



United States Department of Agriculture

Food Safety and  
Inspection Service

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1400 Independence  
Avenue, SW.  
Washington, D.C.  
20250

Fran Freeman  
First Assistant Secretary, Exports Division  
Department of Agriculture  
18 Marcus Clarke Street Canberra City GPO Box 858  
Canberra ACT 2601, Australia

*Fran*  
Dear Ms. Freeman,

Enclosed is a copy of the final audit report for the United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) on-site audit conducted of Australia's meat inspection system from August 6 through August 22, 2018. The comments received from the Government of Australia are included as attachments to the final report.

For any questions regarding the FSIS audit report, please contact the Office of International Coordination, by electronic mail at [InternationalCoordination@fsis.usda.gov](mailto:InternationalCoordination@fsis.usda.gov).

Sincerely,

Michelle Catlin, PhD  
International Coordination Executive  
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN  
AUSTRALIA

AUGUST 6 THROUGH 22, 2018

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

AUGUST 29, 2019

Food Safety and Inspection Service  
United States Department of Agriculture

## **Executive Summary**

This report describes the outcome of an on-site equivalence verification audit conducted by the United States Department of Agriculture's Food Safety and Inspection Service from August 6-22, 2018. The purpose of the audit was to determine whether Australia's food safety inspection system governing meat and poultry (ratite) remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. An additional objective was to assess the regulatory oversight that the government provides to the Australian Export Meat Inspection System (AEMIS) for pork slaughter, in preparation to determine whether AEMIS could be expanded to raw pork products intended for export to the United States as equivalent to the FSIS inspection system. Australia currently exports the following categories of products: raw intact beef, veal, goat, lamb, mutton, and poultry (ratite); heat treated not fully cooked not shelf stable beef; fully cooked ready-to-eat beef; thermally processed commercially sterile beef, lamb, and mutton.

The audit focused on six system equivalence 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 Residue Testing Programs; and (6) Government Microbiological Testing Programs.

An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

### **GOVERNMENT OVERSIGHT**

- The CCA does not include provisions that Australian inspection officials will not sign export certificates for product destined for the United States until all inspection laboratory verification sample test results are received and found acceptable.

### **GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM**

- Government inspection personnel at three of 12 audited establishments failed to identify deficiencies related to hazard analysis requirements.
- Government inspection personnel at seven of 12 audited establishments failed to identify deficiencies related to HACCP plan verification requirements.

The audit findings did not represent a potential to endanger public health because most of them involved recordkeeping and necessary technical clarifications. During the exit meeting, the CCA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

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## I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Australia's food safety system from August 6-22, 2018. The audit began with an entrance meeting held on August 6, 2018, in Canberra, Australia, at which time the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – Department of Agriculture and Water Resources (DAWR).

## II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether the food safety inspection system governing meat and poultry (ratite) remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. An additional objective was to assess the regulatory oversight that the CCA provides to the Australian Export Meat Inspection System (AEMIS) for pork slaughter. Australia submitted in May 2018 a request to FSIS for an equivalence determination for the export of raw pork, produced under AEMIS, to the United States. The audit observations at one pork slaughter establishment contributes to the FSIS evaluation of the request. As of July 30, 2018, Australia is eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-Intact Beef	Beef and Veal - All Products Eligible except Advanced Meat Recovery Product (AMR); Low Temperature Rendered Product (LTRP); Partially Defatted Beef Fatty Tissue (PDBFT); Partially Defatted Chopped Beef (PDCB); and Finely Textured Beef
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise non-intact meat-other (sheep, goat)	Goat, Lamb, Mutton - All Products Eligible except Mechanically Separated and Advance Meat Recovery Product (AMR)
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-Intact Poultry-Other	Ratites - All Products Eligible except Mechanically Separated
Raw - Intact	Raw Intact Beef	Beef and Veal - All Products Eligible
Raw - Intact	Raw Intact Meat-Other (Sheep, Goat)	Goat, Lamb, Mutton - All Products Eligible
Raw - Intact	Raw Intact Poultry-Other	Ratites - All Products Eligible
Thermally Processed - Commercially Sterile	Thermally Processed, Commercially Sterile	Meat - All Products Eligible
Heat Treated - Shelf Stable	NRTE Otherwise Processed Meat	Meat - All Products Eligible
Heat Treated - Shelf Stable	RTE Acidified/Fermented Meat (without cooking)	Meat - All Products Eligible
Heat Treated - Shelf Stable	RTE Dried Meat	Meat - All Products Eligible
Heat Treated - Shelf Stable	RTE Salt-Cured Meat	Meat - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE Fully-Cooked Meat	Meat - All Products Eligible
Heat Treated - Not Fully Cooked - Not Shelf Stable	NRTE Otherwise Processed Meat	Meat - All Products Eligible

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes that beef and veal imported from Australia are subject to the Bovine Spongiform Encephalopathy (BSE) requirements specified in Title 9 of the United States Code of Federal Regulations (9 CFR) § 94.18 and/or § 94.19.

FSIS applied a risk-based procedure that 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) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from the CCA through the self-reporting tool (SRT).

Representatives from the CCA accompanied the FSIS auditors throughout the entire audit. Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (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 Residue Testing Programs; and (6) Government Microbiological Testing Programs.

Administrative functions were reviewed at CCA headquarters, two regional offices, and 12 local inspection offices. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended. A sample of 12 establishments was selected from a total of 123 establishments certified to export to the United States. This included 10 slaughter establishments; one heat treated not fully cooked not shelf stable processing establishment, and one thermally processed commercially sterile processing establishment. The products these establishments produce and export to the United States includes the following categories of products: raw intact beef, veal, goat, lamb, mutton, and poultry (ratite); heat treated not fully cooked not shelf stable beef; fully cooked ready-to-eat beef; thermally processed commercially sterile beef, lamb, and mutton.

During the establishment visits, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditors assessed the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in 9 CFR §327.2 and §381.196, the FSIS regulations addressing equivalence determinations for foreign country inspection systems for meat and poultry.

Additionally, FSIS audited one microbiology laboratory and one chemical residue laboratory to verify their ability to provide adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> <li>Department of Agriculture and Water Resources, Canberra</li> </ul>
	Regional Offices	2	<ul style="list-style-type: none"> <li>Melbourne Regional Office, Melbourne</li> <li>Brisbane Regional Office, Brisbane</li> </ul>
Laboratories		2	<ul style="list-style-type: none"> <li>Silliker, Private Microbiology Analysis, Brisbane</li> <li>National Measurements Institute, Government Chemical Residue Analysis, Melbourne</li> </ul>
Beef slaughter establishments		2	<ul style="list-style-type: none"> <li>Establishment # 486, EC Throsby Pty. Ltd., Whittingham NSW</li> <li>Establishment # 3416, Meramist Pty. Ltd., Caboolture QLD</li> </ul>
Pork slaughter establishment		1	<ul style="list-style-type: none"> <li>Establishment # 48, Swickers Kingaroy Bacon Factory, Kingaroy QLD</li> </ul>
Beef, lamb, and mutton slaughter establishment		1	<ul style="list-style-type: none"> <li>Establishment # 90, Narasell Pty. Ltd., Junee NSW</li> </ul>
Beef, veal, lamb, and mutton slaughter establishment		1	<ul style="list-style-type: none"> <li>Establishment # 180, Midfield Meat International Pty. Ltd., Warrnambool VIC</li> </ul>
Beef, goat, lamb, and mutton slaughter establishments		4	<ul style="list-style-type: none"> <li>Establishment # 195, JBS Australia Pty. Ltd., Longford TAS</li> <li>Establishment # 612, Wodonga Rendering Pty. Ltd., Wodonga VIC</li> <li>Establishment # 688, JBS Australia Pty. Ltd., Brooklyn VIC</li> <li>Establishment # 866, Thomas Foods Int'l Lobethal Pty. Ltd., Lobethal SA</li> </ul>
Beef, veal, goat, lamb, and mutton slaughter establishment		1	<ul style="list-style-type: none"> <li>Establishment # 206, Cedar Meats (Aust.) Pty. Ltd., Brooklyn VIC</li> </ul>
Beef heat treated not fully cooked not shelf stable processing establishment		1	<ul style="list-style-type: none"> <li>Establishment # 265, Patties Foods Ltd., Bairnsdale VIC</li> </ul>
Beef, lamb, and mutton thermally processed commercially sterile processing establishment		1	<ul style="list-style-type: none"> <li>Establishment # 39, HJ Heinz Company, Wagga Wagga NSW</li> </ul>

FSIS performed the audit to verify that the food safety inspection system met requirements equivalent to those 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. 1901-1906);
- The Meat Inspection Regulations (9 CFR § 301 to the end);
- The Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*) and
- The Poultry Products Inspection Regulations (9 CFR § 381).

The audit standards applied during the review of Australia's inspection system for meat and poultry (ratite) included: (1) As part of the initial review process, all applicable legislation originally determined by FSIS as equivalent, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the World Trade Organization's *Agreement on the Application of Sanitary and Phytosanitary Measures*.

### **III. BACKGROUND**

From May 1, 2015 to April 30, 2018, FSIS import inspectors re-inspected 2,495,665,153 pounds of meat and poultry (ratite) exported by Australia to the United State for certification, labeling, and general condition. FSIS also performed additional types of inspection on samples representing 74,073,540 pounds of meat and poultry including physical product examinations and laboratory testing for chemical residues and microbiological pathogens (e.g. Shiga toxin-producing *Escherichia coli* [STEC] O157:H7, O26, O45, O103, O111, 0121, and O145; and *Salmonella*).

In total, FSIS refused entry to 5,299,806 pounds of product exported by Australia to the United States including 747,679 pounds that failed the additional types of inspection due to violations of United States food safety requirements (e.g., off condition, ingesta, fecal materials, extraneous materials, pathological lesions, etc.). An additional 4,552,127 pounds of meat and poultry was refused entry due to shipping damage, missing or invalid shipping marks, etc.

Prior to the on-site equivalence verification audit, FSIS reviewed and analyzed Australia's SRT responses and supporting documentation. The FSIS auditors conducted interviews, reviewed records, and made observations to determine whether Australia's food safety inspection system governing meat and poultry (ratite) is being implemented as documented in the country's SRT responses and supporting documentation.

In 1999, FSIS determined that AEMIS was equivalent to the inspection system of the United States for beef, sheep, and goat based on data submitted by Australia. AEMIS is an alternative meat slaughter inspection program in which establishment employees perform certain duties traditionally performed by government inspectors.

Under AEMIS, establishment employees instead of government inspectors are responsible for post-mortem examination of the heads and viscera of livestock. Official government veterinarians are responsible for performing ante-mortem inspection, verifying post-mortem inspection, verifying establishment examination activities, providing final disposition on animals and carcasses/heads/viscera where there is evidence of disease, verifying HACCP and sanitation standard operating procedures (Sanitation SOPs), and performing other food safety activities. Government inspectors are responsible for final inspection of each carcass for food safety defects.

The Federal Register (FR) Notices that document the FSIS equivalence decisions are in 64 FR 2621, 64 FR 30299, and 76 FR 11752. FSIS determined Australia equivalent for pork based on document reviews for a traditional slaughter inspection system.

In 2016, FSIS audited Australia's raw pork inspection system, but observed that establishments were operating under AEMIS, rather than traditional inspection as defined by DAWR, and FSIS had not determined that AEMIS is equivalent for raw pork exports. FSIS was unable to reinstate equivalence of pork slaughter. On May 14, 2018, Australia submitted an official request to FSIS to expand AEMIS to include raw pork. Australia's submission included five years of microbiological data comparing AEMIS versus traditional inspection and the FSIS baseline study for market hogs. The data included testing results of pork carcasses for aerobic plate count, generic *E. coli*, and *Salmonella*. The data indicates that there is little to no change in microbiological findings on pork carcasses when inspected under AEMIS.

The FSIS final audit reports for Australia's food safety inspection system are available on the FSIS website 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 (E.G., ORGANIZATION AND ADMINISTRATION)**

The first of six equivalence components that the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign food safety 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.

The CCA of Australia is DAWR, which is administered by the national government. The Export Control (Meat and Meat Products) Orders 2005 are orders made under the Export Control Act 1982 to regulate the export of meat and meat products. These orders include the requirement to comply with the Australian Standard for the Hygienic Transportation of Meat and Meat Products for Human Consumption (AS4696). The department oversight includes the authority to create and implement food laws, orders, codes, procedures, guidance, and directives for inspection personnel to enforce. The department has the authority to impose penalties for noncompliance or to revoke the certification of establishments.

The FSIS auditors verified that the Secretary of DAWR has overall responsibility for overseeing meat and poultry (ratite) inspection and ensuring products destined for the United States are not adulterated or misbranded. The Secretary directs four deputy secretaries who lead multiple divisions within DAWR, including the Exports Division and Biosecurity Operations Division. These divisions work together to maintain oversight for meat inspection and exports. The DAWR inspection system has three levels of government oversight: central, regional, and establishment. At the central level, the CCA headquarters is located in Canberra and provides oversight over the regional offices and establishments. The CCA has three regional offices providing oversight for certification of meat exports and oversight over establishments. The regional offices house the Field Operations Managers (FOMs) and oversight of inspection, verification activities, and compliance of meat inspection systems at all export establishments.

The three FOMs assist the Exports Division 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 in-plant veterinarians (OPVs). Under AEMIS, each establishment is staffed by at least one government Food Safety Meat Assessor (FSMA) and one Australian Government Authorized Officer (AAO) who perform inspection verification activities at establishments. The AAOs 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 establishments exporting to the United States. The FSMA is the government inspector that verifies each carcass is free of visual fecal material, ingesta, or milk contamination and pathological lesions of food safety significance after the AAOs' post-mortem assessment. The FSIS auditors verified the personnel structure and responsibilities through review of records and direct observations during the audit.

Government verification testing oversight and audits occur in plants using the *Export Meat Systems Audit Program* policy. The audit program is risk-based and underpins the department's health certification of export eligible meat and meat products. The audit frequencies are monthly or bi-annually and conducted by two ATMs to include one that has not had a government supervisory role at the establishment in the last two years. Plant audits are required so the department can continue to verify critical corrective actions to findings of non-conformance, and these can be scheduled due to a specific event. The FSIS auditors reviewed the audit reports, discussed the auditing process with the ATMs at establishments, and found no reason for concern.

The FSIS auditors' review of the oversight activities carried out at the CCA headquarters, regional offices, and establishments' government offices demonstrate that the CCA: has a single set of rules; has legal authority and responsibility to enforce inspection regulations; and enforces requirements that ensure adulterated or misbranded products are not exported to the United States.

The CCA utilizes the *Critical Incident Response Guideline* to respond to POE rejections, failed audits, and failed verification testing. This provides a guideline for auditing and increased inspection verification activities based on each incidence of POE rejection, failed audit, or failed verification testing. Additionally, the *Export Control Act 1982* gives the authority for enforcement actions and penalties when establishments are not responding to issues that may affect the public's health. Regulatory enforcement includes suspension of operations, retention of areas or product, refusal to certify lots or establishments, and delisting of establishments and could include administrative sanctions or criminal prosecution for fraud. The FSIS auditors verified through interviews, review of records, and review of critical response incidences that the CCA verification activities for critical incidences has the ability to take enforcement actions.

Review of records by the FSIS auditors demonstrated that in-plant government inspection personnel identify noncompliances, take official control actions, document all control actions, and require that establishments adequately correct regulatory noncompliances. Government documents show that CCA inspection personnel took actions, in accordance with established protocol, to ensure that establishments responded accordingly by investigating the causes of the

reported violations and implementing appropriate corrective actions. 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 October 2016 through July 2018. The FSIS auditors verified through review of records and direct observations that the CCA had assessed the adequacy of corrective actions implemented at the audited exporting establishments in response to POE violations. The establishments have identified the likely root causes for the reported violations and instituted measures to prevent recurrence of violations.

Government officials implemented a schedule of fees for service rendered to charge certified establishments for the inspection 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. OPVs and FSMAs are official government employees. The FSIS auditors verified by interviews and review of records that the government employees receive payment from the Australian government.

The AAOs are employed either directly by the establishments or through an independent organization and receive payment for their services from those sources. In both instances, the AAOs are trained for post-mortem activities. The FSIS auditors interviewed the AAOs, who explained that they had training for post-mortem inspection to include a final test on how to identify pathology and contamination issues. The AAOs are also trained to request guidance from the OPVs if they are not sure of a noncompliance, or of an abnormality, or if the establishment disagrees on issues. In the event of a disagreement, the OPV will have final say. Verification of the activities of the AAOs are conducted daily and weekly by the OPVs and monthly (or every six months) by the ATMs per instructions in *Verifying Performance of a Non-Departmental Authorized Officer*. These activities are documented in records at the establishment.

In order to become registered and certified for export each slaughter and processing establishments must submit for approval by DAWR an *Approved Arrangement (AA)* for operations. Once approved, the AA is a set of instructions for how the establishment must operate. Establishments can elect to utilize AAOs for post-mortem assessment of carcasses and parts. If AAOs are utilized, the CCA must have an inspector paid by the government and employed directly by the government conducting inspection activities on each carcass online after the AAO.

The official government veterinarian or government inspector verifies the performance of AAO examination activities, including post-mortem examination of heads and viscera. This oversight is performed by examining the product and reviewing the AAOs, performing inspection procedures once per shift as outlined in the *Work Instruction: Verifying Performance of a Non-Department Authorised Officer*. The plants may also utilize the AAOs as rail out inspectors of the post-mortem procedure for sheep and goats, but not for beef. Sheep and goat carcasses are railed out for gross contamination and any pathology observed on the line, but the OPV must perform any disposition activities for ante-mortem suspect animals. The rail out inspectors are given authority to condemn animals, and they do the final inspection of railed out animals prior

to returning these animals to the line; these animals will then be inspected by the government inspector performing inspection on each and every carcass.

The FSIS auditors verified through direct observations and review of records that the government OPVs conducted daily performance verification of activities by the AAOs. During direct observations at certified establishments, the FSIS auditors verified that the AAOs conducted only the approved activities without any concerns. Furthermore, the FSIS auditors verified that at each slaughter establishment each carcass was inspected by the FSMAs.

The OPVs provide performance verification activities at the in-plant level of the FSMAs, who are equivalent to meat inspectors in the United States, but the OPVs are not direct supervisors of the FSMAs. Senior Meat Inspectors who work for the Biosecurity Operations Division are the supervisors for the FSMAs. The Assistant Director of the Veterinary and Export Meat Operations Division, which is under the Biosecurity Operations Division, is responsible for the performance reviews of FSMAs and OPVs. This division is also responsible for the staffing including relief inspection in eligible establishments and the hiring and firing of inspection personnel. The FSIS auditors verified the supervisory structure and oversight and staffing of establishments through interviews and review of staffing plans and records.

The FSIS auditors verified through interviews and review of records that establishments wishing 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 establishments are free from debt to the Commonwealth of Australia; and the establishment has developed an AA. An AA must contain procedures and programs that establishments are to implement to ensure exporting requirements are maintained. All programs included in the AA are approved by the CCA for implementation to ensure that they meet regulatory and certification requirements.

The FSIS auditors verified through interviews and direct observations that the Australian federal government is responsible for exports and export registered establishments in accordance with national statutes. The Exports Division 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. The CCA utilizes a Request for Permit validator, who is employed and paid by the establishment, for verification of exports prior to shipping at the establishments.

The DAWR maintains adequate government oversight over establishment employees performing certain export certification activities. DAWR requires establishment employees to be trained, implements an integrated set of controls, and performs several verification activities to ensure products meet U.S. requirements. In addition, DAWR issues the final export permit and export certificate after verifying compliance with all requirements.

The FSIS auditors verified through interviews and reviews of notifications that documents are distributed to provide rapid notification of changes in the inspection system including importing country requirements. These notifications are sent by email to all inspection staff and industry participants. As requirements change, the *Manual of Importing Country Requirements* (MICoR)

database is amended. MICoR is available on the department's website to inspection staff and industry.

Changes to all other requirements are notified via a departmental Meat Notice, an official communication to departmental inspection staff and meat establishments on carrying out functions relating to the export meat regulatory system. Departmental Meat Notices are emailed and made available on the department's Electronic Legislation Manuals and Essential Reference known as ELMER 3, an electronic library of information available on the department's website. In addition, the ATMs serve as technical advisers for both the establishments and inspection personnel. Whenever changes occur, the ATMs also conduct verification activities as a means to ensure implementation of the changes.

To assess the technical competency of inspection personnel assigned to the certified establishments, the FSIS auditors confirmed through interviews and reviews of records that OPVs have 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.

FSMAs and AAOs must earn a Meat Safety (MS) IV certificate, issued by a registered training organization. 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 twelve-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. The FSIS auditors verified through interviews and review of training documents that government inspection personnel and the AAOs have completed the appropriate training.

The FSIS auditors verified through records reviews and interviews that the CCA requires establishments to have recall programs. When product poses a health or safety risk, Food Standards Australia New Zealand (FSANZ) coordinates an Australian food recall in consultation with the manufacturer and relevant state and territory authorities. Australian food recalls are designed to prevent unsafe (or potentially unsafe) food from being sold, distributed, or consumed. FSANZ collects information related to the recalled exported product and provides it to the department. The plant recall process is documented in an establishment's AA and verified through ATM auditing. The FSIS auditors noted that, in the event of a recall involving products exported to the United States, the notification will occur through its diplomatic staff in the United States, who maintain a list of key contact staff within FSIS.

The FSIS auditors verified through records review and direct observations that the CCA has traceability requirements for livestock. Requirements are implemented through multiple national programs to include the National Livestock Identification System and verified at the establishments. The FSIS auditors verified that, during ante-mortem inspection, records are presented demonstrating the origin of all livestock.

The CCA has the legal authority and responsibility to approve and disapprove laboratories engaged in analytical testing on regulated products. The CCA and the National Association of Testing Authority (NATA) must approve laboratories that conduct microbiological testing for government sampling programs. All microbiological laboratories must be accredited through NATA and utilize department approved methods for the microbiological testing of meat and meat products to be certified for export. For chemical laboratories, the National Residue Survey (NRS) is accredited by NATA to serve as the entity that audits, approves, and evaluates the proficiency and performance of chemical residue analysis laboratories, and NRS entered into a Memorandum of Understanding (MOU) with NATA to jointly evaluate the performance of the laboratories using the International Organization for Standardization (ISO) 17025 standard. The CCA requires all laboratories to be audited against ISO 17025 standards. The department has an MOU with NATA, which allows NATA to notify NRS if concerns are raised during NATA audits about laboratory competence. The scope of these audits or verification audits includes laboratory facilities, equipment and staff qualifications, and competencies.

CCA-approved methods must be used for the microbiological testing of meat and meat products for certification for export. For residue testing, NRS chemists review test method summaries prior to awarding contracts. NRS also requires NATA accreditation to ISO 17025 of test methods used for NRS testing. All laboratories must have proficiency testing (PT) conducted on a schedule based on the test method and frequency of use. The minimum frequency for participation in PT programs is specified by NATA or the department and is typically twice a year.

For both microbiological and chemical laboratories, the CCA requires procedures to ensure sample integrity and tracking from receiving samples to the reporting of results. These procedures must ensure the quality and fitness of the sample is of for testing. Sample acceptance procedures must be followed and may include the temperature, condition, and physical characteristics of sample. Upon receiving the samples, containers and paperwork are checked ensuring the integrity and proper identification of samples. The samples are logged into the computer database that is utilized to track the sample throughout the entire process.

The FSIS auditors reviewed audit records, conducted direct observations, and interviewed personnel at both microbiological and chemical testing laboratories. During the audit, one concern arose with the government oversight responsibilities for laboratories utilized for establishment or government testing.

The FSIS auditors identified that the CCA does not require that acceptable drug residue test results for routine sampling be received prior to signing certificates for export of products to the United States. Product is held pending the results of targeted testing. The CCA requires establishments have recall programs, and Australian officials have FSIS contact information in event of recall involving product exported to the United States.

- The CCA does not include provisions that Australian inspection officials will not sign export certificates for product destined for the United States until all inspection laboratory verification sample test results are received and found acceptable.

The FSIS auditors determined that Australia's government organizes and administers the country's food safety inspection system, and that the CCA inspection officials at the establishments certified by Australia enforce laws and regulations governing production and export of products to export to the United States. However, the Australian government does not require verification of acceptable drug residue test results prior to issuing export certificates, which are not consistent with the requirements of the United States.

**V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (E.G., 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; ante-mortem inspection of animals; post-mortem inspection of each and every carcass and parts; controls over condemned materials; at least once per shift inspection during processing operations and periodic supervisory visits to official establishments.

The FSIS auditors verified that the CCA maintains its statutory authority and regulatory requirements as outlined in the official documents including *Export Control (Meat and Meat Products) Orders 2005*, the *Export Control Act 1982*, and the *Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products*, which outline Australia's regulatory requirements to protect public health in animal products. There are no other regulatory changes associated with the export of meat products to the United States since the last audit. The CCA manages and coordinates delivery of inspection and verification activities at certified establishments.

The FSIS auditors reviewed documentation, which confirms that inspection verification activities occurred during each processing shift for product prepared for export to the United States. Inspection officials enforce the regulations of the system to ensure that exported meat products meet Australian standards and food safety and consumer protection standards of the United States. As FSIS introduces regulatory changes, the CCA communicates the new regulatory requirements to establishments and inspection officials. The FSIS auditors verified that the CCA officially notified establishments of FSIS regulatory changes.

The FSIS auditors verified that government inspectors ensure that all animals slaughtered at certified establishments undergo ante-mortem inspection, which is conducted by the OPVs. Animals that show clinical signs of disease are segregated and placed in a suspect pen for close evaluation by the OPV. Government inspectors also evaluate the adequacy of ante-mortem facilities and assess compliance of establishments with humane handling requirements set by the CCA and importing countries. The FSIS auditors also reviewed documentation demonstrating that the OPV conducts and verifies humane handling requirements set out in the *Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products* and observes stunning and sticking activities on a daily basis.

The FSIS auditors determined through onsite record review, interviews, and observations that the CCA's requirements concerning ante-mortem inspection examination and humane handling/slaughter of livestock were being implemented and properly documented in all audited slaughter establishments. The FSIS auditors verified that non-ambulatory disabled cattle are excluded from export to the United States and are adequately segregated at establishments certified for export.

Post-mortem inspection at establishments certified to export to the United States is conducted by either a traditional inspection system, using only inspectors that are employees (FSMAs) of the CCA, or using by an alternative inspection system incorporating AAOs. In traditional inspection and AEMIS, FSMAs and AAOs are on-line continuously during slaughter activities. AAOs are appropriately qualified, trained, and skilled persons employed by an establishment, authorized under Section 20 of the Export Control Act 1982 to perform the services for the purposes of AEMIS, and are listed in the establishments' AAs. When the alternative post-mortem inspection system is utilized, AAOs are responsible for the examination of heads, viscera, and carcasses, with an FSMA stationed at the end of the line to verify carcass inspection. The FSIS auditors confirmed that the performance of AAOs is verified on a daily basis by the OPV, including observing AAOs perform post-mortem examination of heads and viscera, per the work instructions outlined in *Verifying the Performance of a Non-Department Authorised Officer*; when deficiencies in the performance of AAOs are detected, corrective actions are implemented by the establishments under the guidance of the OPV.

The FSIS auditors visited certified establishments that slaughter beef, veal, lamb, mutton, goat, and pork and they observed that the post-mortem inspection systems were being conducted as outlined in Australian requirements. The FSIS auditors assessed the proper implementation of post-mortem inspection systems through reviews of inspection records, interviews, and observations of post-mortem inspection examinations in all 10 establishments conducting slaughter activities. The FSIS auditors observed and verified performance and implementation of proper presentation, proper incision, observation, and palpation of required organs and lymph nodes, identification, examination, and disposition of carcasses. The FSIS auditors noted that the results of post-mortem inspection activities and related condemnation of heads, viscera, and carcasses were summarized and recorded daily.

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. Evaluations of the establishments are conducted by ATMs 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. During the periodic supervisory reviews, the ATMs verify requirements for ante-mortem inspection; humane handling and slaughter; post-mortem inspection; microbiological sampling programs; sanitation; and HACCP verification activities including the review of critical control points (CCPs). FSIS evaluated the ATM reports, which adequately document results of reviews and follow-up activities needed to correct deficiencies.

The requirements to ensure control over condemned animals and inedible material are found in the *Export Control Act 1982* and the *Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products*. Condemned animals and inedible material are to be excluded from human consumption. The FSIS auditors verified that the relevant portions of these requirements were applied, including appropriate identification in accordance with the categories described therein; segregation in designated containers and final disposal of these materials at nearby rendering facilities.

FSIS concludes that Australia's food safety inspection system maintains the legal authority and a regulatory framework that is consistent with criteria established for this component.

## **VI. COMPONENT THREE: GOVERNMENT SANITATION**

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation standard operating procedures (Sanitation SOPs) to prevent direct product contamination or insanitary conditions.

The FSIS auditors verified that the CCA requires establishments to develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions. Establishments are also required to monitor the adequacy of the construction of their facilities and develop maintenance programs for equipment and structures. The *Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products (Part 7)* outlines the sanitation requirements for establishments. The CCA requires establishments to outline their sanitation programs within their AAs.

The FSIS auditors verified that each audited establishment maintains a written sanitation program to prevent direct product contamination or adulteration, and each program included maintenance and improvement of sanitary conditions through routine assessment of the establishment's hygienic practices. The FSIS auditors confirmed that the in-plant inspection personnel conduct daily verification procedures of the implementation of each establishment's sanitation program. Inspection verification activities consist of a combination of document reviews and hands-on inspections of production and storage areas and sanitary practices.

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 the FSIS auditors show that establishments and government officials interact to ensure that noncompliances related to maintenance of the facilities are identified and addressed to comply with the regulations of the program.

The audit included observation of the implementation of the pre-operational inspection verification by shadowing the in-plant inspection personnel conducting pre-operational sanitation verification inspection. The in-plant inspection personnel conducted this activity daily and their hands-on verification procedures begin after the establishment personnel conduct their pre-operational sanitation and determine that the facility is ready for in-plant inspector pre-operational sanitation verification activities. 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 reviewed official verification of operational sanitation procedures at all audited establishments. Official verification activities include direct observation of operations and review of establishment records, for which the results are recorded daily. The FSIS auditors also reviewed the establishments' sanitation monitoring and the corresponding verification records and noted that the inspection and establishment records correspond with the actual sanitary conditions of the establishment. All establishments monitored several times during the production shift the sanitary dressing practices, including proper skinning; tying of the esophagus and bung, and evisceration. Inspection personnel on a daily basis verify these practices.

FSIS concluded that Australia's food safety inspection system requires all establishments certified to export to the United States develop, implement, and maintain Sanitation SOPs to prevent the creation of insanitary conditions and contamination of products. The FSIS audit found that the DAWR inspection system has incorporated and implemented Sanitation SOP verification activities.

## **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 food safety inspection system is to require that each official establishment develop, implement, and maintain a HACCP system.

FSIS auditors verified that the CCA conducted HACCP verification activities at the audited establishments. 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, and they assessed 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 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 plans include activities designed to validate adequacy of controls, to monitor implementation of controls, and to document the results of verification activities and implementation of corrective actions.

The FSIS auditors observed the following deficiencies:

- Government inspection personnel at three of 12 audited establishments failed to identify that establishments had not considered all hazards associated with the process in the hazard analysis. In all instances, the establishments maintained that the hazards are not reasonably likely to occur and, therefore, would not need a CCP in the process.
- Government inspection personnel at seven of 12 audited establishments failed to identify that the establishment did not meet one or more of the following HACCP verification requirements: record the time of verification activities; include the verification frequencies and procedures in the HACCP plans; and include direct observation verification activities or all verification activities in the HACCP plans. In all instances, the establishments were performing HACCP plan verification activities, but did not comply with the requirements of the written HACCP plan and associated records regarding verification activities.

Additional documents reviewed by the FSIS auditors included the written responses provided by the CCA related to several POE violations reported by FSIS from October 2016 through July 2018, involving contamination of meat products or temperature abuse of meat products. 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 verified by the CCA. The ATMs and FOMs in turn evaluated the adequacy of implementation and efficacy of the corrective actions implemented by the establishments.

The FSIS auditors noted that the 10 audited slaughter establishments implemented a CCP to monitor carcasses for zero tolerance for the presence of fecal matter, ingesta, and milk. The FSIS auditors' review of the establishment's monitoring and corrective actions records showed that the establishments took appropriate corrective actions in response to the few observed deviations from the zero tolerance critical limit. The FSIS auditors also reviewed the inspection verification records and observed the in-plant inspection personnel's hands-on verification activities for the zero tolerance CCP.

The FSIS auditors determined from records review and direct observation that inspection personnel conduct daily verification of the zero tolerance CCP in accordance with the CCA's requirements. The zero tolerance CCP monitoring and verification location for both the establishment's employees and in-plant inspection personnel is at the end of the process, before entering the cooler for chilling. No issues were identified during the audit with the CCA's verification procedures for the zero tolerance CCP.

The FSIS auditors verified that establishments certified to export to the United States had addressed contamination of carcasses with STEC (O157:H7, O26, O45, O103, O111, O121, and O145) within the context of their HACCP systems. This typically included the zero tolerance CCP as well as additional controls to ensure that carcasses were chilled in a manner sufficient to prevent the outgrowth of microbial pathogens. The FSIS auditors' review of microbiological sampling programs and testing results for carcasses (generic *E. coli*) and beef trimmings (STEC) further supported the conclusions reached in their hazard analyses.

The FSIS auditors verified that the CCA conducted HACCP verification activities at the audited further processing establishment. The FSIS auditors observed the government FSMA and ATM conduct verification activities, which include the establishment-maintained validated cooking instruction for the heat-treated not fully, cooked not shelf stable product produced for export to the United States. Furthermore, the FSIS auditors observed the verification of the process to include support and controls for heating and cooling. The FSIS auditors did not have any concerns with the CCA's ability to conduct verification activities of the process at the establishment.

The FSIS auditors verified that the audited thermally processed commercially sterile products establishment had implemented a HACCP system including a CCP for a validated thermal process to meet applicable food safety and commercial sterility requirements. This included critical limits for time and temperature, in addition to applicable supporting documentation demonstrating that the minimum level of sterilization was applied for food safety purposes (i.e., destruction of *Clostridium botulinum* spores), as required by Australia's *Changes to the Thermal Process Approval Arrangements for Low Acid Canned Foods Containing Meat, Meat Notice 2016-04*.

The FSIS auditors noted that the establishment management maintains sufficient documentation to demonstrate that commercial sterility was achieved by implementing these process schedules and product storage conditions. When establishments make changes to their process schedules, they must submit an updated AA including the relevant heat distribution studies to the CCA for approval prior to implementation. Inspection personnel verify that critical parameters are met through the HACCP system on a daily basis, and process schedules are provided to inspection personnel.

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. However, the Australian government's food safety inspection system failed to require establishments to meet all the written requirements of HACCP plans and implementation of record keeping requirements.

## **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 food safety 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 inspection authorities or by FSIS as potential contaminants.

The FSIS auditors verified through records review and direct observations that NRS, described in Component One, 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. NRS manages the design of the testing programs and operational processes that include sample collection, shipping to laboratories, management, and analysis of data and initiation of trace-back activities. Analysis of samples is delegated to laboratories that NRS contracts through a competitive tender process. NRS programs cover animal products including, cattle, sheep, pigs, goats, camel, deer, emu, horse, kangaroo, ostrich, poultry, wild boar, eggs, fish, and honey.

Additional information provided by the CCA to FSIS indicates that factors considered when determining the annual residue monitoring 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.

Australian export legislation requires that products comply with relevant Australian standards and that products meet importing country requirements such as maximum residue limits (MRLs) or tolerances. To achieve a level of certainty that products will comply with importing country requirements such as United States tolerances for chemicals, Australia has implemented a system of Export Slaughter Intervals (ESIs) to manage differences between the Australian MRL and market requirements. ESIs represent the interval between treatment and slaughter that must elapse to be confident of meeting importing country requirements such as United States tolerances. ESIs are integrated into the export system, producers make a statutory declaration that relevant withholding period, and ESIs have been complied with when supplying cattle for slaughter.

The FSIS auditors visited the National Measurements Institute chemical residue testing laboratory, local government offices, and slaughter establishments to verify the adequacy of the chemical residue testing programs. The CCA delegates to NRS, a governmental organization, the responsibility to maintain monitoring and surveillance programs to detect the presence of chemical residues in animals and edible animal products.

The FSIS auditors verified through interviews 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.

In-plant screening is available for antimicrobial residues in bobby calves, a class of animals identified as being of higher risk of residue detection and requiring ongoing monitoring. The program utilizes a microbiological inhibition test of urine, conducted by the establishment, with confirmation testing on tissue samples required for screen positives.

For residue testing, product is generally not held until test results are received, with exceptions for testing suspect animals, such as those selected by in-plant staff for testing because of suspicions of possible residues (e.g., a condition that might indicate recent antimicrobial use) or

where a screen test, such as microbial inhibition test of bobby calf urine suggests residues may be present, and confirmation results for a tissue sample have not yet been received. Similarly, product may be held if it is linked to a residue incident investigation. DAWR requires establishments to have the ability to recall products when a product poses a health or safety risk which includes chemical or drug residues.

Trace-back following residue violations is required to investigate the likely cause. State and territory governments are responsible for control-of-use of agricultural and veterinary chemicals and for managing environmental contaminants in the production of food. State and territory authorities investigate the cause of violations, take actions, and report results back to the department. States and territories can take a range of actions including warnings, quarantining of properties, prosecution, education, issuing an 'official direction', and deregistration of veterinary surgeons.

Prior to the onsite visit, FSIS residue experts reviewed Australia's Residue Program for 2018, associated methods of analysis, and additional SRT responses outlining the structure of Australia's chemical residue testing program. There have not been any POE violations related to this component since the last FSIS audit.

The result of the onsite audit activities demonstrate that Australia continues to maintain the legal authority to regulate, plan, and execute activities of the food safety system that are aimed at preventing and controlling the presence of residues of veterinary drugs and chemical contaminants in beef and pork products destined for export to the United States.

## **IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS**

The sixth of six equivalence components that the FSIS auditors reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that meat and poultry (ratite) products prepared for export to the United States are safe and wholesome.

The CCA requires all establishments certified to export to the United States to participate in the National Microbiology Carcass Monitoring Program, which requires sampling for aerobic plate count, generic *E. coli*, and *Salmonella*, which are to be collected by establishments. Results are then verified by inspection personnel on a weekly basis. The FSIS auditors verified that this program is consistent with the FSIS *Salmonella* performance standards and generic *E. coli* sampling requirements in 9 CFR § 310.25(b). The CCA requires that establishments only use laboratories that are accredited by NATA to analyze these samples and use methods approved by NATA. The FSIS auditors' review of records associated with establishments generic *E. coli* and *Salmonella* testing did not raise any concerns. The FSIS auditors verified that the sampling programs required by CCA is implemented as designed, and that there were no failed sample sets in recent history.

The CCA requires a test and hold program for sampling of *E. coli* O157:H7 and six additional non-O157 STECs (O26, O45, O103, O111, O121, and O145) in beef components intended for

grinding, which applies to both establishment and inspection verification sampling. The FSIS auditors verified that in-plant inspection personnel are reviewing and verifying each establishment's documents including sampling methodology and testing results on a weekly basis. Establishments certified to export to the United States are required to conduct routine sampling of beef manufacturing trimmings in accordance with N-60 methodology and use laboratories and methods of analysis that are approved by NATA. The FSIS auditors verified that in-plant inspection personnel also conduct independent N-60 official verification sampling, consistent with the CCA's work instructions in *E. coli O157:H7/STEC Testing Verification*. The samples are analyzed by laboratories that are approved by NATA using methods FSIS MLG 5 or ISO 16654:2001 for *E. coli O157:H7* and FSIS MLG 5B for non-O157 STECs.

During the audit of a private microbiology laboratory, FSIS reviewed documentation of analysts' proficiency evaluations, inter-laboratory PT results, and records of evaluations of corrective actions taken in response to audit findings. The audit also verified that the laboratory maintained appropriate discard criteria to ensure the integrity of the sample and testing results. This included written standard operating procedures to ensure that samples arrive within specified timeframes and required temperatures, as well as outlining specific follow-up activities to be undertaken when these requirements are not met. The FSIS auditors confirmed that laboratories conducting microbiological analysis of samples of meat and poultry (ratite) products from certified establishments are audited every 18 months by NATA auditors, and corrective actions were taken when deficiencies were identified.

The result of the onsite audit activities indicate that Australia continues to maintain the legal authority to regulate, plan, and execute activities of the food safety inspection system aimed at controlling the presence of microbiological pathogens in beef products exported to the United States. There have not been any POE violations related to this component since the last FSIS audit.

## **X. CONCLUSIONS AND NEXT STEPS**

An exit meeting was held on August 22, 2018, in Canberra, Australia, with DAWR. At this meeting, the FSIS auditors presented the preliminary findings from the audit.

### **GOVERNMENT OVERSIGHT**

- The CCA does not include provisions that Australian inspection officials will not sign export certificates for product destined for the United States until all inspection laboratory verification sample test results are received and found acceptable.

### **GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM**

- Government inspection personnel at three of 12 audited establishments failed to identify deficiencies related to hazard analysis requirements.

- Government inspection personnel at seven of 12 audited establishments failed to identify deficiencies related to HACCP plan verification requirements

The audit findings did not represent a potential to endanger public health because most of them involved recordkeeping and necessary technical clarifications. During the exit meeting, the CCA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

# 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 Cedar Meats, BROOKLYN VIC	2. AUDIT DATE 8/8/2018	3. ESTABLISHMENT NO. 206	4. NAME OF COUNTRY Australia
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Periodic Supervisory Reviews	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

## 60. Observation of the Establishment

15/51

The written HACCP plans failed to list the frequency for verification activities.

22/51

The HACCP records documenting the HACCP plan verification activities failed to record the time the event took place for all verification activities.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

August 8, 2018

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION HJ Heinz Company Australia Limited Bomen Road Wagga Wagga New South Wales 2650	2. AUDIT DATE 08/07/2018	3. ESTABLISHMENT NO. 39	4. NAME OF COUNTRY Australia
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .	X	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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

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60. Observation of the Establishment

14/51

The establishment's hazard analysis did not identify chlorine as a chemical hazard at the can washing process step prior to filling, which included washing of cans with chlorinated water.

19/51

The establishment's HACCP verification procedures did not include direct observation of monitoring of CCPs.

19/51

The establishment's HACCP plan did not list calibration of process monitoring instruments; however the establishment was regularly calibrating process monitoring instruments used within their HACCP system.

46/51

Water was observed dripping from a roll-up door between the production and dry storage areas. The roll-up door was dripping water due to being in contact with standing water on the ground. No product adulteration was observed.

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61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

08/07/2018

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United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Swickers Kingaroy Bacon Factory 206 Kingaroy Barkers Creek Road Kingaroy Queensland 4610	2. AUDIT DATE 08/15/2018	3. ESTABLISHMENT NO. 48	4. NAME OF COUNTRY Australia
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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.	X	38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .	X	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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	X
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	X
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

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60. Observation of the Establishment

12/51

The establishment's SSOP records did not document list the specific corrective actions taken in response to identified SSOP deficiencies.

14/51

The establishment's hazard analysis did not identify physical hazards at the chilling step, in which data loggers monitoring temperature are inserted into boxes of finished product.

39/51

Peeling paint was observed on the cement surface under the retained rail.

45/51

Carcass hooks were being stored in an exterior area of the establishment, exposed to the environment.

52/51

Excessive electrical prod use was observed on 4/4 pigs as they were loaded into the stunning area.

55/51

While the OPV was conducting his zero tolerance check, the FSMA stepped off the line, and the zero tolerance check only included every other carcass, therefore every other carcass was not inspected for feces, milk, ingesta or pathology while the zero tolerance is taking place (carcasses were not turned or observed). The OPV indicated that the line is moving too fast in order to inspect every carcass during the zero tolerance check.

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61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

08/15/2018

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United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Narasell Pty Ltd. 2882 Byrnes Road Junee New South Wales 2663	2. AUDIT DATE 08/08/2018	3. ESTABLISHMENT NO. 90	4. NAME OF COUNTRY Australia
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

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**60. Observation of the Establishment**

10/51

A plastic tub used to hold edible product in the boning room was observed to have multiple broken plastic areas on the bottom which could lead to possible plastic contamination.

10/51

The sanitary dressing procedures of the second leggers on the slaughter floor were skinning the hind shanks in a manner in which the exterior hide was folding onto the exposed interior carcass. The carcasses were then trimmed and sanitized using a steam vacuum at a later point in the process.

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**61. AUDIT STAFF**

OIEA International Audit Staff (IAS)

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**62. DATE OF ESTABLISHMENT AUDIT**08/08/2018

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United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION E C Throsby Pty Limited Old North Road, CNR New England and Golden Highways Whittingham New South Wales 2330	2. AUDIT DATE 08/13/2018	3. ESTABLISHMENT NO. 486	4. NAME OF COUNTRY Australia
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	X
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58. Government Microbiological Sampling	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

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**60. Observation of the Establishment**

15/51

The establishment's HACCP plan did not include direct observation as a verification activity at two CCPs, for freezing of product and for ambient air temperature in the chiller.

39/51

A wall was observed to be peeling and detaching from the blast chill freezer.

41/51

Frozen condensate was observed in cold store # 2 above exposed product. No product adulteration was observed.

54/51

The ante-mortem records were not signed or documented by the on-plant veterinarian, as required by ante-mortem work instructions.

58/51

The government STEC sampling submissions did not include a lot number as required by STEC sampling work instructions.

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**61. AUDIT STAFF**

OIEA International Audit Staff (IAS)

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**62. DATE OF ESTABLISHMENT AUDIT**08/13/2018

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United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Thomas Foods Int'l Lobethal Pty Ltd Lot 41, Ridge Road Lobethal South Australia 5241	2. AUDIT DATE 08/10/2018	3. ESTABLISHMENT NO. 866	4. NAME OF COUNTRY Australia
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

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**60. Observation of the Establishment**

10/51

Carcasses at the hide puller machine with hide on were contacting an establishment employee's apron, and subsequently came in contact with the employees apron when the hide was pulled and the carcass was exposed. The establishment immediately adjusted the hide puller machine to prevent hide-on carcasses from contacting the establishment employee and carcasses were inspected and trimmed at a later step in the process.

15/51

The establishment's HACCP plan did not list the monitoring frequency of temperature monitoring of chilled carcasses.

39/51

Peeling paint was observed on areas directly above carcass rails in the entry to the boning area and the entry to the carcass chillers.

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**61. AUDIT STAFF**

OIEA International Audit Staff (IAS)

**62. DATE OF ESTABLISHMENT AUDIT**08/10/2018

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United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Meramist Pty Ltd Old Gympie Road Caboolture Queensland 4510	2. AUDIT DATE 08/16/2018	3. ESTABLISHMENT NO. 3416	4. NAME OF COUNTRY Australia
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .	X	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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	X
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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

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60. Observation of the Establishment

14/51

The establishment did not identify chemical hazards in the hazard analysis to address animals with potential drug residues.

18/51

The establishment was not documenting the time of monitoring events at the zero tolerance CCP.

41/51

An excessive buildup of frozen condensate was observed above and around boxed products in the plate freezer.

39/51

Peeling paint was observed on a wall that carcasses were swinging into across from the final rail on the slaughter floor.

45/51

Two belts were observed to have fraying and peeling material used to transport edible product within the boning area.

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61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

08/16/2018

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United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION JBS Australia Pty Ltd, LONGFORD TAS	2. AUDIT DATE 8/13/2018	3. ESTABLISHMENT NO. 195	4. NAME OF COUNTRY Australia
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	X
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Periodic Supervisory Reviews	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

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60. Observation of the Establishment

15/51

The written HACCP plan did not include a records review verification activity.

22/51

The records that record the records review verification activity did not document the time the event occurred.

54

The antemortem records were not signed or documented by the OPV, as required by antemortem work instructions.

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION JBS AUSTRALIA PTY LTD 30 INDUSTRY PARK DRIVE BROOKLYN	2. AUDIT DATE 8/7/2018	3. ESTABLISHMENT NO. 688	4. NAME OF COUNTRY Australia
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Periodic Supervisory Reviews	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

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**60. Observation of the Establishment**

No isolated findings identified

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**61. AUDIT STAFF**

OIEA International Audit Staff (IAS)

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**62. DATE OF ESTABLISHMENT AUDIT**

08/07/2018

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United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Midfield Meat International Pty Ltd, WARRNAMBOOL VIC	2. AUDIT DATE 8/9 & 10/2018	3. ESTABLISHMENT NO. 180	4. NAME OF COUNTRY Australia
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Periodic Supervisory Reviews	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

10/51

Carcasses were rubbing against the cooler wall and door which are not food contact surfaces.

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61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

8/9 &10/2018

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United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Patties Foods Ltd, BAIRNSDALE VIC	2. AUDIT DATE 8/13/2018	3. ESTABLISHMENT NO. 265	4. NAME OF COUNTRY Australia
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	O
29. Records	O	57. Periodic Supervisory Reviews	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

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60. Observation of the Establishment

15/51

The written HACCP plan did not include the frequency or procedures for verification activities.

22/51

HACCP records did not include the direct observation verification activity.

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61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

08/13/2018

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United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Wodonga Rendering Pty Ltd, WODONGA VIC	2. AUDIT DATE 8/17/2018	3. ESTABLISHMENT NO. 612	4. NAME OF COUNTRY Australia
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	X
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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Periodic Supervisory Reviews	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

39/51

Peeling paint was observed on the underside of a refer unit directly over product.

41/51

Condensate in droplet form was observed at one establishment's carcass cooler over product.

61. AUDIT STAFF

OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

08/17/2018

**Appendix B: Foreign Country Response to the Draft Final Audit Report**



Ms Michelle Catlin  
International Coordination Executive  
Office of International Coordination  
Food Safety and Inspection Service  
United States Department of Agriculture  
Washington, DC 20205

Dear Ms Catlin

### Australian Export Meat Inspection System 2018 Audit – Draft Final Audit Report

Thank you for the draft final report of the audit of the Australian Export Meat Inspection System (AEMIS) conducted by the Food Safety and Inspection Service (FSIS) from 6 – 22 August 2018. I note the purpose of the audit was to determine whether Australia's food safety inspection system governing meat and poultry (ratite) remains equivalent to that of the United States.

The Department of Agriculture appreciates the efforts of FSIS in conducting the audit and is grateful for the opportunity to comment on the draft final audit report. **Attachment 1** provides the department's response to the three findings contained in the draft final audit report. **Attachment 2** provides comments on specific text of the draft final audit report for the consideration of FSIS.

The department is pleased to note the audit demonstrated that Australia's Export Meat Inspection System (AEMIS) continues to meet the core criteria for all six components to maintain its equivalence with the United States' system. The analysis of the findings within each component did not identify any deficiencies that represent a potential threat to public health. The department remains committed to implement measures to address the findings.

Thank you again for the opportunity to comment on the draft final audit report. If you require further information, please do not hesitate to contact the department via Cameron Hutchison, Minister Counsellor, Australian Embassy, Washington D.C. at [Cameron.Hutchison@dfat.gov.au](mailto:Cameron.Hutchison@dfat.gov.au). Alternatively, you can contact me directly at [Fran.Freeman@agriculture.gov.au](mailto:Fran.Freeman@agriculture.gov.au) or on +61 2 6272 4300.

Yours sincerely

Fran Freeman  
First Assistant Secretary  
Exports Division

9 August 2019

**Attachment 1** - Response to the three findings of the Draft Final Audit Report

**Attachment 2** – Comments on text of the Draft Final Audit Report



## Attachment 1

### Government Oversight

#### FSIS Finding:

1. The CCA does not include provisions that Australian inspection officials will not sign export certificates for product destined for the United States until all inspection laboratory verification sample test results are received and found acceptable.

#### Department's Response:

Australia's residue control program continues to demonstrate that Australian product is safe and wholesome and the residue monitoring programs are developed and implemented according to international best practice; particularly, the relevant Codex Alimentarius guideline: *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programme Associated with the use of Veterinary Drugs in Food Producing Animals CAC/GL 71-2009*.

The department will ensure that product derived from carcasses sampled under the residue monitoring programs, will not be certified as eligible to be exported to the US unless compliant test results have been returned. To achieve this, carcasses (including parts) selected for sampling under the random monitoring programs will be made ineligible for export to the US unless compliant results have been received.

### Government Hazard Analysis and Critical Control Points (HACCP) System

#### FSIS Finding:

2. Government inspection personnel at three of 12 audited establishments failed to identify deficiencies related to hazard analysis requirements.
3. Government inspection personnel at seven of 12 audited establishments failed to identify deficiencies related to HACCP plan verification requirements.

The department notes that these findings did not represent a potential to endanger public health. The department is however working toward the implementation of measures to reinforce the knowledge and understanding of official auditors, including Food Safety Auditors (FSA), Senior Food Safety Auditors (SFSA), On Plant Veterinarians (OPV) and Area Technical Managers (ATM), to identify deficiencies in HACCP plans and have these corrected.

The corrective actions included in the following table apply to both findings. A period of six months from August 2019 will be required to ensure effective implementation of the corrective and preventive action response outlined below.

Corrective and preventive action response	Timeframe
<p>a. (Initial step) Correction of the defects related to hazard analysis requirements identified at three of 12 audited establishments and the deficiencies related to HACCP plan verification requirements identified at seven of 12 audited establishments.</p> <p>The slaughter / non-slaughter processing establishments have amended the hazard analyses within their HACCP plans to include reference to the identified hazards/ hazard types. The corresponding amendments to HACCP plans have been approved by department senior veterinarians - Area Technical Managers (ATMs) or Senior Food Safety Assessors (SFSAs) and reviewed during periodic audits of the establishments.</p> <p>HACCP plans have been amended to include monitoring frequencies for Critical Control points (CCPs) and direct observation (check the checker) of CCPs monitoring of CCPs. These amendments to HACCP plans have been approved by department ATMs / SFSAs and reviewed during periodic audits of the establishments.</p>	<p>Completed and verified.</p>
<p>b. Review of HACCP plans at all US-listed establishments to ensure the following matters are identified, and where necessary rectified, by the establishment:</p> <ul style="list-style-type: none"> <li>i. Frequencies of monitoring are included</li> <li>ii. All appropriate hazards (chemical, physical and microbiological) are identified</li> <li>iii. Direct observation of CCPs is included as a verification measure.</li> <li>iv. Calibration of monitoring equipment is identified in the plan</li> <li>v. All appropriate verification measures are included in the plan</li> </ul>	<p>6 months from the department response to the draft final audit report.</p>
<p>c. FSA, SFSAs, OPV and ATM review of HACCP plans to ensure they are compliant as per b. above, and any other detected deficiencies are corrected.</p>	<p>6 months from the department response to the draft final audit report.</p>
<p>d. Reinforce the US requirements in relation to HACCP plans to ensure clearer knowledge and understanding by all OPVs and ATMs.</p>	<p>6 months from the department response to the draft final audit report.</p>
<p>e. Reinforce the US requirements in relation to HACCP plans to ensure clearer knowledge and understanding by all SFSAs, FSAs and other department auditors auditing US eligible establishments (other than slaughter and boning, as these are dealt within item d).</p>	<p>6 months from the department response to the draft final audit report.</p>



Attachment 2

Report Section, Page & paragraph Reference	Report Content	Department's comment	Department's Request
<b>Title of the report – front page</b>	EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING MEAT AND POULTY EXPORTED TO THE UNITED STATES OF AMERICA	Suggestion: add '(RATITES)' after poultry to clarify the scope of the Audit.	EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING MEAT AND POULTY (RATITES) EXPORTED TO THE UNITED STATES OF AMERICA
<b>Executive Summary; Page i: Paragraph 4 – dot point</b>	The CCA does not include provisions that Australian inspection officials will not sign export certificates for product destined for the United States until all inspection laboratory verification sample test results are received and found acceptable.	Suggested amendment to clarify the statement specifically relates only to chemical residue monitoring samples.	The department suggests amending the text to the following:  The CCA does not include provisions that Australian inspection officials will not sign export certificates for product destined for the United States until all inspection laboratory verification chemical residue sample test results are received and found acceptable.

<p><b>Section III; Page 4: Paragraph 2</b></p>	<p>In total, FSIS refused entry to 5,299,806 pounds of product exported by Australia to the United States including 747,679 pounds that failed the additional types of inspection due to violations of United States food safety requirements (e.g., off condition, ingesta, fecal materials, extraneous materials, pathological lesions, etc.). An additional 4,552,127 pounds of meat and poultry was refused entry due to shipping damage, missing or invalid shipping marks, etc.</p>	<p>The department's records, which are based on official notifications from FSIS of POE rejections for violation of US food safety standards over the period noted by the FSIS draft final audit report (1 May 2015 to 30 April 2018) show that 342,351 pounds of product failed the additional types of inspection.</p>	<p>The department respectfully requests that FSIS amend the reported amount of rejected product due to violation of US food safety standards from 747,679 pounds to 342,351 pounds.</p>
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<p><b>Section III; Page 4: Paragraph 5</b></p>	<p>Under AEMIS, establishment employees instead of government inspectors are responsible for post-mortem examination of the heads and viscera of livestock. Official government veterinarians are responsible for performing ante-mortem inspection, verifying post-mortem inspection, verifying establishment examination activities, providing final disposition on animals and carcasses/heads/viscera where there is evidence of disease, verifying HACCP and sanitation standard operating procedures (Sanitation SOPs), and performing other food safety activities.</p>	<p>Under AEMIS, post-mortem inspection is undertaken by government meat inspectors, or government-authorized officers who are supervised by a government veterinarian.</p> <p>Official government veterinarians verify post-mortem inspection activities performed by government-authorized officers and government meat inspectors.</p>	<p>The department suggests amending the text to the following:</p> <p>Under AEMIS, post-mortem inspection is undertaken by government meat inspectors, or government-authorized officers who are supervised by a government veterinarian. Official government veterinarians are responsible for performing ante-mortem inspection, verifying post-mortem inspection, verifying authorized officers inspection activities and providing final disposition on animals and carcasses/heads/viscera, where there is evidence of disease; as well as verifying HACCP and sanitation standard operating procedures (Sanitation SOPs), and performing other food safety activities.</p>
<p><b>Section III; Page 5: Paragraph 1</b></p>	<p>Australia’s submission included five years of microbiological data comparing AEMIS <b>versus</b> traditional inspection <b>versus</b> and the FSIS baseline study for market hogs.</p>	<p>Suggested amendment: delete repeated word ‘versus’ after the words ‘traditional inspection’</p>	<p>The department suggests amending the text to the following:</p> <p>Australia’s submission included five years of microbiological data comparing AEMIS versus traditional inspection and the FSIS baseline study for market hogs.</p>

<p><b>Section IV; Page 5: Paragraph 4</b></p>	<p>Specific legislation to regulate meat is in the <i>Australian Standard AS4696</i> within the <i>Export Control Orders 2005</i>.</p>	<p>Both the <i>Australian Standard AS4696</i> and the <i>Export Control Orders 2005</i> provide the basis for the department's regulatory framework. The <i>Australian Standard AS4996</i> is not part of the <i>Export Control Orders 2005</i>.</p>	<p>The department suggests amending the text to the following:</p> <p>The <i>Export Control (Meat and Meat Products) Orders 2005</i> are orders made under the <i>Export Control Act 1982</i> to regulate the export of meat and meat products. These orders include the requirement to comply with the <i>Australian Standard for the Hygienic Transportation of Meat and Meat Products for Human Consumption (AS4696)</i>.</p>
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<p><b>Section IV; Page 6: Paragraph 1</b></p>	<p>The three FOMs assist the Exports Division 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 in-plant veterinarians (OPVs). Under AEMIS, each establishment is staffed by at least one government Food Safety Meat Assessor (FSMA) and one Australian Government Authorized Officer (AAO) who perform inspection verification activities at establishments. The AAOs 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 establishments exporting to the United States. The FSMA is the government inspector that verifies each carcass is free of visual fecal material, ingesta, or milk contamination and pathological lesions of food safety significance after the AAOs' post-mortem assessment. The FSIS auditors verified the personnel structure and responsibilities through review of</p>	<p>It is possible, for small plants, to have only one meat inspector; if this is the case, it must be a FSMA.</p>	<p>The department suggests amending the text to the following:</p> <p>The three FOMs assist the Exports Division in administering and coordinating the delivery of inspection services at certified establishments. The FOMs supervise the Area Technical Managers (ATMs), who in turn provide technical supervision of the on-plant veterinarians (OPVs). Under AEMIS, each establishment is staffed by at least one government Food Safety Meat Assessor (FSMA) who perform verification activities at establishments. The AAOs 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 establishments exporting to the United States. The FSMA is the government official that verifies each carcass is free of visual fecal material, ingesta, or milk contamination and pathological lesions of food safety significance after the AAOs' post-mortem assessment. The FSIS auditors verified the personnel structure and responsibilities through review of records and direct observations during the audit</p>
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	records and direct observations during the audit.		
<b>Section IV; Page 7: Paragraph 2</b>	Government officials implemented a schedule of fees for service rendered to charge certified establishments for the inspection 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. OPVs and FSMAs are official government employees. The FSIS auditors verified by interviews and review of records that the government employees receive payment from the Australian government.	The schedule of fees for services rendered to certified establishments is determined by the Australian Government cost recovery policy.	The department suggests amending the text to the following:  The Australian Government cost recovery policy requires export registered establishments to be charged for regulatory activities 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. OPVs and FSMAs are official government employees. The FSIS auditors verified by interviews and review of records that the government employees receive payment from the Australian government.

<p><b>Section IV; Page 7: Paragraph 4 (last paragraph)</b></p>	<p>The plants may also utilize the AAOs as rail out inspectors of the post-mortem procedure for sheep and goats, but not for beef. Sheep and goat carcasses are railed out for gross contamination and any pathology observed on the line, but the OPV must perform any disposition activities for ante-mortem suspect animals. The rail out inspectors are given authority to condemn animals, and they do the final inspection of railed out animals prior to returning these animals to the line; these animals will then be inspected by the government inspector performing inspection on each and every carcass.</p>	<p>AAOs may conduct rail out post-mortem inspection procedures for beef carcasses.</p>	<p>The department suggests amending the text to the following:</p> <p>The plants may also utilize the AAOs as rail out inspectors of the post-mortem procedure for beef, sheep and goats. Beef, sheep and goat carcasses are railed out for gross contamination and any pathology observed on the line, but the OPV must perform any disposition activities for ante-mortem suspect animals. The rail out inspectors are given authority to condemn animals, and they do the final inspection of railed out animals prior to returning these animals to the line; these animals will then be verified by the government official performing verification on each and every carcass.</p>
<p><b>Section IV; Page 8: Paragraph 4</b></p>	<p>The Exports Division 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.</p>	<p>Suggest adding 'pork and ratite' to better reflect the scope of the audit.</p>	<p>The department suggests amending the text to the following:</p> <p>The Exports Division 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, goat, pork and ratite) export systems.</p>

<p><b>Section IV; Page 9: Paragraph 4</b></p>	<p>FSANZ collects information related to the recalled exported product and provides it to the department.</p>	<p>The department determines if recalled product has been exported and effects any trace forward to recall exported products.</p>	<p>The department suggests adding the following text to the sentence:</p> <p>FSANZ and the state regulator collect information related to the recalled export eligible product and provides it to the department. The department determines if product has been exported and effects any trace forward to recall exported products.</p>
<p><b>Section IV; Page 10: Paragraph 1</b></p>	<p>For chemical laboratories, the National Residue Survey (NRS) is accredited by NATA to serve as the entity that audits, approves, and evaluates the proficiency and performance of chemical residue analysis laboratories, and NRS entered into a Memorandum of Understanding (MOU) with NATA to jointly evaluate the performance of the laboratories using the International Organization for Standardization (ISO) 17025 standard. The CCA requires all laboratories to be audited against ISO 17025 standards. The department has an MOU with NATA, which allows NATA to notify NRS if concerns are raised during NATA audits about laboratory competence.</p>	<p>The NRS is accredited by NATA to conduct Proficiency Testing for contract laboratories performing chemical residue testing for NRS samples. The MOU with NATA is to share information about Proficiency Testing results; which is captured in the last sentence of the paragraph.</p> <p>Laboratories are required to be accredited against ISO 17025.</p>	<p>The department suggests amending the text to the following:</p> <p>For chemical laboratories, the National Residue Survey (NRS) is accredited under ISO/IEC 17043 by NATA to provide proficiency testing samples to contract laboratories. The CCA requires all laboratories to be accredited against ISO 17025 standards. The department has an MOU with NATA, which allows NATA to notify NRS if concerns are raised during NATA audits about laboratory competence.</p>

<p><b>Section IV; Page 10: Paragraph 2</b></p>	<p>NRS also requires NATA accreditation to ISO 17025 of test methods used for NRS testing. All laboratories must have proficiency testing (PT) conducted on a schedule based on the test method and frequency of use. The minimum frequency for participation in PT programs is specified by NATA or the department and is typically twice a year.</p>	<p>Proficiency testing is a NRS requirement for contract laboratories. There is not a specific schedule.</p>	<p>The department suggests amending the text to the following:</p> <p>NRS also requires NATA accreditation to ISO 17025 of test methods used for NRS testing. Under their accreditation, all laboratories must participate in proficiency testing (PT).</p>
<p><b>Section IV; Page 11: Paragraph 1 dot point</b></p>	<p>...all inspection laboratory verification sample test results are received and found acceptable.</p>	<p>Clarification is required to ensure the statement refers to chemical residue monitoring samples.</p>	<p>The department suggests amending the text to the following:</p> <p>...all inspection laboratory verification sample test results, for chemical residue monitoring, are received and found acceptable.</p>

<p><b>Section V; Page 12: Paragraph 2</b></p>	<p>Post-mortem inspection at establishments certified to export to the United States is conducted by either a traditional inspection system, using only inspectors that are employees (FSMAs) of the CCA, or <b>using by</b> an alternative inspection system incorporating AAOs. In <b>traditional</b> inspection and AEMIS, FSMAs and AAOs are on-line continuously during slaughter activities. AAOs are appropriately qualified, trained, and skilled persons employed by an establishment, authorized under Section 20 of the Export Control Act 1982 to perform the services for the purposes of AEMIS, and are listed in the establishments' AAs</p>	<p>Suggested amendments:</p> <ul style="list-style-type: none"> <li>i) delete 'using by' before the words 'an alternative inspection system..'</li> <li>ii) replace the words 'traditional inspection and AEMIS' with 'Under both AEMIS traditional and alternative inspection,' FSMAs and AAOs are on-line continuously...</li> </ul>	<p>The department suggests amending the text to the following:</p> <p>Post-mortem inspection at establishments certified to export to the United States is conducted by either a traditional inspection system, using only inspectors that are employees (FSMAs) of the CCA, or an alternative inspection system incorporating AAOs. Under both AEMIS traditional and alternative inspection, FSMAs and AAOs are on-line continuously during slaughter activities. AAOs are appropriately qualified, trained, and skilled persons employed by an establishment, authorized under Section 20 of the Export Control Act 1982 to perform the services for the purposes of AEMIS, and are listed in the establishments' AAs</p>
<p><b>Section V; Page 12: Paragraph 2</b></p>	<p>The FSIS auditors confirmed that the performance of AAOs is verified on a daily basis by the OPV, including observing AAOs perform post-mortem examination of heads and viscera, per the work instructions outlined in <i>Verifying the Performance of a Non-Department Authorised Officer</i>;</p>	<p>The work instruction includes a verification of product that is missing in the text. Propose adding reference to 're-assessing samples of product inspected by the AAOs' for completeness.</p>	<p>The department suggests amending the text to the following:</p> <p>The FSIS auditors confirmed that the performance of AAOs is verified on a daily basis by the OPV, including observing AAOs perform post-mortem examination of carcasses, heads and viscera; and also re-assessing samples of product inspected by the AAOs, per the work instructions outlined in <i>Verifying the Performance of a Non-Department Authorised Officer</i>;</p>

<p><b>Section VII; Page 16: Paragraph 1</b></p>	<p>The FSIS auditors observed the government <b>FSMA</b> and ATM conduct verification activities, which include the establishment-maintained validated cooking instruction for the heat-treated not fully, cooked not shelf stable product produced for export to the United States.</p>	<p>Food Safety Assessors (FSA) perform food safety auditing of further processing establishments.</p>	<p>The department suggests amending the text to the following:</p> <p>FSIS auditors observed the government Food Safety Assessor (FSA) and ATM conduct verification activities, which include the establishment-maintained validated cooking instruction for the heat-treated, not fully cooked, not shelf stable product produced for export to the United States.</p>
<p><b>Section IX; Page 18: Paragraph 6</b></p>	<p>The CCA requires that establishments only use laboratories that are accredited by NATA to analyse these samples and use methods approved by <b>NATA</b>.</p>	<p>Methods are approved by the <b>department</b>.</p>	<p>The department suggests amending the text to the following:</p> <p>The CCA requires that establishments only use laboratories that are accredited by NATA to analyse these samples and use methods approved by the Department of Agriculture.</p>

<p><b>Section IX; Page 19: Paragraph 1, line 6</b></p>	<p>Establishments certified to the United States are required to conduct routine sampling of beef manufacturing trimmings in accordance with N-60 methodology and use laboratories and methods of analysis that are approved by <b>NATA</b>.</p>	<p>Establishments certified to the United States are required to conduct routine sampling of beef manufacturing trimmings in accordance with N-60 methodology and use laboratories and methods that are approved by the <b>department</b>.</p> <p>Laboratories conducting STEC confirmation must be accredited by NATA. Laboratories conducting STEC screen testing may be accredited by the department or NATA.</p>	<p>The department suggests amending the text to the following:</p> <p>Establishments certified to the United States are required to conduct routine sampling of beef manufacturing trimmings in accordance with N-60 methodology and, for STEC confirmation, use laboratories and methods of analysis that are approved by the Department of Agriculture and accredited by NATA.</p>
<p><b>Section IX; Page 19: Paragraph 2, line 10</b></p>	<p>The samples are analysed by laboratories that are approved by NATA using methods FSIS MLG5 or <b>ISO 16654:2001</b> for <i>E. coli</i> O157:H7 and FSIS MLG 5B for non-O157 STECs.</p>	<p>ISO 16654:2001 is not an approved method for <i>E. coli</i> O157:H7 and non-O157 STEC confirmation testing.</p>	<p>The department suggests amending the text to the following:</p> <p>The samples are analysed by laboratories that are approved by NATA using methods FSIS MLG5 for <i>E. coli</i> O157:H7 and FSIS MLG 5B for non-O157 STECs.</p>

<p><b>Section X; Page 19: Paragraph 6 - dot point</b></p>	<p>The CCA does not include provisions that Australian inspection officials will not sign export certificates for product destined for the United States until all inspection laboratory verification sample test results are received and found acceptable.</p>	<p>Clarification is required to ensure the statement refers to chemical residue monitoring samples.</p>	<p>The department suggests amending the text to the following:</p> <p>The CCA does not include provisions that Australian inspection officials will not sign export certificates for product destined for the United States until all inspection laboratory verification chemical residue sample test results are received and found acceptable.</p>
<p><b>Appendix A</b></p>	<p>For establishments 206, 90, 486, 866, 3416, 195 and 180 there are marks against criteria 36 and 51.</p>		<p>The department respectfully requests that FSIS remove the marks against criteria 36 and 51 of the audit checklists for establishments 206, 90, 486, 866, 3416, 195 and 180.</p>