



United States Department of Agriculture

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Food Safety and  
Inspection Service

October 22, 2024

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

Mr. MORITA Takeshi  
Director  
Food Inspection and Safety Division  
Public Health Bureau  
Ministry of Health, Labour and Welfare  
1-2-2 Kasumigaseki, Chiyoda-ku  
Tokyo 100-8916, Japan

Dear Mr. MORITA Takeshi,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an onsite verification audit of Japan's inspection system May 13–June 6, 2024. 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.

Sincerely,

**MARGARET  
BURNS RATH**

Digitally signed by  
MARGARET BURNS RATH  
Date: 2024.10.22 20:07:04  
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Margaret Burns Rath, JD, MPH  
Assistant Administrator  
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED OF JAPAN

MAY 13–JUNE 6, 2024

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING

RAW INTACT BEEF PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

October 17, 2024

Food Safety and Inspection Service  
U.S. Department of Agriculture

## Executive Summary

This report describes the outcome of an equivalence verification audit of Japan conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) from May 13–June 6, 2024. The purpose of the audit was to verify whether Japan's food safety inspection system governing raw intact beef products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. Japan currently exports raw intact beef products to the United States.

The audit focused on six system equivalence components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Point System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

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

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

- The Ministry of Health, Labor and Welfare, the Central Competent Authority of Japan, does not maintain national guidelines that prescribe the maximum body temperature at which cattle are to be condemned by the veterinarian government inspectors during ante-mortem inspection.
- The Regional Bureau of Health and Welfare (RBHW) personnel's supervisory reviews did not identify that the establishments' personnel were not adequately implementing the generic *Escherichia coli* (*E. coli*) sampling procedures and that government inspection personnel were not properly collecting N60 trim samples for the official government Shiga-toxin producing *E. coli* (STEC) sampling verification program.

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

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## I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) conducted an onsite audit of Japan’s food safety inspection system May 13–June 6, 2024. The audit began with an entrance meeting held May 13, 2024, 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). Representatives from MHLW accompanied the FSIS auditors throughout the entire audit. The audit concluded with an exit meeting June 6, 2024.

## II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

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

Process Category	Product Category	Eligible Products <sup>1</sup>
Raw - Intact	Raw Intact Beef	Beef - All Products Eligible except Boneless Manufacturing Trimmings; Cheek Meat; Head Meat; Heart Meat; and Weasand Meat

The USDA’s Animal and Plant Health Inspection Service (APHIS) recognizes Japan as having negligible risk for bovine spongiform encephalopathy (BSE). Beef imported from Japan is subject to foot-and-mouth disease requirements specified in Title 9 of the U.S. Code of Federal Regulations (9 CFR) 94.11, and BSE requirements specified in 9 CFR 94.18 or 9 CFR 94.19.

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed Japan’s Self-Reporting Tool (SRT) responses and supporting documentation, including official chemical residue and microbiological sampling plans and results. During the audit, the FSIS auditors conducted interviews, reviewed records, and made observations to verify whether Japan’s food safety inspection system governing raw intact 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 capabilities of laboratories. The review process included an analysis of data collected by FSIS over a 3-year period, in addition to information obtained directly from MHLW through the SRT.

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<sup>1</sup> All source meat used to produce products must originate from eligible countries and establishments certified to export to the United States.

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 MHLW's headquarters, two regional offices, and nine local inspection offices within the audited establishments. 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 documented in the country's SRT responses and supporting documentation.

A sample of 9 establishments was selected from a total of 16 establishments certified for export to the United States. This included nine beef slaughter and processing establishments. The products these establishments produce and export to the United States include raw intact beef products.

During the establishment visits, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditors assessed MHLW'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 visited one microbiological and one chemical residue laboratory to verify that these laboratories are capable of providing adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> <li>• MHLW, Tokyo</li> </ul>
	Regional Offices	2	<ul style="list-style-type: none"> <li>• Kanto-Shinetsu Regional Bureau of Health and Welfare, Saitama</li> <li>• Kinki Regional Bureau of Health and Welfare, Osaka</li> </ul>
Laboratories		2	<ul style="list-style-type: none"> <li>• Gunma Prefecture Meat Inspection Center, (local government microbiological), Sawa Gun</li> <li>• Japan Food Research Laboratory, General Incorporation Foundation, (private chemical residue), Tama-shi</li> </ul>
Beef slaughter and raw processing establishments		9	<ul style="list-style-type: none"> <li>• Establishment No. M-1, Miyachiku Corp., Ltd, Takasaki plant, Miyakonojo-shi, Miyazaki</li> <li>• Establishment No. HMJ-1, Wagyu Master Meat Center, Himeji-shi, Hyogo</li> </ul>

	<ul style="list-style-type: none"> <li>• Establishment No. K-2, SANKYO MEAT Ltd. Ariake Meat Plant, Shibushi-shi, Kagoshima</li> <li>• Establishment No. K-4, JA Shokuniku Kagoshima Co., Ltd. Nansatu Plant, Minamikyushu-shi, Kagoshima</li> <li>• Establishment No. K-3, Akune Meat Distribution Center Co., Ltd./STARZEN MEAT PROCESSOR Co., Ltd. Akune Plant, Akune-shi, Kagoshima</li> <li>• Establishment No. K-1, Nanchiku Co., Ltd, Soo-shi, Kagoshima</li> <li>• Establishment No. G-1, Gunma-ken Shokuniku Oroshiuri Shijo Co., Ltd, Sawa-gun, Gunma</li> <li>• Establishment No. KY-1, Kyoto City Slaughterhouse/Kyoto Meat Market Co., Ltd, Kyoto-city, Kyoto</li> <li>• Establishment No. TOC-1, Tochigi Meat Center, Haga-Town, Haga-County, Tochigi</li> </ul>
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FSIS performed the audit to verify that Japan’s 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 Slaughter Act (7 U.S.C. Sections 1901-1907); and
- The Meat Inspection Regulations (9 CFR part 301 to the end).

The audit standards applied during the review of Japan’s inspection system for raw intact 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 November 1, 2020, to October 31, 2023, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 7,396,199 pounds of raw intact beef products from Japan. Of these amounts, additional types of inspection were performed on 457,837 pounds of raw intact beef products. These additional types of inspection included physical examination and chemical residue analysis. As a result of this additional testing no raw intact beef was rejected for issues related to public health. An additional 3,338 pounds of raw beef products were refused for other issues not related to public health including shipping damage, labeling, or other miscellaneous issues.

The most recent 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](http://www.fsis.usda.gov/foreign-audit-reports).

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

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

MHLW is Japan's CCA and has the authority to organize and administer the Japanese meat inspection system. The inspection system consists of central, regional, and local offices. MHLW is the central level office with Regional Bureau of Health and Welfare (RBHW) offices located throughout Japan. Within the RBHW offices, the Food Sanitation Division (FSD) is responsible for oversight and supervision of the establishments certified to export raw beef products to the United States. At the local government level, establishments certified for export to the United States have Meat Inspection Centers (MICs) with government inspection personnel that are responsible for conducting daily inspection activities to verify that these establishments are meeting MHLW's requirements. Laboratories are approved by MHLW to conduct analysis of official government samples collected by government inspection personnel on products intended for export to the United States. MHLW also has the authority to revoke the approval of these laboratories.

MHLW is responsible for directing, planning, and carrying out food safety controls in all establishments and animal health and welfare controls in slaughter establishments. The Abattoir Act (Act No. 114), Regulation for Enforcement of the Abattoir Act (Ordinance No. 44), and the Food Sanitation Act (Act No. 233) grant MHLW the authority to enforce inspection laws. MHLW's documents titled, 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.

FSD oversees establishments at the regional level. RBHW offices review data from establishments and conduct monthly supervisory reviews to verify compliance with MHLW's requirements. These audits include review of the MIC's microbiological laboratories located within the region. Supervisors also conduct reviews of the in-plant government inspection personnel during the monthly supervisory audits.

The FSIS auditors verified at the local government level that government inspection personnel conduct daily verification procedures and enforce MHLW requirements at establishments. These verification procedures are also implemented at establishments certified to export raw beef products to the United States. Each MIC consists of technical, clerical, and commissioned personnel. The technical and clerical personnel provide management oversight and support to the MIC. The commissioned personnel conduct inspection activities at the establishments and consist of veterinarian government inspectors and meat inspector assistants. The meat inspector



assistants do not perform any verification procedures independent of the veterinarian government inspectors. Each MIC designates veterinarian government inspectors responsible for signing export certificates to foreign countries.

The Abattoir Act and Ordinance No. 44 require that inspection personnel assigned to slaughter establishments are government inspectors with appropriate educational credentials, training, and experience to conduct their inspection tasks. Training on livestock inspection, sanitation, and HACCP programs occurs on-the-job and is supplemented by paper-based training at the MIC level. MHLW organizes periodic training at the national level on food safety and inspection requirements pertaining to the production of raw beef products intended for export to the United States. The FSIS auditors interviewed government inspection personnel and reviewed official records without identifying any concerns with government inspection personnel meeting qualifications and having appropriate training.

MHLW is responsible for certifying establishments as eligible to export raw beef products to the United States. MHLW is also responsible for the decertification of establishments that do not meet MHLW's requirements and for maintaining the official list of establishments eligible to export raw beef products 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 its eligibility to export raw beef products to the United States. MHLW's document titled, Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States describes the procedures that establishment operators should follow to obtain approval from MHLW to become certified to export raw beef products to the United States and the actions taken by government personnel at each step of the approval process. The FSIS auditors verified the certification process for establishments certified to export raw beef products to the United States was being implemented in accordance with MHLW's requirements.

The FSIS auditors verified that MHLW has procedures in place for government inspection personnel at MICs to follow when authorizing a shipment of raw beef for export to the United States. The designated veterinarian government inspectors at MICs review establishment records, including HACCP requirements associated with the lots of products intended for export, prior to issuing an export certificate. These inspection procedures include taking official government samples, ensuring that the samples are analyzed using appropriate methods, and ensuring that sample results for chemical residue or pathogenic microorganism analyses are acceptable prior to signing export certificates of products intended for export to the United States. Veterinarian government inspectors sign the export certificate and attach it to the product to be exported. The MIC retains a copy of the certificate and gives another copy to the establishment that submitted the product for export.

MHLW maintains the legal authority and responsibility to suspend the certification of establishments eligible to export raw beef products to the United States and to take enforcement measures, such as withdrawal of inspection, when appropriate. Veterinarian government inspectors document noncompliance and have the authority to require corrective actions in certified establishments. RBHW is responsible for conducting supervisory reviews in establishments. If an establishment is not following the required procedures, then MHLW may take enforcement actions that include instructions for improvement, revocation of certification,

suspension of the issuance of export certificates, and removing the designation of inspectors. In addition to taking enforcement actions, MHLW has the authority to assess penalties for violation of food safety laws, as described in the Abattoir Act. The FSIS auditors interviewed government inspection personnel and reviewed official records without identifying concerns related to MHLW's documentation of noncompliance and implementation of enforcement procedures.

The FSIS auditors verified that prior to certifying establishments for export to the United States, MHLW requires establishments to develop written recall procedures. The production lot to be recalled is determined by the manufacturer records. The Food Sanitation Act requires Food Business operators to mandatorily notify food recall information to governments. Also, the recall procedure regarding chemical residue monitoring is described in MHLW's document titled, Guidelines for Inspection of Certified Establishments Handling Meat for Exportation to the United States. If products exported to the United States need to be recalled, MHLW is responsible for notifying FSIS. Each certified establishment conducts a mock recall periodically year. The FSIS auditors reviewed documentation associated with the mock recalls and did not identify any concerns.

The FSIS auditors verified that MHLW requires certified establishments to have traceability procedures in place to include the origins of each animal processed at establishments. Veterinarian government inspectors ensure all MHLW requirements regarding registration and identification documents are in order prior to allowing animals to enter establishments. In addition, MHLW requires products be traceable until they enter the United States. The FSIS auditors also verified that establishments are complying with MHLW requirements for products intended for export to the United States to be segregated from other products not eligible for export.

The FSIS auditors determined that regulatory verification and inspection activities were consistently implemented at all audited certified establishments. MHLW maintains a single standard of laws and regulations applicable to all establishments certified for export to the United States. RBHW conducts supervisory inspections at a monthly frequency designed to ensure establishments are meeting MHLW's requirements including changes to the inspection system. MHLW disseminates inspection information related to the regulatory and administrative requirements electronically to RBHW and to government inspection personnel at each MIC with establishments certified to export raw beef product to the United States. The FSIS auditors verified that MHLW maintains government inspection system uniformity and disseminates and verifies changes to the inspection system.

The FSIS auditors verified that government inspection personnel assigned to certified establishments exporting raw beef products to the United States are employed and paid by the local Japanese government. Government inspection personnel assigned to certified establishments are civil servants and required to be full-time government employees. The local government with the assistance of the national government pays the salaries of government inspection personnel.

The FSIS auditors verified that slaughter and processing establishments certified for export to the United States have adequate coverage by government inspection personnel. The MIC is

responsible for assigning online and offline government inspection personnel to ensure the required MHLW procedures are conducted during each shift. Each MIC has established procedures for relief assignments if absences of government inspection personnel occur. MHLW requires continuous online inspection during slaughter operations and at least once per shift inspection for raw processing operations in establishments that are certified to export to the United States.

Inspection verification tasks are predetermined and listed on an inspection Daily Monitoring Verification form. Veterinarian government inspectors use this form to record offline inspection verification tasks. These daily verification activities consist of a direct observation of the establishment monitoring of the HACCP system, including zero-tolerance verification, sanitation standard operating procedures (Sanitation SOPs), specified risk materials (SRM) removal, sampling procedures, and sanitation performance standards (SPS). In addition, veterinarian government inspectors review the establishment's records, including HACCP, Sanitation SOPs, SPS, and test results from product sampling in accordance with the MIC daily inspection verification schedule plan outlined in the Daily Monitoring Verification form. The FSIS auditors interviewed government inspection personnel, directly observed government inspection activities, and reviewed official records without identifying any concerns with staffing or inspection verification activities at certified establishments.

The FSIS auditors verified that RBHW conducts monthly supervisory reviews of each MIC, which includes evaluation of government inspection personnel within the establishment and verify that certified establishments are meeting MHLW's requirements. In addition, RBHW conducts an audit of each MIC and registered laboratory at least annually to verify the Salmonella testing, STEC testing and monitoring of chemical residues. MHLW reviews the reports of the monthly supervisory visits by RBHWs every month.

Japan's Food Sanitation Act and the Ordinance for Enforcement of the Food Sanitation Act include requirements for authorizing and assessing laboratories that conduct chemical residue or microbiological analyses of official samples. MHLW has the authority to approve or revoke approval for these laboratories. The registered laboratories are required to establish rules concerning product tests and receive MHLW approval. MHLW also maintains administrative and technical support to operate its laboratory system. Laboratories are required to operate in accordance with standards consistent with the Manual on How to Manage Examinations Etc. at Testing Laboratories" which was established by MHLW based on International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025.

The FSIS auditors verified that MHLW utilizes the Japan Food Research Laboratories (JFRL) to conduct analysis of official government samples submitted by MICs. These are private chemical residue laboratories accredited by the Japanese Accreditation Board (JAB) in accordance with ISO/IEC 17025 standards. JFRL laboratories are audited annually by RBHW in accordance with MHLW's requirements. MHLW has designated JFRL to conduct chemical residue testing of samples of raw beef products intended for export to the United States. JFRL has two laboratories designated as chemical residue testing laboratories under Japan's national residue program (NRP). JFRL implements analytical methods approved by MHLW and has quality assurance programs in place to ensure standards consistent with ISO/IEC 17025.

The FSIS auditors verified that MHLW utilizes MIC laboratories to conduct microbiological analyses of official government samples. MIC laboratories are government laboratories owned and operated by local governments. MHLW does not require MIC laboratories to be accredited to ISO/IEC 17025 standards but requires the laboratories to implement procedures generally consistent with ISO/IEC 17025 standards. MIC laboratories are audited annually by RBHW for confirming GLP and monthly during RBHW supervisory inspections according to MHLW's requirements.

JFRL laboratories conducting analyses of official government samples must be operated and managed in accordance with ISO/IEC 17025 standards, with accreditation by JAB. Also, all MIC laboratories are encouraged to be operated and managed in accordance with ISO/IEC 17025 standards. MHLW requires laboratories to implement quality control procedures, training of personnel, maintenance of equipment and facilities, calibration of equipment, proficiency testing of analysts, and procedures for sample receipt and storage, reporting of results, and traceability of samples. The laboratories follow test methods required by MHLW for official government samples of products intended for export to the United States. Results are reported by the testing laboratory to MHLW, government inspection personnel, and the certified establishment in a timely manner and products are held pending acceptable results prior to products being certified for export to the United States. The FSIS audit scope in each audited laboratory included review of sample receipt, timely analysis, analytical methodologies, analytical controls, analyst qualifications and trainings, proficiency testing, and recording and reporting of results. The FSIS auditors reviewed the most recent accreditation audits, the laboratories' staff training records, and the results of their proficiency testing. The FSIS auditors did not identify any concerns during these reviews.

The auditors verified that Japan's raw beef inspection system is organized and administered by the national government, and that government inspection officials are assigned to enforce the laws and regulations governing raw beef products.

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

The second equivalence component the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of every carcass and its 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.

MHLW outlines humane handling and animal welfare requirements for establishments certified for export to the United States in the document titled, Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States. MHLW's

requirements include handling of animals from unloading until the start of post-mortem inspection. This includes receiving, holding, access to water, feeding when required, movement of animals, stunning, and bleeding of animals. This document further outlines facility and maintenance requirements at these establishments. MHLW provides verification procedures for veterinarian government inspectors regarding humane handling and animal welfare. The FSIS auditors interviewed government inspection personnel, directly observed handling of animals, and reviewed official inspection records without identifying any concerns with humane handling and animal welfare.

Japan's Abattoir Act has requirements for ante-mortem areas, records, and the prohibition of the slaughter and dressing of animals with diseases or abnormalities that may make them unfit for human consumption. MHLW has ante-mortem inspection procedures that veterinarian government inspectors must perform, including ensuring that each animal is inspected at rest and in motion prior to slaughter. Animals suspected of having a disease or abnormality are required to be identified and segregated from other animals and have a disposition performed by veterinarian government inspectors to ensure animals not meeting MHLW's requirements will not be allowed to be slaughtered. If an animal is found unfit for slaughter, it must be identified as such and disposed of according to MHLW's requirements. While interviewing government inspection personnel performing ante-mortem inspection procedures, the FSIS auditors identified the following systemic finding:

- MHLW, the Central Competent Authority of Japan, does not maintain national guidelines that prescribe the maximum body temperature at which cattle are to be condemned by the veterinarian government inspectors during ante-mortem inspection.

The Abattoir Act requires the post-mortem inspection of all livestock carcasses and parts by veterinarian government inspectors. MHLW has written procedures in place that instruct veterinarian government inspectors on how to perform post-mortem inspection. These procedures include visual inspection, palpation, incision of relevant portions of the animal and condemnation of animals as described in MHLW's procedures. MHLW has procedures for veterinarian government inspectors to follow regarding disposition of carcasses and parts inspected during post-mortem inspections and include the condemnation criteria of carcasses or parts deemed unfit for human consumption. Certified establishments must meet MHLW's requirements regarding the facility areas where post-mortem inspection is required. To be certified for export to the United States, establishments must initially meet these facility requirements and maintain them continuously. The FSIS auditors interviewed government inspection personnel, observed post-mortem inspection, and reviewed official inspection records without identifying any concerns with post-mortem inspection.

MHLW's document titled, Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States, describes the procedure for conducting periodic supervisory reviews by a representative of the inspection system to each certified establishment. The FSIS auditors verified that RBHW conducts monthly supervisory reviews at each MIC to evaluate the performance of government inspection personnel. These supervisory inspection reviews include reviews of verification activities conducted by veterinarian government inspectors for humane handling, animal welfare, ante-mortem, post-mortem, sanitation, HACCP,

labeling verification, export certification, separation of finished products, control over condemned materials, official government sample collection practices, and MHLW requirements regarding United States import requirements. In addition, the director of the MIC regularly evaluates the performance of government inspection personnel, including their skill and knowledge on inspection procedures. The director conducts an additional training for designated government inspection personnel, if necessary.

MHLW provides trainings, and periodically holds a meeting with RBHW personnel to provide opportunities for dialogue and exchange of views on the result of recent supervisory reviews, which contributes to maintain the performance level of supervisory reviews by RBHW. The FSIS auditors interviewed government personnel, observed sampling procedures, and reviewed official records and as a result identified the following systemic finding:

- RBHW personnel's supervisory reviews did not identify that the establishments' personnel were not adequately implementing the generic *Escherichia coli* (*E. coli*) sampling procedures, and that government inspection personnel were not properly collecting N60 trim samples for the official government Shiga-toxin producing *E. coli* (STEC) sampling verification program.

The FSIS auditors verified that MHLW requires complete separation of establishments that are certified from those that are not certified. Certified establishments must carry out all required activities from slaughter to fabrication and processing at the same facility. Japan currently does not allow any slaughter establishment to ship products destined for further processing to another establishment. Establishments certified to export to the United States operate continuously under procedures that meet United States import requirements and products destined for export to markets other than the United States are separated at the time of labeling and storage for shipping.

Labels and marks are approved by MHLW and are required to be displayed on outer containers and packages after they have passed inspection. The FSIS auditors verified that labels for products intended for export to the United States are submitted to and approved by MHLW. Label verification is done by the veterinarian government inspectors and during supervisory reviews. The verification activities by veterinarian government inspectors include ensuring scales are calibrated and accurate. In addition, the labels of each lot of products are verified for accuracy prior to signing the export certificate. MHLW performs species verification testing at least once per year in all establishments certified for export to the United States.

The FSIS auditors verified that MHLW and the Ministry of Agriculture, Forestry and Fisheries (MAFF) ensure compliance with APHIS requirements. MAFF communicates with APHIS on animal disease requirements and monitors APHIS' website. MHLW has BSE requirements for cattle that are verified by veterinarian government inspectors and during supervisory reviews. Prior to signing export certificates, the veterinarian government inspector signing the certificate ensures APHIS requirements have been met.

Slaughter of non-ambulatory disabled cattle is not allowed at certified establishments, nor is stunning using a device that deliberately injects compressed air into the cranium or by pithing

per MHLW's requirements outlined in the document titled, Requirements for Certification of Slaughter, Etc., Handling Meat for exportation to the United States. In addition, establishments must consider SRMs as potential hazards when developing their HACCP system. MHLW requires establishments to remove and dispose of SRMs from cattle. Establishments must have procedures designed to remove SRMs without contamination of products intended for human consumption. SRMs must also be kept separate from other inedible materials and disposed of in ways that meet MHLW's requirements. The FSIS auditors noted that MHLW maintains a definition of SRMs that is consistent with the definition outlined in 9 CFR 310.22. SRM verification is performed daily and documented on the Daily Monitoring Verification inspection form. The FSIS auditors interviewed government inspection personnel, directly observed inspection verification for SRM controls, and reviewed official records without identifying any issues regarding verification of SRM removal requirements.

MHLW's document titled, Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States outlines establishment requirements for the disposal of inedible and condemned materials. Because of infectious disease issues, discarded materials are put in special containers used solely for that purpose and incinerated at the establishment or transported to an incineration plant in the presence of a veterinarian government inspector. SRMs and inedible condemned materials are stored in a container separate from all other inedible materials prior to disposal. Inedible animal parts and waste must be placed in containers used exclusively for this purpose, must be colored, denatured, or otherwise processed, and removed from the establishment on the same day of occurrence. If condemned and inedible materials cannot be removed on the date of the occurrence, then the materials must be placed in a locked container under the control of a veterinarian government inspector until removal. The FSIS auditors observed the control of condemned and inedible materials and did not identify any concerns.

The FSIS auditors concluded, except for the systemic findings regarding maximum allowable temperatures for cattle and microbiological sampling procedures, that MHLW continues to maintain the legal authority, a regulatory framework, and adequate verification procedures to ensure sufficient official regulatory control over establishments certified to export raw beef products to the United States using statutory authority consistent with criteria established for this component.

## **VI. COMPONENT THREE: GOVERNMENT SANITATION**

The third equivalence component the FSIS auditors reviewed was Government Sanitation. The food safety inspection system is to require that each official establishment develop, implement, and maintain written Sanitation SOPs to prevent direct product contamination or insanitary conditions, and to maintain requirements for SPS and sanitary dressing.

MHLW's document titled, Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States describes sanitation requirements for sanitation. This document outlines requirements regarding the facility and equipment, which are consistent with FSIS requirements in 9 CFR part 416. All establishments certified for export to the United States

are required to develop and implement Sanitation SOPs in accordance with MHLW requirements, which are consistent with FSIS Sanitation SOP requirements in 9 CFR part 416.

MHLW has requirements for standards of construction and facilities, which include ante-mortem, post-mortem, processing, and storage areas. MHLW has the authority to take enforcement action to direct an establishment to rectify both hygiene and structural deficiencies identified with the establishment's construction, facilities, or equipment. Establishments are required to develop, implement, and monitor at least daily Sanitation SOPs that include pre-operational and operational procedures designed to ensure meat is not adulterated during production and storage. Pre-operational procedures must outline the cleaning of food contact surfaces and equipment. Veterinarian government inspectors perform verification activities each day to verify establishments are meeting Sanitation SOP requirements and that products are not being contaminated or adulterated. Government inspection personnel conduct daily pre-operational verification activities for each piece of equipment in the animal holding pens, slaughter rooms, and processing rooms. In addition to the equipment and food contact surfaces, the overall condition of the area, such as ceilings, walls, and floors, is verified by government inspection personnel daily prior to production to be structurally sound, in good repair, and maintained in a sanitary manner. The FSIS auditors interviewed government inspection personnel, observed government inspection verification activities, and reviewed official inspection records and did not identify any concerns regarding Sanitation SOP requirements.

MHLW requires establishments to operate in a sanitary manner and maintain sanitary standards specific to all production areas. Veterinarian government inspectors verify that the establishments' procedures are adequate to prevent contamination of carcasses and parts during production. MHLW's document titled, Guidelines for Inspection of Certified Establishments Handling Meat for Exportation to the United States describes government inspection personnel verification activities for sanitary dressing procedures during production. Veterinarian government inspectors at the final rail position ensure that carcasses with visible contamination are further trimmed and reinspected before entering the chiller and verify the establishment's corrective actions after instances of noncompliance. The FSIS auditors interviewed government inspection personnel, observed inspection verification activities, and reviewed official inspection records without identifying any concerns regarding sanitary dressing requirements.

MHLW enforces a zero-tolerance standard for the presence of visible fecal material, ingesta, and milk on beef carcasses and parts, and requires slaughter establishments to address these hazards in their HACCP plans. MHLW requires veterinarian government inspectors to conduct daily verification procedures of the HACCP plan to address contamination of carcasses and parts with fecal material, ingesta, and milk. These procedures include directly observing the establishment's monitoring of its CCP. Additionally, veterinarian government inspectors are required to perform daily zero tolerance verification activities by examining carcasses at the end of the post-mortem inspection process prior to entering the chiller. The frequency of carcass examinations performed by government inspection personnel is dependent on the number of animals slaughtered during the shift. The FSIS auditors interviewed government inspection personnel, observed inspection verification activities, and reviewed official inspection records without identifying any concerns regarding MHLW's zero tolerance verification procedures.



The FSIS auditors determined that MHLW requires establishments certified to export products to the United States to develop, implement, and maintain sanitation programs, including requirements for SPS, Sanitation SOPs, zero tolerance, and sanitary dressing.

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

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

MHLW requires establishments certified to export raw beef products to the United States to develop, implement, and maintain a HACCP system in accordance with MHLW's document titled, Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States. MHLW requires certified establishments to evaluate the food safety system and identify 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. MHLW's requirements for HACCP in establishments certified to export to the United States are consistent with FSIS requirements in 9 CFR part 417.

Certified establishments exporting products to the United States must prepare and maintain a flow diagram and conduct a hazard analysis for each process (e.g., slaughter or raw processing). The HACCP plan must identify critical control points (CCP), critical limits (CL), monitoring of CLs at CCPs, verification activities, and corrective actions to be taken when a deviation of a CL occurs. The hazard analysis decisions must be supported, and the HACCP plan must address hazards identified as likely to occur. A record-keeping system for the monitoring, verification, and corrective actions must meet MHLW's HACCP requirements and records must be accessible to government inspection personnel and maintained for a minimum of one year.

Certified establishments exporting products to the United States must conduct pre-shipment reviews to ensure that all critical limits, corrective actions, and other HACCP system requirements, such as prerequisite programs, are met for each lot of products prior to shipping. Certified establishments must conduct a reassessment of their HACCP systems at least annually, and as required for other reasons, such as when any changes occur that could affect the hazard analysis or alter the HACCP plan. The HACCP plans must be signed and dated by a qualified establishment employee that has been trained on HACCP principles. The FSIS auditors interviewed government inspection personnel and reviewed official inspection records without identifying any concerns regarding MHLW's HACCP requirements or implementation of those requirements by certified establishments.

Government inspection personnel are required to verify the validity of an establishment's HACCP system by assessing whether the plan complies with all requirements in MHLW's document titled, Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States. Veterinarian government inspectors perform HACCP verification activities at certified establishments according to the instructions outlined in

MHLW's document, Guidelines for Inspection of Certified Establishments Handling Meat for Exportation to the United States. The official verification activities include direct observation and record reviews of the establishment's implementation of its HACCP system. This document outlines the frequencies of HACCP system verification procedures conducted by veterinarian government inspectors. The FSIS auditors interviewed government inspection personnel, observed inspection verification activities, and reviewed official inspection records without identifying any concerns regarding MHLW's verification of the establishments' HACCP systems.

The FSIS auditors determined that MHLW requires and verifies establishments certified to export products to the United States to develop, implement, and maintain a HACCP system for each processing category consistent with FSIS requirements in 9 CFR 417.

## **VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS**

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

The 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 veterinary drugs or other chemical contaminants in bovine slaughtered for human consumption in accordance with provisions contained in Japan's Food Sanitation Act and Abattoir Act. The Consumer Affairs Agency (CAA) has the authority to set maximum residue limits (MRL) that are not to be exceeded, and in setting these MRLs, CAA ensures that limits are to be harmonized with those set in the United States and other international standards based on scientific rationale. Japan's NRP describes the frequency and sample allocations among species and the classes of compounds that must be analyzed.

The FSIS auditors verified that MHLW has the authority to require the establishment to dispose of product that exceeds MRLs set as part of the NRP. In addition, to prevent the violations from recurring, the cause of the chemical residue violation is investigated. When performing analysis on samples generated from products intended for export to the United States, any level of detection is reported to MHLW, and the results are compared against U.S. MRLs. FSIS auditors verified that official government chemical test results are communicated to MHLW headquarters, regional offices, and government inspection personnel through email. The local authorities publish a written disposition order or a written improvement order for products with violative levels of chemical residues.

The FSIS auditors verified that government inspection personnel who collect residue samples are following MHLW's sampling protocol. MHLW's Guidelines for Inspection of Certified Establishments Handling Meat for Exportation to the United States stipulates that designated government inspection personnel collect samples for the NRP and sends them to JFRL for

analysis. This protocol includes sampling methodology, selection of animals to be sampled, sampling frequency, traceability, and secure delivery of residue samples to designated laboratories. Beef carcasses and parts intended for export to the United States are not allowed to be certified for export to the United States until acceptable results are received by MHLW.

The FSIS verification activities indicated that MHLW has overall authority for implementation of a chemical residue testing program that is designed to prevent and control the presence of veterinary drugs and other chemical contaminants in raw intact beef products intended for export to the United States. There have not been any POE violations related to this component since the previous FSIS audit in 2022.

## **IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS**

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

MHLW requires microbiological sampling programs be implemented by MICs and establishments for verification of the adequacy of the beef slaughter process controls for the prevention and removal of fecal contamination and associated bacteria at establishments certified to export raw beef products to the United States. This includes requirements for official sampling of beef carcasses for *Salmonella* and beef trimmings for STEC by the MICs. Certified establishments exporting products to the United States are also required to have a STEC sampling program meeting MHLW's requirements. Implementation of this program is verified by the veterinarian government inspectors and during RBHW supervisory reviews.

Establishments certified to export raw beef products to the United States are also required to sample and test beef carcasses for generic *E. coli* as outlined in MHLW's document titled, Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States. This document outlines random selection of carcasses, locations of sampling, sampling methodology, evaluation criteria, and frequency of sampling. Certified establishments must implement an analytical method that is externally validated.

MHLW's document titled, Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States describes official sampling by veterinarian government inspectors for *Salmonella* in bovine carcasses. This document outlines random selection of carcasses, locations of sampling, sampling methodology, evaluation criteria, and frequency of sampling. MHLW's official verification sampling program for *Salmonella* in beef carcasses is consistent with FSIS requirements for *Salmonella* performance standard criteria described in 9 CFR 310.25(b). MHLW requires that MIC laboratories implement FSIS' Microbiology Laboratory Guidebook Chapter 4 method for detection of *Salmonella*.

The FSIS auditors interviewed government inspection personnel, reviewed official verification records, and directly observed implementation of the STEC and generic *Escherichia coli* (*E.*

*coli*) sampling procedures and determined that RBHW's personnel's supervisory reviews did not identify that the establishments' personnel were not adequately implementing the generic *Escherichia coli* (*E. coli*) sampling procedures, and that government inspection personnel were not properly collecting N60 trim samples for the official government Shiga-toxin producing *E. coli* (STEC) sampling verification program. These observations resulted in the systemic finding related with RBHW's supervisory visits noted in Component 2 above.

MHLW's document titled, Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States specifies official government and establishment sampling requirements for STEC at establishments certified for export to the United States. These requirements include procedures for selection of samples, sampling methodology, and frequency of sampling. Certified establishments may choose a private laboratory to perform the analysis with a method approved by MHLW. Sampled lots are not to be certified for export to the United States until acceptable results are received by MHLW.

The FSIS auditors determined, except for the systemic finding regarding sampling procedures of both government inspection personnel and establishment personnel, that MHLW maintains the legal authority and implements microbiological sampling and testing programs to ensure that products intended for export to the United States are unadulterated, safe, and wholesome.

## **X. CONCLUSIONS AND NEXT STEPS**

An exit meeting was held June 6, 2024, with MHLW. At this meeting, the FSIS auditors presented the preliminary findings from the audit. An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

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

- MHLW, the Central Competent Authority of Japan, does not maintain national guidelines that prescribe the maximum body temperature at which cattle are to be condemned by the veterinarian government inspectors during ante-mortem inspection.
- RBHW's personnel's supervisory reviews did not identify that the establishments' personnel were not adequately implementing the generic *Escherichia coli* (*E. coli*) sampling procedures, and that government inspection personnel were not properly collecting N60 trim samples for the official government Shiga-toxin producing *E. coli* (STEC) sampling verification program.

During the audit exit meeting, MHLW committed to address the preliminary finding as presented. FSIS evaluated the adequacy of MHLW's documentation of proposed corrective actions and will 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 Gunma-ken Shokuniku Oroshiuri Shijo Co., Ltd. Sawa-gun, Gunma	2. AUDIT DATE 5/28/2024	3. ESTABLISHMENT NO. G-1	4. NAME OF COUNTRY Japan
	5. OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
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	X
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .	X	41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	X	56. European Community Directives	O
29. Records		57.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Beef slaughter and raw processing
Prepared Products:	Raw beef

60. Observation of the Establishment

28-The establishments sample that was collected for *G. Ecoli* was not representative of the entire surface of the area being swabbed.

39-The carcass cooler room's floor was cracked in spots and also breaking up in areas. These areas of the carcass cooler room's floor are hard to clean and the inside areas of the floor can harbor microorganisms.

14-The establishment's zero fecal tolerance CCP critical limit monitoring did not include the time the event occurred.



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## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Wagyu Master Meat Center Himeji-shi, Hyogo	2. AUDIT DATE 5/15/2024	3. ESTABLISHMENT NO. HMJ-1	4. NAME OF COUNTRY Japan
	5. OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	X	56. European Community Directives	O
29. Records		57.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Beef slaughter and raw processing
Prepared Products:	Raw beef

60. Observation of the Establishment

28- The establishment's written sampling procedure for Generic E. coli did not address swabbing the entire area where the collection template was applied. As a result, the sample that was collected was not representative of the entire surface of the area being swabbed.

United States Department of Agriculture  
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## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION NANCHIKU CO.,LTD. , Soo-shi, Kagoshima	2. AUDIT DATE 5/23/2024	3. ESTABLISHMENT NO. K-1	4. NAME OF COUNTRY Japan
	5. OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .	X	41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Beef slaughter and raw processing
Prepared Products:	Raw beef

60. Observation of the Establishment

14-The establishment's hazard analysis did not identify metal as a potential hazard in the slaughter and cutting process.

United States Department of Agriculture  
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## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION SANKYO MEAT Ltd. Ariake Meat Plant Shibushi-shi, Kagoshima	2. AUDIT DATE 5/22/2024	3. ESTABLISHMENT NO. K-2	4. NAME OF COUNTRY Japan
	5. OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.	X	43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Beef slaughter and raw processing
Prepared Products:	Raw beef

60. Observation of the Establishment  
16-Establishment critical limit monitoring verification records did not include a result of the verification activities.

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Akune Meat Distribution Center Co., Ltd. STARZEN MEAT PROCESSOR Co., Ltd. Akune Plant Akune-shi, Kagoshima	2. AUDIT DATE 5/20/2024	3. ESTABLISHMENT NO. K-3	4. NAME OF COUNTRY Japan
5. OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

Establishment Operations:	Beef slaughter and raw processing
Prepared Products:	Raw beef

60. Observation of the Establishment

46-While observing the carcasses separation in the fabrication area of the establishment an employee’s shoe contacted the bottom section of a loin. The contamination was not identified. MIC was notified of the observation and immediately notified the establishment. Corrective actions were taken meeting MHLW requirements, the part of the contaminated carcass was removed.



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## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION JA Shokuniku Kagoshima Co., Ltd. Nansatu Plant Minamikyushu-shi, Kagoshima	2. AUDIT DATE 5/17/2024	3. ESTABLISHMENT NO. K-4	4. NAME OF COUNTRY Japan
	5. OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Beef slaughter and raw processing
Prepared Products:	Raw beef

60. Observation of the Establishment

No findings observed

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Kyoto City Slaughterhouse / Kyoto Meat Market Co., Ltd. Kyoto-city, Kyoto	2. AUDIT DATE 5/16/2024	3. ESTABLISHMENT NO. KY-1	4. NAME OF COUNTRY Japan
	5. OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.	X	43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.	X	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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Beef slaughter and raw processing
Prepared Products:	Raw beef

60. Observation of the Establishment

16-Zero tolerance CCP monitoring record does not capture the time the event occurred for all results.

18-Establishment employee monitoring the Zero tolerance CCP did not record results as required by the establishments written procedure.

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## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION MIYACHIKU Corp., Ltd. Takasaki Plant Miyakonojo-shi, Miyazaki	2. AUDIT DATE 5/21/2024	3. ESTABLISHMENT NO. M-1	4. NAME OF COUNTRY Japan
	5. OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. STEC sampling	X
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Beef slaughter and raw processing
Prepared Products:	Raw beef

60. Observation of the Establishment

57- The MIC inspector was not following MHLW requirements while implementing the STEC sampling N60 procedure. One of the surface area samples was smaller than the required size.

United States Department of Agriculture  
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## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Tochigi Meat Center Haga-County, Tochigi	2. AUDIT DATE 5/29/2024	3. ESTABLISHMENT NO. TOC-1	4. NAME OF COUNTRY Japan
	5. OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .	X	41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.	X	43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57.	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Beef slaughter and raw processing
Prepared Products:	Raw beef

60. Observation of the Establishment

10-During pre-operational verification by the MIC it was observed they did not verify the cutting benches molding where the cutting boards sit, are clean which is a potential harbor site for residue from the previous days production. This area could potentially affect the product and contact surfaces during production.

16-When the establishment monitored CCP # 5 they did not document the activity on the record. Instead, they took notes on a piece of paper then transferred the results later in the day.

46-During slaughter operations carcass halves were observed to contact one another at the MIC's carcass verification stand and the establishment's final trim stand. These areas are located before the zero tolerance CCP and final wash cabinet. The carcasses were trimmed and then run through the final wash cabinet.

52-While observing the movement of cattle into the knocking box, the floor had areas that are smooth and flat stainless steel. This potentially allows the cattle to slip and be uncomfortable moving into the box.

14-The establishment's flow diagram did not include the head and viscera MIC inspection activities.



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



## **Food Inspection and Safety Division**

Public Health Bureau

Ministry of Health, Labour and Welfare, JAPAN

1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-8916 Japan Tel: 81-3-3595-2337

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October 16, 2024

Dr. Margaret Burns Rath  
Acting International Coordination Executive  
Food Safety and Inspection Service  
United States Department of Agriculture  
1400 Independence Avenue, SW  
Washington, D.C. 20250  
**UNITED STATES OF AMERICA**

### **Subject: Corrective Actions and Comments on the Draft Final Audit Report**

Dear Dr. Margaret Burns Rath,

Thank you very much for your letter of August 22, 2024 with the draft final report regarding the onsite verification audit of Japan's meat inspection system conducted from May 13-June 6, 2024.

In response to the audit findings provided in the draft final audit report, I enclose the Corrective Actions (attachment1) for your review.

Also, I would like to submit comments on the content of the draft final audit report, as attached (attachment2). I would be most grateful if you would review our comments and revise the report with taking our inputs into consideration before finalizing the report.

I look forward to continued collaboration between the USDA-FSIS and the MHLW. Please do not hesitate to contact me should you have any questions.

Sincerely,

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Takeshi MORITA, DVM  
Director of Food Inspection and Safety Division  
Public Health Bureau  
Ministry of Health, Labour and Welfare, JAPAN

Attachment 1 Corrective actions taken by JAPAN

<i>Findings</i>	<i>Corrective Actions</i>
GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)	
<p>MHLW, the Central Competent Authority of Japan, does not maintain national guidelines that prescribe the maximum body temperature at which cattle are to be condemned by the veterinarian government inspectors during ante-mortem inspection.</p>	<p>The Ministry of Health Labor and Welfare (MHLW) issued a revised guideline on August 9, 2024 to specifically address the point raised.</p> <p>The revised guideline, titled “Guidelines for Inspection of Certified Establishments Handling Meat for Exportation to the United States” provides a clear instruction on the maximum body temperature of cattle to designated inspectors by saying that “Any cattle having a temperature of 40.5°C or higher shall not be slaughtered, dressed and divided in the certified establishment. When for reasons a designated inspector deems such action warranted, any such cattle can be reinspected.”</p> <p>Furthermore, all the Meat Inspection Centers (MICs) were requested to update their manuals by the end of September 2024 to reflect the above revision of the guideline, and to submit them to MHLW and Regional Bureaus of Health and Welfare (RBHWs) for review.</p>
<p>RBHW’s personnel’s supervisory reviews did not identify that the establishments’ personnel were not adequately implementing the generic <i>Escherichia coli</i> (<i>E. coli</i>) sampling procedures, and that government inspection personnel were not properly collecting N60 trim samples for the official government Shiga-toxin producing <i>E. coli</i> (STEC) sampling verification program.</p>	<p>Together with the other preliminary findings presented at the audit exit meeting, the findings about microbiological sampling procedures were shared with the RBHW personnel including those who had not been involved in this year’s audit during the MHLW- RBHW regular meeting held on July 2, 2024, which provided equal opportunities for all the RBHW personnel to learn from experiences of the audit and led to enhance their performance at supervisory reviews.</p> <p>All the RBHW personnel re-evaluate own performance respectively to see if the level of supervisory reviews regarding microbiological sampling procedures is adequate based on the shared experiences, and review and ensure that establishments/MICs’ sampling procedures meet the requirements through their periodic supervisory visits. In particular, the three RBHWs that were pointed out their inadequate level of supervisory reviews regarding microbiological sampling procedures – Kanto-Shinetsu, Kinki and Kyushu RBHW had confirmed at their monthly supervisory visits conducted from June to August that corrective actions were done appropriately at the establishments/MICs concerned.</p> <p>Furthermore, MHLW is planning to share the best practices of sampling procedures with inspectors at MICs and RBHW personnel during a periodic training workshop to be held in January 2025.</p>

Attachment 1 Corrective actions taken by JAPAN

Appendix A: Individual Foreign Establishment Audit Checklists G-1: Gunma-ken Shokuniku Oroshiuri Shijo Co., Ltd.	
28-The establishments sample that was collected for <i>G. Ecoli</i> was not representative of the entire surface of the area being swabbed.	The MIC instructed G-1 to take corrective actions on May 28, 2024. The establishment immediately conducted a training program to those who are responsible for the sampling. On May 30, 2024, the MIC confirmed that G-1 collected the sample for generic <i>E. coli</i> in an appropriate procedure. Furthermore, the MIC verified the establishment's training program and judged the content was adequate on June 5, 2024.
39-The carcass cooler room's floor was cracked in spots and also breaking up in areas. These areas of the carcass cooler room's floor are hard to clean and the inside areas of the floor can harbor microorganisms.	The MIC instructed G-1 to take corrective actions on May 28, 2024. G-1 had entirely repaired the deep layers of the cracked floor in the carcass cooler room during the establishment's summer break from August 16 to 18 2024. The current plan of the establishment is to repair the surface of the cracked floor during the winter break in December and January, which will subsequently be verified by MIC as soon as possible.
14-The establishment's zero fecal tolerance CCP critical limit monitoring did not include the time the event occurred.	The MIC instructed G-1 to take corrective actions on May 28, 2024. On August 1, 2024, G-1 revised the recording chart of zero fecal tolerance so that it can capture all the time the event occurred. The MIC has confirmed that the times were recorded in the chart properly.
Appendix A: Individual Foreign Establishment Audit Checklists HMJ-1: Wagyu Master Meat Center	
28- The establishment's written sampling procedure for Generic <i>E. coli</i> did not address swabbing the entire area where the collection template was applied. As a result, the sample that was collected was not representative of the entire surface of the area being swabbed.	A training on sampling methods for swab tests was conducted for three HMJ-1 quality control personnel on May 21, 2024. Based on this, HMJ-1 revised the procedure manual to ensure proper sampling on May 21, 2024. The MIC conducted an on-site inspection of the sampling method to confirm the effectiveness of the training on May 22, 2024. As a result, the MIC determined that the techniques and procedures were appropriate.
Appendix A: Individual Foreign Establishment Audit Checklists K-1: NANCHIKU CO.,LTD.	
14-The establishment's hazard analysis did not identify metal as a potential hazard in the slaughter and cutting process.	On August 27, 2024, the establishment conducted a reassessment of the HACCP system by including metal as a potential hazard in the slaughter and cutting process where edged tools are used. MIC verified that the hazard analysis table that was updated by K-1 was adequate on September 4, 2024.

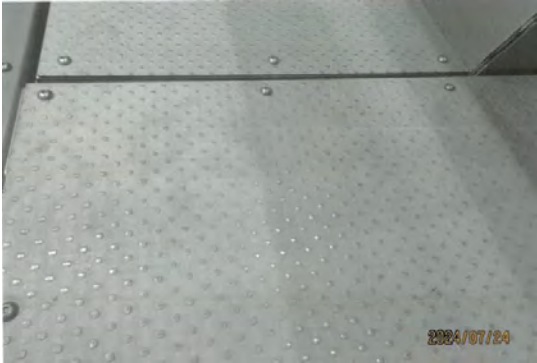
Attachment 1 Corrective actions taken by JAPAN

Appendix A: Individual Foreign Establishment Audit Checklists K-2: SANKYO MEAT. Ltd. Ariake Meat Plant	
16-Establishment critical limit monitoring verification records did not include a result of the verification activities.	As of August 27, the establishment revised all CCP Monitoring Record Forms to include the verification results. The measures above had been verified by the MIC to be acceptable on September 2,3 and 6 2024.
Appendix A: Individual Foreign Establishment Audit Checklists K-3: Akune Meat Distribution Center Co., Ltd. / STARZEN MEAT PROCESSOR Co., Ltd. Akune Plant	
46-While observing the carcasses separation in the fabrication area of the establishment an employee's shoe contacted the bottom section of a loin. The contamination was not identified. MIC was notified of the observation and immediately notified the establishment. Corrective actions were taken meeting MHLW requirements, the part of the contaminated carcass was removed.	<p>MIC instructed the establishment to take corrective actions on May 20, 2024. The following corrective actions were implemented by K-3, which have been verified by MIC on July 22, 2024.</p> <p>May 20, 2024 (Audit Date)</p> <ul style="list-style-type: none"> <li>▪ The affected portion was moved to the trimming table for processing.</li> <li>▪ The contaminated part of the primal cut was removed.</li> <li>▪ On-site explanations and instructions were provided to the employee whose shoe contacted the bottom section of a loin.</li> <li>▪ The processing department manager, facility manager, and quality control manager discussed preventive measures, including modifications to the lift platform.</li> <li>▪ The quality control staff and processing manager agreed on the importance of carefully monitoring for any potential contamination of carcasses, prime cuts, and other products during operational inspections.</li> </ul> <p>May 20-21, 2024</p> <ul style="list-style-type: none"> <li>▪ The issue was explained to all processing department staff, and a training was conducted to prevent carcasses and parts from coming into contact with shoes and other non-food materials.</li> </ul> <p>July 20, 2024</p> <ul style="list-style-type: none"> <li>▪ A contact-prevention bar was added to the lift platform used for primal cutting to prevent the carcasses from coming into contact with shoes.</li> </ul> <p>July 22, 2024</p> <ul style="list-style-type: none"> <li>▪ The quality control staff validated the effectiveness of the contact-prevention bar.</li> </ul>

Attachment 1 Corrective actions taken by JAPAN

Appendix A: Individual Foreign Establishment Audit Checklists K-4: JA Shokuniku Kagoshima Co., Ltd. Nansatu Plant	
No findings observed	N/A
Appendix A: Individual Foreign Establishment Audit Checklists KY-1: Kyoto City Slaughterhouse / Kyoto Meat Market Co., Ltd.	
16-Zero tolerance CCP monitoring record does not capture the time the event occurred for all results.	<p>The MIC instructed the establishment to take corrective actions on May 16, 2024.</p> <p>The establishment revised the monitoring record form to add a column for recording the time the event occurred for all results, and retrained its employees monitoring the Zero tolerance CCP on May 18, 2024.</p> <p>The corrective actions above were verified by the MIC to be acceptable on May 18, 2024.</p> <p>The establishment verified the effectiveness of employee training from May 18 to 27, 2024, and reported the completion of its corrective actions to the MIC on May 28, 2024.</p> <p>The corrective actions above were verified by the MIC to be acceptable on May 30, 2024.</p>
18-Establishment employee monitoring the Zero tolerance CCP did not record results as required by the establishments written procedure.	<p>The MIC instructed the establishment to take corrective actions on May 16, 2024.</p> <p>The establishment retrained its employees monitoring the Zero tolerance CCP to record the results each time they monitored as required by the establishment's written procedure on May 16, 2024.</p> <p>The corrective actions above were verified by the MIC to be acceptable on May 18, 2024.</p> <p>The establishment verified the effectiveness of employee training from May 18 to 27, 2024, and reported the completion of its corrective actions to the MIC on May 28, 2024.</p> <p>The corrective actions above were verified by the MIC to be acceptable on May 30, 2024.</p>
Appendix A: Individual Foreign Establishment Audit Checklists M-1: MIYACHIKU Corp., Ltd. Takasaki Plant	
57- The MIC inspector was not following MHLW requirements while implementing the STEC sampling N60 procedure. One of the surface area samples was smaller than the required size.	<p>On May 24, 2024, the Takasaki MIC conducted training for all inspectors who collect STEC samples to implement N60 sampling in accordance with the guidelines indicated by MHLW.</p> <p>The director of the Takasaki MIC confirmed that the inspectors were able to collect samples appropriately during this training.</p>

Attachment 1 Corrective actions taken by JAPAN

Appendix A: Individual Foreign Establishment Audit Checklists TOC-1: Tochigi Meat Center	
10-During pre-operational verification by the MIC it was observed they did not verify the cutting benches molding where the cutting boards sit, are clean which is a potential harbor site for residue from the previous days production. This area could potentially affect the product and contact surfaces during production.	On August 5, 2024, the MIC revised the inspection and verification manual by adding a sentence “including areas that cannot be verified without moving instruments”. The revised manual was circulated to all the MIC inspectors. On August 20, 2024, the MIC director verified that the MIC inspector was performing the pre-operational verification correctly.
16-When the establishment monitored CCP # 5 they did not document the activity on the record. Instead, they took notes on a piece of paper then transferred the results later in the day.	On May 29, 2024, the MIC instructed the establishment to take corrective actions. On June 19, 2024, the establishment trained establishment employees to document the monitoring results of CCPs on the record on site, which has been verified by the MIC.
46-During slaughter operations carcass halves were observed to contact one another at the MIC's carcass verification stand and the establishment's final trim stand. These areas are located before the zero tolerance CCP and final wash cabinet. The carcasses were trimmed and then run through the final wash cabinet.	On May 29, 2024, the MIC instructed the establishment to take corrective actions. On June 4, 2024, the establishment trained establishment employees that carcass halves must not come into contact each other. On June 17, 2024, the SSOP was revised by adding procedures that carcass halves must not come into contact each other, and that in cases where they did come into contact, those parts should be trimmed. The MIC has verified that they took measures appropriately and that there have been no issues since June 4, 2024.
52-While observing the movement of cattle into the knocking box, the floor had areas that are smooth and flat stainless steel. This potentially allows the cattle to slip and be uncomfortable moving into the box.	<p>On May 29, 2024, the MIC instructed the establishment to take corrective actions. On July 25, 2024, the establishment covered the floor of the knocking box with slip resistance boards made of stainless steel (please refer to the following photo). On July 26, 2024, the MIC verified that the cattle didn't slip moving into the box.</p> 

Attachment 1 Corrective actions taken by JAPAN

14-The establishment's flow diagram did not include the head and viscera MIC inspection activities.	On May 29, 2024, the MIC instructed the establishment to take corrective actions. On June 27, 2024, the establishment added the ante-mortem, head, and viscera MIC inspection activities to the flow diagram. On August 8, 2024, the establishment added the ante-mortem, head, viscera and carcass MIC inspection activities to the hazard analysis table and reported it to the MIC.
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