United States Department of Agriculture

Food Safety and Inspection Service

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

November 6, 2023

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

Dear Dr. Zohrab,

The U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted a remote verification audit of New Zealand's meat inspection system March 1–April 13, 2022. FSIS provided New Zealand with a draft audit report, and New Zealand provided responses to that draft report. FSIS is evaluating your responses, including New Zealand's preliminary corrective actions, and will be evaluating those actions to determine whether New Zealand is maintaining a meat inspection system equivalent to that of the United States. Enclosed is a copy of the final audit report. The comments received from the Government of New Zealand are included as an attachment to the report.

New Zealand's actions in response to the FSIS audit findings will guide the scope and frequency of future equivalence verification activities, including the frequency at which FSIS reinspects products from New Zealand at the U.S. point-of-entry. For any questions regarding the FSIS audit report, please contact the Office of International Coordination, by email at InternationalCoordination@usda.gov.

Sincerely,

MARGARET BURNS RATH

Digitally signed by MARGARET BURNS RATH
Date: 2023.11.06 08:47:47 -05'00'

On behalf of
Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF A REMOTE AUDIT CONDUCTED OF

NEW ZEALAND

MARCH 1 TO APRIL 13, 2022

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING

BEEF, VEAL, GOAT, LAMB, AND MUTTON MEAT PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

October 11, 2023

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a remote ongoing equivalence verification audit of New Zealand conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) from March 1 to April 13, 2022. Due to the global COVID-19 pandemic, the audit was conducted remotely using video conferences to conduct interviews and records review. The purpose of the audit was to verify whether New Zealand's food safety inspection system governing meat (beef, veal, goat, lamb, and mutton) remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. New Zealand currently exports raw intact, raw non-intact, ready-to-eat, not ready-to-eat otherwise processed, and thermally processed, commercially sterile meat products to the United States.

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 Point (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 Chemical Residue Testing Programs

- The Ministry for Primary Industries (MPI), the Central Competent Authority of New Zealand, does not ensure that any livestock carcass or parts subjected to routine chemical residue testing are not certified for export to the United States until receipt and confirmation of acceptable testing results, including review of results against United States tolerances when different from New Zealand tolerances.

Government Microbiological Testing Programs

- MPI does not implement adequate official government sampling verification activities to ensure control of *Listeria monocytogenes* and *Salmonella* in all types of ready-to-eat products and to ensure control of *Listeria* species in the environment, including food contact surfaces, of all establishments that produce post-lethality exposed ready-to-eat products intended for export to the United States.

FSIS will evaluate MPI's proposed corrective actions and base future equivalence verification activities on the information provided.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted a remote audit of New Zealand's food safety system from March 1 to April 13, 2022. The audit began with an entrance meeting held via videoconference on March 1, with the Central Competent Authority (CCA)–the Ministry for Primary Industries (MPI). Representatives from MPI participated throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit that was conducted remotely. The audit objective was to determine whether the food safety inspection system governing meat (beef, veal, lamb, mutton, goat) 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 the following categories of products to the United States:

Process Category	Product Category	Eligible Products[1]
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Beef	Beef and Veal - All Products Eligible except Advanced Meat Recovery Product (AMR); Low Temperature Rendered Product (LTRP); Partially Defatted Beef Fatty Tissue (PDBFT); Partially Defatted Chopped Beef (PDCB); and Finely Textured Beef (FTB)
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Meat-Other (Sheep, Goat)	Goat, Lamb, and Mutton - All Products Eligible except Mechanically Separated and Advanced Meat Recovery Product (AMR)
Raw - Intact	Raw Intact Beef	Beef and Veal - All Products Eligible
Raw - Intact	Raw - Intact Meat-Other (Sheep, Goat)	Goat, Lamb, and Mutton - All Products Eligible
Thermally Processed - Commercially Sterile (TPCS)	Thermally Processed, Commercially Sterile	Beef, Veal, Goat, Lamb, and Mutton - All Products Eligible
Heat Treated - Shelf Stable	Not Ready-to-Eat (NRTE) Otherwise Processed Meat	Beef, Veal, Goat, Lamb, and Mutton - All Products Eligible

[1] All source meat used to produce products must originate from eligible countries and establishments certified to export to the United States.

Process Category	Product Category	Eligible Products[1]
Heat Treated - Shelf Stable	Ready-to-Eat (RTE) Dried Meat	Beef, Veal, Goat, Lamb, and Mutton - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE Fully-Cooked Meat	Beef, Veal, Goat, Lamb, and Mutton - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE Meat Fully-Cooked Without Subsequent Exposure to the Environment	Beef, Veal, Goat, Lamb, and Mutton - All Products Eligible
Not Heat Treated - Shelf Stable	RTE Salt-Cured Meat	Beef, Veal, Goat, Lamb, and Mutton - All Products Eligible
Heat Treated - Not Fully Cooked - Not Shelf Stable	NRTE Otherwise Processed Meat	Beef, Veal, Goat, Lamb, and Mutton - All Products Eligible

The USDA's Animal and Plant Health Inspection Service recognizes New Zealand as negligible risk for bovine spongiform encephalopathy, Level I for brucellosis, free of foot-and-mouth disease, and free of scrapie.

Prior to the remote equivalence verification audit, FSIS reviewed and analyzed New Zealand's Self-Reporting Tool (SRT) responses and supporting documentation. During the audit, the FSIS auditors conducted interviews and reviewed records to determine whether New Zealand's food safety inspection system governing meat is being implemented as documented in the country's SRT responses and supporting documentation.

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) reinspection and 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 MPI through the 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 Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors reviewed records related to administrative functions and oversight at the MPI headquarters, government verification records from two establishment team offices, and verification records from three local inspection offices within the establishments. The audit involved meetings with government personnel and laboratory staff. FSIS scheduled two meetings

each week over a seven-week period. Through records review, the FSIS auditors evaluated the implementation of control systems that ensure the national system of inspection, verification, and enforcement is being implemented as documented in the SRT and supporting documentation.

A sample of 3 establishments was selected for the audit from a total of 140 establishments certified to export to the United States. This included one beef and veal slaughter and processing establishment and two beef, veal, lamb, and mutton slaughter and processing establishments. The products these establishments produce and are eligible to export to the United States include raw non-intact lamb and mutton; raw intact beef, veal, lamb, and mutton; TPCS beef; and not heat-treated shelf stable lamb and mutton.

This audit focused on a review of records associated with official government verification activities conducted at the selected establishments. It did not include review of establishments' conditions or records. The FSIS auditors assessed the ability of MPI to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) 327.2.

The FSIS auditors also audited one government microbiological testing laboratory and one government chemical residue testing laboratory to verify that these laboratories are capable of providing adequate technical support to the food safety inspection system.

Remote Audit Scope		#	Locations
Competent Authority	Central	1	• Ministry of Primary Industries headquarters, Wellington
	Establishment Team Offices	2	• Invercargill South, Invercargill • Bay of Plenty, Mt. Maunganui
Laboratories		2	• L1953, Institute of Environmental Science and Research Ltd., Enteric Reference Laboratory (government microbiological), Wellington • L1923, AsureQuality Ltd. (government chemical residue-testing), Wellington
Beef and veal slaughter establishment		1	• Establishment No. ME82, Greenlea Premier Meats Limited, Morrinsville
Beef, veal, lamb, and mutton slaughter and processing establishments		2	• Establishment No. ME50, Alliance Group Limited, Underwood • Establishment No. ME100, Silver Fern Farms Limited, Waitotara

FSIS performed the audit to verify that the food safety inspection system meets requirements equivalent to those under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] Section 601 et seq.);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. Sections 1901-1906); and
- The Meat Inspection Regulations (9 CFR Parts 301 to the end).

The audit standards applied during the review of New Zealand's inspection system for 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 Agreement on the Application of Sanitary and Phytosanitary Measures.

III. BACKGROUND

From October 1, 2018, to September 30, 2021, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 1,230,522,721 pounds of meat exported by New Zealand to the United States.

Additional types of inspection were performed on 65,204,564 pounds of meat. These additional types of inspection included physical examination, condition of container examination for TPCS products, chemical residue analysis, and testing for microbiological pathogens (e.g., Shiga toxin-producing *Escherichia coli* (STEC) in beef or veal, and *Listeria monocytogenes* (*Lm*) and *Salmonella* in RTE products). As a result of this additional testing, 72,159 pounds of meat were rejected for issues related to public health, including fecal and ingesta contamination, testing positive for STEC, and detection of chemical residues. MPI provided additional information related to the FSIS rejection of meat products due to the detection of DDT metabolites in the Appendix of this report.

The previous FSIS audit in 2018 identified the following findings:

Summary of Findings from the 2018 FSIS Audit of New Zealand
Component 2: Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling)
• MPI 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.
Component 4: Government Hazard Analysis and Critical Control Point (HACCP) System
• MPI has determined that STECs 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 MPI 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 current audit, the FSIS auditors verified through interviews and review of records that the corrective actions for the previously reported findings were implemented and effective in resolving the findings.

The most recent FSIS final audit reports for New Zealand's food safety inspection system are available on the FSIS website at: www.fsis.usda.gov/foreign-audit-reports.

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

The first equivalence component the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign food safety 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 that provides oversight for New Zealand's meat inspection system and ensures the safety of exported meat products. MPI establishes and administers the standards and regulations for New Zealand's food safety, biosecurity, and primary production systems. The main branches within MPI responsible for meat inspection and the export of meat products to the United States include the New Zealand Food Safety (NZFS) branch and the Policy and Trade branch. The Policy and Trade branch includes the Market Access Directorate, which is responsible for negotiating market access, international assurances, coordinating POE issues, and sanitary and phytosanitary negotiations and implementation. The NZFS branch includes the Food Regulation Directorate, Verification Services (VS) Directorate, Assurance Directorate (AD), and Food Science and Risk Assessment Directorate. The Food Regulation Directorate sets standards for domestic, import, and generic export and regulatory implementation for all foods and other animal products. The VS Directorate provides a range of predominantly export related food safety, biosecurity and animal welfare verification, inspection, and certification-related services. The AD includes the Chemical and Microbiological Assurance (CMA) and Systems Audit Team (SAT). The AD also provides oversight of the animal products electronic certification system, establishes maximum residue levels for the chemical residue program, and performs good manufacturing practice audits. The Food Science and Risk Assessment Directorate is responsible for providing science and risk assessment advice associated with both the development of food and processing standards and their implementation.

MPI has its own technical staff and approves third-party agencies to carry out a range of verification functions on its behalf. Currently, regulatory oversight of the establishments sector of the system is provided by VS and AsureQuality New Zealand (AQNZ), a state-owned enterprise under the Ministry for State-Owned Enterprises. Consequently, AQNZ employees meet equivalence criteria specified by FSIS as government employees in certified establishments. The primary function of VS is to verify the risk management programs (RMP) of animal product processors and provide export certification for dairy, meat, game, seafood, live animals, and germplasm. VS is accredited as an inspection agency to the International Organization for Standardization (ISO) standards and is audited annually by International Accreditation New Zealand (IANZ) to comply with requirements of the Animal Products Act of 1999 (the Act). VS personnel include veterinarians, veterinary technical supervisors (VTS) that are mainly assigned to conduct regulatory verification at slaughterhouses, and non-veterinarians, traveling technical supervisors (TTS), that do likewise at processing establishments. AQNZ employs official assessors (OA) to perform official ante-mortem and post-mortem inspection,

sampling activities, and when needed, act for the VTS.

The FSIS auditors verified that VS is comprised of circuit teams and establishment teams. Circuit teams carry out performance-based verification activities at establishments that do not require full-time VS services. Circuit teams have two team managers, North Island and South Island. There are four circuit teams managed by the North Island team manager and there are three circuit teams managed by the South Island team manager. Some circuits cover a larger geographical area so there may be more than one physical office for staff within each circuit. Each circuit is led by a team leader. Establishment teams are based at meat slaughter establishments requiring full-time VS presence to be eligible for export. Establishment teams are supervised by team managers.

The SAT conducts audits across the MPI regulatory spectrum when requested by MPI branches. The SAT is responsible for gathering information on how MPI's processes, guidance, and standards are performing for regulatory accountability. The results of the SAT audits are entered into the Piritahi SAT tracking system. The SAT only verifies corrective actions when specifically requested by MPI.

The FSIS auditors verified that the VS personnel are direct hires and salaried employees of MPI. Salaries of VS personnel and AQNZ OA 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, for example, due to recurrent noncompliance, must 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 potential conflicts of interest according to MPI's policy.

The FSIS auditors verified that the VTS assigned to slaughter establishments are required to hold a current practicing certificate issued by the Veterinary Council of New Zealand. TTS assigned to processing establishments are required to have a post-high school education. The FSIS auditors reviewed documentation of training in the Tiritiri system, MPI's learning management system, for new VTS and TTS. The training for newly hired VTS and TTS lasts 6-12 months and includes classroom and hands-on learning. The classroom training includes courses in legislation, risk management systems, Overseas Market Access Requirements (OMAR), certification, verification, HACCP, ante-mortem inspection, and post-mortem inspection. Additionally, VTS and TTS must complete the ISO 9001, Lead Auditor training course. New VTS and TTS must participate in the HACCP Unit Standard 28265: Develop, Implement, and Review a HACCP Application for a Food Processing Business. At the completion of the course, the new VTS and TTS participate in a one-on-one assessment by a registered workplace assessor. VTS and TTS participate in continuing professional development and correlations which consist of online learning, external conferences, customized programs, and national correlation activities. Every two years, VTS and TTS must participate in a HACCP skills maintenance course which covers HACCP validation, New Zealand HACCP requirements, and MPI HACCP requirements for products exported to the United States. The FSIS auditors concluded that initial and ongoing VTS and TTS training follows MPI's established standards.

OA assigned to slaughter establishments are required to meet qualifications for proficiency in meat inspection as designated by the Director-General. The FSIS auditors verified that OA undergo species-specific and job-specific training prior to being assigned. AQNZ submits the OA's applications, declarations, and assessment outcomes to the MPI approvals team to enable their appointment. The FSIS auditors concluded that initial and ongoing OA training follows AQNZ's established standards.

The FSIS auditors confirmed that MPI maintains a communication system to convey inspection requirements throughout its inspection system, including to industry stakeholders, in a timely manner. MPI maintains an internal web portal, Verification Online (VOL), where employees can access information applicable to their respective roles. The FSIS auditors reviewed task-specific information within the VOL system and verified it contained detailed task information for each task. A monthly update that includes new technical information must be read and electronically documented by VTS and TTS. In addition, updates to any technical documents and inspection requirements relevant to both industry stakeholders and MPI employees are continually uploaded on MPI's public site. Links to important documents are also communicated via e-mail notification.

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 internal audit program uses trained auditors from other establishments. The VTS assigned to the slaughter establishments are required to verify that AQNZ effectively delivers inspection services consistent with MPI requirements. VTS conduct meetings with AQNZ supervisors every two weeks in each slaughter establishment. In addition, the VTS at each slaughter establishment reviews AQNZ records and procedures every three months. The FSIS auditors reviewed examples of AQNZ records as well as VTS reports. No concerns were identified as a result of the FSIS auditors' review.

All laboratories recognized under the Recognized Laboratory Program (RLP) must be accredited to the ISO standard 17025, General Requirements for the Competence of Testing and Calibration Laboratories, 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 that fails to meet the conditions outlined in the Animal Products (Specification for Laboratories) Notice 2015. The FSIS auditors reviewed a sample of IANZ issued accreditation certificates and IANZ audit reports to verify that MPI ensures laboratories comply with ISO 17025 standards.

MPI requires each establishment's RMP to contain a recall procedure which includes criteria for when a recall will be initiated and how retrieval and disposition of the relevant products will be

managed. Additionally, their RMP must contain a system for notifying MPI. Technical supervisors (TS) verify the establishments' recall procedures annually as part of the Identification, Traceability, and Management task. The FSIS auditors verified the TS at each establishment included in the audit has performed this task at the required frequency according to documentation in the VOL system.

In August 2021, MPI's SAT undertook an audit that included five recognized laboratories. The audit determined that three of the five recognized laboratories could not provide evidence that IANZ accreditation assessment reports had been provided to MPI, as required by the Animal Products Notice, Specifications for Laboratories. This was a repeat finding identified during the 2017 SAT audit for one of these laboratories; therefore, the finding in 2020 was elevated to a serious noncompliance. The FSIS auditors verified the issue was documented in the Piritahi SAT tracking system. Corrective actions were declined to be taken by MPI pending a regulatory redesign, due for implementation in July 2022, that will remove the requirement for all IANZ audit reports to be provided by the laboratories to MPI. Instead, the new regulations will require laboratories to notify and report certain matters to MPI. Once MPI implements changes from the regulatory redesign, further guidance for recognized laboratories will be documented in a supplementary notice. Additionally, MPI is currently evaluating its laboratory oversight across the Food Safety Regulatory Framework, and recommendations will be documented in a report. In order to verify that the changes under the regulatory redesign ensure adequate oversight of the laboratories in the RLP by MPI, the FSIS auditors requested that MPI provide FSIS with a copy of the relevant supplementary notice and any actions taken in response to the recommendations from the report evaluating MPI's laboratory oversight.

The FSIS auditors reviewed the AsureQuality Limited Laboratory Services, L1923, chemical residue testing program. This laboratory is owned and operated by AQNZ and approved by MPI under the RLP. L1923 operates a fully commercialized business model, fee for service laboratory testing. L1923 currently performs all chemical residue and contaminants testing, other than metals, using methods listed in the CLT for establishments eligible to export to the United States. Test methods are validated to international standards and included in the scope of the laboratory's accreditation. The FSIS auditors verified L1923 is accredited to the ISO 17025 standard by IANZ. The FSIS auditors reviewed IANZ assessment reports from the audits conducted over the last four years. There were some minor findings, which were corrected and determined acceptable to IANZ. FSIS auditors reviewed records pertaining to staff qualifications, credentials, and training; internal audits; noncompliance; and corrective actions. 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 summary of proficiency testing for 2021. No concerns were identified as a result of these reviews.

The Institute of Environmental Science and Research Ltd. (ESR), Enteric Reference Laboratory (ERL), L1953, is a government-owned laboratory that performs final confirmation and serotyping for *Salmonella* and culture isolation for STEC in raw beef trimmings from adult cattle. The FSIS auditors verified L1953 is accredited to the ISO 17025 standard by IANZ. Confirmation testing for STEC in raw veal trimmings from bobby calves is conducted by the GeneSeek Operations Ltd. laboratory in Lincoln, Nebraska. The FSIS auditors reviewed IANZ assessment reports from the audits conducted over the last three years. The FSIS auditors

verified that corrective actions related to identified findings were deemed acceptable by IANZ. The FSIS auditors reviewed records pertaining to staff qualifications, credentials, and training; internal audits; noncompliance; and corrective actions. The FSIS auditors verified that the analysts' training program comprises an ongoing training segment and a program designed for new hires. The laboratory demonstrated records of proficiency testing in the ILCP. No concerns were identified as a result of these reviews.

The FSIS auditors verified that MPI's food safety inspection system governing meat products has the organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements for this component.

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 equivalence component 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 all animals; post-mortem inspection of every carcass and part; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

New Zealand's Animal Welfare Act of 1999 (AWA) 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 AWA includes the codes of welfare and requires a documented quality assurance program. VTS are required to audit the documented quality assurance program annually. The FSIS auditors confirmed through interviews that humane handling and slaughter are verified daily by VTS or OA. The FSIS auditors reviewed documented noncompliances relating to humane handling and slaughter as well as an example of a warning letter that was sent to a farmer regarding the arrival of a recumbent cow for slaughter. The FSIS auditors determined that compliance with MPI's humane handling and slaughter requirements is being effectively verified by VTS.

The FSIS auditors verified through interviews that either the VTS or OA perform ante-mortem inspection on all animals to determine their suitability for slaughter. If ante-mortem inspection is missed, the products are ineligible for export. The FSIS auditors reviewed noncompliance reports relating to missed ante-mortem inspection and verified those products were identified as ineligible for export. MPI requires that animals showing evidence of disease or any other condition that would make the product unfit for human consumption during the ante-mortem inspection are condemned and animals showing evidence of disease that does not warrant condemnation are segregated and placed in a separate pen. The FSIS auditors verified through interviews and records review that ante-mortem inspection is performed on all animals and animals showing signs of disease are either condemned or segregated for a clinical exam.

Identification of suspect animals is required to be maintained until after post-mortem inspection and the post-mortem inspector must be informed of suspect animals in advance. The FSIS auditors reviewed records associated with suspect animals including advance notification to the post-mortem inspectors of suspect animals slaughtered. The establishments are required to maintain a record of dead animals, including those humanely killed, and all details relating to the circumstances of the death. The FSIS auditors reviewed the establishments' records of dead animals which included dead-on arrival and non-ambulatory animals. Every instance of non-ambulatory cattle is documented in the VOL system and their carcasses and parts are identified as ineligible for export to the United States. VTS documents the total number of condemned animals in the VOL system. The FSIS auditors reviewed the condemned animal statistics in the VOL system and confirmed they were being documented as required. Additionally, the FSIS auditors reviewed documentation relating to non-ambulatory cattle and confirmed they were identified as ineligible for export to the United States.

Processors are required to obtain evidence from suppliers of animals, intended for processing into food, as to the origin of the animal and any relevant history of disease or treatment with veterinary drugs. This information is provided in the Animal Status Declarations (ASD). Bobby calves, which are unweaned calves weighing less than 99 pounds dressed carcass weight, are covered by seasonal ASD. Bobby calf suppliers sign contracts with the processors. The processors then issue ear tags with unique numbers and barcodes for each calf to be slaughtered during the season. The VTS review the ASD for completeness and verify if the animals are on a restricted animal list for residue surveillance, imported animal or tuberculosis. The FSIS auditors verified that VTS and OA are reviewing ASD for livestock presented for slaughter and are checking them against the restricted animal lists. Pen cards or kill sheets are used to record animal identification information and to document when ante-mortem inspection has been performed. The FSIS auditors reviewed pen cards and verified they contained the required animal identification information and were stamped by VS to indicate they had passed ante-mortem inspection.

Through interviews, the FSIS auditors verified that slaughter establishments may operate under either an alternative post-mortem inspection system (APMIS) which utilizes establishment employees to perform dispositions on non-food safety related carcass and viscera conditions or the traditional government only post-mortem inspection program. APMIS establishments utilize an AQNZ roving inspector to supervise and assess the performance of establishment post-mortem inspectors, detain rail activity personnel, and OA. In traditional slaughter establishments, post-mortem inspection is performed by OA under the supervision of an AQNZ Statistical Process Control System checker. The FSIS auditors verified that the MPI requires a government inspector to inspect every carcass prior to the detain rail for food safety-related conditions.

Technical reviews of each establishment eligible to export to the United States are performed to ensure the New Zealand standards and the FSIS requirements are met and the standards and specifications are interpreted and applied consistently. The technical review includes evaluation of the establishment's processes and assessment of the TS. The frequency of the technical reviews is based on performance; however, they are performed at a minimum frequency of once every three months. Technical reviews are tracked and documented in the VOL system. The FSIS auditors reviewed the frequency of technical reviews at the three establishments included in

the audit and verified they were conducted every three months. The technical reviews are conducted by TS that have been authorized as technical reviewers. Team managers assess TS to determine if they are competent to perform technical reviews and then make recommendations to the Agency Technical Manager (ATM) for the TS to become authorized as technical reviewers. The ATM will issue a Technical Review Letter of Authorization and Certificate of Competency for the newly authorized TS. The FSIS auditors reviewed an example Technical Review Letter of Authorization and Certificate of Competency for a newly authorized technical reviewer. The FSIS auditors reviewed technical review reports from each of the three establishments included in this audit and did not identify any concerns.

One of the elements in the current audit scope was to verify the implementation of MPI's corrective actions in response to the 2018 FSIS audit finding related to MPI 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. In response to this finding, MPI amended their specifications to further emphasize their risk-based focus and establishment visits would be targeted to those times during the day when the critical hygiene activities posing the greatest risk to public health are occurring. Over the period of a month, all substantive processing activities occurring at any time of the day are required to be viewed. Additionally, pre-operative sanitation standard operating procedures (Sanitation SOPs) at processing establishments were increased to once per month from once per year and they introduced a required monthly critical review of key metrics applicable to the establishment. The TTS are required to document their daily market access visits in processing establishments when they are producing products for export to the United States including the time of the visit. The FSIS auditors reviewed documentation of the daily market access visit, monthly pre-operational Sanitation SOP verification, and monthly critical record review in the VOL system for processing establishments and verified they are being performed at the required frequency. The FSIS auditors confirmed through interviews and record review that these corrective actions were implemented.

MPI requires establishments to have documented procedures to segregate products that are ineligible for export to the United States (referred to as restricted market meat by MPI) from products that are eligible for export to the United States. TS verify the segregation program for United States eligible products through an annual task called US: Inventory Control including Retained Product. Additional verification occurs during load out checks, monthly critical record reviews, and daily walk-through visits. The FSIS auditors reviewed the documented tasks in the VOL system and verified they were being performed at the required frequency. The FSIS auditors reviewed noncompliances and corrective actions related to restricted market meat and did not have any concerns.

Materials condemned during post-mortem inspection are required to be held under the control of OA until they have been denatured. TS verify the condemned materials in establishments eligible to export to the United States are controlled through a weekly task called United States: Weekly Condemned Material Inspection. The FSIS auditors reviewed the documented condemned materials verification tasks in the VOL system and verified they were being performed at the required frequency. The FSIS auditors reviewed noncompliances and corrective actions related to condemned materials and did not have any concerns.

TS verify export market labeling requirements on an annual basis. This task includes verifying all relevant United States requirements for each type of product. Additional verification occurs during load out checks, monthly critical record reviews, and daily walk-through visits. The FSIS auditors reviewed labeling noncompliances including corrective actions and did not have any concerns. The FSIS auditors reviewed the documented labeling verification tasks in the VOL system and verified they were being performed at the required frequency.

The species verification program aims to demonstrate truth in labeling and detect species substitution in exported meat products. The program applies to fresh and frozen boneless meat products. At least 300 randomly selected samples are tested each year. ESR performs species testing for establishments eligible to export to the United States. The results from the 2019/2020 species testing revealed no species substitution. The FSIS auditors reviewed sample documentation related to species testing for the establishments included in the audit. No concerns were identified as part of this review.

The FSIS auditors verified that New Zealand's meat inspection system continues to maintain the legal authority, a regulatory framework, and adequate verification procedures to ensure sufficient official regulatory control using statutory authority consistent with criteria established for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component the FSIS auditors reviewed was Government Sanitation. The FSIS auditor verified that MPI requires each official establishment to develop, implement, and maintain written Sanitation SOPs to prevent direct product contamination or insanitary conditions, and to maintain requirements for sanitation performance standards and sanitary dressing.

The Animal Products Notice, 18/17 Animal Product from RMP Operations: Specified Markets, requires that during dehiding and evisceration, carcasses be kept separated until after they have passed post-mortem inspection to prevent cross-contamination. That notice has requirements related to sanitary dressing including preventing urine and milk spillage, preventing the bung from touching the external surfaces of adult cattle carcasses and bagging the bung, and the carcass splitting saw must be cleaned after each carcass and sanitized when contaminated. The VTS conducts an annual audit of hygienic dressing for each species. The VTS performs hands-on verification of sanitary dressing during their daily market access visits. The FSIS auditors reviewed documentation in the VOL system of the annual sanitary dressing task for the establishments included in the audit and confirmed they were being conducted at the required frequency.

Establishments perform 100% inspection of carcasses for contamination with milk, feces or ingesta at the zero fecal tolerance (ZFT) inspection point which is located at or close to the post-mortem inspection point. The Red Meat Code of Practice 5 (COP5) requires establishments to use statistical process control (SPC) to monitor the level of fecal and ingesta contamination for each run. The results from each run are compared against the species-specific establishment

mean as well as the species-specific national performance level. Breaches of the national performance level require notification to MPI with escalating actions. The monthly critical records review includes review of hygienic dressing contamination rates. The FSIS auditors reviewed documentation of COP5 SPC monitoring as part of the VTS monthly critical records review. The FSIS auditors also reviewed nonconformance records and corrective actions associated with establishments' breaches of upper control limits for fecal and ingesta contamination. There were no concerns regarding this review.

The TS conduct an annual audit of establishments to verify their sanitation programs related to construction, facilities, and equipment are adequate to prevent the contamination or adulteration of products designated for export to the United States. Additionally, the TS observe the condition of the establishments during their daily market access visit. During the monthly critical record review, the TS review the potable water test results. The FSIS auditors reviewed documentation in the VOL system of the annual audit of sanitation programs and monthly review of potable water test results performed at the establishments included in the audit and verified they were being conducted at the required frequency. A review of noncompliance records indicate that TS are identifying, and documenting sanitation program deficiencies identified during operation. No concerns were identified relating to this review.

MPI requires establishments eligible to export to the United States to develop, implement, and maintain written Sanitation SOPs. Areas of verification include hygiene of facilities and equipment, operator hygiene, dropped meat program, food contact materials, chemicals, damaged product, and waste disposal. TS perform an audit of the Sanitation SOP program once a year with a focus on requirements for export to the United States. TS perform hands-on verification of pre-operational Sanitation SOPs once a month. VTS verify operational Sanitation SOPs during their daily market access verification visit to the slaughter floor in establishments eligible to export to the United States. Additionally, TS perform a monthly critical record review task which includes review of Sanitation SOP records. The FSIS auditors verified through document review that the establishments included in the audit were conducting pre-operational Sanitation SOP verification once a month and were conducting audits of the Sanitation SOP programs annually. The FSIS auditors verified through records review that TS are identifying and documenting Sanitation SOP deficiencies before and during operations. No concerns were identified relating to this review.

The FSIS auditors concluded the MPI's meat inspection system continues to maintain sanitary regulatory requirements that meet the core requirements for this component.

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

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

The TS perform annual audits of the HACCP system which includes the review of the seven Codex principles of HACCP, New Zealand HACCP requirements, and MPI's requirements for

export to the United States. The FSIS auditors verified the annual audit of the HACCP systems at the establishments included in the audit occurred at the required frequency as documented in the VOL system. Initial validation must include both scientific support and onsite validation to verify the operational parameters identified from the scientific support can consistently be met under real life processing conditions. The onsite validation data must be completed over an initial 90-day period. Establishments that slaughter and process bobby calves are required to consider the STEC as a hazard that is reasonably likely to occur and develop a control measure for the hazard.

One of the elements in the current audit scope was to verify the implementation of MPI's corrective actions in response to the 2018 FSIS audit finding related to adult beef slaughter establishments failing to conclude that STEC was a hazard that was reasonably likely to occur after verification samples were confirmed positive for STEC. In response to this finding, MPI began requiring the HACCP coordinator in establishments that slaughter and process cattle older than bobby calves to conduct a reassessment to determine if STEC hazards can continue to be considered as not reasonably likely to occur after STEC is confirmed through product testing. The adequacy of this review is required to be formally assessed and approved by an ATM, with MPI tracking and critically reviewing any trends at the central level. If the HACCP reassessment identifies good hygienic practices deficiencies that can be corrected, then the establishment can make the determination that hazards related to STEC are not reasonably likely to occur. A TS would then complete an external risk evaluation of the establishment's microbiological and compliance performance data, including review of the HACCP reassessment, to determine if they can support the hazard as being reasonably unlikely to occur. An ATM will initiate an onsite food safety assessment (FSA) if the risk evaluation identifies serious performance deficiencies and the operator's response is inadequate. An ATM will initiate an FSA if an establishment has two confirmed detections of STEC within a 12-month period without the HACCP coordinator determining that STEC is reasonably likely to occur. If the HACCP reassessment does not identify deficiencies within the prerequisite programs covering good hygienic practices, yet the unforeseen hazard has occurred, this indicates that the HACCP system is inadequate. In this case, the HACCP plan will need to be modified to incorporate a control measure for the hazards related to STEC. There was a confirmed positive for *E. coli* O157:H7 in adult cattle at one of the establishments included in the audit. The FSIS auditors verified the establishment conducted a HACCP reassessment and identified actual and potential deficiencies related to hygienic dressing. The establishment concluded that corrective actions relating to the hygienic dressing will prevent conditions that make hazards relating to STEC as being reasonably likely to occur. The FSIS auditors verified that MPI performed a risk evaluation to assess the adequacy of the establishment's HACCP reassessment and determined that no additional actions needed to be taken.

The TS review HACCP monitoring, verification, and corrective action records when performing the monthly critical record review task. The FSIS auditors verified through documentation in the VOL system that the TS at the establishments included in the audit are performing this task at the required frequency. The TS perform oversight of edible areas as part of their daily market access visits. The TS do not perform hands-on verification of critical control points (CCP), but if the establishment is conducting monitoring or verification activities during their daily market access visit, the TS will observe these activities. Daily market access visits at slaughter establishments

with acceptable outcomes are not documented. The FSIS auditors reviewed examples of HACCP noncompliance and determined the TS are identifying and documenting deficiencies related to HACCP monitoring, verification, and corrective actions.

One additional element in the current audit scope was to verify the implementation of MPI's corrective actions in response to the 2018 FSIS audit finding related to slaughter establishments failing 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. In response to this finding, MPI specified that establishments that perform 100% CCP monitoring for zero tolerance 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 FSIS auditors were able to review summary records and determine they contained information regarding the monitoring period, the name of the person who performed the monitoring, and deviations. Due to scope limitations of this remote audit, the FSIS auditors were unable to verify if all HACCP requirements for corrective actions were taken for each deviation.

The CCP for zero tolerance for contamination with milk, feces, and ingesta is divided into three parts. The first part of the CCP is the inspection point for ZFT located at or close to the post-mortem inspection point. Carcasses that are identified as not meeting ZFT are diverted for trimming and clearance, which is considered the second part of the CCP. The third part of the CCP is monitoring of the effectiveness of parts one and two of the CCP. The VTS do not perform hands-on verification of ZFT, but they do observe the establishment performing monitoring of ZFT if it is being conducted during their daily market access visit. The VTS review CCP records relating to ZFT during their monthly critical record review.

The establishment performs pre-shipment verification on every consignment eligible for export to the United States. It includes reviewing CCP records of monitoring, CCP records of verification of monitoring, CCP records of corrective actions in response to deviations, and review of STEC results. Pre-shipment verification by TS is performed every three months. The TS verify microbiological results, ZFT results, CCP records, the establishment's pre-shipment verification, and control of product ineligible for export to the United States. The FSIS auditors reviewed examples of documented pre-shipment noncompliance and corrective actions and did not have any concerns. The auditors verified that TS are performing pre-shipment reviews at the required frequency according to documentation in the VOL system.

The FSIS auditors determined that MPI requires each certified establishment to develop, implement, and maintain HACCP systems. The FSIS auditors concluded that MPI's food safety inspection system continues to meet the core requirements for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth equivalence component the FSIS auditors reviewed was Government Chemical Residue Testing Programs. The food safety 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, or muscle of carcasses for chemical residues identified by the exporting country's meat products inspection authorities or by FSIS as potential contaminants.

The National Chemical Residues Program (NCRP) is established under the Animal Products Act 1999 for official monitoring, surveillance, and surveys of animal material and products for chemical residue and contaminants. Prior to the onsite visit, FSIS' residue experts reviewed the NCRP for July 1, 2020–June 30, 2021, associated methods of analysis, and additional SRT responses outlining the structure of New Zealand's chemical residue testing program.

Each year, MPI issues the Animal Products Notice, Contaminant Specifications, which provides New Zealand's maximum permissible levels (MPL) for agricultural compound residues and contaminants in animal material and animal product and provides a list of contaminants for which no MPL applies. MPI then applies more restrictive tolerance levels to determine export market eligibility. Each year, MPI issues the Animal Products Notice, Contaminant Monitoring and Surveillance, to provide the scope of random sampling. The sampling regime contains information on the substances, number of samples to be collected, and animal class. The NCRP is divided into two parts: monitoring and surveillance. Monitoring takes samples from randomly selected live and slaughtered animals. Surveillance takes targeted samples from live and slaughtered animals where a risk has been found. Additionally, MPI requires suppliers of animals for slaughter to sign legal statements attesting that the supplied animals are not within any holding period for any veterinary medicines.

The FSIS auditors reviewed the criteria used to select compounds for inclusion in the NCRP. 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.

The CMA team manages the government chemical residue program. The CMA is a part of the Assurance Directorate within the NZFS branch. NCRP operational implementation is coordinated by MPI VS residue program coordinators (RPC). The TS manage the program at the establishment level verifying compliance with the requirements of the NCRP. Sample collectors are either TS or an AQNZ-nominated person. Sampling plans are developed and issued confidentially to samplers through the VOL system. Sampling plans outline sampling requirements for species, animal class, animal material or animal product, and assay test number. Samplers enter the sample information into the password-protected E-star database. The E-star database generates unique sample numbers when sample records are created. The E-star database electronically transfers sample details to the laboratory's information management system. Laboratories do not have access to information about the supplier of the sampled animal for confidentiality.

MPI requires laboratories to complete confirmatory testing on all samples where an initial test result indicates a residue above an action level. The confirmatory testing includes complete retesting in duplicate on the original blended portion and the retained unblended portion. The average of the five results are reported to MPI and uploaded to the E-star database. Samplers do not have access to the sample result section of E-star. The E-star database emails reports of all non-zero test results to the CMA Specialist Advisor (SA). The SA interprets the results against regulatory levels and advises RPC of any non-conforming results that need to be followed-up on. The RPC investigates the cause of the non-conforming result. After a non-conforming result, the supplier of at-risk animals is entered into a surveillance list and the supplier is given directions in relation to at-risk animals. The surveillance list is provided to all processing premises to allow for identification of at-risk animals prior to slaughter. Targeted sampling of at-risk animals and product retention are measures taken to prevent violative product from entering the food chain. The FSIS auditors reviewed surveillance list notices, investigation reports, and targeted sampling results and determined that MPI is following their procedures related to targeted sampling of at-risk animals.

MPI's random monitoring program is designed to monitor the effectiveness of wider controls and is not used for individual animal disposition judgements. For this reason, unlike samples that are collected through the targeted sampling program, samples collected through random sampling are not held pending acceptable results, and the results are not verified against United States tolerances before determining eligibility for export of the product to the United States. The FSIS auditors identified the following finding:

- MPI does not ensure that any livestock carcass or parts subjected to routine chemical residue testing are not certified for export to the United States until receipt and confirmation of acceptable testing results, including review of results against United States tolerances when different from New Zealand tolerances.

Through interviews and document review, the FSIS auditors confirmed that MPI has legal provisions that provide for risk source mitigations, such as livestock movement control and prosecution of the violator. The FSIS auditors reviewed the summary of results for testing carried out in 2019-2020 which exceeded 99% compliance. The FSIS auditors confirmed that the sampling and testing for the 2021-2022 NCRP plan is on schedule.

The FSIS auditors concluded that MPI continues to maintain a chemical residue testing program, organized and administered by the national government, that meets the core requirements for this component, except that MPI does not require that livestock carcasses and parts subjected to routine chemical residue testing be precluded from export to the United States until receipt of acceptable results.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth equivalence component the FSIS auditors reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and

testing programs to ensure that meat prepared for export to the United States is safe and wholesome. This component also addresses requirements for TPCS meat products.

MPI implements the National Microbiological Database (NMD) program, a standardized microbiological sampling and testing program for monitoring process control in slaughter establishments. The NMD program 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. Sampling plans must include a randomly selected time each week to sample all product types for each species. The NMD program includes analytical procedures to detect *Salmonella* and quantify generic *E. coli* and Aerobic Plate Count (APC) for bovine and caprine carcasses and raw meat products and APC for ovine carcasses. The NMD program includes microbiological results for individual establishments and provides tools for trend analysis and comparison to national performance.

Establishment operators are responsible for sample collection and submission to a recognized laboratory. Establishment operators must utilize approved samplers that are trained by certified trainers for the species and product type sampling being performed. Sample takers must be reviewed annually by a recognized laboratory. MPI maintains lists of certified trainers and approved samplers on its website. TS supervise NMD sample collection, packaging, and reporting every six months. The FSIS auditors verified through documentation in the VOL system that TS performed the NMD supervisory task at the required frequency at the establishments included in the audit. The FSIS auditors reviewed a documented noncompliance report related to insufficient NMD sampling location within the premises that was identified during the NMD supervisory task and did not identify any concerns. NMD sample results are reported to the E-star database, which can be accessed by MPI, VS, and establishment operators. Operators must review NMD results weekly. MPI sets maximum allowable regulatory limits, M-limits, for APC and generic *E. coli* by species. If two or more samples within a processing week exceed the M-limit or if three or more samples in a five-week window exceed the M-limit an alert, M-alert, is generated. The FSIS auditors reviewed the APC and generic *E. coli* results at the establishments included in the audit. There was one M-alert issued for exceeding M-limits for APCs in adult beef, and the TS generated a noncompliance report.

The TS review NMD results during the monthly critical records review task. The FSIS auditors verified through documentation in the VOL system that the critical records reviews were being conducted at the required frequency at the establishments included in the audit. The FSIS auditors verified the critical records reviews included verification that NMD sampling was conducted at the required frequency, NMD results were reviewed, and corrective actions were taken in response to M-alerts.

The *Salmonella* Performance Standard sampling program is implemented during slaughter operations, which is seasonal for different livestock. Bovine and caprine slaughter and processing establishments must collect weekly composite samples for each product type until achieving a minimum of six acceptable composite results for each product type. Bovine and caprine establishments that export to the United States must collect weekly samples from 5 carcasses within 24 hours of the onset of chilling until achieving a minimum of acceptable results for 30 carcasses. For every *Salmonella* positive result, the establishment operator must

investigate and implement corrective and preventive actions. In addition, each positive *Salmonella* result resets the sampling window. The FSIS auditors reviewed the *Salmonella* results for adult cattle from 2022 and bobby calves from 2021 for the establishments included in the audit and verified samples were conducted at the required frequency. There were no *Salmonella* positive results reported.

MPI requires establishments eligible to export to the United States to implement one of the *Listeria* alternatives listed in New Zealand's United States OMAR for post-lethality exposed (PLE) RTE products. These alternatives are consistent with the definitions in 9 CFR 430.4. However, MPI does not implement sampling verification activities, either by official government inspectors or through required establishment testing, to ensure control of *Lm* on all PLE RTE products, including those that receive a post-lethality treatment or that receive an antimicrobial agent or process or for *Listeria* species in the environment, including both food contact surfaces and non-food contact surfaces, of establishments producing PLE RTE products that are eligible to export to the United States. Results from establishment *Listeria* testing are provided directly to the establishment operators by the laboratory and are routinely reviewed by TS.

Additionally, MPI does not implement official government verification sampling or requirements for establishment sampling verification activities for *Salmonella* in PLE and non-PLE RTE products or for *Lm* on non-PLE RTE products. The FSIS auditors did confirm that the two establishments currently exporting PLE RTE products to the United States have opted to conduct testing for *Salmonella* through their own written microbiological sampling control programs. The FSIS auditors identified the following finding related to RTE microbiological sampling:

- MPI does not implement adequate official government sampling verification activities to ensure control of *Listeria monocytogenes* and *Salmonella* in all types of ready-to-eat products and to ensure control of *Listeria* species in the environment, including food contact surfaces, of all establishments that produce post-lethality exposed ready-to-eat products intended for export to the United States.

New Zealand's United States OMAR stipulates a zero tolerance policy for STEC in raw bovine products intended for grinding or other non-intact product exported to the United States. MPI requires that beef and veal establishments eligible to export to the United States perform sampling and testing for the top seven STEC serotypes as defined in New Zealand's United States OMAR. Establishments eligible to export to the United States must perform daily N60 sampling of bulk manufacturing beef from each lot. Establishments must use a recognized laboratory that has an approved analytical method for STEC testing in their scope of accreditation. TS conduct 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. STEC test results for bobby calves are reported by the laboratory directly to MPI and MPI verifies the results before uploading them to the E-star database. For adult beef, STEC results are loaded directly into the E-star database by the laboratory and MPI reviews the results within the E-star database. The FSIS auditors verified through interviews and document reviews that the establishments included in the audit implement STEC sampling

programs consistent with MPI requirements. The FSIS auditors also reviewed laboratory results and corrective actions documented by MPI in response to positive STEC results.

The Animal Products Notice, Specifications for Products Intended for Human Consumption requires compliance with either the Codex Code of Hygienic Practice for Canned Foods or the United States Food and Drug Administration requirements for thermally processed low-acid foods. TTS in TPCS establishments are required to verify one canning topic during every performance-based verification audit. The canning topics include canning competencies, container and container closure evaluations, incubation and product release, product development and validation, product formulation and preparation, retort operations, thermal processing and post processing handling, and water chlorination or sanitation. All canning topics are required to be covered over the period of a year. The FSIS auditors reviewed documentation of canning tasks in the VOL system for one TPCS establishment and confirmed that all canning topics were covered over a 12-month period.

The FSIS auditors concluded that, except for the finding related to official government microbiological verification sampling for RTE products, MPI organizes and administers official government microbiological testing programs to verify that meat products destined for export to the United States are unadulterated, safe, and wholesome in accordance with United States requirements.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held April 13, 2022, by videoconference with representatives from 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 Chemical Residue Testing Programs

- MPI does not ensure that any livestock carcass or parts subjected to routine chemical residue testing are not certified for export to the United States until receipt and confirmation of acceptable testing results, including review of results against United States tolerances when different from New Zealand tolerances.

Government Microbiological Testing Programs

- MPI does not implement adequate official government sampling verification activities to ensure control of *Listeria monocytogenes* and *Salmonella* in all types of ready-to-eat products and to ensure control of *Listeria* species in the environment, including food contact surfaces, of all establishments that produce post-lethality exposed ready-to-eat products intended for export to the United States.

FSIS will evaluate the adequacy of MPI's proposed corrective actions and determine whether those corrective actions satisfy FSIS' equivalence requirements.

Appendix: Foreign Country Response to the Draft Final Audit Report

24 August 2023

Dr Michelle Catlin
International Coordination Executive
Office of International Coordination
Food Safety Inspection Service
United Stated Department of Agriculture
UNITED STATES OF AMERICA

Dear Dr Catlin,

MPI Comments on the Draft Final Report of the Remote Audit Conducted of New Zealand, 1 March to 13 April 2022

Thank you for sending the draft final audit report of the FSIS remote audit of the New Zealand meat regulatory system. I would like to thank [redacted] and [redacted] for their well organised and cooperative approach to the remote audit. There were two findings in the audit for which I will respond in detail. There are some other details in the audit report on which I will comment first.

In section III Background, the report includes the recent DDT metabolites detection as a residue violation leading to rejection of the corresponding meat consignment. As we have previously highlighted in communications, the level found was less than 1% of the relevant international standard and much lower than levels the US allows for in a wide variety of other foods and animal feeds. New Zealand was one of the first countries in the world to ban the use of DDT on grazing land over 50 years ago. Low level incidental findings such as this are not associated with any form of non-compliance by any party and do not constitute a health risk. As such MPI would appreciate if this was removed or restated in a more appropriate context reflecting our previous discussions on this incidental finding.

On page 20, in the description of the NMD system the report states: "The NMD program includes analytical procedures to detect and quantify Salmonella, generic E. coli, and Aerobic Plate Count (APC)…" we suggest this phrasing should be more accurately re-worded as while the rest are quantitative, the salmonella testing is qualitative.

Also on page 20 further down, there is mention of carcass sampling within the NMD programme. This is somewhat juxtaposed with mention of the salmonella component of the NMD programme, which is only carried out on boned out meat. This juxtaposition may convey the impression that carcasses are sampled for salmonella testing. Carcasses are only sampled for APC and generic *E. coli*. FSIS may wish to amend this paragraph to ensure there is no mis-conception of what the carcass sampling covers.

On Page 21, in the description of the STEC programme the report states: "Results from confirmation testing are reported directly to MPI. MPI verifies and accepts the results before uploading them to the E-star database." The second sentence only applies to the bobby calf STEC testing programme. For adult beef where the detection of STEC is a relatively rare event the results are loaded directly into E-star by the laboratory and MPI reviews any aberrant results directly from here.

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MPI response to the substantive findings of the draft audit report:

Government Microbiological Testing Programs

- *MPI does not implement adequate official government sampling verification activities to ensure control of Listeria monocytogenes and Salmonella in all types of ready-to-eat products and to ensure control of Listeria species in the environment, including food contact surfaces, of all establishments that produce post-lethality exposed ready-to-eat products intended for export to the United States.*

While MPI acknowledges and thanks FSIS for the further correspondence on this matter subsequent to the audit, MPI does not agree that the application of additional "official government sampling verification" for salmonella and *Listeria monocytogenes* as advised by FSIS are necessary in the New Zealand context. Our inspectors already verify MPI approved and validated industry controls and appropriate testing at each site. However, we do understand the different context that exists within the US for such programmes and as such in this case MPI will agree to implement an additional programme of testing consistent with recent FSIS correspondence with a view to revisiting elements of the programme once sufficient testing data is generated. The testing requirement has been implemented and the relevant section of the United States OMAR is attached.

Government Chemical Residue Testing Programs

- *The Ministry for Primary Industries (MPI), the Central Competent Authority of New Zealand, does not ensure that any livestock carcass or parts subjected to routine chemical residue testing are not certified for export to the United States until receipt and confirmation of acceptable testing results, including review of results against United States tolerances when different from New Zealand tolerances.*

As per New Zealand's 2020 and 2022 answers, in response to the additional information requested regarding test and hold of randomly selected routine samples from non-suspect animals New Zealand believes its existing responses provided an appropriate risk-based rationale, consistent with the relevant international standard, and thus should be sufficient.

While targeted (for cause) sampling is used as part of post-mortem inspection and market eligibility judgements, the national survey which is based on non-biased sampling is not. The statistical design of the national survey is such that there is no scientifically valid risk-based rational for differentially treating a randomly selected animal from the general population from the millions of other animals in that general population that also by pure chance happen to not be selected. While non-compliant results from randomly sampled animals are relatively rare events, where they are found they are statistical representation of a sub-population of animals in the wider population that may be similarly affected. Accordingly, unless there is a direct and acute risk to consumers identified, New Zealand's corrective actions focus on identifying which part of the control system may have been at fault and ensuring appropriate controls are put in place to prevent recurrences. However, as is the case with all substantive food safety risks, wherever New Zealand identifies any result that indicates a real and direct risk to human health, appropriate efforts are made to recall any affected product.

MPI further notes that the New Zealand legislated controls are consistent with the relevant international standard CAC/GL 71-2009. This standard emphasises that the role of National non-biased (random) residue verification sampling is to monitor whether aspects of the control system as a whole are operating at an appropriate level to protect human health (assurances at the population level). It also notes that randomly

taken samples are not intended for product disposition judgements. Where appropriate this is the role for targeted sampling programmes. To this effect the standard (CAC/GL 71-2009) specifically says:

"10.2 Retention of consignments during laboratory analysis
Competent authorities should not routinely retain lots of production associated with randomly selected samples pending the availability of the analytical results. Competent Authorities may routinely retain lots of production where it is considered likely that a risk targeted test will produce non-compliant results that present a potential risk for consumer health".

As such the CAC/GL 71-2009 emphasises that from a risk mitigation point of view, that regulatory reactions to any non-compliant random monitoring sample should focus on analysing which control (drug registration, use labelling, use practice or communication of animal status between purchasers) is not delivering and where appropriate adjust this. The standard further goes on to state: *"Respective action should be proportionate in time and intensity to the consumer health hazard, scale and frequency of the noncompliance."* Recalls are only indicated where analysis of the likely associated risks constitute a direct (i.e. quantifiable) risk to human health.

Lastly New Zealand notes that it has previously directly commented to FSIS when it was formulating its internal policy of withholding the product from randomly selected animals within the United States until a compliant result is returned. The formal reply from the FSIS in response to comments supplied by foreign governments [Federal Register Volume 77, Issue 237 (December 10, 2012)] stated: "*Foreign establishments and inspection services will not be directly affected by this policy."*

It is also noted that in the summary and conclusions section of the Federal Register Notice it states: *"After consideration of all comments and for the reasons discussed above, FSIS will implement a new policy that requires official establishments and importers of record to maintain control of product tested for adulterants by FSIS and not allow such products to enter commerce until negative test results are received."* Official establishments in this context means establishments where FSIS inspection is maintained and excludes foreign establishments.

In summary, New Zealand's results over many years provide good evidence of the appropriateness and effectiveness of New Zealand's control system which is based on and exceeds the relevant international standard (as recognised by the WTO/SPS Agreement). Based on this well-established performance, we do not feel there is any risk-based rational for retaining those carcasses, or product subsequently derived from them, that were randomly selected as part of the non-biased survey component of our residue monitoring programme.

New Zealand would be happy to discuss further if the FSIS has an appropriate risk assessment justifying the necessity (from a human health point of view) of its internal policy being extended to New Zealand.

Yours sincerely,

Tony Zohrab
Chief Market Access Officer
Policy and Trade
Ministry for Primary Industries

Cc: **Bill Jolly – Chief Assurance Strategy Officer**