



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Office of
International
Affairs

Washington, D.C.
20250

Mr. Greg Read
Executive Manager, Exports and Food Policy
Department of Agriculture, Fisheries and Forestry
Australian Quarantine and Inspection Service
Edmund Barton Building
Canberra, ACT, Australia

DEC 11 2008

Dear Mr. Read:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Australia's meat and poultry inspection system August 7 to September 1, 2008. Comments from Australia have been included as an attachment to the final 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) 690-5646, by facsimile at (202) 720-0676, or electronic mail at donald.smart@fsis.usda.gov.

Sincerely,

Donald Smart
Director
International Audit Staff
Office of International Affairs

Enclosure

FINAL REPORT OF AN AUDIT
CARRIED OUT IN AUSTRALIA COVERING AUSTRALIA'S MEAT
AND POULTRY INSPECTION SYSTEM

AUGUST 7 THROUGH SEPTEMBER 1, 2008

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

AGSEMP	Australian Government Supervised Export Meat Program
ATM	Area Technical Manager
AQIS	Australian Quarantine & Inspection Service
CCA	Central Competent Authority – (AQIS for this report)
CCP	Critical Control Point
CFR	U.S. Code of Federal Regulations
<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
IES	International Equivalence Staff
MSEP	Meat Safety Enhancement Program
MSQA	Meat Safety Quality Assurance
NEVS	National Establishment Verification System
NATA	National Association of Testing Authorities
NOID	Notice of Intent to Delist
OPV	On-Plant Veterinarian
POE	US ports of entry
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
RTE	Ready-to-eat
<i>Salmonella</i>	<i>Salmonella</i> species
SSOP	Sanitation Standard Operating Procedures
VU	Verification Unit

1. SUMMARY

1.1 Description/Eligibility

This report summarizes the outcome of the audit conducted in Australia from August 7 through September 1, 2008. This was a routine audit. Australia is eligible to export red meat, red meat products, and ratite meat to the United States. Between January 1, 2007 and June 30, 2008, Australia exported more than 1.14 billion pounds of meat products to the United States, of which 60 million pounds were reinspected at US ports of entry (POE). A total of 3.4 million pounds were rejected at POE, of which no rejections were for food-safety concerns. The activities of the current audit appear in the table below.

The findings of the previous audit during August-September 2007 resulted in no restrictions of any Australian establishment's ability to export meat products to the US.

1.2 Comparison of the Current Audit and the Previous Audit

		08/07-09/01, 2008	08/22-09/20, 2007
Levels of Government Oversight Audited			
	Headquarters	1	1
	Regional	1	2
	Establishment Level	7	8
Laboratories Audited			
	Microbiology	0	2
	Residue	0	0
Establishments Audited			
	Slaughter/processing	7	6
	Processing	0	0
	ID Warehouses	0	2
Enforcement Actions Initiated			
	NOID	0	0
	Delistment	0	0
Risk Area Findings		(7 Ests. audited)	(8 Ests. audited)
	Sanitation Controls (SSOP, SPS)	3	6
	Animal Disease Controls	1	0
	Slaughter/Processing (PR/HACCP)	4	4/6 Slt./Proc. Ests.
	Residue Controls	0	0
	Microbiology Controls	0	1
	Inspection/Enforcement Controls	6	6
	Special Emphasis (HH, O157:H7)	0	0
	Facilities for Inspection	3	1/6 Slt./Proc. Ests.
	Chemical Storage	2	1

1.3 Summary Comments for the Current Audit

The results of this audit reflected general improvement in sanitation, Hazard Analysis/Critical Control Points (HACCP), and microbiology controls. An increase in deficiencies was reported regarding lighting on some inspection surfaces and chemical storage. The deficiencies did not reflect serious concerns in the five risk areas (see Section 4).

2. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the US Department of Agriculture conducted an audit of the Australian meat inspection system August 7 through September 1, 2008.

An opening meeting was held on August 7, 2008, in Canberra with the Central Competent Authority (CCA) – Australia Quarantine and Inspection Service (AQIS). At this meeting, the auditor confirmed the objective and scope of the audit and the auditor's itinerary, and requested additional information needed to complete the audit of Australia's meat inspection system.

Representatives from AQIS's headquarters and/or representatives from AQIS's regional and local inspection offices accompanied the auditor during each audit activity.

3. OBJECTIVES OF THE AUDIT

The objectives were (1) to determine whether the concerns identified during the 2007 audit had been appropriately addressed and (2) to evaluate the performance of AQIS with respect to government oversight and enforcement of the AQIS and FSIS regulatory requirements relative to maintaining an inspection system equivalent to that of the United States. This included the following areas of special emphasis:

- Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) Requirements
- Controls in the establishment operating under the Meat Safety Enhancement Program
- Humane handling and slaughter of livestock
- Government oversight
- Controls for *E. coli* O157:H7
- Daily inspection
- Payment of inspectors
- The CCA's oversight of slaughter establishments' implementation of controls to prevent contamination of carcasses with feces or ingesta
- Field inspection personnel's knowledge and application of the FSIS regulatory requirements

4. PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with AQIS officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records and personnel interviews in the country's inspection headquarters and in one regional office. The third part involved on-site visits to seven slaughter-and-processing establishments. Program effectiveness determinations of Australia's inspection system focused on five areas of government controls and oversight and five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP), (2) animal disease controls, (3) slaughter/ processing controls, including the implementation and operation of HACCP programs and a testing program for generic *Escherichia coli* (*E. coli*), (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella* species.

During the establishment visits, the auditor evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditor also assessed how inspection activities are carried out by AQIS and determined if controls were in place to ensure that the production of meat and meat products were safe, unadulterated and properly labeled.

In the opening meeting, the auditor explained that Australia's meat inspection system would be audited against the following standards: (1) FSIS regulatory requirements, as applicable, (2) AQIS requirements specific to exporting meat and meat products to the US, and (3) FSIS equivalence determinations specific to Australia. FSIS requirements include, among other things, daily inspection in all applicable certified establishments, periodic supervisory visits to certified establishments, humane handling and slaughter of animals, ante-mortem inspection of animals and post-mortem inspection of carcasses and parts thereof, the handling and disposal of inedible and condemned materials, sanitation of facilities and equipment, residue testing, species verification, and requirements for HACCP, SSOP, and testing programs for generic *E. coli* and *Salmonella* species.

The following FSIS equivalence determinations were made for Australia under the provisions of the World Trade Organization Sanitary/Phytosanitary Agreement:

- Australia's Meat Safety Enhancement Program (MSEP), also called the Australian Government Supervised Export Meat Program (AGSEMP) allows product to be produced under an alternative inspection program (MSEP). MSEP establishments have one AQIS meat inspector performing ante-mortem inspection and verification checks and one government veterinarian performing post-mortem carcass-by-carcass inspection following "sorting" by establishment employees.
- Testing of ready-to-eat products for *Listeria monocytogenes*:
 - Establishment employees collect samples
 - Private laboratories perform the analyses

- Alternative testing program for *E. coli* O157:H7 in raw ground beef components (approved July 9, 2008):
 - Companies test all US-eligible production lots unless not destined for the US.
 - Sample size: minimum of 5 approx. 5-10g pieces from each of a minimum of 12 cartons for a minimum of 60 pieces (N60 method). The total sample weight must be at least 375g.
 - Positive lots will not be exported to the US and AQIS will determine disposition.
 - AQIS verifies that commercial testing programs meet requirements and are performed correctly.
 - Independent AQIS verification testing is conducted at least once per quarter; samples are analyzed in AQIS-approved laboratories using AQIS-approved methods; all results are reported directly to AQIS.
 - For both commercial and regulatory programs, sampled lots are held by the company until test results are obtained and are negative.

- Private laboratories may analyze commercial samples for *E. coli* O157:H7 in raw ground beef components (approved December 5, 2007).

- Testing of raw product for *Salmonella* species:
 - Establishment employees collect samples.
 - Private laboratories analyze samples.
 - A year-round *Salmonella* testing and enforcement strategy is used.
 - For every *Salmonella*-positive test result, a corrective action is required where a cause can be identified.

- Samples of raw product for generic *E. coli* may be analyzed in both government and private laboratories.

- Slaughtering of equines for Australia's domestic market may be conducted in the same establishment (Est. 3416) in which bovines are slaughtered for export to the United States.

- The MPSC¹ rinse and chill technique may be used on bovines slaughtered in exporting establishments.

- Australia may export meat to the United States from adult sheep and swine carcasses on which post-mortem inspection is conducted without the heads (but only when tissue from the heads were not saved for human consumption).

- *Listeria monocytogenes* laboratory testing methods:
 - AOAC 995.22; AOAC 997.03; AOAC 996.06; AOAC 996.14; AOAC 2002.09; AS 1766.2.16.1:1998; FDA BAM Chapter 10 (January 2003); BAX *Lm*

- *Salmonella* laboratory testing methods:
 - AOAC 978.24, AOAC 989.14, AOAC 992.12, AOAC 996.08, AOAC 998.09, AOAC 999.08, AOAC 999.09, AOAC 2000.07, AOAC 2001.07, AOAC 2001.08, AOAC 2001.09, AOAC OM 2003.09, AOAC 5013.10-2004, and AS 1766.2.5
- Generic *Escherichia Coli* (*E. coli*) laboratory testing methods:
 - AOAC 998.08, AOAC 991.14, and AS 5013.15-2004
- *E. coli* O157:H7 laboratory testing methods:
 - AOAC 2002.14, FDA BAM Chapter 4a, BAX O157:H7, ISO 16654:2001, AOAC 996.09, AOAC 2000.13, and AOAC 996.10.

5. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of U.S. 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 PR/HACCP regulations.
- The Poultry Products Inspection Act (21 U.S.C. 451 et seq.) and the Poultry Products Inspection Regulations (9 CFR, Part 381)

6. SUMMARY OF THE PREVIOUS TWO FSIS AUDITS

Final audit reports are available on FSIS' website at:
http://www.fsis.usda.gov/regulations/Foreign_Audit_Reports/index.asp.

August-September 2007

Eight establishments and one regional office were audited; there were no delistments or Notices of Intent to Delist (NOIDs). The following deficiencies were reported:

- Deficiencies that should have been identified in advance by AQIS were reported in six of the eight establishments audited.
- No establishments were delisted and none received a NOID.

¹ "MPSC" is not an acronym, but rather the name of the company producing the product.

- SSOP deficiencies were reported in five establishments.
- Deficiencies regarding HACCP programs were reported in three of the six establishments in which they were required.

- Deficiencies regarding Sanitation Performance Standards were reported in three of the six establishments in which they were required.
- In one of the six establishments in which slaughter was conducted, the lighting at two post-mortem inspection stations was inadequate.
- No ready-to-eat (RTE) products were being produced in any of the establishments audited, so testing for *Listeria monocytogenes* was not required in these establishments. The FSIS auditor determined, however, that in other establishments producing RTE products that were eligible for export to the US, establishment personnel were continuing (under AQIS supervision) the practices of performing the sampling and packaging of samples to be tested for *Listeria monocytogenes* (and *E. coli* O157:H7) and submitting them to private laboratories for analysis, although no request for an equivalence determination regarding these alternative procedures had as yet been submitted to FSIS' International Equivalence Staff (IES). Since these are regulatory sampling programs, and no equivalence determination had been granted, these functions were required to be performed by AQIS inspection personnel and the samples tested in government laboratories. This was a repeat deficiency from the previous FSIS audit in August 2006.
- In one microbiology laboratory, the temperature of the incubator in which samples of U.S.-eligible product were incubated was not being recorded daily, as required, although a quality-control check sheet indicated that all controls were being adequately met.

August 2006

Ten establishments, two regional offices, and two microbiology laboratories were audited; there were no delistments and one NOID. The following deficiencies were reported:

- One establishment received a NOID for non-compliance with the requirements for the zero-tolerance policy for visible contamination with ingesta or feces. Corrective actions were taken within thirty days of receiving the NOID.
- Deficiencies regarding enforcement of U.S. requirements were found in four of the 10 establishments audited.
- Sampling, packaging, and submission of RTE samples for *Listeria monocytogenes* and *E. coli* O157:H7 were being performed by establishment personnel rather than by AQIS personnel.
- In one of the nine establishments in which slaughter was conducted, spinal cords were not being removed until after the final inspection station.
- Deficiencies regarding SSOP implementation were identified in three of the 10 establishments audited.
- Deficiencies regarding Sanitation Performance Standards were identified in four of the nine establishments in which they were required.
- Deficiencies regarding HACCP implementation were identified in two of the nine establishments in which they were required.

7. MAIN FINDINGS

7.1 Government Oversight

All official veterinarians and inspectors assigned to traditional establishments certified by AQIS to export meat and meat products to the United States are official Australian government employees, receiving no remuneration from either industry or establishment personnel. The sole exception to this is Est. 80, which directly employs Meat Safety Inspectors for post-mortem inspection duties under the recently-approved alternative equivalent MSEP/AGSEMP program.

AQIS incorporates various levels of government oversight as part of its role in managing its export meat program. In addition to the in-plant verification role by the AQIS inspection team, AQIS employs Area Technical Managers (ATMs) to conduct routine supervisory audits and Field Operation Managers (FOMs) to conduct in-depth audits as means to help to ensure compliance with importing country requirements. In addition, AQIS has a Verification Unit (VU), which is independent of daily inspection activities, to verify national system compliance. This VU answers to an executive management group comprised of senior executive officers of the various export branches. The VU audits particular elements or activities within the system as a whole, across a number of establishments. The frequency of the VU audits of the elements varies according to each one's importance in the system. Some may be done at least annually, whereas others may be performed every two or three years. The VU reports its results to the Executive Management Group and the Program Management. Program Management reviews the recommendations and implements corrective actions. The FOMs and the VU perform additional reviews as needed. In the event of a suspected deliberate legal breach, the Compliance and Investigations Unit investigates.

AQIS has implemented a National Establishment Verification System (NEVS), which provides an integrated, consistent, auditable record of both establishment-management and AQIS monitoring and verification activities in all export establishments. NEVS tracks the status of Corrective Action Requests and company corrective actions and preventive measures and forms the basis for formal, regulatory communications between AQIS and export plant company management.

7.1.1 CCA Control Systems

AQIS has the organizational structure and staffing to assure uniform implementation of the U.S. import inspection requirements.

The Regional Offices manage the administration of staffing, resources, finances, budget, day-to-day operational issues, and export certification, and uphold the Meat Inspection Staffing Standard, which matches inspection staffing to needs according to line speeds, daily kill volumes, etc. The Central Office in Canberra covers all the above on a national basis to ensure consistent national application, and also manages the national meat program budget, the technical integrity of the regulatory systems through the FOMs and

ATMs, training programs, and national surveillance programs, such as the national residue testing plan and tuberculosis surveillance.

AQIS uses an interactive computer program called Electronic Legislation Manuals and Essential Requirements (ELMER3), which provides essential information, including US import inspection requirements, to inspection personnel. ELMER3 is accessible by in-plant inspection staff in certified establishments and is managed by the Meat Program Manager and respective staff.

7.1.2 Ultimate Control and Supervision

AQIS has the ultimate legal control over and supervision of the official activities associated with the exports of meat products to the US.

On-Plant Veterinarians (OPVs) supervise meat inspectors daily and send reports to the ATMs weekly. ATMs review the on-plant performance of OPVs monthly. The FOMs meet with the ATMs regularly, either face-to-face or via telephone, usually monthly.

Establishment noncompliance is usually managed through NEVS (see Section 6.1). If warranted, establishments may be entered into a "Scheme for Corrective Action" or sanctions may be applied, such as suspension of parts or all of Approved Arrangements operations or of operations, up to full delistment, deregistration and criminal prosecution.

7.1.3 Assignment of Competent, Qualified Inspectors

7.1.3.1 Employment

Official veterinarians and inspectors in the traditional establishments certified as eligible to export to the US are employed by AQIS either as permanent or contract employees. Permanent inspectors are assigned to most establishments by the regional offices; at other establishments or for seasonal shifts, inspection personnel are provided from a pool of contracted (part-time) personnel; relief is also provided from this pool. In both cases, they are official government employees having the authority and the responsibility to carry out official AQIS inspection requirements. All AQIS employees are required to sign conflict-of-interest statements when they are hired and when their contracts come up for annual renewal. They are required by law (under the Australian Public Service Act) to report any actual or implied conflict of interest to their supervisors. Also, each "contractor" veterinarian and inspector has a clause in his/her contract specifically dealing with real or perceived conflict-of-interest prevention. Veterinarians with large-animal practices are not offered contracts for the pool of available alternate staff.

One establishment directly employs Meat Safety Inspectors for post-mortem inspection duties under the newly-approved alternative equivalent MSEP/AGSEMP. These MSEP inspectors are authorized officers under the Export Control Act of 1982 with powers to make disposition decisions and to take enforcement actions. Post-mortem inspection performance is verified by the AQIS Meat Safety Inspector at the end of the chain and also by the OPV.

7.1.3.2 Training

AQIS has implemented various training programs for its inspection personnel, which include induction training for all newly hired veterinarians and meat inspectors and ongoing training for OPVs and Senior Meat Inspectors. Induction training, which includes AQIS inspection requirements, must be successfully completed before trainees become authorized officers.

Ongoing training includes developmental seminars given in a class-room environment and in-plant (hands-on) training. The ATMs and FOMs identify the field officials who are in need of training and who will attend the training sessions. The policy of training is set centrally; recruitment and practical delivery are done regionally.

The responsibility for ensuring that field inspection personnel maintain up-to-date working knowledge of FSIS requirements lies with the Export Meat Program Manager, and is a Central Office function. Mechanisms to achieve this end include the following:

- The Animal Products Market Access Branch distributes “Market Access Advices” to inspection personnel, establishments and industry.
- A data base called “Volume 2” on the AQIS intranet carries all requirements and is updated constantly.
- AQIS Meat Notices in electronic format are provided to field personnel.
- Teleconferences are held between headquarters and the field (2-3 per year per State/Territory).
- There is a program of On-Plant-Vet Professional Development Weekends, 14 per year in the country and twice per year in each State/Territory (four times per year in the Queensland Regional Office in Brisbane because of the larger number of OPVs).
- All Senior Meat Inspectors attend an annual, three-day “Senior Meat Inspector Leadership Conference,” in which information similar to that which is provided to OPVs is disseminated, including summaries of recent third-party audit results. The Senior Meat Inspectors also attend one of the two OPV professional development weekends to update their skills and promote the AQIS plant management team approach to oversight.

AQIS uses ELMER3 as a tool to provide training modules and competency verification for the OPVs. Such training is required to be conducted within a specified time frame and is monitored by the ATMs. AQIS also provides instructional material (standard operating procedures and work instructions, etc.) through ELMER3 and an Instructional

Material Library that can be accessed by all staff. In addition, there is a “Meat Inspector Step-Up” training program, which gives the opportunity for on-line meat inspectors to develop the knowledge and skills to step up into more senior positions.

7.1.4 Authority and Responsibility to Enforce the Laws

The *Export Control Act of 1982* and applicable regulations give AQIS the authority and responsibility to enforce Australia’s meat inspection laws, including meat and meat products produced for export to the US. From this law, AQIS has implemented regulations to enforce the FSIS inspection requirements.

7.1.5 Adequate Administrative and Technical Support

AQIS maintains a program designed to increase direct oversight and involvement in the conduct of the microbiology testing programs that support the export of meat products to the United States. In addition, AQIS has a Memorandum of Understanding with the National Residue Survey as a means to ensure adequate oversight and involvement in the conduct of residue testing programs that support the export of meat products to the US.

A list of FSIS-approved methods and alternative methods for which an equivalence determination has been provided is maintained in ELMER 3 and the use of these tests is verified during the above-described audits, and no deviations are accepted.

AQIS also has a Deed of Agreement with the National Association of Testing Authorities (NATA), according to which all labs that test US-eligible product must be NATA-accredited for those regulatory tests. All labs must be AQIS-approved and must agree to independent audits by NATA and AQIS as well as joint NATA/AQIS audits. NATA provides its (annual) reports directly to the Senior Principal Scientist (Microbiologist). NATA must provide details of any serious non-compliance to AQIS immediately. The Principal Scientist also accompanies NATA on reviews and conducts his own independent reviews.

7.2 Headquarters Audit

The auditor conducted a review of inspection system documents at the headquarters and regional offices, and also in inspection offices in the audited establishments. These document reviews focused primarily on food safety hazards and included the following:

- Internal review reports
- Supervisory visits to establishments that were certified to export to the US
- New laws and implementation documents such as regulations, notices, directives and guidelines
- Sanitation, slaughter and processing inspection procedures and standards

- Export product inspection and control including export certificates
- Enforcement records, including examples of seizure and control of non-compliant product, and withholding and suspending export eligibility of an establishment that is certified to export product to the US

No deficiencies arose as a result the examination of these documents.

7.2.1 Audits of Regional and Local Inspection Sites

The FSIS auditor reviewed government oversight and enforcement activities at AQIS' regional office in Adelaide, South Australia, and in the inspection offices of the seven establishments audited.

8. ESTABLISHMENT AUDITS

Seven slaughter-and-processing establishments certified by the government of Australia as eligible to export to the US were audited. No establishment was issued a NOID and none was delisted.

9. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

No residue or microbiology laboratories were audited. The National Residue Testing Plan for 2008 was on schedule.

10. SANITATION CONTROLS

As stated earlier, the FSIS auditors focused on five areas of risk to assess Australia's meat inspection system. The first of these risk areas that the FSIS auditor reviewed was Sanitation Controls.

Based on the on-site audits of establishments, and except as noted below, Australia's inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene practices, and good product handling and storage practices.

In addition, Australia's inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

10.1 Sanitation Standard Operating Procedures

Each of the establishments audited was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program. The SSOP in all seven establishments were found to meet the basic FSIS regulatory requirements, with some exceptions. Some SSOP requirements were not adequately enforced in three of these seven establishments:

- In three establishments, documentation of corrective actions taken in response to some deficiencies identified during pre-operational sanitation inspection did not include adequate documentation of preventive measures. During the previous FSIS audit, this deficiency was reported in five of the eight establishments audited.

10.2 Sanitation Performance Standards

Sanitation Performance Standards in all establishments were found to meet the basic FSIS regulatory requirements, with some exceptions. Some requirements were not adequately enforced in three of the seven establishments audited:

- In two establishments, cleaning chemicals were stored under insanitary conditions. During the previous FSIS audit, this deficiency was reported in one of the eight establishments audited.

11. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, humane handling and humane slaughter, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that Australia's inspection system had adequate controls in place.

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit.

12. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. The controls include the following areas: Ingredients identification; control of restricted ingredients; formulations; processing schedules; equipment and records; and processing controls of cured, dried, and cooked products.

The controls also included the implementation of HACCP systems in the six establishments in which they were required and implementation of generic *E. coli* testing programs in the slaughter establishments.

12.1 Humane Handling and Humane Slaughter

No deficiencies were reported.

12.2 HACCP Implementation

All slaughter and processing establishments certified to export meat products to the US are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the U.S. domestic inspection program.

The HACCP programs were reviewed during the on-site audits of the seven establishments.

Deficiencies regarding HACCP implementation were found in four of the seven establishments audited. These were:

- In one establishment, written corrective actions to be taken when critical limits were exceeded did not include reinspection of product back to the last acceptable monitoring check. This was reported in one establishment during the previous FSIS audit.
- In one establishment, the verification procedures in the HACCP plan did not contain an adequate description of the requirement for direct observation of the monitoring procedures.
- In two establishments, the documentation of the verification of monitoring did not contain the actual times when the verification procedures were performed. This was reported in one establishment during the previous FSIS audit.
- In one establishment, the verification of the monitoring and the pre-shipment document review were both being performed by the same person.
- In one establishment, the times when the pre-shipment reviews were being performed were not recorded.

12.3 Testing for Generic *E. coli*

Australia has developed an alternative program for testing for generic *E. coli* that has been recognized as equivalent by FSIS. The details of this program are provided in Section 3 of this report.

All of the seven establishments audited were required to meet the regulatory requirements for the alternative generic *E. coli* testing program and were evaluated according to the criteria set out in this program.

No deficiencies were reported.

12.4 Testing for *Listeria monocytogenes*

No RTE products were being produced in any of the establishments audited, so testing for *Listeria monocytogenes* was not required in these establishments.

13. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviewed was Residue Control records. Australia's residue program is controlled by the government's National Residue Survey, which is part of the Ministry of Agriculture, Fisheries, and Forestry, and separate from AQIS.

No residue laboratories were included in this audit. The residue controls at the establishment level were audited and found to be in compliance with FSIS requirements.

Documentation was provided at the headquarters level that the National Residue Testing Plan was on schedule.

14. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviewed was Enforcement Controls. These controls included the enforcement of inspection requirements such as required inspection coverage and the testing programs for *Salmonella* and species verification.

- Deficiencies that should have been identified in advance by AQIS and corrected prior to this audit were reported in six of the seven establishments audited.

14.1 Daily Inspection in Establishments

Inspection was being conducted daily in all of the seven establishments audited.

14.2 Testing for *Salmonella* species

Australia has adopted the FSIS requirements for testing for *Salmonella* with the exception of the following equivalent measures:

1. Establishment employees collect the samples.
2. Private laboratories analyze the samples.
3. Year-round, continuous sampling is conducted.
4. For every *Salmonella*-positive test result, a corrective action is required where a cause can be identified.

All of the seven establishments audited were required to meet the basic FSIS regulatory requirements and the equivalent measures for *Salmonella* testing and were evaluated according to the criteria employed in the U.S. domestic inspection program and those recognized by FSIS as equivalent.

Testing for *Salmonella* was properly conducted in all six establishments.

14.3 Species Verification

Species verification was being conducted in those establishments in which it was required.

14.4 Periodic Supervisory Reviews

During this audit, it was found that in all establishments visited, supervisory reviews of certified establishments were being performed and documented as required.

14.5 Inspection System Controls

The CCA had controls in place for ante-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the US with product intended for the domestic market.

There were two areas of concern:

- In one establishment, the AQIS inspector performing post-mortem inspection of the beef lungs was not routinely incising and observing the left tracheobronchial lymph nodes.
- In each of three establishments, lighting on some inspection surfaces at one post-mortem inspection station was inadequate. During the previous FSIS audit, lighting at two post-mortem inspection stations was inadequate in one establishment.

In addition, controls were in place for the importation of only eligible meat products (from New Zealand) for further processing (into beef jerky).

Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources. All product transferred from an export facility to another establishment is accompanied by a (numbered) AQIS Meat Transfer Certificate. Products transferred to the ports for export are sealed with bolt seals that may be broken only with bolt cutters.

15. CLOSING MEETING

A closing meeting was held on September 1, 2008, in Canberra with the CCA. At this meeting, the primary findings were presented by the auditor.

The CCA understood and accepted the findings.

Gary D. Bolstad, DVM

G. D. Bolstad 12/10/08

15. ATTACHMENTS

- Individual Foreign Establishment Audit Forms
- Foreign Country Response to Draft Final Audit Report

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Nolan Meats Pty Ltd 88 East Deep Creek Rd. Gympie, QLD	2. AUDIT DATE August 15,	3. ESTABLISHMENT NO. 0080	4. NAME OF COUNTRY Australia
	5. NAME OF AUDITOR(S) Gary D. Bolstad, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

Establishment # 80, Nolan Meats Pty. Ltd.; Gympie, QLD, Australia; bovine slaughter; beef cutting, boning, and freezing

There were no significant findings to report after consideration of the nature, extent, and degree of all observations.

61. NAME OF AUDITOR
Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION John Dee Warwick Proprietary Limited Rosehill Road Warwick, QLD 4370	2. AUDIT DATE 08/11/2008	3. ESTABLISHMENT NO. 243	4. NAME OF COUNTRY Australia
5. NAME OF AUDITOR(S) Gary D. Bolstad, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

60. Observation of the Establishment

Date: 08/11/2008 Est #: 243 (John Dee Warwick Proprietary Limited [S/P/CS]) (Warwick, Australia)

40/51. US regulations require 50 foot-candles (fc) (equivalent to 550 lux) of shadow-free light at inspection surfaces. Light intensity as low as 12 fc (132 lux) was measured on the anterior portion of beef carcasses at the inspection station. AQIS ordered prompt correction; additional light providing adequate intensity was installed before the end of the day. [Regulatory reference(s): 9 CFR §307.2(m), 327(a)(2)(i)(D)]

61. NAME OF AUDITOR

Gary D. Bilstad, DVM

62. AUDITOR SIGNATURE AND DATE



12/10/08

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Southern Queensland Exporters Pty Ltd Longs Lane Wallangarra, QLD 4383	2. AUDIT DATE Aug. 11, 2008	3. ESTABLISHMENT NO. 344	4. NAME OF COUNTRY Australia
	5. NAME OF AUDITOR(S) Dr. Gary D. Bolstad		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

Est. 344, Southern Queensland Exporters Pty Ltd Wallangarra, QLD; mutton/lamb/goat slaughter/processing

- 13/51 Documentation of corrective actions taken in response to some deficiencies identified during pre-operational sanitation inspection did not include preventive measures. The AQIS officials ordered immediate correction. [Regulatory references: 9CFR §416.15(b) and 416.17]
- 16/51 The verification procedures in the HACCP plan did not contain an adequate description of the requirement for direct observation of the monitoring procedures. The documentation of the verification of monitoring did not contain the actual times when the verification procedures were performed. The AQIS officials ordered prompt correction. [9CFR §417.5(b) and 417.8]
- 46/51 Cleaning compounds and pesticides were stored under insanitary conditions in unsealed outside cages in which neglected housekeeping was evident. The AQIS officials ordered prompt correction. [9CFR §416.4(c), 416.15]

NOTE: The establishment was not operating on the day of the audit, due to lack of stock; maintenance was being performed.

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE

G.D. Bolstad 12/18/08

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Swift Australia (Southern) Pty Ltd Yarrowonga Abattoir, Hicks Road Yarrowonga, VIC 3730	2. AUDIT DATE 08/25/2008	3. ESTABLISHMENT NO. 383	4. NAME OF COUNTRY Australia
	5. NAME OF AUDITOR(S) Gary D. Bolstad, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

Date: 08/25/2008 Est #: 383 (Swift Australia (Southern) Pty Ltd [S/P/CS]) (Yarrawonga, Australia)

12/51. The documented corrective actions taken for pre-operational sanitation deficiencies did not include adequate documentation of preventive measures. The AQIS officials ordered prompt correction. [Regulatory reference(s): 9 CFR §327(a)(2)(i)(D), 416.15, 416.17]

40/51. FSIS requires 50 foot-candles (fc) (equivalent to approximately 550 Lux) of shadow-free lighting at inspection surfaces. Light intensity of only 14 fc (155 Lux) was measured on the anterior aspect of the beef forequarters (in the area of the pre-scapular lymph nodes) at the carcass inspection station. The AQIS officials ordered immediate correction; the line was stopped and additional temporary lighting that provided the required illumination was provided before the operation was allowed to resume, and the establishment management provided assurances that a permanent solution would be provided promptly. [9 CFR §307.2(m), 327(a)(2)(i)(D)]

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE

 12/15/08

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Teys Bros (Naracoorte) Propriety Limited Hynam Road Naracoorte 5271	2. AUDIT DATE 08/22/2008	3. ESTABLISHMENT NO. 423	4. NAME OF COUNTRY Australia
5. NAME OF AUDITOR(S) Gary D. Bolstad, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

60. Observation of the Establishment

Date: 08/22/2008 Est #: 423 (Teys Bros (Naracoorte) Propriety Limited [S/P/CS]) (Naracoorte, Australia)

12/51. Most documented corrective actions taken for pre-operational sanitation deficiencies did not include preventive measures. The AQIS officials ordered prompt correction. [Regulatory reference(s): 9 CFR §327(a)(2)(i)(D), 416.15, 416.17]

22/20/51. The corrective actions cited in the written HACCP plan, to be taken in the event that Critical Limits for the CCP for zero tolerance for visible contamination with feces, ingesta, or milk, did not include reinspection of the product back to the last acceptable monitoring check. The AQIS officials ordered prompt correction. [9 CFR §327(a)(2)(i)(D), 417.3(a)(b)(c), 417.8]

39/51. Cleaning chemicals, hand soap, and pesticides were stored under insanitary conditions in an unsealed cage in which housekeeping had been neglected. The AQIS officials ordered prompt correction. [9 CFR §327(a)(2)(i)(D), 416.17, 416.2(b)]

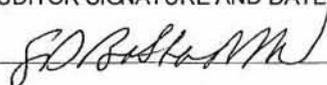
40/51. FSIS requires 50 foot-candles (fc) (equal to 550 Lux) of shadow-free light at inspection surfaces. Light intensity of only 30 fc (330 Lux) was available on the inspection surfaces of the medial masseter muscles in beef heads. AQIS ordered immediate correction; additional light that provided the required illumination was provided before the audit was concluded. [9 CFR §307.2(m), 327(a)(2)(i)(D)]

55. The AQIS inspector performing post-mortem inspection of the beef lungs was not routinely incising and observing the left tracheobronchial lymph nodes. The On-Plant Veterinarian corrected this immediately. [9 CFR §310.1]

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE

 12/10/08

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Harvey Industries Group PTY LTD Seventh Street Harvey, WA 6220	2. AUDIT DATE 08/18/2008	3. ESTABLISHMENT NO. 648	4. NAME OF COUNTRY Australia
	5. NAME OF AUDITOR(S) Gary D. Bolstad, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

Date: 08/18/2008 Est #: 648 (Harvey Industries Group PTY LTD [S/P/CS]) (Harvey, Australia)

22/51 The documentation of verification of the monitoring of the Critical Control Points did not contain the actual times when the verification activities were performed. The AQIS officials ordered immediate correction. [Regulatory reference(s): 9 CFR §327(a)(2)(i)(D), 417.5, 417.8]

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE

G. D. Bolstad 10/10/08

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Tabro Meat Propriety Limited 2140 Korumburra-Wonthaggi Road Lance Creek, VIC 3995	2. AUDIT DATE 08/27/2008	3. ESTABLISHMENT NO. 1912	4. NAME OF COUNTRY Australia
	5. NAME OF AUDITOR(S) Gary D. Bolstad, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

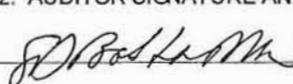
Date: 08/27/2008 Est #: 1912 (Tabro Meat Propriety Limited [S/P/CS]) (Lance Creek, Australia)

19/51. The verification of the monitoring and the pre-shipment document review were both being performed by the same person. Also, the times when the pre-shipment reviews were being performed were not recorded. The AQIS officials ordered prompt correction. [Regulatory reference(s): 9 CFR §327(a)(2)(i)(D), 417.2(c)(7), 417.5(c), 417.8]

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE

 12/18/08



Australian Government

Australian Quarantine and Inspection Service

Mr Donald Smart
Director
International Audit Staff
Office of International Affairs
Food Safety and Inspection Service
Washington DC 20250

Dear Mr Smart

Thank you for your letter of 7 October 2008 accompanying the draft final report of the Food Safety Inspection Service (FSIS) audit of Australia's meat inspection system from 7 August through 1 September 2008. The Australian Quarantine and Inspection Service (AQIS) values the constructive working relationship that exists between our two countries and we appreciate the work of the auditor in completing the audit and providing the draft report in such a timely manner.

We note that on the first page of the individual establishment results, that FSIS lists the establishment number as no.80, while the establishment name is Harvey Industry Group Pty Ltd. Establishment no.80 is actually Nolan Meats Pty Ltd, located at 88 East Deep Creek Rd, Gympie, Queensland, 4570 and AQIS believes that this first individual establishment report is with reference to Nolan Meats rather than Harvey Industry Group. We note that the draft report contains a separate individual establishment report for Harvey Industry Group.

We have two minor comments to add for further clarification.

- On page 7 the second last dot point on the Meat Safety Enhancement Program (MSEP) states that "one government veterinarian performing PM carcass by carcass inspection". We believe this should read as a "AQIS Meat Inspector" instead of "government veterinarian".
- On page 13, the third dot point reads - "AMNs both in electronic and also hard copy form are provided to field personnel". This is not correct, as hard copy versions of AQIS Meat Notices are no longer provided to field personnel.

AQIS continues to ensure that the performance of establishment based staff is acceptable in relation to regulation and enforcement activities. AQIS is appreciative of the opportunity to respond to this audit report and takes the findings very seriously.

Deficiencies noted by the FSIS auditor in individual establishments have been addressed. Attached for your consideration is a summary of the corrective actions and preventative measures undertaken to address deficiencies identified at individual establishments.

I would like to take this opportunity to thank you and the FSIS staff involved in the audit process, and we look forward to demonstrating the quality and integrity of our inspection and food safety systems in future audits.

Regards,

A handwritten signature in black ink, appearing to read 'Greg Read', is written over the typed name. The signature is stylized and includes a large, sweeping flourish that extends to the right.

Greg Read
Executive Manager
Exports Division
Australian Quarantine and Inspection Service

5 December 2008