USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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

OCT 14 2015

Dr. Tony Zohrab
Chief Market Access Officer
Ministry of Primary Industries
Pastoral House, 25 The Terrace,
PO Box 2526
Wellington, 6140
New Zealand

Dear Dr. Zohrab:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of New Zealand's meat and poultry inspection system from April 8 through April 23, 2015. Enclosed is a copy of the final audit report. The comments received from the Government of New Zealand are included as an attachment to the report.

For technical questions regarding the FSIS audit report, please contact Dr. Shaukat H. Syed, Director of the International Audit Staff with the Office of Investigation, Enforcement and Audit (OIEA) at telephone number (202) 720-8609, by facsimile at (202) 720-0676, or by electronic mail at international.audit@fsis.usda.gov.

If you have any other questions, please feel free to contact me directly.

Sincerely,

Jane H. Doherty

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

DRAFT FINAL REPORT OF AN AUDIT CONDUCTED IN

NEW ZEALAND

APRIL 8 TO APRIL 23, 2015

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT AND POULTRY PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

July 20, 2015

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from April 8 to April 23, 2015. The purpose of the audit was to determine whether New Zealand's food safety system governing meat and poultry products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and accurately labeled. New Zealand currently exports predominately raw intact beef. Other products include ready-to-eat (RTE) dried beef, thermally processed/commercially sterile beef, and raw-intact ovine primal cuts.

The audit focused on six system equivalence components: Government Oversight (Organization & Administration), Statutory Authority and Food-Safety Regulations (Inspection System Operation and Product Standards), Sanitation, Hazard Analysis and Critical Control Points (HACCP) Systems, Government Chemical Residue Control Programs, and Government Microbiological Testing Programs.

The audit results indicate that New Zealand's food safety inspection system is performing at an adequate level in meeting the core criteria for all six equivalence components. However, FSIS identified several findings within the following two components.

- *Statutory Authority and Food-Safety Regulations*: FSIS identified a need for the CCA to improve its verification of post-mortem inspection requirements, as outlined in New Zealand's *Animal Products (Export Requirement: Company Ante-Mortem and Post-Mortem Inspection)*.
- *Sanitation*: FSIS identified a need for increased surveillance by the CCA with regard to sanitation non-compliances within certified establishments.

The audit analysis did not identify any systemic deficiencies that represent an immediate threat to public health. FSIS requests that the Central Competent Authority (CCA) provide a detailed response addressing these findings within 60 calendar days of receipt of this report in order for FSIS to timely review and conclude that equivalency is maintained.

TABLE OF CONTENTS

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of New Zealand's food safety system from April 8 to April 23, 2015.

The audit began with an entrance meeting held on April 8, 2015, in Wellington, with the participation of representatives from the Central Competent Authority (CCA) – the Ministry for Primary Industries (MPI), and two FSIS representatives.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

The audit objective was to ensure the food safety system governing meat and poultry products maintains equivalence to that of the United States, with the ability to export products which are safe, wholesome, unadulterated, and correctly labeled and packaged.

Areas of special emphasis included:

- Corrective actions implemented by MPI in response to the previous FSIS audit in 2011 and ongoing point-of-entry (POE) import testing.
- Implementation of a post-mortem inspection procedure, which involves the use of company employees to perform dispositions on non-food safety related carcass and viscera conditions. This measure was granted equivalence by FSIS in October 2011.
- Implementation of New Zealand's control measures, including the government verification testing program for up to seven Shiga toxin-producing *Escherichia coli* (STEC) in specific raw beef products. This program was updated in order to address changes in FSIS domestic policy, which occurred in May of 2012, as outlined in the *Federal Register*, Vol. 77, No. 105.
- Information provided by MPI via the FSIS foreign country self-reporting tool (SRT), concerning control of:
    - Thermally-processed commercially-sterile products
    - Ready-to-eat (RTE) products (beef jerky)

In pursuit of this objective, FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, POE testing results, and specific oversight and testing activities of government offices and laboratories. The review process included an analysis of New Zealand-specific data collected by FSIS over a three-year timeframe, in addition to information obtained directly from the CCA.

This analysis resulted in the determination that no ratite slaughter establishments would be included in the current scope, as there were no establishments actively exporting this type of product to the United States. Additional considerations included: a) the lack of significant findings identified during previous FSIS visits to ratite slaughter facilities; b) the absence of any significant recent changes within the either the FSIS or New Zealand domestic systems governing ratites; and c) the understanding that a common CCA (MPI) is responsible for both

meat and poultry (ratite) systems within New Zealand. Consequently, FSIS considers the active POE testing on products from New Zealand and current on-site verification of inspection system controls sufficient to determine the equivalence status for both these systems.

The FSIS auditors were accompanied throughout the entire audit by representatives from the CCA. Determinations concerning program effectiveness focused on performance within the following six equivalence components upon which system equivalence is based: (1) Government Oversight (Organization and Administration), (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP), (5) Government Chemical Residue Control Program , and (6) Government Microbiological Testing Programs.

Administrative functions were reviewed at CCA headquarters, two regional offices, and 10 local inspection offices, during which the auditors evaluated the implementation of management control systems in place that ensure that the national system of inspection, verification, and enforcement was being implemented as intended.

A sample of 10 establishments was selected from 68 establishments certified to export to the United States. During the establishment visits, particular attention was paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with 9 CFR 327.2.

In addition, one chemical residue laboratory and one microbiological laboratory were audited to verify their ability to provide adequate technical support to the inspection system.

Competent Authority Visits		**#**	**Locations**
Competent Authority	Central	1	MPI, Wellington
	Regional	2	Verification Services (VS) Offices: • Christchurch • Whanganui
Laboratories (state-owned)		2	• AsureQuality, Lynfield (Microbiology) • AsureQuality Laboratory, Gracefield (Residues)
Establishments		10	• One (1) meat processing establishment, producing RTE product • One (1) meat processing establishment, producing thermally-processed/commercially-sterile product • Two (2) bovine slaughter and processing establishments • One (1) ovine slaughter and processing establishment • Five (5) "mixed ruminant" establishments slaughtering and processing bovine, ovine, and caprine species

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 Humane Methods of Livestock Slaughter Act (7 U.S.C. Title 7),

- The Food Safety and Inspection Service Regulations for Imported Meat (9 CFR Part 327),
- The Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and
- The Food Safety and Inspection Service Regulations for Imported Poultry (9 CFR Part 381, Subpart T).

The audit standards applied during the review of New Zealand's inspection system for meat and poultry products included: (1) All applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the Sanitary/Phytosanitary Agreement.

Currently, New Zealand has equivalence determinations in place for the following:

- Generic *Escherichia coli (E. coli)* sampling
  - New Zealand samples cattle at three sites: flank, brisket, and outside hind-leg
  - New Zealand samples bob veal calves prior to chilling at three sites: flank, foreleg, and fore-rump, using a round 25 cm template
  - New Zealand uses a swab sampling tool
- *Salmonella* sampling
  - Establishments take samples under government supervision
  - Accredited 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
- Slaughter operations
  - Equivalent post-mortem inspection procedures for lamb and goat carcasses:
    1. Presentation of head and tongue is not required
    2. Visual-only inspection (except for palpation of the inner surface of the ventro-lateral abdomen) is permitted
  - Post-mortem (PM) inspection system (non-food-safety conditions addressed by establishment personnel)
  - Removal of head and tongue not required prior to post-mortem inspection of adult cattle and young calves (5-10 days old)
  - Procedures for PM inspection of sheep
  - Exemption for specified risk material (SRM) removal
  - Slaughter, dressing, and/or processing of equines in an establishment in which other species are also slaughtered, dressed, and/or processed, is permitted (However, New Zealand is not currently exporting product derived from equines to the United States).

- Testing for relevant STEC, for which greater detail is provided under *Component 6: Government Microbiological Testing Programs*

III. BACKGROUND

New Zealand is eligible to export meat and poultry (ratite) products. An analysis of the last three fiscal years of data, from October 1, 2012 to September 30, 2014, demonstrated that FSIS import inspectors performed 100% re-inspection on labeling and certification on 912,101,066 pounds of meat products that New Zealand has exported to the United States. FSIS performed additional types of inspection (TOI) on 61,663,722 pounds at POE of which a total of 1,257,861 pounds (2%) were rejected, predominately due to spoilage during transport or fecal contamination on lamb carcasses. In addition, a 6,746-pound lot of RTE beef jerky was rejected due to the presence of *Listeria monocytogenes (Lm)* identified during FSIS microbiological testing conducted at POE. Specific verification activities conducted by the FSIS auditors in response to the *Lm* violation are discussed under *Component 4: HACCP*.

New Zealand currently exports predominately raw intact beef, most of which is intended for further grinding. Other products include RTE dried beef, thermally processed/commercially sterile beef, and raw intact ovine primal cuts.

Previous FSIS final audit reports for New Zealand's food safety system are available on the FSIS' website at:
http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components that FSIS reviewed was Government Oversight. FSIS import regulations require the foreign inspection system to be organized by the national government in such manner to provide ultimate control and supervision over all official inspection activities; insure the uniform enforcement of requisite laws; provide sufficient administrative technical support; and assign competent qualified inspection personnel at establishments where products are prepared for export to the United States.

Oversight of the New Zealand meat and poultry inspection system is provided by the MPI, which was formed from a merger initiated in July 2011 between the previous competent authority for meat and poultry inspection, the Ministry of Agriculture and Forestry (MAF), and the Ministry of Fisheries. This merger was completed in April 2012.

MPI is structured into six (6) branches along the following functional lines:

1. *Operations*: manages border and compliance activities as well as preparing for, and responding to, any biosecurity incursions that may occur. Also manages MPI's centralized intelligence, planning, and co-ordination group, which was established to manage food, biosecurity, and animal welfare responses consistently and effectively.

2. *Policy and Trade*: provides sector-level, strategic thinking, policy advice and analysis, and oversees government-to-government relationships to maximize export opportunities. This branch includes the Market Access Directorate, which acts as the focal point for MPI's sanitary and phytosanitary (SPS) government to government functions, and leads negotiation of SPS and related export conditions and assurance systems with counter-part Competent Authorities. It is also promulgates all bilateral overseas market access requirements.
3. *Regulations and Assurance*: supports primary producers and consumers by implementing the full range of MPI's legislative and regulatory frameworks.
4. *Sector Partnerships and Programs (SPP):* oversees programs and initiatives for promoting innovation and sustainable economic growth, and maintains MPI's relationship and commitments to Māori arising from the Treaty of Waitangi and Treaty settlement agreements.
5. *Office of the Director-General*: provides direction-setting and supporting services across MPI, and directly supports MPI's Director-General.
6. *Corporate Services*: provides legal support services and maintains systems and work practices that enable MPI to deliver its core functions.

The branches which have the most bearing on the export of meat and poultry products to the United States include *Policy and Trade* (Market Access Directorate) and *Regulations and Assurance*, for which the latter includes the following divisions:

- *Animal & Animal Products*: center for animal-related technical expertise, risk management, and regulatory systems. Focuses on animal-based primary industries, including animal welfare, animal-related production & processing and animal related imports and exports. Develops and publishes regulatory standards.
- *Biosecurity Science, Food Science & Risk Assessment*: advises both internal MPI and external stakeholders (including industry, consumers, and funders of scientific research).
- *Branch Planning, Systems & Support:* involved with risk management program (RMP) approvals, and approvals of recognized persons and agencies.
- *Systems Audit, Assurance & Monitoring* (SA)*:* provides assurance that New Zealand's food safety systems are being operated in line with MPI's standards. This is done through chemical/microbiological monitoring, species verification, and systems audit.
- *VS:* provides a range of food safety and biosecurity verification and certification activities. The export meat sector accounts for 80% of VS's activities. This includes slaughterhouses, meat packing houses, cold storage facilities and other specialized premises processing animal products.

Within New Zealand, AsureQuality (AQNZ), a State Owned Enterprise under the Ministry of State Owned Enterprises, performs official PM inspection activities in slaughterhouses. AQNZ is legally recognized under the New Zealand Animal Products Act 1999 and is also certified to meet ISO 17020. MPI specifies the standards that AQNZ post-mortem inspectors must meet in order to perform official PM inspection activities. Consequently, AQNZ employees meet the

criteria specified by FSIS as government employees in certified establishments and are the only employees besides those employed by VS authorized by the CCA to conduct inspection activity.

The FSIS auditors verified that MPI ensures daily presence of government inspectors at certified establishments. Personnel from both AQNZ and the VS constitute the cadre of government inspectors and they interact to maintain adequate inspection of slaughter and verification activities of the establishments' food safety systems. The salaries for both MPI VS and AQNZ designated inspection employees are funded from monies collected for services rendered in accordance with statutory mechanisms that require that operators of certified establishments pay to the government for inspection and verification services following an official schedule of payments. The government agencies in turn pay their personnel from those funds. Establishments that require additional services (e.g., increased supervisory visits) because of recurrent non-compliance must therefore pay for the additional services associated with increased verification activities. VS personnel record time in an electronic time-recording system (E4SE), and are paid every two weeks by direct deposit. AsureQuality pays their inspectors.

An additional level of oversight is provided by the MPI SA division, which enforces standards and gathers evidence to establish levels of regulatory compliance maintained by producers, as well as compliance with export market requirements. Officials in this group provide feedback on effectiveness to the standard setting groups, and manage corrective actions and sanctions imposed by the CCA upon producers. The SA also audits the functions of the VS to ensure that it effectively verifies the adequacy of food safety systems at certified establishments. During this audit, FSIS reviewed reports of SA technical reviews conducted at certified establishments over a six-month timeframe with special emphasis on the ability to meet export requirements. Information contained in the examined documents and observations conducted by the FSIS auditors at these establishments revealed that this group of the MPI effectively evaluates the functions of producers and official inspectors (i.e., both MPI VS and AQNZ) of the meat inspection system at the establishment level.

Specific training plans for new-hires were verified during visits to the VS offices in Christchurch and Whanganui. This included a 5-6 week induction course as well as a 6-12 month post warranting plan which is delivered through a combination of electronic, classroom, and workplace training prior to independent assignment to establishments certified for export to the United States.

Continuing professional development is accomplished using e-learning modules, face-to-face meetings with sector experts, and attendance at regional or external technical conferences where appropriate. 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). The following table summarizes training programs particularly relevant to product being exported to the United States during 2014.

Topic	Attendees	Dates

Animal welfare coordinator calibration	Animal welfare coordinators	March 31 - April 1, 2014
Procedures workshop	Representatives from regional teams	Last week of June 2014
HACCP (meat) e-learning assessment (NZ and USA requirements)	Online refresher course for all VS employees with Meat HACCP Unit standards	July 2014
Listeria	VS employees at establishments producing ready-to-eat products	28-29 July 2014
Technical enhancement (HACCP for new staff)	Annual course for all new VS employees employed since the last course in 2013	22-23 July 2014 26-27 August 2014
Listeria	VS employees at establishments producing ready-to-eat products	22-23 October 2014
Poultry	Poultry sector VS employees	4-8 December 2014
Exotic animal disease response e-learning	All VS staff	January 2015

While the on-site assessment of VS activities indicated that the training program is largely effective, the audit findings discussed under component two of this report represent a need for MPI to conduct additional instruction so as to ensure adequate ongoing verification of the post-mortem inspection requirements outlined in *Animal Products (Export Requirement: Company Ante-Mortem and Post-Mortem Inspection) Notice*. Although formal training was provided to VS supervising veterinarians at the time each establishment received approval to conduct post-mortem inspection activities related to this Notice (which could be as early as 2009), ongoing training has relied on informal train-the-trainer activities. In some cases, supervising veterinarians assigned to establishments after initial approval had only received train-the-trainer training.

Oversight provided by MPI to its technical support was evaluated during the audit of two state-owned laboratories. The *Laboratory Approval Scheme* (LAS) and the National Microbiological Database Program of MPI oversee the functions of testing laboratories. Through the LAS, MPI assesses and accredits laboratories to carry out official microbiological and chemical testing and verification testing for the establishments to verify compliance with regulatory and market access program requirements. Approved laboratories are required by LAS to participate and perform satisfactorily in recognized proficiency testing programs. Approval, suspension, and revocation of accreditation are based on the ability of laboratories to meet the requirements of ISO 17025. In addition, the LAS maintains inter-laboratory proficiency testing programs to verify continuity of eligibility of approved and accredited laboratories and certifies and evaluates personnel assigned to positions of overall authority in the laboratories.

While on-site, FSIS reviewed reports of audits conducted by government officials, analysts' proficiency evaluations, and records of corrective actions taken as well as their evaluations for acceptability. The result of this review indicated that the laboratories continued to meet LAS requirements, and successfully maintained accreditation and approval to conduct microbiological and chemical analyses for certified establishments.

FSIS determined that the CCA's inspection system is organized and administered by the national government, provides standards equivalent to those of the Federal system of meat inspection in the United States and can effectively implement those standards. Based on the observations made on-site in conjunction with the analysis of objective evidence gathered during the audit, the FSIS auditors concluded that the CCA continues to demonstrate the ability to meet the core equivalence requirements for this component and operates at an average level.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS (INSPECTION SYSTEM OPERATION AND PRODUCT STANDARDS)

The second of six equivalence components that FSIS reviewed was Statutory Authority and Food Safety Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; daily inspection; periodic supervisory visits to official establishments; and requirements for thermally processed/commercially sterile products. There are no other regulatory changes associated with the export meat products in the United States since the last audit that would have required changes by the CCA.

In October 2011, FSIS granted equivalence to New Zealand's post-mortem inspection procedure which involves the use of company employees to perform dispositions on non-food safety related carcass and viscera conditions, as outlined in *Animal Products (Export Requirement: Company Ante-Mortem and Post-Mortem Inspection) Notice.* The official AQNZ inspectors continue to make carcass and viscera dispositions on conditions that affect food safety. There are currently 10 slaughter establishments that are authorized to operate under the post-mortem inspection system described in this Notice, six of which were visited during the current audit. Species slaughtered under this system include bovine, ovine, and caprine.

The on-site audit methodology was designed to focus on the commitments made in the initial equivalence determination, as well as to follow-up on specific concerns raised by consumer groups in both the United States and New Zealand. Specific areas of concern raised by these groups regarding the use of company employees to perform dispositions on non-food safety related carcass and viscera conditions included: insufficient training, ability of the establishment to provide coverage during employee breaks, overcrowding of the detained rail, incomplete sorting procedures (shortcuts), insufficient lighting at statistical process control (SPC) verification stands, advanced notice of when SPC checks were to be conducted, failure to report diseases to government inspectors, failure to keep up with the speed of the slaughter line speed, and lack of oversight by the roving official AQNZ inspector.

The current audit indicated that New Zealand's implementation of its PM inspection activities continues to provide an accurate assessment of conditions that could impact carcass wholesomeness and safety. This determination was based the positive outcome of the following on-site activities, paired with the relatively high sampling rate (60%) of establishments presenting this type of system, which were visited:

- *Observation of post-mortem activities conducted by company employees performing dispositions for non-food safety related conditions and inspection tasks performed by official AQNZ inspectors*: FSIS auditors paid particular attention to the manner which establishment employees and official AQNZ inspectors examined heads, viscera, and carcasses, proper incision, observation, and palpation of required organs and lymph nodes were conducted in accordance with New Zealand's post-mortem inspection requirements, which FSIS has determined to be equivalent. No overcrowding of the detained rails was observed, and the official AQNZ inspectors properly conducted dispositions of detained animals exhibiting food safety related conditions. Establishments maintained sufficient levels of trained employees to ensure that staffing requirements were met. The auditors' review of the actual training records indicated that company employees had achieved the necessary qualifications for their assigned positions, although in one case relevant information was omitted from a training certificate for the respective employee (further discussed below).
- *Review of AQNZ SPC records*: the auditors' on-site analysis of SPC records and in-depth discussions held with government supervisory personnel (AQNZ supervisors) indicated that both company employees and official AQNZ inspectors were meeting the expected accuracy rates for fecal contamination (98%) and pathology (96%), as expressed in FSIS' equivalence determination (although MPI VS in-plant officials had some difficulty in explaining how they assess this information, see below). The auditors verified that lighting at SPC monitoring stations was sufficient to conduct such activities. AQNZ supervisors provided written protocols to ensure that these checks were conducted at random frequencies, without prior notification to the establishment.
- *Review of establishment CUSUM data for finished product*: section 2.7.3 of the *United States OMAR* requires that all carcasses exported to the Unites States in carcass form, and carcasses during pre-trim checking prior to boning, be subject to a documented quality control program (CUSUM). Sampling frequencies are outlined in Appendix 1 of New Zealand's *Industry Standard 6*. The auditors' on-site review of records indicated that these programs were being implemented as intended, and that sampled product was regularly free of contamination or pathological defects that would render the product adulterated.
- *Review of National Microbial Database (NMD) information*: during this audit, FSIS observed that testing being conducted at the audited establishments yielded results that were within acceptable parameters associated with adequate process control. Additional information regarding the NMD is provided under *Component 6: Government Microbiological Testing Programs*.

However, the audit did identify a need for MPI to improve its verification of PM inspection requirements outlined in Animal Products (Export Requirement: Company Ante-Mortem and Post-Mortem Inspection) Notice 2013.

- *Verification of Memoranda of Understanding (MOU):* One establishment presented an MOU for which it was agreed upon that a company employee would assist the official AQNZ inspector at final rail inspection when the slaughter speed exceeded 44 carcasses/hour. The MOU indicated that company personnel would be responsible for inspection of the forequarter, and the official AQNZ inspector would be responsible for inspection of the rear quarter. However, this arrangement was neither consistent with the expectations expressed by FSIS nor the competent authority (MPI), which requires that the (entire) final carcass

disposition be performed only by the official AQNZ inspector. Further discussions with the MPI supervising government veterinarian indicated that the MOU, as written, mischaracterized the activities of what is actually occurring, and that the official AQNZ inspector via mobile stand was actually performing a full carcass inspection. Nevertheless, the accuracy of this document should have been verified by MPI prior to the on-site audit. During the audit exit meeting, MPI informed FSIS that this MOU had already been revised accordingly, and that an investigation was underway to ensure the accuracy of similar documents at the nine remaining establishments with post-mortem agreements.

- *Verification of SPC Information:* in one establishment audited, official AQNZ inspectors had not provided SPC information to the VS supervising government veterinarian in accordance with the expected timeframe (weekly). Furthermore, when provided, the information was presented in a manner that was difficult to interpret. While, in theory, a conclusion as to whether process control was being maintained could be extrapolated based on the information presented, it did not appear that a few of the inspection officials had been provided with the necessary training to do so. In some cases VS supervising government veterinarians were unable to explain the difference between performance information:
  1. Expressed as a simple fraction (failures/total inspected), e.g., two carcasses of 100 presenting defects = 98%.
  2. Expressed within the context of a statistical confidence rating (e.g., 95% confidence level that a 98% accuracy rating is achieved).
- *Verification of time spent by the AQNZ roving inspector on the slaughter floor*: while this element was met, it was noted at one establishment that the records documenting the (80% required) presence of the roving official AQNZ inspector on the kill floor did not lend themselves to simple verification. Rather than clearly indicating the time spent on the floor as a single percentage, the MPI VS government official would need to add up the total in/out minutes for each day and then perform additional calculations to determine the overall on-floor presence percentage. However, government inspection records maintained by the official AQNZ inspector at other locations clearly indicated the percentage of time spent on the slaughter floor. This discrepancy represents an opportunity for New Zealand to standardize these records within its system, so that MPI verification of roving official AQNZ inspector presence can occur in a uniform manner.
- *Verification of company meat inspector training records:* while reviewing the training qualifications for company inspection personnel at one establishment, it was noted that a certificate issued by the certifying body (the New Zealand Qualifications Authority - NZQA) omitted the actual training level achieved.

In all slaughter establishments, animals are accompanied by the appropriate *Animal Status Declaration*, and undergo ante-mortem inspection that is conducted by either the resident VS government veterinarian or a specially trained official AQNZ inspector under the direct supervision of the VS government veterinarian. The FSIS auditors verified that only animals that pass ante-mortem inspection and have been properly documented on pen cards continue to slaughter, and government inspection officials routinely assesses compliance of operators with humane handling and prohibited slaughter of non-ambulatory disabled cattle requirements.

Periodic supervisory reviews of certified establishments were conducted by VS regional technical managers (RTM) and were well-documented for all intervals during which production for the United States had occurred in all 10 of the establishments audited. Additional RTM reports for United States-eligible establishments within each representative region were reviewed during visits to the VS offices in Christchurch and Whanganui.

Within New Zealand's inspection system, the principal documents governing the export of thermally processed commercially sterile product include:

- New Zealand *Industry Standard 6*, Amendment 5. In particular, section 8.6 of IS 6 requires operators to ensure that an F_0 of 3 or greater is achieved in the product, unless full scientific justification for a lower F_0 has been validated in the risk management program. Thermal processes are to result in the inhibition or inactivation of spoilage organisms capable of growing under normal non-refrigerated conditions at which the product is likely to be held during distribution and storage during its shelf life.
- *Animal Products Act 1999*. In particular, section 25, requires that when establishment risk management programs (RMP) are initially registered, or significantly amended, they are subject to evaluation. Evaluators of RMPs for canned products are required to meet the competency criteria specified in the *Recognized Agencies and Persons Notice*. The evaluator recommends the RMP for registration by MPI.
- Section 2.6.10 of the *United States OMAR*, which explicitly states that all canned meat products, must meet the FSIS requirements.

The FSIS auditor noted that the RMP had been registered in accordance with established protocols, and that the thermal process was adequate to meet applicable food-safety and commercial sterility requirements at the cannery that was visited. The auditor also verified requirements related to closure of containers, training of technicians, and additional operations (e.g., posting of processes, retort traffic control, initial temperature) conducted in thermal processing areas. No concerns were identified.

The analysis and onsite verification activities indicate that New Zealand continues to maintain equivalence and is operating at an adequate level for this component provided the one finding for Component Two is timely and completed addressed.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components that FSIS reviewed was Sanitation. To be considered equivalent to FSIS' program, the CCA is to provide general requirements for sanitation, sanitary handling of products, and development and implementation of sanitation standard operating procedures (SSOP).

The FSIS auditors observed in-plant inspection verification of operational sanitation procedures at all 10 establishments visited, of which pre-operational verification activities were also reviewed at two locations. Audit evidence was gathered through direct observation of operations and review of the establishments' associated records. These establishments maintained sanitation records sufficient to document the implementation and monitoring of the SSOP and

any corrective actions taken. The establishment employees responsible for the implementation and monitoring of the SSOP procedures correctly authenticated these records with initials or signatures and the date. No concerns arose as the result of these document reviews.

However, during the on-site tour at two facilities, FSIS observed the following deficiencies that should have been identified by MPI government inspection personnel (i.e., the official AQNZ inspector or the VS government veterinarian) prior to the FSIS audit:

- In one establishment, a heavy build-up of condensation was seen above the door leading to the carcass chiller, although no direct product contamination observed by the FSIS auditor at this time. While MPI government inspection personnel took official action to correct the issue and address any potentially affected product, the amount and specific location of the condensation indicated a problem that was ongoing and recurring in nature, i.e., insufficient ventilation in this area.
- One establishment presented several carcass hooks where the plastic radio frequency identification (RFID) housing was worn and frayed to an extent that flaking could occur, and impact overall cleanability. This could result in direct contamination of the underlying carcass while in use.

FSIS' assessment of the significance of these observations considered the following aspects: a) the auditors' largely positive assessment of sanitary conditions in the remaining areas of the facilities in question, as well at the eight additional establishments visited; b) the manner which VS government personnel addressed the specific deficiencies when it was brought to their attention by the FSIS auditors; and c) the proactive nature of commitments made by MPI management during the audit exit conference, which included system-wide communication of these deficiencies through technical briefs and increased verification tasks for these elements within the VS web-based inspection assignment system (Gen2) for a one-month time period, with two additional one-month task periods scheduled for the future..

Consequently, FSIS concludes that while New Zealand's inspection system provides for sanitation requirements and verification activities equivalent to that of the United States, these isolated incidences represent a need for increased surveillance in these areas on the part of MPI. FSIS requests that the MPI verify and document the adequacy of implementation of the long-term corrective measures proposed at the audit exit conference, and provide FSIS the results of the verification activities within its comments to this report.

FSIS concludes that the CCA is operating at an adequate level for this component.

VII. COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP)

The fourth of six equivalence components that FSIS reviewed was HACCP. The auditors verified that the CCA has issued regulations to require that each official establishment develops, implements, and maintains a HACCP system. MPI requires that all establishments operate under a registered RMP, which includes good operating practices (GMP) and HACCP requirements.

The auditors evaluated the design and execution of HACCP programs at ten certified establishments against the requirements prescribed in section 2.6.5 – 2.6.6 of the *United States OMAR,* and observed that the CCA exerts its legal authority to require that operators comply with its HACCP system rules.

At the eight slaughter establishments visited, FSIS auditors conducted an on-site review of the zero tolerance (feces, ingesta, and milk) records generated during the past year. The review of the establishment's corrective actions in response to observed deviations from the zero tolerance critical limit indicated that all four parts of the corrective actions were correctly addressed, in accordance with the section 2.6.5.d.iii of the *United States OMAR*. Furthermore, the FSIS auditors confirmed that the physical CCP monitoring location for government verification was appropriate. Lastly, measures to address the previous (2011) FSIS audit finding were verified, for which the auditors noted that establishment operators were able to provide a justification to support the frequency at which direct observation of monitoring verification activities ("check-the-checker") for the zero-fecal-tolerance (ZFT) CCP were conducted.

At the single establishment currently exporting beef jerky to the United States, the FSIS auditor visiting this establishment reviewed the HACCP program with a special emphasis on lethality for *Salmonella* and other relevant pathogens. It was noted that this establishments had adopted the recommendations included in the *FSIS Compliance Guideline for Meat and Poultry Jerky* and included appropriate measures to address lethality: relative humidity within the cooking cycle, cooking temperature, and water activity. The auditor also reviewed the validation documents at these establishments, which indicated that the actual lethality achieved by these processes exceeded the minimum five-log reduction for *Salmonella* prescribed in the aforementioned FSIS guidelines. The establishment had included a validated CCP for water activity within its HACCP system, and was consequently operating under Alternative 2 guidelines for the control of *Lm* in the post-lethality environment.

On-site follow-up of corrective actions taken in response to the March 2013 POE positive for *Lm* involving 6,746 lbs. of RTE beef jerky from this establishment was also conducted. Specific points of verification included the following, for which no additional concerns were identified:

- Review of new written procedures for disassembly and application of sanitizing compounds for the equipment identified as the source of the contamination (rotary dumper), and follow-up testing for *Lm* conducted by the establishment to validate their effectiveness.
- Confirmation that product produced on 11 production days between the date of production of the rejected lot (02/21/2013) and FSIS notification of the detection were tested at n=30 per lot, with all samples returning negative results for *Lm*.
- Review of documented supervisory reports carried out at the establishment on 02/26/2013 by the Regional Technical Specialist and 05/16/2013 by the Regional Technical Manager. The outcome for both reviews was acceptable with no issues identified.
- Review of a documented investigation undertaken by an MPI Verification Services Specialist Adviser, in conjunction with specialist staff from an AsureQuality laboratory conducted on April 2013. The review recommended several further areas where particular care and attention was needed for cleaning and sanitation but overall concluded that the company had

correctly identified areas of risk and was managing these appropriately. Several areas were swabbed during the review visit but none of these came back positive for *Listeria* spp.

Each bovine slaughter establishment had adequately reassessed their HACCP plans for the presence of STEC (O157:H7, O26, O45, O103, O111, 0121, and O145) in boneless manufacturing beef. In cases where the hazard was determined as reasonably likely to occur (slaughter of bobby calves), establishments presented validated interventions for these pathogens (steam vacuum). All establishments exporting boneless manufacturing beef were implementing preventive controls supplemented with final product testing for STEC. No concerns arose from the auditors' review of these programs.

FSIS concludes that the CCA continues to maintain equivalence and is operating at an adequate level for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that FSIS reviewed was Chemical Residues. The inspection system is to have a written chemical residue control program that is organized and administered by the national government and that includes random sampling of the internal organs, fat, and muscle of carcasses for chemical residues as identified by the exporting country's relevant authorities or by FSIS as potential contaminants.

MPI responsibilities for the control of chemical residues are grounded in the Animal Products Monitoring and Surveillance Regulations 2004, which requires the maintaining of monitoring and surveillance of animals and animal products to detect evidence of chemical residues in edible tissues and further describes the responsibilities and procedures to be followed by government officials, operators, and laboratories. To meet these responsibilities, MPI administers its National Chemical Residue Program (NCRP) for which the purpose is to randomly monitor or selectively target at-risk animals and animal products and to implement increased sampling or restricted movement of use of at-risk animals, and the disposition of non-complying product. The program involves *risk-based sampling* of livestock at saleyards, a *monitoring program* at slaughter or processing, and an *in-plant surveillance program* that targets suspect animals. Carcasses deriving from animals targeted within the *in-plant surveillance program* are held pending laboratory results.

The risk criteria used for the selection of substances to be sampled for the NCRP include:

- Farming practices in New Zealand,
- New registrations of active ingredients and substances,
- Toxicity of the substance,
- Exposure routes, including feed and environment,
- Potential for misuse or abuse (including extra-label use),
- Persistence in the environment (risk prone areas),

- Previous monitoring frequencies and findings (across both MPI and industry programs),
- Availability of a practical regulatory analytical method,
- International concern about residues of the substance, or contaminants, and
- Regulatory requirements of international markets.

When contaminants are found to exceed the Maximum Permissible Limit (MPL), an investigation is conducted, after which the animal supplier may be entered onto a national surveillance list, available to all slaughter premises. Listing results in targeted sampling of the supplier, which remains in place until there is evidence that the risk has been eliminated. MPI may take legal action if deemed necessary.

This year's NCRP and results from the previous year were not made available until the start of the current audit, for which an in-depth review of these materials is currently being conducted by the FSIS Office of Public Health and Science. However, the FSIS auditors were able to verify several aspects of program implementation while on-site. Most significantly, FSIS was able to conclude that this delay impacted solely the publication of this information, and that continued operation of the monitoring program for the current year was otherwise unaffected.

The FSIS auditors verified that all chemical residues testing performed on samples submitted under the NCRP must be undertaken by the MPI approved laboratories, using internationally approved and validated methods of analysis. Approved laboratories must be accredited by New Zealand's accreditation body, International Accreditation New Zealand (IANZ) and must also be approved under the MPI *Laboratory Approval Scheme* (LAS).

The auditors' review of the NCRP 2013-14 testing results demonstrated that samples from randomly selected poultry and livestock, including cattle, sheep and lambs, goats, and ostriches, were collected by in-plant officials. Substances tested for in the program are agricultural compounds and veterinary substances such as growth promoters, antibiotics, pesticides, anti-parasite substances, heavy metals, and environmental contaminants in adherence to the prepared plan. Results of testing demonstrated that three out 2,657 tissues of sampled animals exceeded the New Zealand MPL of 0.25 mg/kg for cadmium in farmed goats. An on-site investigation was performed, for which no unexpected source of cadmium (a ubiquitous environmental contaminant) was identified on the farms visited. Consequently, no suppliers were placed on the national surveillance list.

During the evaluation of ante-mortem inspection at slaughterhouses, FSIS auditors observed that government inspectors verify that all lots of animals are accompanied by documentation that discloses their origin, describes their registered branding, and included a signed affidavit that attests that owners have adhered to veterinary pharmaceutical withdrawal periods. It was noted that MPI headquarters had distributed instructions to the official veterinarians for the random sampling of internal organs, fat, and muscle of carcasses for chemical residues, which is provided in 6-8 week sampling blocks. An on-site review of the yearly reconciliation database maintained by MPI indicated that the current year's sampling schedule was on track.

During the audit of the AsureQuality (Gracefield) laboratory, FSIS reviewed the training records and certifications associated with the qualifications of the analysts. The documents reviewed made evident that analysts had successfully participated in intra- and inter-laboratory evaluations administered by the laboratory manager and accrediting bodies. Furthermore, records and past internal laboratory audit reports showed that laboratory managers readily respond to correct non-conformities identified during internal and external audits. The documentation on file also showed that the analysts possess the academic qualifications, technical credentials, and accreditations required to conduct analyses within their accreditation scope. FSIS has not identified any violations for chemical residues during the ongoing testing of product that occurs at POE.

In conclusion, MPI has regulatory requirements for a chemical residue control program that is organized and administered by the national government. The program includes random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified as potential contaminants. However, the delayed submission of this year's NCRP and previous year's results may result in the need for follow-up communication outside the context of the current audit, once FSIS has had a chance to review this information in its entirety. In addition, FSIS and MPI are currently working together to expedite sharing of NCRP-related information outside of the routine publication process, either through the FSIS SRT or other electronic means.

FSIS concludes that the CCA continues to maintain equivalence and is operating at an adequate level for this component.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component that FSIS reviewed was government Microbiological Testing Programs. The system is to implement certain sampling and testing programs to ensure that meat or poultry products produced for export to the United States are safe and wholesome.

MPI implements a *National Microbiological Database Program* (NMDP) for slaughter and processing plants regardless of whether their products are destined for the domestic market or exported to the United States. This program has been determined to be equivalent by FSIS and encompasses standardized sampling plans, sample transportation procedures, and prescribed analytical methods to detect and quantify *Salmonella*, generic *E. coli*, and Aerobic Plate Count (APC) in raw meat and poultry (ratite) products. Furthermore, the NMDP verifies laboratory proficiency, accredits laboratory personnel and maintains the *National Microbiological Database* (NMD) that includes microbiological profiles for individual establishments. All NMD sampling must be undertaken by persons trained and deemed competent for the species being sampled. Sampling plans must include a randomly selected time each week to sample all products types for each species.

MPI routinely monitors this information determine if sanitary control measures within specific premises and nationally are performing in accordance with regulatory requirements. Regulatory requirements of the inspection system prescribe actions to be taken when operators fail to

achieve and maintain an acceptable microbiological control status. In those cases, the VS verifies that the operator re-assess the effectiveness of hygienic dressing of carcasses and modify their systems appropriately. In addition, VS conducts an in-depth verification of the collection, packaging, and reporting of a complete sample set against the NMDP specifications at a minimum of twice per processing year.

MPI maintains a "zero-tolerance" for *Salmonella* in raw products in the sense that any detection requires a response to investigate the contributing factors and source of the organism. If weekly results are outside the national *Salmonella* performance standards, an escalating response comes into play. Upon occurrence of a positive result, the operator is responsible to provide for identification, retention and/or detention and disposition of affected product, which is subsequently verified by VS. Laboratories are to submit purified cultures of isolates of the confirmed positive colonies to a specialized laboratory for serotyping.

FSIS verified that the collection of samples occurred in accordance with program standards, where sampling is to be conducted after final inspection from pre-chilled carcasses, post-chilled carcasses, primal cuts and cartons of bulk meat. FSIS also assessed the data gathering activities of the program and verified that operators of certified establishments register with the NMDP and disclose basic identification on the establishment, the manager's contact information, and the plant official who will serve as NMD controller, and which laboratory coordinates sampling and analyses the samples. Electronic and hard copy documents reviewed by the FSIS auditors indicate that results of the tests were being consistently entered into the NMD and establishment operators regularly accessed and evaluated the processed data to assess their individual microbiological profile, their ranking against other premises, and national microbiological profiles and thus verify the adequacy of their food safety controls. FSIS observed that establishment testing yielded results that were within acceptable parameters associated with adequate process control.

During the audit of the microbiological laboratory, FSIS reviewed official reports of laboratory audits, documentation of analysts' proficiency evaluations and records of evaluations of corrective actions taken in response to audit findings. The laboratory are in compliance with all requirements of the LAS and had successfully maintained accreditation and approval to conduct microbiological analyses for certified establishments as attested in the official documents presented for examination to the FSIS auditor visiting this location.

Section 12 of the *United States OMAR* stipulates a zero tolerance policy for *E. coli* O157:H7, O26, O45, O103, O111, 0121, and O145 in raw bovine products intended grinding or other non-intact product exported to the United States. This document further outlines requirements for establishment sampling and testing of boneless manufacturing meat used as raw ground beef components or non-intact products processed concurrently through the cutting/boning room. Section 2.5.3 instructs MPI officials to verify the sample collection and submission procedures, and section 2.5.4 directs in-plant officials to verify the HACCP plans, control system for eligible and ineligible product and pre-shipment HACCP records. MPI officials regularly review test results as part of routine verification. Supervisory reviews routinely include aspects of processing that can contribute to microbial contamination, e.g. hygienic dressing, HACCP and SSOPs. MPI implements an enforcement strategy that includes immediate corrective actions,

followed by HACCP reassessment, review of HACCP and SSOP records and which may include other results from the days before and after the positive result to identify any trends and additional verification for STEC

The *United States OMAR* also specifies that an N-60 sample collection method is to be used. MPI requires the test portion of 375g, and has approved the following methods:

- BioControl Assurance screening method for *E. coli* 0157:H7
- Six serotypes:
    - Assurance GDS® Top 6 STEC (eae)
    - Assurance GDS® Shiga Toxin Genes (Top 6)
    - Assurance GDS® Top 7 STEC MPX

The presence of STECs in presumptive positive enrichment broths are confirmed by Institute of Environmental Science and Research Ltd, Enteric Reference Laboratory (ESR-ERL), Wallaceville, using procedures equivalent to the FSIS Microbiology Laboratory Guidebook (MLG 5B.02).

While on-site, the FSIS review of three years of establishment records identified several presumptive positive test results, all of which were followed-up with confirmatory testing in accordance with the above-outlined protocols. From the set of presumptive positives reviewed, the auditors noted that two of these resulted in confirmed positive results (from separate establishments). A review of related records indicated that the government and industry worked effectively to ensure HACCP reassessment, proper disposition of product (cooking), appropriate follow-up sampling, and that no adulterated product was shipped to the United States.

MPI considers *Lm* to be a hazard of concern in the production of RTE products that are exposed to the environment post lethality step. Processors of RTE products are to identify hazards that are reasonably likely to occur and the means to control them as part of their risk management program required under the Animal Products Act. The types of hazards and controls will depend on the particular process, e.g. *Salmonella* may be a hazard associated with incoming raw material and controlled by a cooking step, *Lm* may be a hazard associated with both incoming raw material and the processing environment and controlled by both cooking and a sanitation program with food contact surface and environmental monitoring carried out as a verification step.

Specific requirements related to *Lm* control are contained in section 2.6.18 of the *United States OMAR*, replicating the controls in 9 CFR 430.4 by providing the same three alternative controls to prevent post-lethality *Lm* adulteration in exposed RTE by *Lm*. Section 2.3.1.d of this document prohibits the export of any RTE product either contaminated with *Lm* or that has come into direct contact with a food contact surface that is contaminated with *Lm*.

Risk management programs are subject to evaluation by a recognised evaluator and registration by MPI. Once registered the entire RMP, including any *Listeria* management and testing programs, are subject to verification. MPI verification elements include whether the specified

testing regime is being followed, the results, and product disposition in response to positive results which ensures it is not exported and is appropriately handled (e.g. destroyed, reworked).

Where an RTE processor is using one of the two alternatives for *Lm* that require a food contact surface monitoring program, MPI has used the FSIS compliance guidelines in assessing the frequency of testing the operator has defined as part of their program. MPI has legal provision to access all test results. This is covered in the *Animal Products (Risk Management Programs) Specifications*, clause 17.

Section 2.7.6 of the *United States OMAR* instructs operators producing RTE meat products to ensure that *Lm* testing is carried out by a LAS laboratory where the accredited signatory has Official Test 2.6 in the scope of their accreditation, to conduct the *Lm* analysis. An *Lm* enumeration *Inter-Laboratory Comparison Program* is carried out on all LAS- approved laboratories undertaking *Lm* enumeration and *Lm* presence/absence, and in the most recent round of this (February 2015) all laboratories passed.

During the audit of the single establishment currently exporting RTE product to the United States, it was noted that the industry testing of food contact surfaces (FCS), non-food contact surfaces (NFCS), and product were conducted at frequencies greater than the values outlined in the aforementioned FSIS compliance guidelines. Establishment records indicated that product is routinely held until all (three types) testing results are received. Furthermore, it was noted that establishment testing results were routinely verified by local representatives of VS, as well as during periodic supervisory reviews. No concerns arose from the review of these programs.

FSIS follow-up activities conducted in response to the March 2013 positive for *Lm* identified at POE has already been discussed under *Component 4: HACCP* of this report. No additional positive tests for pathogens have been identified at FSIS POE since that time. FSIS concludes that the CCA continues to maintain equivalence and is operating at an average level for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on April 23, 2015, in Wellington with MPI. At this meeting, the preliminary findings from the audit were presented by the FSIS auditors. The audit results indicate that New Zealand's food safety inspection system is performing at an adequate level in meeting the core criteria for all six equivalence components. However, FSIS identified several findings within the Statutory Authority and Food-Safety Regulations and Sanitation components.

The audit results indicate that New Zealand's food safety inspection system is performing at an adequate level in meeting the core criteria for all six equivalence components. However, FSIS identified the following findings within the following components:

- *Statutory Authority and Food-Safety Regulations*: FSIS identified a need for the CCA to improve its verification of post-mortem inspection requirements, as outlined in New Zealand's *Animal Products (Export Requirement: Company Ante-Mortem and Post-Mortem Inspection)*.

- *Sanitation*: FSIS identified a need for increased surveillance by the CCA with regard to sanitation non-compliances within certified establishments.

During the audit exit meeting, the CCA committed to addressing the preliminary findings as presented. FSIS will evaluate the adequacy of CCA's proposed corrective actions once received.

Appendices

Appendix A: Individual Foreign Establishment Audit Checklist

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
AFFCO Imlay Whanganui	April 17, 2015	ME 39	New Zealand
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Oto Urban, 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	0
28. Sample Collection/Analysis	0
29. Records	0
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	0
31. Reassessment	0
32. Written Assurance	0

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
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	
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

April 17, 2015 | Est #: ME39 | Whanganui | (S/P) | New Zealand

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

Species slaughtered and processed: ovine and bobby calves

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Oto Urban. DVM for	Signature 4/17/2015

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
Silver Fern Farms Belfast	4/13/2015	ME15	New Zealand
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Alexander L. Lauro		[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	
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	
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	
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

April 13, 2015 |'Est #:ME15 | Belfast | (S/P) | New Zealand

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

Species slaughtered and processed: bovine.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Alexander L. Lauro	Alexander L. Lauro 4/13/2015

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 Links Mangere Auckland	April 10, 2015	JL1	New Zealand
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Oto Urban, 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	0
28. Sample Collection/Analysis	0
29. Records	0
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	0
31. Reassessment	0
32. Written Assurance	0

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
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	
52. Humane Handling	0
53. Animal Identification	0
54. Ante Mortem Inspection	0
55. Post Mortem Inspection	0
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

April 10, 2015 | Est #: JL 1 | Auckland | (P) | New Zealand

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

Species processed: Bovine

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
for Oto Urban, DVM	Laurence S. Jones, DVM 4/10/2015

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 Pukeuri	4/15/2015	ME18	New Zealand
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Alexander L. Lauro		[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	
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	
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	
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

April 15, 2015 | Est #: ME18 | Pukeuri | (S/P) | New Zealand

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

Species slaughtered and processed: ovine and bovine (including bobby calves)

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Alexander L. Lauro	Alexander L. Lauro, DVM 4/15/2015

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
ANZCO Blenheim	4/9 – 4/10/2015	ME70	New Zealand
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Alexander L. Lauro		[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	
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	
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	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

51/55. The establishment presented a memorandum of understanding (MOU) between the official assessor (AsureQuality) and the company for which it was decided that a company inspector would assist the official assessor at final rail inspection when the slaughter speed exceeded 44 carcasses/hour. Furthermore, the MOU indicated that, when this occurs, the company personnel would be responsible for inspection of the forequarter, and the official inspector would be responsible for inspection of the rear quarter. However, this arrangement neither consistent with the expectations expressed by FSIS nor the competent authority (MPI), which requires that the (entire) final carcass disposition be performed by the official assessor (AsureQuality). Further discussions with the MPI official veterinarian indicated that the MOU, as written, mischaracterized the activities of what was actually occurring, and that a full carcass inspection was actually being performed by AsureQuality (via mobile stand).

Species slaughtered: bovine

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Alexander L. Lauro	Alexander L. Lauro, DVM 4/10/2015

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
Taylor Preston Wellington	April 9, 2015	ME86	New Zealand
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Oto Urban, 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	
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	
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	
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

April 9, 2015 | Est #: ME-86 | Wellington | (S/P) | New Zealand)

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

Species slaughtered and processed: ovine, caprine, and bovine (including bobby calves)

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
FOR Oto Urban. DVM	4/9/2015

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
AFFCO Moerewa	April 15, 2015	ME-47	New Zealand
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Oto Urban, 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	
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	
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	X
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.	

41/51. A heavy build-up of condensation was seen above the door leading to the carcass chiller (product transit area). No direct product contamination was observed at this time. Although MPI personnel took official action to correct the problem and address any potentially affected product, the amount and specific location of the condensation indicated a problem which was ongoing and recurring in nature, i.e., insufficient ventilation in this area. Consequently, this problem should have been identified and controlled by inspection staff prior to the FSIS audit.

Species slaughtered and processed: ovine and bovine (including bobby calves)

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
McCallum, MIHINI Henderson Auckland	April 13, 2015	PH134	New Zealand
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Oto Urban, 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	0
28. Sample Collection/Analysis	0
29. Records	0
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	0
31. Reassessment	0
32. Written Assurance	0

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
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	
52. Humane Handling	0
53. Animal Identification	0
54. Ante Mortem Inspection	0
55. Post Mortem Inspection	0
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

April 13, 2015 | Est #: PH134 | Auckland | (P) | New Zealand

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
for Oto Urban, DVM	4/13/2015

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
Silver Fern Farms Pareora	4/16/2015	ME34	New Zealand
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Alexander L. Lauro		[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	
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	
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

April 16, 2015 | Est #: ME34 | Pareora | (S/P) | New Zealand

51/45. The establishment presented numerous carcass hooks where the plastic radio frequency identification (RFID) housing on the base/slide was worn and frayed to the extent that flaking could occur. This could result in direct contamination of the underlying carcass while in use.

Species slaughtered and processed: ovine, caprine, and bovine (including bobby calves)

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Alexander L. Lauro	Alexander L Lauro, DVM 4/16/2015

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 Smithfield (Timaru)	4/17/2015	ME17	New Zealand
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Alexander L. Lauro		[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	
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	
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	
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

April 17, 2015 | Est #: ME17 | Timaru | (S/P) | New Zealand

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

Species slaughtered and processed: ovine

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Alexander L. Lauro	Alexander L. Lauro, DVM 4/17/2015

Appendix B: Foreign Country Response to Draft Final Audit Report

Ministry for Primary Industries
Manatū Ahu Matua

28 September 2015

Jane H Doherty,
International Coordination Executive
Office of International Co-operation
Food Safety and Inspection Service
United States Department of Agriculture
1400 Independence Avenue, SW.
WASHINGTON, DC 20250

Dear Jane

MPI Response to FSIS Draft Final Report – FSIS Audit of New Zealand Meat and Poultry Food Safety Systems – April 2015

Thank you for providing MPI with the opportunity to comment on the FSIS draft final audit report. MPI is pleased to have advice from FSIS that New Zealand's implementation of its' PM inspection activities continues to provide an accurate assessment of conditions that could impact carcass wholesomeness and safety.

I have divided our response to the draft audit report into 4 sections. The penultimate section provides a summary of MPI's actions that have, or are intended to be, taken in response to matters raised by the draft report.

1. General Comments on the Audit and the draft report

Page 12 of the draft report lists MPI's branches and notes that *"From an operational perspective, the branch that has the most bearing on the export of meat and poultry products to the United States is Regulations and Assurance, which includes the following divisions".*

MPI would like to note that the draft report neglects to mention the role of the Market Access Directorate within the Policy and Trade Branch. That Directorate acts as the focal point for MPI's sanitary and phytosanitary (SPS) government to government functions, and leads negotiation of SPS and related export conditions and assurance systems with counter-part Competent Authorities. It is also promulgates all bilateral overseas market access requirements.

Policy and Trade Branch
Market Access Directorate
Pastoral House, 25 The Terrace, PO Box 2526
Wellington 6140, New Zealand
Telephone: +64 4 894 0100,

2. Specific Technical Comments on the Draft Report

Table 1, column 1 shows the page number reference from the draft FSIS report, and column 2 contains the relevant text from the report that is the subject of MPI's comment. The third column shows MPI's comment or suggestion.

TABLE 1:

Page Number	Report text	MPI Comment
2	Table showing Competent Authority Visits and Locations	Under "Establishments" two amendments should be made. Two bovine slaughter and processing establishments (not one) were visited; and only five (not six) "mixed ruminant" establishments were visited. It is unclear what "0073" refers to in the table.
3	Currently, New Zealand has equivalence determinations in place for the following: • Generic *Escherichia coli (E. coli)* sampling o The testing frequency in lambs and sheep is five carcasses per week	New Zealand is not required to test for generic E. coli in lambs and sheep under FSIS's equivalence determination.
4	**III Background** FSIS performed additional types of inspection (TOI) on 61,663,722 pounds at POE of which a total of 1,257,861 pounds (2%) were rejected, predominately due to spoilage during transport or fecal contamination on lamb carcasses.	MPI respectfully requests further detail on what is meant by "spoilage during transport"? MPI suggests that damage to cartons during transport may be a more likely cause of rejection than "spoilage" to the products contained therein.
4	**III Background** Due to persistent problems with fecal contamination findings at POE by FSIS, MPI has voluntarily suspended the export of whole lamb carcasses to the United States until further notice.	This is not correct. MPI has not voluntarily suspended export of whole lamb carcasses to the US. MPI did require certain high risk products destined for export to the US (lamb flaps and whole carcasses) to be subjected to an additional quality control check.
6	AQNZ is legally recognized under the New Zealand Animal Products Act 1999 and certified to meet ISO 17020.	AQ have made a commercial decision to be ISO 17020 certified. There is no regulatory imperative for ISO 17020 certification.
6	AQNZ hires individuals that have completed training offered by industry training organizations that are certified by MPI to provide basic inspection training.	MPI does not certify industry training organisations (ITO). MPI specifies the competency standards that individuals must meet in order to perform official PM inspection activities. AQ is the only ITO legally permitted by MPI to train post mortem inspectors.
7	Second paragraph: "The LAS assesses and accredits laboratories...."	MPI, who operate the LAS programme, approves laboratories which have been assessed and accredited by an Accreditation Body.
11	• *Animal Product (Specifications for Products Intended for Human Consumption) Notice 2013*	Replace this reference with: *Animal Products Act 1999*
11	• New Zealand *Industry Standard 6*, Amendment 5.	Replace "section 2.4.2" with "section 8.6"

	In particular, section 2.4.2 of IS 6...	
12	c) the proactive nature of commitments made by MPI management during the audit exit conference, which included system-wide communication of these deficiencies through technical briefs and increased verification tasks for these elements within the VS web-based inspection assignment system (Gen2) for a three-month time period.	System-wide communication of these deficiencies occurred through an Agency Technical Manager specified task in VOL (Gen2) for a one-month time period, with two additional one-month tasks scheduled for the future.
14	Final paragraph: "MPI and its business groups in conjunction with AsureQuality administer the National Chemical Residue Program (NCRP)."	AsureQuality has no role in administering the NCRP, however it does perform sample collection as directed by MPI
14	Final paragraph: "The program involves risk-based on farm sampling of livestock"	MPI's sampling of at risk animals involves sampling livestock at saleyards and at slaughterhouses, but not directly on farms.
17	MPI has maintains a zero-tolerance for the presence of *Salmonella* in raw products. Consequently, the CCA requires that producers comply with the requirements related to *Salmonella* sampling and testing included in the NMDP. Upon occurrence of a positive result, the operator is responsible to provide for identification, retention and/or detention and disposition of affected product, which is subsequently verified by VS.	MPI maintains a zero-tolerance for Salmonella in the sense that any detection requires a response to investigate the contributing factors and source of the organism. If weekly results are outside the national salmonella performance standards, an escalating response comes into play.
18	Section 12 of the *United States OMAR* stipulates a zero tolerance policy for *E. coli* O157:H7, O26, O45, O103, O111, 0121, and O145 in raw bovine products exported to the United States.	Section 12 of the United States OMAR stipulates a zero tolerance policy for in raw bovine products intended for use in ground or other non-intact product exported to the United States
18	MPI implements an enforcement strategy that includes, immediate corrective actions, followed by HACCP reassessment, review of HACCP and SSOP records and other results from the days before and after the positive result to identify any trends and additional verification for STEC.	Suggest rewording: MPI implements an enforcement strategy that includes immediate corrective actions, followed by HACCP reassessment, review of HACCP and SSOP records and which may include other results from the days before and after the positive result to identify any trends and additional verification for STEC
18	The *United States OMAR* also specifies that an N-60 sample collection method is to be used. MPI requires the test portion of 375g, and has approved the following methods: • BioControl Assurance screening method for *E. coli* 0157:H7 • Six serotypes: o Assurance GDS® Top 6 STEC (eae) o Assurance GDS® Shiga Toxin Genes (Top 6) o Assurance GDS® Top 7 STEC (eae) o Assurance GDS® Shiga Toxin Genes (Top 7) o Assurance GDS® Top 7 STEC MPX	The Assurance GDS Top 7 STEC (eae) and the Assurance GDS Shiga Toxin Genes (Top 7) tests are not used. The list should read as follows: • BioControl Assurance screening method for *E. coli* 0157:H7 • Six serotypes: o Assurance GDS® Top 6 STEC (eae) o Assurance GDS® Shiga Toxin Genes (Top 6) o Assurance GDS® Top 7 STEC MPX

3. Response to Matters raised in the draft Report

3.1 In relation to matters raised within Section V of the draft report and in particular pages 7, 9 and 10, MPI has;

- Reviewed the Memoranda of Understandings between establishments and AQNZ and made any necessary documentary adjustments so they reflect New Zealand's legislative requirements.
- Developed an e-learning module to facilitate training of staff involved in verification activities.
- Held a face-to-face workshop in September 2015 for all supervising veterinarians based at the 10 establishments.

3.2 In relation to matters raised within Section VI of the draft report and in particular pages 12 and 16;

- The report raises two instances (page 12) of sanitary deficiencies. MPI would note that in relation to the build-up of condensation in a doorway leading to a carcass chiller MPI VS has commenced a targeted verification programme to assess the management of condensation in all US-listed establishments. This programme included setting up an Agency Technical Manager (ATM) specified verification task in Verification Online. The task was for one month's duration during May – June 2015. Two further ATM specified verification tasks are scheduled for February 2016 and October 2016.

- In relation to carcass hooks presented with worn and frayed radio frequency identification (RFID) housing the establishment operator has purchased additional RFID skids to replace any damaged ones. The establishment's documented system was also updated to describe a process for inspecting and removing any skids that may become defective in the future. MPI VS verification of the new process confirms this area is being well managed.

4 Other Matters

The draft report (page 16) indicates that FSIS wishes, outside the context of the April 2015 audit, to discuss the submission of National Chemical Residues Programme related information. MPI would like to confirm that such further written correspondence has occurred, and that the annual NCRP report and sampling plan will be submitted via the SRT or other electronic means in future.

I have attached a copy of the draft FSIS report which contains a few other suggested changes.

Finally I would like to commend the FSIS auditors for their professional approach during this audit.

Yours sincerely

Dr Tony Zohrab
Chief Market Access Officer
Ministry for Primary Industries