



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

MAR 31 2005

Dr. Shunsaku Minami
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. Minami:

This letter transmits the final report of the Food Safety and Inspection Service's system audit of Japan's meat inspection system conducted August 26 through September 16, 2004. Comments from the government of Japan have been included in the final report.

If you have any questions or need additional information regarding the enclosed report, please contact me by telephone at 202-720-3781, by fax at 202-690-4040, or by e-mail at sally.white@fsis.usda.gov.

Sincerely,

Sally White, Director
International Equivalence Staff
Office of International Affairs

Enclosure

Cc:

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Country File (Japan Audit)

FINAL

MAR 18 2005

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

AUGUST 26 THROUGH SEPTEMBER 16, 2004

Food Safety and Inspection Service
United States Department of Agriculture

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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
<i>E. coli</i>	<i>Escherichia coli</i>
<i>Salmonella</i>	<i>Salmonella</i> species
MIC	Meat Inspection Center
SRM	Specified Risk Material
<i>Lm</i>	<i>Listeria monocytogenes</i>

1. INTRODUCTION

The audit took place in Japan from August 26, 2004 through September 16, 2004.

An opening meeting was held on August 26, 2004 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 annual 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, two regional inspection offices, four meat inspection centers, four beef slaughter and processing (deboning) establishments, one semi-national private laboratory performing residue analyses, one meat inspection center laboratory performing *Escherichia coli* (*E. coli*) and *Salmonella* species (*Salmonella*) analyses, and one in-plant laboratory performing generic *E. coli* analysis.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	Regional	2	
	Local Meat Inspection Center	4	Establishment level
Laboratories		3	
Meat Slaughter/Processing Establishments		4	

3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection headquarters or regional offices. The third part involved on-site visits to four slaughter and processing establishments. The fourth part involved visits to one private semi-national laboratory, one government laboratory and one establishment laboratory. SANKYO MEAT Ltd., Ariake Meat Plant II in-plant laboratory was conducting analyses of field samples for the presence of generic *Escherichia coli* (*E. coli*). Sueyoshi Meat Inspection Center Laboratory was conducting analyses of field samples for *E. coli*

O157:H7 and *Salmonella* species. Japan Food Research Laboratories Tama-Laboratory 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, (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of HACCP programs and a testing program for generic *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) FSIS regulatory requirements and (2) any equivalence determinations made for Japan. FSIS requirements include, among other things, daily inspection in all certified establishments, monthly 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, the only equivalence determination is that Japan has agreed that in those cases where *Salmonella* samples cannot be analyzed on the same day as they are received, the samples will be stored at 4° C.

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 February 8 through February 16, 2000, and from August 20, 2001 through September 1, 2001. The following findings, grouped by category, were noted in the 2001 audit:

Government Oversight - Assignment of Inspectors:

- In one establishment, the government inspectors were observed to “chop” head and visceral lymph nodes rather than incising them carefully and observing the cut surfaces.

This deficiency was corrected by the 2004 FSIS audit.

Government Oversight – Enforcement of U.S. Regulations:

- In two of three establishments audited, condemned product was not properly identified.
- In all three establishments audited, condemned product was not properly denatured.
- In two establishments, the light in the ante-mortem inspection area was inadequate. In one establishment, the light in the deboning room inspection area was inadequate.
- In all three establishments, suspect animals were not physically separated from non-suspect animals.

These specific deficiencies were corrected by the 2004 FSIS audit.

Animal Disease:

- In one establishment, no marks of inspection were visible on several carcasses in the carcass cooler.

This deficiency was corrected by the 2004 FSIS audit.

Sanitation Standard Operating Procedures (SSOP):

- In two establishments, there was incomplete definition of preventive measures as a part of corrective actions.
- In one establishment, there were no preventive measures in the SSOP plan.
- In one establishment, the employee performing bleeding failed to sanitize his knife after cutting through the skin.
- In one establishment, the employee removing viscera cut through the intestine and continued to work without sanitizing his knife.
- In one establishment, water was observed dripping from the ceiling in the offal wash area.
- In one establishment, the employee responsible for head washing did not wash the nostrils.
- In one establishment, one carcass in the cooler was contaminated by hair.

- During pre-operational sanitation verification inspection in one establishment, paint was observed on the conveyor belt.
- During pre-operational sanitation verification inspection in one establishment, dripping condensation was observed over production areas in the offal room.
- In one establishment, inadequate cleaning of a rolling combo bin was observed.

All deficiencies except those concerning missing or incomplete definition of preventive measures had been corrected by the 2004 FSIS audit.

Sanitation Performance Standards (SPS):

- In one establishment during pre-operational sanitation inspection verification, flaking paint was observed over a product traffic area in the tongue washing area.
- In one establishment, flaking paint was observed over cartons in the box room.
- In one establishment, during pre-operational sanitation verification inspection, non-dripping condensation on the ceiling was observed in the deboning room.
- In one establishment, during pre-operational sanitation verification inspection, non-dripping condensation was observed in the pre-chill and offal rooms.
- In one establishment, several holes were observed under doors in the product shipping area.
- In one establishment, rusty supports in the packaging and pre-trim rooms, and rusty wheels on a conveyor belt were observed.
- In two establishments, spider webs were observed on the slaughter floors.
- In two establishments, flies were observed in the slaughterhouse during pre-operational sanitation verification inspection.
- In one establishment, rodent poison was used in the carton storage room.
- There were no bait stations outside of one establishment. Pest control reports indicated a history of rodent activity inside this establishment.
- Lighting was inadequate in the ante-mortem inspection area of two establishments and in the deboning room inspection area of one establishment.
- Dirt and dust were observed on cartons and boxes in the box room of one establishment.
- In one establishment, much discarded material was observed in the mechanical room providing potential pest harborage.

These specific deficiencies were corrected by the 2004 FSIS audit.

Hazard Analysis and Critical Control Points (HACCP) Implementation:

- Pre-shipment document reviews were not being performed at the time of the audit in any of the three establishments since Japan was not eligible to export to the US at the time of the audit. However, the structure for this requirement was in place when it became necessary again.

Pathogen Reduction - Generic *Escherichia coli* (*E. coli*) testing:

- In all three establishments, the sponge method was used for collecting samples and the excision method criteria were used for analysis. Statistical process control was not being used for the evaluation of results.

In one establishment this deficiency had been corrected by the 2004 FSIS audit.

- In all three establishments, baseline studies for generic *E. coli* had not been conducted.

This deficiency had been corrected by the 2004 FSIS audit.

6. MAIN FINDINGS

6.1 Government Oversight

The CCA is the Ministry of Health, Labour and Welfare, specifically the Inspection and Safety Division, Department of Food Safety. This level writes the national residue plan, contracts with private semi-national laboratories for residue analysis, and is responsible for the translation and distribution of U.S. documents impacting on export. The next level consists of the seven regional offices, two of which contain establishments certified to export beef to the United States. The Food Sanitation Division of these regional offices performs the monthly reviews of the establishments. The region concept was initiated in 2001, prior to that time the full responsibilities fell to the MHLW. 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 health authorities, a total of 127 all together. 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.

6.1.1 CCA Control Systems

The Director General of the Inspection and Safety Division 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 followed by incineration. All SRMs are incinerated according to a written standard.

6.1.3 Assignment of Competent, Qualified Inspectors

The Director of the Inspection & Safety Division of the Food Safety Department of MHLW designates all the veterinarians for inspection. The regional bureaus 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 Headquarters bringing in at least one person from each MIC. Promotion in the field is accomplished by a series of examinations. Promotion in the bureaus 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 monthly 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.
- Enforcement records, including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

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

6.3.1 Audit of Regional and Local Inspection Sites

Two regional bureaus were audited, the Kanto-Shinetsu Regional Bureau of Health and Welfare in Saitama with responsibility for the monthly reviews of Establishment G-1 and the Kyushu Regional Bureau of Health and Welfare in Fukuoka with responsibility for the monthly reviews of Establishments K-1, K-2, and M-1. In both regional bureaus, a courtesy visit was made to the Director General and the Director of the Bureau. Present at the interviews were the respective Chiefs of the Food Sanitation Division, the Senior Food Sanitation Specialists or Inspectors and the Food Sanitation Specialists or Inspectors. These regional bureaus were audited because of their responsibilities connected with the monthly reviews of the U.S. exporting establishments. Four Meat Inspection Centers were audited, each one having the responsibility of the assignment of inspectors to the four establishments and also each one containing a laboratory for analysis of samples collected in the respective establishments. These four MIC were located in Gunma, Takasaki, Sueyoshi, and Shibushi. 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), Miyazaki (Est. M-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. None of the four establishments were delisted by Japan. Two establishments received a Notice of Intent to Delist (NOID) the establishment from Japan for repeat findings from the 2001 audit. These findings were in the areas of the lack of statistical process control chart evaluation of generic *E. coli* results and the lack of preventive measures within the corrective actions of the SSOP plans.

These establishments may retain their certification for export to the United States provided that they correct all deficiencies noted during the audit within 30 days of the date the establishment was reviewed.

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 following laboratories were reviewed:

The laboratories audited are as follows: the in-plant private laboratory at Establishment K-2, Sankyo Meat Ltd., Ariake Meat Plant II; the government laboratory in the Sueyoshi Meat Inspection Center; and the semi-public Tama Laboratory of the Japan Food Research Laboratories.

No deficiencies were noted.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses 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 SSOP

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 SSOP in one of the four establishments was found to meet the basic FSIS regulatory requirements, with no deficiencies. In the other three establishments, the following deficiencies were noted:

- In one establishment, there were several small pipes that ran directly across the far end of the moving viscera table. There was liquid dripping from these pipes unto the end of the table. At the end of this table were the chutes for edible offal to enter that room.
- In two establishments, there were no provisions for preventive measures in the corrective actions in the SSOP. This is a repeat finding from the last FSIS audit.
- In one establishment, the SSOP did not provide for the recording of the disposition of product as a part of corrective actions. The SSOP also did not

provide for the recording of preventive measures. However, preventive measures were present on many monitoring records for deficiencies and corrective action records.

9.2 Sanitation Performance Standards

In three of the four establishments audited, the following deficiencies in sanitation performance standards were noted:

- In one establishment, on the wall in the offal room that was farthest from the entrance from the slaughter floor, a gap had been filled by caulking that was shredding and was not able to be cleaned and sanitized. This was very recently filled due to a requirement by inspection.
- In one establishment, there was peeling paint on the walls of the box storage room. In the same establishment, the wall under the windows in the “green tripe” area of the offal room had flaking paint.
- In one establishment, there was inadequate light at the re-inspection table in the boning room and at the final rail inspection area in slaughter. The inspection service was using a light meter that measured in LUX and at some places this measured as sufficient, but the readings did not match the foot-candles measured by the auditor. Also, from a purely visual observation from the auditor, the light did not appear to be adequate.
- In one establishment, during pre-operational sanitation verification inspection in the boning room, it was noted that several of the stainless steel bins used for edible product had rough welds which could allow for the formation of biofilms. The establishment will protect product put into these bins by an intermediary measure until all have been corrected or replaced. The inspection service will verify these actions.
- In another establishment, during pre-operational sanitation verification inspection in the boning room and in slaughter, it was noted that several of the stainless steel edible product bins and product contact tables as well as several product contact areas along the slaughter line had rough welds which could allow for the formation of biofilms.

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. However, Japan is currently not eligible to export beef to the United States because of the presence of BSE.

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 any of the four 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 four establishments. Two establishments had not adequately implemented the HACCP requirements.

The specific findings for those establishments are as follows:

- In one establishment, BSE was not considered in the HACCP analysis as a hazard likely to occur. However, all of the measures required by Japanese law concerning BSE testing and the removal and destruction of SRMs were in place and the procedures were being followed as required.
- In one establishment, the monitoring of the CCP for Zero Tolerance was not clearly understood by the establishment or the inspection personnel. These actions were not identified as a CCP. Instead of true monitoring, the establishment (the employee on the last trim stand) was examining each carcass for hair, fecal, ingesta, and other foreign material. Therefore, the records did not reflect monitoring for the CCP as required by FSIS for HACCP slaughter. Inspection was only conducting a final carcass inspection.
- In one establishment, the descriptions of verification in the HACCP plan did not include all three required procedures. These procedures are (a) the calibration of process-monitoring instruments; (b) direct observations of monitoring activities and corrective actions; and (c) the review of records generated and maintained in accordance with 9 CFR 417.5(a)(3).
- In one establishment, the HACCP plan did not include direct observation of the monitor as a step in verification. The plan also did not include calibration of

measuring instruments. However, very complete plans and records for calibration of measuring instruments were provided, just not included as a part of the HACCP system.

11.3 Testing for Generic *E. coli*

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

All of the 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 two of the four slaughter establishments. Two of the four establishments were using excision sampling and the appropriate evaluation of their analyses. In the other two establishments, the sponging method of sampling was employed; however, the required statistical process control chart evaluations of the results of the analyses were not performed.

11.4 Testing for *Listeria monocytogenes (Lm)*

None of the four 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 Japan Food Research Laboratories. 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. The Regional Office regularly visits the laboratory for an audit.

No deficiencies were noted. However, it was noted that the payment for sample analysis was paid directly from the establishments to the laboratory. The collection and shipping of the samples was accomplished by the inspection service. The reporting chain does not go directly to the establishments, but goes through the inspection service to the MHLW headquarters and to the Meat Inspection Centers. 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 animal quarantine.

Japan's National Residue Testing Plan for 2004 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/processing establishments. However, as can be noted from the findings listed above and the establishment reports attached to this report, inspection personnel were not adequately enforcing U.S. inspection requirements.

13.2 Testing for *Salmonella*

Japan has adopted the FSIS requirements for testing for *Salmonella* with the exception of the following equivalent measure(s).

Japan has agreed that in those cases where *Salmonella* samples cannot be analyzed on the same day as they are received, the samples will be stored at freezing temperatures.

All four 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 all four of the establishments audited.

13.3 Species Verification

Species verification was being conducted in those establishments in which it was required in 2003. The testing is scheduled but has not yet been conducted for 2004.

13.4 Monthly Reviews

During this audit it was found that in all establishments visited, monthly supervisory reviews of certified establishments were being performed and documented as would be required if the establishments were actively exporting.

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 September 16, 2004 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
International Audit Staff Officer

A handwritten signature in cursive script, appearing to read "Rori K. Craver", is written over a horizontal line. The signature is positioned to the right of the typed name.

15. ATTACHMENTS

Individual Foreign Establishment Audit Forms

Individual Foreign Laboratory Reports

Foreign Country Response to Draft Final Audit Report

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOVT AGENCY Kagoshima Prefecture MHLW	CITY & COUNTRY Sueyoshi-cho, Japan	ADDRESS OF LABORATORY 6608-10, Suwarata, Sueyoshi-cho, So-gun, Kagoshima Prefecture, Japan 896-8604
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NAME OF REVIEWER Rori K. Craver, DVM	NAME OF FOREIGN OFFICIAL Drs. Eiji Sakanashi, MHLW, Daisaku Inoue, Kyushu Region, Toshihisa Tanaka, Kagoshima Prefecture, Hideki Fujimoto, Sueyoshi Meat Inspection Center
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Residue Code/Name			Sal	EC O	gen											
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE													
	Sample Handling	01		A	A	A										
	Sample Frequency	02		A	A	A										
	Timely Analysis	03		A	A	A										
	Compositing Procedure	04		O	O	O										
	Interpret Comp Data	05		O	O	O										
	Data Reporting	06	A	A	A											
ANALYTICAL PROCEDURES			EVALUATION CODE													
	Acceptable Method	07		A	A	A										
	Correct Tissue(s)	08		A	A	A										
	Equipment Operation	09		A	A	A										
	Instrument Printouts	10	O	O	O											
QUALITY ASSURANCE PROCEDURES			EVALUATION CODE													
	Minimum Detection Levels	11		O	O	O										
	Recovery Frequency	12		O	O	O										
	Percent Recovery	13		O	O	O										
	Check Sample Frequency	14		A	A	A										
	All Analyst W/Check Samples	15		A	A	A										
	Corrective Actions	16		A	A	A										
	International Check Samples	17	O	O	O											
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE	O	O	O										
OTHER REVIEW		19	EVAL. CODE													
		20														

Signature of reviewer: *Rori K. Craver DVM* Date: *7 Sept 04*

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN COUNTRY AGENCY
MHLW

CITY & COUNTRY
Tokyo, Japan

ADDRESS OF LABORATORY
6965, Nakura, Akasaka-cho
So-gun, Kagoshima, Japan

NAME OF REVIEWER
Ron K. Craver, DVM

NAME OF FOREIGN OFFICIAL
Drs. Yuuka Konishi, MHLW, Daisaku Inoue, Kyushu Region, Toshinisa Tanaka, Kagoshima Prefecture, Takashi Kishita, Shibushi Meat Inspection Center

Residue Code/Name	Item #	EVAL. CODE	EVALUATION CODE									
SAMPLING PROCEDURES												
REVIEW/ITEMS	01	A										
Sample Handling	02	A										
Sample Frequency	03	A										
Timely Analysis	04	O										
Compositing Procedure	05	O										
Interpret Comp Data	06	A										
Data Reporting	07	A										
Acceptable Method	08	A										
Correct Issue(s)	09	A										
Equipment Operation	10	O										
Instrument Printouts	11	O										
Minimum Defection Levels	12	O										
Recovery Frequency	13	O										
Percent Recovery	14	O										
Check Sample Frequency	15	O										
All Analyst W/Check Samples	16	A										
Corrective Actions	17	O										
International Check Samples	18	O										
Corrected Prior Deficiencies	19											
OTHER REVIEW	20											

Signature of reviewer: *Ron K. Craver* Date: *8 Sept. 04*

FOREIGN COUNTRY LABORATORY REVIEW

Sept 13, 2004

Tama-Laboratory

FOREIGN GOVT AGENCY Private	CITY & COUNTRY Tokyo, Japan	ADDRESS OF LABORATORY 8-11-10, Nagayama, Tama-shi, Tokyo
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NAME OF REVIEWER Rori K. Craver, DVM	NAME OF FOREIGN OFFICIAL Drs. Yutaka Konishi, MHLW, Tetsuo Hamamoto, FAS, Y. Hirata, Tama Lab, Tatsuko Yamakawa, Tama Lab, Shigeru Sugimoto, JFR Labs
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Residue Code/Name			Iver	Sulf	Chl o	Thia	As	Hg	Pb	Cd	CH C	HC B	Car	Org	
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE	A	A	A	A	A	A	A	A	A	A	A	
	Sample Handling	01		A	A	A	A	A	A	A	A	A	A	A	A
	Sample Frequency	02		A	A	A	A	A	A	A	A	A	A	A	A
	Timely Analysis	03		A	A	A	A	A	A	A	A	A	A	A	A
	Compositing Procedure	04		O	O	O	O	O	O	O	O	O	O	O	O
	Interpret Comp Data	05		O	O	O	O	O	O	O	O	O	O	O	O
Data Reporting	06	A	A	A	A	A	A	A	A	A	A	A	A	A	
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A	A	A	A	A	A	A	A	A	A	A	
	Correct Issue(s)	08		A	C	C	A	A	A	A	A	A	A	C	C
	Equipment Operation	09		A	A	A	A	A	A	A	A	A	A	A	A
	Instrument Printouts	10		A	A	A	A	A	A	A	A	A	A	A	A
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	A	A	A	A	A	A	A	A	A	A	A	
	Recovery Frequency	12		A	A	A	A	A	A	A	A	A	A	A	A
	Percent Recovery	13		A	A	A	A	A	A	A	A	A	A	A	A
	Check Sample Frequency	14		A	A	A	A	A	A	A	A	A	A	A	A
	All Analyst W/Check Samples	15		A	A	A	A	A	A	A	A	A	A	A	A
	Corrective Actions	16		A	A	A	A	A	A	A	A	A	A	A	A
	International Check Samples	17		C	C	C	C	C	C	C	C	C	C	C	C
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE	O	O	O	O	O	O	O	O	O	O	O	
OTHER REVIEW		19	EVAL. CODE												
		20	EVAL. CODE												

Signature of reviewer: *Rori K. Craver, DVM*

Date: *13 Sept 04*

FOREIGN COUNTRY LABORATORY REVIEW

Sept 13, 2004

Tama Food Research Laboratories
Tama-Laboratory

FOREIGN GOV. AGENCY Private	CITY & COUNTRY Tokyo, Japan	ADDRESS OF LABORATORY 6-11-10, Nagayama, Tama-shi, Tokyo
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NAME OF REVIEWER Rori K. Craver, DVM	NAME OF FOREIGN OFFICIAL Drs. Yutaka Konishi, MHLW, Teisuo Hamamoto, FAS, Y. Hirata, Tama Lab, Tatsuko Yamakawa, Tama Lab, Shigeru Sugimoto, JFR Labs
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Residue Code/Name			Orc	Pyr	Thio	SP										
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE													
	Sample Handling	01		A	A	A	A									
	Sample Frequency	02		A	A	A	A									
	Timely Analysis	03		A	A	A	A									
	Compositing Procedure	04		O	O	O	O									
	Interpret Comp Data	05		O	O	O	O									
Data Reporting	06		A	A	A	A										
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A	A	A	A									
	Correct Tissue(s)	08		A	A	A	A									
	Equipment Operation	09		A	A	A	O									
	Instrument Printouts	10		A	A	A	O									
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	A	A	A	O									
	Recovery Frequency	12		A	A	A	O									
	Percent Recovery	13		A	A	A	O									
	Check Sample Frequency	14		A	A	A	A									
	All Analyst W/Check Samples	15		A	A	A	A									
	Corrective Actions	16		A	A	A	A									
	International Check Samples	17		C	C	C	C									
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE	O	O	O	O									
OTHER REVIEW		19														
		20	EVAL. CODE													

Signature of reviewer: *Rori K. Craver DVM*

Date: *13 Sept 04*

FOREIGN COUNTRY LABORATORY REVIEW (Comment Sheet)		REVIEW DATE Sept. 13, 2004	NAME OF FOREIGN LABORATORY Japan Food Research Laboratories Tama-Laboratory
FOREIGN GOVT AGENCY Private	CITY & COUNTRY Tokyo, Japan	ADDRESS OF LABORATORY 6-11-10, Nagayama, Tama-shi, Tokyo	
NAME OF REVIEWER Rof. K. Craver, DVM		NAME OF FOREIGN OFFICIAL Drs. Yutaka Konishi, MHLW, Tetsuo Hamamoto, FAS, Y. Hirata, Tama Lab, Tatsuko Yamakawa, Tama Lab, Shigeru Sugimoto, JFR Labs	

RESIDUE	ITEM NO.	COMMENTS
Iver		Ivermectin
Sulf	8	Sulfonamides Japan uses liver and muscle
Chlo	8	Chloramphenicol Japan uses kidney and muscle
Thia		Thiamphenicol
As		Arsenic
Hg		Mercury
Pb		Lead
Cd		Cadmium
CHC		Chlorinated Hydrocarbons
HCB		Hydrochlorinated Biphenyls
Car		Carbamates
Org	8	Organophosphates Japan uses liver and muscle
Orc		Organochlorides
Pyr		Pyrethroides
Thio		Thiocarbamates
Sp		Species test
ALL	17	International check samples involving tissue are not allowed to be imported into Japan.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Gunma-ken Shokuniku Oroshiuri Shigo Co. LTD & Gunma-ken Shokuniku Kosha 1189 Kamifukushima Tamamura Sawa, Gunma 370-1104	2. AUDIT DATE 31 Aug. 2004	3. ESTABLISHMENT NO. G-1	4. NAME OF COUNTRY Japan
5. NAME OF AUDITOR(S) Rori K. Craver, 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.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	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/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	X	56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Est. G-1 Japan 8/31/04

Note: Establishment G-1 is actually two companies operating under one roof. The slaughter establishment is the first company listed in the company name and the boning establishment is the second. They have separate management and separate SSOP and HACCP plans.

10. There are several small pipes that run directly across the far end of the moving viscera table. There was liquid (water?) dripping from these pipes unto the end of the table. At the end of this table are the chutes for edible offal to enter that room. 9 CFR 416.13

12/51. There were no provisions for preventive measures in the corrective actions in the SSOP. This is a repeat finding from the last FSIS audit. 9 CFR 416.15(b), 416.17

28/51. Generic *Escherichia coli* sampling is accomplished using the sponge method. There was no analysis using statistical process control. This is a repeat finding from the last FSIS audit. 9 CFR 310.25, 417.8

58. This establishment was issued an NOID because of the repeat findings.

61. NAME OF AUDITOR

Roni K Craver DVM

62. AUDITOR SIGNATURE AND DATE

Roni K Craver DVM 31 Aug 04

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Miyachiku Co. Ltd. Takasaki Plant 4268-1 Oomuta Takasaki-Cho Miyazaki-ken 889-4505 Japan	2. AUDIT DATE 3 Sept. 2004	3. ESTABLISHMENT NO. M-1	4. NAME OF COUNTRY Japan
5. NAME OF AUDITOR(S) Rori K. Craver, 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	
12. Corrective action when the SSOPs 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	X
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.	X	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.	X	46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	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/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	X	56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Est. M-1 Japan 9/3/04

12/51. There were no provisions for preventive measures in the corrective actions in the SSOP. This is a repeat finding from the last FSIS audit. 9 CFR 416.15(b) & 416.17

15/51. Bovine Spongiform Encephalopathy (BSE) was not considered in the HACCP analysis as a hazard likely to occur. However, all of the measures required by Japanese law concerning BSE testing and the removal and destruction of SRMs were in place and the procedures were being followed as required. 9 CFR 417.2(a) & 417.8

18/51. Monitoring of the CCP for Zero Tolerance was not clearly understood by the establishment or the inspection personnel. These actions were not identified as a CCP. Instead of true monitoring, the establishment (the employee on the last trim stand) was examining each carcass for hair, fecal, ingesta, and other foreign material. Therefore, the records did not reflect monitoring for the CCP as required by FSIS for HACCP slaughter. Inspection was only conducting their own final carcass inspection. 9 CFR 417.5(a)(3) & 417.8

19/51. The descriptions of verification in the HACCP plan did not include all three required procedures. These procedures are (a) the calibration of process-monitoring instruments; (b) direct observations of monitoring activities and corrective actions; and (c) the review of records generated and maintained in accordance with 9 CFR 417.5(a)(3). 9 CFR 417.4(a)(2) & 417.8

28/51. Generic *Escherichia coli* sampling is accomplished using the sponge method. There was no analysis using statistical process control. This is a repeat finding from the last FSIS audit. 9 CFR 310.25 & 417.8

39. On the wall in the offal room that was farthest from the entrance from the slaughter floor, a gap had been filled by caulking that was shredding and was not able to be cleaned and sanitized. This was very recently filled due to a requirement by inspection. 9 CFR 416.2(b)(2)

58. This establishment was issued an NOID.

61. NAME OF AUDITOR

Rori K. Craver DVM

62. AUDITOR SIGNATURE AND DATE

Rori K. Craver DVM 3 Sept 04

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Minami Kyushu Chikusan Kogyo Corp., Ltd. 1828, Ninokata, Sueyoshi-cho so-gun, Kagoshima, Japan	2. AUDIT DATE 6 Sept. 2004	3. ESTABLISHMENT NO. K-1	4. NAME OF COUNTRY Japan
5. NAME OF AUDITOR(S) Rori K. Craver, 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	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	X
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	X
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/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. K-1 Japan 9/6/04

39/51. There was peeling paint on the walls of the box storage room. This is NOT a repeat of the finding of the last FSIS audit as it was obvious to the auditor that the ceiling and walls of the room had been recently renovated and painted. The wall under the windows in the "green tripe" area of the offal room had flaking paint. 9 CFR 416.2(b) & 416.6

40. There was inadequate light at the re-inspection table in the boning room and at the final rail inspection area in slaughter. The inspection service was using a light meter that measured in LUX and at some places this measured as sufficient, but the readings did not match the foot-candles measured by the auditor. Also, from a purely visual observation from the auditor, the light did not appear to be adequate. 9 CFR 416.2(c)

45/51. During pre-operational sanitation verification inspection in the boning room it was noted that several of the stainless steel bins used for edible product had rough welds which could allow for the formation of biofilms. The establishment will protect product put into these bins by an intermediary measure until all have been corrected or replaced. The inspection service will verify these actions. 9 CFR 416.3(a) & 416.6

61. NAME OF AUDITOR

Rori K Craver DVM

62. AUDITOR SIGNATURE AND DATE

Rori K Craver DVM 6 Sept 04

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION SANKYO MEAT Ltd. Ariake Meat Plant II 6965, Noikura, Ariake-cho so-gun, Kagoshima, Japan	2. AUDIT DATE 8 Sept. 2004	3. ESTABLISHMENT NO. K-2	4. NAME OF COUNTRY Japan
5. NAME OF AUDITOR(S) Rori K. Craver, 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	
12. Corrective action when the SSOPs 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	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	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/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. K-2 Japan 9/8/04

12/51. The SSOP did not provide for the recording of the disposition of product as a part of corrective actions. The SSOP also did not provide for the recording of preventive measures. However, preventive measures were present on many monitoring records for deficiencies and corrective actions records. 9 CFR 416.15 (b) & 416.17

19/51. The HACCP plan did not include direct observation of the monitor as a step in verification. The plan also did not include calibration of measuring instruments. However, very complete plans and records for calibration of measuring instruments were provided, just not included as a part of the HACCP system. 9 CFR 417.4 (a)(2) & 417.8

45/51. During pre-operational sanitation verification inspection in the boning room and in slaughter, it was noted that several of the stainless steel edible product bins and product contact tables as well as several product contact areas along the slaughter line had rough welds which could allow for the formation of biofilms. 9 CFR 416.3(a) & 416.6

61. NAME OF AUDITOR

Rori K. Craver DVM

62. AUDITOR SIGNATURE AND DATE

Rori K. Craver DVM 8/27/04

Arthur, Deborah

From: Furey, Todd
Sent: Wednesday, March 16, 2005 8:10 AM
To: Arthur, Deborah
Cc: Craver, Aurora
Subject: Japan Audit Comments

-----Original Message-----

From: Tetsuo.Hamamoto@usda.gov [mailto:Tetsuo.Hamamoto@usda.gov]
Sent: Wednesday, March 16, 2005 8:43 AM
To: Todd.Furey@fsis.usda.gov
Cc: Clay.Hamilton@usda.gov; Richard.Battaglia@usda.gov; konishi-yutaka@mhlw.go.jp@FASPOST@FASNJ
Subject: RE: Fw: Questions for Japan

Mr. Furey,

Please find following comments from MHLW on the audit report.

Page 5, Paragraph 1, and Page 15, 13.2, Paragraph 2:
"at freezing temperature" to be changed to "at 4 C" (Because Salmonella samples are kept at refrigerated temperature (4 C), not frozen.)

Page 8, Last line:
"hires all the veterinarians" to be changed to "designates all the veterinarians" (Because it is too strong to use "hire.")

Page 14, Last line of the second paragraph from the bottom:
"by law" to be changed to "by animal quarantine" (To clarify that the reason for difficulties in obtaining samples is an animal quarantine problem.)

Tetsuo Hamamoto (Mr.)
Agricultural Specialist, U.S. Embassy, Tokyo tetsuo.hamamoto@usda.gov (English)
agtokyo@bekkoame.ne.jp (Japanese)