USDA

United States Department of Agriculture

Food Safety and
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AUG 13 2019

Dr. Tony Zohrab
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New Zealand

Dear ~~Dr. Zohrab~~ Tony,

Enclosed is a copy of the final audit report for the United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) on-site audit conducted of New Zealand's meat inspection system from February 26 through March 13, 2018. The comments received from the Government of New Zealand are included as attachments to the final report.

For any questions regarding the FSIS audit report, please contact the Office of International Coordination at InternationalCoordination@fsis.usda.gov.

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN NEW ZEALAND

FEBRUARY 26 - MARCH 13, 2018

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING BEEF, VEAL, SHEEP, AND GOAT MEAT PRODUCTS EXPORTED TO THE UNITED STATES OF AMERICA

June 25, 2019

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from February 26 - March 13, 2018. The purpose of the audit was to determine whether New Zealand's food safety system governing raw, ready-to-eat (RTE), and other processed meat products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. New Zealand currently exports to the United States raw intact and non-intact, RTE fully cooked not shelf stable, shelf stable and thermally processed commercially sterile (TPCS) beef, veal, sheep, and goat products.

The audit focused on six system equivalence components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations

- The Central Competent Authority (CCA) is not ensuring that government inspection occurs once per shift in processing establishments that produce product for export to the United States during multiple production shifts.

Government Hazard Analysis and Critical Control Points (HACCP) System

- The CCA has determined that Shiga toxin-producing *Escherichia coli* (STEC) are not likely to occur in adult cattle in New Zealand. Two of nine beef slaughter establishments had confirmed positive STEC findings; however, no establishment nor the CCA concluded that STEC were a hazard reasonably likely to occur.
- Eight of nine slaughter establishments failed to document monitoring records meeting HACCP requirements.

During the audit exit meeting, the CCA committed to respond to the preliminary findings as presented. Once FSIS receives the documented proposed corrective actions, FSIS will evaluate the adequacy of the information to determine the scope of future equivalence verification activities.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of New Zealand's food safety system from February 26 - March 13, 2018. The audit began with an entrance meeting held on February 26, 2018, in Wellington, New Zealand, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – the Ministry for Primary Industries (MPI).

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether the food safety system governing raw and processed meat products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. New Zealand is eligible to export raw intact and non-intact, RTE (fully cooked not shelf stable, shelf stable and thermally processed commercially sterile) beef, veal, sheep, and goat products to the United States. New Zealand is not currently under any animal health restrictions identified by USDA's Animal and Plant Health Inspection Service (APHIS).

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, point-of-entry (POE) testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from the CCA through the self-reporting tool (SRT).

Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors reviewed administrative functions at the CCA headquarters, two regional offices, 11 local inspection offices at the audited establishments, one government microbiological laboratory, and one government chemical residue laboratory. The FSIS auditors evaluated the implementation of management control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended. This evaluation included onsite verification of the implementation of those corrective actions proffered to FSIS by New Zealand to remedy the April 2015 audit findings.

The FSIS auditors also reviewed the administrative functions of the local inspection offices as part of the establishment review. The FSIS auditors assessed the CCA's sampling and testing methodology through a review of records at the regional inspection offices, evaluation of

sampling procedures at audited establishments, and the audit of two laboratories. The FSIS auditors visited 11 establishments from 73 establishments certified as eligible to export to the United States. The 11 establishments included nine (beef, veal, sheep, and goat) slaughter and processing establishments and two processing establishments for beef, lamb, and mutton that produce RTE products including shelf stable and thermally processed commercially sterile products for export to the United States.

During the establishment visits, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditors examined the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §327.2.

Additionally, FSIS audited one government microbiological laboratory and one government chemical residue laboratory to verify their ability to provide adequate technical support to the inspection system.

Competent Authority Visits		**#**	**Locations**
Competent Authority	Central	1	• Ministry for Primary Industries, Wellington
	Regional	2	• Regional Office, Waikato • Regional Office, Christchurch
Laboratories		2	• AsureQuality Limited Laboratory, Auckland (government-microbiological) • AsureQuality Limited Laboratory, Lower Hutt (government-chemical residue)
Bovine and ovine slaughter and processing establishments		6	• Establishment ME 18, Alliance Group Limited, Oamaru • Establishment ME 23, AFFCO New Zealand Limited, Horotiu • Establishment ME 26, Silver Fern Farms Limited, Balclutha • Establishment ME 50, Alliance Group Limited, Invercargill • Establishment ME 78, CMP Canterbury Limited, Ashburton • Establishment ME 132, Prime Range Meats Limited, Waikiwi
Bovine slaughter and processing establishments		2	• Establishment ME 84, Silver Fern Farms Limited, Te Aroha • Establishment ME 127, UBP Limited, Te Kuiti
Bovine, ovine, and caprine slaughter and processing establishments		1	• Establishment ME 137, Lean Meats Oamaru Limited, Oamaru
Bovine processing establishments		1	• Establishment JL 1, Jack Link's New Zealand Limited, Auckland
Bovine and ovine processing establishments		1	• Establishment PH 134, McCallum Industries Limited, Auckland

FSIS performed the audit to verify that New Zealand's food safety inspection system was equivalent to FSIS' system regarding specific provisions of United States' laws and regulations, in particular:

- The Federal Meat Inspection Act (FMIA) (21 United States Code [U.S.C.] 601, *et seq.*);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901, *et seq.*); and
- The Federal Meat Inspection Regulations for Imported Products (9 CFR Part 327).

The audit standards applied during the review of New Zealand's inspection system for slaughtered and processed meat 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 World Trade Organization's Sanitary/Phytosanitary Agreement.

III. BACKGROUND

From October 1, 2014, to September 30, 2017, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 1,560,949,000 pounds of meat products imported from New Zealand. This amount of meat product included a total of 1,323,633,711 pounds of beef (raw intact, raw not intact, not RTE, fully cooked not shelf stable, shelf stable and thermally processed commercially sterile product types), 57,076,494 pounds of veal (raw intact), 28,940,631 pounds of mutton, 149,966,198 pounds of lamb, and 1,331,966 pounds of goat meat.

FSIS also performed reinspection on 86,107,300 pounds at point-of-entry (POE) for additional types of inspection. The reinspection included testing for chemical residues and microbiological pathogens (including *Listeria monocytogenes* (*Lm*) and *Salmonella* in RTE products and Shiga toxin-producing *Escherichia coli* (STEC, including O157:H7 and non-O157)) of which a total of 149,132 pounds were rejected for food safety reasons (e.g., ingesta, fecal materials, etc.) and an additional 128,160 pounds due to pathological lesions.

The previous FSIS audit in 2015 identified findings related to the Government Statutory Authority and Food Safety and Other Consumer Protection Regulations and Government Sanitation components. The FSIS auditors confirmed that the MPI's Verification Services had effectively implemented corrective actions in response to the 2015 FSIS audit findings. In addition, the audit included a visit to three establishments involved in the 2016 and 2017 POE violations. FSIS verification concluded that the CCA worked with the establishments to identify the root causes of the POE violations and instituted appropriate corrective actions.

The evaluation of all six equivalence components included a review and analysis of documentation previously submitted by MPI as support for the responses provided in the SRT. The FSIS onsite audit included record reviews, interviews, and observations made by the FSIS auditors.

The 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 (E.G., ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components that the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign inspection system to be organized by the national government in such a manner as to provide ultimate control and supervision over all official inspection activities; ensure 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.

The FSIS auditors verified that MPI is the CCA, which provides the oversight for New Zealand's meat inspection system and ensures the safety of exported meat products. The sectors pertaining to food safety and biosecurity of animal origin products covered by MPI include administrative, advisory, and policy development. MPI officials provide technical input into government policy on safety in food production and processing, and provide official assurances of export product compliance with the requirements of foreign governments. The main branches within MPI that are responsible for the delivery of meat inspection and have the most bearing on the export of meat and poultry products to the United States include the Policy and Trade Branch, under which the Market Access Directorate manages sanitary and phytosanitary negotiations. The Regulations and Assurance Branch supports primary producers and consumers by implementing MPI's legislative and regulatory frameworks. Other support programs within MPI with significant importance to the food safety and meat inspection include the Sector Partnerships and Programs Branch; Corporate Services Branch; and Operations Branch. The Operations Branch engages in planning, coordination, compliance, and border management.

MPI's Verification Services (VS) within the Regulations and Assurance Branch ensures establishment compliance with requirements and serves as the verification arm of the CCA nationwide. The technical staff within VS is responsible for conducting verification of requirements at the meat establishments certified as eligible to export to the United States (hereafter, certified establishments). The main workforce in the VS is comprised of veterinarians. The VS maintains offices in 70 locations organized into 11 establishment teams across seven circuits throughout New Zealand. The Team Manager Establishments (TMEs) are responsible for overall supervision and management of VS personnel assigned to certified establishments.

Prior to the current audit, officials in six geographically marked regions administered the responsibilities of establishment teams. Transition to the new supervisory structure was completed in April 2018. Verification Services is accredited by the International Organization for Standardization (ISO) as an inspection agency and is audited annually by International Accreditation New Zealand (IANZ) to comply with requirements of the *Animal Products Act of 1999*.

The FSIS auditors verified that VS designates Animal Product Officers (APOs), who in slaughter establishments are veterinarians and also known as Veterinary Technical Supervisors (VTSs). In the processing establishments, the APOs are either veterinarians or non-veterinarians. APOs

assigned to certified establishments are responsible for verifying establishments' food safety programs, evaluating and approving Risk Management Programs (RMPs), and conducting inspection activities related to HACCP, sanitation, ante-mortem inspection, and post-mortem inspection.

AsureQuality Limited (AQNZ), an organization under the Ministry of State Owned Enterprises, supports the slaughter establishment's VS inspection personnel. The accredited inspectors of AQNZ, designated as Official Assessors (OAs), perform ante-mortem and post-mortem inspection activities in slaughter establishments. AQNZ is legally recognized under the *Animal Products Act of 1999* and is certified to meet ISO 17020 standards as an inspection agency. MPI specifies the standards that AQNZ OAs must meet in order to conduct ante-mortem and post-mortem inspection activities. Consequently, AQNZ employees meet the criteria specified by FSIS as government employees in certified establishments.

The Systems Audit Team (SAT) within the Assurance and Monitoring Division of MPI's Regulations and Assurance Branch is a team of trained system auditors who provide an additional level of oversight in order to enforce standards for compliance with export market requirements. The system auditors also audit the functions of VS to ensure that they effectively verify the adequacy of food safety systems at certified establishments.

Prior to the current FSIS audit, SAT conducted a pre-audit of the New Zealand system with a primary focus on assessing the level of compliance at certified establishments with *United States of America -Overseas Market Access Requirements (USA-OMAR).* An additional focus of the SAT audit included establishment corrective actions in response to the 2015 FSIS audit and FSIS POE violations. The SAT audits of the laboratories were to assess whether the laboratories had successfully phased into a Recognized Laboratory Program (RLP), which began in 2015 and required all laboratories to complete the transition by August 2017.

The SAT audit identified issues in the government's communication of FSIS POE violations to the certified establishments and provided recommendations to MPI on how to minimize delay by gathering and disseminating information in real time to the certified establishments. The SAT audit of the laboratories resulted in two findings and four recommendations provided to MPI. In addition to the SAT audit report discussed above, the FSIS auditors also reviewed a sample of the system auditors' technical reviews conducted at the certified establishments to assess the establishments' ability to comply with *USA-OMAR* and national requirements.

The FSIS auditors verified that the VS personnel are direct hires and salaried employees of MPI. Remunerations of VS personnel and AQNZ inspectors are funded from monies collected for services rendered in accordance with statutory mechanisms that require that operators of certified establishments pay 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, as a result of recurrent noncompliance, must therefore pay for the additional services associated with increased verification activities. VS personnel may only work outside the agency if no conflict of interest exists, and employees must report any conflict of interest situations according to MPI's conflict of interest policy.

The FSIS auditors verified that the Veterinary APOs assigned to establishments are graduates of accredited colleges and have received the required training in auditing, legislation, industry standards, animal welfare, HACCP, residues, and certification procedures prior to reporting to their duty stations. Interviews conducted with MPI revealed that veterinarians must be registered with the Veterinary Council of New Zealand and undergo training administered by VS. All newly hired staff must have a tertiary qualification in addition to minimum academic requirements for the position as an APO. A university graduate certificate in food science, for example, is considered a tertiary qualification for the recruitment. All new entrants in VS undergo a 5-6 week induction course, which is followed by post induction training in subjects referenced above. Ongoing training of the staff includes e-learning, participation in regional conferences, and annual seminars. The FSIS auditors concluded that initial and ongoing training follows MPI's established standards. The same is also true for AQNZ staff based on the interviews conducted and documents reviewed at AQNZ local offices in certified establishments.

The FSIS auditors confirmed that MPI maintains a communication system to convey inspection requirements throughout its inspection system (including industry) in a timely manner. MPI maintains an internal web portal where employees can access information applicable to their respective roles. In addition, updates to any technical documents and inspection requirements relevant to both industry and MPI employees are continually uploaded on MPI's public site. Links to important documents are also communicated via e-mails. Sensitive communications are provided via a password protected website available to all processors and exporters. The law requires that exporters be registered with MPI and abide by all such notifications. The FSIS auditors received demonstrations of employee access to both sites.

MPI requires AQNZ to conduct internal audits of their inspection activities covering ante-mortem and post-mortem inspections and other verification activities at the slaughter establishments. The VTSs assigned to the certified slaughter establishments are required to verify that AQNZ effectively delivers inspection services consistent with MPI and FSIS requirements. VS conducts meetings with AQNZ supervision every two weeks in each slaughter establishment. In addition, the VTS at each slaughter establishment conducts verification activities of AQNZ records and procedures every three months. The FSIS auditors reviewed examples of AQNZ records as well as VS reports. No concerns were identified as a result of the FSIS auditors' review.

One of the elements in the current audit scope was to verify the implementation of MPI's corrective actions in response to findings identified in the 2015 FSIS audit. The 2015 audit identified multiple findings related to verification of post-mortem inspection requirements including verification of memoranda of understanding (MOU), statistical process control information, time spent by roving AQNZ inspectors on the slaughter floor, and verification of company meat inspector training records. In addition, the 2015 audit also identified a need for increased surveillance for sanitation noncompliance. In response to the audit findings MPI reviewed the MOUs to ensure they met New Zealand requirements, developed an e-learning module to facilitate training of inspection personnel, and held a training session for all supervisors of APMIS establishments. In response to sanitation findings MPI implemented a targeted inspection program to verify effective management of condensation. Lastly, MPI verified that establishment corrective actions resolved the isolated sanitation findings identified

during the audit. The FSIS auditors confirmed that MPI had remedied systemic as well as localized findings of the audit by implementing a host of measures appropriate to specific situations.

As briefly discussed above in context with the SAT pre-audit of laboratories, it is important to note that since the 2015 FSIS audit, MPI introduced a new laboratory program, the requirements of which were detailed in the *Animal Products (Specification for Laboratories) Notice 2015.* The salient features of the program included an alignment of the Export Laboratory Programme, Dairy Recognized Laboratories, and the Laboratory Approval Scheme into one program known as the Recognized Laboratory Program (RLP). National programs requiring use of MPI's RLP laboratories include the National Chemical Residue Programme, National Microbiological Database, Pathogen Strategies including *Salmonella,* and STEC. A total of 19 RLP laboratories perform routine microbiological testing for the meat industry.

All laboratories recognized under RLP had until August 2017 to complete the requirements contained in the *Animal Products (Specification for Laboratories) Notice 2015*. The notice addresses the requirements for laboratory facilities, equipment, and personnel qualifications. Laboratories under RLP must be accredited to the ISO 17025 standard for the regulatory tests performed. For each test for which the RLP laboratory is recognized, the laboratory must have at least one Key Technical Person (KTP) who has a relevant tertiary qualification and appropriate experience and training in the discipline of interest. The KTP is responsible to affix his or her signature and release the certificate of analysis for the list of tests described in the *Consolidated List of Tests* (CLT). IANZ conducts the accreditation and ongoing audits of each RLP-approved laboratory. Approved laboratories are required to participate in the Interlaboratory Comparison Programme's (ILCP) proficiency testing. MPI holds the right and can refuse to grant recognition, refuse to renew recognition, or suspend and revoke recognition of a laboratory who fails to meet the conditions outlined in the *Animal Products (Specification for Laboratories) Notice 2015.*

The FSIS auditors concluded that MPI maintains both legal authority and a regulatory framework to implement equivalent regulatory requirements.

V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (E.G., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

The second of six equivalence components that the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection 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; inspection at least once per shift during processing and on-line inspection during slaughter operations; periodic supervisory visits to official establishments; and requirements for thermally processed commercially sterile products.

The *Animal Welfare Act of 1999* establishes the provisions to ensure animal welfare and holds responsible the handlers and caretakers of livestock for welfare and humane treatment of animals presented for slaughter. The *Animal Welfare (Commercial Slaughter) Code of Welfare 2010* includes recommended best practices and *Part 2* of *USA-OMAR* details the requirements for animal welfare to ensure United States requirements are met at all certified establishments. The FSIS auditors assessed the humane handling and slaughter practices at all audited slaughter establishments to determine the adequacy of ante-mortem facilities and compliance of operators with humane handling requirements imposed by MPI and *USA-OMAR*.

The FSIS auditors verified that the VTSs were performing ante-mortem inspection and verification activities at each certified establishment. The FSIS auditors observed that the VTSs were reviewing documents accompanying the livestock shipments for slaughter and observing conditions of animals during unloading and later when animals are at rest. The FSIS auditors interviewed the VTSs and reviewed shipping documents, kill sheets, and other records at all audited establishments and concluded that ante-mortem procedures followed MPI's established standards. No concerns were identified as a result of audit verification.

Two distinct types delineate the post-mortem inspection procedures: traditional, and an Alternate Post Mortem Inspection System (APMIS). FSIS has previously determined the APMIS alternative as equivalent to traditional inspection. The *Animal Product Act of 1999* and MPI's associated notices *Animal Products (Export Requirement: Inspection Agencies Ante-Mortem and Post-Mortem Inspection) Notice 2009, Animal Products (Export Requirement Inspection Agencies Ante-Mortem and Post-Mortem Inspection) Amendment Notice 2013* delegate recognized agencies to conduct post-mortem inspection. Procedures to conduct post-mortem inspection are detailed in the *Red Meat Code of Practice (CoP) Chapters 6 (presentation for post-mortem), 7 (post-mortem examination)* and *8 (post-mortem dispositions)*.

In eight of the nine audited slaughter establishments, the facilities were operating under traditional post-mortem inspection. In traditional slaughter establishments, post-mortem inspection is performed by AQNZ's OAs under the supervision of an AQNZ supervisor in accordance with the national standards. The FSIS auditors observed OAs conducting post-mortem inspection in beef and lamb slaughter establishments. In beef slaughter establishments, OAs were conducting inspection of heads, viscera, and carcasses. For carcasses diverted to the detain rail for further trimming, either the AQNZ supervisor or qualified OA verified each one before allowing it to leave the detain rail. FSIS auditors identified that the OA's were not incising the cheek muscles to expose and examine the masticatory muscles during head inspection at traditional cattle slaughter establishments. FSIS auditors verified this alternative post-mortem inspection procedures is carried out as decribed in the individual sanitary measure that was determined equivalent on May 21, 2003.

At the lamb slaughter facilities, the FSIS auditors verified the adequacy of the chain speed, the number of inspectors, and the lighting requirements at the inspection stations. The FSIS auditors determined that the system was meeting United States requirements applicable to post-mortem inspection at the traditional inspection slaughter establishments. No issues were identified as a result of this verification.

At the time of the FSIS audit, MPI had approved ten certified slaughter establishments to operate under APMIS and one of these establishments was included in the scope of the current audit. According to the FSIS equivalence determination, under APMIS, establishment employees are allowed to perform dispositions on non-food safety (other consumer protection-OCP) related carcass and viscera conditions. The FSIS auditors verified the alternative post-mortem examination procedures, ensured that each carcass was free of feces, milk and ingesta prior to being determined eligible for the mark of inspection. The establishment employees were responsible for re-inspecting product on the detain rail, except for condemnable pathology. Additionally establishment employees were performing post-mortem examinations and dispositions on the heads and viscera. This practice is consistant with the individual sanitary measure determined equvalent by FSIS on October 24, 2011.

The TMEs conduct periodic supervisory visits of each certified establishment at a minimum frequency of once every three months. The purpose of the supervisory visits is to ensure that the New Zealand standards and the United States requirements are consistently met. The FSIS auditors reviewed supervisory visit reports conducted by the TMEs at the certified slaughter establishments. The FSIS auditors concluded that the reviews are conducted at the frequency specified and document the supervisory assessment of compliance with United States requirements in each certified establishment. In some cases, the FSIS auditors identified isolated findings that were not been previously addressed by the assigned VS personnel or the TMEs.

The FSIS auditors verified that the CCA ensures daily presence of government inspectors at the certified establishments. All certified establishments slaughtering beef, sheep, and goats receive uninterrupted inspection, including on line, by government inspectors under the supervision of AQNZ for each shift when slaughter activity is occurring. In addition, the VTS is also present throughout each slaughter shift. The FSIS auditors identified one audited processing establishment for which VS was providing daily, but not per shift government inspection during the periods when the operation is processing meat products for the United States market. The FSIS auditors identified the following:

- The CCA is not ensuring that government inspection occurs once per shift in processing establishments that produce product for export to the United States during multiple production shifts.

New Zealand's meat inspection system continues to maintain the legal authority and a regulatory framework to implement its regulatory requirements. However, the daily deployment (less than once per shift) of the government inspection staff at processing plants is inadequate for program implementation to meet the FSIS requirements for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation standard operating procedures (sanitation SOPs) to prevent direct product contamination or insanitary conditions.

The requirements for development and implementation of written sanitation SOPs at the certified establishments are prescribed in Part 2.6.4 of *USA-OMAR*. The range of sanitation requirements within this part include hygiene of facilities and equipment, personnel hygiene, repair and maintenance, cleaning material, pest management, dropped meat product and rework, and waste disposal. The *Animal Products (Export Verification Requirements) Notice 2016* and its relevant schedules provide verification frequencies based on the outcome of verification checks. An establishment operating in lower steps of performance (e.g., steps 1-5) may be subject to more frequent government verification activities than one operating on step 6 or higher.

The FSIS auditors reviewed written sanitation SOPs and related records pertaining to design and implementation of sanitation requirements at all audited establishments. The FSIS auditors confirmed that government inspection personnel are responsible for verifying compliance with *USA-OMAR* and MPI requirements to ensure sanitary operations are maintained at certified establishments. In slaughter establishments, the FSIS auditors observed that the VTSs verify the adequacy of sanitary dressing of carcasses.

In two of the 11 audited establishments, the FSIS auditors verified whether the pre-operational inspection was equivalent to FSIS's by observing the VTSs conducting pre-operational sanitation verification. The FSIS audit identified that government inspection personnel verify pre-operational sanitation SOP requirements a minimum of once per year at one audited RTE establishment. The infrequent verification coupled with the VTS findings identified during pre-operational sanitation verification suggest this frequency may be inadequate to ensure each certified establishment consistently meets pre-operational sanitation requirements.

The FSIS auditors reviewed verification reports containing the outcome of VTS verification activities as documented in *Verification Online (Gen2)*, the VS inspection database. Verification includes the level of operator compliance with New Zealand standards (e.g., RMP), general export requirements, and overseas market requirements, including sanitary practices. The FSIS auditors determined that overall, the sanitary conditions observed during the audit matched inspection and supervisory records, except for noted isolated findings at multiple audited establishments.

The FSIS auditors observed additional noncompliance related to pre-operational and operational sanitation requirements in multiple audited establishments that MPI failed to identify. The auditors' observations are detailed in individual establishment checklists provided in the Appendix A of this report.

The FSIS auditors concluded the New Zealand's inspection system provides for sanitation requirements and verification activities equivalent to that of the United States. FSIS requests that MPI verify and document the adequacy of implementation of the long-term corrective measures, and provide FSIS the results of the verification activities within its comments to this report.

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

The fourth of six equivalence components that the FSIS auditors reviewed was Government HACCP System. The inspection system is to require that each official establishment develop, implement, and maintain a HACCP system.

In New Zealand the HACCP system is an integral component of a broader food safety program which is mandated in the *Animal Products Act* of *1999 (Part 2, Section 17)* and recognized as *"Contents and Requirements of Risk Management Programs - RMP."* Some of the fundamental requirements that each food operating business must integrate into the RMP include hazard identification, the nature of the hazard whether isolated or systemic, and its impact on production of food derived from animal and animal product. These requirements lead establishments to conduct a hazard analysis and develop HACCP plans for the products they intend to prepare for domestic overseas markets. MPI provides the initial evaluation of each establishment's RMP, including the HACCP system, at the time an establishment initially registered with MPI. If an establishment makes significant changes to its RMP, management must provide prior notification to MPI. Country specific requirements pertaining to HACCP are addressed in OMAR of each importing country.

The FSIS auditors reviewed MPI's *Verification Online (Gen2)* records and confirmed that APOs perform daily verification activities to ensure that establishments meet United States requirements as defined in *USA-OMAR*. *Parts 2 (amended)* and *12 (amended)* of *USA-OMAR* intend to meet the United States-specific requirements pertinent to HACCP systems that all certified establishments must comply with in order to be certified for export to the United States. MPI has amended *Parts 2* and *12* of *USA-OMAR* (5 amendments) since the last audit conducted in 2015. Some of these amendments required certified establishments to incorporate additional requirements pertaining to HACCP controls and monitoring programs for STEC in bobby calves. These controls include: discontinuation of steam vacuums as a sole STEC intervention; STEC antimicrobial interventions must cover the entire carcass; introduction of carcass hot water wash interventions; and new requirements for listing of operators carrying out slaughter and dressing and/or cutting and boning of bobby calves.

At one RTE processing establishment, the FSIS auditors reviewed the HACCP program with a special emphasis on lethality for *Salmonella* and other relevant pathogens. The establishment had included validated CCPs to achieve *Salmonella* lethality as well as an antimicrobial process to control *Lm* in the post-lethality environment. At another RTE establishment producing TPCS product the FSIS auditors reviewed the HACCP system and determined that the establishment identified biological, chemical, and physical hazards associated with TPCS product and addressed them accordingly.

At the nine slaughter establishments, the FSIS auditors evaluated the written HACCP systems of each establishment and conducted an on-site review of the zero tolerance (feces, ingesta, and milk) CCP and records. The FSIS auditors identified the following:

- Eight of nine slaughter establishments failed to document monitoring records meeting HACCP requirements including the failure to document actual results at the time the event

occurs and failure to document the time and initials or signature of the employee making the entry. This is not consistent with *USA-OMAR, Part 2.6.5*, that states, "Monitoring and verification records must include the date, time when the activity or check was performed and initials of the person performing the activity or check."

Each veal slaughter establishment had adequately addressed in their HACCP plans controls for the presence of STEC in all product types including boneless manufacturing veal. In cases where the hazard was determined as reasonably likely to occur (e.g., slaughter of bobby calves), establishments presented validated interventions (hot water wash) for these pathogens. All establishments exporting boneless manufacturing veal were implementing preventive controls supplemented with final product testing for STEC. However, in adult cattle slaughter establishments the FSIS auditors identified the following finding:

- MPI has advised certified adult cattle slaughter establishments that STEC are not likely to occur in adult cattle and consequently there are no requirements for antimicrobial interventions in these establishments. The FSIS audit identified 2 of 9 adult cattle slaughter establishments that have had confirmed positive STEC results but did not document reassessment of the HACCP plan or support that STEC is not likely to occur. None of the establishments had implemented any validated measures to reduce or eliminate STEC. The CCA had determined the HACCP systems at each establishment met requirements.

The FSIS auditors determined that MPI requires operators of establishments certified as eligible to export to the United States to develop, implement, and maintain HACCP systems. However, the MPI's inspection system did not effectively verify the adequacy of design and implementation of HACCP systems. Furthermore, the confirmed positive STEC results in adult cattle slaughter establishments fail to support the establishments' determination that STEC is not likely to occur in these establishments. FSIS expects MPI to provide FSIS with corrective action plans and support for the determination that STEC would still be consider not likely to occur.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that the FSIS auditors reviewed was Government Chemical Residue Testing Programs. The inspection system is to present a chemical residue testing program, organized and administered by the national government, which includes random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants.

Prior to the onsite audit, FSIS' residue experts reviewed the National Chemical Residues Program (NCRP) for 2017, associated methods of analysis, and additional SRT responses outlining the structure of New Zealand's chemical residue testing program. There have not been any POE violations related to this component since the last FSIS audit.

The NCRP is instituted pursuant to Sections 40 and 167 of the *Animal Products Act of 1999* and the *Animal Products (Regulated Control Scheme – Contaminant Monitoring and Surveillance) Regulations 2004*. To facilitate the implementation of the aforementioned act and regulation, MPI issued the *Animal Products Notice: Contaminants Monitoring and Surveillance effective*

July 1, 2017 to June 30, 2018. The notice assigns the competent authority for the implementation of NCRP, as well as management of sampling for animal material and animal products. The notice further establishes the maximum permissible levels (MPLs) above which residues or contaminants cannot be present in animal products intended for human consumption, which are produced or processed under a registered RMP or regulated authority. MPLs are set at levels equivalent to or lower than the Codex Alimentarius Commission's Guidelines (CAC/GL 71-2009) or other overseas requirements to ensure compliance of animal products. In designing the NCRP for the subsequent year, a wide variety of available sources on new compounds and associated risks, analytical methods, and instrumentation are utilized to keep the NCRP as up to date as possible.

The FSIS auditors reviewed the criteria used in compounds selection for NCRP for future developed plans and for the subsequent year. Normally, compounds are included based on their likely exposure, the potential for a contaminant to be present in animal products, and lastly, the objective of demonstrating that residues and contaminants are being managed effectively. In the plan, some compounds are included due to international interest or due to an importing country's requirements even when these compounds might not be used or found in meat or meat products in New Zealand. Each year MPI issues the *Animal Products Notice on Contaminants Monitoring and Surveillance* with a sampling regime provided in Schedule 1 of the notice. Schedule 1 contains information on the chemicals and number of samples to be collected, type of product, and location of collection (establishment or farm) and forms the basis of the sampling plan for the next monitoring year.

The Assurance and Monitoring Directorate within the Regulation and Assurance Branch of MPI administers the NCRP, which is implemented by VS system auditors. There is broader coordination among other factions of government to achieve the objectives and goals of the NCRP during the implementation phase. The FSIS auditors verified that Veterinary APOs manage the program at the establishment level and verify compliance with the requirements of the NCRP. The sampling plan is confidential and is issued via a VS database. Samples are collected by the government officials, either Veterinary APOs or qualified AQNZ AOs. At one audited establishment the Veterinary APO demonstrated the process of sample collection up to the sample packing and storing stage. The FSIS auditors confirmed that the process follows MPI's established procedures for matrices collection, sample integrity, and security of and data entry into the MPI residues database using Veterinary APO's login credentials.

Through interviews conducted at the regional offices in conjunction with document review, the FSIS auditors confirmed that MPI has measures to keep residue violations to a minimum and to deter recurrence through a series of stringent controls. For example, MPI maintains a surveillance list of source providers of violative product and provides the list to the slaughter facilities. Target sampling in conjunction with product retention are other deterrents used to prevent violative product entering the food chain. Additionally, there are legal provisions available such as livestock movement control and other measures leading ultimately to prosecution of the violator. The review of the results for testing carried out in 2016-2017 revealed a high level of compliance. The FSIS auditors confirmed that the sampling and testing for the 2017-2018 NCRP plan is on schedule.

The FSIS auditors reviewed AsureQuality Limited Laboratory Services for its chemical residue testing program. This laboratory is owned and operated by AQNZ, approved by MPI under RLP, and conducts testing of chemical residues using methods listed in the CLT. The laboratory audit included interviews with the officials and document reviews and concluded with a site visit to the chemical testing portion of the laboratory. This laboratory is accredited to the ISO 17025 standard by IANZ. The FSIS auditors reviewed the most recent accreditation audit, for which a certificate of accreditation was issued on February 23, 2018. There were some minor findings, which were corrected and acceptable to IANZ.

During the laboratory audit, the FSIS auditors also reviewed the laboratory's Quality Manual and the standard operating procedures for equipment calibration and validation of test methods. Additionally, the FSIS auditors requested records pertaining to staff qualifications, credentials, and training, internal audits, noncompliance, and corrective actions. The Quality Manual correctly identifies the KTPs for each test method. The FSIS auditors verified that the analysts' training program comprises an ongoing training segment and a program designed for new hires. Lastly, the FSIS auditors reviewed the proficiency testing program for the audited laboratory. Proficiency test providers include the Department of Agriculture & Water Resources (Australia), National Residue Survey, Food Analysis Performance Assessment Scheme, Test Veritas Progetto (Trieste, Italy). No concerns were identified as a result of the laboratory audit.

MPI continues to demonstrate the ability to meet the equivalence requirements for this component to present a chemical residue testing program, organized and administered by the national government.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

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

MPI implements the National Microbiological Database Programme (NMDP), a standardized microbiological sampling and testing program for monitoring process control in slaughter establishments. This program has been determined to be equivalent by FSIS and encompasses standardized sampling plans, sample collection and transportation procedures, analytical methods, verification of laboratory proficiency, establishment and national database results, and the national reporting of results. The NMDP includes analytical procedures to detect and quantify *Salmonella*, generic *E. coli*, and Aerobic Plate Count (APC) of carcasses and raw meat products. The NMDP includes the *National Microbiological Database* (NMD) that documents microbiological results for individual establishments, and provides tools for trend analysis and comparison to national performance.

The *Animal Products (National Microbiological Database Specifications) Amendment Notice 2016* details requirements for establishment operators as well as laboratories. Establishment operators are responsible for sample collection and submission to a laboratory that MPI has

accepted under the RLP. Establishment operators must utilize approved samplers; trained by certified trainers for the species and product type sampling they perform. The RLP laboratories are responsible for oversight of the NMDP- approved sample takers, including an annual review of those submitting samples to the laboratory. MPI maintains lists of certified trainers and approved samplers on its website.

The NMD notice specifies the requirements for sampling and testing including species, product type, frequency of sampling, and required microbiological analyses. Sampling plans must include a randomly selected time each week to sample all products types for each species. Operators sample bovine and caprine carcasses and parts for APC, generic *E. coli,* and *Salmonella* and ovine carcasses for APC only.

The *Salmonella* Performance Standard sampling program is seasonal and consists of collecting weekly samples from five carcasses until achieving a minimum of six acceptable composite results for each product type. For every *Salmonella* positive result the establishment operator must investigate and implement corrective and preventive actions. In addition, each positive resets the sampling window.

The microbiological laboratory is responsible for entering all NMDP results into "E-Star", the online NMD. Establishment operators are obligated to review results on a weekly basis to determine if the maximum allowable regulatory limit (M-limit) has been exceeded or *Salmonella* detected. MPI routinely monitors the NMD results to determine if sanitary control measures within specific premises and nationally are performing in accordance with regulatory requirements. In addition, VS verifies that the operator reassess the effectiveness of hygienic dressing of carcasses and modify their systems appropriately. Lastly, VS performs routine verification activities including product sampling and test procedures as well as review of NMD (E-Star) results demonstrating compliance. At least twice per year VS performs a comprehensive assessment of red meat NMDP requirements, including establishment procedures and verification, observation of sample selection and collection, observation of sample handling and integrity, compliance with number and frequency of required samples, and review of establishment results and actions in response to any alerts.

FSIS verified that the sample collection methodology was consistent with NMDP requirements. The FSIS auditors also 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. NMD results reviewed by the FSIS auditors indicate that the laboratories enter results of the tests and establishment operators regularly accessed and evaluated the NMD data to assess their individual microbiological profile, their ranking against other premises, and national microbiological profiles and thus verify the adequacy of their slaughter process controls. FSIS observed that the establishment NMDP yielded results that were within acceptable parameters associated with adequate process control.

During the audit of the microbiological laboratory, FSIS reviewed reports of laboratory audits, documentation of analysts' proficiency evaluations and records of evaluations of corrective actions taken in response to audit findings. IANZ accredited the laboratory as meeting Standards

New Zealand ISO 17025 and *Animal Products Notice – Specifications for Laboratories* standards in accordance with MPI's RLP. The FSIS auditors confirmed that the laboratory maintained accreditation and approval to conduct microbiological analyses for certified establishments as attested in the official documents presented for examination to the FSIS auditors visiting this location.

MPI requires that certified establishments producing RTE meat products that are exposed to the post-lethality environment have food safety system controls in place to prevent adulteration by *Lm*. To achieve the controls, establishments must implement alternatives listed in *USA-OMAR*, Part 2.6.19, RTE products, corresponding to the requirements in 9 CFR Part 430.4. MPI requires establishments producing RTE products to conduct both product and environmental sampling (both food contact and non-food contact surface) for the presence of *Lm* in accordance with the *Animal Products (Specifications for Products Intended for Human Consumption) Notice 2016*. When certified RTE establishments eligible to export RTE product are using one of the two alternatives for *Lm* that require a food contact surface monitoring program, MPI references the FSIS Compliance Guideline: *Controlling Listeria monocytogenes (Lm) in Post-lethality Exposed Ready-to-Eat (RTE) Meat and Poultry Products* in assessing the frequency of testing the operator has defined as part of their program. Certified RTE establishments are required to ensure that an RLP laboratory with the appropriate analytical scope performs analyses for *Lm*. No method is specified by MPI under the CLT Official Test 2.6; however the laboratory's scope of accreditation must include the *Lm* method. In addition, MPI prohibits the export of any RTE product that contains *Lm* or that comes into direct contact with a food contact surface contaminated with *Lm* (*USA-OMAR Part 2.3.1 (f)*).

FSIS audited a certified RTE establishment and verified that the establishment's food safety program incorporates an antimicrobial process that limits the growth of *Lm*. The establishment had a written sanitation program providing for testing of food contact surfaces (FCS) in the post-lethality exposed environment. The establishment's program for sampling for *Listeria spp.* addressed sampling at a minimum quarterly frequency, defined a hold-and-test program following a positive FCS result, and identified the size and location of sites to be sampled. In addition, the establishment utilized an RLP laboratory to perform analyses of environmental surfaces and RTE product for *Listeria spp.*, *Lm*, and *Salmonella*.

MPI provides the initial evaluation of each establishment's RMP, including HACCP, at the time it is initially registered. If an establishment makes significant changes to their RMP they must provide notification to MPI. The FSIS auditors reviewed MPI's Verification Online (Gen2) records and confirmed that VS performs daily verification activities to ensure that establishments meet United States requirements as defined in *USA-OMAR*, including requirements specific to RTE products.

USA-OMAR Parts 2, 10, and *11* stipulate a zero tolerance policy for *E. coli* O157:H7, O26, O45, O103, O111, 0121, and O145 (STEC) in raw bovine products intended grinding or other non-intact product exported to the United States. MPI requires that certified beef and veal establishments perform sampling and testing for STEC as defined in *USA-OMAR Parts 10* and *11* respectively. Certified establishments must perform daily N60 sampling of bulk manufacturing beef from each lot. VS conducts verification activities to ensure establishment

sample collection and submission procedures, HACCP plans and records, inventory control systems for eligible and ineligible products, and regularly review STEC test results. All sampled products are held pending acceptable results.

Currently there are six MPI-approved RLP laboratories for STEC screen testing. MPI identifies the approved analytical methods for STEC screen tests in the CLT as CLT 23.1 - BioControl Assurance GDS® *E. coli* O157:H7 test and CLT 23.2 using both Assurance GDS® Top 6 STEC and Assurance GDS® Shiga Toxin Genes (Top 6) methods. Alternately, the laboratory may utilize the CLT 23.3 Assurance GDS® MPX Top 7 STEC method. The presence of STECs in presumptive positive enrichment broths are confirmed by the Institute of Environmental Science and Research Ltd., Enteric Reference Laboratory (ESR-ERL), using procedures equivalent to the FSIS Microbiology Laboratory Guidebook (MLG 5B.02). The FSIS audit of an MPI-approved laboratory confirmed that IANZ had accredited the laboratory to perform the CLT 23.1 and CLT 23.3 STEC methods. The laboratory demonstrated a minimum of two KTPs for each method. In addition, the laboratory demonstrated records of proficiency testing in the Interlaboratory Comparison Programme (ILCP) with two rounds of testing annually for STEC methods. The laboratory has sampling receipt procedures consistent with MPI requirements. No significant concerns were identified.

The FSIS auditors verified through document reviews and direct observation that the six audited bovine slaughter establishments had implemented STEC N60 sampling consistent with MPI requirements. The FSIS auditors also reviewed establishment records, laboratory results, and documented corrective actions in response to positive STEC results.

There have not been any POE violations related to this component since the last FSIS audit. The FSIS audit confirmed that New Zealand is maintaining equivalence with this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on March 13, 2018, in Wellington, New Zealand, with MPI. At this meeting, the FSIS auditors presented the preliminary findings from the audit. An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations

- The CCA is not ensuring that government inspection occurs once per shift in processing establishments that produce product for export to the United States during multiple production shifts.

Government Hazard Analysis and Critical Control Points (HACCP) System

- The CCA has determined that Shiga toxin-producing *Escherichia coli* (STEC) are not likely to occur in adult cattle in New Zealand. Two of nine beef slaughter establishments had confirmed positive STEC findings; however, no establishment nor the CCA concluded that STEC were a hazard reasonably likely to occur.
- Eight of nine slaughter establishments failed to document monitoring records meeting HACCP requirements.

During the audit exit meeting, the CCA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

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
Jack Link's New Zealand Limited 137-159 Montgomerie Road Mangere Auckland	03/01/2018	JL1	New Zealand
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	X
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	X
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	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

The following non-compliances were not identified by New Zealand's inspection officials during the establishment review:

15/51. The establishment's HACCP plan for CCP H-1, Drier Operation, does not identify the hazards being controlled by the critical control point. In addition, the critical limits for achieving lethality of ready-to-eat product does not include parameters for ensuring adequate relative humidity during the lethality process. The establishment does monitor relative humidity and closes dampers but failed to include the essential elements in the HACCP plan itself.

25/51. In the establishment's formulation room there were multiple bags of soy protein powder present on the stainless working table that were not bearing any label or identification of the contents.

38/51. The establishment's load-out room had boxed product on racks stacked directly abutting the room wall precluding the ability to assess sanitation of the floor and wall juncture for evidence of pest activity. In addition, there was an approximate 5 x 10 x 5 foot high pile of empty boxes and packaging material in the rear of the room providing potential harborage for pests and rodents.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/01/2018

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 New Zealand Limited State Highway 1 Horotiu	03/06/2018	ME23	New Zealand
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	X
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

The following non-compliances were not identified by New Zealand's inspection officials during the establishment review:

10/51. In the red offal room an angled inedible material trough is located on the wall and directly above the edge of the edible product work stations. The head meat employee was observed to toss rejected product into the inedible trough, above the level of her head, and this process resulted in splash out of the inedible trough and directly onto the edible product work space. In addition, these actions also resulted in beaded droplets of fluid from the inedible trough on the ventral surface of the same trough directly over edible product. Direct product contamination was identified as well as direct contamination of the edible product table. Immediate corrective actions were taken to restore sanitary conditions.

10/46/51. A door to a carcass chiller was in poor repair with torn and protruding galvenized molding on the lower border of the door. Further inspection identified that there was a significant gap at the seam of the metal interior door panel and the edge extending from the base of the door to approximately 5 foot height. This entire gap had accumulated fat and meat debris from carcasses moving through this door. The condition and maintenance of the door preclude effective cleaning and sanitizing. Further, the door is not treated as a food contact surface. No product was moved through the area at the time the observation was made but the condition posed a distinct threat of directly contaminated product. The establishment initiated immediate corrective actions.

15/51. The establishment's written HACCP plan for CCP 1 does not define the ongoing verification activities and frequencies. There are no defined review of records procedures or frequency and “check the checker” is not specifically defined to include direct observation of monitoring at a specific frequency.

18/51. The establishment's slaughter CCP 1, zero fecal/ingesta, monitoring records are not documenting the time, monitor initials, and result for every carcass monitoring. The HACCP records are not sufficient to document implementation and results of the defined monitoring procedure and frequency.

20/51. The CCP 1 HACCP corrective actions in response to a deviation from a critical limit did not include required elements including identification and elimination of the cause of the deviation; documentation that the CCP was under control; and no measures to prevent recurrence were identified.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/06/2018

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 Limited - Te Aroha Stanley Road South Te Aroha	03/08/2018	ME84	New Zealand
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

The following non-compliances were not identified by New Zealand's inspection officials during the establishment review:

10/51. During movement of carcasses along the chain rail at the post-mortem inspection stand an oxtail, still attached to the carcass, was observed to directly contact the housing of an overhead light fixture. The light fixture was not a food contact surface. The establishment took immediate corrective actions to include removal of oxtails prior to that point in the chain.

15/51. The establishment's HACCP plan for CCP 1, zero tolerance fecal, did not define the ongoing verification activity and frequency for review of records and did not define the frequency for direct observation of monitoring.

22/51. The establishment is not documenting CCP 1 monitoring records including date, time, initials and actual result at the time the event occurs. In addition, the establishment is not documenting ongoing verification activity records to include results.

38/51. In the packaging storage, boxed cold storage, and box storage rooms the establishment had stacked packaging materials, boxed product and other items directly against the walls and precluding visualization of the floor and wall junctures to assess sanitary conditions. Also, in the box storage room there was a disorganized pile of boxes and other items not associated with packaging that created potential harborage for pests and rodents.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/08/2018

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
UBP Limited Waitete Road Te Kuiti	03/07/2018	ME127	New Zealand
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	X
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

The following non-compliances were not identified by New Zealand's inspection officials during the establishment review:

12/51. Operational Sanitation monitoring records for QA Personal Gear Check Report documents deficiencies but not corrective actions documenting the measures to restore sanitary conditions.

16/51. The establishment is not producing records documenting the monitoring of CCP 1, zero fecal/ingesta, for which the monitoring frequency is 100% or every carcass. There are no specific records documenting monitoring of every carcass; documenting the actual time the monitoring occurred; documenting the monitor's initials or signature; nor documenting the actual result of the monitoring.

In addition, the ongoing verification review of records do not include the time and results of the verification activity.

20/51. The documented HACCP corrective actions for a February 22, 2018 deviation from a critical limit (fecal/ingesta) at CCP 1 do not meet all required elements of HACCP corrective action including identification and elimination of the cause and measures to prevent recurrence.

The establishment has determined that *E. coli* O157:H7 is not reasonably likely to occur in the slaughter process. In response to a confirmed positive *E. coli* O157:H7 result, the establishment failed to implement and document corrective actions meeting all the required elements for an unforeseen hazard. Specifically, the establishment could not demonstrate reassessment of the hazard analysis.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/07/2018

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 Industries Limited 21 Mihini Road Henderson Auckland	03/02/2018	PH134	New Zealand
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

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

60. Observation of the Establishment

The following non-compliances were not identified by New Zealand's inspection officials during the establishment review:

15/51. The establishment's written HACCP plan for CCP 3, Heat Process and Cooling, failed to define a frequency for direct observation of monitoring, an ongoing verification activity.

22/51. The establishment is conducting the HACCP ongoing verification activity of review of records but is not documenting the result of that review.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/02/2018

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 . Works Road Pukeuri Junction Oamaru	03/05/2018	ME18	New Zealand
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
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.	X
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	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

18/51 The HACCP records are not sufficient to document implementation and results of the defined monitoring procedure and frequency.
41/51 Four of the six chillers toured where product for export are stored had beaded condensation. Some of the beaded condensation were observed right above the carcasses. Immediate corrective actions were initiated by establishment management; product was removed from the affected area and retained for proper disposition.
45/51 a) Peeling paint and grease build up were observed in chillers in some production rooms that could potentially contaminate product if left neglected any further.
b) Conveyor belts to move raw product was frayed from places with readily detaching fibers were posing potential for product contamination from these plastic fibers.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/05/2018

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 Limited- Finegand Yorston Road Balclutha	03/02/2018	ME26	New Zealand
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
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.	X
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	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	X
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.	

60. Observation of the Establishment

18/51 The HACCP records are not sufficient to document implementation and results of the defined monitoring procedure and frequency.

41/51 Over the product condensation were observed on the carcass rail in multiple chillers and at the overhead rail in the boning room. Immediate corrective actions and proper product disposition were applied to address the finding.

45/51 Multiple vacuum packing machine had plastic boards with jagged corners and frayed gaskets around them posing product contamination with extraneous material.

52/51 Walkway for animal had broken and uneven floor. The suspect pen for sick animals did not have provision for water supply to animals held in pen for further evaluation.

55 Muscles of mastication (cheek muscles) were not being incised by head inspector to detect the presence of cyst of worms.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/02/2018

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 . State Highway 99 Underwood Invercargill	03/01/2018	ME50	New Zealand
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
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.	X
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.	

60. Observation of the Establishment

18/51 The HACCP records are not sufficient to document implementation and results of the defined monitoring procedure and frequency.

41/51 Beaded condensation were observed on overhead rails over exposed carcasses in two of the six chillers examined. Immediate corrective actions were initiated by establishment including removal of affected product for further evaluation and disposition accordingly.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/01/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
CMP Canterbury Limited. RD 7 Seafield Road Ashburton	03/02/2018	ME78	New Zealand
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
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.	X
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	X
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	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

18/51The HACCP records are not sufficient to document implementation and results of the defined monitoring procedure and frequency.

38/51 Unknown chemical spillage on outside ground close to production and chilling rooms were attracting flies and creating potential for indirect product contamination. Additionally, the auditor observed a container of chemical having no label to identify the chemical in the container.

41/51 Over the product beaded condensation was observed in one cooler. Immediate corrective action was initiated by the establishment.

55. Muscles of mastication (cheek muscles) were not being incised by head inspector to detect the presence of cyst of worms.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/02/2018

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
Prime Range Meats Limited Sussex Street Waikiwi	02/28/2018	ME132	New Zealand
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	X
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.	X
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	X
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	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

14/51 The establishment identify only E. coli O157:H7 without considering other non O157H7 STEC s as biological hazards in the Hazard Analysis for HACCP plan for Bovine Slaughter.
18/51 The HACCP records are not sufficient to document implementation and results of the defined monitoring procedure and frequency
38/41The auditor noted the storage bins stored outside premises of establishment had pieces of meat, fat, trash objects, and pieces of cloth soaked in stagnant rainwater. Storage site was emitting foul smell in the vicinity.
44/51During pre-op the auditor noted the plastic covering a pipe over the conveyor belt for moving raw product was frayed and deteriorating from places. This could result in product contamination with plastic pieces.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	01/21/2018

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
Lean Meats Oamaru Limited Recastle Road Oamaru	03/06/2018	ME137	New Zealand
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
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.	X
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

18/51 The HACCP records are not sufficient to document implementation and results of the defined monitoring procedure and frequency.

22/51The ongoing verification of calibration of pH meter did not include the documentation of calibration results.

41/51Three of the five chillers had over the product condensation. The carcasses stored underneath the affected were retained for evaluation and proper disposition.

45/51 In boning room conveyor belt had worn edges along its length. Readily detaching loose fiber of the belt could potentially contaminate the product with foreign material.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/06/2018

Appendix B: Foreign Country Response to Draft Final Audit Report

Ministry for Primary Industries
Manatū Ahu Matua

15 March 2019

Michelle Catlin
International Coordination Executive
Office of International Coordination
Food Safety and Inspection Service-USDA
Room 3143, South Building
Washington, DC 20250

Dear Michelle

RE: New Zealand response to FSIS 2019 Meat System Draft Final Audit Report

Thank you for the Draft Final Audit Report dated 7 January 2019, where we note that there were no deficiencies found that represented an immediate threat to public health. The following outlines the responses MPI intends to implement in response to the findings in the Conclusions and Next Steps section.

1. Government Statutory Authority and Food Safety and Other Consumer Protection Regulations:
   - The Central Competent Authority (CCA) is not ensuring that government inspection occurs once per shift in processing establishments that produce product for export to the United States during multiple production shifts.

Current MPI specifications require daily circuit supervision of operations which are processing, but not slaughtering, bovine, caprine and ovine products for the United States with verification activity occurring with sufficient variation in day, time, shift, and interval between verifications to avoid predictability. The intent of these specifications is to ensure all activities happening over the period the establishment is operating are potentially subject to review. Other specifications emphasise, within these bounds, that verifiers focus on those activities most critical to processing hygiene and both frequency and intensity are increased in response to critical findings.

Taking in account that US domestic policy settings have moved to once per shift verification, MPI intends to clarify and enhance its existing, especially with respect to the monitoring of critical hygiene outcomes and associated activities. In line with our discussions, MPI proposes to amend our specifications to further emphasize their risk-based focus and to additionally routinely require a formal review of performance metrics. The timing of the daily visits to US listed establishments operating multiple shifts producing products in the categories of heat treated-shelf stable and thermally processed / commercially sterile will be further risk-targeted according to the type of activities occurring and their potential impact on hygiene. Under this approach, visits would be targeted to those times during the day when the critical hygiene activities are occurring regardless of

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what time of the day / shift they occur. However over the period of a month, all substantive processing activities occurring at any time of the day would still be required to be viewed. The minimum frequency for a MPI reality check of the adequacy of the pre-operative hygiene system to these premises will also be increased to at least monthly (annual at the time of the audit), and verifiers will be required to introduce a monthly critical review of key metrics applicable to the establishment, such as microbiological sampling results, HACCP records, SSOP, and preoperative hygiene. Any critical findings will result in an escalation of frequency and activity in line with our performance based verification (PBV) policy. We trust this is acceptable to the FSIS.

2. Government Hazard Analysis and Critical Control Points (HACCP) System
    - The CCA has determined that Shiga toxin-producing Escherichia coli (STEC) are not likely to occur in adult cattle in New Zealand. Two of nine beef slaughter establishments had confirmed positive STEC findings; however, no establishment nor the CCA concluded that STEC were a hazard reasonably likely to occur.

Current MPI specifications require the operator to do a "STEC alert systems review" for any and all STEC positive findings and to initiate appropriate corrective and preventative actions. The actions of the operator are subject to MPI Verification Services (MP VS) verification. In addition operators are required to annually review their HACCP plans and this is also subject to MPI VS verification. MPI is supplied with all STEC monitoring results centrally, plots trends and does an at least annual critical review of the efficacy of programmes and their basis.

In response to the matters raised by the FSIS auditors as to the variation of the New Zealand's process from that described in the CFR, MPI will amend the current "STEC alert system review" requirement to more closely mirror those elements described in the US CFR. The specification will now more explicitly require each establishment's HACCP coordinator to conduct a reassessment of whether STECS can still be considered as not reasonably likely to occur each and every time a STEC positive is confirmed. The HACCP coordinator will be required to formally consider and document whether there were any process control factors that may have contributed, evidence for or against a possible change in risk profile with respect to STECs, address any preventative controls that may need adjustment and confirm whether STECS can still be regarded as a hazard not reasonably likely to occur in adult cattle at that establishment. The adequacy of this review will be required to be formally assessed and approved by MPI VS, with MPI tracking and critically reviewing any trends centrally. The criteria applied will tighten where there are multiple findings at an establishment within a single season and especially where these occur within a relatively short period of time.

2. Government Hazard Analysis and Critical Control Points (HACCP) System
    - Eight of nine slaughter establishments failed to document monitoring records meeting HACCP requirements.

We understand this finding pertained to the way New Zealand has chosen to apply the FSIS requirement that each establishment has a minimum of one Critical Control Point (CCP) on the slaughter floor. While New Zealand has always maintained there is no real CCP on the slaughter floor (according to international definitions), to meet the FSIS requirement all New Zealand FSIS listed establishments have for many years used zero fecal tolerance (ZFT) as a CCP. New Zealand has historically allowed three options for how this CCP could be monitored and the corrective and preventative actions applied. The most commonly applied option, especially for sheep slaughtering establishments, is 100% monitoring by the operator before the carcases leave the slaughter floor where the lot may be split between different chillers based on individual carcase grading results. This allows for both the monitoring and the bringing any non-compliant lots / product back into compliance to be

effectively achieved at the same time. Feedback loops have been required to be in place to ensure appropriate corrective actions are taken when an unacceptable level of non-compliance is found. MPI has also allowed the use of digital records, with digital signatures and references. .

While the above system has allowed MPI to verify that each establishment is effectively monitoring its CCP and responding appropriately to non-compliant findings, we understand the FSIS have an expectation that a discrete record be identifiable with all of the elements prescribed in the relevant part of the CFR for each time period that the CCP monitoring result represents. MPI will accordingly further specify that each establishment must create a summary record for each time period that the CCP monitoring result represents (typically a two hour run). This record will identify the date and time period represented, the signature (or digital signature) of the person who monitored the CCP, the results found, any corrective actions taken and any preventative actions instigated. The sections in the establishment's operating procedures will continue to be able to be referenced where routine corrective and preventative actions are taken. MPI's expectation will continue to be that the CCP failure criteria applied by each establishment should be no higher than the thresholds MPI has set for the Statistical Process Control System (SPCS) criteria that are currently applied in the monitoring of inspector performance. We trust this will more closely align MPI's requirements with FSIS monitoring record expectations.

In closing we would like to thank the FSIS for the professionalism of the audit staff and the subsequent engagements.

Yours sincerely,

Dr Tony Zohrab
Chief Market Access Officer

Cc Dr Bill Jolly, MPI Chief Assurance Strategy Officer
Cc Jason Frost, New Zealand Embassy

15 May 2019

Michelle Catlin
International Coordination Executive
Office of International Coordination
Food Safety and Inspection Service-USDA
Room 3143, South Building
Washington, DC 20250

Dear Michelle

RE: Response to the FSIS 15 April audit letter

Thank you for your latest response to our letter of 15 March 2019. We note that you have highlighted that FSIS requests additional information for finding 3 and has requested supporting documentation demonstrating that MPI implements measures in response to a STEC positive government sample result that are equivalent to the measures the FSIS implements. In this regard you have provided details of US domestic procedures as referenced in the FSIS Self Reporting Tool (SRT) questionnaire.

I note that we discussed this issue at length during my and Dr Jolly's visit to Washington DC in November last year and thought FSIS had agreed to our proposed response to that finding as discussed in our letter of 15 March 2019. In this regard we noted that existing equivalence decisions had recognised that there was a significant difference in risk profile and regulatory system context between the two countries and so the comparison at the procedure to procedure level was not appropriate. What is important of course is whether the two systems deliver the same public health outcome.

Initial observations/comments:

I would like to make the following observations prior to addressing the substance of your letter;

- The FSIS has previously recognised that New Zealand has 1) a reduced indigenous prevalence and level of hazard [coming into establishments]; 2) effective regulatory measures to verify that establishments maintain prevention of contamination practices and 3) an excellent historical record for controlling E. coli O157:H7 as evidenced by both the Central Competent Authority (CCA) and FSIS verification programs.

- FSIS has never reported a confirmed positive STEC result from New Zealand adult beef from its port of entry (POE) or in market testing programs in all the years of testing. Furthermore none of the Pulsed Field Gel Electrophoresis (PFGE) patterns or Whole Genome Sequence (WGS) implicated in

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any FSIS testing or public health outbreaks have ever been linked to a PFGE or WGS recorded by New Zealand (noting that we share these libraries).

- There are a number of fundamental differences in approach recognised in the historical series of determinations of equivalence by the FSIS of New Zealand's controls and testing program for STECs. Inherent to all of these has been New Zealand's emphasis of a preventative based approach to any and all microbial contamination getting onto the carcass in the first place. MPI has always required the New Zealand industry to focus on prevention not just in its prerequisite programs and Sanitation Standard Operating Procedures (SSOP), but also in its day to day application of Good Hygienic Practice (GHP), especially during initial work up through to hide removal. New Zealand's focus on prevention has meant it has neither had to rely on STECs being classified as hazards RLTO nor on the use of decontamination CCPs to achieve levels of performance better or comparable to the US.

- The New Zealand joint industry / government STEC sample and testing program uses MPI mandated standardised personnel training, sampling protocols and analytical methodologies, with all testing undertaken at MPI approved laboratories. Both the screen and confirmed positive results are provided at the same time to both MPI and the company at each establishment. MPI head office and MPI's Verification Service's Technical Specialists similarly get notified of any confirmed positive result.

- Results of the joint industry / government STEC testing program are used as an ongoing verification of the efficacy of New Zealand's preventative controls in dealing with the historically lower prevalence and level of STEC contamination on adult cattle being presented for slaughter in New Zealand. The reaction to any positive result under the joint industry / government STEC testing program is not differentiated by whether it is an industry or government sample. Similarly the results in the context of our differently designed program are not a verification of the specific use of HACCP and efficacy of decontamination CCPs to control STECs (as in the US). MPI directly sees all results and ensures industry reacts appropriately to all results. For the most part this focuses on looking at whether a root cause can be identified and what area of preventative control may have failed. However MPI escalates the level of its involvement and reactions to confirmed positives should any establishment have more than a single isolated finding in any production year.

- Consistent with the historical equivalence determinations, MPI also continues to enforce a regulatory requirement that no product of the relevant classes be released for export to the United States until the joint industry / government STEC testing program confirms the whole day's production is negative for all 7 STECs. This joint program operates at each U.S. eligible establishment at a minimum frequency of at least once per US eligible processing day.

- The 2015 FSIS audit report correctly concluded: "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 focus of both the industry and MPI reviews in the New Zealand context is to look for the potential root cause and identify which of the preventative controls was most likely to have been deficient on the day in question. This is so appropriate prevention focussed corrective actions can be put in place.

- The most recent audit appeared to not fully understand the basis for and extent of the historical equivalence decisions and accordingly mistakenly applied its own interpretation of what the reactions should have been taken by MPI. However, the auditors did correctly report that the level of documentation of the reassessments done after the two isolated findings was not consistent with

MPI's OMAR. This is something we were also not happy with and intend to address in our proposed amended reactions.

- Lastly I would like to note that New Zealand STEC samples are taken almost exclusively from fresh product even though all of the manufacturing trim exported to the U.S. is frozen. This is despite Chapter IV, Section IV.D of Directive 10010.2 states that freezing can be used as critical control point in the Hazard Analysis and Critical Control Point (HACCP) plan and specifies that in such cases it is appropriate for the IPP to collect frozen samples. Accordingly New Zealand's monitoring results will very likely overestimate any potential risk to human health.

The specifics of your letter:

Your letter states that "if a U.S. establishment determines in its hazard analysis that STEC is not reasonably likely to occur (NRLTO) after it receives a STEC positive results from a FSIS testing program, FSIS would determine that an establishment's HACCP is inadequate and take enforcement action." Hopefully I have explained above why it is not appropriate to extrapolate interpretations and expected actions between the two very differently designed STEC control and monitoring programs, as already determined as equivalent.

New Zealand maintains that it is not whether the individual procedures applied by the different regulatory systems are similar but more importantly whether the level of residual risk emanating out of our system is at least comparable to that emanating out of the US system. I would suggest the evidence over an extended period of time strongly supports this.

MPI continues to closely monitoring not only the national prevalence of STEC positive results but also where any establishment has more than an isolated confirmed positive detection result over a twelve month window. While we have over the past few years noticed an upwards trend in detections, MPI is hesitant to move away from its emphasis and enforcement of preventative approaches. In my previous letter I noted some of the enhanced actions MPI was proposing in response to these detections and the identified inconsistency with New Zealand's own specifications of the level of documentation.

In recognition of some of the concerns you raised in your letter we are prepared, after further discussion, to consider some additional enhancements.

Proposed MPI responses to a joint industry / government STEC positive result:

1. MPI will mandate that the establishment's HACCP coordinator review the establishment's process controls each and every time a STEC screen positive is reported and for them to initiate and document corrective actions where appropriate. Should the screen positive be confirmed (noting 100% of samples are taken through to full confirmation but that this can take upwards of two weeks), the HACCP coordinator will also be required to undertake a full reassessment of their hazard analysis as it relates to microbiological controls.

2. The entire day's production of product potentially able to enter the US grinding / non-intact processing system that is associated with any screen positive result will continue to be deemed U.S. ineligible, unless it is subsequently confirmed as STEC negative.

3. Where an establishment has a confirmed STEC positive result in adult beef, MPI will schedule an offsite external Risk Evaluation (RE) of the establishment's performance by a Technical Specialist (TS) who will evaluate the establishment's microbiological and compliance performance data over the weeks pre and post the detection. The TS will also, in conjunction with the Supervising Veterinarian (SV) at the establishment, review the adequacy of the establishment's HACCP coordinator's

reassessment of their hazard analysis as it relates to the microbiological controls and produce a report recommending what if any further action by MPI is required. These reports will be required to be reviewed by MPI Verification Service's Central Management. Should serious performance deficiencies be identified that are not being adequately responded to by the establishment, MPI Verification Service's Central Management will schedule a visit by a MPI Regulatory Expert Assessment Team (REAT) to undertake a Food Safety Assessment (see below).

4. Should the establishment have any subsequent confirmed STEC positive results in adult beef in the same production year MPI will move directly to schedule a visit by an MPI Regulatory Expert Assessment Team (REAT) to undertake a Food Safety Assessment (FSA).

   The focus of the FSA will be on assessing and analysing the appropriateness and performance of the establishment's food safety system as a whole. Should the REAT find any substantive regulatory or performance deficiencies in the way the establishment is operating its program then enforcement actions will be initiated. Such enforcement actions may include for example the issuance of notices of direction, the requirement to additionally further test product in store and or the suspension of the establishment's U.S market eligibility. Establishments that are not able to demonstrate the control of STECs by preventative controls after the above processes have been worked through will be required to classify STECs as RLTO and introduce validated interventions until such time as their preventative controls are revalidated, or they will lose their U.S. listing.

5. All of the above will be overseen by the Verification Service's Central Management with any assessments leading to enforcement actions directly reported to myself and MPI's Chief Assurance Strategy Officer, Dr Jolly.

As always Dr Jolly and I are available to discuss this matter further. If appropriate we are both willing to travel to Washington DC for further meetings to provide further clarifications or to further agree on what other measures could be applied within the New Zealand system.

In closing we would like to again thank the FSIS for its continued engagements in hopefully bringing this audit to a final mutually agreed conclusion.

Yours sincerely,

Dr Tony Zohrab
Chief Market Access Officer

Cc Dr Bill Jolly, MPI Chief Assurance Strategy Officer