United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

AUG 15 2007

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 January 24 to February 8, 2007. You were invited to provide comments regarding the information in the draft final audit report. No comments were received from the government of Japan within 60 days. 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 (402) 344-5100, by facsimile at (402) 344-5169, or electronic mail at donald.smart@fsis.usda.gov.

Sincerely,

Donald Smart
Director
International Audit Staff
Office of International Affairs

Enclosure

cc list:

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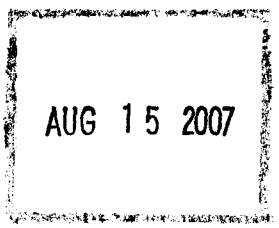
Country File

FSIS:OIA:IAS:D SMART:402.344.5100:8/15/07:Japan Audit Final Letter Aug07

FINAL



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

JANUARY 24 THROUGH FEBRUARY 8, 2007

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

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

1. INTRODUCTION

The audit took place in Japan from January 24, 2007 through February 8, 2007.

An opening meeting was held on January 24, 2007 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 one Regional Bureau of Health and Welfare (RBHW), two meat inspection centers (MIC), two beef slaughter and processing (deboning) establishments, one private laboratory performing residue analyses, and one MIC laboratory performing *Salmonella* species (*Salmonella*) analyses.

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

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 two slaughter and processing establishments. The third part involved visits to one private laboratory, and one government laboratory. The Sueyoshi Meat Inspection Center Laboratory was conducting analyses of field samples for *Salmonella* species. Japan Food Research Laboratories (JFRL) Tama-Laboratory was conducting analyses of field samples for Japan's national residue control program for certified exporting facilities.

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 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 Hazard Analysis and Critical Control Point Systems (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 AUDIT

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 occurred from August 26 through September 16, 2004, and from January 6 through January 21, 2005.

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 corrected by the January 2007 FSIS audit in the establishments audited in 2007.

6. MAIN FINDINGS

6.1 Government Oversight

The CCA is the Ministry of Health, Labour and Welfare (MHLW), specifically the Inspection and Safety Division (ISD), Department of Food Safety (DFS). 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 region concept was initiated in 2001; prior to that time the full responsibilities fell to the MHLW in Tokyo. 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 ISD of MHLW has the authority to withdraw U.S. establishment approval or suspend production. The Director General develops and updates the list of approved 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. There are also control programs such as the Standard for Disease Deinfection which includes rendering for all inedible materials followed by incineration. All Specified Risk Materials (SRM) are incinerated according to a written standard.

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 hires all veterinarians at the CCA level. The RBHW hire only for the bureaus. 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 series of examinations. Promotion in the RBHW is on merit but some positions are restricted by required non-veterinary background, such as engineering or legal.

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 the examination of these documents.

6.3.1 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 MICs were audited, each one having the responsibility of the assignment of inspectors at one of the 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 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 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 two slaughter/processing establishments. Neither of the two establishments received a Notice of Intent to Delist (NOID) or were delisted by Japan.

Specific deficiencies are noted in the attached individual establishment review forms.

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 Sueyoshi MIC; and the private Tama Laboratory of the JFRL doing residue analyses.

- No deficiencies were noted in the microbiology laboratory.

- In the records reviewed at TAMA Laboratories, there were two instances of delayed arrival of samples from the establishments (5 and 7 days from shipment to arrival at the lab). No action was taken by the receiving personnel to investigate the status of the samples during this delay. Normal arrival is within one day.

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 deficiency was noted:

- In both 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.

9.2 Sanitation Performance Standards

In one of the two establishments audited, the following deficiencies in sanitation performance standards were noted:

- 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.

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, humane handling and humane slaughter, 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 32 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; post-mortem inspection procedures; post-mortem disposition; 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 systems in all establishments and implementation of a generic *E. coli* testing program in slaughter establishments.

11.1 Humane Handling and Slaughter

There were no deficiencies noted in humane handling and slaughter in either of the two establishments audited.

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 two establishments. The following deficiency was found in HACCP implementation in both establishments:

- There was no supporting documentation for many of the monitoring and verification frequencies and a number of the other decisions made in the Hazard Analyses and HACCP plans.

11.3 Testing for Generic *E. coli*

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

Both of the 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 both of the slaughter establishments. One of the two establishments was using excision sampling and the appropriate evaluation of their analyses. In the other establishment, the sponging method of sampling was employed and they were performing the required statistical process control chart evaluations of the results of the analyses.

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 laboratory audited was the Tama Laboratory, part of the JFRL. These laboratories are registered with and overseen by the Japanese government, but there is not an actual contract awarded and they consider the laboratory as a semi-public institution. The laboratory is authorized under the law to perform the testing and the oversight is from the Health Minister. RBHW personnel in the region in which a specific JFRL section is located regularly audit that location.

One deficiency is noted above. Also, it was noted that the payments for sample analyses were paid directly from the establishments to the laboratories. The collection and shipping of the samples was accomplished by the inspection personnel. The reporting chain does not go directly to the establishments, but goes through the inspection service to the MHLW headquarters and to the MIC. MHLW transmits any new FSIS information to the laboratory. There are no international sample proficiency tests for any substance that would have a meat substrate as the importation of these samples into Japan is forbidden by law.

Japan's National Residue Testing Plan for 2007 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 both of the slaughter/processing establishments audited.

13.2 Testing for *Salmonella*

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

Both of the 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 both of the establishments audited.

13.3 Species Verification

Species verification was conducted in all four certified establishments in 2006. The testing is scheduled but has not yet been conducted for 2007.

13.4 Periodic Supervisory Reviews

During this audit it was found that in both 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 counties 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 February 8, 2007 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.

Rori K. Craver, DVM
Senior Program Auditor

15. ATTACHMENTS

Individual Foreign Establishment Audit Forms
Foreign Country Response to Draft Final Audit Report *(no comments were received)*

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Gunma-ken Shokuniku Oroshiuri Shijo Co. LTD & Gunma-ken Shokuniku Kosha 1189 Kamifukushima Tamamura-town Gunma 370-1104	2 Feb. 2007	G-1	Japan
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Rori K. Craver, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
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	
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.	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

Est. G-1
Tamamura-town, Gunma
Japan
2 February 2007

12/51. 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. 9 CFR § 416.15, 416.17

22/51. There was no supporting documentation for many of the monitoring and verification frequencies and a number of the other decisions made in the Hazard Analysis and HACCP plan for slaughter. 9 CFR § 417.5(a), 417.8

61. NAME OF AUDITOR
Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE
Ron K Craver DVM 2 Feb 2007

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Minami Kyushu Chikusan Kogyo Corp., Ltd. 1828 Ninokata, Sueyoshi-cho Soo-shi, Kagoshima, Japan	30 Jan 2007	K-1	Japan
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Rori K. Craver, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

JAPAN Est. K-1
Sueyoshi-cho
30 January 2007

12/51. 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. 9 CFR § 416.15, 416.17

22/51. There was no supporting documentation for many of the monitoring and verification frequencies and a number of the other decisions made in the Hazard Analysis and HACCP plan for slaughter. 9 CFR § 417.5(a), 417.8

39/51. There was rust on the underside of some overhead pipes in the slaughter area. 9 CFR § 416.2(b)

41/51. 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 also beaded condensation in the carcass cooler on the rails over carcasses. The establishment took action to move these carcasses before the condensation was removed. 9 CFR § 416.2(d)

46. 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.
9 CFR § 416.4

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Rori K. Craver, DVM	Rori K Craver DVM 30 Jan 2007

Country Response Not Received