



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250



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 March 19 through April 10, 2008. The government of Japan stated that they had no comments to the draft final report and a statement to that effect has been included as an attachment to the final report. Enclosed is a copy of the final audit report. We apologize for the delay in the submission of this report

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 205-3873, by facsimile at (202) 720-0676, or electronic mail at [manzoor.chaudry@fsis.usda.gov](mailto:manzoor.chaudry@fsis.usda.gov).

Sincerely,

*by Don Carlson, acting Director*

For Manzoor Chaudry  
Deputy Director  
International Audit Staff  
Office of International Affairs

Enclosure

U. S. DEPARTMENT OF AGRICULTURE  
FOOD SAFETY AND INSPECTION SERVICE  
OFFICE OF INTERNATIONAL AFFAIRS  
INTERNATIONAL AUDIT STAFF  
WASHINGTON, DC  
202-205-3873  
FAX 202-720-0676

FEB 10 2009

**MEMORANDUM**

TO: Daniel Berman, Minister-Counselor  
US Embassy, Tokyo  
10-5, Akasaka 1-Chome  
Minato-ku  
Tokyo 107-8045 Japan

FROM: Manzoor Chaudry  
Deputy Director  
International Audit Staff, OIA, FSIS, USDA

SUBJECT: FSIS FINAL AUDIT REPORT FOR JAPAN

Dear Mr. Berman,

Please deliver the attached final audit report to Dr. Yoshifumi Kaji, Director, Inspection and Safety Division, Food Safety Department, Ministry of Health, Labor and Welfare. Please contact me via email at [manzoor.chaudry@fsis.usda.gov](mailto:manzoor.chaudry@fsis.usda.gov), if you have any further questions.

Best regards,

*Manzoor Chaudry*

Manzoor Chaudry

cc list:

Daniel Berman, Minister-Counselor, US Embassy, Tokyo  
Masahiro Mori, First Secretary, Health & Welfare, Embassy of Japan  
OSTA/FAS  
Daryl Brehm, North Asia Area Director, FAS  
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Gerald Zirnstein, IES, OIA  
Japan Country File

FSIS:OIA:IAS:DIRECTOR:202-205-3873:Japan  
FINAL AUDIT LETTER February 9, 2009

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

**MARCH 19 THROUGH APRIL 10, 2008**

**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. INTRODUCTION

The audit took place in Japan from March 19, through April 10, 2008.

An opening meeting was held on March 19, 2008, 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 needed 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.

## 2. 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 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 two offices of the Regional Bureau of Health and Welfare (RBHW), four meat inspection centers (MIC), four beef slaughter and processing establishments, two laboratories performing analytical testing on United States-destined product.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	Region	2	
	Local MIC	4	Establishment level
Laboratories		2	
Meat Slaughter/Processing Establishments		4	

## 3. 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 four slaughter and processing establishments. The third part involved visits to one private laboratory, and one government laboratory. A government laboratory "The Shibushi Meat Inspection Center Laboratory" was conducting analyses of field samples for *Salmonella*. A private laboratory "Japan Food Research Laboratories" (JFRL), located in the Osaka prefecture, 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 opening 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. Currently, there are no equivalence determinations made by FSIS for Japan.

#### 4. 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

#### 5. 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](http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp)

The previous two audits for Japan were conducted from January 6 through January 21, 2005, and from January 24 through February 8, 2007.

The following findings were noted in the 2005 audit:

- In one establishment, condensation was noted dripping from overhead structures on to product-contact surfaces in the offal processing room. Production was stopped in the area until the condensation could be controlled.

- In one establishment, there was an accumulation of dust and grease on many surfaces attached to walls throughout the establishment. These surfaces included trays above sinks, light switch boxes, other electrical boxes, and scale platforms. In addition, several power cords also had accumulations of dust and grease.

These specific deficiencies were found to have been corrected by the January 2007 FSIS audit in the establishments audited in 2007.

The following findings were noted in the 2007 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.

## 6. MAIN FINDINGS

### 6.1 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 127 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.

### 6.1.1 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.

### 6.1.2 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 Standard for Disease Deinfection 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."

### 6.1.3 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.

### 6.1.4 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.

### 6.1.5 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.

## 6.2 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
- 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

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

### 6.3.1 Audit of Regional and Local Inspection Sites

The Kyushu and Kanto-Shinetsu RBHW were 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.

Four MIC were audited, each one having the responsibility of the assignment of inspectors at four establishments audited and also each one containing a laboratory for analysis of samples collected in the respective establishments. These four MIC were located in Miyazaki, Gunma 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), Gunma (Est. G-1), and Kagoshima (Ests. K-1 and K-2) also were present for the interviews and in-plant and laboratory visits.

## 7. ESTABLISHMENT AUDITS

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

Specific deficiencies are noted in the attached individual establishment reports.

## 8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During laboratory audits, 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 laboratories audited were as follows: The government microbiology laboratory in the Shibushi MIC; and the private residue laboratory of the JFRL, in Osaka.

- No deficiencies were noted in the microbiology and residue laboratory, however, Japan is using a private laboratory to perform analytical tests on product destined for the United States.

## 9. 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.

### 9.1 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 three of the four establishments, the ongoing SSOP requirements were not met.
- 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.

## 9.2 Sanitation Performance Standards

The following deficiencies were noted:

- 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.
- 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

## 10. 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 Bovine Spongiform Encephalopathy (BSE) in Japan; however, Japan is eligible to export beef to the United States under special circumstances and with special export certificate provisions.

## 11. 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.

### 11.1 Humane Handling and Slaughter

The following deficiencies were noted:

- 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.

### 11.2 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 four establishments. The following deficiencies were noted:

- 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.
- 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.

### 11.3 Testing for Generic *E. coli*

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

All four 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 all of the four slaughter establishments.

#### 11.4 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.

### 12. 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 located in the Osaka prefecture. Japan is using a private laboratory to perform analytical tests on product destined for the United States.

Japan's National Residue Testing Plan for 2008 was being followed and was on schedule.

### 13. 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*.

#### 13.1 Daily Inspection in Establishments

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

#### 13.2 Testing for *Salmonella*

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

All of the four 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 all of the four establishments.

#### 13.3 Species Verification

Species verification was conducted in all of the four establishments.

#### 13.4 Periodic Supervisory Reviews

During this audit it was found that in all establishments visited, periodic supervisory reviews of certified establishments were being performed and documented.

### 13.5 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.

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.

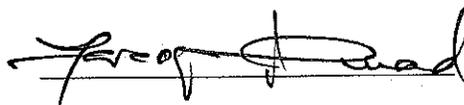
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

### 14. CLOSING MEETING

A closing meeting was held on April 10, 2008, 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



## 15. 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 Gunma-ken Shokuniku Oroshiuri Shijo Co. LTD 1189 Kamifukushima Tamamura-town Gunma 370-1104	2. AUDIT DATE April 7, 2008	3. ESTABLISHMENT NO. G-1	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.

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

60. Observation of the Establishment

Date: 04/07/2008 Est #: G-1 (Gunma-ken Shokuniku Oroshiuri Shijo Co. LTD [S]) (Tamamura-town, Japan)

There were no significant findings to report after consideration of the nature, degree and extent of all audit observations.

61. NAME OF AUDITOR  
Farooq Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE

*Farooq Ahmad* 7-7-2008

United States Department of Agriculture  
Food Safety and Inspection Service

**Foreign Establishment Audit Checklist**

1. ESTABLISHMENT NAME AND LOCATION Minami Kyushu Chiksan Kogyo Corp; Ltd. 1828 Ninokata, Sueyoshi-cho, Soo-shi, Kagoshima	2. AUDIT DATE March 26, 08	3. ESTABLISHMENT NO. K-1	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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	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.	X	39. Establishment Construction/Maintenance	X
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	X
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	X
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58. SRM	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 03/26/2008 Est #: K-1 (Minami Kyushu Chiksan Kagyo Corp; Ltd. [S]) (Soo-shi, Kagoshima, Japan)

12/51 (a) product residue build-up was observed on knives and a knife sharpening steel rod during pre-operational sanitation. The government officials assured that immediate corrective actions would be taken. [Regulatory references: 9 CFR 416.15 and 416.17]

(b) 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. The government officials assured that appropriate corrective actions would be taken. [9 CFR 416.15 and 416.17]

12/13/51 Preventive measures were not included as a part of documentation for corrective actions for SSOP deficiencies in the establishment and official inspection records. The inspection officials assured that immediate corrective actions would be taken. [9 CFR 416.15, 416.16 and 416.17]

38/51 Weeds were observed outside the building, metal containers were stacked outside the building, and pellets to kill pests and rodents were hanging on a rope under the elevated building without a pest and rodent control box. The inspection officials assured to take immediate correction actions. [9 CFR 416.2(a)]

39/51 Rust was observed on metal brackets at the hand wash station, above locker cabinets in the employees' preparation room, and on overhead structures in the packaging room and carcass cooling chamber # 16, during pre-operational sanitation. The inspection officials assured that immediate corrective actions would be taken. [9 CFR 416.2(b)]

52 Although cattle were present in the holding pens at the time of the audit water buckets were empty. The government officials took immediate corrective action. [9 CFR 313.2(e)]

54/51 The establishment had not incorporated appropriate procedures and controls for the handling of non-ambulatory disabled cattle into HACCP, SSOP, or prerequisite programs as required by new regulations, although establishment personnel had told verbally that non-ambulatory disabled cattle are not accepted and will be returned to the owner. The inspection officials assured to take immediate corrective actions would be taken. [9 CFR 309.3(e) and 417.8]

58/51 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 as 30 months or older for the removal, segregation, and disposition of the SRMs. The inspection officials assured to take immediate corrective actions would be taken. [9 CFR 310.22(d)]

61. NAME OF AUDITOR  
Faroq Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE



7-7-2008

United States Department of Agriculture  
Food Safety and Inspection Service

**Foreign Establishment Audit Checklist**

1. ESTABLISHMENT NAME AND LOCATION Sankyo Meat Limited 6965 Noikura, Ariake-cho, Shibushi-shi, Kagoshima	2. AUDIT DATE March 25, 08	3. ESTABLISHMENT NO. K-2	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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	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.	X	39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	X
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58. SRM	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

## 60. Observation of the Establishment

Date: 03/25/2008 Est #: K-2 (Sankyo Meat Limited [S]) (Shibushi-shi, Kagoshima, Japan)

12/13/51 Preventive measures were not included as a part of documentation for corrective actions for SSOP deficiencies in the establishment and official inspection records. The inspection officials assured that immediate corrective actions would be taken. [Regulatory references: 9 CFR 416.15, 416.16 and 416.17]

22/51 Pre-shipment review records did not indicate that all CCP (CCP-1, CCP-2 and CCP-3) limits were met. The inspection officials assured that immediate corrective actions would be taken. [9 CFR 417.5(c) and 417.8]

46/51 Oil containers in the chemical storage room did not properly marked/identified. The inspection officials assured that immediate corrective actions would be taken. [9 CFR 416.4(c)]

52 Although cattle were present in the holding pens at the time of audit, two large water troughs were empty.. The government officials took immediate corrective action. [9 CFR 313.2(e)]

61. NAME OF AUDITOR

Farooq Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE

 7-7-2008

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Miyachiku Corporation Limited, Takasaki, Takasaki Plant  4268-1 Omuta, Takasaki-cho, Miyakonojyo-shi, Miyazaki	2. AUDIT DATE March 27, 08	3. ESTABLISHMENT NO. M-1	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	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	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.	X	39. Establishment Construction/Maintenance	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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	X
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58. SRM	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 03/27/2008 Est #: M-1 (Miyachiku Corporation Limited [S]) (Miyakonojyo-shi, Miyazaki, Japan)

12/13/51 Preventive measures were not included as a part of documentation for corrective actions for SSOP deficiencies in the establishment and official inspection records. The inspection officials assured that immediate corrective actions would be taken. [Regulatory references: 9 CFR 416.15, 416.16 and 416.17]

22/51 The hazard analysis did not clearly indicate at which step in the slaughter process that carcasses may become contaminated by feces, ingesta and milk. The inspection officials assured to take immediate corrective actions would be taken. [9 CFR 417.2(a), 417.5 and 417.8]

54/51 The establishment had not incorporated appropriate procedures and controls for the handling of non-ambulatory disabled cattle into HACCP, SSOP, or prerequisite programs as required by new regulations, although establishment personnel were told verbally that non-ambulatory disable cattle will not be accepted by the company. The inspection officials assured to take appropriate corrective actions. [9 CFR 309.3(e) and 417.8]

58/51 The establishment had not addressed, in their SSOP program which includes 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 as 30 months or older for the removal, segregation, and disposition of the SRMs. The inspection officials assured to take appropriate corrective actions. [9 CFR 310.22(d)]

61. NAME OF AUDITOR  
Farooq Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE

*Farooq Ahmad* 7-7-2008

Comments to the Draft Final Report for JAPAN:

The government of Japan states that they have no comments to the Draft Final Report for the audit of FY 2008..