United States Department of Agriculture

Food Safety and
Inspection Service

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

February 1, 2019

Dr. Hideshi MICHINO
Director
Food Safety and Inspection Division
Department of Food Safety, Pharmaceutical and Food Safety
Bureau, Ministry of Health, Labor and Welfare Department
1-2-2 Kasumigaseki, Chiyoda-ku
Tokyo 100-8916, Japan

Dear Dr. MICHINO,

The FSIS on-site audit conducted from July 27 through August 10, 2018, supports that Japan's meat inspection system governing raw beef products continues to remain equivalent to that of the United States. Enclosed is a copy of the final audit report. The comments received from the Government of Japan are included as an attachment to the report.

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

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN JAPAN

JULY 27 TO AUGUST 10, 2018

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

RAW BEEF PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

January 29, 2019

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from July 27 to August 10, 2018. The purpose of the audit was to determine whether Japan's food safety inspection system governing raw beef products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Japan currently exports raw intact beef 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 Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

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

Government Oversight (e.g., Organization and Administration)

- The Central Competent Authority (CCA) allows inspection personnel to issue an export certificate for product intended for export to the United States before test results are known from the CCA's routine chemical residue program.

Government Microbiological Testing Programs

- The CCA has not fully implemented their government Shiga toxin-producing *Escherichia coli* (STEC) verification program to ensure that raw beef products are free of STEC at the end of the production process. The CCA has also not yet implemented sampling and testing of beef trimmings for STEC because an appropriate method for detection of STEC has not been adopted by the laboratories.

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

TABLE OF CONTENTS

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Japan's raw beef food safety system from July 27 to August 10, 2018. The audit began with an entrance meeting held on July 27, 2018, in Tokyo, Japan, during which the FSIS auditor discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – Ministry of Health, Labor, and Welfare (MHLW).

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether the food safety system governing raw beef products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Japan as free of foot and mouth disease, and negligible risk for Bovine Spongiform Encephalopathy (BSE). Japan is currently eligible to export raw intact beef products to the United States.

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 CCA through the self-reporting tool (SRT).

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

Administrative functions were reviewed at CCA headquarters, one regional office, and six local inspection offices. The FSIS auditor evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of six establishments was selected from ten establishments certified to export to the United States. This included six slaughter and processing establishments. The products these establishments produce and export to the United States include raw intact beef. During the establishment visits, the FSIS auditor paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety and public health. The FSIS auditor assessed the CCA's ability 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.

Additionally, one chemical residue laboratory was audited to verify its ability to provide adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• Ministry of Health, Labor and Welfare, Tokyo
	Regional	1	• Kyushu Bureau of Health and Welfare, Fukuoka
Laboratory		1	• Japan Food Research Laboratories Tama (private)(residue), Tama
Beef slaughter and processing establishments		6	• Establishment #K-1, Nanchiku Co., Ltd., Sueyoshi-cho, Soo • Establishment #K-3, Akune Meat Distribution Center Co., Ltd., Shiohama-cho, Akune • Establishment #K-4, JA Shokuniku Kagoshima Co., Ltd. Nansatu Plant, Chiran-cho, Minamikyushu • Establishment #KU-2, Kumamoto Chikusan Ryutsu Center Co. Ltd., Shichijyo-machi, Kikuchi • Establishment #M-1, Miyachiku Corp. Ltd, Takasaki Plant, Takasaki-cho, Miyakonojo • Establishment #M-2, Miyachiku Corp. Ltd, Tsuno Plant, Tsuno-cho, Koyu-gun

FSIS performed the audit to verify the food safety inspection system met 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.] 601 *et seq.*);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901-1906); and
- The Meat Inspection Regulations (9 CFR Parts 301 to the end).

The audit standards applied during the review of Japan's inspection system for raw beef products included: (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the World Trade Organization's *Agreement on the Application of Sanitary and Phytosanitary Measures*.

III. BACKGROUND

From June 1, 2015 to May 31, 2018, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 2,014,701 pounds of raw intact beef products and 152 pounds of raw intact veal exported by Japan to the United States. Of these amounts, additional types of

inspection were performed on 156,109 pounds of meat, including testing for chemical residues and microbiological pathogens (Shiga toxin-producing *Escherichia coli* (*E. coli*) [STEC] O157:H7, O26, O45, O103, O111, 0121, and O145). No products were rejected for issues related to public health.

Prior to the on-site equivalence verification audit, FSIS reviewed and analyzed Japan's SRT responses and supporting documentation. During the on-site audit, the FSIS auditor conducted interviews, reviewed records, and observed procedures to determine whether Japan's food safety inspection system governing raw beef products is being implemented as documented in the country's SRT responses and supporting documentation. The FSIS final audit reports for Japan's food safety inspection system are available on the FSIS website at: http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports.

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

The first of six equivalence components that the FSIS auditor 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 auditor verified that the inspection system is organized and administrated by the national government of Japan. There have been no major changes in the CCA's organizational structure since the last audit. Japan's administration of food safety is divided between national and local government levels. At the national level, the MHLW is Japan's CCA. MHLW has one central and seven regional offices. At the central level, the Inspection and Safety Division (ISD) of the Department of Environmental Health and Food Safety of MHLW prepares the national residue plan and designates the private laboratories for residue analysis. In addition, MHLW issues all directives and guidelines concerning meat export to other countries, certifies or decertifies slaughter establishments for export, and is responsible for the translation, distribution, and implementation of all the United States requirements in certified establishments.

Of MHLW's seven Regional Bureau of Health and Welfare (RBHW) offices throughout Japan, only four of them (Kanto, Kyusyu, Tohoku, and Tokai) have certified establishments within their jurisdictions. The Food Sanitation Division (FSD) of these regional offices is responsible for conducting supervisory reviews of the certified establishments and recommending the approval and withdrawal of establishments.

At the local government level, inspection oversight is managed through Public Health Centers also described as Meat Inspection Centers (MICs). The MICs have meat inspectors that implement and enforce inspection laws daily at the certified slaughter establishments. The FSIS auditor verified that there is a specific and sufficient number of meat inspectors assigned to each

of the certified establishments to carry out inspection activities. These meat inspectors complete specific training in food safety controls and meat inspection techniques provided by MHLW, RBHW, and local governments.

MHLW administers the Japanese food safety inspection system and is responsible for directing, planning, and carrying out food safety and animal health and welfare controls. MHLW oversees the functions of the inspection system by designing and implementing inspection-related procedures in accordance with national standards, in addition to those standards imposed by importing countries. MHLW's authority to enforce inspection laws is outlined in the *Abattoir Law (Law No. 114), Abattoir Law Enforcement Regulation (Ordinance No. 44),* and *Ordinance for Enforcement of the Food Sanitation Act (Ordinance No. 23).*

Japan has issued national legislation to address the implementation of the inspection activities. These laws delineate responsibilities for each of the inspection levels, as well as enforcement of the *Food Sanitation Act*. In addition, a supplemental document entitled *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States* is implemented and enforced at establishments certified to export beef to the United States. MHLW has the legal authority and responsibility to enforce regulatory requirements equivalent to those governing the system of meat inspection organized and maintained in the United States.

MHLW issues guidelines and instructions that define the frequency of supervisory reviews and the procedures for registration, approval, conditional approval, or suspension. MHLW also provides instructions on the withdrawal of approval of regulated establishments; the verification of the microbiological sampling program; how to perform official inspection tasks; and the development of the residue monitoring plan and the method for carrying out the Japanese Residue Control Program.

The FSIS auditor performed on-site observations and reviewed records maintained by inspection personnel at headquarters, RBHW, and inspection offices within establishments certified to export to the United States. The FSIS audit of the MHLW headquarters included an examination of its oversight activities, including the verification of government supervisory review audits of establishments conducted by FSD and MHLW's verification of actions taken in response to FSIS' 2015 audit findings. In addition, FSIS examined enforcement activities, verification activity reports, and training records for official personnel by interviewing departmental personnel and reviewing documentation.

The FSIS auditor's review of MHLW's verification of actions taken in response to FSIS' 2015 audit findings identified that all actions taken by MHLW were adequately addressed with the exception of one finding.

- The CCA allows inspection personnel to issue an export certificate for product intended for export to the United States before test results are known from the CCA's routine chemical residue program.

MHLW's routine chemical residue testing program does not require the selected carcass (lots) and product to be held or controlled until sample results are received and found negative. This allows for the possibility that product that may have a violative result ends up exported to the

United States. However, product is held and precluded from export during any subsequent follow-up sampling that occurs as part of an initial violative result. This follow-up sampling is until MHLW's investigation into the cause of the violation is complete, and serves as an additional mechanism to ensure that no further adulterated product enters commerce. Any carcasses or portions thereof, presenting violative results are subject to recall, including those identified during routine monitoring.

MHLW is responsible for regulating the meat industry and certifying establishments to export meat products to the United States. It is also responsible for the official certification or decertification of establishments and maintaining the official list of establishments eligible to export to the United States. FSD is responsible for conducting supervisory reviews in establishments certified as eligible to export to the United States.

The FSIS auditor verified through record reviews and POE violations that no adulterated or misbranded products have been sent to the United States. The FSIS auditor verified that certification labels and marks are approved by MHLW and are displayed on outer containers and packages or affixed to dressed carcasses after they have passed inspection for each certified establishment as required by MHLW. MHLW issues an *Official Meat Inspection Certificate for Fresh Meat and Byproducts* that certifies that the product being exported to the United States has passed inspections and is not adulterated or misbranded. MHLW has the authority to assess penalties for violations of food safety laws, as stated in the *Abattoir Law*.

MHLW has the sole authority to grant final certification of a new establishment, permit an existing certified establishment to maintain its eligibility to export to the United States, and decertify the establishment. The FSIS auditor reviewed the approval procedures for establishments to be certified as eligible to export to the United States. The FSIS auditor verified that the documented assessment of the most recent establishment certified to export to the United States was in accordance with the *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States.* These documents contain a registration form, initial approval determinations, and certification documents maintained at MHLW headquarters. The certification included a comprehensive establishment audit, which consists of a review of the establishment's documentation including sanitation, HACCP, and sampling documents as well as on-site visits to the establishment to verify that all regulatory requirements specific to an importing country have been met.

The FSD is responsible for conducting supervisory reviews in establishments certified as eligible to export to the United States. If the establishment is not following the required procedures, then MHLW may take enforcement actions that include instructions for improvement, revocation of certification, suspension of the issuance of export certificates, and revocation of the designation of inspectors. The FSIS auditor verified that the MHLW officials have conducted the approval process in accordance with Japan's prescribed procedures to meet regulatory requirements before granting certification to export meat products to the United States.

The FSIS auditor observed that the same set of laws, regulations, and policies are applied consistently to all establishments certified to export raw beef products to the United States. The FSIS auditor assessed the performance evaluation of in-plant inspection personnel (IIP) and the

completion of supervisory reviews of establishments certified eligible to export to the United States. The FSIS auditor determined that regulatory verification and inspection activities were consistently implemented at all audited establishments, and MHLW enforces the rules of their food safety inspection system to identify and document noncompliances and verify the adequacy of corrective actions and preventive measures.

The FSIS auditor observed and verified that source beef used in processing operations originates from certified establishments. Each certified slaughter and processing establishment only processes beef that originated in Japan and was slaughtered at their establishment. According to the *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States*, the meat processing establishment must be an annex to the slaughter establishment and must carry out processing all the way from slaughter and dressing through fabrication. Japan does not allow imported meat product to be exported to the United States.

In addition, an official meat inspection certificate for fresh meat and byproducts of fresh meat for exportation is issued and accompanies the product to be exported. As part of the application process for product exported to the United States, the FSIS auditor verified all tracking information of the products' origin and movement throughout the processing of the product. Records reviewed included establishment sanitation standard operating procedures (sanitation SOP) and HACCP monitoring and verification records that are associated with each lot of product. The designated inspector (DI) signs the certificate and the original is attached to the product to be exported. A duplicate is then given to the applicant and copies of the originals are retained at the MIC.

The FSIS auditor verified that MHLW ensures that when issued, new United States import requirements are communicated to the certified establishments. MHLW maintains a communication system by disseminating electronically FSIS new legislation, regulations, and guidelines including MHLW instructions to the RBHW and local government via e-mail. MHLW also checks the distribution of these requirements to inspection personnel through supervisory review.

The FSIS auditor observed that government inspection occurs continuously during slaughter operations, and/or at least once per production shift during the processing of raw beef products intended for export to the United States. The FSIS auditor verified that MHLW has a written staffing standard based on the species slaughtered and line speeds for use at establishments certified to export to the United States.

The FSIS auditor verified that slaughter and processing establishments certified to export to the United States slaughter an average of 70 cattle per day. The MIC assigns three inspectors for post-mortem inspection at these establishments (one head inspector, one viscera inspector, and one carcass inspector). There is also one off-line inspector and one inspector for conducting ante-mortem examination at each establishment. The MIC has established procedures for relief assignments in the event that absences of inspection personnel occur.

The FSIS auditor verified that government inspection personnel assigned to certified establishments exporting raw beef products to the United States are employees of and paid by the

Japanese government. The inspection personnel assigned to certified establishments are civil servants and required to be full-time government employees. The local government pays the salaries of the food safety inspection system personnel. The national government financially supplements the local governments' payment for food safety inspection. The FSIS auditor verified this through a review of employment records, certificates, and identification documents of employees assigned to establishments certified to export to the United States.

The FSIS auditor verified that government inspection personnel have appropriate educational credentials, disciplinary backgrounds, and training to carry out their inspection tasks. In Japan, inspection personnel are all required to be veterinarians. MHLW ensures that a veterinary medical officer must have a Doctor of Veterinary Medicine or equivalent degree. The FSIS auditor reviewed documentation for a select number of inspection personnel at establishments certified to export to the United States to verify that they had the required veterinary degrees.

The FSIS auditor verified that MHLW has implemented and conducted ongoing training programs intended to ensure that DIs are aware of specific food safety and inspection requirements for beef products being exported to the United States. The FSIS auditor reviewed the recent training provided by MHLW, which included requirements for sanitation SOP, HACCP, generic *E. coli* and *Salmonella,* and implementation of STEC verification sampling.

The FSIS auditor verified that certificates of participation, training material, and training participation records were maintained at each level of authority. MHLW has implemented a system used to assess the technical competence and performance of individual DIs in conducting official inspection activities at establishments that export to the United States. A performance evaluation of inspection personnel at certified establishments is required annually. The FSIS auditor observed the IIP while they were conducting their inspection activities and did not identify any concerns or issues.

The FSIS auditor observed that MHLW provides oversight of laboratories that perform analyses for official government sampling and testing programs for meat products that are exported to the United States, including oversight to ensure that laboratories conducting official government analyses comply with the general quality assurance and control criteria provided in International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Guide 17025. MHLW maintains administrative and technical support to operate its laboratory system. Government laboratories operate in accordance with criteria aligned with the ISO/IEC 17025 standard.

Private laboratories are accredited by the Japanese Accreditation Board (JAB) annually according to the ISO/IEC 17025 criteria and are approved by MHLW. The JAB is a member of International Laboratory Accreditation Cooperation (ILAC), which is the overarching group that ensures global harmonization of laboratory accreditation. MHLW establishes the requirements and written procedures that laboratory quality assurance programs demonstrate that there are properly trained personnel, suitable facilities and equipment, and that equipment is verified, calibrated, and maintained in a manner consistent with international norms. The laboratories participate in appropriate proficiency testing schemes for food analysis, and maintain reporting

and recordkeeping capabilities that can clearly track and link a test result to the correct establishment.

The FSIS auditor verified that MHLW maintains oversight of its residue laboratories through the RBHW's regional auditors of FSD that conduct the prescribed annual audit of the residue laboratory quality system in accordance with *Japan's Food Sanitation Law* and *Manual on How to Manage Examination, etc. at Testing laboratories*. In addition, the RBHW auditors perform reviews of the government MIC microbiological laboratories on a monthly basis as part of the supervisory review conducted at the establishment. The FSIS auditor verified that *Laboratory Quality Control Manual* and *Quality Assurance Handbooks* are being followed as required and MHLW is conducting annual audits of private laboratories and monthly audits of MIC laboratories. The MHLW annual audit report for private laboratories includes administrative and technical aspects of the analytical methodology, operational procedures, laboratory personnel qualifications, training, and maintenance of the laboratory equipment and facilities.

The FSIS auditor selected the Japan Food Research Laboratories (JFRL), a private laboratory located in Tama, to verify the functions and oversight provided by MHLW. JFRL has been designated to run samples for chemical residues testing of beef products to be exported to the United States. The FSIS auditor verified that the laboratory was accredited in accordance with protocols designed by MHLW consistent with ISO/IEC 17025 and is operating in accordance with those criteria. The accreditation covers the management and quality assurance aspects of the functions of the laboratory to ensure that it has the capability to support MHLW's inspection program for certified establishments eligible to export to the United States. The FSIS auditor verified through records review that the methods of analysis used in official laboratories were included in the scope of accreditation for the laboratory.

The FSIS auditor reviewed records of the inter-laboratory proficiency testing conducted at the laboratory. The qualifications and training records of the laboratory personnel showed that the analysts met the qualification requirements and successfully passed the proficiency tests. Documentation on file also demonstrated that the analysts possess the academic qualifications, technical credentials, and accreditations required to conduct analysis within their accreditation scope. The FSIS auditor verified that the RBHW conduct the prescribed annual audits of the laboratory quality system in accordance with Japan's *Food Sanitation Law* and the aforementioned manual. The FSIS auditor reviewed the MHLW third-party reviews and audit reports generated for the previous year at the audited laboratory and its related follow-up reviews and verified that corrective actions were documented in an action plan and were adequate to address the findings, which demonstrated that MHLW provides technical support to the laboratories.

FSIS determined that Japan's government organizes and administers the country's food safety inspection system, and that MHLW officials enforce laws and regulations governing production and export of raw beef at establishments certified to export to the United States. The FSIS auditor identified that MHLW allows the issuance of an export certificate for product intended for export to the United States even though chemical residue test results have not been confirmed negative prior to shipping to the United States. MHLW committed to provide FSIS with corrective action plans, which FSIS will verify once the corrective actions are implemented.

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

The second of six equivalence components that the FSIS auditor reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of each and every carcass and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; periodic supervisory visits to official establishments; and requirements for thermally processed/commercially sterile products. The FSIS auditor evaluated this component via in-plant record reviews, interviews, and direct observation. This evaluation was in correlation with information provided by MHLW in the SRT, POE information, and Japan's history of compliance.

The FSIS auditor reviewed the slaughter practices at each of the six audited establishments and determined that inspection personnel verify that humane handling and slaughter of livestock is conducted in accordance with provisions contained in the *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States - Section IV, Attachment 2*. This document describes the responsibilities and official controls for humane handling. In *Attachment 2*, "*Sanitation Control Standards*," of the same document, it states that non-ambulatory disabled cattle are not to be slaughtered in a certified establishment.

The FSIS auditor confirmed that the IIP verify that operators comply with humane handling and slaughter requirements and document the results on the daily verification inspection report to ensure that livestock are humanely handled and slaughtered. This includes daily observations of loss of consciousness and accompanying indicative signs of adequate stunning before cattle are shackled and bled. The FSIS auditor observed and verified that all animals have access to water in all holding areas, and that establishments have procedures to provide feed if animals are held for more than 24 hours.

The FSIS auditor verified that government inspection personnel perform ante-mortem inspection of livestock prior to slaughter in accordance with procedures listed in the *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States*, as well as requirements for segregation and disposition of animals having abnormalities or suspected of having diseases. Specific diseases and dispositions are listed in the *Abattoir Law (Law No. 114),* and *Abattoir Law Enforcement Regulation, (Ordinance No. 44 and No. 216).* The FSIS auditor verified that veterinarians, as stated in the *Abattoir Law Enforcement Regulation (Ordinance No. 216),* conduct all ante-mortem inspections of livestock prior to slaughter.

The FSIS auditor verified that IIP review the incoming registration and owner identification documents with each load/truck, matching the cattle's ear tag individual identification (ID) number with the receiving documents. Japan employs the National Livestock Breeding Centre System in which each ear tag number is registered. This system allows the animals and carcasses to be traced back to their farms of origin using the ID number.

The complete movement history for each animal is also included in the individual identification information. The IIP also observe all animals at rest and in motion from both sides in designated holding areas before slaughter in order to determine whether the animals are fit for slaughter, and the IPP document the results on a form for ante-mortem inspection. Each audited slaughter establishment maintains a designated holding pen for further examination of sick or suspect animals. The implementation of the ante-mortem inspection complies with Japan's requirements for humane handling and slaughter of livestock.

The FSIS auditor observed inspection personnel and verified through a review of condemnation records that government inspection personnel perform post-mortem inspection of each livestock carcass and parts during and after the slaughter of livestock. MHLW requires the MICs to perform direct and continuous (daily) official supervision of slaughter activities, and the inspection system requires post-mortem inspection at the time of slaughter. The FSIS auditor verified that written procedures are in place that instruct DIs on how post-mortem examination is to be performed. These included visual inspection, palpation, and incision of relevant portions of the animal described within the *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States, Japan's Manual of Procedures of Meat Inspection and Re-inspection of Dressed Carcasses, Abattoir Law (Law No. 114),* and *Abattoir Law Enforcement Regulation (Ordinance No. 44 and No. 216).*

The FSIS auditor observed and verified that proper presentation, identification, examination, and disposition of carcasses and parts were being implemented. All IIP were adequately trained in performing their on-line post-mortem inspection duties. The FSIS auditor observed the performance of the inspection personnel examining the heads, viscera, and carcasses in which the proper incision, observation, palpation of required organs, and lymph nodes were made in addition to digital documentation of condemnation records on-line. The IIP re-inspects and verifies the adequate removal of all abnormalities on carcasses. Line synchronization of carcasses and viscera was properly maintained. The design of the post-mortem inspection stations including proper lighting and the appropriate number of on-line inspectors was consistent with the requirements of 9 CFR 310.1.

The FSIS auditor verified that MHLW provides inspection at least once per shift during processing operations and on-line inspection during slaughter operations at each audited establishment. The inspection verification tasks are predetermined and listed on an inspection *Daily Monitoring Verification* form. The MIC veterinarians use this form to record offline inspection verification tasks. These daily verification activities consisted of a direct observation of the establishment monitoring of HACCP, including zero-tolerance verification, sanitation SOP, and sanitation performance standards (SPS). In addition, the MIC veterinarians review the establishments' records, including HACCP, sanitation SOP and SPS, and generic *E. coli* sampling records in accordance with the MIC daily inspection verification schedule plan outlined in the *Daily Monitoring Verification* form.

The FSIS auditor verified that the inspection personnel are responsible for label verification as part of their inspection. The results of inspections are documented in daily or weekly inspection reports, which are then sent to the local government, RBHW, and MHLW in a summary format

monthly. The FSIS auditor reviewed the daily inspection records and verified that inspection is occurring as prescribed.

The FSIS auditor verified that an MHLW representative of the government inspection system makes periodic supervisory visits to each certified establishment to evaluate the performance of inspection personnel. These reviews are conducted by RBHW's export meat inspection officers (auditors) from the FSD monthly in accordance with the *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States,* and *Guidelines for Inspection of Certified Establishments Handling Meat for Exportation to the United States*. The FSIS auditor reviewed the most recent supervisory review report and determined that supervisory visits are conducted at the prescribed frequencies. Supervisory reviews were conducted using a standard checklist form, *Establishment Audit Checklist*, which consists of a detailed checklist divided into two parts.

The first part consists of five sections for evaluating the adequacy of an establishment's food safety system, including items related to ante-mortem and post-mortem inspection, humane handling and slaughter activities, verification of SPS elements, sanitation SOP, HACCP, and microbiological control for generic *E. coli* and *Salmonella*, separation of United States product within the establishment, and official controls over condemned material. The second part is the inspection requirements section designed for evaluating the knowledge, skills, and abilities of IIP that are assigned to establishments certified to export to the United States, and begins with the evaluation of the IIP interacting with the RBHW audit personnel the day of the audit. RBHW then reviews individual IIP personal performance records documented by the MIC supervisor during each supervisory review visit.

The periodic supervisory review reports are distributed to the audited establishments, in-plant inspection, and the related RBHW office. If deficiencies are identified, the IIP are responsible for verification of corrective actions resulting from the supervisory reviews. The RBHW office is responsible for analyzing the results of the review and for conducting follow-up verification of the corrective actions proposed by the establishment. It is also responsible for confirming that the IIP had verified those corrective actions in order to evaluate the effectiveness and implementation of the establishment's action plan. The RBHW submits a copy of the monthly supervisory reviews to the MHLW headquarters for further review and analysis. The FSIS auditor reviewed the supervisory review reports and inspection-related records and concluded that MHLW demonstrated they were consistent in their evaluation of the adequacy of the establishments' food safety system and the capability of IIP to conduct inspection activities at certified establishments.

The FSIS auditor verified that complete separation is maintained between product certified for export to the United States and domestic product. MHLW requires complete separation of establishments that are certified from those that are not certified. According to the *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States,* slaughter and processing establishments certified to export product to the United States must be separate from establishments that do not export product to the United States. The meat processing establishment must be an annex to the slaughter establishment and must carry out processing all the way from slaughter and dressing to fabrication.

The FSIS auditor verified that within these establishments separation is maintained through either separate production days or separate production times with product for export to the United States produced first and separation of product in storage by control tags that are used for these products. Additionally, the FSIS auditor observed that no beef products restricted by APHIS were being produced for export to the United States. MHLW ensures that only unrestricted beef products are currently exported to the United States by monitoring the APHIS website, and verifying restrictions under 9 CFR 94.1 prior to signing export certificates.

The FSIS auditor verified the adequate identification, removal, and disposal of specified risk materials (SRMs) in beef products and small ruminants through observation records review and interviews of IIP. At each audited slaughter establishment, the establishment considers SRMs (including vertebral column) as one of the causative agents of hazards when developing their HACCP plan. The establishments either designate that all cattle slaughtered at their facility will be treated as ≥ 30 months within the hazard analysis or have adequate controls in place for the segregation of carcasses throughout the process. Each establishment references SRM SOPs for the identification, removal, and disposal of SRMs in their slaughter and processing HACCP plans.

The FSIS auditor verified that SRMs have been removed, and whole cuts of boneless beef products are derived from cattle that were born, raised, and slaughtered in Japan for export to the United States. There are also provisions for disposing of the SRMs in such a way that they will not contaminate dressed carcasses and viscera destined for human consumption. The IIP verify the adequate identification, removal, and disposal of SRMs daily and document the results on inspections *Daily Monitoring Verification* form.

The FSIS auditor verified that control over condemned materials is maintained through the *Abattoir Law (Law No. 114),* and *Abattoir Law Enforcement Regulation (Ordinance No. 44 and No. 216),* including appropriate identification in accordance with the categories described therein; segregation in specially-marked or otherwise secure containers, and final documented disposal of these materials at nearby rendering facilities.

Japan's food safety inspection system continues to maintain the legal authority, a regulatory framework, and adequate verification procedures to ensure sufficient official regulatory control actions to prevent products from contamination when insanitary conditions or practices are present, which as described, is consistent with criteria established for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditor reviewed was Government Sanitation. The FSIS auditor verified that MHLW requires each official establishment to develop, implement, and maintain written sanitation SOPs to prevent direct product contamination or insanitary conditions.

MHLW requires that each official establishment operate in such a manner as to prevent insanitary conditions, focus attention on those aspects of sanitation that pose a risk of causing direct product contamination, take action to prevent product contamination when insanitary

conditions or contaminated products are found, correct insanitary conditions, and properly dispose of contaminated product. Through the *Abattoir Law (Law No. 114),* and *Abattoir Law Enforcement Regulation (Ordinance No. 44 and No. 216),* MHLW requires that establishments operate in a sanitary manner, and has specific requirements to maintain sanitary standards. Sanitation must be maintained around establishments in the following areas: ante-mortem, post-mortem and processing.

The FSIS auditor verified that MHLW ensured that each certified establishment operates in a sanitary manner through record reviews, observations, and interviews. The on-site MIC inspection personnel verify that the establishment implements sanitary dressing procedures throughout the slaughter process on a daily basis. MHLW provides guidance to inspection personnel on official control procedures for slaughter hygiene verification and ongoing assessment of the establishment's compliance with food hygiene requirements from acceptance of animals for slaughter through carcass dressing and chilling.

DIs at the final rail position ensure that carcasses with visible fecal contamination are further trimmed and reinspected before entering the chiller, and they verify an establishment's ability to implement corrective actions and compliance with the *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States,* included in *Attachment 2, "Sanitation Control Standards"* and *Attachment 3, "Standards for Implementation of Sanitation Control by HACCP"*. The slaughter hygiene verification system monitors contamination at final inspection as a key point to comply with MHLW requirements in *Attachment 3, "Standards for Implementation of Sanitation Control by HACCP"* focusing on the need for establishments to take the necessary actions to correct and prevent recurrence.

The FSIS auditor verified that the condition of the certified establishments' construction, facilities, and equipment are adequate to prevent the contamination or adulteration of raw beef products designated for export to the United States. The *Abattoir Law Enforcement Regulation (Ordinance No. 216)* has the requirements for standards of construction and facilities, which cover ante-mortem, post-mortem, and processing areas. MHLW's inspection system has official controls over establishment construction, facilities, and equipment and has the authority to take formal enforcement action to direct an establishment to rectify both hygiene and structural deficiencies.

The FSIS auditor verified that certified establishments develop, implement, and maintain daily pre-operational and operational sanitation procedures sufficient to prevent the direct contamination or adulteration of meat products designated for export to the United States. The *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States* lists requirements for sanitation as well, included in *Attachment 1, "Standards for Structure and Materials of Facilities and Equipment* and *Attachment 2, "Sanitation Control Standards." Attachment 3, "Standards for Implementation of Sanitation Control by HACCP"* requires that all certified establishments develop and implement a sanitation SOP.

The FSIS auditor assessed the adequacy of pre-operational inspection by directly observing the IIP conducting pre-operational verification of the establishment's sanitation program at one of the audited establishments. The IIP conducted this activity in accordance with the established

procedures, including a pre-operational record review of the establishment's monitoring results and an organoleptic inspection of food contact surfaces of facilities, equipment, and utensils, as well as an assessment of SPS requirements (e.g., ventilation, condensation, and structural integrity), with no concerns observed.

The FSIS auditor observed IIP's verification of operational sanitation procedures in all six audited establishments, comparing the overall sanitary conditions of all audited establishments to the government inspection verification records. The FSIS auditor also examined the IIP's documentation of sanitation noncompliance records and verified that the inspection personnel took regulatory enforcement control actions sufficient to ensure that sanitary conditions were restored and product was protected from contamination. The FSIS auditor's observations and record reviews, including the establishment's sanitation monitoring and corrective action records, as well as those of inspection personnel documenting inspection verification results and periodic supervisory reviews, mirrored the actual sanitary conditions of the establishment and found that inspection personnel were adequately verifying whether establishments met requirements.

In three of the audited establishments, the FSIS auditor identified isolated sanitation findings that are noted in their respective individual establishment checklist provided in Appendix A of this report. Except for these findings, MHLW's food safety 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 POINTS (HACCP) SYSTEM

The fourth of six equivalence components that the FSIS auditor 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 FSIS auditor observed that certified establishments develop, implement, and maintain a HACCP system. MHLW, through the *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States, Attachment 3 – "Standards for Implementation of Sanitation Control by HACCP," Section III "Voluntary Sanitation Control Using HACCP System"* contains regulatory requirements requiring establishments certified to export to the United States to develop, implement, and maintain a HACCP plan. MHLW, through the *Guidelines for Inspection of Certified Establishments Handling Meat for Exportation to the United States* requires that the DIs verify the validity of the establishment's HACCP plan by assessing whether the plan complies with all applicable requirements. In addition, MHLW sends an export meat inspection officer from RBHW to certified establishments and the MIC offices located at these establishments at least once a month to verify an establishment's HACCP plan and assess compliance of the plan with all requirements in the aforementioned documents, including an inspection task and procedures performed by MIC inspection personnel.

At the six audited establishments, the FSIS auditor conducted an on-site review of the establishments' HACCP systems, including flow charts, hazard analyses, HACCP plans, and related 60 days of HACCP records. The FSIS auditor, together with the inspection personnel,

observed the establishments' employees conducting hands-on HACCP monitoring and verification activities for the zero-tolerance (feces, ingesta, and milk) critical control point (CCP). Neither the FSIS auditor nor the inspection personnel observed any deviations from the critical limits. The FSIS auditor also reviewed the establishments' zero-tolerance records at each of the six audited beef slaughter establishments. The review of the establishments' corrective actions in response to a few deviations from critical limits indicated that the inspection personnel documented and verified the adequacy of the establishments' corrective actions according to the requirements consistent with 9 CFR 417.3(a).

FSIS verified that IIP conducted daily verification of HACCP plans in accordance with the aforementioned documents. In-plant off-line inspection personnel are responsible for performing verification activities that include the review of the establishment's written HACCP plans and their contents, review of establishment-generated HACCP monitoring and verification records, and direct observation of those procedures by the establishment to assess the adequacy of implementation of HACCP plans on the part of the establishments. The off-line inspection personnel use a daily inspection verification schedule to conduct specific HACCP plan verification tasks and document daily inspection verification activities, including findings and actions taken. There was no indication of any noncompliance trends resulting from the review of these documents.

The FSIS auditor conducted an on-site observation and review of the inspection zero-tolerance verification records in each of the six audited beef slaughter establishments, for which no failures were identified. The FSIS auditor also verified the physical CCP locations by observing the DI conducting HACCP hands-on verification activities. The actions to be taken by IIP of establishments certified to export to the United States are identified in the aforementioned documents. The IIP at establishments certified to export to the United States conducted verification of HACCP plans consistent with FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System*, and HACCP requirements. The IIP verification procedure encompasses the evaluation of written HACCP programs and verification of HACCP prerequisites and plan monitoring, corrective actions, and recordkeeping. During this audit, neither the FSIS auditor nor the IIP observed any deviations from the critical limits on the day of the audits.

The FSIS auditor's HACCP verification activities also included interviews with establishment and inspection personnel, and review of the establishment's records, that provided supporting documents as part of the decision making process for the HACCP system. The FSIS auditor reviewed and compared the contents of the audited establishments' HACCP plans with corresponding establishments' monitoring, corrective actions, and verification records as well as Japanese inspection's verification records for the past 60 days. The FSIS auditor's review indicated that the HACCP documents generated by establishments complied with the aforementioned document. The review of both the establishment monitoring and government verification records found no identified deviations.

The FSIS auditor's on-site verification activities and analysis indicate that MHLW requires operators of establishments certified to export to the United States to develop, implement, and maintain HACCP systems. The FSIS auditor determined that Japan's food safety inspection

system continues to maintain regulatory HACCP requirements that meet the core requirements for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that the FSIS auditor 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, and muscle of carcasses for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants.

Prior to the on-site visit, FSIS' chemical residue experts reviewed Japan's National Residue Program (NRP) for 2018, associated methods of analysis, and additional SRT responses outlining the structure of Japan's chemical residue testing program. FSIS has not identified any United States POE violations related to this component since the last FSIS audit in 2015. FSIS based its verification of Japan's NRP on information contained in its NRP sampling plan and previous years (2016-2017) testing results. The FSIS auditor also conducted an on-site audit of one residue laboratory that performs residue analyses on products exported to the United States.

The FSIS auditor verified that MHLW continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and chemical contaminants in the tissues of bovine slaughtered for human consumption in accordance provisions in the *Food Sanitation Law* and *Abattoir Law*. MHLW additionally has the legal authority for surveillance of chemical residues that exceed the maximum levels accepted nationally and internationally. This regulatory task is accomplished with the participation of the RBHWs and JFRL network. Japan's NRP covers the frequency and sample allocations among species and the group of compounds that must be analyzed. MHLW's document *Guidance for Implementation of Residual Chemical Monitoring* states the substances that should be analyzed for meat products intended for export to the United States.

The FSIS auditor verified that Japan's NRP is designed and conducted in accordance with Japan's *Food Sanitation Law*. Japan's NRP contains provisions that, in accordance with *Food Sanitation Law Article 54*, the "Health, Labor, and Welfare Minister or the governor of the prefecture has the business or the official in charge dispose of the food or orders the other businesses to take necessary actions to eliminate hazards to food sanitation"; in other words, the disposition of product that exceed acceptable residue levels. In addition, to prevent the violations from re-occurring, the cause of the chemical residue violation is investigated using both the domestic and United States standards. Local governments publish a written disposition order or a written improvement order for products with violative levels of chemical residues. Japan's residue plans are recognized as equivalent to FSIS' criteria.

MHLW's routine chemical residue testing program does not require the selected carcass (lots) and products thereof be held or controlled until receipt of negative results of samples. However, product is held and precluded from export during any subsequent follow-up sampling that occurs

as part of an initial violative result. This follow-up sampling continues until MHLW's investigation into the cause of the violation is complete and serves as an additional mechanism to ensure that no adulterated product enters commerce. Any carcasses or portions thereof presenting violative results are subject to recall, including those identified during routine monitoring.

The FSIS auditor verified implementation of Japan's NRP at the six audited slaughter establishments. The official monitoring is conducted according to Japan's NRP, which is defined every year. The plan lists the residue group, the number of samples for the group, and the matrix for each month. The inspection personnel who collect random residue samples at the beef slaughter establishments have received sufficient training that includes such subjects as sampling methodology, identification of animals, traceability, and sample security.

The FSIS auditor verified that the inspection personnel are following Japan's NRP sampling protocol. This protocol includes random sampling and testing of internal organs, fat, and muscle of carcasses for targeted residues, and secure delivery of residue samples to the designated JFRL in accordance with the prescribed methodology provided by MHLW based on Japan's *Food Sanitation Act, Article 22*. The DI completes the laboratory submission form, and a copy is packaged in the sample shipment cooler, which the DI secures with a numbered seal to maintain integrity. Residue results are communicated to the MHLW headquarters, regional offices, and inspection personnel through e-mail.

The FSIS auditor's review of documentation at the six audited slaughter establishments' local inspection offices verified that inspection personnel were collecting samples of the required matrices for detection of specific analytes and adhered to the prescribed sample collection schedule. The FSIS auditor's review of the verification results for the last year at these establishments indicates that no violative samples were detected.

MHLW maintains oversight of its residue laboratory system through an annual audit of residue laboratories conducted by RBHW regional auditors. MHLW's document *Manual on How to Manage Examination, Etc. at Testing Laboratories* outlines requirements to address operational procedures and laboratory audit criteria including annual review of laboratory facilities, equipment, and personnel qualifications.

The residue laboratory network consists of JFRL, which is an independent, private institution accredited by MHLW as a testing laboratory system for conducting analysis of government samples for the presence of chemical residues (pesticides, antibiotics, heavy metals, environmental contaminants, and food additives) in meat products. JFRL has seven locations distributed across Japan and two (Tama and Saito) of them are designated as residue testing laboratories under the NRP for Japan. The FSIS auditor visited the JFRL-TAMA laboratory, which tests the vast majority of substance groups for all of Japan. The FSIS auditor reviewed the JFRL-TAMA laboratory unit's chemical residue testing program and verified that JAB has accredited the laboratory as equivalent to the ISO/IEC 17025 standard in the specific areas of testing.

During the audit of this laboratory, the FSIS auditor's document reviews included an evaluation of management system documents; sample handling and frequencies; timely analyses; data reporting; tissue matrices for analysis; equipment operation and printouts; minimum detection levels; percent recoveries; corrective actions; and the training records and certifications associated with the qualifications of the analysts. The documents reviewed demonstrated that analysts had successfully participated in intra- and inter-laboratory evaluations administered by the laboratory manager and accrediting bodies. The documentation on file also demonstrated that the analysts possess the academic qualifications, technical credentials, and accreditations required to conduct analyses within their accreditation scope. Additionally, records including the most recent internal laboratory audit report demonstrate that laboratory managers readily respond to correct non-conformities identified during internal and external audits.

The FSIS auditor observed a demonstration by laboratory personnel on sample receipt and handling, including checking sample integrity and security, registration of the sample per the laboratory quality assurance system, assigning the identification and storage of samples in accordance with the laboratory's standard operating procedure. The FSIS auditor verified that the private laboratory performs a timely analysis of samples; reports the number of analyzed samples and the results to MHLW in a timely manner; provides MHLW with a quarterly report on the progress of the plan; applies approved analytical methodologies; and has quality assurance programs. No concerns arose from these observations and reviews.

The FSIS auditor verified that Japan's food safety inspection system continues to maintain a chemical residue testing program, organized and administered by the national government. It maintains the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in beef products destined for export to the United States.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components that the FSIS auditor reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that meat products prepared for export to the United States are safe and wholesome.

The evaluation of this component included a review and analysis by the FSIS auditor of the *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States,* which contains the regulatory requirements for establishments exporting meat and meat products to the United States. The document describes the official inspection methodology for a continuous and systematic assessment of inspection activities during routine verifications of microbiological testing, including *Salmonella* species (spp.) by inspection personnel and generic *E .coli* by regulated slaughter establishments. Specific rules for testing and minimum sampling are written in the document. Additionally, MHLW mandates that all establishments have a recall program in place and a trace back system for product produced.

The FSIS auditor accompanied and observed the in-plant inspection verification activities for *Salmonella,* and verification of establishment generic *E. coli* sample collection in audited beef slaughter establishments. The FSIS auditor verified that the establishment's microbiological sampling and testing program for meat verifies process control in slaughter operations using microbiological analyses for indicators of intestinal and fecal contamination. MHLW requires all establishments certified to export product to the United States test for generic *E. coli* (biotype 1) as part of its sanitation control procedures and to assess the effectiveness of process control. Japan's requirements are consistent with FSIS regulatory requirements cited in 9 CFR Part 310.25(a) for generic *E. coli* with a focus on bovine slaughter as the only species eligible for export to the United States. The testing must be conducted using either a method certified by the Association of Official Analytical Chemists (AOAC) International or the most probable number (MPN) method (results have to be within the 95% confidence interval of an appropriate MPN index).

MHLW conducts verification activities that verify an establishment's generic *E. coli* testing program in chilled beef carcasses. MHLW uses the test results to verify the establishment's slaughter dressing controls for fecal contamination are adequate. Furthermore, the DIs verify that each establishment uses appropriate sampling methodology; that their laboratory uses an appropriate method for analysis; documents and correctly evaluates test results; and takes appropriate corrective actions if the upper control limits are exceeded.

The FSIS auditor verified that the six audited slaughter establishments had implemented a microbiological testing program to verify process control by conducting generic *E. coli* testing of livestock carcasses. The FSIS auditor reviewed records, observed sampling, and conducted interviews of IIP to verify that the responsible individuals had the knowledge and skills to implement this type of testing on an ongoing basis. Both establishment and IIP were familiar with the upper and lower control limits, as well as the requirement to take corrective actions if the upper limits are exceeded. The FSIS auditor's observations and reviewed testing results showed that the establishments routinely met their limits, and that there has not been any identified loss of process control.

The FSIS auditor verified that MHLW implements sampling verification activities to ensure that certified establishments reduce and control *Salmonella* in raw meat. MHLW applies a *Salmonella* sampling and testing program to verify that the establishments certified to export to the United States meet the requirements consistent with 9 CFR Part 310.25(b) and the FSIS *Salmonella* performance standard for bovine. The specific *Salmonella* performance standard requirements and sample collection procedures are provided in the *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States.* MHLW requires that one *Salmonella* set be scheduled daily, with a sample collected by a government DI of the beef carcasses in the chiller at certified establishments.

The DIs take the samples as part of the tasks they perform to verify the validity of the establishment's HACCP plan. The percentage of *Salmonella* positives over time have to meet (or be less than) the percentage of positives that is the country's established standard. Japan's performance standard set is based on the number of samples tested (n) and the maximum number of positives to achieve the standard (c). MHLW's *Salmonella* performance standard for beef

heifers (n = 82, c ≤ 1) and cow beef/bull beef (n = 58, c ≤ 2) is the same as FSIS' codified standards. MHLW has an enforcement strategy in place if performance standards are exceeded and an establishment fails a sample set. Establishments are required to identify the cause of the issue, take proper corrective actions, and implement preventive measures.

MHLW's analytical testing is conducted at each on-site MIC microbiology laboratory, which is audited by RBHW regional auditors monthly. MHLW performs documented analyses of the results of microbiological testing programs (including baseline/prevalence/pathogen reduction studies) to determine the ongoing effectiveness of the inspection system for *Salmonella* performance standards. In addition, MHLW through RBHW verifies that all certified establishment inspection sample collection procedures are in accordance with its sample collection protocols described in the aforementioned document.

The FSIS auditor reviewed records, including *Salmonella* spp. results, in addition to the last completed sample set results at the six audited slaughter establishments. Results showed no *Salmonella* set failures during the period reviewed. In addition, the FSIS auditor observed and verified that the DI's sample collection procedures are in accordance with the sample collection protocols described in the aforementioned regulatory requirements. FSIS verification activities confirm aseptic techniques, and procedures for sample collection from chilled beef carcasses for *Salmonella* testing. The demonstrated methodology is consistent with FSIS' method.

The FSIS auditor's review of the government STEC verification program revealed:

- The CCA has not fully implemented their government STEC verification program to ensure that raw beef products are free of STEC at the end of the production process. The CCA has not implemented a method of detection equivalent to the FSIS Microbiology Laboratory Guidebook (MLG) method for detection of *E. coli* O157:H7 and non-O157 STEC in beef trimmings and the implementation of sampling and testing of beef trimmings.

FSIS verified at each of the establishments audited that the written program describes the sample frequencies to be performed by the establishment as once every two months based on the tonnage produced at the establishment and the official government verification as once per month. The program specifies that trimmings will be sampled. The sample collection procedures describe the N60 sample collection procedure, where 60 thin slices 8 centimeters long by 3 centimeters wide and 0.3 centimeters thick of surface area tissue are collected and tested.

The FSIS auditor observed the DIs at each establishment conduct a mock sample collection per the government STEC verification program at each local establishment. The FSIS auditor observed and verified that the DIs' collection procedures are in accordance with the sample collection protocols described in the written STEC verification program. FSIS verification activities confirm aseptic techniques, and procedures for N60 sample collection of beef trimmings for STEC testing. The demonstrated methodology is consistent with Japan's requirements for products exported to the United States and FSIS' method. The FSIS auditor verified through observations and interviews with MHLW that MHLW's STEC verification program has not implemented a method of detection equivalent to the FSIS MLG method for detection of *E. coli* O157:H7 and non-O157 STEC in beef trimmings. MHLW indicated that

when an appropriate STEC test method for beef trimmings is selected, they will submit the method to FSIS for equivalence review.

The FSIS auditor determined that Japan's food safety inspection system continues to maintain equivalent regulatory requirements for its government microbiological testing program that meets the core requirements for this component with one exception. MHLW has not fully implemented their government STEC sampling and non-sampling verification program of establishment testing to ensure that raw beef products are free of STEC at the end of the production process. MHLW has also not yet implemented sampling and testing of beef trimmings for STEC because an appropriate method for detection of STEC has not been adopted by the laboratories. Currently Japan only exports raw intact beef to the United States. There have not been any POE violations related to this component since the last FSIS audit.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on August 10, 2018, in Tokyo, Japan, with MHLW. At this meeting, the FSIS auditor 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 auditor identified the following findings:

Government Oversight (e.g., Organization and Administration)

- The CCA allows inspection personnel to issue an export certificate for product intended for export to the United States before test results are known from the CCA's routine chemical residue program.

Government Microbiological Testing Programs

- The CCA has not fully implemented their government STEC *E. coli* verification program to ensure that raw beef products are free of STEC at the end of the production process. The CCA has also not yet implemented sampling and testing of beef trimmings for STEC because an appropriate method for detection of STEC has not been adopted by the laboratories.

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

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Nanchiku Co., Ltd. 1828 Nonokata, Sueyoshi-cho Soo-shi Kagoshima	08/03/2018	K-1	Japan
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

12/51 SSOP – Corrective Actions

The FSIS auditor's review of the last 90 days of SSOP operational monitoring records for condensation indicated that the establishment was adequately monitoring operational sanitation and taking immediate corrective actions when deficiencies were identified. However, records indicated that condensation was identified in the packaging area, and adjacent cooler 21 times in that 90-calendar day time frame. The establishment failed to take measures to prevent the re-occurrence of condensation with in these areas.

A review of MIC inspection verification documentation did not identify any deficiencies related to condensation during that same 90-day time frame. In addition MIC inspection failed to adequately review the establishments sanitation records and identify the repetitive findings and that the establishments corrective actions failed to take measure to prevent the re-occurrence. The auditor did not observe any condensation during the day of the audit.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Akune Meat Distribution Center Co., Ltd. 10 1-chome Shiohama-cho Akune-shi Kagoshima	08/01/2018	K-3	Japan
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

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

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	08/01/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
JA Shokuniku Kagoshima Co., Ltd. Nansatu Plant 22361 Minamibeppu, Chiran-cho Minamikyushu-shi Kagoshima	08/02/2018	K-4	Japan
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

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

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	08/02/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Kumamoto Chikusan Ryutsu Center Co. Ltd. 9 Hayashibaru, Shichijyo-machi Kikuchi-shi Kumamoto	07/31/2018	KU-2	Japan
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Periodic Supervisory Reviews	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

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

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	07/31/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Miyachiku Corp. Ltd, Takasaki Plant 4268-1 Omuta, Takasaki-cho Miyakonojo-shi Miyazaki	08/06/2018	M-1	Japan
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

45/51 During the FSIS' auditor's observation of pre-operational sanitation verification by Meat Inspection Center (MIC) inspection personnel the following non-compliance in the maintenance of equipment was not identified by Japan's inspection officials. The FSIS auditor observed in the Fabrication Department that a stainless-steel section of a table that comes in contact with exposed product had jagged edges.

The MIC informed the establishment of the non-compliance. The CCA stated that the establishment has initiated a plan of action to address these issues and reassess their maintenance of equipment program to prevent the reoccurrence and will provide the information to inspection personnel.

MHLW will provide FSIS additional measures taken to address the identified deficiency.

Note: The establishment was not producing product that was eligible for export to the United States in the Fabrication Department on the day of the audit.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	08/06/2018

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Miyachiku Corporation, Ltd. Tsuno Plant 15530 Kawakita, Tsuno-cho Koyu-Gun Miyazaki	08/07/2018	M-2	Japan
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

46/51 Sanitation - SPS Sanitary Operations

During the walkthrough of the establishment the FSIS auditor observed in the Fabrication Department a stainless steel tub containing edible product directly under metal pipes and a rusty airlines connection in addition to being placed directly against the wall. Product was not cover leaving it exposed to the possibility of contamination; however there did not appear to be any contamination at the time of the observation.

The MIC took immediate regulatory control and informed the establishment of the non-compliance. Immediate actions were taken by the establishment and MIC will verify establishment's additional measures to prevent the reoccurrence.

MHLW will provide FSIS additional measures taken to address the identified deficiency.

Note: The establishment was not producing product that was eligible for export to the United States in the Fabrication Department on the day of the audit.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	08/07/2018

Appendix B: Foreign Country Response to the Draft Final Audit Report

Food Inspection and Safety Division
Pharmaceutical safety and Environmental Health Bureau
Ministry of Health, Labour and Welfare, JAPAN
1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-8916 Japan Tel: 81-3-3595-2337 Fax: 81-3-3503-7964

December 20, 2018

Dr. Michelle Catlin,
International Coordination Executive
Office of International Coordination
Food Safety and Inspection Service
United States Department of Agriculture
1400 Independence Avenue, SW
Washington, DC 20250
UNITED STATES OF AMERICA

Comments on draft final report of an audit conducted in Japan, July 27 to August 10, 2018 – Evaluating the food safety systems governing raw beef products exported to the United States of America.

Dear Dr. Catlin,

I received your letter of the FSIS's draft final report of an audit conducted in Japan, July 27 to August 10, 2018.

I would like to provide comments regarding the information in the report as attached.

If you have any question, please do not hesitate to contact me.

Yours Sincerely,

Yours Sincerely,

Hideshi MICHINO, DVM
Director of Food Inspection and Safety Division
Pharmaceutical Safety and Environmental Health Bureau
Ministry of Health, Labour and Welfare, **JAPAN**

Comments on draft final report of an on-site equivalence verification audit conducted in Japan evaluating the food safety system governing meat products exported to the United States, July 27 - August 10, 2018.

Findings	*Comments*
Government Oversight (e.g., Organization and Administration)	
The CCA allows inspection personnel to issue an export certificate for product intended for export to the United States before test results are known from the CCA's routine chemical residue program.	Based on the FSIS auditor's remark at the exit meeting and draft report, CCA directed the local governments which authorized certified establishments on November 14, 2018 not to issue any health certificate until confirming compliance in regard to residue monitoring testing and Salmonella testing.
Government Microbiological Testing Programs	
The CCA has not fully implemented their government STEC *E. coli* verification program to ensure that raw beef products are free of STEC at the end of the production process. The CCA has also not yet implemented sampling and testing of beef trimmings for STEC because an appropriate method for detection of STEC has not been adopted by the laboratories.	CCA enforces the STEC control program in certified establishments in January, 2019. Namely, STEC testing program for verification by the establishments and MICs is started in January, 2019. However, from January to March, transition period will be adopted, and testing method shall be accepted based on the previous notification method. From April, 2019, the first month of the Japanese fiscal year, all STEC testing program shall be conducted by methods that are acceptable for FSIS. The STEC control program also includes the requirement that the local governments shall not issue any health certificate until confirming compliance as well as other tests mentioned above.

Comments on draft final report of an on-site equivalence verification audit conducted in Japan evaluating the food safety system governing meat products exported to the United States, July 27 - August 10, 2018.

N° of page and paragraph	*Comments*
II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY	
Page 1 para6 The products these establishments produce and export to the United States include raw intact beef.	As these establishments, for exportation to the United States, produce only raw intact beef, Japan would like to revise the sentence shown below. "The products these establishments produce ~~and export to the United States~~ include raw intact beef to export to the United States."
IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (E.G., ORGANIZATION AND ADMINISTRATION)	
Page 3 para4 At the central level, the Inspection and Safety Division (ISD) of the Department of Environmental Health and Food Safety of MHLW	"Inspection and Safety Division (ISD)" should be "Food Inspection and Safety Division (FISD)." "Department of Environmental Health and Food Safety" should be "Pharmaceutical safety and Environmental Health Bureau" . **The same applies to the following.**
Page 3 para5 seven Regional Bureau of Health and Welfare (RBHW) offices throughout Japan, only four of them (Kanto, Kyusyu, Tohoku, and Tokai)	(Kanto, Kyusyu, Tohoku, and Tokai) should be (Kanto-Shinetsu, Kyusyu, Tohoku, and Tokai-Hokuriku).
Page 3 para6 At the local government level, inspection oversight is managed through Public Health Centers also described as Meat Inspection Centers (MICs).	Public Health Centers and Meat Inspection Centers (MICs) are different organizations. In some cases, meat inspectors belong to the Public Health Centers. In other cases, Meat Inspection Centers are arranged independently for reasons such as the size of the jurisdictional area, the number of inspectors required based on the size of establishments and location. Japan would like to revise the sentence shown below.

Comments on draft final report of an on-site equivalence verification audit conducted in Japan evaluating the food safety system governing meat products exported to the United States, July 27 - August 10, 2018.

N° of page and paragraph	*Comments*
	"At the local government level, inspection oversight is managed through Public Health Centers or ~~also described as~~ Meat Inspection Centers (MICs)."
Page 4 para2 MHLW administers the Japanese food safety inspection system and is responsible for directing, planning, and carrying out food safety and animal health and welfare controls.	As MHLW does not in charge of animal health and animal welfare in general, Japan would like to revise sentence shown below. "MHLW administers the Japanese food safety inspection system and is responsible for directing, planning, and carrying out food safety, animal health in slaughter establishments and animal welfare controls in certified slaughter establishments."
Page 4 para2 MHLW's authority to enforce inspection laws is outlined in the Abattoir Law (Law No. 114), Abattoir Law Enforcement Regulation (Ordinance No. 44), and Ordinance for Enforcement of the Food Sanitation Act (Ordinance No. 23)	As inspection in cutting plant is according to the Food Sanitation Law, Japan would like to revise sentence shown below "MHLW's authority to enforce inspection laws is outlined in the Abattoir Law (Law No. 114) and Food Sanitation Law (Law No.233) ~~Abattoir Law Enforcement Regulation (Ordinance No. 44), and Ordinance for Enforcement of the Food Sanitation Act (Ordinance No. 23)~~"
Page 4 para4 MHLW issues guidelines and instructions that define the frequency of supervisory reviews and the procedures for registration, approval, conditional approval, or suspension.	As guidelines and instructions describe the procedure for approval and issuing health certificate , supervisory reviews and suspension but conditional approval is not describe in the guidelines, Japan would like to revise sentence shown below. "MHLW issues guidelines and instructions that define the frequency of supervisory reviews, ~~the procedures for registration, approval, conditional approval~~ the procedure for approval and issuing health certificate and suspension "
Page 5, para 3 MHLW has the authority to assess	As the Food Sanitation Law also include the provisions of penalties, Japan would like to revise sentence shown below.

N° of page and paragraph	*Comments*
penalties for violations of food safety laws, as stated in the Abattoir Law.	"MHLW has the authority to assess penalties for violations of food safety laws, as stated in the Abattoir Law and Food Sanitation Law."
Page 7 para2 MHLW ensures that a veterinary medical officer must have a Doctor of Veterinary Medicine or equivalent degree.	In Japan, MHLW requires all meat inspectors to be veterinarians. This means that each meat inspectors is required to have a veterinary license. Japan would like to revise sentence shown below. "MHLW ensures that a veterinary medical officer must have ~~a Doctor of Veterinary Medicine~~ a veterinary license or equivalent degree."
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)	
Page 9, para 4 Specific diseases and dispositions are listed in the Abattoir Law (Law No. 114), and Abattoir Law Enforcement Regulation, (Ordinance No. 44 and No. 216). The FSIS auditor verified that veterinarians, as stated in the Abattoir Law Enforcement Regulation (Ordinance No.216), conduct all ante-mortem inspections of livestock prior to slaughter.	The diseases and dispositions stipulate Abattoir Law, Abattoir Law Enforcement Ordinance and Abattoir Law Enforcement Regulation. All ante-mortem inspection of livestock prior to slaughter stipulate in the provision of Abattoir Law. Therefore Japan would like to revise sentence shown below. "Specific diseases and dispositions are listed in the *Abattoir Law (Law No. 114),* ~~*and*~~ *Abattoir Law Enforcement Ordinance (Ordinance No. 216) and Abattoir Law Enforcement Regulation, (Ordinance No. 44* ~~and No. 216~~). The FSIS auditor verified that veterinarians, as stated in the *Abattoir Law (Law No. 114)* ~~*Enforcement Regulation (Ordinance No.216)*~~, conduct all ante-mortem inspections of livestock prior to slaughter."
Page 10, para 2 These included visual inspection, palpation, and incision of relevant	As Abattoir Law Enforcement Ordinance also include the ante- and post-mortem inspection method, Japan would like to revise sentence shown below.

N° of page and paragraph	***Comments***
portions of the animal described within the *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States, Japan's Manual of Procedures of Meat Inspection and Reinspection of Dressed Carcasses, Abattoir Law (Law No. 114),* and *Abattoir Law Enforcement Regulation (Ordinance No. 44 and No. 216).*	"These included visual inspection, palpation, and incision of relevant portions of the animal described within the *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States, Japan's Manual of Procedures of Meat Inspection and Reinspection of Dressed Carcasses, Abattoir Law (Law No. 114),* ~~*and*~~ *Abattoir Law Enforcement Ordinance (Ordinance No. 216)* and *Abattoir Law Enforcement Regulation (Ordinance No. 44* ~~*and No. 216*~~*).*"
Page 12, para4 The FSIS auditor verified that control over condemned materials is maintained through the *Abattoir Law (Law No. 114),* and *Abattoir Law Enforcement Regulation (Ordinance No. 44 and No. 216)*, including appropriate identification in accordance with the categories described therein; segregation in specially-marked or otherwise secure containers, and final documented disposal of these materials at nearby rendering facilities...	As the control of condemned material is included in Abattoir Law Enforcement Ordinance, Japan would like to revise sentence shown below. "The FSIS auditor verified that control over condemned materials is maintained through the *Abattoir Law (Law No. 114),*~~*and*~~ *Abattoir Law Enforcement Ordinance (Ordinance No. 216)* and *Abattoir Law Enforcement Regulation (Ordinance No. 44* ~~*and No. 216*~~*)*, including appropriate identification in accordance with the categories described therein; segregation in specially-marked or otherwise secure containers, and final documented disposal of these materials at nearby rendering facilities."
VI. COMPONENT THREE: GOVERNMENT SANITATION	
Page 13, para1 Through the *Abattoir Law (Law*	As Abattoir Law Enforcement Ordinance also include the sanitary standards, Japan would like to revise sentence shown below.

N° of page and paragraph	*Comments*
No. 114), and *Abattoir Law Enforcement Regulation (Ordinance No. 44 and No. 216)*, MHLW requires that establishments operate in a sanitary manner, and has specific requirements to maintain sanitary standards. Sanitation must be maintained around establishments in the following areas: ante-mortem, postmortem and processing.	"Through the *Abattoir Law (Law No. 114),* ~~*and*~~ *Abattoir Law Enforcement Ordinance (Ordinance No. 216)* and *Abattoir Law Enforcement Regulation (Ordinance No. 44* ~~*and No. 216*~~*)*, MHLW requires that establishments operate in a sanitary manner, and has specific requirements to maintain sanitary standards. Sanitation must be maintained around establishments in the following areas: ante-mortem, postmortem and processing."
VIII. COMPONENT FIVE: OVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS	
Page 17, para3 This protocol includes random sampling and testing of internal organs, fat, and muscle of carcasses for targeted residues, and secure delivery of residue samples to the designated JFRL in accordance with the prescribed methodology provided by MHLW based on Japan's Food Sanitation Act, Article 22.	As NRP sampling protocol including secure delivery of residue sample is prescribed in the Guidelines for Inspection of Certified Establishments Handling Meat for Exportation to the United States - Attachment 3 "Guidance for Implementation of Residual Chemical Monitoring", Japan would like to revise the sentence shown below. "This protocol includes random sampling and testing of internal organs, fat, and muscle of carcasses for targeted residues, and secure delivery of residue samples to the designated JFRL in accordance with the methodology prescribed in *Guidelines for Inspection of Certified Establishments Handling Meat for Exportation to the United States - Attachment 3 "Guidance for Implementation of Residual Chemical Monitoring*". "
Page 17, para3 Residue results are communicated to the MHLW headquarters, regional offices, and inspection personnel through e-mail.	Although the results are shared immediately through e-mail, JFRL also issues certificates of analysis. Japan would like to revise the sentence shown below. "Residue results are communicated to the MHLW headquarters through e-mail, regional offices, and inspection personnel through ~~e-mail~~ certificates. "

Comments on draft final report of an on-site equivalence verification audit conducted in Japan evaluating the food safety system governing meat products exported to the United States, July 27 - August 10, 2018.

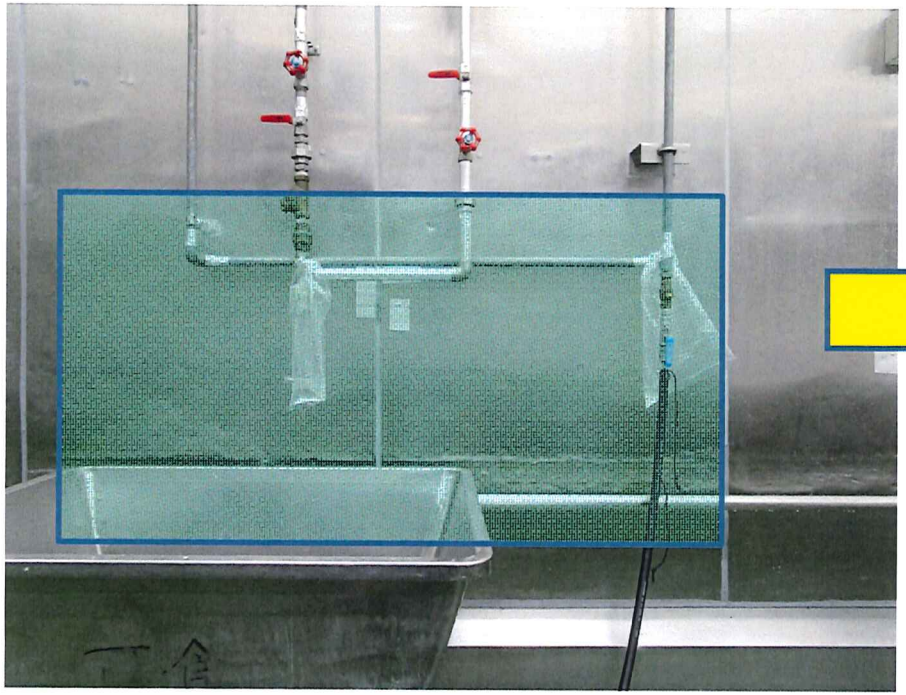
N° of page and paragraph	*Comments*
Foreign Establishment Audit Checklist（M-1）	
The MIC informed the establishment of the non-compliance. The CCA stated that the establishment has initiated a plan of action to address these issues and reassess their maintenance of equipment program to prevent the reoccurrence and will provide the information to inspection personnel. MHLW will provide FSIS additional measures taken to address the identified deficiency.	In accordance with e-mail to FSIS auditor dated on 7th August, M1 had already taken corrective action and preventive action. MIC and RBHW (Kyusyu) verified the corrective action and preventive action by M-1. The similar incident is not found up to now.
Foreign Establishment Audit Checklist（M-2）	
The MIC took immediate regulatory control and informed the establishment of the non-compliance. Immediate actions were taken by the establishment and MIC will verify establishment's additional measures to prevent the reoccurrence. MHLW will provide FSIS additional measures taken to address the identified deficiency.	18th August, 2018, The establishment installed a stainless steel cover which prevents the box or commodities from putting under the pipe (See attachment). MIC and RBHW (Kyusyu) verified the corrective action and preventive action by M-2.

Attachment: corrective action (M-2)

FSIS査察指摘事項改善措置

August 18, 2018

Ｍ－2　改善完了日　平成30年8月18日



指摘事項の改善策としてステンレス製のカバーを取り付ける事で配管下に可食容器が設置出来ない構造を施した。

横からの様子