstatement process.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of Australia's food safety inspection system for meat (i.e., raw beef, lamb, mutton, and goat) from September 12 - 30, 2016. The audit began with an entrance meeting held on September 12, 2016, in Canberra, Australia with the participation of representatives from the Central Competent Authority (CCA) – the Department of Agriculture and Water Resources (DAWR) and the two FSIS auditors.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a combined ongoing equivalence verification audit and reinstatement audit. The audit objective was to verify that Australia's food safety inspection system governing raw beef; lamb; mutton; and goat meat products in the raw intact, non-intact, thermally processed, and ready-to-eat meat process categories maintains equivalence to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and accurately labeled and packaged. An additional objective was to assess the regulatory oversight that the CCA provides to swine (i.e., pork) slaughter and processing establishments, to determine if equivalence of that aspect of Australia's inspection system for pork products could be reinstated. The FSIS auditors were unable to meet this objective since the traditional inspection for swine slaughter operations was not being conducted during the audit.

The audit was undertaken under the specific provisions of United States' laws and regulations, in particular:

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] 601, et seq.);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901, et seq.); and
- The Food Safety and Inspection Service Regulations for Imported Meat (9 Code of Federal Regulations (CFR) Part 327).

The standards applied during the audit of Australia's inspection system for raw beef, lamb, mutton, and goat products included: (1) all applicable legislation originally determined by FSIS to be equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the World Trade Organization's Sanitary/Phytosanitary Agreement.

FSIS applied a risk-based procedure which included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) testing results, and specific oversight and testing capacities of government offices and laboratories. The review process included an analysis of data collected by FSIS over a 3-year timeframe, in addition to information obtained directly from the CCA, through a FSIS reporting process, the Self Reporting Tool (SRT).

The FSIS auditors were accompanied throughout the entire audit by CCA representatives who oversee the inspection operations and the laboratories of the system. Determinations concerning overall program effectiveness focused on performance within the following six components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory

Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Points (HACCP) System; (5) Government Chemical Residues Testing Programs; and (6) Government Microbiological Testing Programs.

The auditors reviewed administrative functions at CCA headquarters and six local inspection offices. During this review, the FSIS auditors evaluated the implementation of control systems in place that ensure that the Australian meat (i.e., raw beef, lamb, mutton, and goat) inspection system is managed and operated as intended. Six establishments were selected for this audit, including 5 of 77 establishments actively exporting raw beef, lamb, mutton, and goat products to the United States. In response to the CCA’s request for reinstatement of equivalence of the pork inspection for its meat inspection system, the FSIS auditors also went to a swine slaughter/processing establishment to evaluate the regulatory oversight being provided to pork producing establishments. The FSIS auditors were unable to verify that traditional inspection for swine operations in place at the time of the audit. Upon the CCA’s submission of data that it is operation a traditional inspection operation, FSIS auditors will return to Australia to verify the operation.

During the establishment visits, particular attention was paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the CCA’s ability to provide oversight through supervisory reviews conducted in accordance with Title 9 of the United States CFR § 327.2, the FSIS regulations addressing eligibility of foreign countries for importation of meat products into the United States.

Additionally, FSIS audited two analytical laboratories that conduct chemical residue and microbiology analysis of tissues and products to support the inspection system.

Sites Audited		#	Locations
Competent Authority	Central	1	DAWR/Canberra
	Local Government Offices at Establishments	6	Wodonga, VIC (612) Brooklyn, Melbourne, VIC (205 and 688) Mackay, QLD (67) Grantham, QLD (203) Kingaroy, QLD (48)
Laboratories		1 1	Private Microbiology Analysis, Brisbane, QLD Government Chemical Residue Analysis, Melbourne, VIC
Establishments • Slaughter and Cut/up		6	Est. 612 (bovine, ovine and caprine) Est. 206 (bovine, ovine and caprine) Est. 688 (bovine, ovine and caprine) Est. 67 (bovine and ovine) Est. 203 (bovine, ovine and caprine) Est. 48 (swine)

III. BACKGROUND

Australia is eligible to export (i.e., raw beef, lamb, mutton, and goat) products to the United States within the following product categories: raw intact and non-intact meat products; thermally processed/commercially sterile meat products; and ready-to-eat meat products. Thermally processed/commercially sterile and ready-to-eat meat products are imported into the United States in relatively small amounts. The FSIS auditors focused the analysis of results of re-inspection at POE on the bulk of raw intact and non-intact meat products imported from Australia, which include raw beef, mutton, lamb, and goat meat.

From October 2014 to August 2016, FSIS import inspectors performed 100 percent re-inspection for labeling and certification of 2,772,637,346 pounds of raw beef, lamb, mutton, and goat products exported by Australia to the United States. From that total, 309,922 pounds were rejected due to POE violations of United States' food safety standards; inadequate product trimming; and inappropriate handling of product during transportation. Additionally, 5,833,496 pounds were rejected due to reasons other than food safety. In response to the reported POE violations, the CCA provided reports describing the results of the investigations conducted by Australian inspection officials and the corrective actions implemented by the establishments. The FSIS auditors used the investigative results and onsite observations to verify that the reported corrective actions were completed.

The FSIS final audit reports for Australia's food safety system are available on the FSIS' Web site at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports>.

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components that the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign inspection system to be organized by the national government in such a manner as to provide ultimate control and supervision over all official inspection activities; ensure the uniform enforcement of requisite laws; provide sufficient administrative technical support; and assign competent, qualified inspection personnel at establishments where products are prepared for export to the United States.

FSIS assessed the current organization and administration of Australia's meat inspection system for raw beef, lamb, mutton, and goat and observed that it has undergone changes in organizational arrangement and name. The government agency that serves as the CCA is now known as the Department of Agriculture and Water Resources (DAWR). The Exports Division of DAWR is supported by the Exports Standards Branch, the Meat Exports Branch (MEB), that oversees the functions of the overall Australian export meat inspection system; and the Residues and the Food branch, responsible for export documentation, national certification; registration and licensing of establishments, and the implementation of the National Residue Survey. Three Field Operations Managers (FOMs) assist the MEB in administering and coordinating the delivery of inspection services at certified establishments. The FOMs supervise the Area Technical Managers (ATMs), who in turn supervise the on-plant veterinarians (OPVs).

The OPVs supervise the Food Safety Meat Assessors (FSMAs) at the in-plant level. Post-mortem inspection is overseen by the OPVs, who are the highest regulatory authority at certified establishments. The OPV is present full time in the plant performing ante-mortem, post-mortem inspection, dispositions, post-mortem inspection verification; and monitoring, verification, and reporting on the establishments' regulatory compliance. OPVs also verify the performance of the Australian Authorized Officers (AAOs), who are non-government officials, authorized by the Australian government to perform post-mortem assessment of heads, viscera, and carcasses of livestock at certified establishments. At least one FSMA is required to be present on each line at plants exporting to the United States. The FSMA is the government inspector that verifies each carcass is free of visual contamination and pathological lesions of food safety significance after the AAO post-mortem assessment.

AAO duties include: taking action when carcasses are presented for post-mortem assessment; conducting post-mortem examinations and dispositions as they relate to nonfood safety carcass conditions; notifying the FSMA or the OPV when assistance is needed for making dispositions; performing post-mortem assessment 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 assessment such as collection of tissues for chemical residue analysis.

The FSIS auditors verified that in Australia, the federal government is responsible for exports and export registered establishments in accordance with national statutes¹. The MEB is responsible for verification, and auditing activities; and ensuring that producers comply with inspection requirements of Australia's meat (i.e., raw beef, lamb, mutton, and goat) export systems.

Establishments that wish to export their products to the United States must first register with the CCA. Registration is granted after the government verifies that managers of an eligible establishment are deemed fit and proper for that responsibility; their operations are free from debt to the commonwealth; and the establishment has developed an Approved Arrangement (AA). An AA contains procedures and programs that establishments are to maintain to ensure implementation of an effective quality and food safety control system. All programs included in the AA are approved by the CCA for implementation to ensure that they meet regulatory and certification requirements.

Regulatory requirements of the meat inspection system of Australia mandate that establishments that wish to export meat and meat products to the United States include a HACCP program in their AA. The CCA also requires that establishments and in-plant government officials conduct visual Meat Hygiene Assessments (MHAs) to verify the adequacy of hygienic conditions of meat products prior to shipping and to determine the Product Hygiene Index (PHI) for the establishments. Results of the MHA conducted by in-plant OPVs and FSMAs, and establishment personnel, are compiled 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

¹ Export Control Act 1982, Export Control (Prescribed Goods-General) Order, 2005, Export Control (Meat and Meat Products) Orders 2005, Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products for Human Consumption (AS4696)

nationwide comparative analysis of the PHI standing of each establishment, which is sent by the CCA to establishments and in-plant government officials.

This monitoring mechanism permits the detection of developing trends for early correction. The FSIS auditors assessed this feature of the Australian meat inspection system for raw beef, lamb, mutton, and goat and observed that government officials and establishment technicians follow an established schedule to sample and examine carcasses, carcass portions, and meat products in accordance with established protocol.

Government officials provide inspection and verification services at establishments, issue export certificates, and audit the performance of establishments in accordance with a fee-for-service arrangement. Government officials follow a schedule of fees for service rendered to charge the certified establishments for the services provided. The CCA authorizes the charges and the establishments make payments to the Office of the National Treasury of Australia, which in turn pays the salaries of the government employees assigned to provide the aforementioned services. The AAOs receive payment for their services directly from the establishments.

To assess the technical competency of inspection personnel assigned to the certified establishments, the FSIS auditors confirmed that OPVs have completed academic work to earn a veterinary degree, which customarily includes courses in HACCP and meat science. Veterinarians also complete induction training to develop and master the technical, regulatory, food safety auditing, and supervisory skills needed to perform their duties. OPVs conduct ante-mortem inspection (AMI); verify adequacy of post-mortem inspection (PMI) conducted by FSMAs and post-mortem assessment by AAOs; make post-mortem dispositions of retained carcasses; monitor and verify compliance of establishments with their AAs; and supervise and manage government inspectors.

FSMAs and AAOs must earn a Meat Safety (MS) IV certificate, issued by a registered training organization (RTO). They must also demonstrate a satisfactory level of proficiency prior to their being assigned to the full scope of their duties. The CCA grants authorization to AAOs who have obtained an MS III certificate, but as a temporary 12-month appointment. This acceptance allows the candidates the opportunity to gain additional experience to obtain a MS IV certificate. FSIS verified that the CCA develops and disseminates Work Instructions based on Australia's export standards and the United States' requirements, tailored to ensure uniform implementation of regulatory oversight at certified establishments that export meat products derived from bovine, ovine, and caprine species to the United States.

Additionally, the FSIS auditors verified that the CCA exercises ultimate control and supervision over the official inspection activities performed by OPVs and FSMAs, and assessment performed by AAOs. Supervisors regularly evaluate the performance and conduct of inspection officials and institute remedial actions when required. The CCA, through its chain of command, ensures that OPVs and FSMAs verify that meat production activities conducted at certified establishments comply with Australia's regulatory requirements that apply to food safety controls. Furthermore, government officials ensure that AMI and PMI of livestock; and carcasses and their parts, respectively, are conducted in accordance with standards equivalent to United States' standards. OPVs and FSMAs stationed at establishments monitor the adequacy of

dressing procedures; collect samples of tissues and products for laboratory analyses; and ensure that establishments verify efficacy of their sanitary controls.

The review of records conducted by FSIS showed that in-plant officials identify non-compliances, take official control actions, document all actions, and require that establishments adequately correct regulatory non-compliances. The records maintained by inspection officials document the actions taken by the CCA and the establishments in response to FSIS reports of POE violations from March 2015 through May 2016. Government documents show that CCA officials took actions in accordance with established enforcement protocol², to ensure that establishments responded accordingly by investigating the causes of the reported violations and implementing appropriate corrective actions. The FSIS auditors verified that the CCA had assessed the adequacy of corrective actions implemented at the audited exporting establishments. The establishments had identified the likely root causes for the reported violations and instituted adequate measures that remain in place to prevent recurrence of violations.

The FSIS auditors verified that the laboratories that provide technical support to the CCA are regularly audited to determine their conformity with the International Organization for Standardization (ISO) 17025 standard, in accordance with Australian regulations. Documents reviewed show that audits conducted by accrediting institutions evaluate the facilities and equipment; staff qualifications and competencies; and the functions and administration of the laboratories. Laboratory audit reports reviewed by FSIS demonstrate that the auditing organizations inform laboratory managers of identified non-conformities and require that corrective actions be implemented within specified timeframes. The records also show that at both audited laboratories, managers have implemented corrective actions to address identified non-conformities.

The CCA has delegated the responsibility to assess the performance of the chemistry laboratories that serve the meat exports program to the National Residue Survey (NRS), which is a governmental organization that provides residue testing and proficiency testing. The National Association of Testing Authorities (NATA) has accredited NRS to serve as the entity that approves and evaluates the proficiency and performance of chemical residue analysis laboratories. NRS has also entered into a Memorandum of Understanding with NATA to jointly evaluate the performance of the laboratories using the ISO 17025 standard. NATA also administers proficiency testing programs for the residue laboratories of the Australian meat inspection system.

Microbiology laboratories are audited directly by the CCA in cooperation with NATA and recognized experts from academia. Laboratories serving the CCA in this capacity are required to only use CCA approved methods of analysis to test meat and meat products for certification for export. The records reviewed by the FSIS auditors showed that during the last audit conducted by the CCA/NATA/academia team of microbiologists in 2016, it was found that the laboratory had elected to modify the prescribed method of analysis for Shiga toxin producing *Escherichia coli* (STECs), namely, the FSIS Manual Laboratory Guidebook (MLG) method 5B.05. Analysts

² Meat Notice Number 2016/03 Daily hygiene verification of finished USA-eligible sheep, lamb and goat product. <http://www.agriculture.gov.au/export/controlled-goods/meat/elmer-3/notices/2016/mn16-03>

had reduced the number of washes for the dyna-beads from four times, as required by the method, to twice in the process. Additionally, the volume of water used in the process was increased from 20 to 200 µl.

The team of microbiologists assessed the significance of the observed deviations and concluded that the changes introduced to the method had a minimal impact on the accuracy of the results obtained. Nonetheless, the laboratory promptly implemented corrective actions that included immediately discontinuing the use of the modified method of analysis and re-instructing analysts and supervisors to use the CCA approved method of analysis for STECs. However, the corrective action implemented by the laboratory did not include measures that can effectively prevent recurrence of similar events in the future. Additionally, the frequency of scheduled CCA audits for microbiology laboratories, reported in the SRT to take place every 18 months, is inadequate for early detection of deviations from analytical methodology such as the one described above. Consequently, the CCA does not have an adequate design and implementation of laboratory oversight measures to ensure that samples of product destined for the United States are consistently analyzed using only CCA approved methods of analysis.

The CCA of the meat inspection system of Australia is an agency of the national government that is organized to uniformly administer enforcement of regulatory standards equivalent to FSIS standards. The ongoing analysis of available data and onsite audit verification activities indicate that the CCA continues to demonstrate the ability to meet the requirements for exporting raw beef, lamb, mutton, and goat products to the United States.

V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

The second of six equivalence components that the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; AMI of animals; PMI of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; daily inspection; periodic supervisory visits to official establishments; and requirements for thermally processed/commercially sterile products. The FSIS auditors reviewed records, interviewed government officials, and conducted observations at six slaughter and processing establishments to assess the ability of inspection personnel to enforce the regulatory requirements of the system.

The CCA has statutory authority to require that certified establishments comply with regulatory requirements to gain and maintain authorization to export meat (i.e., raw beef, lamb, mutton, and goat) products to the United States. The CCA manages and coordinates delivery of inspection and verification activities at certified establishments. Inspection officials enforce the regulations of the system to ensure that exported meat products meet Australian standards and food safety and other consumer protection standards of the United States. As FSIS introduces regulatory changes, the CCA communicates the new regulatory requirements to establishments and

inspection officials. Since the last audit, there have been no regulatory changes associated with the export of meat products to the United States that would have required changes by the CCA.

The FSIS auditors verified that the CCA officially notified establishments of FSIS regulatory changes related to *E. coli* O157:H7 and the six additional STEC strains when they first received notification from FSIS newer testing protocols. In particular, the CCA requires that microbiological independence of sampled lots be established and documented by the establishments. Establishments are also required to specify the actions they will take when confirmed positive results are reported by FSIS at POE, and the CCA has defined the regulatory actions that it will implement in those situations. Trace-back mechanisms are already in place to maintain identity of products and their link to production centers.

The FSIS auditors verified that government inspectors ensure that all animals slaughtered at certified establishments undergo AMI, which is conducted by government officials at beef, lamb, mutton, and goat slaughter establishments. AMI is conducted by OPVs at small establishments and by OPVs with the assistance of FSMAs, at large establishments. Animals that show clinical signs of disease are segregated and placed in a suspect pen to be closely evaluated later by the OPV. Government inspectors also evaluate the adequacy of ante-mortem facilities and assess compliance of establishments with humane handling requirements imposed by the CCA and importing countries.

The CCA delivers PMI at the certified establishments under two approaches. One group of establishments is inspected using the traditional PMI system, where only FSMAs, who are employees of the Australian government, conduct inspection of heads, viscera, and carcasses. The other group, is inspected using the PMI alternative system, where AAOs, who are establishment employees, authorized by the CCA, conduct PMI assessment of heads, viscera, and carcasses on the line and one FSMA, also stationed on the line, performs carcass-by-carcass inspection.

The FSIS auditors visited certified establishments that slaughter bovine, ovine, and caprine species and observed that both approaches of PMI were being conducted in a manner equivalent to that required in the United States. The establishments present heads, viscera, and carcasses properly identified for inspection. The design of the inspection stations meets requirements equivalent to those of the United States. FSMAs demonstrated an acceptable level of proficiency to perform their inspection duties. FSIS also confirmed the functions of the OPVs as they verified the adequacy of PMI conducted by FSMAs and the performance of AAOs.

The FSIS auditors observed that OPVs exert their legal authority to adjust production rates to ensure adequate PMI and maintenance of sanitary dressing activities. Furthermore, OPVs report to plant management the results of daily verification of PMI and ensure that deficiencies in the performance of AAOs are promptly addressed by the establishments. Records reviewed by FSIS showed that OPVs or their designees verify daily the technical competency of the AAOs by monitoring the accuracy and consistency of their PMI decisions and sampling carcasses and parts to assess errors and inconsistencies. In accordance with established procedure, when deficiencies in the performance of AAOs are detected, remedial actions are implemented by the

establishments under the guidance of the OPV and with the assistance of representatives from an RTO.

The FSIS auditors 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. The FSIS auditors confirmed that in-plant officials verify that certified establishments meet the regulatory requirements of the Australian meat inspection system. Government officials regularly evaluate the conditions of the different areas of the establishments, document their findings, and require that establishments implement adequate corrective actions when sanitary deficiencies are identified. Documents reviewed by FSIS during the audit indicate that establishments and government officials interact to ensure that non-compliances related to maintenance of the facilities are identified and addressed to comply with the regulations of the program.

The FSIS auditors determined that, in accordance with the rules of the Australian meat inspection system, OPVs conduct regular onsite reviews of the performance of the food safety systems of the establishments utilizing the AAs of the establishments as standards. ATMs also conduct periodic evaluations of the performance of in-plant officials and verify the level of regulatory compliance maintained by certified establishments. Evaluations of the establishments are conducted in accordance with two schedules that determine the frequencies of visits to be monthly or semiannually. Monthly reviews concentrate on specific areas of the establishment and semiannual reviews are comprehensive assessments of the adequacy of the entire design and implementation of the establishments' quality and food safety programs. FSIS 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. FSIS evaluated the ATM reports, which adequately document results of reviews and follow-up activities needed to correct deficiencies.

The CCA has legal authority to establish regulatory controls over certified meat establishments that export their products to the United States. Inspection officials enforce regulatory requirements equivalent to those governing the United States' system of meat inspection. The FSIS auditors were unable to see the traditional inspection for swine (i.e. pork) slaughter since those operations were not being conducted at the time. The CCA informed FSIS that Australia would be operating under traditional inspection at swine slaughter establishments that produce pork products for export to the United States. A follow-up onsite audit will be conducted to complete the swine slaughter inspection equivalence reinstatement process.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. To be considered equivalent to FSIS' program, the CCA is to provide general requirements for sanitation, sanitary handling of products, and development and implementation of sanitation standard operating procedures (SSOP).

The evaluation of this component included a review and analysis of the information provided by the CCA in the sanitation component portion of the SRT, observations gathered during the onsite

verification audit of slaughter establishments, and review of government and establishment records. Furthermore, FSIS verified that the CCA exercises its legal authority to require establishments to develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions.

The CCA requires that establishments develop and adhere to written programs that prevent direct product contamination and operate in a manner that prevents the creation of insanitary conditions. All certified establishments must operate following AAs, which are to include a portion that describes how the establishments will comply with regulatory requirements for sanitation programs. Establishments are also required to monitor the adequacy of the construction of their facilities, and develop maintenance programs for equipment and structures. The FSIS auditors verified that government officials enforce compliance of certified establishments with sanitation requirements on a daily basis by inspecting production areas, reviewing establishment records, and verifying the adequacy of the establishments' monitoring and implementation of the sanitation programs.

The FSIS auditors verified the adequacy of official verification and inspection activities related to sanitation programs at certified establishments by observing government inspectors as they assessed the implementation of the establishments' sanitation procedures for pre-operational and operational sanitation. The FSIS auditors also reviewed government inspection and establishment records and assessed the overall sanitary conditions of production areas and storage rooms, and production practices at the establishments. The FSIS auditors identified several minor sanitary deficiencies that were promptly corrected by the establishments under the oversight of inspection personnel in accordance with established procedures.

Australia's meat inspection system has legal authority and a well-documented regulatory framework that it implements to ensure compliance of establishments with sanitation requirements equivalent to those governing the United States' system of meat inspection. Minor sanitation deficiencies identified by the FSIS auditors did not pose immediate food safety concerns. Establishments promptly implemented corrective actions that were verified by in-plant inspection personnel.

VII. COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM

The fourth of six equivalence components that the FSIS auditors reviewed was Government HACCP System. The inspection system is to require that each official establishment develop, implement, and maintain a HACCP plan.

The FSIS auditors reviewed records maintained by inspection personnel and the establishments, and interviewed in-plant officials. In addition, the FSIS auditors observed implementation of HACCP plan monitoring activities by assessing the adequacy of the design and implementation of the HACCP programs used by the establishments. Furthermore, the FSIS auditors reviewed documents maintained by the establishments in accordance with CCA requirements that mandate that certified establishments develop, implement, and maintain HACCP programs as part of their AA. The review of documents showed that the establishments prepared written hazard analysis,

flow charts, and HACCP plans to identify, evaluate, and prevent or control food safety hazards in their production processes. The HACCP programs include activities designed to validate adequacy of controls, monitoring of implementation of controls, and recordkeeping to document results of verification activities and implementation of corrective actions.

Additional documents reviewed by the FSIS auditors included the written responses provided by the CCA related to several POE violations reported by FSIS from March 2015 through May 2016, involving contamination of meat products with fecal matter. The information provided by the CCA was corroborated at the establishment level to assess the adequacy of corrective actions implemented. The FSIS auditors verified that each of the establishments involved in the POE violations had developed a plan of action that was evaluated and implemented. The ATM and FOM in turn evaluated the adequacy of implementation and efficacy of the corrective actions implemented by the establishments.

The FSIS auditors observed that preventive measures and improved sanitary dressing procedures had effectively reduced the rate of contamination. Establishments have also adopted practices that are implemented during the periods of the year when livestock arrive at the establishments carrying heavy loads of fecal matter on their coats. Official monitoring records and establishment records show that ante-mortem interventions, increased monitoring of sanitary dressing procedures, and redistribution of workspace along the slaughter lines appeared to have contributed to a reduction in the incidence of accidental contamination of carcasses with fecal matter at the audited establishments. Relative to POE violations that involved product with untrimmed pathology lesions, the establishments have developed programs within their AA to ensure the close examination of meat products. Ongoing practices introduced include the palpation of all carcasses and meat portions at specific packaging stations along each production line and prompt removal of identified lesions prior to packaging of the products.

The FSIS auditors verified that the CCA requires regulated establishments to develop, validate, and implement HACCP programs, which are to be included in the AAs of the certified establishments to meet Australian regulatory requirements. The establishments have developed programs that adequately identify known food safety hazards, and have established controls for such hazards as required by the CCA.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that the FSIS auditors reviewed was Government Chemical Residue Testing Programs. The inspection system is to present a chemical residue testing program, organized and administered by the national government, which includes random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified by the exporting country's meat and poultry inspection authorities or by FSIS as potential contaminants.

The FSIS auditors examined the CCA's residue plan for 2016 and results for 2015 and did not identify any concerns. The FSIS auditors visited a chemical residue testing laboratory, local government offices, and slaughter establishments to verify the adequacy of the chemical residue testing programs. The CCA delegates the responsibility to maintain monitoring and surveillance

programs to detect the presence of chemical residues in animals and edible animal products to the NRS, which is a governmental organization.

In addition, NRS assesses the performance of the chemistry laboratories that serve the meat exports program. NATA is an Australian non-profit organization that is used by the Australian government to provide laboratory accreditation services. NATA has accredited NRS to serve as the entity that approves and evaluates the proficiency and performance of chemical residue analysis laboratories. NRS has also entered into a Memorandum of Understanding with NATA to evaluate the performance of the laboratories using the ISO 17025 standard. NATA also administers proficiency testing programs for the residue laboratories of the Australian meat inspection system. The FSIS auditors observed that 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.

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.

The FSIS auditors verified that 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 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 are also managed by NRS. However, analysis of samples is delegated to laboratories that NRS contracts through a competitive tender process.

The FSIS auditors assessed the type of oversight the CCA provides to the functions of chemical laboratories. All laboratories are accredited by NATA and evaluated by NRS prior to being awarded 3-year contracts to analyze samples. Once integrated into the program, 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. NRS audits the laboratories periodically to evaluate their performance, assessing their technical and managerial competence in accordance with ISO 17025 standard, NATA standards, and CCA and United States' requirements.

The FSIS auditors verified that at the establishment level, government inspectors collect samples in accordance with standard operating procedures, as instructed by 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 in-plant officials have legal authority to condemn food products when laboratory analysis indicates the presence of chemical residues at a level that exceeds Australian standards.

The FSIS auditors' review found no concerns with the CCA's chemical residue testing program. The results of the FSIS auditors' review of the residue testing plan, sampling data, and third party laboratory audit reports conducted by the accrediting institutions show that the chemical residue program for the Australia meat inspection system is organized and effectively administered.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component that the FSIS auditors reviewed was Government Microbiological Testing Programs. The system is to implement certain sampling and testing programs to ensure that raw beef, lamb, mutton, and goat products produced for export to the United States are safe and wholesome.

The FSIS auditors reviewed the responses provided by the CCA in the Pathogen Reduction Standards section of its SRT that describes generic *E. coli* and *Salmonella* sampling, as well as Australia's *E. coli* O157:H7 and non-O157 STECs control program. In addition, the FSIS auditors performed an assessment onsite of the implementation of the microbiological sampling and testing of raw meat product activities conducted by establishments and government officials.

The documents reviewed 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 the effectiveness of the establishments' food safety controls designed to control microbiological pathogens.

The FSIS auditors confirmed that laboratories conducting microbiological analysis of samples of edible meat products from certified establishments are audited every 18 months by NATA/CCA auditors, in accordance with the requirements specified in ISO 17025 and are required to participate in proficiency testing programs. However, as described in the Government Oversight component section of this report, the actions taken when deviations are detected are inadequate.

Documents reviewed by FSIS and observations made at certified slaughter establishments demonstrate that testing of raw products for generic *E. coli* and *Salmonella* is conducted at slaughter facilities. Shipping and handling of randomly collected samples is done by the establishments under the supervision of in-plant government inspection officials and in accordance with instructions issued by the CCA in the *E.coli* and *Salmonella* monitoring programs for export-slaughter establishments. The samples are analyzed at CCA-approved, NATA-accredited laboratories that 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). *Salmonella* results are qualitatively assessed, i.e., detected or not detected.

The FSIS auditors 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 inspection officials verify the adequacy of implementation of sampling and analysis protocols, and track and evaluate sampling results.

The regulations imposed by the CCA upon establishments to control *Salmonella* in raw meat products, considers three consecutive failures to meet the *Salmonella* control standards as a failure of an establishment to maintain the required minimum standard for slaughter hygiene and sanitation. As a result, the CCA will question the adequacy of the HACCP program being implemented by such establishment and in accordance with the statutory framework of the Australian meat inspection system will exclude such operators from the exports program. A review of microbiological analysis results at the audited establishments indicated that none of the audited establishments had failed the performance standard imposed by the CCA.

The FSIS auditors 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 export to the United States and verification of the testing programs used by the establishments to determine that they meet CCA requirements. In addition, the CCA tests raw ground beef components destined for export to the United States at least monthly. The CCA revised this protocol to include the additional six target non-O157 STECs (i.e., *E. coli* strains O26, O45, O103, O111, O121 and O145) and FSIS determined that the *E. coli* O157:H7 and non-O157 STECs control program was equivalent to FSIS controls for those pathogens. Samples collected by the establishment and government officials are analyzed in CCA-approved laboratories.

The FSIS auditors examined 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. The FSIS auditors also confirmed that the officials conducted identification and handling of samples in an adequate manner. Government officials verify that identification of collected samples is consistent with newly communicated CCA requirements that ask establishments to define in their AA, how sampled lots are determined to be microbiologically independent, and the procedures that the establishment will follow to identify the products subject to retention, in the event of a presumptive or confirmed positive result being reported by the laboratory.

In conclusion, the FSIS auditors verified that the government microbiological testing programs component of the Australian meat inspection system is organized and administered by the national government to verify that meat (i.e., raw beef, lamb, mutton, and goat) 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 September 30, 2016, in Canberra, Australia with DAWR. At this meeting, the FSIS auditors presented the preliminary findings from the audit. The CCA understood and accepted the findings as they pertained to the current aspects of Australia's meat (i.e., raw beef, lamb, mutton, and goat) inspection system.

An analysis of each component did not identify any systemic findings representing an immediate threat to public health. However, the FSIS auditors identified the following finding:

Government Microbiological Testing Programs

- The CCA has not verified that laboratories have internal procedures to ensure that only approved methods are used to analyze samples of raw beef, lamb, mutton, and goat product destined for export to the United States.

During the audit exit meeting, the CCA committed to address the preliminary finding as presented. FSIS will further assess the equivalence of Australia's meat inspection system upon receiving the CCA's proposed corrective actions for the reported finding.

In reference to reinstatement of equivalence of Australia's pork inspection system, the FSIS auditors were unable to see the traditional inspection for swine slaughter since those operations were not being conducted at the time. The CCA informed FSIS that Australia would be operating under traditional inspection at swine slaughter establishments that produce pork products for export to the United States. A follow-up onsite audit will be conducted to complete the swine slaughter inspection equivalence reinstatement process.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Swickers Kingaroy Bacon Factory Kingaroy, Queensland	2. AUDIT DATE Sep. 23, 2016	3. ESTABLISHMENT NO. 48	4. NAME OF COUNTRY Australia
	5. NAME OF AUDITOR(S) International Audit Staff		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	X
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

This establishment slaughter feeder pigs.

55. FSIS auditors observed that ante mortem and post-mortem inspection procedures were not conducted in accordance with traditional inspection requirements. In addition, it was observed that head and viscera inspection procedures required further improvement. Slicing of lymph nodes of the head is not done in a manner that would readily permit observation of cut surfaces. Presentation of viscera by the establishment is not consistently uniform and in turn prevents adequate palpation of mesenteric lymph nodes on the part of the viscera inspector.

Determination of equivalence of pork slaughter inspection was not completed since the establishment was not operating under traditional swine slaughter inspection as was expected.

61. NAME OF AUDITOR
International Audit Staff

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 Borthwick & Sons Mackay, Queensland	2. AUDIT DATE Sep. 22, 2016	3. ESTABLISHMENT NO. 67	4. NAME OF COUNTRY Australia
	5. NAME OF AUDITOR(S) International Audit Staff		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	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Beef slaughter establishment.

No deficiencies were observed at this establishment.

61. NAME OF AUDITOR
International Audit Staff

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Stanbroke Beef Grantham, Queensland	2. AUDIT DATE Sep. 26, 2016	3. ESTABLISHMENT NO. 203	4. NAME OF COUNTRY Australia
	5. NAME OF AUDITOR(S) International Audit Staff		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	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

This establishment slaughters bovine.

No deficiencies were identified during this audit.

61. NAME OF AUDITOR
International Audit Staff

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Cedar Meats Pty., Ltd Brooklyn, Victoria	2. AUDIT DATE Sep. 16, 2016	3. ESTABLISHMENT NO. 206	4. NAME OF COUNTRY Australia
	5. NAME OF AUDITOR(S) International Audit Staff		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.	X	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	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

This establishment slaughters ovine, caprine and young bovine.

15. During the review of documents that are part of the HACCP program used by the establishment, the FSIS auditors identified a small flaw in the design of the hazard analysis. At the carcass chilling step, accidental falling of carcasses was considered as an event that could cause physical, rather than microbial contamination of the product.

61. NAME OF AUDITOR
International Audit Staff

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Wodonga Rendering Pty., Ltd Wodonga, Victoria	2. AUDIT DATE Sep. 14, 2016	3. ESTABLISHMENT NO. 612	4. NAME OF COUNTRY Australia
	5. NAME OF AUDITOR(S) International Audit Staff		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	X
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.	X	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	
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	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

This establishment slaughters small livestock (ovine and caprine)

15. During the review of the documents associated with the lamb slaughter HACCP plan and product flow charts, the FSIS auditors noted that a wash cabinet installed right before the critical control point (CCP) monitoring station was not in the written hazard analysis. The establishment had installed that piece of equipment after discussion with the CCA and validated it as an effective way to reduce physical contamination, wool, hair and other solids from the carcass surfaces. Furthermore, only carcasses assessed as free of visible milk, ingesta and fecal contamination are allowed to be washed.

18. During the assessment of production activities, the FSIS auditor identified a lamb leg on a table prior to the point of packaging, with an area of discoloration that was consistent with the appearance of fecal contamination. The establishment had examined the product at several points prior to it reaching the packaging table, but had missed the defect. Inspection personnel promptly conducted an assessment of the incident and conducted multiple evaluations of the process. Carcasses in the holding chillers were further evaluated and the results indicated that the issue was an isolated event. Inspection personnel prepared a record of the occurrence and followed up with the establishment to ensure that an acceptable corrective action was implemented.

FSIS conducted a review of the daily records for official verification of monitoring of the CCPs generated by in-plant inspectors and accompanied the on plant veterinarian OPV to observe him as he assessed the acceptability of several samples of carcasses in the holding coolers. The records did not show evidence of high incidence of fecal contamination on carcasses. Furthermore, recordkeeping maintained by the establishment document the actions taken to ensure that all involved carcasses were visually inspected to verify absence of fecal matter.

39. During pre-operational verification, the FSIS auditor identified several sections of the floor in the packaging and staging room that had become deteriorated. There was also a cooling unit that had accumulated organic residue on the surfaces of grid that cover the fans. The establishment revised the schedule for the cleaning of overhead surfaces to increase cleaning frequency to weekly and planned repairs of the floor in the packaging area.

All reported deficiencies were promptly corrected by the establishment and measures were introduced to the sanitation and HACCP monitoring procedures to prevent recurrence of the identified deficiencies.

61. NAME OF AUDITOR

International Audit Staff

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 Pty., Ltd Brooklyn, Victoria	2. AUDIT DATE Sep. 19, 2016	3. ESTABLISHMENT NO. 688	4. NAME OF COUNTRY Australia
	5. NAME OF AUDITOR(S) International Audit Staff		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.	X	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	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

This establishment slaughters ovine and bovine.

15. The FSIS auditors reviewed the slaughter HACCP plan used by the establishment and observed that it includes a CCP for the temperature of product prepared in the establishment. However, the written plan includes in the described target product to be checked, incoming meats. Although, those meat products are handled in accordance with a pre-requisite program specifically developed to ensure their acceptability, including temperature and condition of products at the point of receiving.

61. NAME OF AUDITOR
International Audit Staff

62. AUDITOR SIGNATURE AND DATE

Appendix B: Foreign Country Response to Draft Final Audit Report



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

Ms Jane Doherty
International Coordination Executive
Office of International Coordination
Food Safety and Inspection Service
U.S. Department of Agriculture
1400 Independence Avenue, SW Room 3143
Washington, DC 20205

Dear Ms Doherty

Australian Export Meat Inspection System 2016 Audit – Draft Final Audit Report

Thank you for your letter dated 3 April 2017 in which you provided the Food Safety and Inspection Service (FSIS) Draft Final Report of the audit of the Australian Export Meat Inspection System (AEMIS) conducted by FSIS from 12 September 2016 through 30 September 2016.

The Department of Agriculture and Water Resources appreciates the efforts of FSIS in conducting the audit and is grateful for the opportunity to comment on the Draft Final Report. Comments for the consideration of FSIS are provided at **Attachment 1**.

The department notes the overall finding that AEMIS meets the core criteria for all six components to maintain its equivalence with the United States' system.

As undertaken at the audit exit meeting, the department has addressed the preliminary finding. Additionally, we would also like to address the reporting of port-of-entry (POE) violations within the Draft Final Report.

The department takes the preliminary finding in relation to microbiological testing very seriously and has addressed it through communication with export laboratories and discussions with the National Association of Testing Authorities (NATA). Further information regarding the department's response to the preliminary finding is presented at **Attachment 2**.

We would like to take this opportunity to address the statements on page 3 of the Draft Final Report regarding POE rejections. The Draft Final Report states that 6,143,418 pounds of product (0.22%) was rejected for various reasons including POE violations of United States food safety standards; inadequate product trimming; and inappropriate handling of product during transportation. For the period in question the department received notification of POE rejections for zero tolerance (ZT) detections and off condition that totalled 309,922 pounds (0.011%).

The department understands that the remaining 5,833,496 pounds of product was rejected for reasons unrelated to food safety. The department respectfully requests that the Draft Final Audit Report be amended to more clearly reflect that only a very small proportion of the quoted 6,143,418 pounds of rejected product, was due to violation of US food safety standards.

Thank you again for the opportunity to comment on the Draft Final report.

If you require further information, please do not hesitate to contact the department via Colin Hunter, Minister Counsellor of the Australian Embassy, Washington, D.C. at Colin.Hunter@dfat.gov.au. Alternatively, you can contact me directly at David.Cunningham@agriculture.gov.au or on +61 2 6272 5954.

Yours sincerely



Dr David Cunningham
Assistant Secretary, Export Standards Branch
Exports Division

2 June 2017

Attachment 1 - Response to Draft Final Audit Report

Attachment 2 - Government Microbiological Testing Programs Report



Attachment 1

Report Section, Page & paragraph Reference	Report Comment	Departmental Response	Department Request
Section II; Page 2: Table; Column 3, Line 3	Reads: Brooklyn, Melbourne VIC (205 and 688)	Should read: Brooklyn, Melbourne VIC (206 and 688)	Please amend.
Section III; Page 3: Paragraph 2	From October 2014 to August 2016, FSIS import inspectors performed 100 percent re-inspection for labelling and certification of 2,772,637,346 pounds of raw beef, lamb, mutton, and goat products exported by Australia to the United States. A total of 6,143,418 pounds were rejected for various reasons, including POE violations of United States food safety standards; inadequate product trimming; and inappropriate handling of product during transportation. In response to the reported POE violations, the CCA provided reports describing the results of the investigations conducted by Australian inspection officials and the	FSIS Draft Audit Report states that 6,143,418 pounds (0.22%) were rejected for various reasons including POE violations of United States food safety standards; inadequate product trimming; inappropriate handling of product during transportation. The department's records are based on official notifications from FSIS of POE rejections for violation of US food safety standards. The department's records show that 309,922 pounds (0.011%) of product was rejected due to ZT detections and off condition. The department understands that the remaining 5,833,496 pounds of product was rejected for reasons unrelated to food safety and the	Please separate the POE rejection statistics into those that were due to violations of US food safety standards and those that were for non-food safety violations.

	corrective actions implemented by the establishments.	department does not receive FSIS notifications for this type of POE rejection.	
Section IV; Page 3: Paragraph 5	The Food Safety and Inspection Service (FSIS) assessed the current organization and administration of Australia’s meat inspection system for raw beef, lamb, mutton, and goat and observed that it has undergone changes in organizational arrangement and name. The government agency that serves as the CCA is now known as the Department of Agriculture and Water Resources (DAWR). The Exports Division of DAWR is supported by the Exports Standards Branch and the Meat Exports Branch (MEB), which oversees the functions of the overall Australian export meat inspection system. Three Field Operations Managers (FOMs) assist the MEB in administering and coordinating the delivery of inspection services at certified establishments . The FOMs supervise the Area Technical Managers (ATMs), who in turn supervise the on-plant veterinarians (OPVs).	The department understands that the term, ‘certified establishments’, which is used throughout the text, refers to export registered establishments operating within AEMIS.	
Section IV; Page 3: Paragraph 5	FSIS assessed the current organization and administration of Australia’s meat inspection system for raw beef, lamb, mutton, and goat and observed that it has undergone changes in organizational arrangement and name. The government agency that serves as the CCA is now known as the Department of Agriculture and Water Resources (DAWR). The Exports Division of DAWR is supported	The Exports Division of the department is supported by Export Standards Branch, Meat Exports Branch (MEB), and Residues and Food Branch. The latter is not mentioned in this document. Residues and Food Branch plays an integral operational role in AEMIS. Key functions include provision of export documentation, registering	Please amend the text to also include the Residues and Food Branch.

	<p>by the Exports Standards Branch and the Meat Exports Branch (MEB), which oversees the functions of the overall Australian export meat inspection system. Three Field Operations Managers (FOMs) assist the MEB in administering and coordinating the delivery of inspection services at certified establishments. The FOMs supervise the Area Technical Managers (ATMs), who in turn supervise the on-plant veterinarians (OPVs).</p>	<p>and licencing, and delivery of the National Residue Survey.</p> <p>Exports to the USA are supported by the Residues and Food Branch through documentation, registration and licencing, and the National Residue Survey. The department therefore requests that they be included in the overview of the Exports Division.</p>	
<p>Section IV; Page 4: Paragraph 3</p>	<p>The FSIS auditors verified that in Australia, the federal government is responsible for exports and export registered establishments in accordance with national statutes¹. The MEB is responsible for administering national certification, verification, and auditing activities; and ensuring that producers comply with inspection requirements of Australia’s meat (i.e., raw beef, lamb, mutton, and goat) export systems.</p>	<p>It is correct that the MEB is responsible for verification and auditing activities; and ensuring that producers comply with inspection requirements of Australia’s meat export systems.</p> <p>However, the MEB is not responsible for administering national certification. This is the responsibility of Residues and Food Branch.</p>	<p>Please amend the text to note that Residues and Food Branch is responsible for administration of national certification</p>
<p>Section IV; Page 4: Paragraph 3</p>	<p>The FSIS auditors verified that in Australia, the federal government is responsible for exports and export registered establishments in accordance with national statutes². The MEB is responsible for</p>	<p>The department understands that ‘producers’ means meat processors that operate registered establishments under AEMIS.</p>	

¹ Export Control Act 1982, Export Control (Prescribed Goods-General) Order, 2005, Export Control (Meat and

Meat Products) Orders 2005, Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products for Human Consumption (AS4696)

² Export Control Act 1982, Export Control (Prescribed Goods-General) Order, 2005, Export Control (Meat and

	administering national certification, verification, and auditing activities; and ensuring that producers comply with inspection requirements of Australia’s meat (i.e., raw beef, lamb, mutton, and goat) export systems.		
Section IV, page 5	Government officials provide inspection and verification services at establishments, issue export certificates, and audit the performance of establishments in accordance with a fee-for-service arrangement. Government officials follow a schedule of fees for service rendered to charge the certified establishments for the services provided. The CCA authorizes the charges and the establishments make payments to the Office of the National Treasury of Australia, which in turn pays the salaries of the government employees assigned to provide the aforementioned services. The AAOs receive payment for their services directly from the establishments.	This is incorrect. Government officials provide inspection and verification services at establishments, issue export certificates, and audit the performance of establishments. The CCA applies fees and charges, prescribed by legislation, to the establishments via a cost-recovery model, for the provision of the aforementioned services. The CCA pays the salaries of the government employees assigned to provide the aforementioned services. A range of CCA authorisation processes apply for AAOs and independent AAO employers.	Please replace with the following text: <i>Government officials provide inspection and verification services at establishments, issue export certificates, and audit the performance of establishments. The CCA applies fees and charges, prescribed by legislation, to the establishments via a cost-recovery model. The CCA pays the salaries of the government employees assigned to provide the aforementioned services. A range of CCA authorisation processes apply for AAOs and independent AAO employers.</i>
Section IV; page 6: Footnote	Footnote: Meat Notice Number 2013/05 Small Stock Processing: Unacceptable Meat Hygiene	This meat notice has been repealed and updated with Meat Notice 2016/03: <i>Daily hygiene verification of finished USA-eligible sheep, lamb</i>	Please update.

	Assessment Results or Rejections for Port of Entry Defects in the US	<i>and goat product</i> . Please note this Meat Notice is due for review 1 July 2018. Link to updated meat notice is as follows: http://www.agriculture.gov.au/export/controlled-goods/meat/elmer-3/notices/2016/mn16-03	
Section V; Page 9: Paragraph 3	The CCA has legal authority to establish regulatory controls over certified meat establishments that export their products to the United States. Inspection officials enforce regulatory requirements equivalent to those governing the United States' system of meat inspection. The FSIS auditors were unable to see the traditional inspection for swine (i.e. pork) slaughter since those operations were not being conducted at the time. The CCA informed FSIS that Australia would be operating under traditional inspection at swine slaughter establishments that produce pork products for export to the United States. A follow-up onsite audit will be conducted to complete the swine slaughter inspection equivalence reinstatement process.	Under Australia's pork AEMIS, there are two inspection models – inspection by departmental Food Safety Meat Assessors (FSMAs), and inspection by Australian Government Authorised Officers (AAOs). Australia considers that both inspection models achieve equivalent outcomes. The inspection model viewed during the September 2016 audit was the AAO inspection model with the inclusion of end-of-chain carcass-by-carcass inspection by an FSMA. The department looks forward to working further with FSIS towards an equivalence determination for pork AEMIS.	
Section X; Page 15: Paragraph 4	In reference to reinstatement of equivalence of Australia's pork inspection system, the FSIS auditors were unable to see the traditional inspection for swine slaughter since those operations were not being conducted at the time. The CCA informed FSIS that Australia would be operating under traditional inspection at swine	Under Australia's pork AEMIS, there are two inspection models – inspection by departmental Food Safety Meat Assessors (FSMAs), and inspection by Australian Government Authorised Officers (AAOs). Australia considers that both inspection models achieve equivalent outcomes.	

	slaughter establishments that produce pork products for export to the United States. A follow-up onsite audit will be conducted to complete the swine slaughter inspection equivalence reinstatement process.	<p>The inspection model viewed during the September 2016 audit was the AAO inspection model with the inclusion of end-of-chain carcass-by-carcass inspection by an FSMA.</p> <p>The department looks forward to working further with FSIS towards an equivalence determination for pork AEMIS.</p>	
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Attachment 2: Microbiological testing programs

Approved Laboratory Program

The department operates a rigorous system, the Approved Laboratory Program, for approval and audit of microbiology laboratories undertaking testing of meat exported to the United States. The department's Approved Laboratory Program is available on the department's website at

<http://www.agriculture.gov.au/SiteCollectionDocuments/aqis/exporting/meat/elmer3/index/methods-microbiological-test-meat/>.

In order to maintain departmental approval, laboratories must meet a number of requirements, including:

- Maintenance of accreditation for specified approved methods;
- Regular assessment by the National Association of Testing Authorities (NATA) or where required, by the department;
- Participation in proficiency testing rounds as required by NATA and/or the department (minimum six monthly).

Internationally, the International Laboratory Accreditation Cooperation (ILAC) requires on-site assessment of laboratories at least once every 24 months. In Australia, NATA has elected to conduct on-site laboratory assessments more frequently at once every 18 months. This frequency applies to all NATA laboratory assessments (e.g. meat and other food testing laboratories) where laboratories are accredited to ISO/IEC 17025. The 18 month frequency has been communicated to FSIS during previous in-country audits and in Australia's Self-Reporting Tool.

The department's Approved Laboratory Program

(<http://www.agriculture.gov.au/SiteCollectionDocuments/aqis/exporting/meat/elmer3/index/methods-microbiological-test-meat/approved-lab.pdf>) requires on page 11 that:

1.5.2.2. Approved methods must be followed without modification, unless such modifications have been agreed to by the department and are under the laboratory's scope of accreditation/approval.

1.5.2.3 Any approved laboratory may undertake testing using approved methods if their scope of accreditation/approval includes the specific tests to be used and the method is included in their annual assessment by NATA or the department. Laboratories must notify the department of any changes to approved methods used by the laboratory for testing as part of export certification before implementing the methods.

Department response

In relation to NATA's audit at Symbio Laboratories on 12-13 July 2016, NATA had not formally published its audit report at the time of the US visit. As such, the department had not been able to review NATA's findings prior to the visit.

Following the audit visit by FSIS, the department met with NATA on 14 November 2016 to discuss the US audit findings. The department reiterated the requirements in the department's Approved Laboratory Program that laboratories must not modify approved methods without

authorisation by the department. The department also advised NATA that any findings of modifications to approved methods must result in a 'condition' finding, meaning that the laboratory must implement a corrective action and provide supporting evidence of the action.

NATA advised that 'condition' findings would normally be attributed to method modifications, but it would advise its audit assessors of the US finding. NATA advised that it would ensure that approved laboratories are aware of the need to follow approved methods without modification and that any method modification detected by NATA in future would result in a 'condition' finding. NATA has confirmed that it discussed the US audit finding with its audit assessors in December 2016.

In addition, the department wrote to all approved laboratories in early May 2017, advising them of FSIS' finding and reminding them that they must not modify any approved microbiological method without prior approval of the department.