



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

OCT 3 1 2012

Dr. Tony Zohrab
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Ministry for Primary Industries
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Dear Dr. Zohrab,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of New Zealand's meat inspection system March 7 to March 15, 2011. FSIS did not receive comments to the audit report. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-6400, by facsimile at (202) 720-7990, or electronic mail at international.audit@fsis.usda.gov.

Sincerely,

Dr. Shaukat Syed, Director
International Audit Staff
Office of International Affairs

Enclosure

OCT 3 1 2012

FINAL REPORT OF AN AUDIT CONDUCTED IN
NEW ZEALAND
MARCH 7-15, 2011

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING
THE PRODUCTION OF MEAT
PRODUCTS INTENDED FOR EXPORT TO
THE UNITED STATES OF AMERICA

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This audit report describes the outcome of an onsite verification audit conducted by the Food Safety and Inspection Service (FSIS) from March 7 through March 15, 2011, to determine if New Zealand's food safety system governing the production of meat is equivalent to that of the United States, with the ability to produce products which are safe, unadulterated, and properly labeled. FSIS also assessed data gathering activities at one slaughter establishment where the CCA conducted the trial of an alternative ovine post mortem inspection system currently being evaluated by FSIS to determine its equivalence.

The focus of the audit was on the ability of the Central Competent Authority (CCA), New Zealand Food Safety Authority (NZFSA), to regulate meat products production. FSIS reviewed and verified the information provided by the CCA in the completed Self Reporting Tool (SRT). The scope of the audit included central, regional and local government offices, one bovine and one ovine slaughter establishments, and one private microbiology laboratory. Determinations concerning the effectiveness of New Zealand's food safety program focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight, (2) Statutory Authority and Food-Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Points Systems, (5) Chemical Residue Control Programs and (6) Microbiological Testing Programs.

The audit outcome made evident that the CCA is able to meet the principal requirements for all six components. However, there was an issue that involves both government oversight and HACCP system components. The issue pertains to ongoing official verification of the adequacy of HACCP plans and the inability of operators to demonstrate why monthly verification of Critical Control Points (CCPs) was adequate for their HACCP plans. NZFSA did not require operators of establishments to support their decision for the frequency chosen to conduct direct observations (monthly). This is an important concern since without a statistically determined acceptable level of confidence, the frequency of verification of monitoring of CCPs being used would prevent establishment and government officials from adequately determining if HACCP plans are working as intended.

New Zealand did not provide comments in response to the above finding contained in this report. However, FSIS will verify the adequacy of the pertinent corrective measures implemented by the New Zealand's CCA during the next audit.

The FSIS auditor also verified that the implementation of the alternative ovine post mortem inspection trial was consistent with the design presented by the NZFSA before FSIS. Establishment employees conducted inspection of carcasses and viscera to identify other consumer protection defects, AssureQuality* inspectors conducted visual inspection of carcasses and viscera for food safety related conditions, and official veterinarians verified adequacy of the functions of both groups. Data being collected from both operation shifts at the establishment will be further analyzed by a team of the NZFSA experts and incorporated into the equivalence determination request package.

**A state owned enterprise that provides inspection services for the NZFSA*

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

AQ	AsureQuality
OA	Official Assessor
CCA	Central Competent Authority (New Zealand Food Safety Authority)
CEG	Compliance and Enforcement Group
CIG	Compliance and Investigation Group
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
NZFSA	New Zealand Food Safety Authority
OMAR	Overseas Market Access Requirements
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point System
<i>Salmonella</i>	<i>Salmonella</i> species
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures
U S	Unit Standard
VA	Verification Agency

1. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture conducted an onsite audit of New Zealand meat inspection system from March 7 through March 15, 2011.

The audit began with an entrance meeting held on March 7, 2011, in Wellington with the participation of representatives from the Central Competent Authority (CCA) – New Zealand Food Safety Authority (NZFSA) and the FSIS, Office of International Affairs (OIA), International Audit Staff (IAS).

2. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

The audit objective was to verify that New Zealand's food safety system governing meat continues to be equivalent to that of the United States, with the resultant capacity to produce products which are safe, unadulterated, and properly labeled. In addition, in response to a request for an equivalence determination of an alternative ovine post mortem inspection system submitted by the CCA, FSIS management sought to observe data gathering activities at the establishment where the trial of the alternative system was being conducted.

In pursuit of this objective, FSIS used the information provided by New Zealand in the FSIS document entitled Self Reporting Tool (SRT), port-of-entry (POE) testing results, and data collected by FSIS during onsite audits conducted in the last three years.

The FSIS auditor was accompanied throughout the entire audit by representatives from the CCA including the Compliance and Enforcement Group (CEG) and the Compliance and Investigation Group (CIG) of NZFSA. Determinations concerning program effectiveness focused on performance within the following six equivalence components upon which system equivalence is based: (1) Government oversight, (2) Statutory authority and food safety regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point Systems, (5) Chemical residues control programs, and (6) Microbiological testing programs.

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

A sample of two establishments was selected from a total of 54 establishments certified to export meat products to the United States. During the establishment visits, particular attention was paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with 9 CFR 327.2.

Additionally, one private microbiological laboratory was audited to verify its ability to provide adequate technical support to the inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	Wellington
	Regional	1	Wanganui Regional Office/Wanganui
	Local	2	Wanganui and Eltham
Laboratories		1	Private Microbiology Laboratory, Eltham
Establishments		2	<ul style="list-style-type: none"> • Wanganui (Ovine Slaughter) • Eltham (Bovine Slaughter)

3. LEGAL BASIS FOR THE AUDIT AND AUDIT STANDARDS

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

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

The audit standards included all applicable legislation and procedures originally determined by FSIS as equivalent as part of the initial review process, and any subsequent equivalence determinations that have been made by FSIS under provisions of the Sanitary/Phytosanitary Agreement.

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

- Method used for collection of samples and use of private laboratories to analyze samples for *Salmonella*.
- Post mortem inspection procedures that include removal of the head and tongue from adult cattle and young calves prior to inspection, visual-only inspection of lamb carcasses except for palpation of the inner surface of the ventro-lateral abdomen, inspection of sheep and goat carcasses after removal of the head, and visual inspection of bob veal calves.
- Sheep and equines can be slaughtered in the same establishment
- Post mortem inspection conducted by third party meat inspectors.
- Carcass separation procedures used during slaughter and dressing.
- Generic E. coli testing program for sheep and goats.
- E. coli O157:H7 program for bob veal calves.
- National program for E. coli O157:H7 testing.
- Equivalent methods of analysis
 - Bax E. coli O157:H7 PCR
 - Neogen Reveal (24h enrichment)

TECRA Visual Immunoassay
Visual Immuno-Precipitate (VIP)

- Port of Entry Production Lot Definition

4. BACKGROUND

New Zealand is eligible to export meat and poultry products to the United States. Between 3/2010 and 3/2011, New Zealand exported 448,341,116 pounds of meat products to the United States of which 33,551,805 pounds were re-inspected at United States Ports of Entry (POE). A total of 858,415 pounds were rejected at POE, none of which was due to laboratory failures of public health significance.

The last audit conducted by FSIS of the New Zealand's meat inspection system was conducted in 2008. Reported findings from that audit have been corrected, verified and documented by the Verification Agency (VA) of the CCA. The FSIS auditor reviewed documentation generated and confirmed that the corrective actions taken by the operators had been verified by the CCA.

The FSIS final audit reports for New Zealand's Food Safety System are available on the FSIS' website at:

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

5. GOVERNMENT OVERSIGHT

The first of the six equivalence components of the meat inspection system of New Zealand that FSIS reviewed was Government Oversight. The evaluation included a review and analysis of documentation submitted as support for the responses provided by the CCA in the SRT and observations gathered during the onsite audit.

FSIS assessed the extent to which the New Zealand's meat and poultry inspection system is organized and administered by the government of New Zealand and verified that the NZFSA serves as the CCA responsible for the safety of food products, promulgation of food safety regulations, and has sole authority to enforce the laws and regulations of the meat products export system.

The auditor verified that the NZFSA is comprised of operational groups that include the Standards Group (SG), the Agricultural Compounds and Veterinary Medicines Group (AACVMG), the Compliance and Investigation Group (CIG), Compliance and Enforcement Group (CEG) and the Science Group. The functions of these groups are complemented by AsureQuality (AQ), a state owned enterprise that conducts inspection at certified establishments and the NZFSA Verification Agency (VA) a division of the CEG which assesses processor's performance and the functions of AQ.

FSIS assessed the design and performance of the above mentioned groups of the NZFSA and verified that they interact with each other to accomplish the overall administrative

and regulatory functions of the inspection system under the coordination of an Executive Director who reports directly to the Minister for Food Safety of the government of New Zealand.

The SG develops, evaluates and reviews the standards implemented for production, importation, exportation, transportation, storage and sale of food and food related products. This group also negotiates market access conditions and certification requirements.

Standards for utilization of agricultural compounds and veterinary medicines that could impact the public health are developed, evaluated and reviewed by the AACVMG which also establishes maximum residue limits of veterinary drugs.

The CIG enforces standards and gathers evidence to establish levels of regulatory compliance maintained by producers, as well as compliance with export market requirements. Officials in this group provide feedback on effectiveness to the standard setting groups, and manage corrective actions and sanctions imposed by the CCA upon producers. The CIG also audits the functions of the VA to ensure that it effectively verifies the adequacy of food safety systems at certified establishments. During this audit, FSIS reviewed reports of CIG establishment's technical reviews conducted as a follow up to reported Port of Entry (POE) violations; past FSIS audit findings and routine audits of VA officials' performance. Information contained in the examined documents and observations conducted by the FSIS auditor at the establishments revealed that this group of the NZFSA effectively evaluates the functions of producers and official verifiers of the meat inspection system at the establishment level.

Oversight provided by the CCA to its technical support was also evaluated by the FSIS during the audit of government offices, establishments and a laboratory. The Laboratory Approval Scheme (LAS) and the National Microbiological Database Program of the NZFSA oversee the functions of laboratories that constitute the technical support of the system. The LAS assesses and accredits laboratories to carry out official microbiological and chemical testing and verification testing for the establishments to verify compliance with regulatory and market access program requirements. Approved laboratories are required by LAS to participate and perform satisfactorily in recognized proficiency testing programs. Approval, suspension and revocation of accreditation are based on the ability of laboratories to meet the requirements of ISO 17025. In addition, the LAS maintains inter-laboratory proficiency testing programs to verify continuity of eligibility of approved and accredited laboratories and certifies and evaluates personnel assigned to positions of overall authority in the laboratories. FSIS audited the functions of an accredited laboratory of the system to establish the level of oversight maintained by the CCA over its functions. The auditor reviewed reports of audits conducted by government officials, analysts' proficiency evaluations and records of corrective actions taken as well as their evaluations for acceptability. The laboratory demonstrated to be in compliance with all requirements of the LAS and had successfully maintained accreditation and approval to conduct microbiological analyses for certified establishments as attested in the official documents presented for examination to the FSIS auditor.

New technical information is distributed to all meat and poultry inspection employees via internet and electronic mail as part of Overseas Market Access Requirements (OMAR),

General Export Requirements (GREX), and Technical Directives (TD). OMAR and GREX documents are based on the Animal Products Act of 1999, and TDs are based on the Meat Act of 1981, but some TD's have been given full legal effect under the Animal products Act of 1999 for access to particular markets, such as the United States.

Regulatory oversight of the establishments sector of the system is provided by two agencies that maintain daily presence at certified establishments. Personnel from both AsureQuality NZ (AQNZ) and the CEG Verification Agency (VA) interact to maintain adequate inspection of slaughter and verification activities of the establishments' food safety systems. Both AQNZ and VA personnel are part of the fully cost recovery program of the NZFSA. The salaries of verifiers and inspectors are funded from monies collected for services rendered in accordance with statutory mechanisms that require that operators of certified establishments pay to the government for inspection and verification services following an official schedule of payments. The government agencies in turn pay their personnel from those funds. Establishments that require additional services, as a result of recurrent non compliance must therefore, pay for the additional services associated with increased verification activities. The effectiveness of this regulatory arrangement is assessed by the CIG of the NZFSA, whose officials regularly conduct audits of the performance of establishments and VA officials.

AQNZ is a State Owned Enterprise (SOE) legally recognised under the New Zealand Animal Products Act 1999 and certified to meet ISO 17020, which is responsible for on line post mortem inspection at slaughter establishments. AQNZ hires individuals that have completed training offered by industry training organizations (ITO), which are certified by NZFSA to provide basic inspection training. The ITOs provide instruction in Unit Standards (US) which prepare the candidates to become inspectors or Official Assessors (OA). After completing the US required, the candidates must also successfully complete on the job training provided by an in plant AQNZ Work Place Assessor (WPA). The WPA evaluates and documents the level of proficiency attained by the candidates and issues recommendation for their official appointment. The AQNZ Technical Manager in turn, acts upon the recommendation submitted by the WPA and issues the corresponding appointment level to the new OAs. After completion of the entry level requirement, the OA continues to complete additional US and progressively gains greater proficiency to reach full official appointment status. That level authorizes the OA to conduct head, viscera and carcass inspection of slaughtered livestock as mandated by NZFSA.

The FSIS auditor verified that the CCA oversees the regulatory functions of both inspection conducted by AQNZ and official verification conducted by the VA. In accordance with established protocols, the CCA provides requirements that apply to the interaction between certified establishments and AQNZ. In the one hand, establishments entering into a contract with the AQNZ must have a currently registered risk management program with NZFSA and agree on staffing levels and corresponding production rates. In the other hand, The CCA requires that AQNZ maintains records that describe incidence of disease, defects, condemnation rates, and volume of kill in a manner approved by the NZFSA. Furthermore, AQNZ is required to make OAs aware of their

obligations towards the NZFSA and must conduct and document performance evaluations of its personnel. The CCA also places restrictions on the type of work and schedules that OAs can perform at the establishments where they are stationed.

FSIS conducted an evaluation of the official oversight that the CCA provided at two certified establishments. The auditor assessed the proficiency of both official inspectors and verifiers and reviewed pertinent records maintained by local AQNZ and the NZFSA personnel. Documents presented for examination demonstrated that, personnel assigned to conduct post mortem inspection had been trained and were being regularly evaluated in accordance with established protocols. OA's had been regularly evaluated by the in-plant WPA, periodically by the AQNZ Technical Manager or its designee and daily by the resident VA veterinarian at the establishment. The results of those evaluations had been presented to the OAs and measures were promptly adopted by the AQNZ in plant supervisor, WPA and the OA to correct detected deficiencies. Records containing results of OAs performance evaluations were being generated by AQNZ supervisors and the actions taken to remedy identified deficiencies were documented. FSIS verified that OAs possessed an ability to perform post mortem inspection routines and also that the resident VA veterinarian closely interacted with the AQNZ supervisor to maintain an acceptable level of performance of the OA's. In addition, establishment officials were observed to cooperate and assist inspection personnel without interfering with their functions.

The VA is the group of the NZFSA that under statutory authority serves as the verification arm of the CCA nationwide. The VA's main function is to audit food safety programs of operators of certified establishments and provide export certification for their products in accordance with New Zealand standards and importing countries requirements. VA personnel include veterinarians that are mainly assigned to conduct regulatory verification at abattoirs and non veterinarians that do likewise at processing establishments. VA veterinarians are graduates of accredited colleges and must complete training in auditing, legislation, industry standards, animal welfare, HACCP, residues and certification procedures prior to reporting to their duty stations. Official appointment of veterinarians takes place gradually corresponding to the level of proficiency that they have attained as verifiers of the different aspects of the food safety systems that they are to regularly audit. Fully warranted veterinarians, who are stationed at certified slaughter establishments verify that OAs effectively deliver inspection services consistent with the NZFSA and FSIS requirements. VA personnel conduct verification tasks generated by an automated system and also as instructed by the Area Technical Managers. Reports of activities are electronically submitted into a database centrally managed that further classifies and packages the reported data for analysis. FSIS conducted a review of electronic records during the audit of the Regional Technical Manager (RTM) office and verified that on a regular basis the data submitted by in-plant officials is assessed by the RTM and utilized to determine verification frequencies based on the assessment of the performance of establishments. The collected data is further utilized to establish the proficiency of the verifiers as they perform verification tasks at their establishments in accordance with their official appointment level. The auditor observed that verifiers document findings and assess implementation of corrective actions within adequate timeframes.

VA personnel evaluate and approve the validity of quality and Risk Management Programs (RMP) used by the industry to ensure food safety and serves as source of technical advice and risk management consulting for producers. However, the FSIS auditor observed that at the two establishments that were audited, the approved RMPs used by the operators called for direct observations of the monitoring of critical control points (CCP), to be conducted monthly. The VA approved the RMP's apparently without establishing if that verification frequency was adequate for the operators to determine that their HACCP plans were working as intended.

In conclusion, the auditor verified that the inspection system is organized and administered by the national government and that it provides standards equivalent to those of the Federal system of meat inspection in the United States. However, the VA's review process of RMPs needs to evaluate further the decisions made by operators to conduct direct observations of the monitoring of CCP's at a frequency not supported by statistical analysis. Without a statistically acceptable level of confidence for the frequency of verification of monitoring of critical control points, inadequacy of controls would inadvertently go undetected by the operators and could compromise the efficacy of their food safety systems.

6. STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. This component pertains to the legal authority and the regulatory framework utilized by the CCA to impose requirements equivalent to those governing the system of meat and poultry inspection organized and maintained by the United States.

The evaluation of this component included an analysis of information provided by the CCA in the SRT and observations gathered during the onsite audit of the system. Upon examining, the information provided, the auditor concluded that the inspection system of New Zealand has statutory authority to deliver inspection to all establishments certified to slaughter and process meat and poultry products. The CCA has rules that require that official inspection personnel, laboratories and establishments meet the requirement of importing countries. In addition, it has regulatory requirements for inspection of slaughter and processing activities, control of inedible and condemned materials and requirements for daily inspection as well as periodic supervisory reviews of certified establishments.

FSIS verified that inspection and verification activities conducted by government officials followed the regulatory framework provided by the CCA as described in the SRT. Animals presented for slaughter undergo ante-mortem inspection which is conducted by either the resident VA veterinarian or a specially trained OA under the direct supervision of the VA veterinarian. The official inspectors follow written procedures to ensure the effective detection of abnormalities in different types of

livestock presented for slaughter. The auditor also verified that official verification assessed the adequacy of ante-mortem facilities and compliance of operators with humane handling requirements imposed by the NZFSA and OMAR. In addition, observations conducted by the FSIS auditor during operations revealed that, in accordance with the regulations of the New Zealand inspection system, certified establishments provide inspection stations adequately furnished to allow post mortem inspection, and present for inspection heads, viscera and carcasses adequately identified. Post mortem inspection is conducted by trained inspectors in accordance with staffing levels and line speeds that are jointly determined and agreed upon by the inspection agency and the operator. Dispositions of suspects and verification of acceptability of the final product is the responsibility of the resident VA veterinarian, who regularly presents feedback to AQNZ personnel and reserves the right to adjust production rates in accordance with the characteristics of the livestock being inspected and the incidence of pathology.

The CCA has submitted before FSIS, an equivalence determination request for an alternative ovine post mortem inspection system in which plant employees conduct inspection of carcasses and viscera to identify other consumer protection defects, AOs visually inspect carcasses and viscera for food safety related conditions and the in-plant VA veterinarian evaluates the acceptability of functions of both groups of inspectors and the safety of the final product. During this audit, the FSIS auditor observed the features of the trial of the alternative inspection system and verified that inspection activities and data collection routines were consistent with the description included in the request submitted by the CCA.

Periodic technical reviews of certified establishments including evaluation of efficacy of food safety systems, inspection and official verification activities are conducted by RTMs of the VA and the NZFSA Compliance and Investigation Group Assessors (CIGAs). During this audit, FSIS observed a CIGA as he evaluated design and maintenance of the facilities, sanitary conditions, efficacy of food safety systems, official verification activities and technical competence of in-plant officials. The CIGA also assessed the level of compliance being maintained by the establishment with the NZFSA regulations and OMAR. The FSIS auditor verified that the functions of the CIGA adequately assessed the three sectors of the system that interact at the establishment level to collectively maintain adequate food safety systems.

FSIS also review reports and records generated to document outcomes of periodic reviews of the performance of official personnel and operators. Documentation is evaluated at several levels within the CCA to analyze reported findings, follow-up corrective measures and reevaluations. Establishments are correspondingly ranked in accordance with their demonstrated ability to maintain compliance with the regulatory requirements of the NZFSA and OMAR. Electronic records reviewed by FSIS showed that only certified establishments that have demonstrated a consistent level of compliance are allowed to remain in the export program. These establishments have gradually moved from lower performance levels to the maximum attainable rank in their class. There are although, NZFSA regulatory provisions that dictate that unacceptable review

outcomes in which the verifiers conclude that meat products produced at a given establishment are not eligible for export, be accompanied by a suspension of the issuance of eligibility documents and export certificates, suspension from participation in the export program and increased official scrutiny.

In conclusion, New Zealand meat and poultry inspection system has legal authority and a regulatory framework to impose requirements equivalent to those governing the system of meat and poultry inspection organized and maintained by the United States. This component of the system therefore, continues to meet equivalence.

7. SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. The inspection system must provide requirements for sanitation, for sanitary handling of products, and for the development and implementation of sanitation standard operating procedures.

The evaluation of this component included a review and analysis of the information provided by the CCA in the SRT and observations gathered during the onsite audit of government offices and establishments within the system. The auditor reviewed legislation, regulations and official instructions and ascertained that the CCA exercises its legal authority to require that operators develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions.

During the auditing of this component, the auditor verified the functions of the CIGA as he reviewed records maintained by establishment operators and in-plant VA officials, and assessed the adequacy of pre-operational and operational sanitation implementation and monitoring, and generated documentation of sanitary deficiencies that required corrective action.

The auditor's assessment of the design and implementation of sanitation programs as well as official verification activities conducted support the conclusion that the CCA effectively implements its requirements for sanitation and sanitary handling of meat and poultry products intended for export to the United States. Therefore, this component of the meat and poultry inspection system of New Zealand meets equivalence requirements.

8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. The inspection system must require that each official establishment develop, implement and maintain a HACCP plan.

of Practice that describes how the operator will meet regulatory requirements and a RMP that is to include Good Operating Practices and HACCP plans. The auditor evaluated the design and execution of HACCP programs at two certified slaughter establishment against the regulatory requirements prescribed in OMAR and observed that the CCA exerts its legal authority to require that operators comply with its HACCP System rules.

FSIS verified that the CCA representatives conducted regular verifications of the adequacy of the HACCP plan used by the operator. Hazard analysis and determinations made at each step of the process were documented and were in compliance with the NZFSA and FSIS requirements. In addition, corrective action protocols and adequate record keeping were maintained and verified in accordance with the plan and the regulations of the system. However, operators could not provide support for the decision made to establish the frequency for verification of direct observations of the monitoring of the critical control point on a monthly basis. Furthermore, official verification of the adequacy of the HACCP plans had deemed the above stated verification frequency as acceptable even when the operator did not provide support for the decision made.

In conclusion, this equivalence component remains equivalent, but there is a need for the CCA to define how the VA will evaluate the adequacy of the verification frequency that operators use to conduct direct observations of the monitoring of CCP's. This is an important concern of the FSIS since in the absence of adequate support for the decisions made; the operators of certified establishments would be less likely to determine if their HACCP plans are being effectively implemented to attain food safety.

CHEMICAL RESIDUES CONTROL PROGRAMS

The fifth of the six equivalence components that the FSIS auditor reviewed was Chemical Residues Control Programs. This component pertains to regulatory requirements for the inspection system to have a chemical residue control program that is organized and administered by the national government. The program must include random sampling of internal organs and fat of carcasses for chemical residues identified by the exporting country's meat and poultry inspection authorities or by FSIS as potential contaminants.

An assessment of the CCA's ability to implement its residue control program was conducted by reviewing the information provided through SRT, onsite visits to the government offices, and slaughter establishments.

NZFSA responsibilities for the control of chemical residues are grounded in the Animal Products Monitoring and Surveillance Regulations 2004, which requires the maintaining of monitoring and surveillance of animals and animal products to detect evidence of chemical residues in edible tissues and further describes the responsibilities and procedures to be followed by government officials, operators, and laboratories. NZFSA and its business groups in conjunction with AsureQuality administer the National Chemical Residue Program (NRCP). The objective of the program is to randomly monitor or selectively target at-risk animals and animal products and to implement increased sampling or restricted movement of use of at risk animals, and the disposition

of non-complying product. The program involves risk based on farm sampling of livestock, a monitoring program at slaughter or processing and an in-plant surveillance program that targets suspect animals.

Factors considered when determining the annual residue program included toxicity of compounds, animal exposure, species, administration route, prevalence, previous monitoring results, analytical methodologies, international concerns and regulatory requirements of foreign markets.

The FSIS auditor verified that all chemical residues testing performed on samples submitted under the NCRP must be undertaken by the NZFSA approved laboratories, using approved and validated methods of analysis, but testing of materials could also be conducted onsite in accordance with specifications and by competent individuals. Analytical services are provided to the CCA through commercial contracts which are allocated to laboratories by analytes characteristics rather than by sample source or type. Approved laboratories must be accredited by New Zealand's accreditation body, International Accreditation New Zealand (IANZ) and must also be approved under the NZFSA Laboratory Approval Scheme (LAS).

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

The NRCF NZ 2009-10 report reviewed by the auditor indicates that samples from randomly selected livestock including cattle, sheep and lambs, goats, pigs, ostriches, broilers, turkeys, ducks among others were collected by in-plant officials. Substances that were included in the program were agricultural compounds and veterinary substances such as growth promoters, antibiotics, pesticides, anti-parasite substances, heavy metals, and environmental contaminants in adherence to the prepared plan. Results of testing revealed that two out of 5221 tissues of tested animals exceeded MPL for the United States. In each instance, the CCA identified the involved producer and followed established protocol to determine the root cause of the problem, implement corrective actions and verify their effectiveness.

NZFSA has regulatory requirements for a chemical residue control program that is organized and administered by the national government. The program includes random sampling of internal organs and fat of carcasses for chemical residues identified by the exporting country's meat and poultry inspection authorities or by FSIS as potential contaminants. Therefore, this component of the meat and poultry inspection system meets equivalence requirements.

MICROBIOLOGICAL TESTING PROGRAMS

The sixth of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs. This component pertains to regulatory requirements for the inspection system to have a microbiological testing program, organized and administered by the national government.

The principal criteria used by FSIS to assess microbiological testing programs for raw meat and poultry include: The inspection system provides for a sampling and testing programs for generic *E. coli*, *Salmonella* and *E. coli O157:H7* in raw products. The CCA uses the test results to verify the adequacy of establishments' sanitary slaughter and dressing controls, food safety systems and pathogen reduction strategies. The program used by a given country must be supported by analytical test results, countrywide microbiological baseline surveys and/or other scientific data.

The evaluation of this component included a review and analysis of information provided by the CCA in the SRT and observations gathered during the onsite audit of two establishments, one microbiological laboratory and four government offices at several locations in New Zealand.

Information provided by the NZFSA to the FSIS auditor indicates that the CCA has implemented a National Microbiological Monitoring Program (NMDP) for slaughter and meat processing plants regardless of whether their products are destined for the domestic market or exported to the United States. The program encompasses standardized sampling plans, sample transportation procedures and prescribed analytical methods to detect and quantify *Salmonella*, generic *E. coli*, Aerobic Plate Count and *Campylobacter* in raw meat products. Furthermore, the NMDP verifies laboratory proficiency, accredits laboratory personnel and maintains a National Microbiological Database (NMD) that includes microbiological profiles for individual establishments and sectors of the New Zealand system. The NMDP provides to operators of establishments and the CCA, tools to conduct microbiological trend analysis. Furthermore, the collected data allows the system to determine if sanitary control measures within specific premises and nationally are performing in accordance with regulatory requirements.

In accordance with program standards, sampling is conducted after final inspection from pre-chilled carcasses, post-chilled carcasses, primal cuts and cartons of bulk meat. Collected samples are then sent to microbiological laboratories that have been accepted by the NZFSA under the LAS to analyze samples for Aerobic Plate Counts (APCs), generic *E. coli*, and *Salmonella* on behalf of establishment operators. Training of samplers is accomplished by persons who have attended an LAS approved sampling course to be classified as Certified Trainers (CT). The CT may train other employees to conduct sampling and they are classified as Associate Trainers (AT). ATs may also in turn train other employees to conduct sampling but those samplers are not qualified to train other employees. FSIS conducted an assessment of the implementation of this portion of the NMDP at one laboratory and verified that the resident CT held LAS approval and certification to coordinate sampling activities and train the ATs that assisted with the sampling routines. The auditor also evaluated the ability of ATs to conduct

sampling routines and observed that they performed their functions in an adequate manner.

Additional provisions of the program require that individuals that administer and operate approved laboratories, be certified by the LAS and pass evaluations administered by IANZ to attain Signatory status. All signatories confirmed by the NZFSA as accredited to participate in the program, are entered on an official roster made available to the public as reference. This roster also shows which approved laboratories employ the signatories and the scope of their analytical qualifications for regulatory testing. FSIS reviewed records and documents that pertained to the qualifications of personnel assigned to work in the laboratory and verified that the Signatory at the audited laboratory was listed in the official roster of approved signatories and the scope of the analytical activities that she conducted was consistent with her listed qualifications.

The LAS and the NMDP of the NZFSA oversee the functions of laboratories. The LAS assesses and accredits laboratories to carry out official microbiological testing and verification testing for the establishments to verify compliance with regulatory and market access program requirements. Approved laboratories are required by LAS to participate and perform satisfactorily in recognized proficiency testing programs. Approval, suspension and revocation of accreditation are based on the ability of laboratories to meet the requirements of ISO 17025. NZFSA also verifies that establishment operators randomly collect samples from the correct products and maintain identity and integrity of the samples during packaging, transporting and delivery at the laboratory in a manner consistent with the specifications of the program. Furthermore, the in-plant VA official tracks sampling results and conducts direct observations to evaluate the sampling routines followed by the samplers.

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

FSIS also assessed the data gathering activities of the program and verified that operators of certified establishments register with the NMDP and disclose basic identification of the establishment, manager's contact information, plant official that will serve as NMD controller, and which laboratory coordinate sampling and analyze the samples. Electronic and hard copy documents reviewed by the FSIS auditor indicated that results of the tests were being consistently entered into the NMD and establishment operators regularly accessed and evaluated the processed data to assess their individual microbiological profile, their ranking against other premises, and national microbiological profiles and thus verify the adequacy of their food safety controls.

Regulatory requirements of the inspection system prescribe actions to be taken when operators fail to achieve and maintain an acceptable microbiological control status. In

those cases, the VA verifies that the operator re-assess the effectiveness of hygienic dressing of carcasses and the processing of product to identify and correct controllable process variables. During this audit, FSIS observed that testing being conducted at the audited establishments yielded results that were within acceptable parameters associated with adequate process control.

Salmonella Performance Standards (SPS) are also included as part of the NMDP. The NZFSA has dictated that there is a zero tolerance for the presence of *Salmonella* in raw products. Consequently, the CCA requires that producers comply with the requirements of the *Salmonella* Sampling Program (SSP) included in the NMDP. The SSP provides to establishment operators and official verifiers, standardized procedural and technical guidance necessary to analyze raw meat products for the presence of *Salmonella*. Upon occurrence of a positive result, operators, the VA and the Export/Standards group of the NZFSA jointly implement identification, retention and/or detention and disposition of affected product. Laboratories are to submit purified cultures of isolates of the confirmed positive colonies to a specialized laboratory for serotyping. The SSP also require that government officials identify the source of involved livestock to establish incidence of animal salmonellosis in the area and to determine if human Salmonellosis has been reported in the community. During this audit, FSIS verified that laboratory personnel and VA officials were familiar with the protocol to be followed in the event of a positive *Salmonella* result.

NZFSA also requires that certified establishment conduct additional microbiological testing as stipulated in the OMAR for the United States. During this audit, the FSIS reviewed records maintained by the VA officials that described the results of evaluations of sampling and analysis of beef products to detect *E. coli* O157:H7 conducted by the establishments. The document review also revealed that producers of ready-to-eat (RTE) products are required to meet the requirements of the United States for the control of *Listeria monocytogenes* in RTE products and in the post lethality environment.

In conclusion, the New Zealand meat inspection system has a microbiological testing program, organized and administered by the national government. This component of the system therefore, remains equivalent.

EXIT MEETING

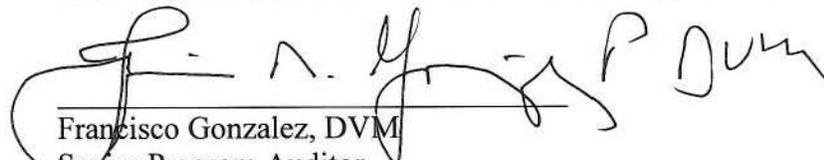
An exit meeting was held on March 15, 2011 in Wellington with representatives of the NZFSA. At this meeting, the preliminary findings from the audit were presented by the FSIS auditor.

The CCA understood the findings and indicated that upon receipt of the draft final report they would submit their comments.

CONCLUSIONS AND NEED FOR FURTHER ACTIONS

The audit outcome made evident that the New Zealand meat inspection system maintains ongoing equivalence, but there was an issue that the CCA needs to address within the government oversight and HACCP components of its meat inspection system. FSIS expects the CCA to define with greater adequacy the strategies that the Verification Agency would implement to assess the adequacy of verification frequencies proposed by operators in their Risk Management Programs. Furthermore, the CCA must convey to certified operators that the FSIS requires that establishment operators support the decisions made to select verification frequencies used in their HACCP plans in a manner that is consistent with current scientific practices.

New Zealand did not provide comments in response to the finding contained in this report. However, FSIS will verify the adequacy of the pertinent corrective measures implemented by the New Zealand's CCA during the next audit.



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Senior Program Auditor

ATTACHMENTS TO THE AUDIT REPORT

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