United States Department of Agriculture

Food Safety and Inspection Service

Washington, D.C. 20250

JAN 0 5 2009

Dr. Andrew McKenzie
Executive Director
New Zealand Food Safety Authority
South Tower, 86 Jervois Quay
PO Box 2835
Wellington, New Zealand

Dear Dr. McKenzie:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of New Zealand's meat inspection system April 18 through May 12, 2008. Enclosed is a copy of the final audit report. Comments received from New Zealand have been included as an attachment to the final report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 205-3969, by facsimile at (202) 690-3856, or electronic mail at don.carlson@fsis.usda.gov.

Sincerely,

Don Carlson

Don Carlson, Acting Director
International Audit Staff
Office of International Affairs

Enclosure

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

APRIL 18 THROUGH MAY 12, 2008

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

ATM	Agency Technical Manager
BSE	Bovine Spongiform Encephalopathy
CCA	Central Competent Authority, the New Zealand Food Safety Authority (NZFSA)
CIG	Compliance and Investigation Group
E. coli	*Escherichia coli*
FSIS	Food Safety and Inspection Service
GREX	General Export Requirements
MAF	Ministry of Agriculture and Forestry
MSOE	Ministry of State-Owned Enterprises
NOID	Notice of Intent to Delist
NZFSA	New Zealand Food Safety Authority
OMAR	Overseas Market Access Requirement
PR/HACCP	Pathogen Reduction/ Hazard Analysis and Critical Control Point Systems
RTM	(NZFSA VA) Regional Technical Manager
SOE	State Owned Enterprise
SPCS	Statistical Process Control System
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures
Salmonella	*Salmonella* species
SRM	Specified Risk Material
TD	Technical Directive
TTS	Traveling Technical Supervisor
VA	Verification Agency
VTS	Veterinary Technical Supervisor

1. INTRODUCTION

The audit took place in New Zealand from April 18 through May 12, 2008.

An opening meeting was held on April 18 in Wellington with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit, the audit itinerary, and requested additional information needed to complete the audit of New Zealand's meat and poultry inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA, the New Zealand Food Safety Authority (NZFSA), and by representatives from the regional and local inspection offices when applicable.

2. OBJECTIVE OF THE AUDIT

This was a routine annual audit with special emphasis on humane handling and slaughter of livestock, as well as programs associated with *E. coli* O157:H7 control. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter and processing establishments certified by the CCA as eligible to export meat and poultry products to the United States.

In pursuit of the objective, the Senior Program Auditor followed routine meat and poultry inspection audit procedures. The following sites were visited: the headquarters of the CCA, one regional inspection office, six slaughter/processing establishments, and two laboratories.

Competent Authority Visits			Comments
Competent Authority	Central	1	Wellington
	Regional	1	Auckland
Slaughter / Processing Establishments		5	
Processing Establishments		1	
Laboratories		2	1 Microbiology lab, 1 Residue lab

3. PROTOCOL

The official on-site audit was conducted in three parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in New Zealand's inspection headquarters and regional offices. The third part involved on-site visits to six establishments (five slaughter/processing establishments and one processing establishment) and two laboratories.

Program effectiveness determinations of New Zealand's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation of Sanitation Standard Operating Procedures (SSOP) and Sanitation Performance Standards (SPS), (2) animal disease controls, (3) slaughter/ processing controls, including the implementation of Hazard Analysis/Critical Control Points (HACCP) programs and the testing program for generic *Escherichia coli (E. coli)*, (4) residue controls, and (5) enforcement controls, including the testing program for *Salmonella* species (*Salmonella*). New Zealand's inspection system was assessed by evaluating these five risk areas.

During all on-site 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 services are carried out by New Zealand and determined if establishment and inspection system controls were in place to ensure the production of meat and poultry products that are safe, unadulterated, and properly labeled.

During the opening meeting, the auditor explained that New Zealand's inspection system would be audited in accordance with two areas of focus. First, the auditor would audit against FSIS requirements. These include daily inspection in all certified establishments, humane handling and slaughter of livestock, the handling and disposal of inedible and condemned materials, species verification, and FSIS' requirements for HACCP, SSOP, SPS, and testing for generic *E. coli* and *Salmonella*.

Second, the auditor would audit against any equivalence determinations that have been made by FSIS for New Zealand under provisions of the Sanitary/Phytosanitary Agreement.

Currently, FSIS has determined that six alternate procedures are equivalent to FSIS requirements; alternate testing measures for generic *E. coli*; alternate testing measures for *Salmonella*; alternate testing for *E. coli* O157:H7; alternate post-mortem inspection procedures for lambs and 5- to 10-day-old "bobby" calves; and permission to slaughter, dress, and/or process equines in an establishment in which other species are also slaughtered, dressed, and/or processed.

4. LEGAL BASIS FOR THE AUDIT

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

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.),
- The Federal Meat and Poultry Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations, and
- The Poultry Products Inspection Act (21 U.S.C. 451 et seq.) and the Poultry Products Inspection Regulations (9 CFR Part 381).

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on the FSIS website at the following address:

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

The last two FSIS audits of New Zealand's inspection system were conducted in October-November 2005 and May 2007.

During the 2005 audit, one establishment was issued a Notice of Intent to Delist (NOID) by the CCA. The following deficiencies were identified during the audit.

- In one establishment, rodent feces were found in several areas of the main carton storage room.
- In two establishments, edible product containers were cracked and in need of repair or replacement.
- In one establishment, general housekeeping and maintenance had been neglected in the carton preparation room.
- In three establishments, the documentation records for verification of the monitoring activities did not contain the actual times when the verification procedures were performed.
- In two establishments, the establishment employee performing the pre-shipment document review was the same person who was performing the verification of the monitoring.
- In two establishments, the details of the verification procedures were not adequately described in the written HACCP plans.
- In one establishment, the monitoring records did not contain the actual times when the monitor observed the critical limits to be exceeded.
- In one establishment, there was insufficient supporting documentation that physical hazards had been considered during the hazard analysis.

During the 2007 audit, no establishments were removed from the list of establishments eligible for export to the US, or issued an NOID by the CCA. The following deficiencies were identified:

- In one establishment, condensation was identified on the overhead structures of a portion of the carcass unloading bay.
- In one establishment, a container designated for edible product was used for collecting meat trim from a conveyor belt transporting inedible product.
- In one establishment, ventilation in the employee equipment washing room was insufficient as it was unable prevent the formation of condensation on the walls and ceiling of this area after peak periods of use.
- At one establishment, blood was accumulating on the operator's stand and was not removed in a manner sufficient to prevent the creation of insanitary conditions in the ovine sticking area.
- Eight of the nine slaughter establishments visited addressed the presence of feces/ingesta identified on product during post-fabrication quality checks through a CUSUM/lot-sampling program rather than the HACCP plan.

- At one establishment, the records documenting monitoring of the CCP for visible feces on ostrich carcasses utilized checkmarks to demonstrate that this procedure was performed, but did not include actual quantifiable values to indicate the monitoring results.
- At one establishment, the written program addressing the removal, segregation, and disposition of specified risk materials (SRM) did not indicate how the distal ileum and applicable bones of the vertebral column were controlled.

6. MAIN FINDINGS

6.1 Government Oversight

6.1.1 CCA Control Systems

Oversight of the New Zealand meat and poultry inspection system is provided by NZFSA which, in July of 2007, separated from the Ministry of Agriculture and Forestry to form an independent public-service unit. Oversight of post-mortem inspection in slaughterhouses is under AsureQuality, a State Owned Enterprise (SOE) under the Ministry of State Owned Enterprises (MSOE). AsureQuality was created on October 1, 2007, by the merger of ASURE New Zealand Limited and AgriQuality Limited, two food-safety/security related SOEs.

NZFSA came into being on July 1, 2002, bringing together domestic and processed food functions from the Ministry of Health and the primary production, processing, and export functions from MAF Food, together with a small part of the MAF policy group, into a semi-autonomous body, the NZFSA, attached to MAF. NZFSA was restructured on July 1, 2005, providing horizontal groups in place of the former vertical, commodity-based groups, to enable it to function in a risk-based environment and facilitate the evolution toward its status as an independent Ministry. NZFSA is comprised of the following groups, each of which is headed by a Director who reports to the Executive Director and is a member of the NZFSA Board:

- New Zealand Standards Group (NZSG)
- Export Standards Group (ESG)
- Approvals and Agricultural Compounds and Veterinary Medicines
- Compliance and Investigation Group (CIG)
- Science
- Policy and Joint Food Standards (with Food Standards Australia and New Zealand)
- Communications and Infrastructure
- NZFSA Verification Agency (usually shortened to NZFSA VA)

There is an additional Director (Market Access) who is not a board member, and who interacts with the Deputy Director (Export Standards) and the Programme Managers (Market Access) within the Export Standards Group. These persons are responsible for ensuring that requirements necessary for access to various markets that are additional to the New Zealand Standards are published for implementation by industry and by AsureQuality NZ, and are verified by VA.

Oversight is provided by NZFSA through the CIG, the ESG, and VA. The Director (Market Access) of ESG is the FSIS contact or chief veterinary officer for New Zealand's meat and poultry inspection system. MSOE provides oversight through AsureQuality New Zealand. The various responsibilities of these organizations are outlined in a Memorandum of Understanding, dated June 2003, stating that MAF/NZFSA/ESG - NZSG (formerly the Animal Products Group) sets the standards, applies sanctions, and provides the statutory authorization to VA and AsureQuality. NZFSA CIG audits the performance of VA, AsureQuality, and industry. VA implements the standards, verifies that they are met, and certifies product. AsureQuality inspects livestock and product and performs associated tasks such as slaughter brand control and product sampling. Both VA and AsureQuality have divided their field staff according to the locations, numbers, and complexity of the establishments. VA is divided into nine regions, each managed by a Regional Technical Manager (RTM, previously known as Team Leader/TL) who maintains technical competence. AsureQuality managers are located in numerous offices around the country as needed to provide oversight for the AsureQuality staff in the establishments.

6.1.2 Ultimate Control and Supervision

VA maintains a physical presence in all establishments where AsureQuality inspectors are assigned. AsureQuality inspectors perform post-mortem inspection and related activities, and may perform ante-mortem inspection as well; most ante-mortem inspection is performed by NZFSA Technical Supervisors, who are veterinarians. VA is required to verify that AsureQuality employees are effectively delivering their mandatory functions and that establishments are in compliance with all New Zealand and FSIS requirements.

New technical information is distributed to all meat and poultry inspection employees via Overseas Market Access Requirements (OMAR), General Export Requirements (GREX), and Technical Directives (TD). OMAR and GREX documents are based on the Animal Products Act of 1999, and TDs are based on the Meat Act of 1981. Furthermore, certain Technical Directives issued under the Meat Act 1981 have been given full legal effect under the Animal products Act of 1999 for access to particular markets, such as the US.

Information on new and updated requirements is sent from NZFSA headquarters directly to all NZFSA field personnel, AsureQuality managers, and establishment management officials via e-mail. The Agency Technical Manager (ATM) conducts a weekly teleconference that is attended by all NZFSA Regional Technical Managers (RTM). The Veterinary Technical Supervisors (VTS) and Traveling Technical Supervisors (TTS) in remote locations provide monthly reports to the RTM specifying the compliance synopses of the establishments and also synopses of the technical information they have received during the month, as well as what they have done to ensure establishment compliance. For less remote locations, there are weekly circuit meetings in which all current issues are discussed and correlated; either the RTM or the RTM's Unit Coordinator attends these meetings. Each RTM provides a (monthly) Approved Signatory Report to the ATM; this report includes the minutes from these meetings, the monthly synopses, certification

issues, complaints and appeals, AsureQuality issues, VA procedural issues, compliance issues, safety issues, and recommendations regarding technical specifications.

6.1.3 Assignment of Competent, Qualified Inspectors

The process of maintaining competency and compliance is approached differently by NZFSA, VA, and AsureQuality. NZFSA performs CIG audits, on a periodic basis, that cover VA, AsureQuality, and industry activities and compliance. VA performs Technical Reviews of establishment compliance and inspection activities and conducts Performance Based Verification (PBV) audits and Bulk Audits of each Establishment and of the AsureQuality presence within that establishment. VA also performs frequent Regulatory Overviews at each establishment. AsureQuality performs Statistical Process Control System (SPCS) Checks on the various aspects (22 Systems) of inspection that they monitor or perform. SPCS Checks include Procedures Checks and Decision Checks.

The VA Technical Reviews, in combination with CIG Audits, comply with the periodic supervisory visits required by FSIS. Regional Technical Managers and Unit Coordinators perform this function for VA and maintain their competency via the Quality Assurance Assessor, who is supervised by the VA Technical Manager.

The Director General, through the Director (Market Access), negotiates a basic formula for AsureQuality staffing, which is subject to some modification according to individual requirements. The basic formula for staffing to meet NZFSA mandatory requirements is determined by AsureQuality; this obligation is placed on AsureQuality in the Memorandum of Understanding between NZFSA, NZFSA VA, and AsureQuality. The VA VTS has the authority to order a decrease in line speed if he/she finds it necessary for the post-mortem inspectors to perform their duties adequately. If the VTS is not confident that the staffing is adequate, he/she informs the RTM, who will confer with his/her counterpart (Regional Manager) in AsureQuality to resolve the issue. If the issue cannot be resolved at this level, it will be elevated to involve the Deputy Director (Market Access, Animal Products) and the CEO for AsureQuality in Wellington.

Concerning training, the NZFSA VA Technical Supervisor Training Program takes trainees approximately ten weeks to complete. NZFSA VA has between three and four block training courses per year. The theory training is provided by the Induction Trainer in the VA training centre at Hamilton and at practical training is undertaken at the trainee's "base Premises". Other training locations may be used if required.

The training program has been developed and is facilitated by NZFSA VA to meet the requirements of the NZFSA and NZFSA VA own specifications. External training providers are used when appropriate.

NZFSA VA Regional Technical Managers are responsible for the final assessment of the Technical Supervisors. Team Leaders hold the New Zealand Qualifications Authority Unit Standard 4098 (Assessment of Adult Learning).

After the Technical Supervisors have passed a final competency assessment and the Team Leaders have a written six-month post warranting plan, application is made to NZFSA that the Technical Supervisors be appointed as Animal Products Officers under the Animal Products Act of 1999. (Technical Supervisors cannot legally perform their duties until they have been appointed as Inspectors under the relevant Acts). After completing specific Animal Welfare training and case studies, the Technical Supervisors are also appointed as Inspectors under Animal Welfare Act 1999.

Technical Supervisors continue to receive ongoing upskilling through training and skills maintenance programs. Team meetings, peer reviews and regular assessments of individuals provide calibration and help to ensure best practices are followed. All Technical Supervisors attend their own team meetings and one of a series of three day conferences held in the off-peak time of the year. Specialized training, which may include postgraduate courses, is provided as appropriate to staff holding specialized positions or working in sectors other than meat game and poultry processing premises.

The RTM appraises the performances of each supervising veterinarian annually. The RTM and the supervising veterinarian together evaluate the performances of each VTS and each TTS, also annually.

6.1.4 Authority and Responsibility to Enforce the Laws

Accountability for administrative and technical activities also varies between VA and AsureQuality. The VA Technical Manager is technically accountable to the Director (Market Access) of the ESG. However, this manager is administratively accountable to and supervised by the General Manager for VA. The Agency Technical Manager is the supervisor of the Regional Technical Managers, who manage the field inspection staff. In contrast, the AsureQuality Technical Manager does not directly supervise the field inspection staff, and most of the Area/Site Managers who do have supervisory responsibilities, do not maintain their technical competence in meat and poultry inspection.

Deficiencies involving the enforcement of U.S. requirements were identified at five of the six establishments visited. Two deficiencies were repetitive, and closely related to findings identified during last year's audit. While improvements to the document used to convey FSIS requirements (US Overseas Market Access Requirements) were noted, NZFSA should continue to ensure that its contents are clearly outlined in a manner sufficient to convey these requirements to its inspection force.

6.1.5 Adequate Administrative and Technical Support

NZFSA VA has the ability to support a third party audit.

6.2 Headquarters Audits

The auditor conducted a review of inspection system documents at the headquarters of the inspection service. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Changes to structure and staffing.
- Training records for inspectors and laboratory personnel, including courses in HACCP and SSOP.
- New laws and implementation documents such as regulations, notices, directives, and guidelines, including official communications with field personnel, both in-plant and supervisory, in which U.S. requirements are conveyed.
- Sampling and laboratory analyses for residues.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.
- Enforcement records, including examples of criminal prosecution, seizure and control of noncompliant product, and delisting an establishment that was certified to export product to the United States.
- A summary of the species verification policy & program.
- Control of products imported from other countries for use in US-eligible product.

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

6.3.1 Audits of Regional Inspection Offices

During this audit, the auditor interviewed one RTM at the Auckland office in order to discuss delivery of oversight and to review documents regarding internal review reports and other supervisory visits to establishments that were certified to export to the U.S., training records for NZFSA officials, and export product inspection and control, including export certificates. No concerns arose as a result of this interview.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of six establishments: five slaughter/processing establishments, and one processing establishment. None of the establishments audited were delisted or issued a NOID.

Specific deficiencies observed during this routine audit are noted in the attached individual establishment checklists.

8. LABORATORY AUDITS

During the laboratory audits, emphasis was placed on the application of procedures and standards that are equivalent to United States' requirements.

Residue laboratory audits focus on sample handling, sampling frequency, timely analysis, data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. If private laboratories are used to test U.S. samples, the auditor evaluates compliance with the criteria established for the use of private laboratories under the PR/HACCP requirements.

The following two laboratories were reviewed:

- One private laboratory (AsureQuality in Auckland) conducting microbiological testing. This laboratory is one of many approved under New Zealand's Laboratory Approval System (LAS) which is accredited by International Accreditation New Zealand (IANZ), and performs both routine microbiological testing as well as testing for level two pathogens.
- One private laboratory in Wellington (AsureQuality), also accredited under IANZ as part of NZFSA's LAS, conducting chemical testing as part of New Zealand's national residue monitoring program.

The findings concerning the residue component of laboratory testing will be discussed in Section 12 (Residue Controls) of this report. No deficiencies were reported regarding the microbiological testing component at the laboratory visited.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditors focus on five areas of risk to assess New Zealand's meat and poultry 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, New Zealand'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, New Zealand'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 establishment 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 following deficiencies were reported:

- In one establishment, a torn conveyor belt used for transporting edible product was identified in one of the processing rooms. This belt was damaged to an extent which would inhibit its thorough cleaning, and could result in product adulteration during operations.
- In two establishments, the records did not document all three parts of corrective actions for operational SSOP deficiencies. This finding is similar to that identified during last year's audit.
- At one establishment, a review of the SSOP records indicated that certain corrective actions taken in response to SSOP deficiencies were inappropriate in that, within a period of a few weeks, approximately nine instances of insufficient cleaning of a specific piece of product-contact equipment ("meat scraper") were documented with similar corrective actions provided on each occasion.

9.2 SANITATION PERFORMANCE STANDARDS

In two of the six establishments audited, the Sanitation Performance Standards were not met:

- In one establishment, weather-stripping under a door leading to the outside was deteriorated to the extent that it could not prevent the entry of rodents or other pests.
- In one establishment, a slaughter-line employee was observed unclogging a drain at his station without subsequently using soap to wash himself before returning to his duties.
- In one establishment, control over blue receptacles identified in the processing room storing inedible materials was insufficient. These containers were neither labeled "inedible", nor were any signs posted in the production area that indicated that these receptacles were intended strictly for inedible use.

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, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that New Zealand's inspection system had adequate controls in place. No deficiencies were reported.

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: ante-mortem inspection procedures, ante-mortem disposition, humane handling and humane slaughter of livestock, post-mortem inspection procedures, post-mortem disposition, ingredients identification, control of restricted ingredients, formulations, processing schedules, equipment and records, and processing controls of cured, dried, and cooked products.

The controls also include the implementation of HACCP systems in all establishments and implementation of a testing program for generic *E. coli* in slaughter establishments.

11.1 Humane Handling and Humane Slaughter

No deficiencies were reported.

11.2 HACCP Implementation

All establishments approved to export meat and poultry products to the United States are required to have developed and adequately implemented HACCP programs. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program. The following deficiencies were noted:

- In four of the six slaughter establishments visited, discussions with plant personnel indicated that corrective actions taken in response to feces/ingesta found on carcasses at the pre-trim station in the cutting/processing area were incomplete in that they sometimes consisted solely in trimming of the carcass. As this point in the process is after the establishment's specified point of monitoring for this hazard, it is required that the presence of contamination of this nature be treated as a deviation from the critical limit in accordance with 9 CFR 417.3(a). This is similar to last year's finding where it was noted that contamination of product by ingesta/feces found at CUSUM was addressed under its own separate program rather than in accordance with the HACCP plan. During the current audit it was observed that, while all of the establishments visited satisfactorily modified their programs to specifically address this type of contamination found at CUSUM, the interpretation of the previous year's finding was too narrow in the sense that it should apply to contamination found at any point after the CCP monitoring point.
- In one establishment, the "direct observation of monitoring" component of verification procedures associated with CCP1 was unclear in that while the actual monitoring frequency was defined as "twenty carcasses per run", the "direct observation of monitoring" records indicated that only ten of these carcasses were being verified. Review of the establishment's written verification procedures did not indicate how many carcasses should actually be verified.
- In one establishment, the documentation of corrective actions taken in response to a deviation from the critical limit for CCP 1 (zero tolerance failure for

feces/ingesta) did not include the date/time that the entry occurred, or the initials/signature of the person making the entry.

- In two establishments, the corrective actions outlined in the HACCP plan addressing the contamination of carcasses or carcass portions with visible feces/ingesta did not clearly indicate that the CCP would be under control after a deviation from the critical limit occurred.
- In one establishment, the records associated with the preshipment review did not address the critical limit for CCP #2 (metal detection). While further investigation indicated that no deviation from this critical limit had occurred recently, failure to include this CCP as part of the preshipment review does not meet the regulatory requirements of 9 CFR 417.5.

11.3 Testing for Generic *E. coli*

New Zealand has adopted the FSIS regulatory requirements for testing for generic *E. coli* with the exception of the following measures, which have been determined to be equivalent by FSIS:

- The testing frequency in lambs and sheep is five carcasses per week; this alternate frequency was written into the HACCP plans as required in all the lamb slaughter establishments visited during this audit.
- New Zealand samples cattle at three sites: flank, brisket, and outside hind-leg.
- New Zealand samples bobby calves prior to chilling, at three sites: flank, foreleg, and fore-rump, using a round 25 cm^2 template.
- New Zealand uses a swab sampling tool.

Five of the six establishments audited were required to meet the basic FSIS regulatory requirements for testing for generic *E. coli* and were evaluated according to the criteria employed in the United States' domestic inspection program in association with the equivalence determinations outlined above.

Testing for generic *E. coli* was properly conducted in all of the five establishments in which it was required.

11.4 Testing of Ready-to-Eat Products

One of the six establishments audited was producing ready-to-eat product (beef jerky) for export to the U.S. As this product is exposed the post-lethality environment, the establishment elected to address possible contamination by *Listeria monocytogenes* under alternative 2. Selection of this alternative is based on suppression of microbial growth related to the low level of water-activity of this product. During the audit, no deficiencies were identified concerning the establishment's program addressing the control of this pathogen, nor with the on-going testing procedures instituted to verify the effectiveness of these controls. Similarly, no deficiencies were identified concerning the testing of product for *Salmonella*.

11.5 Control of Specified Risk Materials (SRM)

National mandates for the implementation of compliance with the requirements for special handling of Specified Risk Materials (SRM) regarding Bovine Spongiform Encephalopathy (BSE) have been implemented as Overseas Market Access Requirements (OMAR). Non-ambulatory cattle are condemned upon ante-mortem inspection, no beef containing SRM is permitted in U.S.-eligible product, mechanically-separated beef is ineligible for use in U.S.-eligible product, and air-injection stunning is not permitted in New Zealand.

No deficiencies were identified after review of these programs at the establishment level.

11.6 Testing for *E. coli* O157:H7

Although New Zealand is not currently exporting ground beef to the U.S., NZFSA has recently modified its US OMAR to include testing for *E. coli* O157:H7 in bulk manufacturing beef and bobby veal. Except as noted, sample collection and testing were conducted in a manner consistent with U.S. policy; including those alternate procedures for which FSIS has granted an equivalence determination.

- At one establishment, the protocols associated with the security of *E. coli* O157:H7 test samples were not adequate. Current procedures indicated that samples were sometimes left unattended while awaiting courier pick-up without the benefit of some form of container security (e.g., locks, security tape). In addition, the lack of a prescribed need for security tape, or similar method to prevent/indicate unauthorized tampering, on all samples submitted by establishments under the National Microbiological Database (NMD) program is an aspect which NZFSA may wish to reevaluate, considering the integral role that establishment testing holds within that program.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviewed was Residue Controls. These controls include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

The following deficiencies were identified at the facility audited:

- The expectations published by NZFSA expressly state that samples submitted for screening of certain classes of antibiotics should be received in a frozen state. During the audit, a sample of unfrozen urine was received and neither the laboratory nor NZFSA officials were certain as to whether the sample should be discarded, indicating a need for further clarification of these expectations to ensure proper testing.
- An electronic record inaccurately reported a sample discarded for insufficient tissue submission as "adequate upon receipt".

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella* species.

13.1 Daily Inspection in Establishments

Documented daily inspection was provided in all six of the establishments audited for production days on which U.S.-eligible product was produced.

13.2 Testing for *Salmonella* Species

New Zealand has adopted the FSIS regulatory requirements for testing for *Salmonella* species with the exception of the following equivalent measures, which have been determined to be equivalent by FSIS:

- Establishments take samples.
- Private laboratories analyze samples.
- A swab sampling tool is used.
- Samples are taken at the end of the slaughter or production process and prior to the carcass being cut and/or packaged.

Five of the six establishments audited were required to meet the basic FSIS regulatory requirements for testing for *Salmonella* species and were evaluated according to the criteria employed in the United States' domestic inspection program.

Testing for *Salmonella* species was properly conducted in all of the establishments in which it was required.

13.3 Species Verification

At the time of this audit, New Zealand was required to test product for species verification. Species verification was being conducted in those establishments in which it was required.

13.4 Periodic Reviews

Periodic reviews had been conducted, and were well-documented, for all intervals during which U.S.-eligible production had been conducted in all six of the establishments audited.

13.5 Inspection System Controls

Except as noted below, the CCA had controls in place for ante-mortem and post-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.

Furthermore, controls were in place for the importation of only eligible meat and poultry products from other countries for further processing, security items, shipment security, and products entering the establishments from outside sources.

Lamb and bobby calf slaughter were performed in accordance with the alternate procedures determined to be equivalent by FSIS:

- Post-mortem inspection of lambs and bobby calves without the heads and tongues is permitted.
- Sheep carcasses are permitted to contact each other after inspection of the outside of the carcass.

Deficiencies which should have been identified in advance by NZFSA were found in five of the six establishments audited. These involved:

- SSOP (4 establishments),
- Sanitation Performance Standards (2 establishments), and
- HACCP Implementation (5 establishments).

14. CLOSING MEETING

A closing meeting was held on May 12, 2008, in Wellington with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

The CCA understood the findings as presented.

For Alexander L. Lauro, DVM by
Senior Program Auditor

Ron Carlson, DVM

15. ATTACHMENTS

Individual Foreign Establishment Audit Checklists
Foreign country response to Draft Final Audit Report

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
PPCS Limited - Belfast Beef Factory Road Belfast Christchurch	04/28/2008	ME 15	New Zealand
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alexander L. Lauro, DVM		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
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.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58. Testing for *E. coli* O157:H7	X
59.	

60. Observation of the Establishment

Date: 04/28/2008 Est #: ME15 (PPCS Limited - Belfast Beef [S/P/CS]) (Christchurch, New Zealand)

20/51. The corrective actions described in the HACCP plan addressing the contamination of carcasses or carcass portions with visible feces/ingesta did not clearly indicate that the CCP would be under control after a deviation from the critical limit occurred. [Regulatory reference(s): 9 CFR §417.2(c)(5), 417.3(a), 417.8]

20/51. Discussions with plant personnel indicated that corrective actions taken in response to feces/ingesta found on carcasses at the pre-trim station in the cutting/processing area were incomplete in that they sometimes consisted solely in trimming of the carcass. As this point in the process is after the specified point of monitoring for this hazard, it is required that the presence of contamination of this nature be treated as a deviation from the critical limit in accordance with 9 CFR 417.3(a). [9 CFR §417.3(a), 417.8]

58/51. The protocols associated with the security of samples taken for E. coli O157:H7 were not adequate. Current procedures indicate that samples are sometimes left unattended while awaiting courier pick-up for which, without the benefit of some form of container security (e.g., locks, security tape), sample integrity could not be guaranteed.

61. NAME OF AUDITOR
Alexander L. Lauro, DVM

62. AUDITOR SIGNATURE AND DATE
Alexander L. Lauro 4/28/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Alliance Group Limited Main Road Stoke Nelson	4/22/2008	ME 40	New Zealand
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alexander L. Lauro, DVM		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
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.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Date: 4/22/2008 Est #: MF 10 (Alliance Group Limited [S/P/CS]) (Nelson, New Zealand)

12/51. A review of the establishment's SSOP records indicated that certain corrective actions taken in response to SSOP deficiencies were inappropriate. Within a period of a few weeks, approximately nine instances of insufficient cleaning of a specific piece of product-contact equipment ("meat scraper") were documented with similar corrective actions provided on each occasion. [Regulatory reference(s): 9 CFR §416.14(a), 416.17]

20/22/51. Discussions with plant personnel indicated that corrective actions taken in response to feces/ingesta found on carcasses at the pre-trim station in the cutting/processing area were incomplete in that they often consisted solely in trimming of the carcass. Additionally, documentation of corrective actions taken did not routinely occur. As this point in the process is after the specified point of monitoring for this hazard, it is required that the presence of contamination of this nature be treated as a deviation from the critical limit in accordance with 9 CFR 417.3(a), and that all corrective actions be documented in accordance with 417.5(a)(3). [9 CFR §417.3(a), 417.5(a)(3), 417.8]

22/51. The records associated with the preshipment review did not include the critical limit for CCP #2 (metal detection). While further investigation indicated that no deviation from this critical limit had occurred recently, failure to include this CCP as part of the preshipment review does not meet the regulatory requirements of 9 CFR 417.5. [9 CFR §417.5(c), 417.8]

45/51. Establishment control over blue receptacles identified in the processing room storing inedible materials was insufficient. These containers were neither labeled "inedible", nor were any signs posted in the production area that indicated that these receptacles were intended strictly for inedible use. [9 CFR § 416.3(c), 416.17]

61. NAME OF AUDITOR
Alexander L. Lauro, DVM

62. AUDITOR SIGNATURE AND DATE
Alexander L. Lauro 4/22/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
CMP Kokiri Limited Main Road Kokiri, West Coast	4/24/2008	ME 66	New Zealand
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alexander Lauro, DVM		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
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.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Date: 4/24/2008 Est #: MI566 (CMP Kokiri Limited [S/P/CS]) (Kokiri, New Zealand)

13/51. While conversations with plant personnel indicated that appropriate measures were being taken, the establishment records did not document all three parts of the corrective actions for operational SSOP deficiencies described in 9 CFR 416.15(b). [Regulatory reference(s): 9 CFR §416.16, 416.17]

20/51. Discussions with plant personnel indicated that corrective actions taken in response to feces/ingesta found on carcasses at the pre-trim station in the cutting/processing area were incomplete in that they sometimes consisted solely in trimming of the carcass. As this point in the process is after the specified point of monitoring for this hazard, it is required that the presence of contamination of this nature be treated as a deviation from the critical limit in accordance with 9 CFR 417.3(a). [9 CFR §417.3(a), 417.8]

20/51. The corrective actions described in the HACCP plan addressing the contamination of carcasses or carcass portions with visible feces/ingesta did not clearly indicate that the CCP would be under control after a deviation from the critical limit occurred. [9 CFR §417.2(c)(5), 417.3(a), 417.8]

61. NAME OF AUDITOR
Alexander Lauro, DVM

62. AUDITOR SIGNATURE AND DATE
Alexander Lauro 4/24/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Auckland Meat Processors Limited 131 Portage Road Otahuhu Auckland	05/01/2008	ME 103	New Zealand
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alexander Lauro, DVM		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
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.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	X
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment Date: 05/01/2008 Est #: ME103 (Auckland Meat Processors Limited [S/P/CS]) (Auckland, New Zealand)

10/51. A torn conveyor belt used for transporting edible product was identified in one of the processing rooms. This belt was damaged to an extent which would inhibit its thorough cleaning, and could result in product adulteration during operations. [Regulatory reference(s): 9 CFR § 416.3(a), 416.17]

12/51. While conversations with plant personnel indicated that appropriate measures were being taken, the establishment records did not document all three parts of the corrective actions for operational SSOP deficiencies described in 9 CFR 416.15(b). In particular, "measures to prevent recurrence" were not routinely documented. [9 CFR §416.15(b)]

20/51. Discussions with plant personnel indicated that corrective actions taken in response to feces/ingesta found on carcasses at the pre-trim station in the cutting/processing area were incomplete in that they sometimes consisted solely in trimming of the carcass. As this point in the process is after the specified point of monitoring for this hazard, it is required that the presence of contamination of this nature be treated as a deviation from the critical limit in accordance with 9 CFR 417.3(a). [9 CFR §417.3(a), 417.8]

39/51. In the ovine slaughter department, the weather-stripping under a door leading to the outside was deteriorated to the extent that it could not prevent the entry of rodents or other pests. [9 CFR § 416.2(b)(3), 416.17]

47/51. An employee was observed unclogging a drain at his station without subsequently using soap to wash himself before returning to his slaughter duties. [9 CFR §416.5, 416.17]

61. NAME OF AUDITOR
Alexander Lauro, DVM

62. AUDITOR SIGNATURE AND DATE
Alexander S. Lauro 5/1/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Rakaia River Meats Limited Knyvetts Road RD 13 Rakaia	04/29/2008	ME 500	New Zealand
	5. NAME OF AUDITOR(S) Alexander Lauro, DVM		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
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.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Date: 04/29/2008 Est #: ME500 (Rakaia River Meats Limited [S/CS]) (Rakaia, New Zealand)

15/51. The "direct observation of monitoring " component of verification procedures associated with CCP1 was unclear in that while the actual monitoring frequency was defined as "twenty carcasses per run". the "direct observation of monitoring" records indicated that only ten of these carcasses were being verified. Review of the establishment's written verification procedures did not indicate how many caresses should actually be verified. [Regulatory reference(s): 9 CFR §417.2(c)(7), 417.8]

22/51. The documentation of corrective actions taken in response to a deviation from the critical limit for CCP 1 (zero tolerance failure for feces/ingesta) did not include the date/time that the entry occurred or the initials/signature of the person making the entry. [9 CFR §417.5, 417.8]

61. NAME OF AUDITOR
Alexander Lauro, DVM

62. AUDITOR SIGNATURE AND DATE
4/29/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Jack Link's New Zealand Limited 137-159 Montgomerie Road Mangere Auckland	05/06/2008	JL 1	New Zealand
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alexander L. Lauro, DVM		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
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.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Date: 05/06/2008 Est #: JL1 (Jack Link's New Zealand Limited [P/CS]) (Auckland, New Zealand)

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

61. NAME OF AUDITOR

Alexander L. Lauro, DVM

62. AUDITOR SIGNATURE AND DATE

Alexander L. Lauro 5/6/08

NEW ZEALAND FOOD SAFETY AUTHORITY

21 November 2008

Donald Smart
Director
International Audit Staff
Office of International Affairs
USDA Food Safety and Inspection Service
Washington DC
United States of America

Dear Don

Response to Final Draft Audit Report

Thank you for the opportunity of responding to the Draft Final Audit Report for the FSIS audit 18 April to 12 May 2008 and your letter that accompanied the report dated 12 September 2008. I would also like to thank you for taking time out to discuss and clarify an approach that is acceptable to FSIS regarding feedback options to the slaughter floor CCP for zero faecal tolerance.

Attached to this letter is an appendix primarily commenting on editorial changes that we recommend be made to enhance the accuracy of the report, but also noting action with regard to the "11.2 HACCP Implementation" section of the draft report.

Yours sincerely

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Appendix 1

6.1.1 First paragraph – AsureQuality on the last line should refer to Asure New Zealand being one of the parties in the merger to form AsureQuality.
Second paragraph, final bullet point - NZFSA Verification Authority should be NZFSA Verification Agency.

6.1.1 Second paragraph – the statement relating to "full legal effect of TDs under the APA" is not strictly accurate. TDs have been mandated for market access purposes only for some markets including the USA. OMAR Notification 01/183 refers.

6.1.2 Paragraph 7 - Official Inspectors should be Animal Products Officers. Also remove the "s" as the correct title is the Animal Welfare Act 1999.

9.1 Last bullet point – these issues have been addressed.

9.2 Third bullet point – under the APA there is allowance for the identification of coloured bins to be covered in documentation which forms part of the establishments Registered Risk Management Programme.

11.2 HACCP Implementation, first bullet point.
Following discussion with FSIS, NZFSA will amend the United States Overseas Market Access Requirements that we issue. The amendment will require establishment operators to revise their HACCP plans noting the fact that faeces/ingesta may become visible, particularly following surface drying during chilling, subsequent to the current CCP for zero faecal tolerance (ZFT). As a consequence and to enhance the performance of the current ZFT CCP the pre-trim prior to the boning room must be designated as a control point. A suitably trained company person will conduct monitoring checks on a selected number of pre-trimmed carcasses each run (normally a two hour period) to verify that no visible faeces or ingesta is present, any faecal/ingesta findings will be recorded and reported back to the slaughter floor CCP at a frequency no greater than once daily.

11.2 HACCP Implementation, second bullet point – "caresses" should read "carcasses".

11.3 HACCP Implementation, final bullet point – the CCP referred to here has been put in place at the insistence of a customer and not to meet any regulatory requirements as the

hazard analysis conducted did not identify metal as a physical hazard. NZFSA seeks clarification on the necessity to include customer CCPs in a regulatory pre-shipment HACCP review.

11.6 Testing for *E. coli O157:H7* – comments regarding security of samples are not considered to be relevant to NZFSA as historically we have never had any security arrangements in place for samples collected under this programme or those for generic E. *coli* and *Salmonella* under the National Microbiological Database Programme. We have no reports from receiving laboratories of any tampering occurring with submitted samples. In instances where tampering is suspected laboratories are required to advise NZFSA accordingly.