



Food Safety and
Inspection Service

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Dear Dr. Akira,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted a remote verification audit of Japan's inspection system July 19–August 17, 2022. 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,

A handwritten signature in blue ink, appearing to read "Michelle Catlin".

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF A REMOTE AUDIT CONDUCTED OF
JAPAN

JULY 19–AUGUST 17, 2022

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING
RAW INTACT BEEF PRODUCTS
EXPORTED TO THE UNITED STATES OF AMERICA

December 27, 2022

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a remote ongoing equivalence verification audit of Japan conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) July 19–August 17, 2022. Due to the global COVID-19 pandemic, the audit was conducted remotely using video conferences to conduct interviews and records review. The purpose of the audit was to verify whether 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 (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

FSIS concluded that Japan's raw intact beef products inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The Ministry of Health Labor and Welfare (MHLW), Japan's central competent authority, has required that establishments certified as eligible to export products to the United States implement sanitation requirements and a HACCP system designed to improve the safety of their products. In addition, MHLW has implemented official microbiological and chemical residue testing programs that are organized and administered by the national government to verify its system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted a remote audit of Japan's food safety system from July 19–August 17, 2022. The audit began with an entrance meeting held via videoconference on July 19, with the Central Competent Authority (CCA)—Ministry of Health Labor and Welfare (MHLW). Representatives from MHLW participated throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit that was conducted remotely. The audit objective was to determine whether 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 correctly labeled and packaged. Japan is eligible to export the following category of products to the United States:

Process Category	Product Category	Eligible Products ¹
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 subjected to APHIS Foot-and-Mouth Disease requirements specified in Title 9 of the U.S. Code of Federal Regulations (CFR) section 94.11, and the BSE requirements specified in sections 9 CFR 94.18 or 9 CFR 94.19.

Prior to the remote 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 auditor conducted interviews and reviewed records to determine 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 three-year period, in addition to information obtained directly from the MHLW through the SRT.

¹ 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 auditor reviewed records related to administrative functions and oversight at MHLW headquarters, as well as government verification records from three regional offices, and three local inspection offices within the establishments. The remote audit involved meetings with government personnel and laboratory staff. FSIS scheduled up to three meetings each week over a five-week period. Through records review, the FSIS auditor evaluated the implementation of control systems that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of three beef slaughter establishments was selected for the remote audit from a total of 15 establishments certified to export to the United States. The products these establishments produce and export to the United States include raw intact beef products.

This remote audit focused on a review of records associated with official government verification activities conducted at the selected establishments. The FSIS auditor 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 auditor also remotely audited one chemical residue laboratory and one microbiological laboratory to verify that these laboratories are capable of providing adequate technical support to the food safety inspection system.

Remote Audit Scope		#	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> • MHLW, Tokyo
	Lower Level Offices	3	<ul style="list-style-type: none"> • Kanto-Shinetsu Regional Bureau of Health and Welfare, Saitama • Kinki Regional Bureau of Health and Welfare, Osaka • Kyusyu Regional Bureau of Health and Welfare, Fukuoka
Laboratories		2	<ul style="list-style-type: none"> • Japan Food Research Laboratory, Private Chemical Residue, Tama-shi • Miyazaki Prefecture Tsuno Meat Inspection Center, Government Microbiological, Miyazaki
Beef slaughter and processing establishments		3	<ul style="list-style-type: none"> • Establishment HMJ-1, Wagyu Master Meat Center, Himeji City

	<ul style="list-style-type: none"> Establishment M-1, Miyachiku Corp. Ltd, Takasaki Plant, Miyazaki Establishment K-4, JA Shokuniku Kagoshima Co., Ltd, Chiran-cho
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FSIS performed the audit to verify that the food safety inspection system meets requirements equivalent to those under the specific provisions of United States laws and regulations, in particular:

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

The audit standards applied during the review of Japan's inspection system for raw 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 July 1, 2019, to June 30, 2022, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 5,341,687 pounds of raw intact beef exported by Japan to the United States. Additional types of inspection were performed on 347,123 pounds of raw intact beef. 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 2,785 pounds of raw beef products were refused for other issues not related to public health including shipping damage, labeling or other miscellaneous issues.

The last FSIS audit in 2020 identified the following findings:

Summary of Findings from the 2020 FSIS Audit of Japan	
Component 1: Government Oversight (e.g., Organization and Administration)	
<ul style="list-style-type: none"> The Ministry of Health Labor and Welfare (MHLW) does not provide adequate oversight over the implementation of inspection tasks and microbiological procedures used for testing official samples. The eight Meat Inspection Centers (MICs) microbiological laboratories are not meeting the quality assurance and control criteria established by the MHLW. Examples include: <ul style="list-style-type: none"> Analyses for <i>Salmonella</i> do not include positive and negative control samples in biochemical confirmation. Analyses for Shiga toxin-producing <i>Escherichia coli</i> (STEC) do not include positive and negative controls in screening or confirmation methods. 	
Component 2: Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling)	

<ul style="list-style-type: none"> At seven establishments, the FSIS auditors observed the MIC inspectors peeling off the hide of cattle head to expose the masseter muscle, but not incising deeply as required by the MHLW to inspect for cysticercosis.
Component 4: Government Hazard Analysis and Critical Control Point (HACCP) System
<ul style="list-style-type: none"> At five establishments, the MHLW does not ensure adequate oversight over the implementation of HACCP recordkeeping and verification requirements. Official records of ongoing verification of critical control points were not maintained or were incorrectly recorded.
Component 5: Government Chemical Residue Testing Programs
<ul style="list-style-type: none"> The MHLW does not have an adequate chain of custody system for laboratory operations. Most residue samples did not have signed security-seals and were not accompanied by transfer-and-storage records.
Component 6: Government Microbiological Testing Programs
<ul style="list-style-type: none"> The eight MIC laboratories are not analyzing the entirety of the N60 sample for <i>Escherichia coli</i> (<i>E. coli</i>) O157:H7 and non-O157 Shiga toxin-producing <i>E. coli</i> (STEC) during screening of official testing; The MHLW has not implemented an appropriate method for STEC confirmation that meets equivalence expectations. The confirmation method does not include appropriate immune-concentration procedures with dilution or an acid wash step to allow for adequate isolation of potentially low levels of STEC in a sample; At seven establishments, the collection of 60 pieces of beef trimming (N60) for STEC testing is performed by establishment's personnel not by MIC inspection personnel; and At seven establishments, the 60 pieces are neither trimmed from the exterior surface of carcass portions nor selected randomly.

The FSIS auditor verified through interviews of government personnel and review of government records that the corrective actions for the previously reported findings were implemented and effective in resolving the findings.

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

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

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

MHLW is Japan's CCA and has the authority to administer the Japanese meat inspection system. The inspection system consists of central, regional, and local offices. MHLW is the central level office with seven Regional Bureau of Health and Welfare (RBHW) offices throughout Japan. Six of these regional level offices oversee the establishments certified to export raw intact beef products to the United States. At the local government level, each establishment certified for export to the United States has Meat Inspection Centers (MICs), responsible for daily inspection oversight. Each MIC conducts daily inspection activities verifying the establishments are meeting requirements set forth by MHLW. Laboratories are approved by MHLW to conduct analysis of official government samples collected by the MIC inspectors on products intended for export to the United States. MHLW also has the authority to revoke the approval of these laboratories.

MHLW organizes and administers the Japanese food safety inspection system and is responsible for directing, planning, and carrying out food safety controls in establishments. Additional responsibilities include 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 the MHLW 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.

At the regional level, the RBHW offices oversee the establishments in their region. Within RBHW is the Food Sanitation Division which is responsible for supervision of establishments. This includes the establishments certified to export products to the United States. These offices review data from the establishments and conduct monthly supervisory inspections (audits) on MHLW requirements. These inspections include the MIC microbiological laboratories located within the region at or near the establishments. Supervisors also conduct reviews of the in-plant government inspection personnel during supervisory inspections.

At the local government level, MIC inspectors conduct daily verification procedures and enforce MHLW requirements at establishments. These procedures include MHLW requirements for products being exported to the United States. Each MIC consists of a technical, a clerical, and a commissioned staff. The technical and clerical staffs provide management oversight and support to the MIC. The commissioned staff carries out inspection activities at the establishment and is made up of veterinarian government inspectors, who are veterinarians, and meat inspector assistants. The 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. MIC inspection procedures include taking samples and ensuring samples are being analyzed and found acceptable for chemical residues or pathogenic microorganisms prior to signing export certificates on products being exported to the United States.

MHLW is responsible for certifying establishments as eligible to export raw beef products to the United States. It is also responsible for the decertification of establishments and maintaining the official list of establishments eligible to export to the United States. MHLW's document titled

Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States which describes the procedures that establishment operators should follow to obtain approval from MHLW to become certified to export and the actions taken by government officials at each step of the approval process. The FSIS auditor verified that the certification of the most recent establishment certified to export to the United States was in accordance with MHLW requirements. The FSIS auditor verified the MHLW has procedures in place to decertify establishments for exporting products to the United States.

MHLW has procedures at establishments that MICs follow when authorizing a shipment of raw beef for export to the United States. At MICs, veterinarian government inspectors review establishment records including HACCP requirements and any test results associated with the lots of products prior to issuing an export certificate. MIC inspection personnel sign the certificate, and the original certificate is attached to the product to be exported. The MIC retains a copy of the certificate and gives a copy to the applying establishment. The FSIS auditor interviewed government personnel and reviewed government records without identifying findings with the certification of products exported to the United States.

MHLW maintains the legal authority and responsibility to suspend the export certification of establishments certified as eligible to export to the United States. MHLW inspection procedures authorize MHLW to take enforcement measures, such as withdrawal of inspection. The veterinarian government inspectors document noncompliance and have the authority to require corrective actions. 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 stated in the Abattoir Act. The FSIS auditor interviewed government personnel and reviewed government records with no findings related to MHLW's documentation of noncompliance and implementation of enforcement procedures.

Prior to being certified for export to the United States, MHLW requires that certified establishments develop procedures for the recall of products. The production lot to be recalled is determined by the manufacturer records. This recall information is described in MHLW's document titled, Guidelines for Inspection of Certified Establishments Handling Meat for Exportation to the United States. In the event that products exported to the United States need to be recalled, MHLW is responsible for notifying FSIS. The FSIS auditor interviewed government personnel and reviewed MHLW procedures without identifying any findings regarding recalls.

The FSIS auditor verified that MHLW requires establishments to have traceability procedures in place to include the origins of each animal processed at establishments. The 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. Within each establishment, MHLW requires products exported to the United States to be segregated from other products. Japan does not import live cattle for slaughter or processing. The FSIS auditor interviewed

government personnel and reviewed government records without identifying any findings with product traceability and segregation.

The FSIS auditor determined that regulatory verification and inspection activities were consistently implemented at all audited 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 requirements. MHLW disseminates inspection information related to the regulatory and administrative requirements electronically to RBHW and to inspection personnel at each MIC with establishments certified to export product to the United States. The FSIS auditor interviewed government personnel and reviewed government records without identifying findings regarding government inspection system uniformity.

The FSIS auditor verified that government inspection personnel assigned to certified establishments exporting raw beef products to the United States are employed and paid by the Japanese government. Inspection personnel assigned to certified establishments are civil servants and required to be full-time government employees. The local government pays the salaries of food safety inspection system personnel. The national government financially supplements the local governments' payment for food safety inspection.

The FSIS auditor verified that slaughter and processing establishments certified to export to the United States have adequate daily coverage by MIC personnel. The MIC is responsible for assigning online and offline veterinarian government inspectors to ensure the required MHLW procedures are conducted each shift. Each MIC has established procedures for relief assignments if absences of inspection personnel occur. MHLW requires continuous online inspection during slaughter operations and at least once per shift for processing.

Inspection verification tasks are predetermined and listed on an inspection Daily Monitoring Verification form. The 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 HACCP, including zero-tolerance verification, sanitation standard operating procedures (Sanitation SOPs), and sanitation performance standards (SPS). In addition, the veterinarian government inspectors review the establishments' records, including HACCP, sanitation SOPs and SPS, and generic *Escherichia coli* (*E. coli*) sampling records in accordance with the MIC daily inspection verification schedule plan outlined in the Daily Monitoring Verification form. The FSIS auditor interviewed government personnel and reviewed government records without identifying any findings with staffing or government inspection verification of MIC establishments.

The Abattoir Act and the Ordinance for Enforcement of the Abattoir Act requires that all inspectors assigned in slaughter establishments are veterinarians and states that inspection personnel shall have appropriate educational credentials, training, and experience to carry out 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. The MHLW organizes periodic training at the national level on food safety and inspection requirements pertaining to beef production for export to the United States. The FSIS auditor interviewed government

personnel and reviewed government records without identifying any findings with veterinarian government inspectors meeting qualifications and having appropriate training.

On a monthly basis the RBHW conducts supervisory inspections of each MIC, which includes the evaluation of the inspection personnel within the establishment. These inspections include verification that requirements for export to the United States are met by the establishment, and that MIC personnel are verifying those requirements. At least annually, the MHLW conducts an audit of each MIC and establishment to verify MHLW requirements are maintained at establishments. These audits also include reviews of the RBHW supervisors. The FSIS auditor interviewed government personnel and reviewed government records without identifying any findings with the government inspection evaluation process.

Japan's Food Sanitation Act includes requirements for authorizing and assessing registered conformity bodies, which includes official laboratories. The registered conformity bodies are required to establish rules concerning product tests and receive MHLW approval. The Ordinance for Enforcement of the Food Sanitation Act adds additional instructions for registered conformity bodies. MHLW also maintains administrative and technical support to operate its laboratory system. Official laboratories operate in accordance with standards consistent with International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025.

The FSIS auditor verified that MHLW utilizes the Japan Food Research Laboratories (JFRL) to conduct analysis of official government samples provided by the MICs. These are private chemical residue laboratories accredited by the Japanese Accreditation Board (JAB) in accordance with ISO/IEC 17025 standards. JAB is signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Agreement, which ensures global harmonization of laboratory accreditation consistent with standards in ISO/IEC 17025. JFRL laboratories are audited annually by MHLW in accordance with MHLW requirements. MHLW has designated JFRL to conduct chemical residue testing of beef to be exported to the United States. JFRL has seven locations across Japan and two of them—Tama-shi and Saito—are designated as residue testing laboratories under Japan's national residue program (NRP). The JFRL applies approved analytical methodologies and has quality assurance programs in place. JFRL provides MHLW with a quarterly report on the progress of the plan and applies approved analytical methodologies.

The FSIS auditor verified that MHLW utilizes MIC laboratories to conduct microbiological analysis on 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. MHLW maintains oversight of MIC laboratories ensuring compliance with ISO/IEC 17025 standards. MIC laboratories are audited annually during RBHW supervisory inspections according to MHLW requirements. Corrective actions from supervisory inspections and audits are required by MHLW.

All JFRL and MIC laboratories conducting analysis on official government samples are required to have positive/negative controls for each analysis. These laboratories must be operated and managed in accordance with ISO/IEC 17025 standards. MHLW requirements include quality control procedures, training/requirements of personnel, maintenance of equipment/facilities,

calibration of equipment, sample receipt/storage, reporting of results, traceability of samples, and proficiency testing. The FSIS auditor interviewed laboratory personnel and reviewed government records without identifying any findings regarding laboratories conducting official analysis of samples collected from products intended for export to the United States.

The FSIS auditor verified that MHLW designated laboratories do not retest samples. The laboratories follow test methods required by the MHLW for official samples of products intended for export to the United States. Test results are reported in a timely manner and products are held pending acceptable results prior to products being shipped to the United States.

The auditor 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 auditor reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of 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 at 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 requirements include handling of animals from the unloading until the start of post-mortem inspection. This includes receiving, holding, access to water, feeding when required, movement, stunning, and bleeding of animals. The 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 auditor interviewed government personnel and reviewed government inspection records without identifying any findings with humane handling and animal welfare.

The 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 receives inspection, at rest and in motion, prior to slaughter. Animals suspected of having a disease or abnormality are required to have a disposition performed by veterinarian government inspectors. Dispositions are performed ensuring animals not meeting MHLW requirements will not be allowed to be slaughtered. Animals awaiting disposition are identified and segregated and not allowed to be slaughtered until veterinarian government inspectors have performed disposition. If an animal is

found unfit for slaughter it must be identified as such and disposed of according to MHLW requirements. The FSIS auditor interviewed government personnel and reviewed government inspection records without identifying any findings with ante-mortem inspection.

The Abattoir Act requires the post-mortem inspection of livestock carcasses and parts by veterinarian government inspectors. MHLW has written procedures in place that instruct veterinarian government inspectors on how post-mortem examination is to be performed. These procedures include visual inspection, palpation, condemnation of animals, and incision of relevant portions of the animal described within MHLW procedures. MHLW has procedures veterinarian government inspectors follow regarding disposition of carcasses and parts inspected during post-mortem inspections and include the condemnation of the carcasses or parts. MHLW requires the MICs to perform continuous official post-mortem inspection by veterinarian government inspectors during slaughter operations. Establishments must meet MHLW requirements regarding the facility areas where post-mortem inspection is required. In order to be certified for export to the United States, establishments must initially meet these facility requirements and maintain them continuously. The number of cattle slaughtered in each establishment audited ranged between 25-70 heads per shift. The FSIS auditor interviewed government personnel and reviewed government inspection records without identifying any findings with post-mortem inspection.

MHLW's document titled, Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States, describes how MHLW provides for periodic supervisory visits by a representative of the inspection system to each certified establishment. RBHW conducts supervisory inspections at each MIC evaluating the performance of government personnel monthly. These supervisory inspections include reviews of veterinarian government inspectors' verification activities 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. The FSIS auditor interviewed government personnel and reviewed government records without identifying any findings regarding RBHW supervisory inspections.

MHLW conducts audits of RBHW personnel regarding the performance of supervisory inspections at MIC establishments. The audits also include verification of MHLW requirements establishments must meet initially and on an ongoing basis to remain certified as eligible to export products to the United States. These audits include evaluating the RBHW personnel performing the supervisory inspections. The FSIS auditor interviewed government personnel and government inspection reviewed records without identifying any findings regarding MHLW audits.

The FSIS auditor 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 a slaughter establishment to ship products destined for further processing to another establishment. Establishments certified to export to the United States always operate meeting

United States export requirements and product destined for export to markets other than the United States are separated at the time of shipping.

The FSIS auditor verified that labels for products exported to the United States are submitted to and approved by MHLW. Label verification is done by the veterinarian government inspectors and during supervisory inspections. The veterinarian government inspectors' verification activities include ensuring scales are calibrated and accurate. MHLW performs species verification testing at least once a year in all establishments certified for export to the United States.

The FSIS auditor verified 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 the APHIS website. MHLW has BSE requirements for bovine which are verified by veterinarian government inspectors and during supervisory inspections. 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, neither is stunning by using a stunner that deliberately injects compressed air into the cranium or by pithing per MHLW 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 specified risk materials (SRM) as hazards when developing their HACCP plan. MHLW requires establishments to remove and dispose of SRMs from bovines. 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 requirements. The FSIS auditor noted that MHLW maintains a definition of SRMs that is consistent with that outlined in 9 CFR 310.22. SRM verification is done daily and documented on the inspection form Daily Monitoring Verification. The FSIS auditor interviewed government personnel and reviewed records noting no findings 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 disposal of inedible and condemned materials. Because of infectious disease concerns, discarded materials are put in special containers used solely for that purpose and incinerated at the establishment in the presence of the inspector or transported to an incineration plant in the presence of a veterinarian government inspector. Inedible SRMs 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 plant the same day of occurrence. If removal can't be done within the date of occurrence, then they must be placed in a lockable container, locked, and managed by a veterinarian government inspector until removal. The FSIS auditor interviewed government personnel and reviewed government inspection records regarding condemned and inedible materials without identifying any findings.

The FSIS auditor concluded that MHLW continues to maintain the legal authority, a regulatory framework, and adequate verification procedures to ensure sufficient official regulatory control over raw beef establishments certified to export their 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 auditor reviewed was Government Sanitation. The FSIS auditor verified that the CCA requires each certified establishment to develop, implement, and maintain written sanitation standard operating procedures (Sanitation SOPs) to prevent direct product contamination or insanitary conditions, and to maintain requirements for sanitation performance standards (SPS) and sanitary dressing.

MHLW's document, Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States, lists requirements for sanitation. This document outlines requirements regarding the facility and equipment and are consistent with FSIS requirements in 9 CFR 416.1-416.5. All establishments certified for export to the United States are required to develop and implement Sanitation SOPs. MHLW requirements for Sanitation SOPs are consistent with FSIS requirements in 9 CFR 416.11-416.17.

MHLW has requirements for standards of construction and facilities, which cover ante-mortem, post-mortem, processing areas, and storage areas. MHLW's inspection system has official controls over establishment construction, facilities, and equipment and has the authority to take formal enforcement action to direct an establishment to rectify both hygiene and structural deficiencies. The veterinarian government inspectors perform verification activities each day to verify establishments are meeting these sanitation standards. The FSIS auditor interviewed government personnel and reviewed government inspection records without identifying any findings regarding sanitation standards.

Establishments certified for exporting products to the United States are required by MHLW to develop and implement Sanitation SOPs. The Sanitation SOPs must include preoperational and operational procedures designed to ensure meat is not adulterated during production and storage. Preoperational procedures must outline the cleaning of food contact surfaces and equipment. Sanitation SOPs are required to be monitored by the establishment at least daily. The 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. The FSIS auditor interviewed government personnel and reviewed government inspection records without identifying any findings regarding Sanitation SOP requirements.

MHLW requires establishments to operate in a sanitary manner and maintain sanitary standards specific to all production areas. This includes ensuring the establishments' procedures 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 addresses verification on slaughter and dressing by providing inspectors verification activities for ensuring that the establishments properly implement sanitary dressing procedures during

production. MIC inspection personnel at the final rail position ensure that carcasses with visible contamination are further trimmed and re-inspected before entering the chiller, and they verify the establishment's corrective actions. The FSIS auditor interviewed government personnel and reviewed government inspection records without identifying any findings regarding sanitary dressing requirements.

MHLW has zero tolerance for fecal, ingesta, and milk and require establishments to address these hazards in their HACCP plan for beef slaughter. MHLW requires veterinarian government inspectors to conduct daily verification procedures of the HACCP plan addressing fecal, ingesta, and milk. These procedures include directly observing the monitoring of the critical limit by the establishment. Additionally, veterinarian government inspectors are required to perform verification of zero tolerance daily by examining carcasses at the end of the post-mortem process prior to entering the chiller. The frequency of the carcass examinations depends on the number of animals slaughtered during the shift. The FSIS auditor interviewed government personnel and reviewed government inspection records without identifying any findings regarding the MHLW's zero tolerance verification procedures.

The FSIS auditor determined that MHLW requires establishments exporting 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 auditor reviewed was Government HACCP System. The food safety inspection system is to require that each certified establishment develop, implement, and maintain a HACCP system.

MHLW requires certified establishments eligible to export 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 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 requirements for HACCP are consistent with 9 CFR 417.

Establishments exporting products to the United States must maintain a flow diagram and conduct a hazard analysis for each process, such as slaughter and raw processing. The hazard analysis decisions must be supported, and a HACCP plan must be written for hazards identified as likely to occur. 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. A record keeping system for the monitoring, verification, and corrective actions must meet the HACCP requirements MHLW has set for recordkeeping. Records must be maintained for a minimum of one year and must be accessible to MHLW personnel.

Establishments exporting products to the United States must conduct pre-shipment reviews ensuring 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. At least annually or when required, establishments must conduct a reassessment on the HACCP system. The HACCP plans must be signed and dated by a qualified establishment employee that has been trained on HACCP. The FSIS auditor interviewed government personnel and reviewed government inspection records without identifying any findings regarding MHLW's HACCP system requirements.

Veterinarian government inspectors 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. Verification includes review of documents that support the HACCP system. Veterinarian government inspectors perform HACCP system verification activities outlined in MHLW's document, Guidelines for Inspection of Certified Establishments Handling Meat for Exportation to the United States. Verification procedures 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 auditor interviewed government personnel and reviewed government inspection records without identifying any findings regarding MHLW's verification of the establishments' HACCP system.

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

Prior to the remote audit, and as part of the annual SRT review for ongoing equivalence determinations, FSIS reviewed Japan's NRP, associated methods of analysis, reported results of the testing program, and additional official documentation outlining the structure of Japan's official chemical residue testing program. There have not been any POE violations related to this component since the previous FSIS audit in 2020.

The FSIS auditor verified that MHLW continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and chemical contaminants in the tissues of bovines

slaughtered for human consumption in accordance with provisions contained in the Food Sanitation Act and Abattoir Act. MHLW has the authority to set maximum residue limits (MRL) that are not to be exceeded. This includes setting MRLs that meet the limits identified by the United States. Japan's NRP covers the frequency and sample allocations among species and the classes of compounds that must be analyzed.

The FSIS auditor verified that Japan's NRP contains provisions from the Food Sanitation Law in which the MHLW has the authority to dispose of product that exceeds acceptable residue levels. In addition, to prevent the violations from recurring, the cause of the chemical residue violation is investigated taking into consideration both the domestic and United States standards. National residue sampling results are communicated to the MHLW headquarters, regional offices, and 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 auditor verified that in-plant government inspection personnel who collect the residue samples are following MHLW sampling protocol. This protocol includes sampling methodology, identification of animals, 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 processed and shipped until any chemical residue test results are reported acceptable.

The FSIS analysis and remote verification activities indicate that MHLW has overall authority of a chemical residue testing program which is designed and implemented to prevent and control the presence of veterinary drugs and contaminants in raw intact beef products destined for export to the United States.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

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

MHLW requires microbiological sampling programs be implemented by MICs and establishments for verification of the beef slaughter process at establishments exporting products to the United States. These requirements include *Salmonella* and Shiga toxin-producing *E. coli* (STEC) sampling by the MICs. Establishments are required to implement a sampling program and test for generic *E. coli* as an indication of process control. Implementation of this program is verified by the veterinarian government inspectors and RBHW supervisors at the MICs.

Establishments certified to export products to the United States are required to sample and test beef carcasses for generic *E. coli* as described in MHLW's document titled, Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States. The document outlines random selection of carcasses, locations of sampling, sampling methodology, evaluation criteria, and frequency of sampling. Establishments must implement an analysis

method that is externally validated, or alternatively, using the most probable number method. The FSIS auditor interviewed government personnel and reviewed government records without identifying any findings with MHLW's verification of the generic *E. coli* testing program implemented by establishments.

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. The document outlines random selection of carcasses, locations of sampling, sampling methodology, evaluation criteria, and frequency of sampling. MHLW's *Salmonella* sampling and testing program for carcasses is consistent with FSIS' *Salmonella* performance standards criteria as described in 9 CFR 310.25(b). MHLW requires that laboratories implement an analytical method for the detection of *Salmonella* in MIC laboratories that is consistent with FSIS' Microbiology Laboratory Guidebook (MLG), Chapter 4. The FSIS auditor interviewed government personnel and reviewed government records without identifying any findings with MHLW's *Salmonella* verification sampling program.

MHLW's document Requirements for Certification of Slaughterhouses, Etc., Handling Meat for Exportation to the United States specifies official government sampling requirements for STECs at establishments certified for export to the United States. These procedures include selection of samples, sampling methodology, and frequency of sampling. The program specifies that beef trim samples are collected according to the N60 collection procedure, by taking 60 thin slices with dimensions of eight centimeters long by three centimeters wide and 0.3 centimeters thick from surface area tissue for STEC analyses. MIC laboratories are required to perform analysis of raw beef trim samples following MHLW requirements. The MIC laboratories must implement a method that is externally validated for STEC screening and then confirmatory analyses are conducted following methods consistent with FSIS' MLG Chapter 5. Lots of products associated with the samples are not to be released for export pending negative test results. The FSIS auditor interviewed government personnel and reviewed government records without identifying any findings with the MHLW's STEC verification sampling program.

The FSIS auditor determined that MHLW maintains the legal authority to implement its microbiological sampling and testing programs to ensure that products destined for export to the United States are unadulterated, safe, and wholesome.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held August 17, 2022, by videoconference with MHLW. The FSIS auditor concluded that Japan's raw intact beef products inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. MHLW, Japan's CCA, has required that establishments certified as eligible to export products to the United States implement sanitation requirements and a HACCP system designed to improve the safety of their products. In addition, MHLW has implemented official microbiological and chemical residue testing programs that are organized and administered by the national government to verify its system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

Appendix: Foreign Country Response to the Draft Final Audit Report



Food Inspection and Safety Division

Pharmaceutical safety and Environmental Health Bureau

Ministry of Health, Labour and Welfare, JAPAN

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December 21, 2022

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

Comments on draft final report of a remote audit conducted in Japan, July 19 to August 17, 2022 – Evaluating the food safety systems governing raw beef products exported to the United States of America.

Dear Dr. Catlin,

I received your letter of the FSIS's draft final report of a remote audit conducted in Japan, July 19 to August 17, 2022.

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

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

Yours Sincerely,

三木 朗

MIKI Akira, DVM

Director of Food Inspection and Safety Division

Pharmaceutical Safety and Environmental Health Bureau

Ministry of Health, Labour and Welfare, JAPAN

Comments on draft final report of a remote audit conducted of Japan evaluating the food safety system governing raw intact beef products exported to the United States of America, July 19– August 17, 2022.

N° of paragraph		Comments															
IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)																	
Page 2 Table		Correction of the address of the Kanto-Shinetsu Regional Bureau of Health and Welfare.															
Kanto-Shinetsu Regional Bureau of Health and Welfare, lab		Kanto-Shinetsu Regional Bureau of Health and Welfare, lab <u>Saitama</u>															
Page 2 Table		The table is modified for the following reasons. <ul style="list-style-type: none"> · JFRL is a private general incorporated association, not a government laboratory. · Miyazaki Prefecture Tsuno Meat Inspection Center is a local government. · It would be better to have a separate column for “Remote Audit Scope” as in the 2020 Audit report. 															
<table border="1"> <thead> <tr> <th>Remote Audit Scope</th><th>#</th><th>Locations</th></tr> </thead> <tbody> <tr> <td>Laboratories</td><td>2</td><td> <ul style="list-style-type: none"> · Japan Food Research Laboratory, Government Chemical Residue, Tama-shi · Miyazaki Prefecture Tsuno Meat Inspection Center, Government Microbiological, Miyazaki </td></tr> </tbody> </table>	Remote Audit Scope	#	Locations	Laboratories	2	<ul style="list-style-type: none"> · Japan Food Research Laboratory, Government Chemical Residue, Tama-shi · Miyazaki Prefecture Tsuno Meat Inspection Center, Government Microbiological, Miyazaki 		<table border="1"> <thead> <tr> <th>Remote Audit Scope</th><th>#</th><th>Locations</th></tr> </thead> <tbody> <tr> <td>Chemical Residue Laboratoryies (private)</td><td>12</td><td> <ul style="list-style-type: none"> · Japan Food Research Laboratory, Government General Incorporation Foundation, Chemical Residue, Tama-shi · Miyazaki Prefecture Tsuno Meat Inspection Center, Government Microbiological, Miyazaki </td></tr> <tr> <td>Microbiological Laboratory (local authorities)</td><td>1</td><td> <ul style="list-style-type: none"> · Miyazaki Prefecture Tsuno Meat Inspection Center, Miyazaki </td></tr> </tbody> </table>	Remote Audit Scope	#	Locations	Chemical Residue Laboratory ies (private)	12	<ul style="list-style-type: none"> · Japan Food Research Laboratory, Government General Incorporation Foundation, Chemical Residue, Tama-shi · Miyazaki Prefecture Tsuno Meat Inspection Center, Government Microbiological, Miyazaki 	Microbiological Laboratory (local authorities)	1	<ul style="list-style-type: none"> · Miyazaki Prefecture Tsuno Meat Inspection Center, Miyazaki
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Page 8 paragraph2 At least annually, the MHLW conducts an audit of each MIC and establishment to verify MHLW requirements are maintained at establishments. These audits also include reviews of the RBHW supervisors. These		<p>This sentence is deleted for the following reasons.</p> <ul style="list-style-type: none"> · Regular inspections of certified establishments are the responsibility of the RBHW, not the MHLW. · Performance evaluation of RBHW personnel by MHLW is described on page 10. 															

Comments on draft final report of a remote audit conducted of Japan evaluating the food safety system governing raw intact beef products exported to the United States of America, July 19– August 17, 2022.

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Page 8 paragraph5 MIC laboratories are audited monthly during RBHW supervisory inspections and annually during MHLW audits according to MHLW requirements.	<p>The following sentence is corrected for more accurate description. Regular inspections of MIC laboratories (once a year) are the responsibility of the RBHW, not the MHLW.</p> <p>MIC laboratories are audited to check the test report monthly during RBHW supervisory inspections and audited annually for confirming GLP by RBHW during MHLW audits according to MHLW requirements.</p>