USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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JUL 24 2020

Dr. Akira MIKI
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Food Safety and Inspection Division
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Bureau, Ministry of Health, Labor and Welfare Department
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Dear Dr. MIKI,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an on-site verification audit of Japan's meat inspection system from January 27 through February 14, 2020. 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.

FSIS is evaluating the response provided by the Ministry of Health, Labor, and Welfare (MHLW) Department including the corrective actions. The outcome of that evaluation will be provided in separate correspondence.

If you have any questions, please contact the Office of International Coordination by email at internationalcoordination@usda.gov.

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

JAPAN

JANUARY 27– FEBRUARY 14, 2020

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

RAW BEEF PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

July 22, 2020

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) January 27 through February 14, 2020. The purpose of the audit was to determine whether Japan's food safety inspection system governing raw beef products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Japan currently exports raw beef products to the United States. The audit focused on six system equivalence components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs. The FSIS auditors identified the following findings:

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

- The Ministry of Health Labor and Welfare (MHLW) does not provide adequate oversight over the implementation of inspection tasks and microbiological procedures used for testing official samples.
- The eight Meat Inspection Centers (MICs) microbiological laboratories are not meeting the quality assurance and control criteria established by the MHLW. Examples include:
  - Analyses for *Salmonella* do not include positive and negative control samples in biochemical confirmation.
  - Analyses for Shiga toxin-producing *Escherichia coli* (STEC) do not include positive and negative controls in screening or confirmation methods.

GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g., INSPECTION SYSTEM OPERATION AND LABELING)

- At seven establishments, the FSIS auditors observed the MIC inspectors peeling off the hide of cattle head to expose the masseter muscle, but not incising deeply as required by the MHLW to inspect for cysticercosis.

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

- At five establishments, the MHLW does not ensure adequate oversight over the implementation of HACCP recordkeeping and verification requirements. Official records of ongoing verification of critical control points were not maintained or were incorrectly recorded.

GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

- The MHLW does not have an adequate chain of custody system for laboratory operations. Most residue samples did not have signed security-seals and were not accompanied by transfer-and-storage records.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- The eight MIC laboratories are not analyzing the entirety of the N60 sample for *Escherichia coli (E. coli)* O157:H7 and non-O157 Shiga toxin-producing *E. coli* (STEC) during screening of official testing;
- The MHLW has not implemented an appropriate method for STEC confirmation that meets equivalence expectations. The confirmation method does not include appropriate immune-concentration procedures with dilution or an acid wash step to allow for adequate isolation of potentially low levels of STEC in a sample;
- At seven establishments, the collection of 60 pieces of beef trimming (N60) for STEC testing is performed by establishment's personnel not by MIC inspection personnel; and
- At seven establishments, the 60 pieces are neither trimmed from the exterior surface of carcass portions nor selected randomly.

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

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of Japan's food safety system January 27 through February 14, 2020. The audit began with an entrance meeting January 27, 2020, in Tokyo, Japan, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – Ministry of Health Labor and Welfare (MHLW). During the audit exit meeting February 14, 2020, the MHLW committed to address the preliminary findings. Representatives from the MHLW accompanied the FSIS auditors throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether the food safety inspection system governing raw beef products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Japan is eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products[1]
Raw – Intact	Raw intact beef	Carcass (including halves or quarters); cuts (including bone in and boneless meats); edible offal; other intact; and primal and subprimal.

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Japan as having negligible risk for bovine spongiform encephalopathy (BSE), consistent with the criteria specified in Title 9 of the U.S. Code of Federal Regulations (9 CFR) Section 92.5, and Japan is free from foot-and-mouth disease (FMD). Beef imported from Japan is subjected to BSE requirements specified in 9 CFR 94.18 / 9 CFR 94.19, and to FMD requirements specified in 9 CFR 94.11.

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed Japan's self-reporting tool (SRT) responses and supporting documentation. During the audit, the FSIS auditors conducted interviews, reviewed records, and made observations to determine whether Japan's food safety inspection system governing raw beef products is being implemented as documented in the country's SRT responses and supporting documentation.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data

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

collected by FSIS over a three-year period, in addition to information obtained directly from the CCA through the SRT.

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

The FSIS auditors reviewed administrative functions at CCA headquarters, two regional offices, and eight local inspection offices within the establishments' vicinities. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of eight establishments was selected from a total of 14 beef slaughter and processing establishments certified to export raw beef to the United States. The 14 certified establishments include one which was recently approved by the MHLW shortly after the start of this audit. The products these establishments produce and export to the United States include raw beef primal and subprimal cuts.

The FSIS auditors paid attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditors assessed the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in 9 CFR 327.2.

The FSIS auditors also audited one chemical residue laboratory and eight microbiological laboratories to verify that these laboratories can provide adequate technical support to the food safety inspection system.

Competent Authority Visits		**#**	**Locations**
Competent Authority	Central	1	• Ministry of Health Labor and Welfare, Tokyo
	Regional Offices	2	• Kinki Regional Bureau of Health and Welfare, Osaka • Kyushu Regional Bureau of Health and Welfare, Fukuoka
Chemical Residue Laboratory (private)		1	• Japan Food Research Laboratory, General Incorporation Foundation, Tama-shi
Microbiological Laboratories (local authorities)		8	• Gifu Prefecture Meat Inspection Center, Gifu • Gunma Prefecture Meat Inspection Center, Gunma • Himeji City Meat Inspection Center, Himeji • Kagoshima Prefecture Sueyoshi Meat Inspection Center, Kagoshima

Competent Authority Visits	#	Locations
		• Kagoshima Prefecture Shibushi Meat Inspection Center, Kagoshima • Miyazaki Prefecture Tsuno Meat Inspection Center, Miyazaki • Miyazaki Prefecture Takasaki Meat Inspection Center, Miyazaki • Oita Prefecture Meat Inspection Center, Oita
Beef Slaughter and Processing Establishments	8	• Establishment G-1, Gunma-ken Shokuniku, Gunma • Establishment GI-1, Hida Meat Agricultural Cooperatives, Gifu • Establishment HMJ-1, Wagyu Master Meat Center, Himeji City • Establishment K-1, Nanchiku Co., LTD, Kagoshima • Establishment K-2, Sankyo Meat Ltd. Ariake Meat Plant, Kagoshima • Establishment M-1, Miyachiku Corp. Ltd, Takasaki Plant, Miyazaki • Establishment M-5, Miyachiku Corporation, Ltd., Tsuno Plant, Miyazaki • Establishment OI-1, Oitaken Chikusankosya Co., Ltd, Oita

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

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

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

III. BACKGROUND

From September 1, 2016 to August 31, 2019, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 2,476,893 pounds of raw intact beef exported by Japan to the United States. Of this amount, additional types of inspection were performed on 190,613 pounds of raw intact beef. These additional types of inspection included physical

examination, chemical residue analysis, and testing for microbiological pathogens (Shiga toxin-producing *Escherichia coli* [STEC] O157:H7, O26, O45, O103, O111, O121, and O145 in beef), and 1057 pounds of products were rejected for issues not related to public health.

The previous FSIS onsite audit in 2018 identified the following findings:

Summary of Findings from the 2018 FSIS Audit of Japan
Component One: Government Oversight (e.g., Organization and Administration)
The CCA allows inspection personnel to issue an export certificate for product intended for export to the United States before test results are known from the CCA's routine chemical residue program.
Component 6: Government Microbiological Testing Programs
The CCA has not fully implemented their government STEC verification program to ensure that raw beef products are free of STEC at the end of the production process. The CCA has also not yet implemented sampling and testing of beef trimmings for STEC because an appropriate method for detection of STEC has not been adopted by the laboratories.

During this audit, the FSIS auditors verified that the corrective actions for the previously reported findings were implemented. This audit included visits to the official chemical residue laboratory, beef slaughter establishments, and official microbiological laboratories to assess the government "hold and test" requirements for livestock carcasses subjected to routine official chemical residue testing and the government implementation of STEC verification program (including the testing method adopted and the sampling procedure of beef trimming) to ensure that raw beef products are free of STEC at the end of the production process. Findings related to these policies are described in subsequent sections of the report.

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

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

The first of six equivalence components the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign food safety inspection system to be organized by the national government in such a manner as to provide ultimate control and supervision over all official inspection activities; ensure the uniform enforcement of requisite laws; provide sufficient administrative technical support; and assign competent qualified inspection personnel at establishments where products are prepared for export to the United States.

In Japan, the MHLW is the CCA with a central office in Tokyo and seven regional offices. Since the previous FSIS onsite audit in 2018, the MHLW appointed a new Director and the FSIS auditors verified that there have been no additional major changes in the CCA's organizational structure. At the central level, the Food Inspection and Safety Division of the Pharmaceutical Safety and Environmental Health Bureau of MHLW prepares the national residue plan and designates private chemical residue laboratories for official residue analyses. In addition, the MHLW issues all directives and guidelines concerning meat export to other countries including

the United States, 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 MHLW's authority to enforce inspection laws is outlined in the *Abattoir Act (Act No. 114), Regulation for Enforcement of the Abattoir Act* (Ordinance No. 44)*,* and *the Food Sanitation Act* (Act No. 233)*.* These laws delineate responsibilities for each of the inspection levels. In addition, the MHLW's supplemental documents entitled *Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States,* and *Guidelines for Inspection of Certified Establishments Handling Meat for Exportation to the United States* are implemented and enforced at establishments certified to export raw beef products to the United States.

The MHLW has the legal authority and responsibility to enforce these laws and requirements. The MHLW has the authority to require corrective actions in certified meat establishments eligible to export to the United States and the ability to take additional enforcement measures as appropriate. The MHLW is responsible for regulating the meat industry, in terms of food safety, official certification or decertification of establishments, and maintaining the official list of establishments eligible to export meat products to the United States.

The MHLW is authorized by the *Abattoir Act* and "*Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States*" to collect any reports it deems necessary from owners or managers of abattoirs, and from slaughterers or other relevant persons. The *Abattoir Act and* the *Requirements for Certification of Slaughterhouses* also authorize MHLW officials to enter abattoirs, offices, warehouses, or other facilities involved in the slaughter and processing of meat products to inspect equipment and review accounting books and production documents. Inspectors carry official identification and are required to present this identification on request.

The regional level consists of seven Regional Bureau of Health and Welfare (RBHW) offices across the country. Six of these RBHW offices (Hokkaido, Kanto-Shinetsu, Kyushu, Kinki, Tohoku, and Tokai-Hokuriku) have certified establishments within their jurisdictions. The Food Sanitation Division (FSD) of these RBHW offices is responsible for conducting monthly reviews of establishments eligible to export beef products to the United States and a yearly review of the chemical residue and microbiological laboratories designated to analyze official verification samples.

At the local level, the authorities (i.e., prefecture, city with health center, or ward) are authorized by the MHLW to oversee meat inspection at the slaughter and processing establishments and to operate the microbiological laboratories designated to analyze official verification samples. In Japan there are 47 prefectures, 84 cities with health center, and 23 special wards. Each local authority which has jurisdiction over the certified establishments has its own meat inspection center (MIC) which has the responsibility to implement and enforce inspection laws and requirements at the certified establishment eligible to export beef products to the United States. The MIC meat inspectors rotate the responsibility for daily inspection activities at slaughter and processing establishments and for the analyses of official

microbiological samples at MIC laboratories. There are enough meat inspectors assigned to each establishment certified for export to the United States to carry out inspection activities. All meat inspectors assigned to certified slaughter establishments and the MIC laboratories are veterinarians hired and supervised by the local authority.

According to the *Abattoir Act*, slaughter establishments must receive a permit from the Governor of the prefecture in order to operate. To receive a permit, a written application must be submitted to the Governor of the prefecture. The application must include information on construction, facilities, and any other matters required by MHLW. If an establishment wants to make changes after the permit is granted, the Governor must be notified in advance. The Governor of the prefecture may refuse to grant permits under Article 5 of the *Abattoir Act*. Governors may also restrict the species and daily number of animals able to be processed as general practice in abattoirs.

MHLW designates the Japan Food Research Laboratories (JFRL) to conduct official chemical residue testing of beef to be exported to the United States. The JFRL are accredited by the Japanese Accreditation Board (JAB) annually according to the International Organization for Standardization (ISO) 17025 standards, *General requirements for the competence of testing and calibration laboratories*, approved by MHLW, and reviewed annually by a food inspector from the FSD-RBHW.

The FSIS auditors performed onsite observations and reviewed records maintained by officials at MHLW, RBHW offices, and MICs overseeing establishments certified to export to the United States. The FSIS audit of the MHLW headquarters included an examination of its oversight activities, including the verification of government review audits of establishments conducted by FSD and MHLW's verification of actions taken in response to FSIS' 2018 audit findings. In addition, FSIS auditors reviewed verification activity reports, and training records for official personnel by interviewing departmental personnel and reviewing documentation.

The MHLW issued a notification to local authorities on November 2018 regarding hold-and-test policy in which the MICs cannot issue health certification (*Official Meat Inspection Certificate for Fresh Meat and Byproducts*) for export to the United States of beef products subjected to routine and suspect chemical residues testing and to microbiological verification activities testing until the receipt of acceptable official test results. The MHLW allows the establishments to divert carcasses selected for routine residue testing to the local market and exclude those carcasses from export to the United States.

MHLW has the sole authority to grant final certification of a new establishment or to permit an existing certified establishment to maintain eligibility to export to the United States. MHLW has a written protocol, *Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States,* which describes the procedures that establishment operators must 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 document also describes the measures to be taken if procedures are not properly followed. The MHLW requires that certified establishments establish a method for the recall of affected products when food safety problems occur.

The FSIS auditors verified through record reviews and POE violation reports that no adulterated or misbranded products have been sent to the United States. The FSIS auditors verified that certification labels and marks are approved by MHLW and, as required by MHLW, are displayed on outer containers and packages, or affixed to dressed carcasses after these products have passed inspection at certified establishment. The MHLW authorizes *Official Meat Inspection Certificate for Fresh Meat and Byproducts* that certifies that the product being exported to the United States has passed inspections at the applying establishment and is not adulterated or misbranded. Penal provisions are stipulated in the articles 81 – 89 of the *Food Sanitation Act* and the articles 24 – 27 of the *Abattoir Act* under the jurisdiction of the MHLW.

The FSIS auditors verified that establishments certified to export beef product to the United States are completely separated from facilities that are not producing meat for export to United States, as stipulated in the *Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States.* FSIS auditors also verified that MIC inspection personnel verify source material on a regular basis; all source meat used in processing operations originate from certified establishments in Japan. In addition, an official meat inspection certificate for fresh meat and byproducts of fresh meat for exportation is issued and accompanies the product to be exported. As part of the application process for product exported to the United States, the FSIS auditors verified all tracking information of the products' origin and movement throughout the processing of the product. Records reviewed included establishment sanitation standard operating procedures (SOP) and HACCP monitoring and verification records that are associated with each lot of product. The MIC inspection personnel sign the certificate, and the original certificate is attached to the product to be exported. The MIC retains a copy of the certificate and gives a copy to the applying establishment.

The MHLW maintains a single standard of laws and regulations applicable to all establishments certified for export to the United States and conducts monthly reviews of establishments certified as eligible to export product to the United States. The MHLW issues guidelines and instructions for registration to export to the United States, approval procedures of regulated establishments, and suspension or withdrawal of export eligibility. It also provides instruction on the verification of microbiological sampling program, the performance of official inspection tasks, and designing and implementing national residue monitoring program. MHLW disseminates inspection information related to the regulatory and administrative affairs electronically to RBHW and to inspection personnel at each MIC with establishments certified to export product to the United States.

At all audited slaughter and processing establishments, the FSIS auditors verified that a sufficient number of inspection personnel are assigned by the local authority's MIC to conduct daily inspection activities that are required to be (1) continuous during slaughter operations and (2) performed by inspection personnel at least once per shift during the processing of raw beef products intended for export to the United States. The FSIS auditors verified that each MIC has a written staffing protocol based on the species slaughtered and line speeds for use at establishments certified to export to the United States. The FSIS auditors also verified that offline inspection tasks such as sanitation verification, HACCP verification, and official product

sampling are implemented as explained in the *Guidelines for Inspection of Certified Establishments Handling Meat for Exportation to the United States.*

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

The FSIS auditors verified that the inspection personnel assigned to establishments certified to export meat to the United States are selected and hired by the local authority that has authority over the certified establishment, as full time or part-time contractual veterinarians. The local authority pays their salaries for performing meat inspection tasks in certified establishments and analyzing official samples in the MIC microbiological laboratories. Inspection personnel are evaluated on their performance once a year by the MIC Directors.

The *Abattoir Act (Act No. 114)* and the *Ordinance for Enforcement of the Abattoir Act* (Ordinance No. 216) explain that all inspectors assigned in slaughter establishments are veterinarians and the *Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States* describe that inspection personnel shall have appropriate educational credentials, training, and experience to carry out their inspection task.

The FSIS auditors verified that inspection personnel assigned to certified establishments have attended training in livestock inspection and food safety programs. Training on livestock inspection, sanitation, and HACCP programs occurs on-the-job and is supplemented by paper-based training at the MIC level. The MHLW organizes periodic training at the national level on food safety and inspection requirements pertaining to beef production for export to the United States to a representative number of the inspection personnel.

The FSIS auditors identified that the microbiological laboratories that test for official samples are approved and managed by the MIC of each local authority. These laboratories are expected to operate under the general quality assurance and control criteria consistent with ISO 17025 standards. The MHLW assigns food inspectors from the RBHW to conduct an annual audit of microbiological laboratories. The FSIS auditors reviewed documented results of these audits at every laboratory and noticed no significant findings at any of these laboratories since the previous audit conducted by FSIS. Similarly, the monthly reviews conducted by representatives of the RBHW of slaughter establishments eligible to export beef to the United States which are also reported no findings since the FSIS audit in 2018.

The microbiological laboratories that test official samples are located at the MICs and are operated by the corresponding local authority that has authority over one or more certified

establishments. The MHLW regional representatives conduct annual audits of the JFRL in accordance with *Japan's Food Sanitation Act* and *Manual on How to Manage Examination, etc. at Testing laboratories.* The MHLW regional representatives conduct annual audits of the microbiological laboratory located at each local authority MIC as well in accordance with the Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States.

and JFRL include administrative and technical aspects of the analytical methodology, operational procedures, laboratory personnel qualifications, training, and maintenance of the laboratory equipment and facilities.

The FSIS auditors verified that the MHLW ensures that every certified establishment that exports to the United States is included in the programs for appropriate official government chemical residue and microbiological sampling and testing, in accordance with the *Guidance for Implementation of Residual Chemical Monitoring*. The FSIS auditors included the JFRL, which is a private laboratory in Tama, in their audit scope to verify the functions and oversight provided by MHLW. The MHLW designated the JFRL to test meat products official samples for chemical residues as planned in the national residue monitoring program. The FSIS auditors verified that the laboratory is accredited by JAB, in accordance with ISO 17025 standards and protocols designed by MHLW. 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 verified through records review that the methods of analysis used in official laboratories were included in the scope of accreditation for the laboratory.

The private laboratories of the JFRL, which are designated by the government as the laboratory to test official samples for chemical residues, are accredited annually by the JAB according to the ISO 17025 standards and are authorized by MHLW. The JAB is a member of International Laboratory Accreditation Cooperation (ILAC), which is the overarching group that ensures global harmonization of laboratory accreditation. The MHLW establishes the requirements and written procedures that laboratory quality assurance programs use to demonstrate that there are properly trained personnel, suitable facilities and equipment, and that equipment is verified, calibrated, and maintained in a manner consistent with international standards.

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

The FSIS auditors found at the microbiological laboratories they audited that these laboratories, operated by MICs, did not participate in third-party audits or internal/ external proficiency

testing. The FSIS auditors reviewed several establishments' monthly reports, and at MIC and RBHW offices included in this audit, the FSIS auditors reviewed the yearly audit reports of the microbiological laboratories. The FSIS auditors observed inspection personnel while conducting sampling, reviewed training records, interviewed analysts and Directors from the eight audited MICs, and met with representatives/ auditors from each applicable regional office and identified gaps in the implementation of basic requirements related to laboratory quality assurance and control criteria and implementation of MHLW official microbiological procedures. The FSIS auditors summarized the findings as following:

- The Ministry of Health Labor and Welfare (MHLW) does not provide adequate oversight over the implementation of inspection tasks and microbiological procedures used for testing official samples.
- The MIC microbiological laboratories are not meeting the quality assurance and control criteria established by the MHLW. Examples include:
  - The internal and external laboratory proficiency testing for *Salmonella* or STEC analysis has not yet been established;
  - The MICs could not produce calibration and certification records of equipment used for official sample testing to verify proper setting and functioning;
  - There are no records for laboratory environmental controls to ensure that the performance of sample testing is not adversely affected;
  - There are no records to confirm sterility of media prepared at the MIC laboratories prior being used to test official samples for *Salmonella* or STEC;
  - The MICs could not produce any records or documentation to show that laboratory officials took appropriate corrective actions for identified non-conforming work; and
  - Most laboratory equipment used for official samples analyses are not calibrated and lack certificate of calibration affixed on equipment;
  - The microbiological analyses conducted for *Salmonella* do not include positive and negative control samples during biochemical confirmation; and
  - The microbiological analyses conducted for Shiga toxin-producing *Escherichia coli* (STEC) do not include appropriate positive and negative controls in screening or confirmation steps.

FSIS determined that Japan's government organizes and administers the country's food safety inspection system, and that MHLW officials enforce laws and regulations governing production and export of raw beef at establishments certified to export to the United States. However, the FSIS auditors identified that MHLW does not ensure adequate performance by the MICs and the MIC laboratories included in this audit of the microbiological procedures set by the MHLW for official verification sampling and testing. The MHLW is committed to provide FSIS with corrective actions plan, which FSIS will verify once the corrective actions are implemented.

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

The second of six equivalence components the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The

government system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of each and every carcass and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

The FSIS auditors verified by means of document review, interview, and observations that the MHLW has verification processes for ensuring compliance with the humane handling of livestock before slaughter in holding pens, during ante-mortem inspection, and during stunning and slaughter processes in accordance with the *Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States.* These requirements include maintenance of stockyards, pens and pathways in good condition as necessary to prevent harm to animals. Animals must have continuous access to water while being held, and feed if held for more than 24 hours.

The FSIS auditors verified that inspection personnel conduct daily and continuous verification of humane handling and slaughter requirements and that inspection personnel document the results on the daily verification inspection report. This includes daily observations of loss of consciousness and accompanying indicative signs of adequate stunning before cattle are shackled and bled. The FSIS auditors observed and verified that all animals have access to water in all holding areas, and that establishments have procedures to provide feed if animals are held for more than 24 hours.

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

The FSIS auditors verified that inspection personnel review the incoming registration and owner identification documents with each load, matching the cattle's ear tag individual identification number with the receiving documents. Japan employs the National Livestock Breeding Centre System in which each ear tag number is registered. This system allows the animals and carcasses to be traced back to their farms of origin using the identification number. The complete movement history for each animal is also included in the individual identification information. As described in *Guidelines for Inspection of Certified Establishments Handling Meat for Exportation to the United States*, the FSIS auditors verified that ante-mortem inspection procedure is performed in a location with adequate lighting and that inspection personnel observe all animals at rest and in motion from both sides in designated holding areas before slaughter to assess their fitness for slaughter and results are documented on a form specific for ante-mortem inspection. Each audited slaughter establishment maintains a specific holding pen designed for further examination of sick or suspect animals. Additionally, FSIS auditors verified

that non-ambulatory disabled cattle are not slaughtered and dressed in any of the audited slaughter establishments as stipulated in Attachment 2 of the *Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States.*

The FSIS auditors verified that the MHLW, through the MICs, ensures that enough inspection personnel are assigned to conduct daily and continuous post-mortem inspection at the time of slaughter of beef cattle intended for export to the United States as required in the *Abattoir Act (Act No. 114)*, Article 14. The FSIS auditors reviewed condemnation records and observed inspection personnel performing post- mortem inspection of each and every livestock carcass and parts during and after the slaughter of livestock.

The FSIS auditors verified that written procedures of post-mortem examination are in place for inspection personnel to follow as described in the *Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States, Guidelines for Inspection of Certified Establishments Handling Meat for Exportation to the United States, Abattoir Act (Act No. 114),* and *Regulation for Enforcement of the Abattoir Act* (Ordinance No. 44 and No. 216). Cattle post-mortem inspection includes visual inspection, palpation, and incision of relevant organs and lymph nodes. The FSIS auditors verified that the MHLW requirement of head inspection consists of observation with checking for abnormalities; incision of lymph nodes (mandibular, lateral retropharyngeal, medial retropharyngeal and the parotid lymph nodes); and incision "deeply" into the lateral and medial masseter and pterygoid muscles to check for cysticercosis.

The FSIS auditors observed and verified that carcasses and parts are properly presented, identified, and inspected by inspection personnel, and the FSIS auditors reviewed documentation of inspection results, disposition, and verification of correct synchronization between carcass, organs, and viscera lines. The design of the post-mortem inspection stations with proper lighting and the appropriate number of online inspectors were consistent with the requirements of 9 CFR 310.1. However, at the head inspection station of seven establishments, the MIC inspectors used knives to peel the hide from the heads of cattle to expose the masseter muscle, but these inspectors did not cut deep through the masseter muscle as required by the MHLW.

- At seven establishments, the FSIS auditors observed the MIC inspectors peeling off the hide of cattle head to expose the masseter muscle, but not incising deeply as required by the MHLW to inspect for cysticercosis.

The FSIS auditors verified that the tongue is palpated, and the carcass thoracic and abdominal cavities are examined for abnormalities. The lungs are visually inspected and palpated and the bronchial and mediastinal lymph nodes are incised. The heart is inspected visually and palpated, and the right and left atria and ventricles incised, and the diaphragm visually inspected and palpated. The liver is visually inspected and palpated, and the intrahepatic bile duct is incised and inspected for abnormalities. Inspection of the viscera involves visual inspection and palpation including the mesenteric lymph nodes. The dressed carcass is inspected after splitting. The outer appearance of both sides is observed from a place that allows close observation of the entire dressed carcass to check for abnormalities. The surrounding adipose tissue from the kidneys is removed and the kidneys are examined for abnormalities by visual inspection and

palpation. The *Regulation for Enforcement of the Abattoir Act* (Ordinance No. 44) has tables listing specific diseases and a table with appropriate dispositions for those disease conditions. Disease conditions are also discussed in the *Abattoir Act (Act No. 114)* and *Regulation for Enforcement of the Abattoir Act* (Ordinance No. 216).

The *Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States* also has requirements for sanitary dressing procedures. It states that the removal of the head, viscera, and hide must be accomplished paying special attention that the removal, segregation and disposition of the head, spinal cord and distal ileum is accomplished according to Attachment 3, "*Standards for Implementation of Sanitation Control by HACCP*". The *Regulation for Enforcement of the Abattoir Act* (Ordinance No. 44) also contains sanitary dressing measures; if contamination occurs, the carcass must be removed from the line under supervision of the inspector. The *Guidelines for Inspection of Certified Establishments Handling Meat for Exportation to the United States* provides for inspection of carcasses for feces, milk and ingesta by official inspectors. Procedures for verification of feces, ingesta and milk, and zero tolerance are specified in Attachment 3 of the *Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States.* The MICs are required to report inspection results and exported amounts to the RBHW, as described in the *Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States*.

The FSIS auditors verified that a representative from the FSD of the RBHW makes monthly review visits of each certified establishment to evaluate their compliance with the national requirements, laws and guidelines in accordance with the *Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States*, and *Guidelines for Inspection of Certified Establishments Handling Meat for Exportation to the United States*. The FSIS auditors reviewed the most recent monthly review reports and observed that the required frequency is maintained and documented on a standard checklist form titled *Establishment Audit Checklist,* prepared by the MHLW.

The checklist, dated January 10, 2020, consists of three sections. The first section covers the standards for construction and materials for facilities and equipment, the second section covers sanitation control of facilities and equipment which includes sanitary dressing and humane handling of livestock, and the third section covers sanitation SOP, *E. coli* testing, HACCP system, and verification by inspection personnel. The RBHW reviewer uses the checklist to evaluate the beef establishments' operation and compliance with laws and requirements. Currently, the individual supervisory evaluation of inspection personnel is conducted once a year by the MIC Director. The FSIS auditors reviewed a sample of these individual supervisory evaluations and noted that the outcomes of these evaluations are not shared with the MHLW or the RBHW.

These monthly reviews of establishments are distributed to the audited establishments, the MICs, and the corresponding RBHW office. The RBHW office is responsible for analyzing the results of the review and conducting follow-up verification of an establishment's corrective actions if non-compliance was identified. It is also responsible for confirming that inspection personnel verify the implementation and evaluate the effectiveness of those corrective actions. The RBHW submits a copy of the establishment monthly reviews to the MHLW headquarters for further

review and analysis. At every establishment audited, the FSIS auditors reviewed several monthly reviews performed by the regional offices and reviewed most recent inspection-related records. These reviews and records documented no occasions of non-compliance.

The MHLW *Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States* provides that slaughter and processing establishments certified to export product to the United States be separate from establishments that do not export product to the United States. Additionally, the meat processing establishment must be an annex to the slaughter establishment, performing all production steps from slaughter and dressing to fabrication. The FSIS auditors verified that complete separation is maintained between beef product certified for export to the United States and domestic product. The FSIS auditors verified that, within these establishments, separation of product is maintained by production on different days or at different times, when product intended for export to the United States is produced first and identified by control tags and barcodes in storage.

The FSIS auditors verified that the inspection personnel are responsible for label verification as part of their inspection. The results of inspections are documented in daily or weekly inspection reports, which are then sent monthly to the local authority, RBHW, and MHLW in a summary format. The FSIS auditors reviewed the daily inspection records and verified that inspection is occurring as prescribed.

The FSIS auditors observed and verified that no beef products restricted by APHIS were being produced for export to the United States. Japan is eligible to export all raw intact beef to the United States except for boneless manufacturing trimmings, cheek meat, head meat, heart meat, and weasand meat. Japan is classified as having negligible risk for BSE and free from FMD. Beef exported from Japan to the United States is subjected to BSE requirements specified in 9 CFR 94.18/ 9 CFR 94.19, and to FMD requirements specified in 9 CFR 94.11. The MHLW and Ministry of Agriculture, Forestry and Fisheries (MAFF) ensure compliance with these requirements by monitoring the APHIS website and verifying restrictions under 9 CFR 94.1 prior to signing export certificates.

The FSIS auditors verified through onsite observation, records review, and interviews of inspection personnel that the specified risk materials (SRMs) in beef products are adequately identified, removed, and disposed of at each audited slaughter establishment. Establishments have identified the SRMs as a biological hazard in their HACCP plan hazard analysis and have implemented adequate measures to control SRMs throughout the processing steps. Establishments either treated all cattle slaughtered as 30 months of age or older and implemented all SRMs control criteria or the establishments have adequate controls in place for the segregation of carcasses throughout the process. The FSIS auditors verified that SRMs have been removed and whole cuts of boneless beef destined for export to the United States are derived from cattle that were born, raised, and slaughtered in Japan. The FSIS auditors also verified that the inspection personnel verify the adequate identification, removal, and disposal of SRMs daily and document the results on the inspection form *Daily Monitoring Verification*.

The FSIS auditors verified that non-ambulatory disabled cattle are not slaughtered and dressed in certified establishments as required by the MHLW *Requirements for Certification of*

Slaughterhouses, Etc., Handling Meat for Exportation to the United States, and that all audited slaughter establishments have control over condemned materials as stipulated in the *Abattoir Act (Act No. 114)* and *Regulation for Enforcement of the Abattoir Act* (Ordinance No. 44 and No. 216). FSIS auditors also verified appropriate identification of condemned material in accordance with the categories described therein, segregation in specially marked or otherwise secure containers, and final documented disposal of these materials at nearby rendering facilities.

The FSIS auditors found instances of the masseter muscle of cattle head was not sufficiently cut sufficiently deep by inspection personnel. The MHLW is committed to provide FSIS with corrective action plans, which FSIS will verify once the corrective actions are implemented.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components the FSIS auditors reviewed was Government Sanitation. The FSIS auditor verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation SOPs to prevent direct product contamination or insanitary conditions, and to include requirements for SPS, and to establish sanitary dressing procedures.

The FSIS auditors observed and verified through record reviews that all audited beef slaughter establishments implement appropriate sanitary dressing procedure in accordance with the MHLW *Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States.* The MHLW requires certified establishments to operate in a sanitary manner and maintain sanitary standards specific to all production areas including ante-mortem, post-mortem, and processing department to prevent direct product contamination and the creation of insanitary conditions, in accordance with the *Abattoir Act* and *Abattoir Act Enforcement Regulation.*

The onsite MIC inspection personnel verify that the establishment implements on a daily basis sanitary dressing procedure throughout the slaughter process. MHLW provides guidance to inspection personnel on official control procedures for slaughter hygiene verification and ongoing assessment of the establishment's compliance with food hygiene requirements from acceptance of animals for slaughter through carcass dressing and chilling, in accordance with *Guidelines for Inspection of Certified Establishments Handling Meat for Exportation to the United States* and with *Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States,* Attachment 2, Sanitation Control Standards.

The *Guidelines* provide for an offline inspector must verify that animals and carcasses are appropriately dressed by the certified establishment according to the standards for sanitary slaughtering, dressing, and splitting procedures. The *Guidelines* address all steps of sanitary dressing processes including receiving, holding, sticking, bunging, brisket opening, head removal, evisceration, carcass splitting, and carcass washing. The MIC inspection personnel at the final rail position ensure that carcasses with visible fecal contamination are further trimmed and re-inspected before entering the chiller, and they verify an establishment's ability to implement corrective actions and compliance with the *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States,* included in Attachment 2,

"Sanitation Control Standards" and Attachment 3, "Standards for Implementation of Sanitation Control by HACCP".

The MHLW requires all certified establishments to develop, implement, and maintain daily preoperational and operational sanitation procedures that are sufficient to prevent the direct contamination or adulteration of meat products intended for export to the United States. The inspection personnel are required to exercise their official authority and follow guidance provided by MHLW to conduct verification of sanitary conditions as outlined in the *Guidelines for Inspection of Certified Establishments Handling Meat for Exportation to the United States.*

The FSIS auditors verified the implementation of preoperational sanitation inspection by the MIC inspection personnel at one of the audited establishments. The 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 SPS requirements (e.g., ventilation, condensation, and structural integrity).

The FSIS auditors observed the MIC inspection personnel performing operational sanitation verification procedures in the eight audited establishments, comparing the overall sanitary conditions of all audited establishments to the government inspection verification records. The FSIS auditors also examined the inspection personnel documentation of verification results and noticed a minimal number of noncompliance recorded. The FSIS auditors' own observations and record reviews of establishments' monitoring, verification, and corrective actions records identified several isolated noncompliance in six of the audited establishments which are listed in their respective individual establishment checklist provided in Appendix A. The isolated noncompliance directly relates to the effectiveness of the establishments' implementation and monitoring activities of sanitation SOP and SPS and the adequacy of the official verification activities by the MICs inspection personnel.

The MHLW is committed to provide FSIS with corrective action plans, which FSIS will verify once the corrective actions are implemented. The MHLW oversight is emphasized to ensure that MIC inspection personnel are adequately verifying the implementation and documentation of sanitation SOP and SPS and able to initiate appropriate enforcement action when corrective actions are ineffective or inadequate by certified establishments.

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

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

The FSIS auditors observed and verified that certified establishments eligible to export beef products to the United States develop, implement, and maintain a HACCP system in accordance with the *Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States,* Attachment 3, "Standards for Implementation of Sanitation Control by

HACCP", Section III Voluntary Sanitation Control Using HACCP System. The MHLW requires establishments to have a written HACCP plan before establishments are certificated to export to the United States. Establishments must identify and evaluate the food safety hazards that can affect the safety of their products, institute controls necessary to prevent those hazards from occurring or keep them within acceptable limits, monitor the performance of controls, and maintain records routinely.

The MHLW requires the MIC inspection personnel to verify the validity and compliance of each certified establishment's HACCP plan with its requirements in accordance with the *Guidelines for Inspection of Certified Establishments Handling Meat for Exportation to the United States.* The MHLW requires the regional officers in each RBHW to audit each certified establishment within their local authority (prefecture) once a month to assess its HACCP plan, assess adequacy of implementation and compliance with requirements and guidelines. The regional officers must also evaluate the adequacy of verification activities performed by the MIC inspection personnel.

The *Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States,* specifically clarifies that hazard analysis must be conducted based on scientific evidence to identify the potential hazards and to employ measures to prevent the hazards from occurring. The HACCP plan must specify the corrective action to be taken at each critical control point (CCP) when a deviation from a critical limit (CL) occurs, as well as the person required to take the corrective action. Also, the corrective action must identify the cause of the deviation, then record and eliminate that cause. Additionally, establishments must record activities to verify that the HACCP plan is effectively implemented, after conducting a validation study to ensure that the hazards identified in the hazard analysis are properly prevented by the measures in the HACCP plan.

The FSIS auditors verified the implementation of HACCP plan at each of the eight audited slaughter establishments through onsite observation and thorough review of the records on hazard analysis, CCP and CL decisions, flow charts, monitoring and verification frequencies, daily documentation, and corrective actions. The MIC inspection personnel are responsible for performing verification activities that include review of the content of the establishment's written HACCP plans, review of establishment-generated HACCP monitoring and verification records, and direct observation of the establishment's personnel performing those procedures to assess the adequacy of implementation of HACCP plans. The offline 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 corrective actions.

The FSIS auditors observed the MIC inspection personnel in the eight audited slaughter establishments conducting the verification procedure for the zero tolerance CCP; the location of their verification procedure is the same used by the establishments' personnel. The number of cattle slaughtered in each establishment audited ranged between 25-70 heads per shift, the monitoring frequency of zero tolerance CCP by establishment management was set appropriately based on the risk analysis of each establishments and the verification frequency by the MIC inspection personnel was two carcasses (four sides). The FSIS auditors' onsite verification did not reveal any deviations from the critical limit.

The FSIS auditors' verification activities also included interviews with establishment and inspection personnel, and review of establishment records, and supporting documents related to the HACCP system decision-making process. The FSIS auditors reviewed and compared the contents of the audited establishments' HACCP plans with records corresponding to establishments' monitoring, corrective actions, and verification activities as well as with the MICs inspection's verification records for the past 90 days. The FSIS auditors' review of the HACCP records generated by the establishments and review of the MICs inspection personnel's daily inspection verification activities documentation showed inadequate implementation of the MHLW requirements and/or guidelines:

- At five establishments, the MHLW does not ensure adequate oversight over the implementation of HACCP recordkeeping and verification requirements. Official records of ongoing verification of critical control points were not maintained or were incorrectly recorded. Examples include:
  - The monitoring of zero tolerance CCP is marked acceptable while the documents are not initialed or signed by the monitor or the verifier. This is a repeat finding from the 2015 audit by the same prefecture.
  - The sequence of processing steps in the hazard analysis and flow charts of the establishments' HACCP plans are not consistent, and the sequence of processing steps in in flow charts are not in the same numbered order as the actual steps of operations in the slaughter and processing departments. In some cases, an essential step in the flow chart such as trimming is missing in the hazard analysis.
  - The HACCP production records for all the CCPs monitoring and verification are not identified correctly as stated in the hazard analysis and HACCP plan.
  - The HACCP plan is not signed by a current plant official.
  - The critical control limit of carcass room temperature is not supported by a validation study to correlate it with carcass surface temperature.
  - Thermometers used for monitoring the CCP of carcass temperature in coolers are not identified in HACCP calibration records.
  - Establishments' preshipment review records for beef products intended for export to the United States are inaccurately recording the wrong review date.
  - The daily official verification records consistently show the incorrect number of CCPs (zero tolerance, carcass cooler temperature, and product storage temperature) which conflict with the CCPs numbers documented in establishment preshipment reviews for products shipped to the United States.
  - The zero tolerance verification activity by official inspection personnel is not performed randomly as they always target the last animal of each slaughter day.

The FSIS auditors' review of documents pertaining to hazard analysis, HACCP plan, monitoring, verification, and corrective actions implementation by establishments as well as onsite 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, official record keeping is not adequate as noted above.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

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

Prior to the onsite visit, FSIS' residue experts reviewed the Japan's National Residue Program (NRP) for 2019, associated methods of analysis, and additional SRT responses outlining the structure of Japan's chemical residue testing program. FSIS based its verification of Japan's NRP on information contained in its NRP sampling plan and previous years testing results. The FSIS auditors also conducted an onsite audit of one residue laboratory that performs residue analyses on products exported to the United States. There have not been any POE violations related to this component since the previous FSIS audit in 2018.

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

The FSIS auditors verified that Japan's NRP is designed and conducted in accordance with the *Guidelines for Inspection of Certified Establishment*. Japan's NRP contains provisions from the *Food Sanitation Law, Article 54*, in which the MHLW, the governor of the prefecture, or the official with the authority to dispose of product that exceed acceptable residue levels. In addition, to prevent the violations from recurring, the cause of the chemical residue violation is investigated using both the domestic and United States standards. The local authorities publish a written disposition order or a written improvement order for products with violative levels of chemical residues. Japan's residue plans are recognized as consistent with FSIS' criteria.

The FSIS auditors verified the implementation of Japan's NRP at the eight audited slaughter establishments. The official monitoring is conducted according to Japan's NRP, which lists the residue group, the number of samples for the group, and the sample matrix for analysis each month. The inspection personnel who collect random residue samples at the beef slaughter establishments have received training in sampling methodology, identification of animals, traceability, and sample security. National residue sampling results are communicated to the MHLW headquarters, regional offices, and inspection personnel through e-mail.

The FSIS auditors verified that the inspection personnel are following Japan's NRP sampling protocol. This protocol includes random sampling and testing of internal organs, fat, and muscle of carcasses for targeted residues, and secure delivery of residue samples to the designated JFRL in accordance with the prescribed methodology provided by MHLW based on the *Guidelines for Inspection of Certified Establishment*. The inspection personnel complete the laboratory submission form, and a copy is packaged in the sample shipment cooler, however, the FSIS auditors observed the following deviation that can compromise the sample integrity or chain-of-custody:

- The MHLW does not have an adequate chain of custody system for laboratory operations. Most residue samples did not have signed security seals and were not accompanied by transfer-and-storage records.

The JFRL is an independent and private institution accredited by the MHLW as a testing laboratory system for conducting analysis of government samples for the presence of chemical residues (pesticides, antibiotics, heavy metals, environmental contaminants, and food additives) in meat products. The JFRL has seven locations distributed across Japan and two (Tama-shi and Saito) are designated as testing laboratories under Japan's NRP. The FSIS auditors reviewed the JFRL- Tama-shi laboratory chemical residue testing program and verified that JAB has accredited the laboratory as equivalent to the ISO 17025 standards in the specific areas of testing.

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

The FSIS auditors observed a demonstration by the JFRL laboratory personnel on sample receipt and handling, including checking sample integrity and security, registration of the sample per the laboratory quality assurance system, and assigning the identification and storage of samples in accordance with the laboratory's standard operating procedure. The FSIS auditors verified that the private laboratory performs a timely analysis of samples, reports the number of analyzed samples and the results to MHLW in a timely manner. The JFRL applies approved analytical methodologies and has quality assurance programs. During the onsite audit of the JFRL, FSIS auditors were not provided documentation to show sample rejection due to absence of signed security seals, yet the FSIS auditor observed that most of the MICs audited did not secure the sample shipping container with signed security seals.

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

The FSIS auditors' review of the verification results for the last year at the eight audited establishments showed no violative samples were detected except for one sample due to Kanamycin in muscle. The MHLW instructed the establishment through the MIC to identify and recall the product, and the MHLW instructed the local authority in charge of the establishment to investigate the cause of the incident such as by reviewing the history of veterinary drug administration to the cattle.

The MHLW issued notification to all MICs on November 2018 regarding hold-and-test policy and as corrective action to previous FSIS audit finding in 2018. The notification stated that the MICs cannot issue health certification until they receive acceptable official test results for beef products tested for routine and suspect chemical residues and for microbiological contaminants. However, the MHLW allows establishments to divert carcasses selected for routine residue monitoring to local market which excludes those carcasses from export to the United States. The MHLW notification titled "The issuance of the Health Certificate" states: "In accordance with the final report of the last audit (2018), for confirmation of acceptable testing results prior to signing the export certificate, MHLW directed the local governments which authorized certified establishments not to issue any health certificate until confirming compliance in regard to residue monitoring testing, *Salmonella* testing and STEC testing". The provision of this rule has been added to the Attachment 2 *of Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States.*

Regarding analyses of pesticides, the JFRL analyzes by gas chromatography using the chromatography column DB-1701 and confirms the selectivity of the test by measurement result using the chromatography column DB-5. The FSIS auditors found that the MHLW does not have a written policy or instructions to laboratories testing official samples stating that samples with unacceptable test results are not to be re-sampled or re-tested. However, the JFRL explained that they only retest residue samples that exceed the lower detection level criteria by 80% or higher. The MHLW informed the FSIS auditors that the aminoglycoside class of antibiotics is confirmed by using liquid chromatography coupled with mass spectrometer by internationally recognized standards methods and reference materials. For differentiation among the four aminoglycosides noted in the NRP, the JFRL uses liquid chromatography-tandem mass spectrometry.

The FSIS auditors verified that Japan's food safety inspection system continues to maintain a chemical residue testing program organized and administered by the national government. The MHLW maintains the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of unacceptable residues of veterinary drugs and contaminants in beef products destined for export to the United States. However, MHLW oversight is warranted to ensure that residue samples shipped from the MICs to the JFRL are properly secured by signed security seal.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

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

The FSIS auditors verified that the eight audited beef slaughter establishments verify their process control by testing carcass samples for generic *E.coli*, as an indicator of intestinal and fecal contamination, as described in MHLW *Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States,* Part II of Attachment 3. The FSIS auditors verified that each of the audited establishments collects swab samples from three regions (i.e., flank, brisket and rump) of selected carcasses aseptically by surface swabbing with a sterilized sponge. Samples are collected once per week or every 300 carcasses processed, and samples are analyzed using a validated method certified by the Association of Official Analytical Chemists (AOAC) International. The MHLW conducts verification activities to evaluate an establishment's slaughter process control of fecal contamination and ensure that each establishment's generic *E. coli* testing program in chilled beef carcasses is adequate.

The FSIS auditors also reviewed establishment generic *E.coli* test results for the previous two months 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 criteria. The FSIS auditors' review of the establishments' generic *E.coli* testing program and records did not reveal any noncompliance or concerns.

The FSIS auditors observed the MIC inspection personnel perform sampling verification activities for *Salmonella* in the eight audited beef slaughter establishments. The MIC inspection personnel aseptically collect samples from three regions (i.e., flank, brisket and rump) of randomly selected carcasses by using a sterile sponge to swab of a 10 cm by 10 cm surface area from each region. The MHLW has a *Salmonella* sampling and testing program for carcasses that is consistent with FSIS' *Salmonella* performance standards criteria as described in 9 CFR 310.25(b). The inspection personnel collect 82 consecutive samples with a maximum number of positives to achieve the standard of ≤ 1. MHLW's *Salmonella* performance standard for beef steer/heifer ($n = 82$, $c \leq 1$) and cow beef/bull beef ($n = 58$, $c \leq 2$). The FSIS auditors reviewed inspection personnel official records, including the last *Salmonella* sample set results at the eight audited slaughter establishments and no *Salmonella* sets exceeded established criteria. The MHLW has an enforcement strategy in place if performance standards are exceeded. Establishments are required to identify the cause of the issue, take proper corrective actions, and implement preventive measures.

The analytical method implemented for *Salmonella* testing in MIC laboratories is the FSIS MLG, Chapter 4.09. The MHLW verifies that all certified establishment inspection sample collection procedures are in accordance with its sample collection protocols described in *Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States.* The

FSIS auditors thoroughly reviewed the implementation of the *Salmonella* method of analysis in eight MIC laboratories.

The FSIS auditors verified through observations and interviews that MHLW has implemented a method for detection of *E. coli* O157:H7 and non-O157 STEC in beef trimmings. The FSIS auditors observed a demonstration of beef trimming sample receipt, handling, and testing for STEC at the eight MICs microbiological laboratories audited using the method developed and approved by MHLW. The FSIS auditors thoroughly reviewed the laboratories quality assurance control programs, trace-back of a selected sample, implementation of the STEC method of analysis, and time taken to report results to the MIC and MHLW and identified the following findings:

- The eight MIC laboratories are not analyzing the entirety of the N60 sample for *Escherichia coli (E. coli)* O157:H7 and non-O157 Shiga toxin-producing *E. coli* (STEC) during screening of official testing;
- The MHLW has not implemented an appropriate official method for STEC that meets equivalence expectations. The STEC culture confirmation procedure does not include appropriate immunoconcentration steps with dilution or an acid wash step to allow for adequate isolation of potentially low levels of STEC in a sample.

The FSIS auditors verified that each of the eight audited establishments has a written sampling program for STEC testing which describes the frequency of sampling according to the production volume and based on the MHLW requirements (12 times/ year for production of >113,400 kg, 6 times/ year for 113,400 kg – 2,270 kg, and 4 times/year for <2,270 kg). The official verification sampling for STEC is conducted once per month. The program specifies that trimmings are collected according to the N60 sample collection procedure, by taking 60 thin slices with dimensions of 8 centimeters long by 3 centimeters wide and 0.3 centimeters thick from surface area tissue for STEC analyses.

The FSIS auditors observed a demonstration of N60 sampling procedure and collection of beef trimming technique by the MIC inspection personnel at certified establishments to verify implementation of MHLW verification program for STEC. The FSIS auditors observed and verified the inspection personnel implemented the sample collection protocol described in the MHLW authored STEC verification program. The FSIS auditors identified the following findings:

- At seven establishments, the collection of 60 pieces of beef trimming (N60) for STEC testing is performed by the establishment's personnel not by MIC inspection personnel.
- At seven establishments, the 60 pieces are neither trimmed from the exterior surface of carcass portions nor selected randomly. For example:
    - The assigned establishment worker selects a primal or subprimal carcass cut from a processing line conveyor belt, which was already trimmed by another worker at the beginning of the line. The assigned worker starts to collect trimmings for N60 from the deep surface of selected carcass portion. The selection of carcass cut for trimming collection was not predetermined by an appropriate randomization method and did not consider all processing lines.

FSIS determined that the MHLW has not fully met the requirements of the STEC verification program due to improper collection procedure of the N60 samples, not implementing an appropriately validated STEC confirmation method, and not using all the N60 sample for official testing purposes at certified establishments to ensure that raw beef products are free of STEC at the end of the production process. There have not been any POE violations related to this component since the FSIS audit in 2018.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held February 14, 2020, in Tokyo, Japan, with the MHLW officials. At this meeting, the FSIS auditors presented the preliminary findings from the audit. The FSIS auditors identified the following findings:

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

- The MHLW does not provide adequate oversight over the implementation of inspection tasks and microbiological procedures used for testing official samples;
- The eight MICs' microbiological laboratories are not meeting the quality assurance and control criteria established by the MHLW. Examples include:
  - Analyses for *Salmonella* do not include positive and negative control samples in biochemical confirmation.
  - Analyses for Shiga toxin-producing *Escherichia coli* (STEC) do not include positive and negative controls in screening or confirmation methods.

GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

- At seven establishments, the FSIS auditors observed the MIC inspectors peeling off the hide of cattle head to expose the masseter muscle and not incising deeply as required by the MHLW to inspect for cysticercosis.

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

- At five establishments, the MHLW does not ensure adequate oversight over the implementation of HACCP recordkeeping and verification requirements. Official records of ongoing verification of critical control points were not maintained or were incorrectly recorded.

GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

- The MHLW does not have an adequate chain of custody system for laboratory operations. Most residue samples did not have signed security-seals and were not accompanied by transfer-and-storage records.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- The eight MIC laboratories are not analyzing the entirety of the N60 sample for *Escherichia coli (E. coli)* O157:H7 and non-O157 Shiga toxin-producing *E. coli* (STEC) during screening of official testing;
- The MHLW has not implemented an appropriate method for STEC confirmation that meets equivalence expectations. The confirmation method does not include appropriate immune-concentration procedures with dilution or an acid wash step to allow for adequate isolation of potentially low levels of STEC in a sample;
- At seven establishments, the collection of 60 pieces of beef trimming for STEC testing is performed by establishment's personnel not by MIC inspection personnel; and
- At seven establishments, the 60 pieces are neither trimmed from the exterior surface of carcass portions nor selected randomly.

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

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Wagyu Master Meat Center 1451-5, Togo-cho, Himeji-shi, Hyogo	01/31/2020	HMJ1	Japan
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw intact beef (cuts, and primals and subprimals).

60. Observation of the Establishment

10.
During preoperational sanitation, the following was identified: Rusty stains on the overhead beams of processing department. Fat particles on the inner surface of a conveyor belt were observed.

55.
The MIC inspectors are peeling off the hide of cattle head to expose the masseter muscle and not incising deeply as required by the CCA to inspect for cysticercosis.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	01/31/2020

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Miyachiku Corp. Ltd, Takasaki Plant 4268-1 Omuta, Takasaki-cho Miyakonojo-shi Miyazaki	02/03/2020	M-1	Japan
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw intact beef (boneless manufacturing trimmings, cuts, and primals and subprimals).

60. Observation of the Establishment

10.
In one of the beef carcass coolers, carcasses were stored closely contacting each other creating insanitary condition of possible cross contamination.

35.
A review of the residue sample packing method showed that no record of transfer from the establishment to the MIC or documentation of storage exists. These records are vital to the chain of custody of the sample. Absence of internal and external box authentication/ security seal with signature exists outside of the tamper resistant tape applied.

36.
Sampling procedure for collecting 60 pieces of trimming from primal cuts to test for STEC is performed by establishment personnel. The procedure of collection does not ensure random sampling and target the inner muscle layer not the external surface.

39.
In the outside premises of this establishment, excessive accumulation of maintenance equipment, tools, trash, cords, leaves, and metal were stored directly on the grounds creating insanitary conditions and potential of harboring rodents and pest.

55.
The MIC inspectors are peeling off the hide of cattle head to expose the masseter muscle and not incising deeply as required by the CCA to inspect for cysticercosis.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	02/03/2020

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Sankyo Meat Ltd. Ariake Meat Plant 6965 Noikura, Ariake-cho Shibushi-shi Kagoshima	02/04/2020	K-2	Japan
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	X
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	!0
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	X
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw intact beef (cuts, and primals and subprimals).

60. Observation of the Establishment

8. and 10.
The establishment documentation of insanitary conditions of product contact surfaces during pre-operational and operational sanitation inspection are consistently entered as acceptable "A" while in fact it's unacceptable "U" is misleading, inaccurate records keeping, and contrary to the instruction of the Form. The description of noncompliance and corrective actions are not documented in the Form; this is a repeated noncompliance of the same prefecture that was previously reported by FSIS audit in 2015. Operational sanitation records show that monitoring of zero-tolerance CCP are acceptable while the documents are not initialed or signed by the persons who perform the monitoring or the verification activities.

16.
The processing steps in the hazard analysis and flow chart of the establishment's HACCP plan are neither matching each other nor orderly numbered to mimic the actual steps of processing in the slaughter and processing departments. The HACCP production records for all of the CCPs monitoring and verification are not identified by the CCP numbers stated in the HACCP plan.

35.
A review of the residue sample packing method showed that no record of transfer from the establishment to the MIC or documentation of storage exists. These records are vital to the chain of custody of the sample. Absence of internal and external box authentication/ security seal with signature exists outside of the tamper resistant tape applied.

55.
The MIC inspectors are peeling off the hide of cattle head to expose the masseter muscle and not incising deeply as required by the CCA to inspect for cysticercosis.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	02/04/2020

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Nanchiku Co., Ltd. 1828 Nonokata, Sueyoshi-cho Soo-shi Kagoshima	02/05/2020	K-1	Japan
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	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	X
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	X
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
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. Periodic Supervisory Reviews	
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.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw intact beef (cuts, and primals and subprimals).

60. Observation of the Establishment

10.
The refrigeration unit of a carcass cooler was framed by black insulation tape that appeared deteriorating and peeling off. The connecting pipes of that unit has excessive accumulation of ice. No product was exposed to this insanitary condition.

15.
The processing steps in the hazard analysis and flow chart of the establishment's HACCP plan are neither matching each other nor orderly numbered to mimic the actual steps of processing in the slaughter and processing departments.

35.
A review of the residue sample packing method showed that no record of transfer from the establishment to the MIC or documentation of storage exists. These records are vital to the chain of custody of the sample. Absence of internal and external box authentication/ security seal with signature exists outside of the tamper resistant tape applied.

36.
Sampling procedure for collecting 60 pieces of trimming from primal cuts to test for STEC is performed by establishment personnel. The procedure of collection does not ensure random sampling and target the inner muscle layer not the external surface.

52.
The FSIS auditors observed cattle are forcefully pulled from the nostrils to stunning box by a rope through a nose-ring while cattle are balking and resisting to enter the box.

55.
The MIC inspectors are peeling off the hide of cattle head to expose the masseter muscle and not incising deeply as required by the CCA to inspect for cysticercosis.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	02/05/2020

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Miyachiku Corporation, Ltd., Tsuno Plant 15530, Kawakita, Tsuno-cho, Koyu-gun, Miyazaki	02/06/2020	M5	Japan
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

Establishment Operations:	Beef processing.
Prepared Products:	Raw intact beef (primals and subprimals).

60. Observation of the Establishment

13.
Establishment's sanitation SOP records does not include category for handling and reworking meat products dropped on the floor.

35.
A review of the residue sample packing method showed that no record of transfer from the establishment to the MIC or documentation of storage exists. These records are vital to the chain of custody of the sample. Absence of internal and external box authentication/ security seal with signature exists outside of the tamper resistant tape applied.

36.
Raw products intended for export to the United States are not properly segregated and identified form other domestic products in the processing depart cutting table, cryo-vac packaging table. Sampling procedure for collecting 60 pieces of trimming from primal cuts to test for STEC is performed by establishment personnel. The procedure of collection does not ensure random sampling and target the inner muscle layer not the external surface.

52.
The FSIS auditors observed cattle with a rope around the head with a loop through a nose-ring being led from the holding pen to the single-file-chute and to the stunning box.

55.
The MIC inspectors are peeling off the hide of cattle head to expose the masseter muscle and not incising deeply as required by the CCA to inspect for cysticercosis.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	02/06/2020

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Oitaken Chikusankosya Co., Ltd. 1580-29 Tahara, Inukaimachi, Bungoono-shi, Oita	02/07/2020	OI1	Japan
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw intact beef (primals and subprimals).

60. Observation of the Establishment

15.
The trimming step in the flow chart of the slaughter plan is not included in the hazard analysis. The HACCP production records for all of the CCPs monitoring and verification are not identified by the CCP number as stated in the HACCP plan.

35.
A review of the residue sample packing method showed that no record of transfer from the establishment to the MIC or documentation of storage exists. These records are vital to the chain of custody of the sample. Absence of internal and external box authentication/ security seal with signature exists outside of the tamper resistant tape applied.

36.
Raw products intended for export to the United States are not properly segregated and identified form other domestic products in the processing depart cutting table, cryo-vac packaging table. Sampling procedure for collecting 60 pieces of trimming from primal cuts to test for STEC is performed by establishment personnel. The procedure of collection does not ensure random sampling and target the inner muscle layer not the external surface.

52.
The FSIS auditors observed cattle with a rope around the head with a loop through a nose-ring being led from the holding pen to the single-file-chute and to the stunning box.

55.
The MIC inspectors are peeling off the hide of cattle head to expose the masseter muscle and not incising deeply as required by the CCA to inspect for cysticercosis.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	02/07/2020

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Gunma-ken Shokuniku Oroshiuri Shijo Corp., Ltd. 1189 Kamifukushima Tamamura-machi, Sawa-gun Gumma	02/10/2020	G-1	Japan
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw intact beef (cuts, and primals and subprimals).

60. Observation of the Establishment

9.
Sanitation SOP is not reviewed or signed by the current manager; it is signed by a former manager years ago.

10.
During operational sanitation of slaughter room, cutting, carcass coolers, and product storage, excessive usage of duct tape in many locations of each department to seal leakage, support pipes, prevent condensation from cooling units or enclose electric wires. This excessive use of tape to correct maintenance problem impede effective sanitation of walls and pipes and creating insanitary condition. Numerous spots of black residue on the stainless-steel surface near hide removal conveyors.

17.
The HACCP plan is not signed by an overall authority; it is signed by an ex-manager approximately three years ago. The summary of all CCPs are also signed by the same ex-manager years ago.

22.
The critical control limit of carcass room temperature 6.9˚ (CCP-2-2) is not supported by a validation study to correlated with carcass surface temperature. Thermometer used for monitoring the CCP of carcass temperature in coolers is not identified in HACCP calibration records.

35.
A review of the residue sample packing method showed that no record of transfer from the establishment to the MIC or documentation of storage exists. These records are vital to the chain of custody of the sample. Absence of internal and external box authentication/ security seal with signature exists outside of the tamper resistant tape applied.

36.
Sampling procedure for collecting 60 pieces of trimming from primal cuts to test for STEC is performed by establishment personnel. The procedure of collection does not ensure random sampling and target the inner muscle layer not the external surface.

55.
The MIC inspectors are peeling off the hide of cattle head to expose the masseter muscle and not incising deeply as required by the CCA to inspect for cysticercosis.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	02/10/2020

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Hida Meat Center/Hida Meat Agricultural Cooperatives 327 Youka-machi, Takayama-shi, Gifu	02/12/2020	GI-1	Japan
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

Establishment Operations:	Beef slaughter and processing.
Prepared Products:	Raw intact beef (cuts, and primals and subprimals).

60. Observation of the Establishment

9.
The sanitation SOP is not signed and dated by an onsite overall authority.

16.
Establishment's HACCP records for all CCPs do not identified the CCP number as listed in the HACCP. Establishment does not maintain records for ongoing verification activities for CCP2 and CCP3, except for thermometer calibration. The verification records of official inspection personnel consistently record the incorrect numbers of CCPs. Official inspectors' verification records are not organized especially when identifying and correlating the slaughter and cutting dates with the pre-shipment review of product intended for export to the United States. Establishment's pre-shipment reviews for products intended for export to the United States are inaccurately dates.

17.
The HACCP plan is not signed and date by an onsite overall authority.

19.
The zero-tolerance verification by official inspection personnel is not done randomly as they always target the last animal of each day slaughter

35.
A review of the residue sample packing method showed that no record of transfer from the establishment to the MIC or documentation of storage exists. These records are vital to the chain of custody of the sample. Absence of internal and external box authentication/ security seal with signature exists outside of the tamper resistant tape applied.

36.
Sampling procedure for collecting 60 pieces of trimming from primal cuts to test for STEC is performed by establishment personnel. The procedure of collection does not ensure random sampling and target the inner muscle layer not the external surface.

52.
The FSIS auditors observed cattle with a rope around the head with a loop through a nose-ring being led from the holding pen to the single-file-chute and to the stunning box.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	02/12/2020

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

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

July 10, 2020

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

Comments on draft final report of an audit conducted in Japan, January 27 to February 14, 2020 – Evaluating the food safety systems governing raw beef products exported to the United States of America.

Dear Dr. Catlin,

I received your letter of the FSIS's draft final report of an audit conducted in Japan, January 27 to February 14, 2020.

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,

三木 謙

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

事　務　連　絡
令和２年７月 10 日

在京米国大使館農務部　御中

厚生労働省医薬・生活衛生局食品監視安全課

FSIS による現地調査の最終報告書案に
関する改善報告及び意見の提出について

本年５月８日付けで米国農務省食品安全検査局から、FSIS による現地調査の最終報告書案が送付され、現地調査における指摘事項に対する改善措置及び本報告書案に対する意見の提出を依頼されているところです。

別添のとおり提出しますので、米国農務省食品安全検査局国際協調相談役 Michelle Catlin 氏宛て送付方よろしくお願いします。

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, January 27– February 14, 2020.

Findings	***Comments***
Government Oversight (e.g., Organization and Administration)	
The Ministry of Health Labor and Welfare (MHLW) does not provide adequate oversight over the implementation of inspection tasks and microbiological procedures used for testing official samples.	The MHLW endeavours to improve the quality of inspections with a training program for the regional officers in each Regional Bureau of Health and Welfare (RBHW) office (Attachment 1) and provides adequate oversight. Moreover, the MHLW secures and assigns the officers who have experience of slaughter inspection to the regional officers in RBHW.
The eight Meat Inspection Centers (MICs) microbiological laboratories are not meeting the quality assurance and control criteria established by the MHLW. Examples include: o Analyses for *Salmonella* do not include positive and negative control samples in biochemical confirmation. o Analyses for Shiga toxin-producing *Escherichia coli* (STEC) do not include positive and negative controls in screening or confirmation methods.	The MHLW instructs the MIC microbiological laboratories to use positive and negative controls properly and to satisfy the quality assurance and control.
GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g., INSPECTION SYSTEM OPERATION AND LABELING)	
At seven establishments, the FSIS auditors observed the MIC inspectors peeling off the hide of cattle head to expose the masseter muscle, but not incising deeply as required by the MHLW to inspect for cysticercosis.	The MHLW instructed the MICs that had not properly implemented a requirement of I 3 (2) “Guidelines for Inspection of Certified Establishment” to make corrective actions. At the same time, the MHLW informs regional officers of the RBHW and the MICs with establishments certified to export product to the United States about compliance with this requirement.
GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM	
At five establishments, the MHLW does not ensure adequate oversight over the implementation of HACCP recordkeeping and verification requirements. Official records of ongoing	Based on the FSIS observations regarding the implementation of HACCP recordkeeping and verification requirements, the MHLW shared them with all regional officers of the RBHW and instructs the thorough inspection on HACCP documentations of establishments.

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, January 27– February 14, 2020.

Findings	***Comments***
verification of critical control points were not maintained or were incorrectly recorded.	In addition, the MHLW plans to start a training program including HACCP for reinforcing their inspection abilities.
GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS	
The MHLW does not have an adequate chain of custody system for laboratory operations. Most residue samples did not have signed security-seals and were not accompanied by transfer-and-storage records.	The MHLW revises "Guidelines for Inspection of Certified Establishment" and also sets the way of recording of collection, transfer and storage of the sample and the packing method including security-seal in the guidelines, and notifies each MIC of it.
GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS	
The eight MIC laboratories are not analyzing the entirety of the N60 sample for *Escherichia coli (E. coli)* O157:H7 and non-O157 Shiga toxin-producing *E. coli* (STEC) during screening of official testing;	The MHLW revises the part of the sample preparation of testing method of STEC so that the entirety of the N60 sample could be used in enrichment broth with 1:4 dilution and notifies each MIC of it.
The MHLW has not implemented an appropriate method for STEC confirmation that meets equivalence expectations. The confirmation method does not include appropriate immune-concentration procedures with dilution or an acid wash step to allow for adequate isolation of potentially low levels of STEC in a sample;	The MHLW adds appropriate immune-concentration procedures with dilution and an acid wash step to testing method of STEC in the notification and directs each MIC microbiological laboratory to observe it.
At seven establishments, the collection of 60 pieces of beef trimming (N60) for STEC testing is performed by establishment's personnel not by MIC inspection personnel; and	The MHLW revises the method of the collection of 60 pieces of beef trimming (N60) in "Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States" in order to ensure the official random sampling from the exterior surface and notifies each MIC of it.
At seven establishments, the 60 pieces are neither trimmed from the exterior surface of carcass portions nor selected randomly.	
Appendix A: Individual Foreign Establishment Audit Checklists	

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, January 27– February 14, 2020.

Findings	***Comments***
ESTABLISHMENT HMJ-1, Wagyu Master Meat Center	
10. During preoperational sanitation, the following was identified: Rusty stains on the overhead beams of processing department. Fat particles on the inner surface of a conveyor belt were observed.	The MIC director retrained the MIC inspectors on how to perform inspectors' preoperational sanitation verification on February 3, 2020. The establishment removed rust and applied rust prevention, and revised the cleaning method of the conveyor on February 5, 2020. MIC verified establishment's corrective actions on February 6, 2020.
55. The MIC inspectors are peeling off the hide of cattle head to expose the masseter muscle and not incising deeply as required by the CCA to inspect for cysticercosis.	MIC revised inspection manual and the MIC director retrained the MIC inspectors about head inspection method on February 3, 2020. From February 3 to March 30, 2020, the MIC director verified that the MIC inspectors were performing head inspection correctly.
ESTABLISHMENT M-1, Miyachiku Corp. Ltd, Takasaki Plant	
10. In one of the beef carcass coolers, carcasses were stored closely contacting each other creating insanitary condition of possible cross contamination.	MIC instructed the establishment to take corrective action on February 3, 2020. The establishment made spaces between carcasses in the carcass coolers by evenly lining up the carcasses on February 3, 2020. MIC verified an improvement on February 3, 2020. It was a deviation from the SSOP because the SSOP stipulates that the carcasses should be evenly lined up in the carcass coolers to prevent cross-contamination. Therefore, the establishment provided strict training to the workers to prevent recurrence on February 3, 2020.
35. A review of the residue sample packing method showed that no record of transfer from the establishment to the MIC or documentation of storage exists. These records are vital to the chain of custody of the sample. Absence of internal and external box authentication/ security seal with	The MHLW sets the way of recording of collection, transfer and storage of the sample and the packing method in the guidelines, and notifies each MIC of it.

Findings	***Comments***
signature exists outside of the tamper resistant tape applied.	
36. Sampling procedure for collecting 60 pieces of trimming from primal cuts to test for STEC is performed by establishment personnel. The procedure of collection does not ensure random sampling and target the inner muscle layer not the external surface.	The MHLW sets the way of method in the guidelines, and notifies each MIC of it.
39. In the outside premises of this establishment, excessive accumulation of maintenance equipment, tools, trash, cords, leaves, and metal were stored directly on the grounds creating insanitary conditions and potential of harboring rodents and pest.	The MIC instructed the establishment to take corrective action on February 3, 2020. The establishment immediately disposed old tools in waste containers and stored equipment that was left directly on the ground into the place where they should be. In addition, additional traps were installed as a rat control measure. MIC confirmed that the establishment has made improvements on February 3, 2020.
55. The MIC inspectors are peeling off the hide of cattle head to expose the masseter muscle and not incising deeply as required by the CCA to inspect for cysticercosis.	The MIC revised the procedure of head inspection so that a large and deep incision is made to check the presence of cysts on February 3, and the MIC director informed the inspector with the procedure.
ESTABLISHMENT K-2, Sankyo Meat Ltd. Ariake Meat Plant	
8. and 10. The establishment documentation of insanitary conditions of product contact surfaces during pre-operational and operational sanitation inspection are consistently entered as acceptable "A" while in fact it’s unacceptable “U” is misleading, inaccurate records keeping, and contrary to the instruction of the Form. The description of noncompliance and	MIC instructed the establishment to take corrective actions on February 4, 2020. The establishment changed the form of pre-operational and operational sanitation records, and the establishment reported its corrective action to MIC on February 7, 2020. MIC verified the corrective actions by K-2 on February 10, 2020.

Findings	***Comments***
corrective actions are not documented in the Form; this is a repeated noncompliance of the same prefecture that was previously reported by FSIS audit in 2015. Operational sanitation records show that monitoring of zero-tolerance CCP are acceptable while the documents are not initialed or signed by the persons who perform the monitoring or the verification activities.	
16. The processing steps in the hazard analysis and flow chart of the establishment's HACCP plan are neither matching each other nor orderly numbered to mimic the actual steps of processing in the slaughter and processing departments. The HACCP production records for all of the CCPs monitoring and verification are not identified by the CCP numbers stated in the HACCP plan.	MIC instructed the establishment to take corrective actions on February 4, 2020. The establishment numbered the flow chart, and matched it with the hazard analysis. The establishment added the CCP numbers on the records of CCPs and reported its corrective action to MIC on February 7, 2020. MIC verified the corrective action by K-2 on February 10, 2020.
35. A review of the residue sample packing method showed that no record of transfer from the establishment to the MIC or documentation of storage exists. These records are vital to the chain of custody of the sample. Absence of internal and external box authentication/ security seal with signature exists outside of the tamper resistant tape applied.	The MHLW sets the way of recording of collection, transfer and storage of the sample and the packing method in the guidelines, and notifies each MIC of it.
55. The MIC inspectors are peeling off the hide of cattle head to expose the masseter muscle and not incising	The SOP was revised and added the sentence, “the masseter muscle should be incised along the lower jawbone widely and deeply enough to inspect for

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, January 27– February 14, 2020.

Findings	***Comments***
deeply as required by the CCA to inspect for cysticercosis.	cysticercosis", and MIC director instructed inspectors on this procedure on May 22, 2020.
ESTABLISHMENT K-1, NANCHIKU CO., LTD.	
10. The refrigeration unit of a carcass cooler was framed by black insulation tape that appeared deteriorating and peeling off. The connecting pipes of that unit has excessive accumulation of ice. No product was exposed to this insanitary condition.	The establishment removed the black tape that had been applied to the refrigeration unit on February 22, 2020 and the contract vender repaired the insulation materials on March 28, 2020. MIC verified the removal of the black tape and the improvement of the insulation materials of refrigeration unit on March 30, 2020. The establishment immediately removed the lump of ice on the connecting pipes of the refrigeration unit on February 5, 2020. In addition, the establishment checks the pipes regularly and removes a lump of ice when it appears on the connecting pipe after the day of audit. MIC verified the removal of the lump of ice on the connecting pipes of the refrigeration unit on February 5, 2020. From February 5, MIC also verifies by the establishment's records that the establishment checks the pipes regularly.
15. The processing steps in the hazard analysis and flow chart of the establishment's HACCP plan are neither matching each other nor orderly numbered to mimic the actual steps of processing in the slaughter and processing departments.	The establishment orderly numbered each processing steps in the flowchart and numbered the same numbers to the hazard analysis on February 7, 2020. MIC verified the order of the number of processing steps in the flowchart and the consistency of the number in the flowchart and that in the hazard analysis on February 7, 2020.
35. A review of the residue sample packing method showed that no record of transfer from the establishment to the MIC or documentation of storage exists. These records are vital to the chain of custody of the sample. Absence of internal and external box authentication/ security seal with signature exists outside of the tamper resistant tape	The MHLW sets the way of recording of collection, transfer and storage of the sample and the packing method in the guidelines, and notifies each MIC of it.

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, January 27– February 14, 2020.

Findings	***Comments***
applied.	
36. Sampling procedure for collecting 60 pieces of trimming from primal cuts to test for STEC is performed by establishment personnel. The procedure of collection does not ensure random sampling and target the inner muscle layer not the external surface.	The MHLW sets the way of method in the guidelines, and notifies each MIC of it.
52. The FSIS auditors observed cattle with a rope around the head with a loop through a nose-ring being led from the holding pen to the single-file-chute and to the stunning box.	Driving method without nose-ring led will be implemented. The relevant organization works on developing the alternative safe driving method by the end of this year.
55. The MIC inspectors are peeling off the hide of cattle head to expose the masseter muscle and not incising deeply as required by the CCA to inspect for cysticercosis.	The MIC recognizes that there was no such observation at the time of the FSIS audit. The MIC inspectors incise the masseter muscle widely and deeply enough to inspect for cysticercosis. However, since MIC did not specify that in the SOP, the SOP was revised on May 20, 2020 and a sentence “The masseter muscle should be incised along the lower jawbone widely and deeply enough to inspect for cysticercosis.” was added. The revised SOP was informed to all MIC inspectors.
ESTABLISHMENT M-5, Miyachiku Corp.,Ltd.Tsuno Plant	
13. Establishment's sanitation SOP records does not include category for handling and reworking meat products dropped on the floor.	The establishment revised the operation log format to record the drop meat, and also instructed their workers on February 7, 2020. The establishment instructed hygiene checker on February 7, 2020. MIC verified the corrective action by direct observation on site on February 7, 2020.
35. A review of the residue sample packing method	

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, January 27– February 14, 2020.

Findings	***Comments***
showed that no record of transfer from the establishment to the MIC or documentation of storage exists. These records are vital to the chain of custody of the sample. Absence of internal and external box authentication/ security seal with signature exists outside of the tamper resistant tape applied.	The MHLW sets the way of recording of collection, transfer and storage of the sample and the packing method in the guidelines, and notifies each MIC of it.
36. (First half) Raw products intended for export to the United States are not properly segregated and identified from other domestic products in the processing depart cutting table, cryo-vac packaging table.	The establishment changed the operation procedure in which they attach an identification sticker on a product before vacuum packaging to segregate. The establishment also instructed their workers on the new procedure on February 7, 2020. MIC verified by direct observation that the corrective action was taken on February 7, 2020.
36. (Second half) Sampling procedure for collecting 60 pieces of trimming from primal cuts to test for STEC is performed by establishment personnel. The procedure of collection does not ensure random sampling and target the inner muscle layer not the external surface.	The MHLW sets the way of method in the guidelines, and notifies each MIC of it.
52. The FSIS auditors observed cattle with a rope around the head with a loop through a nose-ring being led from the holding pen to the single-file-chute and to the stunning box.	Driving method without nose-ring led will be implemented. The relevant organization works on developing the alternative safe driving method by the end of this year.
55. The MIC inspectors are peeling off the hide of cattle	No such scene was confirmed during the walk-through audit of FSIS.

Findings	***Comments***
head to expose the masseter muscle and not incising deeply as required by the CCA to inspect for cysticercosis.	The MIC inspectors usually makes large and deep incisions in the masseter muscle according to the MHLW's requirement to perform the inspection.
ESTABLISHMENT OI-1, Oitaken Chikusankosya Co., Ltd.	
15. (First half) The trimming step in the flow chart of the slaughter plan is not included in the hazard analysis.	At the time of audit, it was pointed out that the monitoring step described in the flowchart of the slaughtering manual was not included in the hazard analysis table. MIC instructed the establishment to take corrective actions on February 7, 2020. The establishment changed hazard analysis table and reported its corrective action to MIC on February 7, 2020. MIC verified hazard analysis table was improved on February 7, 2020.
15. (Second half) The HACCP production records for all of the CCPs monitoring and verification are not identified by the CCP number as stated in the HACCP plan.	MIC instructed the establishment to take corrective actions on February 7, 2020. The establishment changed record format and reported its corrective action to MIC on February 7, 2020. MIC verified record format on February 7, 2020.
35. A review of the residue sample packing method showed that no record of transfer from the establishment to the MIC or documentation of storage exists. These records are vital to the chain of custody of the sample. Absence of internal and external box authentication/ security seal with signature exists outside of the tamper resistant tape applied. Absence of internal and external box authentication/ security seal with signature exists outside of the tamper resistant tape applied.	The MHLW sets the way of recording of collection, transfer and storage of the sample and the packing method in the guidelines, and notifies each MIC of it. On May 18, 2020, MIC revised SOP with temperature control of transfer from establishment to MIC, storage control and their record keeping as well as how to attach security seal. MIC verified the SOP on May 18, 2020.
36. (First half) Raw products intended for export to the United	MIC instructed the establishment to take corrective actions on February 7, 2020.

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, January 27– February 14, 2020.

Findings	***Comments***
States are not properly segregated and identified form other domestic products in the processing depart cutting table, cryo-vac packaging table.	The establishment changed the SSOP of the meat processing. The establishment reported its corrective action to MIC on February 13, 2020.MIC verified SSOP of the meat processing on March 4, 2020.
36. (Second half) Sampling procedure for collecting 60 pieces of trimming from primal cuts to test for STEC is performed by establishment personnel. The procedure of collection does not ensure random sampling and target the inner muscle layer not the external surface.	The MHLW sets the way of method in the guidelines, and notifies each MIC of it.
52. The FSIS auditors observed cattle with a rope around the head with a loop through a nose-ring being led from the holding pen to the single-file-chute and to the stunning box.	Driving method without nose-ring led will be implemented. The relevant organization works on developing the alternative safe driving method by the end of this year.
55. The MIC inspectors are peeling off the hide of cattle head to expose the masseter muscle and not incising deeply as required by the CCA to inspect for cysticercosis.	MIC changed the SOP of the meat inspection manual. MIC verified the SOP of the meat inspection manual on February 10, 2020.
ESTABLISHMENT G-1, Gunma-ken Shokuniku Oroshiuri Shijo Co., Ltd.	
9. Sanitation SOP is not reviewed or signed by the current manager; it is signed by a former manager years ago.	The MIC instructed the establishment to update the SSOP and to get it signed by the current manager on February 10, 2020. The establishment updated and signed the SSOP on February 12, 2020. The establishment reported it to the MIC and the MIC verified the SSOP on February 12, 2020. The establishment ensures that these documents are reviewed and signed by the responsible person if there are any changes.
10.	

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, January 27– February 14, 2020.

Findings	***Comments***
During operational sanitation of slaughter room, cutting, carcass coolers, and product storage, excessive usage of duct tape in many locations of each department to seal leakage, support pipes, prevent condensation from cooling units or enclose electric wires. This excessive use of tape to correct maintenance problem impede effective sanitation of walls and pipes and creating insanitary condition. Numerous spots of black residue on the stainless-steel surface near hide removal conveyors.	About excessive use of the tape, the MIC instructed G-1 to take corrective actions on February 10, 2020. The repair vender came to check the establishment's situation on February 14, 2020 and found out that approximately 160 places need repairing. The MIC inspectors were also present at the vender's check. The establishment started repairing construction on March14, 2020. Currently, more than 80% of the Fabrication Room and the Viscera Processing Room are finished their repairing. However, because of the outbreak of COVID-19 and the necessity of the renewal of the cooling equipment this year, the repairing schedule is behind time. The establishment is planning to carry out the repairing construction of the Slaughtering Room, Carcass Storage Place and the remaining places in order, during the long holiday in August, December and January to intensively repair the facility. The repairing construction of the whole facility is planned to be finished by January 10, 2021. The MIC has been checking the replacement of the tape and repairing of the facility every time the facility is repaired from March 16, 2020. The MIC will continue instructing the establishment to replace the tapes and repair the facility as quickly as possible. About the black spots on the stainless-steel, the MIC instructed the establishment to take corrective actions on February 10, 2020. The establishment cleaned it up and the MIC verified it on February 12, 2020. The stainless-steel surface near hide removal conveyors has been, and is still, currently in good condition.
17. The HACCP plan is not signed by an overall authority; it is signed by an ex-manager approximately three years ago. The summary of all CCPs are also signed by the same ex-manager years ago.	Same as #9 finding, the establishment reviewed its HACCP plan documents and signed it by the current manager. It was verified by the MIC on February 12, 2020.
22.	

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, January 27– February 14, 2020.

Findings	***Comments***
The critical control limit of carcass room temperature 6.9˚ (CCP-2-2) is not supported by a validation study to correlate with carcass surface temperature. Thermometer used for monitoring the CCP of carcass temperature in coolers is not identified in HACCP calibration records.	About the correlation between carcass room temperature and carcass surface temperature, the establishment has the validation data that supports correlation between room temperature and carcass surface temperature for CCP2-1. The MIC verified the data and handed the report to MHLW on February 12, 2020. CCP2-2 is a temporary cooling room to storage carcass that are cooled down. The establishment has decided this as the control point because they think it is possible to control the carcass surface by controlling the carcass room temperature. Considering FSIS's finding, the establishment has decided to monitor and record the carcass surface temperature in CCP2-2 for about 6 months from June, to prove the correlation between the carcass surface temperature and the carcass storage temperature, which the establishment uses it as a validation study. Also, the validation study the establisment provided to the MIC was *Kenneth E. Stevenson Phd., and Dane T. Bernard (1999) "A Systematic Approach to Food Safety, A comprehensive manual for developing and implementing a hazard analysis and critical control point", HACCP, The Food Processors Institute 3rd ed*, the same study the establishment had shown to the FSIS auditors on the day of the audit. In this study, pathogenic *Escherichia coli*'s minimum growth temperature is 7-8℃, and this is the reason the establishment set the critical control point of carcass room temperature at 6.9℃. About the thermometer used for monitoring the CCP,the MIC instructed the establishment to take corrective actions on February 10, 2020. The establishment changed the HACCP document's recording format and specified serial numbers of thermometers in their records so that they could be identified. On February 12, the establishment reported the changes to the MIC and the MIC verified the corrective actions.
35. A review of the residue sample packing method showed that no record of transfer from the	The MHLW sets the way of recording of collection, transfer and storage of the sample and the packing method in the guidelines, and notifies each MIC of it.

Findings	***Comments***
establishment to the MIC or documentation of storage exists. These records are vital to the chain of custody of the sample. Absence of internal and external box authentication/ security seal with signature exists outside of the tamper resistant tape applied.	The MIC revised the "Residue Manual" and created a "sample record table" in order to record the date, time, and responsible inspector for each of the receiving, storage and transfer procedure on February 12, 2020. The sample record table is currently in operation.
36. Sampling procedure for collecting 60 pieces of trimming from primal cuts to test for STEC is performed by establishment personnel. The procedure of collection does not ensure random sampling and target the inner muscle layer not the external surface.	The MHLW sets the way of method in the guidelines, and notifies each MIC of it.
55. The MIC inspectors are peeling off the hide of cattle head to expose the masseter muscle and not incising deeply as required by the CCA to inspect for cysticercosis.	No such scene was confirmed during the walk-through audit. The MIC inspectors makes large and deep incisions in masseter muscle for inspection on a regular basis.
ESTABLISHMENT GI-1, Hida Meat Center/Hida Meat Agricultural Cooperatives	
9. The sanitation SOP is not signed and dated by an onsite overall authority.	The MIC instructed the establishment to take corrective actions on February 12, 2020. The manager of the establishment was previously performing reassessment of SSOP once a year. The establishment decided to record the signature and date as they reassess the document. The establishment reported its corrective action to MIC on February 13, 2020. The MIC verified the corrective actions on February 13, 2020.
16. Establishment's HACCP records for all CCPs do not	The MIC instructed the establishment to take corrective actions on February 12, 2020.

Findings	***Comments***
identified the CCP number as listed in the HACCP. Establishment does not maintain records for ongoing verification activities for CCP2 and CCP3, except for thermometer calibration. The verification records of official inspection personnel consistently record the incorrect numbers of CCPs. Official inspectors' verification records are not organized especially when identifying and correlating the slaughter and cutting dates with the pre-shipment review of product intended for export to the United States. Establishment's pre-shipment reviews for products intended for export to the United States are inaccurately dates.	The establishment undertook the following actions and reported them to the MIC on February 13, 2020; ・Add the CCP numbers in all documents and forms of CCP monitoring. ・Submit records of verification activities for other CCPs. Establishments are performing verification activities for other CCPs in the same way as for CCP1. ・Previously, CCP1 and 2 were given to the process of slaughtering and CCP1-3 were given to process of cutting, which made them difficult to distinguish (because CCP1 and 2 were overlapped in two different processes). Therefore, CCP1-5 were given from slaughtering to cutting process to avoid overlap. ・The format of the pre-shipment review was changed to record not only the month and day but also the year. The MIC verified the corrective actions on February 13, 2020. The MIC submitted the records of HACCP verification activities of CCPs other than CCP1 to MHLW on February 13, 2020. The MIC changed its format of the verification records in accordance with the change of establishment's CCP numbers on February 13, 2020. The MIC added one column on the cut verification record sheet to record the date of slaughter and stated recording the date of slaughter on February 13, 2020.
17. The HACCP plan is not signed and date by an onsite overall authority.	The MIC instructed the establishment to take corrective actions on February 12, 2020. The establishment created a reassessment manual of the HAACP plan and decided to carry out reassessment of the manual in March every year. The establishment reported its corrective action to the MIC on March 6, 2020. The MIC verified the corrective actions on March 6, 2020.
19. The zero-tolerance verification by official inspection personnel is not done randomly as they always target the last animal of each day slaughter	The MIC changed the manual for zero-tolerance verification on February 13, 2020 to select carcass for zero-tolerance verification randomly.
35. A review of the residue sample packing method	

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, January 27– February 14, 2020.

Findings	***Comments***
showed that no record of transfer from the establishment to the MIC or documentation of storage exists. These records are vital to the chain of custody of the sample. Absence of internal and external box authentication/ security seal with signature exists outside of the tamper resistant tape applied.	The MHLW sets the way of recording of collection, transfer and storage of the sample and the packing method in the guidelines, and notifies each MIC of it. On February 13, 2020, the MIC updated the residue sample monitoring inspection manual and made it such that the establishment number and date will be written on the sealing tape on the box of the packaged sample and also signature of the designated inspector who sealed be applied.
36. Sampling procedure for collecting 60 pieces of trimming from primal cuts to test for STEC is performed by establishment personnel. The procedure of collection does not ensure random sampling and target the inner muscle layer not the external surface.	The MHLW sets the way of method in the guidelines, and notifies each MIC of it.
52. The FSIS auditors observed cattle with a rope around the head with a loop through a nose-ring being led from the holding pen to the single-file-chute and to the stunning box.	The MIC instructed the establishment to take corrective actions on February 12, 2020. The establishment decided to lead a cattle by bridles around head after receiving an expecting notification from the MHLW which forbids the practice of leading cattle with a rope through a nose ring on February 13, 2020. On April 1, 2020, however, having made arrangements with the relevant people and finished preparations, the establishment changed its policy to mandate that a cattle wears bridles around head at the farm not to be led by a rope passing through a nose ring during shipment from the farm to slaughter. This was done in advance of the arrival of any such notification from the MHLW. The MIC verified the corrective actions on April 6, 2020. The relevant organization works on developing the alternative safe driving method by the end of this year.

● Chain of custody system (residue testing samples)

MHLW は検査実施要領の残留物質モニタリングプログラムを改正し、検体の記録及び封印を含む梱包方法について規定する予定である。
具体的には、以下のコンテンツについて追加する予定である。
・指名検査員は、サンプリング記録用紙に署名をする
・検体をいれたポリエチレン袋と、検査記録用紙を入れたポリエチレン袋をさらに別の一つの袋で同梱して、シールで封印する。シールには ID 番号と署名をする。
・外箱の封印に当たっては、輸送時の検体のすり替え防止等の観点から、開封により、再使用が不可能となるシール等を使用する。
・MIC は、サンプリング、施設～MIC への搬送、及び JFRL への発送までの保管に係る記録を保管する。
・また、JFRL は、検体受入時に、上記に従い適切に検体が取り扱われていることを確認した上で、検体を受け入れる。

MHLW will revise the residual substance monitoring program procedure and add the way of recording and packing including security-seal.
Specifically, we plan to add the following contents.
・The designated inspector signs the sampling record sheet.
・The polyethylene bag containing the sample and the polyethylene bag containing the test recording sheet should be packed together in another polyethylene bag and sealed with a sticker. ID number and signature of the designated inspector are on the sticker.
・When sealing the outer box, use a seal that cannot be reused after opening in order to prevent replacement of samples during transportation.
・The MIC keeps records related to sampling, transportation from the facility to the MIC, and storage until shipment to JFRL.
・In addition, JFRL accepts the samples after confirming that the samples are properly handled according to the above when receiving the samples.

● N60 sampling

MHLW は米国向け牛肉認定要綱及び検査実施要領に示す N60 サンプリング法に関する記載を改正する予定である。
※　FSIS directive 10.010.1 の別添 2 のような状態のトリミング肉（を入れる容器）をカット室内に常備している施設が日本にはほとんどない。
※　FSIS からの指摘を受け、MHLW は、これらの容器をサンプリングの日にのみ用意することは、サンプル採取の無作為性確保の観点から不適切であると判断した。（作業員が、サンプリングが実施されることを察知できる。）
※　よって、FSIS が求める以下の条件を担保しながら、MHLW は日本の施設の通常の作業に適した N60

サンプリング法を示したい。
○　外表面に由来するトリミング肉から
○　ランダムに（作業員が意図的に検体となるトリミング肉を選択することは不可。一方、指名検査員がパーツ等を作業員に指示して採取することは適切である。）

具体的には、以下の方法により検査を実施することで、FSIS の求める条件を満たすことができると考え、その実施について検討しているが、受け入れ可能か。

１）　サンプリング当日に対象となる製品ロットの製造に投入される枝肉の本数に基づき、採取すべき各枝肉に由来する薄片の数を決定する。
２）　指名検査員は、分割作業中の枝肉（四分割またはそれ以上）から外表面部分を切り取る（これを「外表面トリミング肉」とする）。施設の作業状況に応じて、指名検査員が採取する部位を指定し、指名検査員が立ち会いの下、施設作業員に外表面を切り取らせることでもよい。
３）　外表面トリミング肉は、製品ロット全体を代表するものとするため、由来する枝肉及び部位に偏りがないように採取すること、及び、施設の作業員により選択的に切り出されることがないように指名検査員が確認すること。
４）　指名検査員は、切り取った１つの外表面トリミング肉から、１つの薄片（およそ長さ 8cm×幅 3cm、厚さ 0.3cm）を切り出して、これを 60 枚集め、１検体とする。

MHLW plans to revise the description regarding the N60 sampling method in the certification guidelines for the US and the inspection procedure.
(Background)
There are few establishments in Japan that have trimmed meat (containers) in the cutting room shown in Attachment 2 of FSIS directive 10.010.1. MHLW has found that preparing these containers only on the day of sampling is inappropriate from the perspective of ensuring randomness of sampling (The worker can be aware that sampling will be performed.) as pointed out by FSIS as such.　Therefore, MHLW would like to adjust the N60 sampling method suitable for normal work at Japanese facilities with ensuring the following FSIS requirements,
○ From trimmed meat derived from the exterior surface
○ Randomly (It is not possible for the worker to select the trimming meat that will be the sample. On the other hand, it is appropriate for the designated inspector to decide the parts etc., and to order the worker to trim the exterior surface from the parts.)

Specifically, we would like to ask if the following method is acceptable for you. MHLW thinks that the method meets the level of FSIS requirements.

1) The designated inspector deetermines the number of slices derived from each carcass to be collected based on the number of carcasses that will be used to the target production lot on the day of sampling.
2) The designated inspector cuts out the exterior surface from the part of carcass (quarter or more) during fabrication (this is called "exterior surface trimmings"). According to the working situation of the

establishment, it is also possible to decide the site to be sampled by the designated inspector and order the worker to cut off the exterior surface under the supervision of the designated inspector.

3) Since the exterior surface trimmed meat must represent the production lot, exterior surface trimmings should be collected so that the carcasses and parts from which it is derived are not biased. The designated inspector ensures that the workers of the establishment cannot selectively cut out the meat without order by the designated inspector.

4) The designated inspector cuts out one thin piece (approximately 8 cm in length x 3 cm in width, 0.3 cm in thickness) from one trimmed meat on the exterior surface and collects 60 pieces as one sample.

● The method for STEC detection [Not including positive and negative controls in screening or confirmation methods/ Not including appropriate immune-concentration procedures with dilution/ No acid wash step/ Not using all the N60 sample]

・陽性及び陰性コントロールは、分析時に適切に用いるように、各ラボに指示する。
・酸処理と希釈については、検査法通知に追記する。
・検体の調整においては、N60 サンプリングによって採取した検体の全てを使用するよう、各ラボに指示する。これは、例えば以下のような指示である。検体が 350g の検体の一部を除去して 325g にするのではなく、350g の検体に 1:4 の mTSB を加えるように指示する。つまり MLG5.09-5.5 a. i. 及び MLG5C.00-5C.5 a. i に記載されているとおり、1:4 の mTSB を加える（重量 325±32.5g に対して、975±19.5ml の mTSB を加える）ように、各ラボへ指示する。

・MHLW will instruct each laboratory to use positive control and negative control appropriately during analysis.
・Regarding acid treatment and dilution, we will add those procedures to the detection method.
・MHLW will instruct each laboratory to use all of the samples taken by the N60 sampling method. This is, for example, if the sample is 350g, do not remove a part of it so that it is reduced to 325g. Add 1:4 mTSB to all of the sample (350g). MHLW will instruct each lab to add 1:4 mTSB (325±32.5g with 975±19.5ml mTSB broth) to all of the sample as described in MLG5.09-5.5 a. i. and MLG5C.00-5C.5 a. i.

● The quality assurance and control for MIC microbiological laboratories

・外部精度管理を（国衛研が実施主体となって）行う予定。
・各ラボに対しては適切な精度管理を行うよう、特に以下について指示する予定。
　○　使用機器は全て校正対象とし、実施したことを示すシールを機器に貼ること。また、校正の記録を

保管すること。

○　使用する消耗品（培地含む）について、保管方法や使用期限を明らかにし、マニュアルに定めること。また、自家培地等においては、定めた保管方法及び使用期限が妥当であることに関する検証を行うこと。

○　検査を実施した場合、検査記録文書は適切に作成し、保管すること。

・Proficiency test will be planned to be conducted (with NIAH as the implementing body).

・Regarding quality assurance and control for MIC microbiological laboratories, we plan to instruct each laboratory to perform appropriate quality control as follows.

○ All the equipment to be used should be calibrated. A sticker indicating that calibration was performed should be attached to each equipment and records of calibration should be kept in MIC.

○ The storage method and expiration date of the consumables (including medium) to be used are clarified and specified in the manuals. In addition, for in-house medium, laboratory should verify that the storage method and expiration date are appropriate.

○ When the testing is performed, the testing records should be made and kept in MIC.

Attachment 1

Training Program for the regional officers in Regional Bureau of Health and Welfare (RBHW) [draft]

1. **Training objectives:** To have knowledge and techniques about Meat inspection and HACCP Systems
2. **Target persons:** The regional officers (meat inspector from RBHW)
3. **Programs:**

・Program1: Official Training Courses (Training Courses on Meat Inspection Techniques) organized by the National Institute of Public Health

Meat hygiene

- National administrative policies on meat hygiene
- Risk communication
- International trends
- Meat inspection and pathology
- Zoonotic parasites
- Animal-derived infectious disease,
- Hygiene controls for slaughter,
- Regulations on residues and testing methods,

Microbiological control

- HACCP system
- Sanitary operations
- Escherichia coli in cattle
- Microbiological testing methods
- HACCP workshop presentations

・Program2: OJT for new assigned officers between RBHW

・Program3: Meeting for exchange opinions between RBHW

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, January 27– February 14, 2020.

N° of paragraph	***Comments***
IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (E.G., ORGANIZATION AND ADMINISTRATION)	
Page 3 · Miyazaki Prefecture Tono Meat Inspection Center, Miyazaki	Correction of misspelling. · Miyazaki Prefecture ~~Tono~~ Tsuno Meat Inspection Center, Miyazaki
Page 4 At the central level, the Food Inspection and Safety Division of the Department of Environmental Health and Food Safety of MHLW prepares the national residue plan and designates private chemical residue laboratories for official residue analyses.	Correction of the wording. At the central level, the Food Inspection and Safety Division of the ~~Department of~~ Pharmaceutical Safety and Environmental Health Bureau ~~and Food Safety~~ of MHLW prepares the national residue plan and designates private chemical residue laboratories for official residue analyses.
Page 5 The MHLW's authority to enforce inspection laws is outlined in the *Abattoir Law* (Law No. 114), *Abattoir Law Enforcement Regulation* (Ordinance No. 44), and *Ordinance for Enforcement of the Food Sanitation Act* (Ordinance No. 23). These laws delineate responsibilities for each of the inspection levels, as well as enforcement of the Food Sanitation Act.	Correction of the name of Act. Same correction is applied in the whole report. The MHLW's authority to enforce inspection laws is outlined in the *Abattoir* ~~*Law*~~ *Act* (~~Law~~ Act No. 114), ~~*Abattoir Law Enforcement Regulation*~~ *Regulation for Enforcement of the Abattoir Act* (Ordinance No. 44), and ~~*Ordinance for Enforcement of*~~ the *Food Sanitation Act* (~~Ordinance No. 23~~ Act No. 233). These laws delineate responsibilities for each of the inspection levels~~, as well as enforcement of the Food Sanitation Act~~.

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, January 27– February 14, 2020.

N° of paragraph	***Comments***
Page 5 In addition, the MHLW's supplemental documents entitled *Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States*,	Correction of the wording. Same correction is applied in the whole report. In addition, the MHLW's supplemental documents entitled *Requirements for Certification of ~~Abattoirs~~ Slaughterhouses, Etc., Handling Meat for Exportation to the United States*,
Page 5 The MHLW is responsible for regulating the meat industry, official certification or decertification of establishments, and maintaining the official list of establishments eligible to export meat products to the United States.	"in terms of food safety" is added in the sentence for more accurate description. The MHLW is responsible for regulating the meat industry in terms of food safety, official certification or decertification of establishments, and maintaining the official list of establishments eligible to export meat products to the United States.
Page 5 The MHLW is authorized by the *Abattoir Law* to collect any reports it deems necessary from owners or managers of abattoirs, and from slaughterers or other relevant persons. The *Abattoir law* also authorizes MHLW officials to enter abattoirs, offices, warehouses, or other facilities involved in the slaughter and processing of meat products to inspect equipment and review accounting books and production documents.	In addition to the *Abattoir Act*, "*Requirements for Certification of Slaughters, Etc., Handling Meat for Exportation to the United States*" also gives MHLW necessary authority. The MHLW is authorized by the *Abattoir ~~Law~~ Act* and "*Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States*" (Hereafter "the Requirements") to collect any reports it deems necessary from owners or managers of abattoirs, and from slaughterers or other relevant persons. The *Abattoir ~~law~~ Act* and the *Requirements* also authorize~~s~~ MHLW officials to enter abattoirs offices, warehouses, or other facilities involved in the slaughter and processing of meat products to inspect equipment and review accounting books and production documents.

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, January 27– February 14, 2020.

N° of paragraph	***Comments***
Page 5 Six of these RBHW offices (Hokkaido, Kanto, Kyushu, Kinki, Tohoku, and Tokai) have certified establishments within their jurisdictions.	Correction of the name of RBHW offices. Six of these RBHW offices (Hokkaido, Kanto-Shinetsu, Kyushu, Kinki, Tohoku, and Tokai-Hokuriku) have certified establishments within their jurisdictions.
Page 5 At the local level, the authorities (i.e., prefecture, municipality, or ward) are authorized by the MHLW to oversee meat inspection at the slaughter and processing establishments and to operate the microbiological laboratories designated to analyze official verification samples. In Japan there are 47 prefectures, 84 municipalities, and 23 special wards.	"municipality" is corrected to "city with health canter" for more accurate translation. At the local level, the authorities (i.e., prefecture, ~~municipality~~ city with health center, or ward) are authorized by the MHLW to oversee meat inspection at the slaughter and processing establishments and to operate the microbiological laboratories designated to analyze official verification samples. In Japan there are 47 prefectures, 84 ~~municipalities~~ cities with health centers, and 23 special wards.
Page 5 Each local authority has its own meat inspection center (MIC) which has the responsibility to implement and enforce inspection laws and requirements at the certified establishment eligible to export beef products to the United States.	"which has jurisdiction over the certified establishments" is added in the sentence for more accurate description. Each local authority which has jurisdiction over the certified establishments has its own meat inspection center (MIC) which has the responsibility to implement and enforce inspection laws and requirements at the certified establishment eligible to export beef products to the United States.

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N° of paragraph	***Comments***
Page 7 The MHLW has the authority to assess penalties for violations of food safety laws, as stated in the *Abattoir Law*.	The following sentence is corrected for more accurate description. ~~The MHLW has the authority to assess penalties for violations of food safety laws act, as stated in the *Abattoir Law*.~~ Penal provisions are stipulated in the articles 81 – 89 of the *Food Sanitation Act* and the articles 24 – 27 of the *Abattoir Act* under the jurisdiction of the MHLW.
Page 8 The *Abattoir Law* (Law No. 114) and the *Abattoir Law Enforcement Regulation* (Ordinance No. 216) explain that all inspectors assigned in slaughter establishments are veterinarians	Correction of the name of Act. Same correction is applied in the whole report. The *Abattoir ~~Law~~ Act* (~~Law~~ Act No. 114) and the ~~*Abattoir Law Enforcement Regulation*~~ *Ordinance for Enforcement of the Abattoir Act* (Ordinance No. 216) explain that all inspectors assigned in slaughter establishments are veterinarians
Page 8 The MHLW regional representatives conduct annual audits of the JFRL and of the microbiological laboratory located at each local authority MIC, in accordance with *Japan's Food Sanitation Law* and *Manual on How to Manage Examination, etc. at Testing laboratories*.	The MHLW regional representatives audit the microbiological laboratory located at each local authority MIC as well in accordance with the *Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States.* The MHLW regional representatives conduct annual audits of the JFRL ~~and of the microbiological laboratory located at each local authority MIC,~~ in accordance with *Japan's Food Sanitation ~~Law~~ Act* and *Manual on How to Manage Examination, etc. at Testing laboratories*. The MHLW regional representatives conduct annual audits of the microbiological laboratory located at each local authority MIC as well in accordance with the *Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States*.
Page 9 The private laboratories of the JFRL, which are contracted by the government to test official samples for chemical residues, are accredited annually by the JAB according to the ISO 17025	Changes are made for more accurate description. The private laboratories of the JFRL, which are ~~contracted~~ designated by the government as the laboratory to test official samples for chemical residues, are accredited annually by the JAB according to the ISO 17025 standards and are authorized by MHLW.

N° of paragraph	*Comments*
standards and are authorized by MHLW.	
V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)	
Page 12 However, at the head inspection station of seven establishments, the MIC inspectors used knives to peel the hide from the heads of cattle to expose the masseter muscle, but these inspectors did not cut deep through the masseter muscle as required by the MHLW.	At the time of audit, four establishments were observed the following procedure. However, at the head inspection station of ~~seven~~ four establishments, the MIC inspectors used knives to peel the hide from the heads of cattle to expose the masseter muscle, but these inspectors did not cut deep through the masseter muscle as required by the MHLW.
Page 12 At seven establishments, the FSIS auditors observed the MIC inspectors peeling off the hide of cattle head to expose the masseter muscle, but not incising deeply as required by the MHLW to inspect for cysticercosis	At the time of audit, four establishments were observed the following procedure. At ~~seven~~ four establishments, the FSIS auditors observed the MIC inspectors peeling off the hide of cattle head to expose the masseter muscle, but not incising deeply as required by the MHLW to inspect for cysticercosis
Page 12 The dressed carcass is inspected prior to splitting. The outer appearance of both sides is observed from a place that allows close observation of the entire	At the establishments certified to export to the United States MIC inspector observes the outer and inner side of carcass exhaustively after splitting. The dressed carcass is inspected ~~prior to~~ after splitting The outer and inner appearance of both sides is observed from a place that allows close observation of the entire dressed carcass to check for abnormalities.

N° of paragraph	*Comments*
dressed carcass to check for abnormalities.	
Page 14 The MHLW ensures compliance with these requirements by monitoring the APHIS website and verifying restrictions under 9 CFR 94.1 prior to signing export certificates.	MAFF is responsible for animal health. The MHLW and MAFF closely work together for exporting beef to the US. The MHLW and Ministry of Agriculture, Forestry and Fisheries (MAFF) ensure~~s~~ compliance with these requirements by monitoring the APHIS website and verifying restrictions under 9 CFR 94.1 prior to signing export certificates.
VII. COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM	
Page 17 The number of cattle slaughtered in each establishment audited ranged between 25-70 heads per shift, the monitoring frequency of zero tolerance CCP by establishment management was 100% and the verification frequency by the MIC inspection personnel was two carcasses (four sides).	The monitoring frequency of zero tolerance CCP by establishment is varied according to establishment because it is set based on the risk analysis of establishments. The number of cattle slaughtered in each establishment audited ranged between 25-70 heads per shift, the monitoring frequency of zero tolerance CCP by establishment management ~~was 100%~~ was set appropriately based on the risk analysis of each establishments and the verification frequency by the MIC inspection personnel was two carcasses (four sides).
VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS	
Page 19 The FSIS auditors verified that Japan's NRP is designed and conducted in accordance with Japan's *Food Sanitation Law*.	Changes are made for accurate description. The FSIS auditors verified that Japan's NRP is designed and conducted in accordance with ~~Japan's *Food Sanitation Law*~~ the *Guidelines for Inspection of Certified Establishment*.
Page 19 This protocol includes random sampling and testing of internal	Changes are made for accurate description.

N° of paragraph	*Comments*
organs, fat, and muscle of carcasses for targeted residues, and secure delivery of residue samples to the designated JFRL in accordance with the prescribed methodology provided by MHLW based on Japan's *Food Sanitation Act, Article 22*.	This protocol includes random sampling and testing of internal organs, fat, and muscle of carcasses for targeted residues, and secure delivery of residue samples to the designated JFRL in accordance with the prescribed methodology provided by MHLW based on ~~Japan's *Food Sanitation Act, Article 22*~~ the *Guidelines for Inspection of Certified Establishment*.
Page 20 The FSIS auditors verified that the private laboratory performs a timely analysis of samples, reports the number of analyzed samples and the results to MHLW in a timely manner, and provides MHLW with a quarterly report on the progress of the NRP.	The private laboratory reports the number of analyzed samples and the results to MHLW in a timely manner, but does not provide a quarterly report. The FSIS auditors verified that the private laboratory performs a timely analysis of samples, reports the number of analyzed samples and the results to MHLW in a timely manner~~, and provides MHLW with a quarterly report on the progress of the NRP~~.
IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS	
Page 21 Regarding analyses of pesticides, the MHLW confirmed that gas chromatography is used to analyze samples using different chromatography columns; the first uses the DB-1701 methodology and the second uses the DB-5.	The JFRL uses different measurement condition (chromatography column) in the gas chromatography to confirm the selectivity of the test as one of the internal quality control methods and not to be re-tested. Regarding analyses of pesticides, ~~the MHLW confirmed that gas chromatography is used to analyze samples using different chromatography columns; the first uses the DB-1701 methodology and the second uses the DB-5~~ the JFRL analyzes by gas chromatography using the chromatography column DB-1701 and confirms the selectivity of the test by measurement result using the chromatography column DB-5.

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N° of paragraph	*Comments*
Page 23 and 25 At seven establishments, the collection of 60 pieces of beef trimming (N60) for STEC testing is performed by the establishment's personnel not by MIC inspection personnel.	At the time of audit, six establishments were observed the following procedure. At ~~seven~~ six establishments, the collection of 60 pieces of beef trimming (N60) for STEC testing is performed by the establishment's personnel not by MIC inspection personnel.
Appendix A: Individual Foreign Establishment Audit Checklists	
ESTABLISHMENT NO. K-1 1. ESTABLISHMENT NAME AND LOCATION Minami-Kyushu Chikusan Kogyo Corp., Ltd. 1828 Nonokata, Sueyoshi-cho Soo-shi Kagoshima	Changes are made for accurate description. ~~Minami-Kyushu Chikusan Kogyo Corp., Ltd.~~ Nanchiku Co., Ltd. 1828 Nonokata, Sueyoshi-cho Soo-shi Kagoshima
ESTABLISHMENT NO. K-1,M-5,G-1 55. Post Mortem Inspection Audit Results : X	No such scene was confirmed during the walk-through audit of FSIS. The MIC inspectors usually makes large and deep incisions in the masseter muscle according to the MHLW's requirement to perform the inspection. 55. Post Mortem Inspection Audit Results : ~~X~~
ESTABLISHMENT NO. K-1,M-5,G-1 60. Observation of the Establishment 55. The MIC inspectors are peeling off	No such scene was confirmed during the walk-through audit of FSIS. The MIC inspectors usually makes large and deep incisions in the masseter muscle according to the MHLW's requirement to perform the inspection. 60. Observation of the Establishment

N° of paragraph	*Comments*
the hide of cattle head to expose the masseter muscle and not incising deeply as required by the CCA to inspect for cysticercosis.	~~55.~~ ~~The MIC inspectors are peeling off the hide of cattle head to expose the masseter muscle and not incising deeply as required by the CCA to inspect for cysticercosis.~~