



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

OCT 31 2012

Mr. Greg Read
First Assistant Secretary
Food Division
Australian Quarantine and Inspection Service
Department of Agriculture, Fisheries and Forestry
Edmund Barton Building
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Canberra ACT 2601
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Dear Mr. Read,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Australia's meat inspection system March 17 to March 25. Your comments to the audit report have been included in the report. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-6400, by facsimile at (202) 720-7990, or electronic mail at international.audit@fsis.usda.gov.

Sincerely,

Dr. Shaukat Syed, Director
International Audit Staff
Office of International Affairs

Enclosure

OCT 3 1 2012

FINAL REPORT OF AN AUDIT CONDUCTED IN
AUSTRALIA
MARCH 17-25, 2011

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING
THE PRODUCTION OF MEAT
PRODUCTS INTENDED FOR EXPORT TO
THE UNITED STATES OF AMERICA

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This audit report describes the outcome of an onsite verification audit conducted by the Food Safety and Inspection Service (FSIS) from March 17 through March 25, 2011, to determine if Australia's food safety system governing the production of meat continues to be equivalent to that of the United States, with the ability to produce products which are safe, unadulterated, and properly labeled. FSIS also assessed the preliminary preparations implemented by Australia to transition from its conventional post mortem inspection system to the Australian Export Meat Inspection System (AEMIS) alternative.

The focus of the audit was on the ability of the Central Competent Authority (CCA), Australia Quarantine and Inspection Service (AQIS), to regulate meat production. FSIS reviewed and verified the information provided by the CCA in the completed Self Reporting Tool (SRT). The scope of the audit included central and local government offices, one bovine and one caprine/ovine slaughter establishments, and one commercial laboratory conducting microbiological and chemical analysis. Determinations concerning the effectiveness of Australia's food safety program focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight, (2) Statutory Authority and Food-Safety Regulations, (3) Sanitation, (4) HACCP Systems, (5) Chemical Residue Control Programs and (6) Microbiological Testing Programs.

The CCA informed FSIS that initial plans to gradually introduce AEMIS had been postponed until further notice.

The audit outcome made evident that the Australian meat inspection maintains equivalence with FSIS. However, there is one issue that remains pending resolution. AQIS has initiated corrective actions to resolve the identified discrepancy between FSIS and AQIS confirmation rates for presumptive *E.coli* O157:H7 test results described in the Microbiological Testing Programs Component section of this report. FSIS will consider this issue resolved after reviewing and verifying the effectiveness of the corrective actions instituted by AQIS.

As reported in the Microbiological Control Programs portion of this report, the Australian DAFF has proposed corrective actions to address FSIS concerns related to its *E. coli* O157:H7 control program. FSIS has accepted the proposed corrective measures and will verify adequacy of their implementation during the next audit.

TABLE OF CONTENTS

1. INTRODUCTION
2. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY
3. LEGAL BASIS FOR THE AUDIT
4. BACKGROUND
5. GOVERNMENT OVERSIGHT
6. STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS
7. SANITATION
8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM
9. CHEMICAL RESIDUES CONTROL PROGRAMS
10. MICROBIOLOGICAL TESTING PROGRAMS
11. EXIT MEETING
12. CONCLUSIONS AND NEED FOR FURTHER ACTIONS
13. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

AAO	AQIS Authorized Officer
AEMIS	Australian Export Meat Inspection System
AQIS	Australian Quarantine and Inspection Service
ATM	Area Technical Manager
CCA	Central Competent Authority (Australian Quarantine and Inspection Service)
DAFF	Department of Agriculture, Fisheries and Forestry
<i>E. coli</i>	<i>Escherichia coli</i>
ELMER	E-Legislation Manuals and Essential References
FOM	Field Operations Manager
FSIS	Food Safety and Inspection Service
OPV	On Plant Veterinarian
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point System
<i>Salmonella</i>	<i>Salmonella</i> species
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures

1. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture conducted an audit of Australia's meat inspection system from March 17 through March 25, 2011.

The audit began with an entrance meeting held on March 17, 2011, in Canberra with the participation of representatives from the Central Competent Authority (CCA) – Australia Quarantine and Inspection Service (AQIS) and the FSIS, Office of International Affairs (OIA), International Audit Staff (IAS).

2. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

The audit objective was to verify that Australia's food safety system governing meat continues to be equivalent to that of the United States, with the resultant capacity to produce products which are safe, unadulterated, and properly labeled. In addition, FSIS expected to assess the transition from conventional post-mortem inspection to the Australian Export Meat Inspection System (AEMIS) alternative that AQIS had planned to implement at the certified establishments.

In pursuit of this objective, FSIS used the information provided by Australia in the FSIS document entitled Self Reporting Tool (SRT), port-of-entry (POE) testing results, and data collected by FSIS during onsite audits conducted in the last three years.

The FSIS auditor was accompanied throughout the audit by representatives from the CCA that included one Field Operations Manager (FOM) and the Export Meat Program Manager both members of the Biosecurity Services Group of AQIS. Determinations concerning program effectiveness focused on performance within the following six equivalence components upon which system equivalence is based: (1) Government oversight, (2) Statutory authority and food safety regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point Systems, (5) Chemical residues control programs, and (6) Microbiological testing programs.

The auditor reviewed the administrative functions of the system at CCA headquarters and at two local inspection offices, during which the auditor evaluated the implementation of those management control systems in place which ensure that the national system of inspection, verification and enforcement was being implemented as intended.

Two establishments were selected from a total of 77 establishments certified to export meat products to the United States. During the establishment visits, particular attention was paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the CCA's

ability to provide oversight through supervisory reviews conducted in accordance with 9 CFR 327.2.

Additionally, one commercial laboratory was audited to verify its ability to provide adequate technical support to the inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	Canberra
	Local	2	Gimpy, QSLD and Wodonga, VIC
Laboratories		1	Commercial Microbiology and Chemical Laboratory, Brisbane
Establishments		2	<ul style="list-style-type: none"> • Gimpy, QSLD (Bovine Slaughter) • Wodonga, VIC (Caprine/Ovine Slaughter)

3. LEGAL BASIS FOR THE AUDIT AND AUDIT STANDARDS

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

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.

The audit standards included all applicable legislation and procedures originally determined by FSIS as equivalent as part of the initial review process, and any subsequent equivalence determinations that have been made by FSIS under provisions of the Sanitary/Phytosanitary Agreement.

Currently, Australia has equivalence determinations in place for the following:

- Australian Export Meat Inspection System (AEMIS), an alternative post-mortem inspection program, formerly Meat Safety Enhancement Program (MSEP)
- Slaughter/processing of raites and equines in the same local where amenable species are slaughtered and processed.
- Use of MPSC Rinse & Chill intervention on meat and viscera
- Alternative examination of heads and tongues of sheep and swine carcasses
- Alternative evaluation of atlantal lymph nodes in cattle
- SRM removal exemption
- Alternative examination of medial retropharyngeal, parotid, mandibular, mediastinal and bronchial lymph nodes
- Determination of lot of product and reduction of testing at POE for E. coli 0157:H7
- Year-round continuous *Salmonella* sampling in all U.S. export establishments
- Establishment employees collect samples for *Salmonella*
- Private laboratories analyze samples for *Salmonella*

- Equivalent Analytical Methods for *Salmonella*
 - AS 1766.2.5
 - AOAC 998.09
 - AOAC 999.09
 - AOAC 2000.07
 - AOAC 2001.07
 - AOAC 2001.08
 - AOAC OM 2003.09
 - AS 5013.10-2004
 - AOAC 992.11
 - AOAC Biocontrol 1-2
 - AOAC 978.24
 - AOAC 989.14
 - AOAC 999.08
 - AOAC 996.08
 - AOAC 2001.09
 - AOAC 992.12
 - AOAC 998.08
 - AS 5013.15-2004
 - AOAC 991.14
- Equivalent Generic *E. coli* Testing Program
- Equivalent Analytical Methods for generic *E. coli*
 - SimPlate® *E. coli* (AOAC 2005.03) for testing generic *E. coli*
 - Tempo® EC AFNOR Bio 12/13 – 02/05 for testing generic *E. coli*
 - E. coli* Petrifilm use of 0.1% peptone Salt Solution as a diluent for testing generic *E. coli*
 - Private laboratories analyze samples for *E. coli* O157:H7
- Equivalent Analytical Methods for *E. coli* O157:H7
 - FDA BAM Chapter 4A
 - BAX O157:H7
 - ISO 16654:2001
 - AOAC 996.09
 - AOAC 2000.13
 - AOAC 996.09
 - AOAC 996.10
 - AOAC 2000.14
- Equivalent Analytical Methods for *Listeria monocytogenes* (*Lm*)
 - FDA BAM Chapter 10 (January 2003)
 - AS 1766.2.16.1:1998
 - AOAC 996.14
 - AOAC 996.06
 - AOAC 997.03
 - AOAC 995.22
 - AOAC 2002.09
 - AOAC 2002.09

- Private laboratories analyze samples for *Lm*
- Establishment employees collect the samples for *Lm*
- Equivalent Residue Program
- Equivalent Methods for Chemical Analysis
- Determination of Benzoyl Urea in Bovine Fat
- Qualitative and quantitative analysis of androgenic substances in urine
- Monofluoroacetate (1080) in Muscle
- Analysis of Closantel in Animal Liver Tissues by LC/MS
- Determination of the synthetic corticosteroids betamethasone and dexamethasone in bovine liver using ES-LC/MS
- Animal Liver Determination of Benzimidazole (including triclabenidazole) Residues using HPLC with UV Detection
- Analysis of Dimetridazole and Hydroxydimetridazole in Muscle
- Determination of Cyromazine, Melamine, and Dicyclanil in animal tissue by GC/MS
- Determination of Levamisole in Animal Liver Tissues by HPLC/MSD
- Determination of flunixin, phenylbutazone, oxyphenylbutazone and ketoprofen in bovine liver using ES-LCMSMS
- Determination of Cyromazine, Melamine, and Dicyclanil in animal tissue by GC/MS
Chloramphenicol Detection by ELISA; Confirmation of Chloramphenicol by LCMSMS
- Determination of Metals in Liver, Eggs and Grains by Inductively Coupled Plasma Mass Spectrometry
- Sample Homogenization of Liver and Eggs for Trace Metals Determination by Inductively Coupled Plasma Mass Spectrometry
- Determination and confirmation of beta agonists in urine using HPLC/MS/MS
- Determination of OC/OP/SP's in Fat (Modified Mills Method)
- Determination of OC/OP/PCB's in Fat by ADU method
- Determination of Organochlorine type pesticides and Polychlorinated Biphenyls in Animal Fat by Gas Chromatography
- MIT screen for all program specified analytes except sulphonamides
- HPLC screen for sulphonamides
- Analysis of Anabolic Compounds in Liver and Feces

4. BACKGROUND

Australia is eligible to export meat to the United States. Between 3/2010 and 3/2011, Australia exported 530,732,352 pounds of meat products to the United States of which 37,118,132 pounds were re-inspected and a total of 2,204,869 pounds rejected at U.S. Ports of Entry (POE).

FSIS audited Australia's meat inspection system in 2008. Reported findings from that audit included minor deficiencies in sanitary conditions and inadequacies in the implementation of non critical food safety verification activities, i.e Recordkeeping activities on the part of establishment operators and government officials. The deficiencies were corrected and FOM verified and documented the actions taken by

establishment and government officials. The FSIS auditor confirmed that the CCA had developed and implemented a nationwide plan of action to require and verify that corrective actions were adequate.

The FSIS final audit reports for Australia's Food Safety System are available on the FSIS' website at:

http://www.fsis.usda.gov/Regulations_&Policies/Foreign_Audit_Reports/index.asp

5. GOVERNMENT OVERSIGHT

The first of the six equivalence components of the meat inspection system of Australia that FSIS reviewed was Government Oversight. The evaluation included a review and analysis of documentation submitted as support for the responses provided by the CCA in the SRT and observations gathered during the onsite audit.

FSIS assessed the extent to which Australia's meat and poultry inspection system is organized and administered by the AQIS. Documents that accompanied the SRT provided by the CCA to the FSIS indicated that the Department of Agriculture, Fisheries and Forestry (DAFF) of Australia, had initiated consolidation of the AQIS with other agencies of that Department to form the Biosecurity Services Group (BSG). During the audit, FSIS verified that the consolidation continues to take place and the BSG is currently comprised of six divisions one of which is the Food Division (FD). The FD constitutes the CCA responsible for the full spectrum of production of safe food for domestic consumption and for export.

The Executive Manager of the FD oversees the functions of several General Managers (GM). GMs develop and maintain export standards; oversee production of food for export; ensure food safety and residue control, and implement export reform. The GM for Food Exports manages regulatory oversight of the system in the field and is assisted by three Field Operations Managers (FOM), one Export Meat manager, and one Business Support Manager. The FOMs and Regional Senior Managers for Exports supervise the functions of Area Technical Managers (ATM) who are in charge of supervising On Plant Veterinarians (OPV). OPVs in turn, supervise the Food Safety Assessors (FSA/Food Inspectors) stationed at certified establishments. The auditor reviewed the current organizational structure and verified that the system operates as it is described in the documents provided by the CCA. Onsite observations and document reviews conducted during the audit of government offices, establishments and laboratories, indicate that the CCA promulgates food safety regulations and has sole authority to oversee enforcement of the laws and regulations of the Australian meat and meat products inspection system.

The CCA provided information to FSIS that indicates that the CCA certifies establishments that become eligible to export meat products to the United States. Documents reviewed by FSIS described the procedures that establishment operators follow to obtain approval from AQIS to become certified and the actions taken by government officials at each step of the approval process. Prior to obtaining certification,

an establishment must register with AQIS, maintain consistent regulatory compliance, and be free from debt to the commonwealth. In addition, the operators are required to file an application for certification with AQIS and have in place an Approved Arrangement (AA). The AA must contain written description of processes and practices that an establishment operator will follow to maintain adequacy of its quality systems, food safety controls, and to meet regulatory and certification requirements. The ATM of AQIS review and approve the AA after corroboration of its contents against the actual conditions at the establishment. The AA for slaughter facilities include production activities from sourcing livestock to consigning of meat products, humane livestock handling, good hygienic practices program, and HACCP program. In addition, the AA includes descriptions of supply chain integrity strategies, commitment to non-interference with the duties of AOs, internal auditing systems, and managerial commitment to adhere to AA. The FSIS auditor reviewed electronic and hard copy documents maintained by government officials and verified that registration, assessment of AAs, and certification are conducted by officials of AQIS. In addition, the auditor observed that AAs of the establishments audited had been periodically revised by the establishment and reassessed by the ATMs in accordance with the regulations of the AQIS.

During the audit, FSIS verified that the Australian meat inspection system has the legislative basis to exert uniform regulatory control over the production activities of meat exporting establishments. Government officials have legal authority to verify that operators adequately meet all provisions contained in their AAs, document non-compliance and take official control actions that can escalate to administrative actions and criminal prosecution if necessary. Furthermore, local inspection officials enter the results of inspection and verification activities into data banks managed by the CCA that are used to assess the adequacy of food safety industry controls nationwide and to conduct objective data analysis that support performance based decisions. Uniformity of enforcement of regulatory requirements is also assessed by evaluating the results of onsite periodic reviews that ATMs enter into the system to make adjustments and correlations where required.

The development, communication and dissemination of food safety regulations and export standards are managed by the CCA by means of automated information distribution networks. The CCA provides notification to plant operators and government officials on standardized procedures that would be followed to evaluate results of performance audits conducted by AQIS or foreign government auditors. The procedures describe how the CCA would assess compliance with export program requirements and the specific sanctions that would be imposed upon non compliant producers. FSIS verified that AQIS personnel stationed and plant officials at the audited establishments were familiar with technical and administrative guidance generated and distributed by the CCA as Standard Procedures and Work Instructions of the Australian meat inspection system.

Consistent with the information reported in the SRT, FSIS verified that the CCA provides oversight to its technical support. This is accomplished by conducting verification of

adequacy of functions of laboratories at different levels. At the in-plant level, collection, handling and shipping of samples to accredited laboratories is conducted under the oversight of AQIS officials and in accordance with the protocols prescribed by the laboratories of the system. Laboratories that are part of the technical support of the system gain and maintain accreditation which is granted by the International Laboratory Accreditation Cooperation (ILAC) and the National Association of Testing Authorities (NATA). NATA is an Australian agency, member of ILAC that provides assurances to AQIS that laboratory services are in line with government regulations and meet market access requirements. This aspect of the system is further described in the Microbiological and Chemical Residue program components portions of this report.

AQIS also requires that accredited laboratories use approved methods of analysis, perform satisfactorily in proficiency testing programs administered by the accrediting bodies and report results directly to AQIS. Adequacy of the functions of microbiological laboratories is verified by the Technical Standards group of AQIS. Conversely, chemical laboratories are audited by scientists of the DAFF assigned to the National Residue Survey program. In both instances, auditors frame their audits within the expectations of the meat inspection system and ISO standard 17025. The audits thus, evaluate managerial and technical aspects of the laboratories. Records reviewed by the FSIS showed that accreditation entities evaluate AQIS auditing methods and the functions of laboratories. Identified non conformities, results of verification of adequacy of corrective actions and reassessments of functions are documented in reports that were made available for review. The FSIS reviewed auditing procedures, checklists and results of past audits and verified that NATA and AQIS regularly evaluate the functions of laboratories and verify adequacy of corrective actions.

In-plant regulatory oversight includes operational inspection and system verification activities that are conducted by veterinarians and non veterinary officials. During the audit, FSIS confirmed that qualifications and roles of the official veterinarians assigned to certified establishments were consistent with the description reported by the CCA in its SRT. OPVs stationed at certified slaughter establishments have completed academic work to earn a veterinary degree, which customarily includes courses in HACCP and Meat Science. Veterinarians also complete induction training to develop and master technical, regulatory, food safety auditing, and supervisory skills needed to perform their duties. The main responsibilities of OPVs are to conduct ante-mortem inspection, make post-mortem dispositions of retained carcasses, verify adequacy of post-mortem inspection, monitor and verify compliance of establishments with their AAs and supervise and manage inspection personnel.

Currently, the Australian meat inspection system uses two approaches to deliver post-mortem inspection of heads, viscera and carcasses at certified establishments. At the time of the audit, some establishments were operating under traditional post-mortem inspection system (TIS) and others were preparing to transition to the Australian Export Meat Inspection System (AEMIS) currently being used at one establishment. In both types of post-mortem inspection, OPVs supervise the performance of meat inspectors and verify the adequacy of their inspection decisions.

Regardless of the type of inspection system, before conducting meat inspection duties inspectors earn a certificate in meat processing (Meat Safety IV), issued by registered training organizations and demonstrate a satisfactory level of proficiency in the performance of meat inspection. In addition, meat inspectors must accept their responsibilities as stated in instruments of appointment, i.e. Public Service Act and Deed of Obligation if they are to work as Traditional meat inspectors or as AQIS Authorized Officer (AAO) of the AEMIS respectively.

In the traditional inspection system, all inspection activities including food safety and other consumer protection inspection tasks are performed by government officials. Meat inspectors stationed along the slaughter line, conduct post-mortem inspection of heads, viscera and carcasses and identify conditions of food safety importance and other consumer protection defects under the supervision of an OPV. The OPV in turn is responsible for ante-mortem inspection, dispositions of all suspect animals and retained carcasses; verification of adequacy of post-mortem inspection, and in large establishments is assisted by a Food Safety Meat Assessor (FSMA)-floor inspector to verify the adequacy of the establishment's food safety controls.

In AEMIS, government officials conduct post-mortem inspection to identify conditions that impact food safety and identification of other consumer protection defects in heads, viscera and carcasses is conducted by establishment's employees designated as AAOs. In-plant government officials evaluate the adequacy of AAO's inspection procedures throughout the production day, verifying and documenting the accuracy of their post-mortem decisions in accordance with performance standards developed by the CCA. Each slaughter line is staffed with one government FSMA who verifies that each carcass is free of visual contamination and pathological lesions of food safety significance. The duties of the OPV remain essentially the same in AEMIS as in TIS.

FSIS verified that the CCA exercises ultimate control and supervision over the official activities of all employees or licensees of the system. Furthermore, in-plant inspection and verification activities are administered by the CCA on a fully cost recovery basis. Producers make payment for services rendered by government officials to the office of the national treasury, which in turn releases funds for the CCA to pay the salaries of AQIS officials that provide regulatory oversight. FSIS assessed the adequacy of post-mortem inspection and verified that meat inspectors, who were employees of the establishment* and those who were government employees adequately performed their functions. The auditor verified that inspection personnel properly conducted post-mortem inspection and observed the OPV conduct verification of post-mortem inspection in an adequate manner.

Government officials in both types of establishments also monitor the adequacy of dressing procedures and verify that establishments collect and analyze samples of their products to detect the presence of pathogens. In addition, inspection officials ensure adequate disposition of contaminated or adulterated products and collect samples of tissues to be analyzed by chemical laboratories as part of the National Residue Control program of Australia. Inspection personnel stationed at both types of establishments report post-mortem findings and results of verifications to the CCA and input establishment performance information into the national databank maintained by the Australian meat inspection system.

FSIS verified that past audit's findings related to record keeping deficiencies had been corrected. AQIS officials provided to the FSIS auditor information that indicated that the CCA had verified the adequacy of corrective actions and had issued further guidance to certified establishments and government officials on U.S. record keeping requirements. Additionally, FSIS verified the actions taken by the CCA in response to POE violations concerning fecal contamination on carcasses that FSIS reported to AQIS. Documentation examined by FSIS showed that government officials had informed the plant operators of the occurrences and required in each instance, an investigation to determine the cause of the violations. FSIS verified that plant operators had in fact conducted the investigation, but had not been able to determine the cause of the contamination. Plant officials also reassessed the HACCP plan and concluded that there was no need for changes to be made. FSIS accompanied the AQIS ATM to observe evisceration activities and verified that plant personnel were performing dressing procedures in a sanitary manner.

In conclusion, the Australian meat inspection system is organized and administered by the national government and provides standards equivalent to those of the Federal system of meat inspection in the United States. This component of the Australian meat inspection system therefore, continues to be equivalent.

**During the exit conference held on March 25, 2011, the FSIS auditor indicated to the CCA that plant management at the audited AEMIS establishment had notified AQIS and the FSIS auditor that AAOs at that establishment received salaries and profit sharing benefits from the company. The auditor further indicated that subsequent to that event, the CCA needed to characterize and analyze the financial transactions that take place between establishment's operators and their AAOs to assess the apparent conflict of interest that had been disclosed by plant management and that FSIS would in turn also analyze the matter at hand. FSIS officials have since concluded that receipt of salaries and profit sharing benefits by AAOs do not have an impact on the decision made by FSIS to determine that AEMIS provides the same acceptable level of public health protection as conventional inspection does.*

6. STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. This component pertains to the legal authority and the regulatory framework utilized by the CCA to impose requirements equivalent to those governing the system of meat inspection organized and maintained by the United States.

The evaluation of this component included an analysis of information provided by the CCA in the SRT and observations gathered during the onsite audit of the system. The review of the information revealed that the inspection system of Australia has statutory authority to deliver inspection to all certified slaughter and processing establishments. Furthermore, the CCA has rules that require that official inspection personnel, laboratories and establishments meet the requirements of importing countries. In addition, the system has regulatory requirements for daily inspection of slaughter and

processing activities, control of inedible and condemned materials, and periodic supervisory reviews of certified establishments.

FSIS verified that all animals presented for slaughter undergo ante-mortem inspection which is conducted by the OPV with the assistance of a FSMA, at large establishments. Consistent with what was reported in the SRT, AQIS verifies that livestock arrives to slaughter establishments accompanied by required documentation and identification that allow the system to trace products back to primary centers of production. Officials detect abnormalities in livestock presented for slaughter in accordance with work instructions issued by the CCA and input ante-mortem inspection results into a data bank managed by the CCA. The officials also evaluate the adequacy of ante-mortem facilities and assess compliance of operators with humane handling requirements imposed by AQIS and importing country requirements.

During the audit, FSIS assessed delivery of post-mortem inspection at two establishments and verified that certified establishments presented properly identified heads, viscera and carcasses for inspection. In addition, the design of the inspection stations met AQIS requirements and inspection personnel, identified food safety and other consumer protection defects in inspected carcasses and parts. Official inspectors in both of the systems of post-mortem inspection demonstrated an acceptable level of proficiency to perform their duties. FSIS also verified the functions of the resident veterinarians and observed that they monitored delivery of post-mortem inspection and verified adequacy and accuracy of decisions made by the inspectors, performed dispositions of retained carcasses and verified acceptability of the final product as well. Furthermore, FSIS verified that OPVs have legal authority to modify production rates to respond to situations in which adequate post-mortem inspection requires adjustment of production lines' speed.

FSIS assessed the supervision of the performance of post-mortem inspectors and observed that the OPV continuously communicates with meat inspectors and in the case of AEMIS, also with plant management to make adjustments to consistency and accuracy of the decisions made by official inspectors and AAOs. At the AEMIS establishment audited, the OPV conducted daily verification of post-mortem inspection. The sample size selected for this purpose corresponded to 2.5% of the first 2000 animals slaughtered and 1% of the remainder for each shift. These verifications included evaluations of the ability of inspectors to identify pathological lesions and the adequacy of their inspection procedures.

The Australian meat inspection system demonstrated to FSIS that it enforces regulations that require that establishment operators adhere to their AAs and ensure that their premises are properly built and maintained in good repair to prevent the creation of insanitary conditions. FSIS confirmed that AQIS officials verify that operators of certified establishment meet the regulatory requirements. Government officials regularly evaluate the conditions in the different areas of the establishments, document their findings and require that operators implement adequate corrective actions. Documents reviewed by the FSIS during the audit indicate that operators of the establishments and

government officials interact to ensure that non compliances are identified and abated to comply with the regulations of the program as attested by the fact that the premises of the audited establishments were maintained in good condition.

FSIS determined that in accordance with the rules of the Australian meat inspection system OPVs conduct regular onsite reviews of the performance of the food safety systems of the establishments utilizing the AAs of the establishments as standards. ATMs also conduct periodic evaluations of the performance of AQIS officials and verify the level of regulatory compliance maintained by operators of certified establishments. Periodic evaluations are also conducted by FOMs who assess performance of establishments and verify corrective actions to deficiencies identified by foreign auditors. FSIS reviewed records and reports generated by the OPVs to document assessments of the establishments AA's and verified that deficiencies are identified, documented and corrected by the operators. Reports of ATMs' reviews were also evaluated and seen to adequately document results of reviews and follow-up activities needed to correct deficiencies. As part of this audit, FSIS observed ATM's conduct assessments of the food safety systems of certified establishments by conducting evaluations of production areas and reviewing documentation generated and maintained by the operators of the establishments and AQIS in-plant personnel. The manner in which the ATMs conducted the establishment reviews made evident to the FSIS that the CCA maintained adequate official oversight over the production functions of the establishments in accordance with the AQIS regulations. Furthermore, forms, records and reports presented to FSIS for review, indicated that reviews were framed within the National Establishment Verification System (NEVS) of AQIS, to ensure standardization of audit approaches, capturing of data and generation of standardized reports based on findings and data from the Audit Management System (AMS).

AQIS personnel demonstrated to the FSIS how AMS was used at the in-plant and ATM levels. The auditor verified that AMS is being used to store and organize audit outcomes, AQIS daily verification activities data, ante and post-mortem inspection results and all identified non-compliances. Both OPVs and ATMs input data into the system as they complete their official tasks. The information is then packaged to generate output that government officials at several levels can access and analyze to determine compliance levels maintained by establishments and performance trends developing at local and national levels. Furthermore, the collected data allows the CCA to identify establishments that require greater official oversight. FSIS observed that the resident veterinarians and ATMs could access the data bank from their establishment and were proficient gathering and filtering data to generate examples of post-mortem disposition and condemnation summary reports.

In conclusion, Australia's meat inspection system has legal authority and a regulatory framework to impose requirements equivalent to those governing the system of meat inspection organized and maintained by the United States. This component of the system therefore continues to meet equivalence.

7. SANITATION

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

The evaluation of this component included a review and analysis of the information provided by the CCA in the SRT and observations gathered during the onsite audit of the establishments and government offices sectors of the system. FSIS reviewed legislation, regulations and official instructions and concluded that the CCA has and exercises its legal authority to require operators to develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions.

Results of the review conducted by FSIS indicate that the meat inspection system of Australia requires that establishments operate in a manner that prevents the creation of insanitary conditions and also requires that operators develop written programs by which they will prevent direct product contamination. Official verification includes assessment of the conditions and maintenance of certified establishments, review of their written sanitation procedures and their implementation. Establishments are required to monitor adequacy of their facilities, conduct analysis of product and personnel flow, develop preventive maintenance programs of equipment and structures, and a method to classify the severity of the deficiencies. The rules of the system also require that operators develop sanitation programs that prevent direct product contamination. Official verification also evaluates the written sanitation programs that establishments prepare to describe the procedures they will follow to ensure that all product contact surfaces will be cleaned and sanitized prior to the beginning of production and the measures to be implemented to prevent direct product contamination throughout the production day.

During the onsite auditing of this component, FSIS verified the functions of the ATMs and OPVs as they evaluated the sanitary conditions of the plants and reviewed electronic and hard copy documents; and monitoring and verification records. FSIS observed the ATMs as they assessed the adequacy of pre-operational and operational sanitation monitoring and inspection, establishments' recordkeeping, and documentation of non-compliance generated by the OPVs. FSIS also verified that upon conclusion of the establishments' reviews, AQIS officials prepared and delivered to the managers of the establishments Corrective Action Requests to address identified sanitary deficiencies. The findings reported by the ATM's were consistent with the observations made by the FSIS and made evident an acceptable level of proficiency on the part of the AQIS auditor to assess the adequacy of sanitation programs. In addition, the sanitary conditions of processing rooms before and during operations, actions taken by establishment and government officials to address deficiencies and documentation of findings met AQIS regulatory requirements deemed equivalent to FSIS.

FSIS's assessment of the design and implementation of sanitation programs as well as official verification activities conducted by official personnel support the conclusion that

the CCA effectively implements its requirements for sanitation and sanitary handling of meat products intended for export to the United States. Therefore, this component of the meat and poultry inspection system of Australia meets the equivalence criteria.

8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. The component pertains to the requirement that an inspection system must have regulatory requirements for certified establishments to develop, implement and maintain HACCP programs as set forth in the regulations of the FSIS.

The auditor evaluated this component by reviewing and analyzing information provided by the CCA in its SRT and by auditing onsite, the performance of establishments, laboratories and government offices sectors of the system.

Documents reviewed by the FSIS auditor included regulatory standards, training materials, and regulatory guidelines issued by the CCA. FSIS also assessed the adequacy of HACCP program verification activities conducted by government officials and establishment operators at the establishment level, by observing verification activities onsite and reviewing electronic and hard copy versions of monitoring and verification records generated by operators and in-plant government officials. The observations, reviews and analysis of information conducted by FSIS revealed that the Australian meat inspection system imposes on operators of certified establishments, regulatory requirements for the development, implementation and maintenance of HACCP programs as set forth in the regulations of the FSIS. Furthermore, FSIS verified that in-plant AQIS officials and ATMs periodically assess the adequacy of establishments' HACCP programs. Records and documents reviewed and onsite observations indicate that official verification activities assesses the design and execution of the HACCP programs including adequacy of hazard analysis, monitoring of Critical Control Points, corrective actions, record keeping and verification activities.

In conclusion, during this audit FSIS verified that the adequacy of HACCP programs and certified establishments, as well as official verification activities conducted by AQIS personnel support the conclusion that this component of the meat and poultry inspection system of Australia meets the equivalence criteria.

9. CHEMICAL RESIDUES

The fifth of the six equivalence components that the FSIS auditor reviewed was Chemical Residues Control Programs. This component pertains to regulatory requirements for the inspection system to have a chemical residue control program that is organized and administered by the national government. The program must include random sampling

of internal organs and fat of carcasses for chemical residues identified by the exporting country's meat and poultry inspection authorities or by FSIS as potential contaminants.

An assessment of the CCA's residue control program was conducted by reviewing the information provided through SRT, as well as the 2009-10 National Residue Survey (NRS) results report submitted by Australia and onsite visits to government offices, laboratories and slaughter establishments.

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

Official documents reviewed by FSIS indicate that the NRS operates within a statutory framework that permits it to finance its functions on a fully cost recovery basis. Industries thus, pay for the analytical services provided to the NRS which in turn pays the laboratories upon receipt of invoice and results of analyses conducted. Participation in the residue monitoring programs that NRS manages is voluntary, but necessary for operators to meet market access expectations. However, results of the analyses provide the CCA with indicators of the adequacy of controls of chemical residues at primary centers of production. The database that laboratory analyses generate is managed and packaged by the NRS, which distributes among stakeholders and trading partners, quarterly and annually reports of analytical results.

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

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

The type of oversight the CCA provides to the functions of chemical laboratories was also assessed by FSIS. All laboratories are accredited by NATA and evaluated by NRS prior to being awarded three year contracts to analyze samples. Once integrated into the program, the contracted laboratories use the methods of analysis that they used at the time their proficiency was established, and participate in proficiency testing, inter-laboratory and intra-laboratory check sample programs as part of their ongoing performance evaluation. The NRS audits the laboratories periodically to evaluate their performance, assessing their technical and managerial competence.

FSIS audited the performance of one chemical laboratory and reviewed documents and records maintained by overseeing officials that included Guidelines for Contracting Laboratories, NRS Proficiency Testing Handbook and NRS laboratory visit checklists. As well as documents maintained by laboratory personnel such as proficiency evaluation results, corrective actions records, internal audits reports and records of NRS past evaluations. FSIS observed that the laboratory adhered to established official protocols and its functions were being adequately overseen by the Australian government. During the audit of this component of the Australian meat inspection system, FSIS also evaluated the auditing process of the functions of chemical laboratories that the CCA provides and verified that the NRS auditor effectively verified and documented acceptability of laboratory conditions, adequacy of records generated, and corrective actions taken to address results of past audits.

Furthermore, during the audit of the functions of officials stationed at certified abattoirs, FSIS verified that government inspectors collect samples in accordance with a standard operating procedure, when 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 then sent to Central Receiving and Dispatch (CRAD) in Canberra and from there the samples are distributed to the laboratories for analyses. FSIS also verified that provisions of the regulatory controls managed by the CCA confer legal authority upon AQIS in-plant officials to condemn food products when laboratory analysis indicates the presence of chemical residues at a level that exceeds Australian standards

The NRS report received by FSIS for the period of 2009-2010 monitoring program shows one cattle fat sample out of 321 exceeded USA standards for Abamectin, an anthelmintic in the class of macrocyclic lactones, and two out of 1117 cattle fat samples exceeded the limits for Chlorfenvinphos, a pesticide in the organophosphate class.

In conclusion, the Australian meat inspection system has a residue control program that includes random sampling of internal organs and fat of carcasses to detect chemical residues recognized by Australia and the FSIS as potential contaminants. Therefore, this component of the Australian meat inspection system meets equivalence requirements.

10. CCA MICROBIOLOGICAL TESTING PROGRAMS

The sixth of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs. This component pertains to regulatory requirements for the inspection system to have a microbiological testing program, organized and administered by the national government.

The principal criteria used by FSIS to assess microbiological testing programs for raw meat and poultry include: The inspection system provides for a sampling and testing programs for generic *E. coli*, *Salmonella* and *E. coli O157:H7* in raw products. The CCA uses the test results to verify the adequacy of establishments' sanitary slaughter and dressing controls, food safety systems and pathogen reduction strategies. The program used by a given country must be supported by analytical test results, countrywide microbiological baseline surveys and/or other scientific data.

The evaluation of this component included a review and analysis of information provided by the CCA in the SRT and observations gathered during the onsite audit of the establishments and data obtained from the laboratories and government offices.

During the audit of this component of the system, FSIS verified that the meat inspection system of Australia administers a national regulatory microbiological monitoring program for slaughter and meat processing plants regardless of whether their products are destined for the domestic market or for export to the United States. Furthermore, the auditor established that the program provides indicators of the adequacy of dressing procedures and hygienic practices conducted by operators and also serves to verify that food safety controls are effective in reducing the presence of pathogens in meat products.

FSIS confirmed that laboratories conducting microbiological analysis of meat samples are participants of the Approved Laboratory Program (ALP). The ALP is an important aspect of the meat inspection system strategy that enables operators to gain market access. Laboratories participating in the ALP conduct microbiological analyses of edible meat products from certified establishments. Prior to initiate testing of products, the laboratories successfully complete a performance evaluation of their performance by NATA. Laboratories also submit their scope of accreditation, an agreement to participate in proficiency testing programs and the details of the approved laboratory methods they intend to use to analyze products.

Once incorporated into the ALP, laboratories are audited every year by NATA or AQIS, in accordance with ISO/IEC 17025, must participate in proficiency testing every six months and maintain accreditation for the analytical methods in their scope. Audits are conducted by AQIS officials from the Technical Standards Branch or by Technical Assessors (TA) appointed by the CCA. TAs are selected from a pool of subject-matter experts, usually University professors, who are free of conflicts of interest.

FSIS audited the performance of one microbiological laboratory and reviewed official documents that confirmed that results of evaluations, proficiency tests and verification of

corrective actions were documented in reports and records generated by officials of AQIS and other accrediting bodies. FSIS established that the laboratory followed official protocols and its functions were being adequately overseen by the Australian government.

FSIS observed an onsite audit of the performance of a microbiological laboratory and verified that the AQIS auditor adequately assessed acceptability of laboratory conditions, scope of accreditation, adequacy of records generated, and corrective actions taken to address results of past audits.

Documents reviewed by FSIS and observations made at certified slaughter establishments indicated that the rules of the Australian meat inspection system require testing of raw products for Generic *E. coli* and *Salmonella*. Operators collect samples of carcasses in accordance with standardized sampling, handling and shipping protocols, under the supervision of AQIS in-plant personnel. The samples are analyzed at AQIS approved, NATA accredited laboratories which report results of the analyses to AQIS and establishment operators at the same time. Results of analyses of samples for Generic *E. coli* are quantified and reported in colony forming units per square centimeter (cfu/cm²). *Salmonella* results are qualitatively assessed, i.e. detected or not detected. When *Salmonella* is detected, the samples are forwarded to a reference government laboratory to be serotyped. The FSIS auditor assessed the implementation of the microbiological verification activities overseen by AQIS and verified that certified slaughter establishments conduct microbiological sampling of carcasses and parts in accordance with official protocols. In addition, FSIS assessed the official oversight that in-plant officials provide over the sampling activities of the certified establishments and determined that government officials verify the adequacy of the microbiological verification and track and evaluate sampling results.

AQIS personnel verify that sampling of carcasses, meat products and product contact surfaces, is conducted by the establishment in accordance with standardized procedures. Sampling of carcasses is verified on a weekly basis for Generic *E. coli* and twice a week for *Salmonella*. Furthermore, government officials enter reported results into the national *E. coli* and *Salmonella* Monitoring Program (ESAM), MeatTech Database which is managed by the CCA to track establishment's performance and to analyze the national status of microbial control strategies.

When Generic *E. coli* results exceed the established maximum limits, the Australian meat inspection system requires that the establishment initiate a review of its carcass dressing procedures to identify possible causative factors contributing to the high cfu/ cm² results and determine the actions it will take to prevent recurrence. The results of the review are to be documented and made available for the AQIS on-plant staff and the ATM for auditing purposes. Establishments audited by FSIS had maintained control of their sanitary dressing procedures and their sampling results were being maintained within the acceptable parameters.

FSIS reviewed regulatory requirements imposed by the CCA upon producers and determined that in instances where test results for *Salmonella*, indicate that an establishment has exceeded the standard, the operator must investigate production activities and records to determine if a processing deviation occurred during slaughter or during pre-slaughter. The operator also has to immediately commence daily sampling until satisfactory results are obtained and institute sanitation and hygienic procedures deemed acceptable by the ATM to prevent recurrence. If the standard is exceeded a second time, the establishment must re-assess its HACCP plan, take appropriate corrective action and start sampling a third time. Failure by the establishment to meet that standard for the third consecutive time is deemed by the Australian authorities as a failure to maintain the minimum standard for slaughter hygiene and sanitation, and consequently would bring into question the adequacy of the HACCP plan of the establishment. Accordingly, the CCA would impose regulatory sanctions consistent with the statutory frameworks of the Australian meat inspection system and exclude such operator from the exports program.

The initial assessment of *Salmonella* controls maintained by establishments and verified by the CCA was followed up with a request for additional information presented to the managers of the microbiological control program of the system. Australian officials reported via electronic mail that in Australia all serotypes are considered to be human pathogens and the most common *Salmonella* serotypes isolated from carcasses sampled are *S. anatum* and *S. typhimurium*. Officials also reported that in 2010, 4800 samples were collected and tested from bovine carcasses and 13 were found positive. In that same time period, AQIS identified one establishment that had repetitive positives. Government official required the establishment to implement corrective actions and follow up sampling was implemented. The second sampling cycle did not show any positive results out of 58 consecutive samples.

FSIS also assessed the *E. coli* O157:H7 control program managed by the CCA. Documents reviewed indicate that both operators and government officials conduct testing of raw ground beef components for *E. coli* O157:H7. The CCA in cooperation with the Australian meat industry defined “production lot” for the purpose of *E. coli* O157:H7 testing, restricting its size to a maximum of 700 boxes or the equivalent of one conveying container and requires test and hold for raw ground beef components destined for the USA. AQIS officials verify the testing programs used by operators to determine that they meet the requirements of the meat inspection system and that they are performed correctly. AQIS conducts verification testing of raw ground beef components destined for the United States at a minimum frequency of once per quarter. Samples collected by the establishment and government officials are analyzed in AQIS approved laboratories using AQIS approved methods and all results are reported directly to AQIS. Presumptive positives are reported to operators and in-plant AQIS officials to facilitate identification and segregation of implicated lots and confirmed positives, come under control of AQIS and are handled in accordance with the AA of the establishment.

FSIS receives a monthly *E.coli* O157:H7 Test Summary from AQIS. This report includes the number of presumptive positive results and the number of confirmed

positives identified by designated laboratories using an analytical methods equivalent to the FSIS. However, upon reviewing the summaries for the last nine months, the auditor observed that the proportion of presumptive positives that are confirmed positives by the approach being used by AQIS is not consistent with what FSIS laboratories report. The percentage of confirmed positives that are obtained by FSIS is 95% of the total of presumptive positives, but in the case of samples taken by industry in Australia, the percentage reported as confirmed positive from the total of presumptive positives is reportedly less than one. This issue was brought to AQIS' attention to obtain clarification and a response has been received in which Australian officials indicate that in their view, this might be an issue of terminology. However, AQIS also proffered a corrective action plan that will enhance verification of testing of beef trimmings to be finished by the end of April of the current year. Consequently, FSIS expects to receive additional information concerning the results of the steps taken by the CCA to address the concern for the observed discrepancy in confirmation rates presented by FSIS**.

FSIS evaluated onsite, the ability of government officials to provide oversight over the collection and handling of samples for *E. coli O157:H7* analysis and verified that plant employees adhere to proper aseptic protocols and conducted identification and handling of samples in an adequate manner. Government officials were seen to adequately verify that identification of collected samples was consistent with AQIS requirements.

The regulations of the system also include provisions that apply to microbiological testing of ready-to-eat (RTE) products for the presence of *Listeria monocytogenes*, *E. coli O157:H7* and *Salmonella* at certified establishments. Documents reviewed by FSIS indicate that operators must address the above listed microbial hazards in their HACCP plans. Furthermore, AQIS oversight of this aspect of microbial controls consists of maintaining continuous verification of processing at establishments producing RTE products to ensure that they meet the regulatory requirements of the United States. In addition, AQIS officials must verify that the risk based selection of testing frequency is consistent with the type of production that is conducted by the establishment and that monitoring and verification activities are adequately performed.

FSIS assessed the oversight provided by the CCA to microbiological laboratories, the official auditing process of microbiological laboratories and the manner in which laboratory analysis results are communicated to the government and establishment operators. The audit of this component also included an assessment of laboratory conditions and a review of past audit reports and records generated. FSIS concluded that this component of the Australian meat inspection system adequately fulfills the established parameters for equivalence.

*** In letter received from the Australian CCA on May 17th, 2012, the Department of Agriculture, Fisheries and Forestry (DAFF) indicates to FSIS that they have confirmed the effectiveness of its sampling program and have made improvements to the testing methodologies for E. coli O157:H7. The letter also describe the actions that would be implemented to better understand and define the conversion of potential positive samples*

to confirmed positive samples. The actions, as described in the above mentioned letter are presented below:

- *Conduct a verification sampling baseline study to define the 'true' prevalence and conversion rate of potential/to confirmed positive samples.*
- *Investigate sample transport- DAFF has initiated research by the Commonwealth Scientific and Industrial Research Organisation (sic) (CSIRO) into the effects of transport on the recovery of E. coli O157:H7 from potential positive enrichment broths. Early results from this study show that there appears to be no effect on the recovery rate.*
- *Improvements to screen testing – DAFF has mandated that during screen testing, laboratories are required to re-verify their enrichment protocols for E. coli O157:H7. In addition, lateral flow devices will be phased out by 4 June 2012 and all laboratories must use PCR-based screening technologies for the analysis of STEC and E. coli O157:H7.*
- *Improvements to confirmatory testing – DAFF conducted a blind confirmation trial in two laboratories. A number of factors were investigated including the use of different plating media and variations in the number and type of colonies screened. As a result of this study, DAFF has required the inclusion of Cefixime-Tellurite Supplemented Sorbitol MacConkey (CT-SMAC) Agar with Rainbow agar in the confirmation process.*

FSIS has accepted the course of action that the DAFF proposes in its letter and will verify adequacy of its implementation on the next audit.

11. EXIT MEETING

An exit meeting was held on March 25, 2011 in Canberra with representatives of the AQIS. At this meeting, the results of the audit were presented by the FSIS auditor.

The CCA understood the findings and indicated that upon receipt of the draft final report they would present their view on the findings.

12. CONCLUSIONS AND NEED FOR FURTHER ACTIONS

The Australian meat inspection system was audited in two phases. The initial phase involved the analysis of information provided by the CCA in the SRT followed by the on-site audit phase that included government offices, establishments, and laboratories of the system. Planned observations of the transition between post-mortem inspection systems were not possible due to administrative requirements that reportedly delayed the transition changes. Verifications and observations made during the audit provided information to conclude that the AQS meat inspection system components are equivalent to FSIS. However, FSIS requests information concerning the effective resolution of the identified discrepancy between presumptive and confirmed *E. coli* O157:H7 results to resolve the pending matter concerning the microbiological control component of the system described in this report.

As reported in the Microbiological Control Programs portion of this report, the Australian DAFF has proposed corrective actions to address FSIS concerns related to its *E. coli* O157:H7 control program. FSIS has accepted the proposed corrective measures and will verify adequacy of their implementation during the next audit.

A handwritten signature in black ink, appearing to read 'Francisco Gonzalez, DVM', written over a horizontal line.

Francisco Gonzalez, DVM
Senior Program Auditor

13. ATTACHMENTS TO THE AUDIT REPORT

Foreign Country Response to Draft Final Audit Report



Australian Government

Department of Agriculture, Fisheries and Forestry

Dr Andreas Keller
Acting Director, International Audit Staff
Office of International Affairs
Food Safety and Inspection Service
United States Department of Agriculture
Washington, DC 20250-3700

Dear Dr Keller

United States Audit of Australian Meat Inspection System

Thank you for your letter dated 16 March 2012, in which you provided the Food Safety and Inspection Service (FSIS) Draft Final Report of the audit conducted from 17 – 25 March 2011 on the Australian Export Meat Inspection System.

The Department of Agriculture, Fisheries and Forestry (DAFF) appreciates FSIS' effort in conducting the audit and in providing comprehensive feedback to DAFF in the Draft Final Report.

We note in the report that FSIS requires further information in relation to Australia's testing program for *Escherichia coli* O157:H7. In particular, FSIS requested information on how DAFF plans to improve the conversion rate of presumptive to confirmed test results.

DAFF recently advised FSIS of the differences in terminology used between the Australian and US testing protocols for *E. coli* O157:H7 (letter from Paul Vanderlinde to Francisco Gonzalez dated 7 February 2012 and in discussions at our meeting in Washington on 23 April 2012). The letter explained that in the Australian testing program, a presumptive positive represented a result where the screen test returned a positive result, whereas in the USA this term refers to a positive screen test result with isolation of a latex agglutinating colony of *E. coli*. DAFF has since amended its terminology to more closely reflect that used by FSIS to avoid further confusion in this matter.

DAFF is in the process of undertaking the following actions in order to better understand and define the conversion of potential positive samples to confirmed positive samples in Australia:

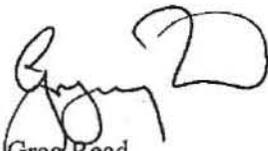
1. Conduct a verification sampling baseline study to define the 'true' prevalence and conversion rate of potential/ to confirmed positive samples.
2. Investigate sample transport – DAFF has initiated research by the Commonwealth Scientific and Industrial Research Organisation (CSIRO) into the effects of transport on the recovery of *E. coli* O157:H7 from potential positive enrichment broths. Early results from this study show that there appears to be no effect on the recovery rate.
3. Improvements to screen testing – DAFF has mandated that during screen testing, laboratories are required to re-verify their enrichment protocols for *E. coli* O157:H7. In addition, lateral flow devices will be phased out by 4 June 2012 and all laboratories must use PCR-based screening technologies for the analysis of STEC and *E. coli* O157:H7.
4. Improvements to confirmatory testing – DAFF conducted a blind confirmation trial in two laboratories. A number of factors were investigated including the use of different plating media and variations in the number and type of colonies screened. As a result of this study,

DAFF has required the inclusion of Cefixime-Tellurite Supplemented Sorbitol MacConkey (CT-SMAC) Agar with Rainbow agar in the confirmation protocol and an increased number of colonies screened to improve the confirmation process.

In summary, DAFF has confirmed the effectiveness of its sampling program and has made improvements to the testing methodologies for *E. coli* O157:H7. Preliminary results from DAFF's verification baseline survey indicate that the prevalence of *E. coli* O157:H7 in beef is consistent with that of previous studies (prevalence of approximately 0.1%). DAFF can provide confirmation of the survey results once this study is completed. DAFF considers that the measures undertaken to date and in progress will lead to improvements in analysis of samples for *E. coli* O157:H7 in beef trim exported to the USA.

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

Yours sincerely



Greg Read
First Assistant Secretary
Food Division

17 May 2012