



United States Department of Agriculture

Food Safety and
Inspection Service

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Dear Dr. Michino,

The USDA, Food Safety and Inspection Service (FSIS) conducted an on-site audit of Japan's meat inspection system from September 24 through October 9, 2015. 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.

If you have any questions, please feel free to contact me directly at jane.doherty@fsis.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Jane H. Doherty". The signature is fluid and cursive, written over the typed name and title.

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

JAPAN

SEPTEMBER 24 through OCTOBER 9, 2015

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING

MEAT PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

March 22, 2016

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from September 24 – October 9, 2015. The purpose of the audit was to determine whether Japan's food safety system remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and accurately labeled. Japan is eligible to export fresh (chilled or frozen) intact beef, processed beef, and processed pork to the United States although they currently only export fresh intact beef.

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

FSIS identified several findings within the following components.

Government Oversight:

- The Central Competent Authority (CCA) has no system or method to regularly assess the technical competence and performance of individual in-plant inspection personnel at establishments that export to the United States.
- The residue control program administered by the CCA does not include provisions that require establishments to control all affected products that the CCA tests for adulterants, so that they do not enter commerce until negative test results are received.

Statutory Authority and Food-Safety Regulations:

- The CCA in-plant inspection personnel inadequately performed the verification procedures related to the ability of an establishment to meet the standard for zero-tolerance contamination.
- The CCA in-plant inspection personnel failed to follow post-mortem inspection procedures to verify that carcasses identified with abnormalities have the abnormality properly removed by the establishment.
- The CCA in-plant inspection personnel failed to identify a deficiency regarding animal welfare (construction) in one of the six establishments audited.
- The CCA has not developed procedures for the implementation of adequate official control actions associated with sanitation non-compliances.

Sanitation:

- The CCA in-plant officials failed to identify sanitation non-compliances as they relate to sanitary dressing procedures and product handling at three of six establishments audited.
- The CCA in-plant officials failed to enforce sanitary performance standards (SPS) regarding construction and equipment deficiencies identified at three of six establishments audited to ensure that they remain in compliance with the regulations of the system.

During the audit exit meeting, the CCA committed to addressing the preliminary audit findings as presented. FSIS received a written response from the CCA addressing all outstanding concerns within 60 days of communication of the draft final audit report.

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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 meat inspection system from September 24 to October 9, 2015. The audit began with an entrance meeting in Tokyo, Japan with representatives from the Central Competent Authority (CCA) – Ministry of Health, Labor and Welfare (MHLW).

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This audit was a routine ongoing equivalence verification audit. The audit objective was to verify that Japan's food safety system for meat products is equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and accurately labeled.

To meet this objective, FSIS applied a risk-based procedure that included analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, Point-of-Entry (POE) testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process included an analysis of data collected by FSIS over a 3-year timeframe, in addition to information obtained directly from the CCA, through the FSIS Self-Reporting Tool (SRT).

MHLW representatives from headquarters, regional, and local inspection offices accompanied the FSIS auditors throughout the entire audit. A determination of program effectiveness was based on the CCA's performance within the six equivalence components: (1) Government Oversight (Organization and Administration), (2) Statutory Authority and Food Safety Regulations (Inspection System Operation and Product Standards), (3) Sanitation, (4) Hazard Analysis Critical Control Point (HACCP) System, (5) Government Chemical Residues Control Programs, and (6) Government Microbiological Testing Programs.

The FSIS auditors reviewed administrative functions at CCA headquarters, one regional office, and six local inspection offices. The FSIS auditors evaluated the implementation of a management control system that is in place to ensure the national system of inspection is implemented as intended.

FSIS audited six beef slaughter and processing establishments, certified as eligible to export raw fresh intact beef products to the United States. During the establishment visits, particular attention was paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight in accordance with 9 CFR 327.2, the FSIS regulations addressing equivalency determinations for foreign country inspection systems.

The Prefectural Meat Inspection Laboratory in Gunma, a government laboratory that conducts microbiological analyses related to United States exports was audited to verify its ability to provide technical support to Japan's meat inspection system. The evaluation of each component of Japan's meat inspection system also included a review of the answers they submitted to the

FSIS SRT documentation, as well as on-site record reviews, interviews, and observations made by the FSIS auditors at government offices and in the audited establishments.

A summary of specific audit locations is provided in the following table:

| Competent Authority Visits | | # | Locations |
|--|----------|---|---|
| Competent Authority | Central | 1 | • Tokyo |
| | Regional | 1 | • Fukuoka |
| Laboratories: Microbiological | | 1 | • Prefectural Meat Inspection Laboratory in Gunma – Government |
| Establishments: Beef Slaughter and Processing | | 6 | <ul style="list-style-type: none"> • Akune-shi, Kagoshima • Koyu-gun, Miyazaki • Miyakonojo-shi, Miyazaki • Soo-shi, Kagoshima • Sawa-gun, Gunma • Shiwa-gun, Iwate |

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

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.),
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. Title 7), and
- The Food Safety and Inspection Service Regulations for Imported Meat (9 CFR Part 327).

The audit standards applied during the review of Japan’s inspection system included: (1) all applicable legislation originally determined by FSIS as equivalent as a 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 Agreement.

Japan has an equivalence determination in place for the use of private laboratories for residue testing of official samples.

III. BACKGROUND

Japan is eligible to export raw intact beef and processed beef or pork products to the United States. Japan has no processing establishments certified as eligible to export processed beef or pork products to the United States market. An analysis of import data from May 29, 2013, to August 6, 2015, demonstrated that FSIS import inspectors performed 100% re-inspection on labeling and certification on 715,881 pounds of beef products that Japan has exported to the United States. FSIS performed additional Types of Inspection (TOI) on 286,366 pounds at POE. No product was rejected for food safety reasons.

FSIS last audited Japan in 2013 and reported that Japan’s meat inspection system remained equivalent with no systemic findings but for isolated deficiencies pertaining to the implementation of sanitation programs and adequacy of HACCP verification procedures. The CCA proffered corrective actions that were acceptable to FSIS to address the audit findings. The FSIS final audit reports for Japan’s food safety system are available on the FSIS’ website at:

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

The first of six equivalence components that the auditors reviewed was Government Oversight. FSIS import regulations require the foreign inspection system to be organized by the national government in such a manner as to provide ultimate control and supervision over all official inspection activities. In addition, these systems need to 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 verification of this component was based on information previously submitted in the SRT, in addition to on-site record reviews, interviews, and observations.

The FSIS auditors verified that the inspection system is organized and administered by the national government of Japan. There have been no major changes in the CCA's organizational structure since the last FSIS audit. Japan's administration of food safety is divided between national and local government levels. At the national level, the Ministry of Health, Labor, and Welfare (MHLW) is Japan's CCA. The 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, the 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.

The regional level consists of seven Regional Bureau of Health and Welfare (RBHW) offices across the country. The Food Sanitation Division (FSD) of these regional offices is responsible for conducting supervisory reviews of the United States-eligible establishments and recommending the approval and withdrawal of establishments.

At the local government level, there are 47 prefectural and 72 municipal governments. Local governments, through their Meat Inspection Centers (MIC), are in charge of the control of slaughter establishments. Each MIC has the responsibility to implement and enforce inspection laws at the United States-eligible establishments. The meat inspectors assigned to the MIC are responsible for carrying out all daily inspection activities. There are a specific and sufficient number of meat inspectors assigned to each of the United States-eligible establishments to carry out inspection activities. These meat inspectors complete specific training in food safety controls and meat inspection techniques provided by the CCA and local governments. All of the meat inspectors in certified slaughter establishments are veterinarians.

The MHLW administers the Japanese meat inspection system and is responsible for directing, planning, and carrying out food safety and animal health and welfare controls. The CCA 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.

The CCA's authority to enforce inspection laws is outlined in the *Abattoir Law (Law No. 114, August 1, 1953, as of June 27, 2007)*, *Abattoir Law Enforcement Regulation (Ordinance No. 44, September 28, 1953, as of March 27, 2015)*, and *Ordinance for Enforcement of the Food Sanitation Act (Ordinance No. 23, July 13, 1948, as of September 28, 2015)*. 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. The CCA 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.

FSIS requires that the selected carcass or products sampled for chemical residue testing be held or be controlled until the laboratory test results are reported negative. The FSIS auditors identified and were informed by the CCA that there is no requirement for establishments to hold or maintain control over any livestock carcass or products that the CCA selected to test for adulterants as part of the chemical residue testing control program.

The MHLW issues guidelines and instructions that deal with the frequency of supervisory reviews and the procedures for registration, approval, conditional approval or suspension. It also provides instructions on the withdrawal of approval of regulated establishments; the verification of the microbiological sampling program; how to perform an official inspection tasks; and the formulation of the residue monitoring plan and the method for carrying out the Japanese Residue Control Program. The CCA disseminates inspection information related to the regulatory and administrative affairs electronically by email to RBHW and to inspection personnel and establishments certified to export product to the United States.

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, and maintaining the official list of, establishments eligible to export to the United States. The FSD under the RBHW is responsible for conducting supervisory reviews in establishments certified as eligible to export to the United States.

The FSIS audit of the CCA Headquarters included an examination of its oversight activities, including the verification of audits of establishments conducted by the RBHW's FSD. These audits represent supervisory reviews. In addition, FSIS examined enforcement activities, verification activity reports, and training records for official personnel by interviewing departmental personnel and reviewing documentation.

The CCA has a written protocol, *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States*, which describes the procedures that establishment operators should follow to obtain approval from MHLW to become certified to export and the actions taken by government officials at each step of the approval process. The CCA has the

sole authority to grant final certification of a new establishment or to permit an existing United States-certified establishment to maintain its eligibility to export to the United States or decertify the establishment.

The FSIS auditors verified elements of *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States*. These documents include a registration form, initial approval determinations, and certification documents maintained by government officials at the CCA headquarters, including sections that correspond to the sanitation requirements, facility maintenance, Sanitation Standard Operating Procedures (SSOP) and HACCP programs, and generic *E. coli* testing. The FSIS auditors verified that the CCA officials have conducted the approval process in accordance with Japan's prescribed procedures. These documents corresponded to an establishment that MHLW certified to export to the United States in 2011. The auditors observed that inspection officials had reviewed the documents submitted by the establishments, audited the facilities, and evaluated their ability to meet regulatory requirements before granting certification to export meat to the United States.

MHLW certifies designated inspectors assigned to establishments eligible to export products to the United States. The inspection personnel assigned to establishments certified to export meat to the United States are civil servants paid by the government and are required to be full-time government employees. The local government pays the salaries of the meat inspection system personnel. The national government financially supplements the local governments' payment for meat inspection.

During this audit, the FSIS auditors verified that the CCA has implemented and routinely conducted ongoing training programs intended to ensure that inspection officials are aware of specific food safety and inspection requirements that pertain to beef production for export to the United States. All training conducted by the CCA is presented to inspection personnel as a maintenance program in addition to conducting training related to program updates on inspection related issues and procedures. The auditors observed in-plant inspection personnel while they were conducting their inspection activities and laboratory personnel performing daily activities.

The FSIS auditors verified that both in-plant inspection and laboratory personnel have attended training programs. However, the CCA has no system or method in use to regularly assess the technical competence and performance of individual in-plant inspection personnel in conducting official inspection activities at establishments that export to the United States. Individual inspection personnel are not evaluated on their performance.

The CCA maintains adequate administrative and technical support to operate its laboratory system. Government laboratories operate in accordance with criteria aligned with International Organization for Standardization (ISO) 17025 standard. Private laboratories are accredited by the Japanese Accreditation Board (JAB) annually according to the ISO 17025 standard and are approved by MHLW. The CCA through the RBHW's regional auditors of FSD conduct the prescribed annual audit of the laboratory quality system in accordance with *Japan's Food Sanitation Law and Manual on How to Manage Examination, etc. at Testing laboratories – Annex 20*. The CCA annual audit report includes administrative and technical aspects of the analytical methodology, laboratory personnel qualifications, training, and maintenance of the

laboratory equipment. In addition, the RBHW auditors audit the microbiological laboratories on a monthly basis.

FSIS auditors selected the Prefectural Meat Inspection Laboratory, a government laboratory located in Gunma to verify the functions and oversight provided by the CCA. The laboratory was accredited in accordance with protocols designed by the CCA that are in line with ISO 17025. The FSIS auditors reviewed the CCA, third-party reviews, and audit reports generated for the previous year at CCA Headquarters and at the audited laboratory. No concerns arose as the result of these reviews. FSIS' on-site audit did not identify any issues with the government microbiological laboratories.

The audit determined that the Japanese government organizes and administers the country's meat inspection system, and that CCA officials enforce laws and regulations governing production and export of meat at certified establishments. However, the on-site audit findings indicate a need for the CCA to develop and implement procedures for the evaluation of the performance of individual inspectors.

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

The second of the six equivalence components that the FSIS auditors reviewed was Statutory Authority and Food Safety Regulations. The system is to provide for humane handling and slaughter of livestock, ante-mortem inspection of animals, post-mortem inspection of carcasses and parts, controls over condemned materials, controls over establishment construction, facilities, and equipment, daily inspection, and supervisory visits to official establishments.

The FSIS auditors verified that the CCA maintains regulatory authority as outlined in official legislation, regulations, ordinances, and other regulatory instructions issued in accordance with Japan's *Abattoir Law*, *Abattoir Law Enforcement Regulation*, *Food Sanitation Act*, *Ordinance for Enforcement of the Food Sanitation Act*, and *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States*. These documents outline Japan's sanitation policies and sanitary measures to protect public and animal health in live animals and animal products, and HACCP requirements. There are no other regulatory changes associated with the export of meat products to the United States since the last audit that would have required changes by the CCA.

The FSIS auditors performed on-site observations and reviewed records maintained by inspection personnel at headquarters, regional, and in-plant MIC inspection offices. The FSIS auditors verified that the CCA provides to its inspection personnel stationed at the six beef slaughter and processing establishments audited with appropriate oversight and direction for them to use their regulatory authority to enforce requirements for Japan's food safety system governing meat products exported to the United States. The FSIS auditors, accompanied by the CCA representatives, observed the performance of verification activities by the in-plant inspection personnel. The verification activities observed included ante-mortem inspection; humane handling and slaughter monitoring; post-mortem inspection; zero-tolerance verification

of establishment's procedures for controlling of feces, ingesta, and milk contamination; *Salmonella* sample collection; analysis of establishment generic *Escherichia coli* (*E. coli*) sample results; verification of pre-operational and operational sanitation verification procedures; and HACCP verification activities.

Additionally, FSIS auditors assessed the performance evaluation of in-plant inspection personnel and the completion of supervisory reviews of establishments certified eligible to export to the United States. The FSIS auditors determined that regulatory verification and inspection activities were consistently implemented at all establishments audited. Officials use the authority conferred upon them by the laws of Japan to enforce the rules of their meat inspection system, to identify and document non-compliances, and to verify the adequacy of corrective actions and preventive measures.

The FSIS auditors verified through direct observation, on-site record reviews, and interviews that in-plant inspection personnel's ante-mortem inspection activities complied with Japan's *Guideline of Meat Inspection, Abattoir Law, Article 14 and 19*, and *Abattoir Law Enforcement Regulation, Article 14 and 16*. Inspection personnel reviewed the in-coming registration and 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 (NLBC) System where 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 inspection personnel also observe all animals from both sides while at rest and in motion in designated holding areas before slaughter in order to determine whether the animals are fit for slaughter. Each establishment audited maintains a designated holding pen for further examination of sick or suspect animals. The FSIS auditors observed and verified that all animals have access to water in all holding pens, and that establishments have procedures to provide feed if animals are held for more than 24 hours.

In-plant inspection personnel verify that operators comply with humane handling requirements and document the results of daily verification to ensure that livestock are humanely handled and slaughtered. The FSIS auditors verified at each establishment audited that the CCA implemented adequate corrective actions to address the finding reported during the audit conducted by FSIS in 2013 related to government inspectors not being able to describe the procedures to be followed to verify adequacy of stunning procedures. The inspectors verify through observation loss of consciousness and accompanying indicative signs of adequate stunning before cattle are shackled and bled. However, the FSIS auditors did identify one finding associated with the humane handling in regards to the construction and maintenance of the livestock barn.

- In one establishment, a stainless steel grate anchored on the floor of the livestock-holding barn had several bolts that protruded out of the floor surface. Although the FSIS auditors did not observe any incidents involving livestock becoming injured, the protruding bolts create a condition that could cause injuries to the feet of livestock.

The implementation of the ante-mortem inspection complies with Japan's requirements for humane handling and slaughter of livestock.

The FSIS auditors verified that written procedures are in place that instruct inspection personnel on how post-mortem examination is to be performed. These included visual inspection, palpation, and incision of relevant portions of the animal described within Japan's *Manual of procedures of Meat Inspection and Re-inspection of Dressed carcasses, Abattoir Law (Article 14 and 19)*, and *Abattoir Law Enforcement Regulation (Article 14 and 16)*.

The FSIS auditors verified, through direct observation that proper presentation, identification, examination, and disposition of carcasses and parts is being implemented. The FSIS auditors observed the performance by the inspection personnel of their examination of bovine heads, viscera, and carcasses using the proper incision, observation, and palpation of required organs and lymph nodes. Their examinations were made in accordance with the aforementioned document, which has been recognized as equivalent to FSIS requirements. However, the FSIS auditors did identify the following deficiency at one slaughter establishment recently added to the list of certified establishments:

- The MIC carcass inspector instructed the trimmer to remove a bruise located on the rump of the carcass; however, the inspector did not verify that the trimmer correctly performed the required trimming, and the carcass continued to the cooler without adequate trimming of the bruise.

FSIS' 2013 audit reported that the CCA had no written staffing standard in place. During this audit, the FSIS auditors verified that the CCA has developed a written staffing standard based on the species slaughtered and line speeds for use at United States-eligible establishments to meet FSIS equivalency requirements and to ensure sufficient staffing in the event of increased production volume. The FSIS auditors also verified that MIC inspection supervisors were aware of this standard, and that the number of inspection personnel conducting post-mortem inspection activities is sufficient for the existing production volume and line speed. In Japan, the United States-eligible establishments slaughter an average of 70 cows per day. The MIC assigns inspectors for head inspection, viscera inspection, and carcass inspection. There is also one off-line inspector and one inspector for conducting ante-mortem examination at each establishment.

The FSIS auditors also observed the functions of the off-line inspectors who conduct daily inspection and verification activities in all six audited establishments. These off-line daily verification activities include direct observation and record review procedures related to SSOP, Sanitation Performance Standards (SPS), HACCP, and generic *E. coli* sampling, in accordance with the MIC daily inspection verification schedule plan outlined in the *Daily Monitoring Verification* form.

The FSIS auditors conducted direct observations of in-plant inspection personnel as they conducted verification of adequacy of establishment's monitoring of the critical control point for zero-tolerance of feces, ingesta, and milk contamination and reviewed documented inspection verification results. The FSIS auditors did not observe any non-compliance related to zero-

tolerance deviations on the day of the audit. However, FSIS auditors did identify the following finding in one establishment.

- FSIS auditors observed that the MIC inspector performs the verification of zero-tolerance at the same point where the establishment conducts final trimming of carcasses, not permitting the inspector to evaluate the ability of the establishment to meet the zero-tolerance standard because the assessment is not being made after the carcass has passed establishments trimming/monitoring step.

In addition, the FSIS auditors identified the following findings associated with daily inspection activity:

- In one establishment, the off-line inspector was not documenting non-compliances on the daily inspection verification report as the form instructs and is prescribed by the RBHW. The records show that areas and surfaces identified during pre-operational sanitation inspection as deficient are entered in the record as acceptable after corrective measures are implemented, thus preventing the record from showing the results of the initial inspection. This practice could lead to possible confusion in analysis of trends that may emerge at the local level.
- In two establishments, the MIC inspectors did not take official control action to preclude use of equipment and production areas that were unacceptable, or when direct product contamination occurred.

The FSIS auditors also reviewed and verified the application of CCA's supervisory reviews at certified establishments. The reviews of records demonstrated that government officials evaluate the adequacy of the establishments' food safety system and the capability of inspection as a whole in conducting inspection activities at certified establishments. These reviews are conducted by the RBHW's export meat inspection officers from the FSD in accordance with updated *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States (4-27-15)* and *Guidelines for Inspection of Certified Establishments Handling Meat for Exportation to the United States (3-31-14)*. This document contains instructions for inspection officers carrying out the verification of ante-mortem examination, humane handling and slaughter activities, post-mortem examination, *Salmonella* and generic *E. coli* sample collection, verification of pre-operational and operational sanitation procedures, and HACCP verification activities (including the zero-tolerance Critical Control Point (CCP) verification) and where to document the outcome of the reviews.

During this audit, FSIS verified that RBHW had documented outcomes of supervisory reviews, which are conducted at least once a month for establishments that are eligible to export to the United States. The supervisory reviews are conducted using a standardized 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 inspection verification of SSOP, HACCP, Economic/Wholesomeness, Generic *E. coli*, *Salmonella*, Economic Sampling, and Other Requirements. The second part is the inspection requirements section designed for evaluating the knowledge, skills, and abilities of in-plant inspection personnel stationed at the United States-eligible establishments. However, as

discussed in the government oversight section of this report, the evaluation is based on the workforce as a whole, rather than on an individual basis.

The supervisory review report is distributed to the audited establishment, in-plant inspection, and the related RBHW office. The in-plant inspection personnel 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 verifying that the in-plant inspection personnel had verified those corrective actions in order to verify the effectiveness and implementation of the establishment's action plan. RBHW submits a copy of the monthly supervisory reviews to the CCA headquarters for further review and analysis. The FSIS auditors reviewed the supervisory reviews and inspection related records and concluded that they were consistent with their observations at the establishments.

The FSIS auditors identified several isolated non-food safety deficiencies. These deficiencies included several bolts protruding out of the floor surface in the holding pen, one MIC inspector not verifying completion of required trimming, inadequate placing of trimmer station, inadequate assessment of the ability of the establishment to meet the zero-tolerance for contamination standard, and inadequate official control actions related sanitation non-compliances and product contamination. The FSIS verified that the CCA and the establishments have adequately addressed the reported deficiencies.

VI. COMPONENT THREE: SANITATION

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

FSIS reviewed the legislation, regulations, official instructions, and guidelines of the CCA and verified that the MHLW uses its legal authority in *Abattoir Law* and *Abattoir Law Enforcement Regulation* to require that certified establishments develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions.

The FSIS auditors verified that the in-plant inspection personnel at six audited establishments exercise their official authority as prescribed by the regulations of the system and follow guidance provided by MHLW to conduct verification of sanitary conditions. These actions are in accordance with *Guidelines for Inspection of Certified Establishments Handling Meat for Exportation to the United States* and with requirements cited in *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States, Attachment 2, Sanitation Control Standards, Parts I, II, and III*.

The CCA demonstrated that it enforces these requirements in that the in-plant inspection personnel at certified establishments conduct verification of sanitary conditions in accordance with the aforementioned documents, including the evaluation of written sanitation programs, verification of both pre-operational and operational sanitation implementation and monitoring of sanitation procedures including hands-on verification inspection, and records reviews. FSIS

auditors observed that the frequency at which inspection personnel perform verification of standard sanitation operating procedures (SSOP) and sanitation performance standards (SPS) procedures is set to a daily occurrence at all visited establishments.

The FSIS auditors assessed the adequacy of pre-operational inspection by directly observing the in-plant inspection personnel conducting pre-operational verification of the establishment's sanitation program at one of the audited establishments. The in-plant inspection personnel 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 sanitation performance standard requirements (e.g., ventilation, condensation, and structural integrity).

In addition, the FSIS auditors observed in-plant inspection personnel's verification of operational sanitation procedures in all six establishments audited, comparing the overall sanitary conditions of all audited establishments to the MIC inspection verification documentation. The FSIS auditors' verification activities included direct observation of operations and review of the establishments' sanitation monitoring and corrective action records over a 3-month period at all establishments, as well as the MIC documentation of inspection verification results, including the non-compliance report and RBHW supervisory reviews of each establishment. The FSIS auditors noted that the inspection and establishment records mirrored the actual sanitary conditions of the establishment, and that there were no major concerns identified during the document reviews.

The FSIS auditors identified SPS findings at several audited establishments concerning the CCA's ability to exercise regulatory control over facility construction and maintenance of equipment above exposed product areas, maintenance of direct product contact equipment, and sanitary operations – in the slaughter and product holding areas of establishments eligible to export to the United States.

- In two establishments, sanitary dressing procedures were found to be deficient.
 - One establishment was not completely removing the “stick wound” from the neck of the carcasses during the slaughter dressing process.
 - On the slaughter floor of one of the audited establishments, an employee assigned to remove the hide from the hind leg was causing cross contamination from the unskinned leg of the carcass to the employee's work clothes and from his work clothes to the skinned leg.
- In one establishment, the carcasses held in the coolers were not consistently segregated by age. Carcasses of different ages were hung in close proximity to each other in the coolers. Carcasses from cattle older than 30 months of age contacted the surfaces of carcasses less than thirty months of age.

FSIS also observed that inspection personnel did not exercise regulatory control when SSOP implementation deficiencies were identified at the establishments audited that are eligible to export to the United States.

- In one establishment, an establishment employee at the “hide pulling station” was not consistently washing his hands after touching the hide of the carcass and thereby creating cross contamination when touching the skinned head of the carcasses.
- In one establishment, an employee in the fabrication area resumed duties without washing and sanitizing his contaminated gloves after touching the wheel of a product transport cart.

The CCA required that corrective actions be taken immediately to address the FSIS auditors’ observations of direct product contamination and issued instructions for the establishment to correct the deficiencies. The CCA did not, however, establish control of the equipment and product that was involved in the reported events. Discussions with inspection personnel, verification of records, and supervisory reviews did not show that the establishment or the MIC inspection personnel had observed similar findings in the previous 120 days.

The CCA needs to ensure that in-plant officials improve their ability to evaluate the sanitation programs implemented by the establishments. In addition, the CCA needs to increase its surveillance of sanitation non-compliances within certified establishments.

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

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

The verification and evaluation of this component included the documents that MHLW issued as instructions for the implementation of HACCP programs in United States-eligible establishments. These documents included *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States, Attachment 3 - Standards for Implementation of Sanitation Control by HACCP* and *Guidelines for Inspection of Certified Establishments Handling Meat for Exportation to the United States*. These documents require that establishments exporting to the United States develop, implement, and maintain HACCP programs. Furthermore, they require that the CCA verify the validity of the establishment’s HACCP plan by assessing whether the plan complies with all applicable requirements. In addition, the MHLW sends an export meat inspection officer from RBHW to certified establishments and the MIC offices at least once a month to conduct inspection/verification of procedures of the HACCP program that are performed by the establishment and MIC.

The verification of the validity includes the review of all aspects of the written HACCP programs, based on procedures in *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States, Attachment 3 - Standards for Implementation of Sanitation Control by HACCP*. This verification includes such activities as the evaluation of written HACCP programs and observing the establishment personnel perform monitoring, verification, corrective actions, and recordkeeping activities.

The FSIS auditors reviewed *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States, Attachment 3 - Standards for Implementation of Sanitation*

Control by HACCP and compared the contents of the audited establishment's HACCP plans with corresponding establishment's monitoring, corrective actions, and verification records as well as Japanese inspection's verification records for the past three months. The FSIS auditors' review indicated that the HACCP documents generated by establishments were in compliance with the aforementioned documents. However, in one establishment the FSIS auditors identified that the Slaughter Hazard Analysis does not identify the possibility of Specified Risk Materials (SRMs) as a possible hazard at the carcass chilling step in the process that is prevented by the segregation of carcass in the coolers. The establishment has a SOP for the removal and control of SRMs that states that all cattle slaughtered at the facility will be treated as ≥ 30 months. However, the establishments does not reference the SRM SOP at this step in the process or make any reference that all cattle slaughtered at this facility will be treated as ≥ 30 months within the Hazard Analysis.

FSIS verified that in-plant inspection personnel conducted daily verification of HACCP plans in accordance with aforementioned *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States, Attachment 3 - Standards for Implementation of Sanitation Control by HACCP*. 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 that direct them to conduct specific HACCP plan verification tasks and document daily inspection verification activities, including findings and actions taken. There was no indication of any non-compliance trends resulting from the review of these documents.

At the six beef slaughter processing establishments audited, the FSIS auditors conducted an on-site review of the zero-tolerance (feces and ingesta contamination) CCP records generated during the past three months. In addition, the FSIS auditors reviewed the verification records associated with MIC zero-tolerance inspection tasks. The review of these records found no identified deviations from the critical limit. Inspection verification records showed no zero-tolerance non-compliances for the same timeframe.

The FSIS auditors observed the inspection personnel conducting HACCP hands-on verification activities at this CCP location, making a direct examination of bovine carcasses. The inspection personnel and the FSIS auditors observed no deviation from the critical limits on the day of the audits.

The FSIS auditors' review of documents pertaining to hazard analysis, HACCP plan, monitoring, verification, and corrective actions implementation by establishments as well as on-site observation of the inspection personnel conducting inspection task and associated inspection verification records, revealed an adequate HACCP food safety system in the audited establishments. However, the CCA should ensure uniform implementation of regulatory requirements that all potential hazards are identified at each step of the process within the hazard analysis as related to the described audit observation within this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

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

FSIS based its verification of Japan's Residue Control Program (JRCP) on information contained in Japan's *Food Sanitation Law*, *Abattoir Law*, and Annual Residue Control Plan (2015), in association with the previous two year's (2013 and 2014) testing results. These documents indicate 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 contaminants in the tissues of bovine slaughtered for processing into meat for human consumption. This regulatory task is accomplished with the participation of the RBHW. The CCA maintains oversight of its residue laboratory system through an annual audit of residue laboratories conducted by RBHW regional auditors. The CCA'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 CCA's document *Guidance for Implementation of Residual Chemical Monitoring* states that meat products intended for export to the United States should be analyzed for the following substances: antibiotics, synthetic antimicrobials, anti-parasitics, heavy metals, and pesticides.

The residue laboratory network consists of the Japan Food Research Laboratories (JFRL), which is an independent, private institution accredited by the CCA 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 for the testing laboratories under JRCP.

The FSIS auditors verified that JRCP is designed and conducted in accordance with Japan's *Food Sanitation Law*. The program 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 addition, to prevent the violations from re-occurring, the cause of the residue violation is investigated using both the domestic and the United States standards. Local governments publish a written disposition order or a written improvement order when they identify violative products. Japan's residue plans are recognized as equivalent to FSIS' criteria.

FSIS's review of JRCP indicated that Japan's national testing plan for 2014 was effectively implemented as designed, and that the 2015 plan was on schedule. Inspection personnel within

the slaughter facilities collect samples that include muscle, fat, and organ tissues of randomly selected slaughtered animals in accordance with the prescribed methodology provided by the CCA based on Japan's *Food Sanitation Act, Article 22*. FSIS's review of documentation at the six local inspection offices audited showed that in-plant officials were collecting samples of the required matrices for detection of specific analytes and adhering to the prescribed sample collection schedule. FSIS' review of the monitoring results for 2013, 2014, and 2015 to date found that no violative samples were detected. FSIS' review of POE import data has not identified any violations for chemical residues during routine testing of product from Japan that occurs at United States POE since the last audit in 2013.

During interviews with CCA, regional and establishment inspection officials, it was determined that the CCA does not have a requirement for establishments to hold or maintain control over any livestock carcass or products that the CCA tests for adulterants pending reporting of the test results. The CCA has no policy or procedure to address what measures it would take in response to a violative level. FSIS discussed this deficiency in the Government Oversight component of this report.

The meat inspection system of Japan has regulatory requirements that are necessary for a chemical residue control program that is organized and administered by the national government. The program includes random sampling of internal organs, muscle, and fat of carcasses for chemical residues, and the program is adjusted on a yearly basis to address emerging concerns. The program also 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. However, the CCA has no policy or procedure to address what measures it would implement to respond if livestock carcasses or affected products that had entered commerce were found to have residue levels over the level for adulteration in Japan's Residue Monitoring Control Plan.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

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

The evaluation of this component included a review and analysis of Japan's document *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 aforementioned document describes the official inspection methodology for a continuous and systematic assessment of inspection activities during routine verifications of microbiological testing, including *Salmonella* spp. by inspection personnel and generic *E. coli* by regulated slaughter establishments. Specific rules for testing and minimum sampling are written in the aforementioned document.

The MHLW provides for a sampling and testing program for generic *E. coli* in raw product. These requirements have been developed especially for those establishments exporting to the United States and represent a “same as” adoption of the United States requirements found in 9 CFR 310.25, with a focus on bovine slaughter as the only species eligible for export to the United States.

The CCA conducts verification activities that monitor the establishment’s generic *E. coli* testing program in chilled bovine carcasses. The CCA uses the test results to verify establishment slaughter dressing controls for fecal contamination. Inspection personnel verify that an establishment’s written plan addresses the location of sampling, randomness of sampling, and sample integrity. Furthermore, the in-plant inspectors verify that establishments use appropriate sampling methodology; that their laboratory use an appropriate method for analysis; that the results are correctly evaluated; and that establishments take appropriate corrective action when a violation occurs.

The FSIS auditors verified through document reviews and direct observation that the six audited slaughter and processing certified establishments had implemented a generic *E. coli* testing program to verify process control of livestock carcasses in accordance with Japan’s, *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States*. The FSIS auditors also reviewed testing results for the last year showing that the establishments routinely met their limits, and that there has not been any loss of process control as determined by statistical process control. The FSIS auditors’ review of the establishment’s generic *E.coli* in-plant testing program and of the establishment’s records did not reveal any non-compliance or concerns because of this review. The testing program complies with FSIS’s equivalence criteria.

The FSIS auditors also reviewed sampling results for the last 180 days, which showed that the establishments routinely met their limits as determined by statistical process control. The FSIS auditors’ review of the establishment’s generic *E.coli* in-plant testing program and of establishments’ records did not reveal any non-compliance or concerns because of this review.

The CCA has a *Salmonella* sampling and testing program in raw product that mirrors FSIS’s *Salmonella* Performance Standards requirements cited in 9 CFR 310.25(b). In-plant inspection personnel collect *Salmonella* samples from chilled bovine carcasses without prior notice given to the establishments. The analytical testing is conducted in the MIC microbiology laboratory, which is audited by RBHW regional auditors on a monthly basis. *Salmonella* set consisted of 82 samples with a maximum number of positives to achieve the standard to be ≤ 1 , which is equivalent.

The FSIS auditors reviewed Japan’s *Salmonella* sampling and testing program, the implementation of the program within certified establishments by the inspection personnel, and the results and records resulting from the program. Sampling and testing of carcasses for *Salmonella* occur in all certified establishments that slaughter livestock. The MIC inspection personnel perform carcass sampling for *Salmonella* species at all establishments audited. The CCA verifies that all certified establishment inspection sample collection procedures are in accordance with its sample collection protocols described in *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States*.

The FSIS auditors reviewed 180 days of records at the six slaughter and processing establishments audited which identified that no *Salmonella* failures had occurred. In addition, the FSIS auditors accompanied and observed the in-plant inspection verification activities for sponge sampling collection from bovine carcasses for *Salmonella* testing in one of the audited establishments. The demonstrated methodology is in compliance with Japan's United States-export requirements. It should be noted that Japan chooses to only export raw intact beef to the United States. Therefore, *E. coli* O157:H7 and Shiga Toxin-Producing Escherichia coli (STEC) testing is not conducted for product exported to the United States. No concerns arose as the result of these observations.

The CCA 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.

The FSIS auditors also reviewed the Prefectural Meat Inspection Laboratory in Gunma, a government microbiological laboratory. The FSIS auditors verified that the laboratory is operating in accordance with criteria aligned with ISO 17025. 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 auditors' document review made evident that analyst had successfully participated in inter-laboratory proficiency testing. Documentation on file also demonstrated that the analysts possess the academic qualifications, technical credentials, and accreditations required to conduct analysis within their accreditation scope.

In addition, the FSIS auditors observed and verified sample handling, sampling frequency, and the trace-back of a selected sample from a United States eligible establishment. The FSIS auditors verified that the laboratories do a timely analysis of samples, and that they timely report data to the CCA, apply approved analytical methodologies, and have laboratory quality assurance programs including standards books and corrective actions. No concerns arose because of these observations and reviews. The FSIS auditors verified that a RBHW regional auditors conducts the prescribed annual audit of the laboratory quality system in accordance with Japan's *Food Sanitation Law* and the aforementioned manual. During the regional audit the FSIS auditors reviewed the last annual audit report of the laboratory. There were no findings from the document review.

Japan's meat inspection system has regulatory requirements for a microbiological sampling and testing program that is organized and administered by the national government in accordance with Japan's equivalent requirements.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on October 9, 2015, in Tokyo, Japan with MHLW. At this meeting, the FSIS auditors presented their preliminary findings. The CCA understood and accepted the findings.

The audit results and analysis did not identify any audit findings that reflect a deficiency in the inspection system that presented a potentially imminent threat to public health requiring an immediate regulatory response by FSIS. However, FSIS identified several findings within the following components.

Government Oversight:

- The Central Competent Authority (CCA) has no system or method to regularly assess the technical competence and performance of individual in-plant inspection personnel at establishments that export to the United States.
- The residue control program administered by the CCA does not include provisions that require establishments to control all affected products that the CCA tests for adulterants, so that they do not enter commerce until negative test results are received.

Statutory Authority and Food-Safety Regulations:

- The CCA in-plant inspection personnel inadequately performed the verification procedures related to the ability of an establishment to meet the standard for zero-tolerance contamination.
- The CCA in-plant inspection personnel failed to follow post-mortem inspection procedures to verify that carcasses identified with abnormalities have the abnormality properly removed by the establishment.
- The CCA in-plant inspection personnel failed to identify a deficiency regarding animal welfare (construction) in one of the six establishments audited.
- The CCA has not developed procedures for the implementation of adequate official control actions associated with sanitation non-compliances.

Sanitation:

- The CCA in-plant officials failed to identify sanitation non-compliances as they relate to sanitary dressing procedures and product handling at three of six establishments audited.
- The CCA in-plant officials failed to enforce sanitary performance standards (SPS) regarding construction and equipment deficiencies identified at three of six establishments audited to ensure that they remain in compliance with the regulations of the system.

During the audit exit meeting, the CCA committed to addressing the preliminary audit findings as presented. FSIS received a written response from the CCA addressing all outstanding concerns within 60 days of communication of the draft final audit report.

Appendices

Appendix A: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|--|---|-----------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION Akune Meat Distribution Center Co., Ltd. / Starzen Meat Processor Co., Ltd. 10, 1-chome Shiohama-cho Akune-shi, Kagoshima | 2. AUDIT DATE 09/29/2014 | 3. ESTABLISHMENT NO. K-3 | 4. NAME OF COUNTRY Japan |
| | 5. NAME OF AUDITOR(S) Kenneth E. Witek – SPA, CSO & Francisco Gonzalez – SPA, DVM | | 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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. Monthly Review | |
| Salmonella Performance Standards - Basic Requirements | | 58. | |
| 30. Corrective Actions | | 59. | |
| 31. Reassessment | | | |
| 32. Written Assurance | | | |

60. Observation of the Establishment Akune Meat Distribution Center Co., Ltd. / Starzen Meat Processor Co., Est. K-3, Bovine Slaughter/Processing, 09/29/2015

Residue Sampling Program:

The CCA has not issued instructions to in-plant inspectors this establishment that requires them to hold or maintain control over any livestock carcass selected for directed residue sampling until the CCA's laboratory test results are reported. This establishment does not hold the selected carcass pending the test results for residue sampling.

61. NAME OF AUDITOR
Kenneth E. Witek – SPA, CSO &
Francisco Gonzalez – SPA, DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|--|---|-----------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION Minami-Kyusyu Chikusan Kogyo Corp., Ltd. 1828 Ninokata, Sueyoshi-cho Soo-shi, Kagoshima | 2. AUDIT DATE 09/30/2015 | 3. ESTABLISHMENT NO. K-1 | 4. NAME OF COUNTRY Japan |
| | 5. NAME OF AUDITOR(S) Kenneth E. Witck – SPA, CSO & Francisco Gonzalez – SPA, DVM | | 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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. | X | 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. Monthly Review | |
| Salmonella Performance Standards - Basic Requirements | | 58. Inspection Verification Documentation | X |
| 30. Corrective Actions | | 59. | |
| 31. Reassessment | | | |
| 32. Written Assurance | | | |

60. Observation of the Establishment Minami-Kyusyu Chikusan Kogyo Corp., Ltd., Est. K-1, Bovine Slaughter/Processing, 09/30/2015

15/51 HACCP Hazard Analysis:

The establishments Slaughter Hazard Analysis does not identify the possibility of SRMs as a biological hazard to control or prevent in the carcass coolers. Additionally, the establishment has a standard operating procedure (SOP) for the removal and control of SRMs that states that all cattle slaughtered at this facility will be treated as \geq 30 months. Implementation of that SOP was verified by the FSIS auditors. However, the establishments does not reference in the hazard analysis, the SRM SOP or make any reference that all cattle slaughtered at this facility will be treated as \geq 30 months.

[Regulatory reference: 9 CFR 310.22, 327(a)(2)(i)(D), 417.2, 417.5, 417.8]

58 Inspection Verification Documentation:

The review of inspection daily verification reports identified that the off-line inspector that conducts sanitation, HACCP and other verification tasks was not documenting the non-compliances as stated in the instructions on the document from the CCA (RBHW). The instructions on the report indicate that a "U" should be indicated for a task where non-compliances were identified by the inspector and "A" when conditions were acceptable. However, non-compliances for pre-operational sanitation were documented with an "A" for acceptable instead of "U". It should be noted that a description of the non-compliance was always recorded by the inspector. When asked, the inspector stated that he marked an "A" because he verified that it was corrected. The record did however include a section on the back of the form for the follow-up verification of a non-compliance by the inspector which was also filled out adequately.

[Regulatory reference: 9 CFR 327(a)(2)(i)(C), 416.17]

Residue Sampling Program:

The CCA has not issued instructions to in-plant inspectors this establishment that requires them to hold or maintain control over any livestock carcass selected for directed residue sampling until the CCA's laboratory test results are reported. This establishment does not hold the selected carcass pending the test results for residue sampling.

61. NAME OF AUDITOR
Kenneth E. Witek – SPA, CSO &
Francisco Gonzalez – SPA, DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|---|---|-----------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION Miyachiku Corp., Ltd. - Takasaki Plant 4268-1, Omuta Takasaki-cho Miyakonojo-shi, Miyazaki | 2. AUDIT DATE 10/01/2015 | 3. ESTABLISHMENT NO. M-1 | 4. NAME OF COUNTRY Japan |
| | 5. NAME OF AUDITOR(S) Kenneth E. Witek - SPA, CSO & Francisco Gonzalez - SPA, DVM | | 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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/Park 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. Monthly Review | |
| Salmonella Performance Standards - Basic Requirements | | 58. | |
| 30. Corrective Actions | | 59. | |
| 31. Reassessment | | | |
| 32. Written Assurance | | | |

60. Observation of the Establishment Miyachiku Corp., Ltd. - Takasaki Plant, Est. M-1, Bovine Slaughter/Processing, 10/01/2015

Residue Sampling Program:

The CCA has not issued instructions to in-plant inspectors this establishment that requires them to hold or maintain control over any livestock carcass selected for directed residue sampling until the CCA's laboratory test results are reported. This establishment does not hold the selected carcass pending the test results for residue sampling.

61. NAME OF AUDITOR
Kenneth E. Witek – SPA, CSO &
Francisco Gonzalez – SPA, DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|---|---|-----------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION Miyachiku Corp., Ltd. - Tsuno Plant 15530, Kawakita Tsuno-cho Koyu-gun, Miyazaki | 2. AUDIT DATE 10/02/2015 | 3. ESTABLISHMENT NO. M-2 | 4. NAME OF COUNTRY Japan |
| | 5. NAME OF AUDITOR(S) Kenneth E. Witek – SPA, CSO & Francisco Gonzalez – SPA, DVM | | 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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 | X |
| 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 | X |
| 24. Labeling - Net Weights | | 52. Humane Handling | X |
| 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 | X |
| 27. Written Procedures | | Part G - Other Regulatory Oversight Requirements | |
| 28. Sample Collection/Analysis | | 56. European Community Directives | O |
| 29. Records | | 57. Monthly Review | |
| Salmonella Performance Standards - Basic Requirements | | 58. | |
| 30. Corrective Actions | | 59. | |
| 31. Reassessment | | | |
| 32. Written Assurance | | | |

60. Observation of the Establishment Miyachiku Corp., Ltd. - Tsuno Plant, Est. M-2, Bovine Slaughter/Processing, 10/02/2015

46/51 Sanitary Operations:1. Sanitary Dressing Procedures:

During the auditors observation of the slaughter and inspection procedure the FSIS auditors observed a deficiency in that the establishment was not removing the "stick wound" completely during the slaughter dressing process. This was also observed in the initial "drip cooler/ hot box" and addition carcass holding coolers. This creates a potential cross contamination condition in the processing of the carcasses. A review of establishment and inspection verification documents provided no evidence that this deficiency was previously identified.

2. Segregation of carcasses over and under 30 months of age:

The FSIS auditors observed that carcasses held in the coolers were not consistently segregated by age. In various carcasses coolers carcasses of different ages were hung in close proximity to each other. Carcasses from cattle older than 48 months of age contact the surfaces of carcasses less than thirty months of age. It was further identified that the CCA had not issued instructions that apply to segregation of carcasses from cattle older than thirty from cattle younger than thirty months of age for establishments that do not treat all animals as thirty months of age and above. [Regulatory reference: 9CFR 416.4(d), 9CFR 327(a)(2)(i)(D), 416.17, and 417.8

It should be noted that the establishment has a system in place to segregate carcasses that will be shipped to the U.S. There were no carcasses identified as eligible to export to the U.S. in the coolers at the time of the audit.

52/51 Establishment Construction:

Deficiency in the construction of a stainless steel grate on the floor of the livestock holding barn was observed by the FSIS auditors. Observation included that several bolts that anchored the stainless steel grate were protruding out of the floor surface, creating a condition that could cause injury to the animal if it walked over the protruding bolt. A review of establishment and inspection verification documents provided no evidence that this deficiency was previously identified.

[Regulatory reference: 9CFR 416.2(b), 9CFR 327(a)(2)(i)(D), 416.17]

55/51 Post-mortem Inspection:1. Final Rail Carcass Inspection Procedures:

It was observed by the FSIS auditors that the carcass inspector instructed the trimmer to remove a bruise located on the rump of the carcass; however the inspector did not verify that the trimmer performed the trimming. As a result the carcass was allowed to continue with the bruise partially trimmed off. The location of the carcass inspector in the slaughter line process seems to be located in the wrong position in the line as the trimmer is located on a different "lift" stand approximately 20 ft. away down the line. The Meat Inspection Staff stated that the line moves slow enough for the inspector to verify any trimming that the inspector requires and also has the option to stop the line. However, the auditor did not observe the inspector verifying the inspector's requested action taken.

2. Inspection Zero-Tolerance Verification:

The auditors observed that the inspector performs the verification of zero-tolerance for contamination caused by feces, and milk at the same point where the establishment conducts final trimming of carcasses. This arrangement causes interference of the inspector with the work of the trimmer and at the same time the trimmer interferes with the verification task conducted by the inspector. Furthermore, the selected verification site does not permit the inspector to evaluate the ability of the establishment to meet the zero-tolerance standard because the assessment is not being made after the carcass has passed establishments trimming/monitoring step.

[Regulatory reference: 9CFR 310, 310.14, 9CFR 327(a)(2)(i)(C) & (D), 416.17, and 417.8]

Residue Sampling Program:

The CCA has not issued instructions to in-plant inspectors this establishment that requires them to hold or maintain control over any livestock carcass selected for directed residue sampling until the CCA's laboratory test results are reported. This establishment does not hold the selected carcass pending the test results for residue sampling.

61. NAME OF AUDITOR
Kenneth E. Witek – SPA, CSO &
Francisco Gonzalez – SPA, DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|--|-----------------------------|---|-----------------------------|
| 1. ESTABLISHMENT NAME AND LOCATION Iwate Chikusan Ryutsu Center Co., Ltd. 120, Minami-yachi Inubuchi Shiwa-cho, Shiwa-gun, Iwate | 2. AUDIT DATE 10/05/2015 | 3. ESTABLISHMENT NO. I-1 | 4. NAME OF COUNTRY Japan |
| 5. NAME OF AUDITOR(S) Kenneth E. Witek – SPA, CSO & Francisco Gonzalez – SPA, DVM | | 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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. | X | 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 | X |
| 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 | X |
| 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 | X |
| 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. Monthly Review | |
| Salmonella Performance Standards - Basic Requirements | | 58. | |
| 30. Corrective Actions | | 59. | |
| 31. Reassessment | | | |
| 32. Written Assurance | | | |

60. Observation of the Establishment Iwate Chikusan Ryutsu Center Co., Ltd., Est. I-1, Bovine Slaughter/Processing, 10/05/2015

10/51 SSOP Implementation:

During the auditors assessment of the slaughter and inspection procedures, the FSIS auditors observed that an establishment employee at the “hide pulling station” was not consistently washing his hands after handling the hide and pulling chains for hide removal and touched the skinned head of the carcass with his contaminated hand during the dressing process creating cross contamination. Establishment’s SSOP has a procedure for the monitoring operational hygiene practices of the employees in place with SOPs associated with each stage of the cattle dressing process. A review of 90 days of establishment and inspection verification documents provided no evidence that this deficiency was previously identified.

[Regulatory reference: 9CFR 416.13, 327(a)(2)(i)(D), 416.17, and 417.8]

While observing inspection pre-operational verification procedures the auditors observed the following deficiencies in the maintenance of the facility and equipment.

39/51 Establishment Maintenance:

1. In the carcass processing room (fabrication) it was observed that the rail which transports carcass cuts for further processing along the fabrication line had extensive black grease on the trolley system creating a potential source for the contamination of product. Inspection verified the corrective action taken by the establishment prior to beginning of operations.
2. In two carcass coolers it was observed that there was exposed electrical wiring that lead to nowhere that could not be readily cleaned.

[Regulatory reference: 9CFR 416.2(b), 327(a)(2)(i)(D), 416.17]

45/51 Equipment:

In a cooler that holds fabricated beef product it was observed that a “blue” edible product storage vat that is used for both exposed and vacuum package product had a jagged crack hole on the bottom on the vat opening it to the floor. The inspector documented the finding once the auditors identified the deficiency.

However during further audit verification process by the FSIS auditors it became evident that the inspection staff has no official control action in place to preclude any use of the rejected equipment or area in the facility.

[Regulatory reference: 9CFR 416.3(a), 416.6, 327(a)(2)(i)(D), 416.17]

A review of 90 days of establishment and inspection verification documents provided no evidence that any of the above deficiencies had been previously identified.

Residue Sampling Program:

The CCA has not issued instructions to in-plant inspectors this establishment that requires them to hold or maintain control over any livestock carcass selected for directed residue sampling until the CCA’s laboratory test results are reported. This establishment does not hold the selected carcass pending the test results for residue sampling.

61. NAME OF AUDITOR
Kenneth E. Witek – SPA, CSO &
Francisco Gonzalez – SPA, DVM

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|---|---|-----------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION Gunma-ken Shokuniku Oroshiuri Shijo Co., Ltd. 1189, Kamifukushima Tamamura-machi Sawa-gun, Gunma | 2. AUDIT DATE 10/07/2015 | 3. ESTABLISHMENT NO. G-1 | 4. NAME OF COUNTRY Japan |
| | 5. NAME OF AUDITOR(S) Kenneth E. Witek – SPA, CSO & Francisco Gonzalez – SPA, DVM | | 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> 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. | X | 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 | X |
| 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 | X |
| 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 | X |
| 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. Monthly Review | |
| Salmonella Performance Standards - Basic Requirements | | 58. | |
| 30. Corrective Actions | | 59. | |
| 31. Reassessment | | | |
| 32. Written Assurance | | | |

60. Observation of the Establishment Gunma-ken Shokuniku Oroshiuri Shijo Co., Ltd., Est. G-1, Bovine Slaughter/Processing, 10/07/2015

10/51 SSOP Implementation:

During the auditors' observation of the processing (fabrication) and inspection procedure the FSIS auditors observed the following deficiency, an employee in the fabrication area contacted his gloved hand on the wheel of a product transporting cart and resumed duties without washing and sanitizing his contaminated gloves
[Regulatory reference: 9CFR 416.13, 327(a)(2)(i)(D), 416.17, and 417.8]

39/51 Establishment Construction:

In the carcass processing room (fabrication) it was observed that there were several sections in which wires were arranged in coils, bundles, some tied with a piece of rope, some frayed, and some exposed at the end of the conduit creating surfaces in an exposed product area that could not be readily cleaned.
[Regulatory reference: 9CFR 416.2(b), 327(a)(2)(i)(D), 416.17]

46/51 Sanitary Operations - Sanitary Dressing Procedures:

During the auditors' observation of the slaughter, processing (fabrication) and inspection procedure the FSIS auditors observed the following deficiency, an employee on the slaughter floor assigned to remove the hide from the hind leg, was allowing contamination from the leg to be transferred to his work clothes, and from his work clothes to the skinned portion of the leg. This practice was creating cross contamination.
[Regulatory reference: 9CFR 416.4(d), 9CFR 327(a)(2)(i)(D), 416.17, and 417.8]

A review of establishment and inspection verification documents provided no evidence that any of the above deficiency was previously identified.

Residue Sampling Program:

The CCA has not issued instructions to in-plant inspectors this establishment that requires them to hold or maintain control over any livestock carcass selected for directed residue sampling until the CCA's laboratory test results are reported. This establishment does not hold the selected carcass pending the test results for residue sampling.

61. NAME OF AUDITOR
Kenneth E. Witek – SPA, CSO &
Francisco Gonzalez – SPA, DVM

62. AUDITOR SIGNATURE AND DATE

Appendix B: Foreign Country Response to Draft Final Audit Report



Inspection and Safety Division

Department of Environmental Health and Food Safety

Ministry of Health, Labour and Welfare, JAPAN

1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-8916 Tel:81-3-3595-2337/fax:81-3-3503-7964

March 18, 2016

Ms. Jane H. Doherty,
International Coordination Executive
Office of International Coordination
Food Safety and Inspection Service
United States Department of Agriculture

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, September 24 - October 9, 2015.

Dear Ms. Doherty:

I received your letter of the FSIS's draft final report of an on-site equivalence verification audit conducted in Japan from September 24 through October 9, 2015.

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,

Hideshi Michino, D.V.M.
Director of Inspection and Safety Division
Department of Environmental Health and Food Safety
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, September 24 - October 9, 2015.

IV. Component one: Government oversight (Organization and Administration)

Page 3

“At the central level, the Inspection and Safety Division (ISD) of the Department of Food Safety of MHLW prepares the national residue plan and contracts with private laboratories for residue analysis.”

MHLW’s comment:

“Department of Food Safety” should be “Department of Environmental Health and Food Safety.” The same applies to the following.

“contracts with private laboratories for residue analysis” should be “designates the private laboratories for residue analysis”.

Page 3

“At the local government level, there are 47 prefectural and municipal governments.

MHLW’s comment:

“47 prefectural and municipal governments” should be “47 prefectural and 72 municipal governments”.

Page 4

“The CCA’s authority to enforce inspection laws is outlined in the Abattoir Law (Law No. 114, August 1, 1953, as of June 27, 2007), Abattoir Law Enforcement Regulation (Law No. 44, September 28, 1953, as of February 1, 2013), and Ordinance for Enforcement of the Food Sanitation Act (Ordinance No. 23, July 13, 1948).”

MHLW’s comment:

“(Law No. 44, September 28, 1953, as of February 1, 2013)” should be “(Ordinance No. 44, September 28, 1953, as of March 27, 2015)”.

“(Ordinance No. 23, July 13, 1948)” should be “(Ordinance No. 23, July 13, 1948, as of September 28, 2015)”.

Page 4

“FSIS requires that the selected carcass or products sampled for chemical residue testing be held or be controlled until the laboratory test results are reported negative. The FSIS auditors identified and were informed by the CCA that there is no requirement for establishments to hold

or maintain control over any livestock carcass or products that the CCA selected to test for adulterants as part of the chemical residue testing control program.”

MHLW’s comment:

Relevant competent authorities of Japan are providing instructions and supervisions to producers for thorough control of chemical residue in feed and proper use of drugs under the relevant laws and regulations. Accordingly, chemical residue testing programs which had been organized and administered by MHLW for beef export to the United States have not found any cases exceeding the MRLs in the target tissues such as kidney nor the edible parts of muscle over last twenty years. In addition, any residues have never been even detected in the muscle beyond the limit of detection.

Therefore, MHLW recognizes it is not under a situation that needs uniformly requiring the establishments to hold or maintain the sampled carcass or products in the establishment until the test results are reported negative.

Nevertheless, in response to the FSIS’s finding, MHLW has provided a specific procedure to maintain control over the products for the case where the test results were found to be violation level or suspected to be so. This procedure includes identification of products derived from sampled carcasses, a prompt report to MHLW in case of detection, recall of the affected products and investigation of the cause of violation. MHLW believes that the safety of Japanese beef to be exported to the United States will be further ensured by this treatment.

Page 4

“The CCA has a written protocol, Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States based on Abattoir Law,”

MHLW’s comment:

“based on Abattoir Law” should be deleted.

Page 5

“The FSIS auditors verified that both in-plant inspection and laboratory personnel have attended training programs. However, the CCA has no system or method in use to regularly assess the technical competence and performance of individual in-plant inspection personnel in conducting official inspection activities at establishments that export to the United States. Individual inspection personnel are not evaluated on their performance.”

MHLW’s comment:

In light of the FSIS finding, MHLW has decided to introduce a method for evaluating the technical competence and performance of individual inspection personnel as follows.

- The director of meat inspection center or a person who is assigned by the director shall evaluate and record the performance of individual inspection personnel on a regular basis.
- Evaluation results shall be put in a management record prepared for each individual

inspector. Training attendance of each inspector relating to inspection activities shall be also included in this management record.

- The RBHW auditor shall review the performance of inspector who engages inspection on the day of regular audit while referring to this book.

Page 5

“Government and private laboratories are accredited by the Japanese Accreditation Board (JAB) annually according to the International Organization for Standardization (ISO) 17025 standard and are approved by MHLW.”

MHLW’s comment:

“Government and” should be deleted and “Government laboratories are operating in accordance with criteria aligned with ISO 17025” should be added as follows;

“Private laboratories are accredited by the Japanese Accreditation Board (JAB) annually according to the International Organization for Standardization (ISO) 17025 standard and are approved by MHLW. Government laboratories are also operating in accordance with criteria aligned with ISO 17025.”

V. Component two: Statutory authority and food safety regulations (Inspection system operation and product standards)

Page 7

“The FSIS auditors verified through direct observation, on-site record reviews, and interviews that in-plant inspection personnel’s ante-mortem inspection activities complied with Japan’s Guideline of Meat Inspection, Abattoir Law, Article 14 and 19, and Abattoir Law Enforcement Regulation, Article 10 and 16.”

MHLW’s comment:

“Abattoir Law Enforcement Regulation, Article 10 and 16” should be “Abattoir Law Enforcement Regulation, Article 14 and 16”.

Page 7

“In one establishment, a stainless steel grate anchored on the floor of the livestock-holding barn had several bolts that protruded out of the floor surface. Although the FSIS auditors did not observe any incidents involving livestock becoming injured, the protruding bolts create a condition that could cause injuries to the feet of livestock.

MHLW’s comment:

That situation was immediately improved by cutoff the protruded bolts and attaching nuts.

Page 8

“These included visual inspection, palpation, and incision of relevant portions of the animal described within Japan’s Manual of procedures of Meat Inspection and Re-inspection of Dressed carcasses, Food Sanitation law (Article 11), Abattoir Law (Article 5, 14 and 19), and Abattoir Law Enforcement Regulation (Article 10 and 16).”

MHLW’s comment:

“Food Sanitation law (Article 11)” should be deleted.

“Abattoir Law (Article 5, 14 and 19)” should be “Abattoir Law (Article 14 and 19)”.

“Abattoir Law Enforcement Regulation (Article 10 and 16)” should be “Abattoir Law Enforcement Regulation (Article 14 and 16)”.

Page 8

“The MIC carcass inspector instructed the trimmer to remove a bruise located on the rump of the carcass; however, the inspector did not verify that the trimmer correctly performed the required trimming, and the carcass continued to the cooler without adequate trimming of the bruise.”

MHLW’s comment:

Following corrective actions have been taken.

- The said carcass was immediately identified and the bruise was removed by trimming.
- Other carcasses in the cooler were re-examined for bruise and found to be no abnormalities.
- Instruction has been provided to the inspectors to make thorough confirmation of proper removal of parts/area which they instructed the trimmer to remove.

Page 9

“FSIS auditors observed that the MIC inspector performs the verification of zero-tolerance at the same point where the establishment conducts final trimming of carcasses, not permitting the inspector to evaluate the ability of the establishment to meet the zero-tolerance standard because the assessment is not being made after the carcass has passed establishments trimming /monitoring step.”

MHLW’s comment:

The process has been changed so that the verification of zero-tolerance by an off-line inspector shall be made after the final carcass trimming/monitoring by the establishment.

Page 9

“In one establishment, the off-line inspector was not documenting non-compliances on the daily inspection verification report as the form instructs and is prescribed by RBHW. The records show that areas and surfaces identified during pre-operational sanitation inspection as deficient are entered in the record as acceptable after corrective measures are implemented, thus

preventing the record from showing the results of the initial inspection. This practice could lead to possible confusion in analysis of trends that may emerge at the local level.”

MHLW’s comment:

Further procedure has been stipulated in the MIC’s manual in order that “NC” shall be surely recorded in the inspection verification report in case when non-compliances were observed during operational/pre-operational sanitation inspection. Educational training has been also provided to the inspectors.

Page 9

“In two establishments, the MIC inspectors did not take official control action to preclude use of equipment and production areas that were unacceptable, or when direct product contamination occurred.”

MHLW’s comment:

Following corrective actions have been taken.

- A procedure manual has been provided stipulating that equipments which inspectors judged not suitable for use shall be put an identifiable tag immediately and be confirmed those equipments were properly disposed.
- MIC has given a guidance for proper handling of heavy equipments in the production area, and procedure for storage management of those equipments and checking procedure of cleaning conditions during pre-operational checks have been stipulated in the SOP.

VI. Component three: Sanitation

Page 11

“One establishment was not completely removing the “stick wound” from the neck of the carcasses during the slaughter dressing process.”

MHLW’s comment:

Following corrective actions have been taken.

- Stick wound were removed by trimming from all the carcasses processed on that day and previous day.
- HACCP plan was reviewed and procedure for proper removal of contamination has been added into the SSOP of the carcass trimming process. That change of SSOP has been disseminated to establishment employees.

Page 11

“On the slaughter floor of one of the audited establishments, an employee assigned to remove

the hide from the hind leg was causing cross contamination from the unskinned leg of the carcass to the employee's work clothes and from his work clothes to the skinned leg.”

MHLW's comment:

As an immediate measure, unskinned hind leg has been covered with plastic bag in order not to arise cross contamination of work clothes, and educational training was provided to establishment employees. A shower booth will be newly installed in the work space by the end of March this year that enables the employee to wash his work cloth by each cattle or each time contaminated so as to surely prevent the cross contamination.

Page 11

“In one establishment, the carcasses held in the coolers were not consistently segregated by age. Carcasses of different ages were hung in close proximity to each other in the coolers. Carcasses from cattle older than 30 months of age contacted the surfaces of carcasses less than thirty months of age.”

MHLW's comment:

Provision not to contact carcasses older than 30 months of age with carcasses less than 30 months of age was added to the SSOP, and that change has been disseminated to establishment employees.

Page 12

“In one establishment, an establishment employee at the “hide pulling station” was not consistently washing his hands after touching the hide of the carcass and thereby creating cross contamination when touching the skinned head of the carcasses.”

MHLW's comment:

A guidance and educational training were promptly provided to establishment employees for the compliance of SSOP. After that, any non-compliances with SSOP have been identified during the operational sanitation inspection.

Page 12

“In one establishment, an employee in the fabrication area resumed duties without washing and sanitizing his contaminated gloves after touching the wheel of a product transport cart.”

MHLW's comment:

Thorough instruction was promptly provided to establishment employees to resume their duties after washing and sanitizing, or changing their gloves in case when they touched unsanitary parts of equipment.

Page 12

“The CCA needs to ensure that in-plant officials improve their ability to evaluate the

sanitation programs implemented by the establishments. In addition, the CCA needs to increase its surveillance of sanitation non-compliances within certified establishments.”

MHLW’s comment:

MHLW had a meeting with the MICs of certified establishments and the RBHW auditors and shared all the findings identified by the FSIS auditors in order to pay further attention to those cases in their regular surveillance of sanitation non-compliances.

Page 13

“However, in one establishment the FSIS auditors identified that the Slaughter Hazard Analysis does not identify the possibility of Specified Risk Materials (SRMs) as a possible hazard at the carcass chilling step in the process that is prevented by the segregation of carcass in the coolers. The establishment has a SOP for the removal and control of SRMs that states that all cattle slaughtered at the facility will be treated as ≥ 30 months. However, the establishments does not reference the SRM SOP at this step in the process or make any reference that all cattle slaughtered at this facility will be treated as ≥ 30 months within the Hazard Analysis.”

MHLW’s comment:

Hazard Analysis has been performed taking the SRMs in the carcass chilling process into consideration and then SRM control measure was added to the SOP of that process.

VIII. Component five: Government chemical residue testing programs

Page 14

“JFRL has seven locations distributed across Japan.”

MHLW’s comment:

“and two (Tama and Saito) of them are designated for the testing laboratories under JRCP.” should be added.

Page 15

“During interviews with CCA, regional and establishment inspection officials, it was determined that the CCA does not have a requirement for establishments to hold or maintain control over any livestock carcass or products that the CCA tests for adulterants pending reporting of the test results. The CCA has no policy or procedure to address what measures it would take in response to a violative level. FSIS discussed this deficiency in the Government Oversight component of this report.”

MHLW’s comment:

Already commented in the IV. Component one: Government oversight (Organization and administration)

IX. Component six: Government microbiological testing programs

Page 17

“The FSIS auditors verified that the laboratory had been accredited by the accreditation agency of the Japanese government using criteria aligned with ISO 17025.”

MHLW’s comment:

“laboratory had been accredited by the accreditation agency of the Japanese government using criteria aligned with ISO 17025” should be “laboratory is operating in accordance with criteria aligned with ISO 17025”.

Final MHLW’s comment:

All corrective actions toward the findings stated in the audit report, also include that mentioned in the Attachment A: Individual Foreign Establishment Audit Checklist, have been reviewed by MIC. RBHW has also reviewed those corrective actions and verified their implementations by an on-site audit. Finally, MHLW reviewed those reports and determined that they are appropriate.