



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

OCT 20 2009

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

Dear Dr. Kaji:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Japan's meat inspection system July 8 to July 23, 2009. Comments received from the government of Japan have been included as an attachment to the final report. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 205-3969, by facsimile at (202) 720-0676, or electronic mail at james.adams5@fsis.usda.gov.

Sincerely,

James Adams, DVM
Director
International Audit Staff
Office of International Affairs

Enclosure

OCT 20 2009

FINAL REPORT OF AN AUDIT CARRIED OUT IN JAPAN
COVERING JAPAN'S MEAT INSPECTION SYSTEM

JULY 8 THROUGH JULY 23, 2009

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

BSE	Bovine Spongiform Encephalopathy
CCA	Central Competent Authority, Ministry of Health, Labour and Welfare (MHLW)
DFS	Department of Food Safety
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
ISD	Inspection Safety Division
JFRL	Japan Food Research Laboratories
<i>Lm</i>	<i>Listeria monocytogenes</i>
MIC	Meat Inspection Center
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
RBHW	Regional Bureau of Health and Welfare
<i>Salmonella</i>	<i>Salmonella</i> species
SPS	Sanitation Performance Standards
SRM	Specified Risk Materials
SSOP	Sanitation Standard Operating Procedures

1. SUMMARY

1.1 Description/Eligibility

This report summarizes the outcome of the audit conducted in Japan from July 8 through July 23, 2009. This was a routine audit. Japan with indigenous Bovine Spongiform Encephalopathy (BSE) cases, may export whole cuts of boneless beef to US. At the time of the audit, four establishments were eligible to export to the United States. During calendar year 2008 Japan exported 259,506 pounds of whole cuts of boneless beef to the United States; there was one rejection of 318 pounds for food-safety concerns and the product was destroyed. Activities of the current audit appear in the table below.

The findings of the previous audit during March 19 through April 10, 2008, resulted in no restrictions of any Japan establishment ability to export whole cuts of boneless beef to the United States.

1.2 Comparison of the Current Audit and the Previous Audit

		CURRENT AUDIT DATES: July 8 through 23, 2009	PREVIOUS AUDIT DATES: March 19 through April 10, 2008
Levels of Government Oversight Audited			
	Headquarters	1	1
	Regional	1	2
	Establishment Level	2	4
Laboratories Audited			
	Microbiology	0	1
	Residue	1	1
Establishments Audited			
	Slaughter/processing	2	4
	Processing only	0	0
Enforcement Actions Initiated			
	NOID	0	0
	Delistment	0	0
Risk Area Findings			
	Sanitation Controls (SSOP, SPS)	3	11
	Animal Disease Controls	0	0
	Slaughter/Processing (PR/HACCP)	1	6
	Residue Controls	0	0
	Microbiology Controls	0	0
	Inspection/Enforcement Controls	3	14
	Special Emphasis (HH, O157:H7)	0	0

1.3 Summary Comments for the Current Audit

The results of this audit reflected non-compliances in Sanitation Controls, Slaughter/Processing Controls, and Inspection/Enforcement Controls. Specific non-compliances are noted on the attached establishment reports and in sections 10, 12 and 14 of this report.

2. INTRODUCTION

The audit was conducted in Japan from July 8 through July 23, 2009.

An entrance meeting was held on July 8, 2009, in Tokyo, Japan with the Central Competent Authority (CCA). At this meeting the auditor confirmed the objective and scope of the audit, the auditor's itinerary, and requested additional information necessary to complete the audit of Japan's meat inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA, the Ministry of Health, Labour and Welfare (MHLW), and representatives from the regional and local inspection offices.

3. OBJECTIVE OF THE AUDIT

This audit was a routine audit. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the laboratories, slaughter and processing establishments certified by the CCA as eligible to export meat products to the United States.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, the headquarters of one office of the Regional Bureaus of Health and Welfare (RBHW), two meat inspection centers (MIC), two beef slaughter and processing establishments, and one private laboratory performing analytical testing on product certified by Japan as eligible for export to the United States.

4. PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved on-site visits to two slaughter and processing establishments. The third part involved visit to one private laboratory "Japan Food Research Laboratories"(JFRL) Tama Laboratory, located in Tokyo, was conducting analyses of field samples for Japan's national residue control program.

Program effectiveness determinations of Japan's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP), (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) programs and a testing program for generic *Escherichia coli* (*E. coli*), (4) residue controls, and (5) enforcement controls, including a

testing program for *Salmonella*. Japan's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health. The auditor also assessed how inspection services are carried out by Japan and determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated, and properly labeled.

At the entrance meeting, the auditor explained that Japan's meat inspection system would be audited against two standards: (1) Food Safety and Inspection Service (FSIS) regulatory requirements and (2) any equivalence determinations made for Japan. FSIS requirements include, among other things, daily inspection in all certified establishments, periodic supervisory visits to certified establishments, humane handling and slaughter of animals, ante-mortem inspection of animals and post-mortem inspection of carcasses and parts, the handling and disposal of inedible and condemned materials, sanitation of facilities and equipment, residue testing, species verification, and requirements for HACCP, SSOP, and testing for generic *E. coli* and *Salmonella*.

Equivalence determinations are those that have been made by FSIS for Japan under provisions of the Sanitary/Phytosanitary Agreement. Use of private Japanese laboratories for residue testing was found equivalent by FSIS.

5. LEGAL BASIS FOR THE AUDIT

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

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations

6. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address:
http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp

The previous two audits for Japan were conducted from January 24 through February 8, 2007, and from March 19 through April 10, 2008.

The following findings were noted in the January/February 2007 FSIS audit:

- In two establishments, the SSOP written plan did not mention the disposition of product in the section outlining steps to be taken as a part of corrective actions.
- There was rust on the underside of some overhead pipes in the slaughter area.
- There was excessive steam present in the slaughter room which had produced condensation on many surfaces.

- Condensation was observed dripping from some of these surfaces, but not noted dripping directly on to product. The Regional Food Sanitation Specialist stopped production until the surfaces were dried.
- There was beaded condensation in the carcass cooler on the rails over carcasses. The establishment took action to move these carcasses before the condensation was removed.
- The cloths originally brought to dry condensation were black and smudged from previous use. These were replaced with clean cloths before the drying actions occurred.

These specific deficiencies were found to have been corrected by the March/April 2008 FSIS audit.

The following findings were noted in the March/April 2008 FSIS audit:

- In three of the four establishments, the ongoing SSOP requirements were not met.
- In two of the four establishments, the establishment had not addressed in their SSOP program which include SRMs controls, that all cattle would be considered 30 months or older for the removal, segregation, and disposition of the SRMs, although it was verified during the on-site audit that the establishment had considered all cattle 30 months of age or older for the removal, segregation, and disposition of the SRMs.
- In one establishment, product residues build-up was observed on the knives and knife sharpening steel during pre-operational sanitation.
- In one establishment, edible livers and hearts were being transported from the evisceration room to the offal room via a trough which was contaminated by ingesta and feces.
- In three establishments, preventive measures were not included as a part of documentation for corrective actions for SSOP deficiencies in the establishment and official inspection records.
- In two of the four establishments, the SPS requirements were not met.
- In one establishment, weeds were observed outside the building, metal containers were stacked outside the building, and pellets to kill pests and rodents were hanging with a rope under the elevated building without a pest and rodent control box.
- In one establishment, rust was observed during pre-operational sanitation on the metal brackets at the hand wash station, above locker cabinets in the employees' preparation room, on overhead structures in the packaging room and in carcass cooling chamber # 16.
- In one establishment, oil containers in the chemical storage room were not properly marked/identified.
- In two of the four establishments, the Humane Handling and Slaughter requirements were not met.
- In one establishment, although cattle were present in the holding pens at the time of the audit, water buckets were empty.
- In one establishment, although cattle were present in the holding pens at the time of audit, two large water troughs were empty.

- In two of the four establishments, the HACCP requirements were not met.
- In one establishment, pre-shipment review records did not indicate that all CCP (CCP-1, CCP-2 and CCP-3) limits were met.
- In one establishment, the hazard analysis did not clearly indicate at which step in the slaughter process that carcasses may become contaminated by feces, ingesta and milk.
- In two of the four establishments, the establishment had not incorporated appropriate procedures and controls for the handling of non-ambulatory disabled cattle into their HACCP, SSOP, or prerequisite programs as required by FSIS regulations, although establishment personnel had told verbally, that non-ambulatory disabled cattle are not accepted and will be returned to the owner.

These specific deficiencies were found to have been corrected by the July 2009 FSIS audit.

7. MAIN FINDINGS

7.1 Government Oversight

The CCA is the Ministry of Health, Labour and Welfare (MHLW), specifically the Pharmaceutical and Food Safety Bureau, the Department of Food Safety (DFS), and the Inspection and Safety Division (ISD). This level writes the national residue plan, contracts with private laboratories for residue analyses, and is responsible for the translation and distribution of U.S. documents impacting on export. The next level consists of the seven Regional Bureau of Health and Welfare (RBHW) offices, two of which contain establishments certified to export beef to the United States. The Food Sanitation Division of these regional offices performs the periodic reviews of the establishments. The next level consists of the 47 prefectural governments and municipal governments. This is the level at which the payment for inspectors is generated. This level contains a total of 136 health authorities. Under the supervision of these health authorities are the Meat Inspection Centers which assign veterinarians to inspection positions at the local slaughterhouses and processing facilities under their jurisdiction as well as assign the MHLW designated veterinarians to work at U.S. export certified facilities.

7.1.1 CCA Control Systems

The Director General of the DFS of MHLW has the authority to withdraw U.S. establishment approval or suspend production. The Director General approves the list of establishments for U.S. export. MHLW personnel perform on-site visits to certify the establishments.

7.1.2 Ultimate Control and Supervision

Recall is mandatory in Japan, but mandatory recall can be generated by the establishment. There are also control programs such as the sanitation control of abattoirs article 3, which includes rendering for all condemned and inedible materials which may be followed by incineration. All Specified Risk Materials (SRM) are incinerated

according to a written law “Law on Special Measures Against Bovine Spongiform Encephalopathy (Law No. 70, June 14, 2002) and etc.”

7.1.3 Assignment of Competent, Qualified Inspectors

The Director of the ISD of the DFS of MHLW designates all the veterinarians with the recommendation of the Governor of the individual prefectures. The Director of ISD hires all veterinarians at the CCA level including the RBHW. The requirements are a veterinary license, no criminal record, and passing the veterinary examination for government service. The training then occurs at the MIC level with on-the-job training and some formal training. This training takes approximately six months. When new skills are needed, the training can take a number of avenues including formal university training, notices to the field employees, conferences at various levels, and conferences at MHLW in Tokyo bringing in at least one person from each MIC. Promotion in the field is accomplished by a selection process. The Director of ISD is involved in the promotion for RBHW veterinarians.

7.1.4 Authority and Responsibility to Enforce the Laws

The authority and responsibility to enforce the laws is spelled out in the Abattoir Law, Law No. 114, August 1, 1953, as of February 27, 2004. This law delineates responsibilities for each of the levels. In addition to this, a document, a supplement to the law, entitled “Requirements for Certification of Abattoirs, Etc., Handling Meat for Exportation to the United States” is used for those establishments wishing to export.

7.1.5 Adequate Administrative and Technical Support

The written criteria for the evaluation of programs are developed at the CCA level. However, the other levels mentioned above carry out the periodic and everyday evaluation and support of programs. The review of decisions and supporting documentation by industry is done at both the establishment and regional levels. Each level has written job descriptions for each position. The headquarters has the responsibility for the transposition and distribution of all relevant legislation/ regulations to all other levels.

7.2 Headquarters Audit

The auditor conducted a review of inspection system documents at MHLW Headquarters in Tokyo. The records review focused primarily on food safety hazards and included the following:

- Internal review reports
- Supervisory visits to establishments that were certified to export to the United States
- Training records for inspectors
- New laws and implementation documents, such as regulations, notices, directives and guidelines
- Sampling and laboratory analyses for residues
- Sanitation, slaughter and processing inspection procedures and standards

- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials
- Export product inspection and control, including export certificates
- Enforcement records, including examples of criminal prosecution, consumer complaints, and control of noncompliant product

No concerns arose as a result of the examination of these documents.

7.2.1 Audit of Regional and Local Inspection Sites

The Kyushu RBHW was audited. Records evaluated at this level were the periodic supervisory reviews and the follow-up actions contained therein.

No concerns arose as a result of the examination of these documents.

Two MIC were audited, each one having the responsibility of the assignment of inspectors at two establishments audited and also each one containing a laboratory for analysis of samples collected in the respective establishments. These two MIC were located in Miyazaki, and Kagoshima prefectures. In each MIC, the interviews included the veterinarians present including the Director, those assigned to the establishments and those from the laboratories. Representatives of the prefectural governments of Miyazaki (Est. M-1), and Kagoshima (Ests.K-1) also were present for the interviews and in-plant visits.

8. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of two slaughter/processing establishments. Neither of the two establishments received a Notice of Intent to Delist (NOID) or was delisted by Japan.

Specific deficiencies are noted in the attached individual establishment reports.

9. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During laboratory audit, emphasis was placed on the application of procedures and standards that are equivalent to United States requirements.

Residue laboratory audits focus on sample handling, sampling frequency, timely analysis data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. If private laboratories are used to test United States samples, the auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS Pathogen Reduction/HACCP requirements.

The following laboratory was reviewed:

The private residue laboratory of the JFRL, Tama Laboratory, in Tokyo.

Use of private Japanese laboratories for residue testing was found equivalent by FSIS.

- No deficiencies were noted during the audit of private residue laboratory.

10. SANITATION CONTROLS

As stated earlier, the FSIS auditor focused on five areas of risk to assess Japan's meat inspection system. The first of these risk areas that the FSIS auditor reviewed was Sanitation Controls.

Based on the on-site audits of establishments, and except as noted below, Japan's inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene practices, and good product handling and storage practices.

In addition, and except as noted below, Japan's inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

10.1 Sanitation Standard Operating Procedures

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the United States' domestic inspection program.

The following deficiencies were noted:

- In two establishments, the ongoing SSOP requirements were not met.
- In two establishments, in the evisceration department, leakage of SRM (brain/fluid) from opening of the skulls due to stunning was observed after the head skinning operation. The establishment had included SRM controls in their SSOP program. It was noticed during the review of establishment's SRM monitoring records; there were no corrective actions due to contamination of carcass head by SRM. Also it was noticed during the review of government inspection's SRM verification records; there were no corrective actions due to contamination of carcass head by leakage of SRM from skulls. The records review of monthly visits conducted by Kyushu Regional Officials did not record observation of contamination by SRM; which indicates lack of control by the CCA for FSIS regulatory SRM control requirements. The CCA did not take enforcement actions if establishment did not address carcass head contamination due to leakage of SRM in their monitoring records including the corrective actions that would be taken, as required by FSIS regulations. The establishment decided to condemn the contaminated heads until the establishment implemented alternative methods to prevent the contamination.

10.2 Sanitation Performance Standards

The following deficiencies were noted:

- In one of the two establishments, the SPS requirements were not met.
- Flies were observed in the evisceration and offal room during tour of the facilities. During the establishment and government inspection's records review, there were no records of presence of flies in the production areas and concerns regarding the lack of pest and rodent control program.

11. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that Japan's inspection system had adequate controls in place. No deficiencies were noted.

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit. There have been 34 cases of BSE in Japan; however, Japan is eligible to export beef to the United States under special circumstances and with special export certificate provisions.

12. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures; ante-mortem disposition; humane handling and humane slaughter; post-mortem inspection procedures; post-mortem disposition; specified risk materials (SRM) controls; ingredients identification; control of restricted ingredients; formulations; processing schedules; equipment and records; and processing controls of cured, dried, and cooked products.

The controls also include the implementation of HACCP in all establishments and implementation of a generic *E. coli* testing program in slaughter establishments.

12.1 Humane Handling and Slaughter

No deficiencies were noted.

12.2 HACCP Implementation.

All establishments approved to export meat products to the United States are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program.

The HACCP programs were reviewed during the on-site audits of the two establishments.

The following deficiencies were noted:

- In one of the two establishments, the HACCP requirements were not met.
- It was noticed during the review of HACCP program, the establishment was conducting its monitoring and verification activities for controlling fecal material, ingesta, and milk (CCP1) in slaughter operation after the final wash. The establishment did not provide decision making and/or supporting documentation for the selection of CCP1 location after the final wash. Government inspection officials were also conducting the verification of procedures for controlling fecal material, ingesta, and milk in slaughter operation after the final wash.

12.3 Testing for Generic *E. coli*

Japan has adopted the FSIS regulatory requirements for generic *E. coli*.

The two establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing and were evaluated according to the criteria employed in the United States' domestic inspection program.

Testing for generic *E. coli* was properly conducted in two slaughter establishments.

12.4 Testing for *Listeria monocytogenes (Lm)*

None of the establishments audited were producing ready-to-eat products for export to the United States. Therefore, reassessment and testing for *Lm* is not required.

13. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviewed was Residue Controls. These controls include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

The residue laboratory audited was the private laboratory JFRL, Tama laboratory, located in the Tokyo.

Japan's National Residue Testing Plan for 2009 was being followed and was on schedule.

14. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella*.

14.1 Daily Inspection in Establishments

Inspection was being conducted daily in all slaughter and processing establishments.

14.2 Testing for *Salmonella*

Japan has adopted the FSIS requirements for testing for *Salmonella*.

The two establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing and were evaluated according to the criteria employed in the United States' domestic inspection program.

Testing for *Salmonella* was properly conducted in two establishments audited.

14.3 Species Verification

Species verification was conducted in the establishments audited.

14.4 Periodic Supervisory Reviews

During this audit it was found that in two establishments visited, periodic supervisory reviews of certified establishments were being performed and documented; except the following deficiency was noted:

- In two establishments, the records review of monthly visits conducted by Kyushu Regional Officials did not record observation of contamination by SRM; which indicates lack of control by the CCA for FSIS regulatory SRM control requirements. The CCA failed to detect this non-compliance during their supervisory review.

14.5 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the United States with product intended for the domestic market; except the following deficiencies were noted:

- In two establishments, in the evisceration department, leakage of SRM (brain/fluid) from opening of the skulls due to stunning was observed after the head skinning operation. The establishment had included SRM controls in their SSOP program. It was noticed during the review of establishment's SRM monitoring records; there were no corrective actions due to contamination of carcass head by SRM. Also it was noticed during the review of government inspection's SRM verification records; there were no corrective actions due to contamination of carcass head by leakage of SRM from skulls. The records review of monthly visits conducted by Kyushu Regional Officials did not record observation of contamination by SRM; which indicates lack of control by the CCA for FSIS regulatory SRM control requirements. The CCA did

not take enforcement actions if establishment did not address carcass head contamination due to leakage of SRM in their monitoring records including the corrective actions that would be taken, as required by FSIS regulations. The establishment decided to condemn the contaminated heads until the establishment implemented alternative methods to prevent the contamination.

- In one establishment, it was noticed during the review of HACCP program, the establishment was conducting its monitoring and verification activities for controlling fecal material, ingesta, and milk (CCP1) in slaughter operation after the final wash. The establishment did not provide decision making and/or supporting document for the selection of CCP1 location after the final wash. Government inspection officials were also conducting the verification of procedures for controlling fecal material, ingesta, and milk in slaughter operation after the final wash.

In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other countries for further processing.

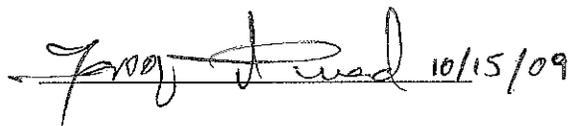
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

15. CLOSING MEETING

A closing meeting was held on July 23, 2009 in Tokyo, Japan with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Farooq Ahmad, DVM
Senior Program Auditor

A handwritten signature in black ink that reads "Farooq Ahmad" followed by the date "10/15/09". The signature is written in a cursive style.

16. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Reports

Foreign Country Response to Draft Final Audit Report (when it becomes available)

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Minami-Kyusyu Chikusan Kogyo Corp., Ltd. 1828 Ninokata, Sueyoshi-cho So-Gun Kagoshima, Soo-shi	2. AUDIT DATE 07/15/09	3. ESTABLISHMENT NO. K1	4. NAME OF COUNTRY Japan
	5. NAME OF AUDITOR(S) Farooq Ahmad, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

Date: 07/15/09 Est #: K1 (Minami-Kyusyu Chikusan Kogyo Corp., Ltd. [S/P]) (Kagoshima, Japan)

12/51. In the evisceration department, leakage of SRM (brain/fluid) from opening of the skulls due to stunning was observed after the head skinning operation. The establishment had included SRM controls in their SSOP program. It was noticed during the review of establishment's SRM monitoring records; there were no corrective actions due to contamination of carcass head by SRM. Also it was noticed during the review of government inspection's SRM verification records; there were no corrective actions due to contamination of carcass head by leakage of SRM from skulls. The records review of monthly visits conducted by Kyushu Regional Officials did not record observation of contamination by SRM; which indicates lack of control by the CCA for FSIS regulatory SRM control requirements. The CCA did not take enforcement actions if establishment did not address carcass head contamination due to leakage of SRM in their monitoring records including the corrective actions that would be taken, as required by FSIS regulations. The establishment decided to condemn the contaminated heads until the establishment implemented alternative methods to prevent the contamination.

[Regulatory reference(s): 9 CFR §310.22, 327.2(a)(2)(i)(D), 416.15, 416.17]

22/51. It was noticed during the review of HACCP program, the establishment was conducting its monitoring and verification activities for controlling fecal material, ingesta, and milk (CCP1) in slaughter operation after the final wash. The establishment did not provide decision making and/or supporting document for the selection of CCP1 location after the final wash. Government inspection officials were also conducting the verification of procedures for controlling fecal material, ingesta, and milk in slaughter operation after the final wash. The establishment decided to change the CCP1 location before the final wash due to lack of decision making and/or supporting document; and the government officials assured to verify this activity before the final wash. 9 CFR §327.2(a)(2)(i)(D), 417.5, 417.8]

38. Flies were observed in the evisceration and offal room during tour of the facilities. Establishment's employees took immediate corrective actions to catch the flies by fly nets. During the establishment and government inspection's records review, there were no records of presence of flies in the production areas and concerns regarding the lack of pest and rodent control program. Government officials assured proper corrective actions and improvement of pest and rodent control program by the establishment. [9 CFR §416.2(a)]

61. NAME OF AUDITOR

Farooq Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE

Farooq Ahmad 10/15/09

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Miyachiku Co. Ltd. Takasaki Plant Miyazaki 0	2. AUDIT DATE 07/14/09	3. ESTABLISHMENT NO. MI	4. NAME OF COUNTRY Japan
	5. NAME OF AUDITOR(S) Faroq Ahmad, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

Date: 07/14/09 Est #: M1 (Miyachiku Co. Ltd. [S/P]) (Miyazaki, Japan)

- 12/51. In the evisceration department, leakage of SRM (brain/fluid) from opening of the skulls due to stunning was observed after the head skinning operation. The establishment had included SRM controls in their SSOP program. It was noticed during the review of establishment's SRM monitoring records; there were no corrective actions due to contamination of carcass head by SRM. Also it was noticed during the review of government inspection's SRM verification records; there were no corrective actions due to contamination of carcass head by leakage of SRM from skulls. The records review of monthly visits conducted by Kyushu Regional Officials did not record observation of contamination by SRM; which indicates lack of control by the CCA for FSIS regulatory SRM control requirements. The CCA did not take enforcement actions if establishment did not address carcass head contamination due to leakage of SRM in their monitoring records including the corrective actions that would be taken, as required by FSIS regulations. The establishment decided to condemn the contaminated heads until the establishment implemented alternative methods to prevent the contamination. [Regulatory reference(s): 9 CFR §310.22, 327.2(a)(2)(i)(D), 416.15, 416.17]

61. NAME OF AUDITOR

Farooq Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE

 10/15/09

Ahmad, Farooq

From: Obara, Kakuyu [Kakuyu.Obara@fas.usda.gov]
Sent: Thursday, October 15, 2009 2:57 AM
To: Ahmad, Farooq
Cc: Chaudry, Manzoor; Wixom, Stephen
Subject: RE: 2009 Draft Audit Report - MHLW Comment

Dr. Ahamd,

MHLW came back and they are okay with the change you will make on the report. They said the change will reflect the situation appropriately.

K. Obara

From: Ahmad, Farooq [mailto:Farooq.Ahmad@fsis.usda.gov]
Sent: Thursday, October 15, 2009 3:46 AM
To: Obara, Kakuyu
Cc: Chaudry, Manzoor; Ahmad, Farooq
Subject: RE: 2009 Draft Audit Report - MHLW Comment

Obara-san
Please forward this FSIS audit response to Dr. Abe. Thanks.
Best regards,
Farooq

Dr. Abe

Greetings!

Thanks for your comments, please keep in mind that 4 establishments were audited during FSIS 2008 audit, and only 2 establishments were audited during FSIS 2009 audit. In other words in the comparison table the non-compliances reflected audit of 4 establishments during FSIS 2008 audit, and non-compliances reflected audit of 2 establishments during FSIS 2009 audit.

The following will be new statement after including your comments:

The results of this audit reflected non-compliances in Sanitation Controls, Slaughter/Processing Controls, and Inspection/Enforcement Controls.

In case you have further comments regarding above statement, please do not hesitate to contact us. Thanks.

Best regards,

Farooq Ahmad, DVM
Senior Program Auditor
International Audit Staff
Office of International Affairs
USDA, FSIS
Tel ph: (202) 205-4097

10/19/2009

Fax: (202) 720-0676

From: Kakuyu.Obara@fas.usda.gov [mailto:Kakuyu.Obara@fas.usda.gov]
Sent: Tuesday, October 13, 2009 8:05 PM
To: Ahmad, Farooq
Subject: FW: 2009 Draft Audit Reprot - MHLW Comment

Sorry, MHLW sender is Dr. Abe, not Dr. Okoba!

K. Obara

From: Obara, Kakuyu
Sent: Wednesday, October 14, 2009 9:01 AM
To: Ahmad, Farooq
Cc: Chaudry, Manzoor; Wixom, Stephen
Subject: FW: 2009 Draft Audit Reprot - MHLW Comment

Dear Dr. Ahmad,

Below is MHLW message (from Dr. Okoba) concerning the 2009 draft audit report.

They are referring to the text on the page 5 which describes if the number of noncompliance is up or down in Sanitation Controls and Slaughter/Processing Controls.

They inclined to think the underlined wording in red below should say □\$B!H□(Bdecrease□\$B!I□(B, in stead of □\$B!H□(Bincrease□\$B!I□(B based on the information from the chart on Page 4.

[The draft text says - The results of this audit reflected increased non-compliance in Sanitation Controls and Slaughter/Processing Controls.]

[MHLW think the text should say - The results of this audit reflected decreased non-compliance in Sanitation Controls and Slaughter/Processing Controls.]

Please let us know if the above comment makes sense to you. If yes, please make a change as appropriate.

Best regards,

K. Obara

From: □\$B0\$It□(B □\$BB@(abe-taiju) [mailto:abe-taiju@mhlw.go.jp]
Sent: Tuesday, October 13, 2009 5:37 PM
To: Obara, Kakuyu
Cc: □\$BEINI□(B □\$B=S9'□(B(higashira-toshitaka)
Subject: RE: 2009 Draft Audit Reprot

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10/19/2009