

United States Department of Agriculture Food Safety and Inspection Service Washington, D.C. 20250

FEB - 6 2008

Mr. Greg Read Executive Manager, Exports and Food Policy Australian Quarantine and Inspection Service (AQIS) Department of Agriculture, Fisheries, and Forestry Edmund Barton Building GPO Box 858 Canberra ACT 2601 Australia

Dear Mr. Read,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Australia's meat and ratite inspection system August 22 through September 20, 2007. Comments received from the government of Australia have been included as an attachment to the final report. Enclosed is a copy of the final audit report.

We have noted that two of the issues mentioned in the final audit report were not addressed in the comments FSIS received from the government of Australia:

1. One of the issues identified during the FSIS audit of Australia's inspection system conducted in August 2006 (please refer to Section 6.1.2. of the country report from that audit and slide number 11 in the entrance conference presentation from August 23, 2007) was that establishment personnel were 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. The country report from August 2006 further stated that, since these are regulatory sampling programs, the functions shall be performed by AQIS inspection personnel and the samples tested in government laboratories.

Information provided by AQIS confirmed that establishment personnel were continuing to sample, package, and submit for analysis the samples for *Listeria monocytogenes* and *E. coli* O157:H7, although the International Equivalence Staff (IES) of the Office of International Affairs has not deemed these alternate procedures to be equivalent, nor has IES received a request from AQIS for an equivalence determination; therefore, FSIS considers this deficiency from the previous audit unresolved, and so it remains a continuing issue for the 2007 audit; we are satisfied that all other concerns from the 2006 audit have been adequately addressed and corrected.

Until such time as AQIS submits a request for an equivalence determination and the Equivalence Staff has determined that these alternate procedures are equivalent, FSIS expects these functions to be performed by AQIS personnel and the samples to be analyzed in government laboratories.

2. In the EML microbiology laboratory, temperatures for incubators were not reliably recorded daily as required according to the written QC program (only five entries had been made for the month of August); further, the corresponding monthly check sheets had been initialed, indicating that the daily checks had been made and were in compliance.

If you have any questions or need additional information, please contact me at telephone number (202) 690-5646, by facsimile at (202) 720-0676, or by electronic mail at donald.smart@fsis.usda.gov.

Sincerely,

Manzov H Chandrey Donald Smart

Director International Audit Staff Office of International Affairs

Enclosure

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

August 22 through September 20, 2007

Food Safety and Inspection Service United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

ATM	Area Technical Manager
AQIS	Australian Quarantine & Inspection Service
CCA	Central Competent Authority - (AQIS for this report)
ССР	Critical Control Point
CFR	U.S. Code of Federal Regulations
E. coli	Escherichia coli
ELMER	E-Legislation Manuals and Essential References
FOM	Field Operations Manager
FSIS	Food Safety and Inspection Service
IES	International Equivalence Staff
MOU	Memorandum of Understanding
MSQA	Meat Safety Quality Assurance
NATA	National Association of Testing Authorities
NOID	Notice of Intent to Delist
OPV	On-Plant Veterinarian
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
RTE	Ready-to-Eat
Salmonella	Salmonella species
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 the Australian meat inspection system August 22 through September 20, 2007.

An opening meeting was held on August 22, 2007, 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' headquarters and/or representatives from AQIS' regional and local inspection offices accompanied the auditor during each audit activity.

2. OBJECTIVE OF THE AUDIT

The objective was to (1) determine whether the concerns identified during the 2006 audit had been appropriately addressed, and (2) 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 special emphasis regarding the CCA's oversight of slaughter establishments' implementation of controls to prevent contamination of carcasses with feces or ingesta and knowledge and application of the FSIS regulatory requirements.

In pursuit of the objective, the following were visited:

Competent Authority Visits			Comments
Competent Authority (Interviews with AQIS	Central	1	Canberra
Officials)	Regional Offices	2	Queensland and Victoria
	Local Office	8	Establishments/Cold Storage Facilities
Laboratories (Microbiology)		2	
Meat Slaughter / Processing Establishments			
ID Warehouses		2	

3. PROTOCOL

This on-site audit was conducted in four 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 regional offices. The third part involved on-site visits to eight establishments: Six slaughter and processing establishments and two ID Warehouses. The fourth part involved visits to two private laboratories certified by AQIS to conduct microbiological testing of meat products destined for the United States. 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 SSOP, (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of Hazard Analysis/Critical Control Point (HACCP) programs and a testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including 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 United States, and (3) FSIS equivalence determinations specific to Australia. FSIS requirements include, among other things, daily inspection in all applicable certified establishments, monthly 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:

- 1. Establishment employees collect carcass samples for *Salmonella* testing, and private laboratories analyze samples collected for *Salmonella* species. Year-round, continuous sampling is conducted.
- 2. Equines for Australia's domestic market may be slaughtered in the same establishment (Est. 3416) in which bovines are slaughtered for export to the United States.
- 3. The use of the MPSC rinse and chill technique is allowed on bovines slaughtered in establishments certified to export to the United States.

- 4. Australia is allowed to export meat to the United States from sheep and swine carcasses whereby post-mortem inspection is conducted without examination of the heads. (This is permitted only when tissue from the heads was not saved for human consumption.)
- 5. The following laboratory testing methods are allowed for the detection of generic *E. coli*: AOAC 998.08, AOAC 991.14, and AS 5013.15-2004.
- 6. The following laboratory testing methods are allowed for the detection of *E. coli* O157:H7: AOAC 2000.14, FDA BAM Chapter 4A (Sept 2002 protocol), *E. coli* O157:H7 BAX 0157:H7, AOAC 996.09, AOAC 996.10, AOAC 2000.13, and ISO 16654:2001.
- 7. The following laboratory testing methods are allowed for the detection of *Salmonella*: AOAC 978.24, AOAC 989.14, AOAC 992.11, 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, and AOAC 5013.10-2004.
- 8. The following laboratory testing methods are allowed for the detection of *Listeria monocytogenes:* AOAC 995.22, AOAC 997.03, AOAC 999.06, AOAC 996.14, AOAC 2002.09, AS 1766.2.16.1998, FDA BAM Chapter 10 (January 2003), and BAX *Lm*.
- 4. 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.
- 5. SUMMARY OF PREVIOUS AUDITS

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

The following concerns were identified during the last two FSIS audits of Australia's meat inspection system:

August 2006

- Deficiencies regarding enforcement of U.S. requirements were found in four of the 10 establishments audited.
- 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.

- Sampling, packaging, and submission of ready-to eat samples for *Listeria monocytogenes* and *Escherichia coli* (*E.coli*) O157:H7 were being performed by establishment personnel rather than by AQIS personnel.
- In one establishment, 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 establishments.
- Deficiencies regarding HACCP implementation were identified in two establishments.

<u>May 2005</u>

- Deficiencies regarding enforcement of U.S. requirements were found in 11 of the 19 establishments audited.
- One establishment was delisted for non-compliance with requirements for effective food safety and sanitation procedures and a history of non-compliance resulting from the previous (June 2004) audit. This establishment was relisted following corrective actions.
- One establishment received a Notice of Intent to Delist (NOID) for non-compliance with requirements for effective food safety and sanitation procedures. Corrective actions were taken within thirty days of receiving the NOID.
- Laboratories were using some non-FSIS approved testing methods for the detection of pathogens and residues.
- Samples of incorrect size (25 grams) were used for the detection of *Salmonella* species in ready-to-eat products.
- Oversight by AQIS of laboratories conducting microbiological and chemical testing of meat products being exported to the United States was inadequate.
- Deficiencies regarding SSOP implementation were found in 11 of the 19 establishments audited.
- Deficiencies regarding Sanitation Performance Standards were identified in 7 establishments.
- Deficiencies regarding HACCP implementation were identified in two establishments.
- The frequency of inspection by AQIS of cold stores handling US-eligible product was inadequate.
- Sampling, packaging, and submission of samples of ready-to-eat products for *Lm* were being performed by establishment personnel and the samples were being analyzed in private laboratories.

6. MAIN FINDINGS

6.1 Government Oversight

All official veterinarians and inspectors assigned to 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.

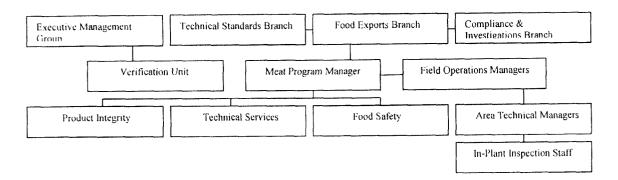
AQIS utilizes various levels of government oversight as part of its role in managing its export meat program. In addition to the in-plant verification role by the AQIS inspection tcam, AQIS employs Area Technical Managers (ATMs) to conduct routine supervisory audits and Field Operation Managers (FOMs) to conduct in-depth audits as means to help assure compliance with importing country requirements. In addition, AQIS has a Verification Unit, which is independent of daily inspection activities, to address specific non-compliance or potential non-compliance issues. This Verification Unit now answers to an executive management group comprised of senior executive officers of the various export branches; before, the Unit answered only to the Executive Manager of Exports. Since the previous FSIS audit, the Verification Unit has begun a program of audits of particular elements or activities within the system as a whole, across a number of establishments, whereas previously there was more concentration on single-establishment systems from the sourcing of stock to the consignment to export, which duplicated other establishment assessment controls. 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 Verification Unit reports its results to the Executive Management Group and the Program Management: Program Management then reviews the recommendations and implements corrective actions.

6.1.1 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 Field Operations Managers (FOMs) and Area Technical Managers (ATMs), training programs, and national surveillance programs, such as the national residue testing plan and tuberculosis surveillance.

The Verification Unit now answers to an executive management group, comprised of senior executive officers of the various export branches; previously, the Unit answered only to the Executive Manager of Exports.



AQIS utilizes an interactive computer program called ELMER 3 as an essential tool in providing essential information, including US import inspection requirements, to inspection personnel. ELMER 3 is accessible by in-plant inspection staff in certified establishments and is managed by the Meat Program Manager and respective staff.

6.1.2 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 United States.

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

Establishment noncompliance is usually managed through the National Establishment Verification System (previously the National Plant Monitoring System). If warranted, establishments may be entered into a "Scheme for Corrective Actions" 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.

AQIS had satisfactorily addressed and corrected all of the FSIS 2006 audit concerns, with one exception: Establishment employees were continuing the practice of sampling and packaging samples of ready-to-eat (RTE) product and submitting them to private laboratorics for analysis, although no equivalence determination had been granted by the International Equivalence Staff for these alternative practices.

With regard to the 2006 FSIS audit issue concerning contamination of product with ingesta, extensive effort has been completed to improve the establishments' monitoring and verification programs, as well as oversight of those programs by field inspection personnel and their supervisors.

6.1.3 Assignment of Competent, Qualified Inspectors

6.1.3.1 Employment

Official veterinarians and inspectors are employed by AQIS either as permanent or contract employees. Permanent inspectors are assigned to most establishments by 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 to report any actual or implied conflict of interest to their supervisors. Veterinarians with large-animal practices are not offered contracts for the pool of available alternate staff.

6.1.3.2 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 Meat Inspection Division Operations Coordinator, and is a Central Office function.

- 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, both in electronic and also hard-copy form, 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 ELMER 3 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.

6.1.4 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 United States. From this law, AQIS has implemented regulations to enforce the FSIS inspection requirements.

6.1.5 Adequate Administrative and Technical Support

AQIS has implemented 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 signed 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 United States.

6.2 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 records 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 United States
- 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 criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States

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

6.2.1 Audits of Regional and Local Inspection Sites

The FSIS auditor reviewed government oversight and enforcement activities at AQIS' regional offices in Brisbane, Queensland, and Melbourne, Victoria, and in the inspection offices of the six slaughter/processing establishments audited.

7. ESTABLISHMENT AUDITS

Eight establishments certified by the government of Australia as eligible to export to the US were audited. This included six slaughter-and-processing establishments and two cold-storage facilities (ID Warehouses). No establishment was issued a NOID and none was delisted.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

No residue laboratories were audited. The audit of laboratories conducting microbiological testing was limited to verification of testing methods used by laboratories and oversight by the AQIS. The following microbiology laboratories were visited:

- The EML Consulting Services Laboratory in Brisbane, Queensland
- The Tasman Laboratory Services in Launceston, Tasmania

One deficiency was identified:

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.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor 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.

9.1 SSOP

Each of the six slaughter/processing establishments 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 six establishments were found to meet the basic FSIS regulatory requirements, with some exceptions. Some SSOP requirements were not adequately enforced in five of these six establishments:

- In one establishment, common contact was observed between beef carcasses and a steel guard, prior to the final inspection station.
- Preventive measures were not included in the documentation of some corrective actions for pre-operational sanitation deficiencies in five establishments, and for operational sanitation deficiencies in three establishments.
- 9.2 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 8 establishments audited:

- In two establishments, maintenance and cleaning of over-product structures had been neglected.
- In one establishment, cleaning chemicals were stored under insanitary conditions.

10. 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.

11. 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.

11.1 Humane Handling and Humane Slaughter

No deficiencies were reported.

11.2 HACCP Implementation

All slaughter and processing establishments certified to export meat products to the United States are required to have developed and adequately implement 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 six slaughter/ processing establishments. The two ID Warehouses were not required to implement HACCP programs.

Deficiencies regarding HACCP implementation were found in four of the six establishments in which they were required. These were:

- In two establishments, the actual times when some of the monitoring checks were performed were not recorded.
- In two establishments, the actual observations made during some of the monitoring activities were not recorded.
- In one establishment, the monitor's initials or signature were not included in the monitoring documentation.
- 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.
- In one establishment, the actual times when the verification procedures were performed were not documented.

11.3 Testing for Generic E. coli

Australia has adopted the generic *E. coli* testing methods that met the PR/HACCP criteria.

Six of the eight establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing and were evaluated according to the criteria employed in the U.S. domestic inspection program.

No deficiencies were reported.

11.4 Testing of Ready-to Eat (RTE) Products for *Listeria monocytogenes* and *E. coli* O157:H7

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 equivalence determination had been granted by the International Audit Staff (IAS) for these alternative procedures; in fact, no request for an equivalence determination regarding these procedures had as yet been received by IAS. Since these are regulatory sampling programs, and no equivalence determination has been granted, these functions are 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,

12. 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 program was on schedule.

13. 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.

13.1 Daily Inspection in Establishments

Inspection was being conducted daily in all of the six slaughter/processing establishments audited.

AQIS reviews of the two cold-store facilities audited were being conducted every three months, at a minimum, as required.

13.2 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.

Six of the eight establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing and were evaluated according to the criteria employed in the U.S. domestic inspection program.

Testing for Salmonella was properly conducted in all six establishments.

13.3 Species Verification

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

13.4 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.

13.5 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 United States with product intended for the domestic market.

There was one area of concern: In one establishment, light at two post-mortem inspection stations was inadequate.

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. Product transferred to the port for export is sealed with bolt seal that may be broken only with bolt cutters.

14. CLOSING MEETING

A closing meeting was held on September 20, 2007, in Canberra with the CCA. At this meeting, the primary findings were presented by the lead auditor.

The CCA understood and accepted the findings.

່ມາ Gary D. Bolstad, DVM

Mangoor H. Chaudry

15. ATTACHMENTS

Individual Foreign Establishment Audit Forms Foreign Country Response to Draft Final Audit Report (when it becomes available)

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United States Department of Agriculture								
Food Safety and Inspection Service								
Foreign Establishment Audit Checklist								
1 ESTABLISHMENT NAME AND LOCATION 2. AUDIT DATE			3 EST	ABLISHMENT NO	4 NAME OF COUNTRY			
Australia Meat Holdings Pty., Ltd.,	Aug. 31, 2007		4		Australia			
Townsville	5. NAME OF AU	DITOR	R(S)		6. TYPE OF AUDIT			
	Dr. Gar	v D. 1	Bols	stad		TAUDIT		
Place an X in the Audit Results block to indi		mpli	iance	•		•		
Part A - Sanitation Standard Operating Procedures (S Basic Requirements		ludit esults	<u> </u>		rt D - Continued momic Sampling	ALICI: Results		
7. Written SSOP			33. S	cheduled Sample				
8 Records documenting implementation,		$ \longrightarrow $	34. 5	Species Testing		ļ		
9 Signed and dated SSOP, by on-site or overall authority.			35. F	lesidue				
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements				Part E -	Other Requirements			
10 Implementation of SSOP's, including monitoring of implement	ation		36 E	xport		1		
11. Maintenance and evaluation of the effectiveness of SSOP's.			37. 1	mport				
 Corrective action when the SSOP's have failed to prevent dire product contamination or adulteration. 	ict .		38 E	stablishment Grounda :	and Pest Control			
13 Daily records document item 10, 11 and 12 above.		х	39. E	stablishment Construct	tion/Maintenance	x		
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements			40. L					
14. Developed and implemented a written HACCP plan			41. \	/entilation				
 Contents of the HACCP list the food safety hazards, ontest control points, entical limits, procedures, corrective actions. 			42 9	Plumbing and Sewage				
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17 The HACCP plan is signed and dated by the responsible establishment individual.				Dressing Rooms/Lavato Equipment and Utensils		+		
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18 Monitoring of HACCP plan.			47. 1	Employee Hygiene				
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27 Written Procedures			55. 1	Post Mortem Inspection				
28 Sample Collection/Analysis			ļ	Part G . Other Recu	latory Oversight Requirements			
29 Records			'					
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30 Corrective Actions			57	Monthly Review				
31 Raussessment			58					
32 Written Assurance			59					

FSIS- 5000-6 (04/04/2002)

60 Observation of the Establishment

Est. 4, Australia Meat Holdings Pty. Ltd., Townsville, Australia; August 31, 2007; Beef Slaughter/Processing

- 13/51 Documentation of corrective actions taken in response to some deficiencies identified during preoperational 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 daily documentation of the monitoring and verification procedures did not contain the initials or signatures of the persons performing the monitoring, although the signatures were entered electronically into the computer system soon after (within an hour or two of) completion of the monitoring and verification procedures. [9CFR §417.5(b) and 417.8]
- 39/51 Small amounts of rust and flaking paint were observed on overhead structures in several exposedmeat production areas. The AQIS officials ordered prompt repair and an improved general overhead-structure maintenance program. [9CFR §416.2(b), 416.15]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE	
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	Strand In	10/26/07

	d States Departm od Safety and Ins	nent of Agriculture pection Service	
Foreign E	stablishme	nt Audit Checklist	
		3. ESTABLISHMENT NO. 4. NAME OF COUNTRY	A
Thomas Borthwick & Sons Pty. Ltd.	Sep. 4, 2007	67 Australia	
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Basic Requirements)†) Audit Results	Economic Sampling	Results
7 Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9 Signed and dated SSOP, by m-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 implementati	ion	36. Export	
11. Maintenance and evaluation of the effectivaness of SSOP's.		37. Import	
12 Conective action when the SSOPs have falled to prevent direct product contemination or adulteration.	1	38. Establishment Grounds and Pest Control	
13 Daily records document item 10, 11 and 12 above.		39 Establishment Construction/Maintenance	x
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40 Light	
14. Developed and implemented a written HACCP plan		41 Ventilation	
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16 Records documenting implementation and monitoring of the HACCP plan		43 Water Supply	
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20 Corrective action written in HACCP plan		Part F - Inspection Regulaements	
21 Reassessed adequacy of the HACCP plan.			
22 Records documenting: the written HACCP plan, monitoring of th critical control points, dates and times of specific event occurrent	NC 85.	49 Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	_
23 Labeling - Product Standards		51. Enforcement	x
24 Labeling - Nat Weights 25. General Labeling		52. Humane Handling	
26 Fin Prod Standards/Boneless (Defects/AQL/Pork Skins/Moistu	re)	53. Animal Identification	
Part D - Sampling Generic E. coll Testing	· ·	54. Ante Mortem Inspection	
27 Written Procedures		·	
28. Sample Collection/Analysis		55 Post Mortem Inspection	
29 Records		Part G - Other Regulatory Oversight Requirements	
Salmonella Performance Standards - Basic Requirem	nents	56. European Community Directives	0
30. Corrective Actions		57. Monthly Review	
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FSIS- 5000-6 (04/04/2002)

FSIS 5000-6 (04/04/2002)

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60. Observation of the Establishment

Est. 67, Thomas Borthwick & Sons Pty. Ltd., Mackay, Queensland, Australia; September 4, 2007; Beef slaughter/cutting/boning

- 16/51 The monitoring records did not contain the actual observed results of each monitoring activity unless a deviation was observed. The AQIS officials ordered immediate correction. [9CFR §417.5, 417.8]
- 45/51 Split beef carcasses were routinely contacting a stainless steel guard at the head-drop station. The AQIS officials ordered prompt correction. [9CFR §416.13(c), 416.17]

61 NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
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establishment name and location Tasman Group Service Pty. Longford, Tasmania	2. AUDIT DA 9/13/07 5. NAME OF Garv F	VTE 3	Audit Checklis	st	
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0 Implementation of SSOP's, including monitoring of implement	entation.	3	6. Export		
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Part D - Sampling Generic <i>E. coli</i> Testing		5	4. Ante Mortem Inspection	ו	
7 Written Procedures		5	5. Post Mortem Inspection	}	
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2 Written Assurance		5	9	anna ann an a	

FSIS- 5000-6 (04/04/2002)

Est. 195, Tasman Group Service Pty., Longford, Tasmania, Australia; September 13, 2007. Bovine/ovine slaughter/processing.

12/51. Most documented corrective actions for pre-operational sanitation deficiencies did not include preventive measures. [9 CFR 416.15(b), 416.17]

20/51. The written description of corrective actions for the CCPs for "zero tolerance" for feces, ingesta, and milk did not include measures to demonstrate that the CCP was under control after a deviation occurred. [Regulatory reference 9 CFR 417.2(c)(5),417.3(a), 417.8]

22/51. Some monitoring records did not include the times when the monitoring was performed. [9 CFR 417.5(b), 417.8]

22/51. The verification documentation did not include the times when the verification activity was performed. [9 CFR 417.5(b), 417.8]

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62. AUDITOR SIGNAT	URE	A٢	ND DATE	. 1	i-1 a	1
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United States Department of Agriculture Food Safety and Inspection Service									
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Australia Meat Holdings Pty. Ltd.	Sep.6, 2007		384		Australia				
Rockhampton, Queensland	5 NAME OF AL				6. TYPE OF AUDIT				
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8. Records documenting implementation.			34 Spec	es Testing		ļ			
9 Signed and dated SSOP, by on-site or overall authority.			35. Resid	lue					
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12 Corrective action when the SSOP's have falled to prevent dis product contamination or adulteration.	rect		38 Estal	sishment Crounds	and Peal Control				
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18 Monitoring of HACCP plan.			47. Empl	oyee Hygiene					
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20 Corrective action written in HACCP plan 21 Reassessed adequacy of the HACCP plan.	· · _ · _ ·			Part F - I	nspection Requirements				
22 Records documenting: the written HACCP plan, monitoring of			49 Gove	thment Staffing		-			
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24 Labeling - Net Weights			51 Enfor	cement		<u> </u>			
25. General Labeling			52 Hum	ena Handling		ļ			
26 Fin Prod Standards/Bonelesa (Defects/AQL/Pork Skins/Mo	visture)		53 Anim	al Identification					
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27 Written Procedures			55 Post	Mortem Inspection	٦	1			
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32 Written Assurance			59.			<u> </u>			

FSIS- 5000-6 (04/04/2002)

60. Observation of the Establishment

Est. 384, Australia Meat Holdings Pty. Ltd.; Rockhampton, Queensland; September 6, 2007; Beef slaughter/cutting/boning

13/51 Documentation of corrective actions taken in response to some deficiencies identified during preoperational sanitation inspection did not include preventive measures. The AQIS officials ordered immediate correction. [Regulatory references: 9CFR §416.15(b) and 416.17]

61 NAME OF AUDITOR

Garv D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE 10/26/07

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Foreig	n Establ	ishme	nt Audit Checkli	ist	
1 ESTABLISHMENT NAME AND LOCATION	2. AUDITI	DATE	3. ESTABLISHMENT NO.	4 NAME OF COUNTRY	
Wingham Abattoirs Pty. Ltd.	Sep. 7,	2007	628	Australia	
Macksville, Queensland	5. NAME C		R(S)	6. TYPE OF AUDIT	
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11 Maintenance and evaluation of the effectiveness of SSOP			37 Import		
12 Convective action when the SSOPs have falled to prevent product contamination or adulteration	direct		38 Establishment Grounds	s and Pest Control	
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23 Labeling - Product Standards		0	51. Enforcement		x
24. Labeling - Net Weights		0	52. Humane Handling		0
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26 Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/A	vioisture)	0	53. Animal Identification		0
Part D - Sampling Generic E. coll Testing		-	54. Ante Mortem Inspectio	n	O
27 Written Procedures		0	55. Post Mortem Inspectio	n	U
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32 Written Assurance		0	59		
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FSIS- 5000-8 (04/04/2002)

FSIS 5000-6 (04/04/2002)

Est. 628, Wingham Abattoirs Pty. Ltd.; Macksville, Queensland, Australia; September 7, 2007; cold store.

4.

13/51 Documentation of corrective actions taken in response to some deficiencies identified during preoperational and operational sanitation inspection did not include preventive measures. [Regulatory references: 9CFR §416.15(b) and 416.17]

61 NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
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U	nited States Departr Food Safety and In:			
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	Scp. 17, 2007	716	Australia	
Greenham Tasmania Pty. Ltd	5. NAME OF AUDITO		6. TYPE OF AUDIT	
Longford, Tasmania				
Gary D. B			X ON-SITE AUDIT DOCUMENT AUDIT	
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8. Records documenting implementation,		34. Species Testing		
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue		
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13 Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance		X
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14. Developed and implemented a written HACCP plan.				
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 44. Dressing Rooms/Lavatories		
17 The HACCP plan is signed and dated by the responsible establishment individual.		45. Equipment and Utensils		
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18 Monitoring of HACCP plan.		47 Employee Hygiene		
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20 Corrective action written in HACCP plan.				
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24 Labeling - Net Weights		52 Humane Handling		
25 General Labeling 26 Fin Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		53 Animal Identification		
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FSIS- 5000-6 (04/04/2002)

Establishment # 716: Greenham Tasmania Pty. Ltd,; Longford, Tasmania, Australia; Sept. 17, 2007; bovine slaughter, cutting, and boning

- 39/51 Maintenance and cleaning of some over-product structures had been neglected in several production areas, especially behind refrigeration/ventilation units. The AQIS officials ordered prompt correction. [Regulatory references: 9CFR §416.4(b) and 416.17]
- 40/51 FSIS requires 50 foot-candles (fc), equivalent to 550 Lux, of shadow-free light at the inspection surface; levels of 18 fc (200 Lux) and 38 fc (420 Lux) were measured at the carcass and head inspection stations, respectively. This was in the process of being corrected before the day's audit was completed. [9CFR 307.2(m)(2)]

62. AUDITOR SIGNATURE AND DATE SUBASIAND 10/26/07

	United States De Food Safety ar			<u>, , , , , , , , , , , , , , , , , , , </u>	
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1 ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE		ESTABLISHMENT NO.	4. NAME OF COUNTRY	
Fletcher International Exports Pty. Ltd. 9/10/(2309	Australia	
Dubbo, NSW	5. NAME OF AU	JDITOR(S	;)	6. TYPE OF AUDIT	
		ry D. Bolstad. DVM		X ON-SITE AUDIT DOCUMENT A	
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7 Written SSOP		3	3. Scheduled Sample		
8 Records documenting implementation		3	4 Species Testing		
9 Signed and dated SSOP, by on-site or overall authority.		3	5. Residue		
Sanitation Standard Operating Procedures (SSOP)			Part E - Other Requirements		
Ongoing Requirements 10 Implementation of SSOP's, including monitoring of implement	entation	3	6. Export		
11 Maintenance and evaluation of the effectiveness of SSOP's			7 Import		
 Conjective action when the SSOP's have failed to prevent of product contamination or adulteration 	f	X 3		and Pest Control	
13 Daily records document item 10, 11 and 12 above		3	9 Establishment Construc	ction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		4		• • • • • • • • • • • • • • • • • • •	
14 Developed and implemented a written HACCP plan		4	1 Ventilation		
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17 The HACCP plan is signed and dated by the responsible establishment individual.			4. Dressing Rooms/Lavato 5. Equipment and Utensil		
Hazard Analysis and Critical Control Point					
(HACCP) Systems - Ongoing Requirements			46. Sanitary Operations		X
18 Monitoring of PACCP plan 19 Verification and validation of HACCP plan		- 4	47. Employee Hygiene		
20 Conective action written in HACCP plan		4	8 Condemned Product C		
21 Reassessed adequacy of the HACCP plan			Part F - I	nspection Requirements	
22 Records documenting the written HACCP plan, monitoring		4	9. Government Staffing	Seman mark (1997) same dana (1991 - 199	
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24 Labeling - Net Weights		5	1. Enforcement		X
25. General Labeling		5	2. Humane Handling		
26 Fin Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		5	3. Animal Identification		
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27 Written Procedures		5	5 Post Mortem Inspection	n	t ·
28 Sample Collection/Analysis			• • • • • •		
29 Records			Part G - Other Reg	ulatory Oversight Requirements	
Salmonella Performance Standards - Basic Req	uirements	5	5. European Community D	Prectives	0
30 Corrective Actions		5	7 Monthly Review		
31 Reassessment	· · · · · · · · · · · · · · · · · · ·	5	8.		
32. Written Assurance	and a second	5	9	aanaa ka k	
ESIS- 5000-6 (04/04/2002)	<u>_</u>	l			

FSIS- 5000-6 (04/04/2002)

60. Observation of the Establishment

Est. 2309, Fletcher International Exports Pty. Ltd., Dubbo, NSW, Australia; Sep. 10, 2007 (S/P)

12/51 Some of the documentation for corrective actions taken as a result of pre-operational sanitation inspection did not include preventive measures. [Regulatory references: 9 CFR 416.15(b), 416.17]

16/51 Some monitoring records did not contain actual observed results for all units checked (observations were noted only if there was a deviation). [9 CFR 417.5(a)(3), 417.8]

16/51 The actual times of some monitoring activities were not documented. [9 CFR 417.5(b), 417.8]

46/51 Some cleaning chemicals were stored under insanitary conditions. [9 CFR 416.4(c)]

the second s	
61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Garv D. Bolstad. DVM	mangers # Chandig 215708

	nited States Departn Food Safety and Ins			
Foreign	Establishme	nt Audit Checklis	st	
1 ESTABLISHMENT NAME AND LOCATION Harbourside Services Pty. Ltd. Townsville	2. AUDIT DATE 3 ESTABLISHMENT NO. Sep. 3, 2007 5153 5. NAME OF AUDITOR(S)		4. NAME OF COUNTRY Australia 6. TYPE OF AUDIT	
	Gary D. Bolst	ad, DVM	X ON-SITE AUDIT DOCUMENT AUD	
Place an X in the Audit Results block to ind				
Part A - Sanitation Standard Operating Procedures (S Basic Requirements	SSOP) Audit Results		rt D - Continued pnomic Sampling	Audit Results
7 Written SSOP		33. Scheduled Sample		0
8 Records documenting implementation.		34. Species Testing		0
9 Signed and dated SSOP, by cn-site or ovamil authority.		35. Residue		
Sanitation Standard Operating Procedures (SSOP)		Part E - Other Requirements		
Ongoing Requirements		36. Export		-
10 Implementation of SSOP's, including monitoring of implement	ntation.			
11 Maintenance and evaluation of the effectiveness of SSOP's 12 Corrective action when the SSOP's have falled to prevent dur	rect	37. Import 38. Establishment Grounds	and Pest Control	
product contamination or adulteration. 13 Daily records document flem 10, 11 and 12 above.	x	39. Establishment Construc	tion/Maintenance	-
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light		
14. Developed and implemented a written HACCP plan.	0	41. Ventilation		
15 Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective ac		42. Plumbing and Sewage		
 Records documenting implementation and monitoring of the HACCP plan. 		43. Water Supply	Las - and Managements - regarding and they a set an	
17 The HACCP plan is signed and dated by the responsible establishment individual.	44 Dreasing Rooms/Lava O 45. Equipment and Utens			
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		46. Sanitary Operations		
18 Monitoring of HACCP plan.	0	47 Employee Hygiene		
19 Venfication and valdation of HACCP plan.	0	48 Condemned Product Co	ontrol	
20. Corrective action written in HACCP plan.	0			
21. Roassessed adequacy of the HACCP plan.	0	Part F - Inspection Requirements		
 Records documenting: the written HACCP plan, monitoring o critical control points, dates and times of specific event occ. 		49. Government Statfing		
Part C - Economic / Wholesomeness		50 Daily Inspection Covers	age	0
23 Labeling - Product Standards	0	51. Enforcement		x
24 Labeling - Net Weights	0	52. Humane Handling		0
25 General Labeling 26 Fin Prod. Standards/Boneless (Defects/AQL/Park Skins/Mo	visture) ()	53 Animal Identification		0
Part D - Sampling		54. Ante Mortem Inspection	3	0
Generic /E. coll Testing 27 Written Procedures	0	55. Post Mortem Inspection		0
28 Sample Collection/Analysis	0			_
29 Records	0	Part G - Other Regu	ulatory Oversight Requirements	
Salmonella Performance Standards - Basic Requi	rements	56. European Community D	rectives	0
30. Corrective Actions	0	57 Manthly Review		
31 Reassessment	0	58		
32 Wrtten Assurance	0	59.		!

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60 Observation of the Establishment

Est. 5153, Harbourside Services Pty. Ltd., Townsville, Australia; September 3, 2007; cold store.

13/51 Documentation of corrective actions taken in response to some deficiencies identified during preoperational sanitation inspection did not include preventive measures. The AQIS officials ordered immediate correction. [Regulatory references: 9CFR §416.15(b) and 416.17]

61.	NAM	E OF	AUDI	TOR
G	arv D	Bolst	ad. DV	'M

62 AUDITOR SIGNATURE AND DATE AUDITOR SIGNATURE AND DATE

Country Response Not Received