United States Department of Agriculture

Food Safety and Inspection Service

Washington, D.C. 20250

JUL 1 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 January 6 through January 21, 2005. No comments from the government of Japan were received for this 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,

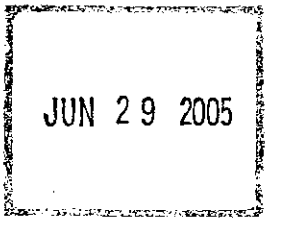
Steven McDermott
for

Sally White, Director
International Equivalence Staff
Office of International Affairs

Enclosure

Cc:
Daniel Berman, Minister-Counselor, US Embassy, Tokyo
Tadashi Sato, Agricultural Attaché, Embassy of Japan, Washington, DC
Susan Schayes, FAS Area Officer
Barbara Masters, Acting Administrator, FSIS
Linda Swacina, Executive Director, FSIA, OIA
Robert Macke, Assistant Deputy Administrator, ITP, FAS
Karen Stuck, Assistant Adm., OIA, FSIS
Bill James, Deputy Assistant Administrator, OIA, FSIS
Donald Smart, Director, Review Staff, OPEER, FSIS
Sally White, Director, IES, OIA
Clark Danford, Director, IEPS, OIA
Mary Stanley, Director, IID, OIA
Amy Winton, State Department
Armia Tawadrous, Director, FSIS CODEX
Todd Furey, IES, OIA, FSIS
Nancy Goodwin, IES, OIA, FSIS
Country File (Japan Audit)

FINAL



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

JANUARY 6 THROUGH JANUARY 21, 2005

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
SPS	Sanitation Performance Standards
E. coli	*Escherichia coli*
Salmonella	*Salmonella* species
MIC	Meat Inspection Center
SRM	Specified Risk Materials
Lm	*Listeria monocytogenes*

1. INTRODUCTION

The audit took place in Japan from January 6, 2005 through January 21, 2005.

An opening meeting was held on January 6, 2005 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 follow-up 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, four meat inspection centers, four beef slaughter and processing (deboning) establishments, one semi-national private laboratory performing residue analyses, and one meat inspection center laboratory performing *Escherichia coli* (*E. coli*) and *Salmonella* species (*Salmonella*) analyses.

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

3. PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved on-site visits to four slaughter and processing establishments. The third part involved visits to one private semi-national laboratory and one government laboratory. The Central 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 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, (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 freezing temperatures.

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 20 through September 1, 2001, and from August 26 through September 16, 2004. The following findings, grouped by category, were noted in the 2004 audit:

Government Oversight – Enforcement of U.S. Regulations:

- In one establishment, there was peeling paint on the walls of the box storage room.
- In one establishment, the wall under the windows in the "green tripe" area of the offal room had flaking paint.
- 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.
- In one establishment, the SSOP did not provide for the recording of the disposition of product as a part of corrective actions.
- In one establishment, the SSOP did not provide for the recording of preventive measures. However, preventive measures were present on many monitoring records for deficiencies and corrective action records.
- In one establishment, the HACCP plan did not include direct observation of the monitoring activity 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.
- In one 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.
- In two establishments, there were no provisions for preventive measures in the corrective actions in the SSOP.
- In one establishment, 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 Specified Risk Materials (SRMs) were in place and the procedures were being followed as required.
- In one establishment, monitoring for the Critical Control Point (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.
- In one establishment, the descriptions of verification in the HACCP plan did not include all three required procedures.
- In two establishments, generic *E. coli* sampling was accomplished using the sponge method. There was no analysis using statistical process control.

Two of the establishments audited received a Notice of Intent to Delist (NOID) during this audit.

These specific deficiencies were corrected by the January 2005 FSIS audit.

Animal Disease:

There were no deficiencies in Animal Disease.

Sanitation Standard Operating Procedures (SSOP):

- 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 on to 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.
- In one establishment, the SSOP did not provide for the recording of preventive measures. However, preventive measures were present on many monitoring records for deficiencies and corrective action records.
- In one establishment, the SSOP did not provide for the recording of the disposition of product as a part of corrective actions.

These specific deficiencies were corrected by the January 2005 FSIS audit.

Sanitation Performance Standards (SPS):

- In one establishment, there was peeling paint on the walls of the box storage room.
- In one establishment, the wall under the windows in the "green tripe" area of the offal room had flaking paint.
- In one establishment, the lighting at the re-inspection table in the boning room and at the final rail inspection area in slaughter did not meet the 50 foot-candle requirement.
- 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.
- In one 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.
- 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.

These specific deficiencies were corrected by the January 2005 FSIS audit.

Hazard Analysis and Critical Control Points (HACCP) Implementation:

- In one establishment, 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 Specified Risk Materials (SRMs) were in place and the procedures were being followed as required.
- In one establishment, monitoring for the Critical Control Point (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.
- In one establishment, the descriptions of verification in the HACCP plan did not include all three required procedures.
- In one establishment, the HACCP plan did not include direct observation of the monitoring activity 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.

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

- In two establishments, generic *E. coli* sampling was accomplished using the sponge method. There was no analysis using statistical process control.

These specific deficiencies had been corrected by the January 2005 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 and Safety Division of the Food Safety Department of MHLW hires 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 have 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

No regional bureaus were audited. However, representatives of the regional bureaus did accompany the auditor to the respective Meat Inspection Centers and 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 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 following laboratories were reviewed:

The laboratories audited are as follows: the government laboratory in the Takasaki 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 three of the four establishments audited were found to meet the basic FSIS regulatory requirements, with no deficiencies. In the other establishment, the following deficiency was noted:

- 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.

9.2 Sanitation Performance Standards

In one of the four establishments audited, the following deficiency in sanitation performance standards was noted:

- 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.

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. All four establishments had adequately implemented the HACCP requirements.

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 all 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 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 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. The importation of these samples into Japan is forbidden by law.

Japan's National Residue Testing Plan for 2005 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* species.

13.1 Daily Inspection in Establishments

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

13.2 Testing for *Salmonella*

Japan has adopted the FSIS requirements for testing for *Salmonella* with the exception of the following equivalent measure:

- 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 conducted in all four certified establishments in 2004. The testing is scheduled but has not yet been conducted for 2005.

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 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 January 21, 2005 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

Manzoor H. Chaudry

15. ATTACHMENTS

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

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: Jan. 7 2005

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: Rori K. Craver, DVM

NAME OF FOREIGN OFFICIAL: Drs. Yutaka Konishi, MHLW; Tetsuo Hamamoto, FAS; Yoshiaki Hirata, Tatsuko Yamakawa, Kitahara Yumi, Iwata Hitoshi, Tomoko Tsubosaka, Tama Lab; Shigeru Sugimoto, Tsutomu Nishimura, JFR Labs,

	Residue Code/Name ►			Iver	Sulf	Chlo	Thia	As	Hg	Pb	Cd	CHC	HCB	Car	Org
SAMPLING PROCEDURES	REVIEW ITEMS: Sample Handling	ITEM # 01	EVLUATION CODE	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
ANALYTICAL PROCEDURES	Acceptable Method	07	EVLUATION CODE	A	A	A	A	A	A	A	A	A	A	A	A
	Correct Tissue(s)	08		A	C	C	A	A	A	A	A	A	A	A	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	EVLUATION CODE	A	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	O
OTHER REVIEW		19	EVAL. CODE												
		20													

Signature of Reviewer: Rori K. Craver DVM

Date: 1-7-05

FOREIGN COUNTRY LABORATORY REVIEW (Comment Sheet)	REVIEW DATE Jan. 7,2005	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 Roni 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 and add other names	

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.

FOREIGN COUNTRY LABORATORY REVIEW

DATE
Jan 7, 2005

NAME OF FOOD OR LABORATORY
Japan Food Research Laboratories
Tama-Laboratory

FOREIGN GOVT AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Private	Tokyo, Japan	6-11-10, Nagayama, Tama-shi, Tokyo

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Rori K. Craver, DVM	Drs. Yutaka Konishi, MHL; Tetsuo Hamamoto, FAS; Yoshiaki Hirata, Tatsuko Yamakawa, Kitahara Yumi, Iwata Hitoshi, Tomoko Tsubosak, Tama Lab; Shigeru Sugimoto, Tsutomu Nishimura JFR Labs

	Residue Code/Name ▶			Orc	Pyr	Thio	SP
SAMPLING PROCEDURES	REVIEW ITEMS Sample Handling	ITEM # 01	EVLUATION CODE	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	EVLUATION 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	EVLUATION CODE	A	A	A	0
	Recovery Frequency	12		A	A	A	0
	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	EVAL. CODE				
		20					

Signature of reviewer: Rori K Craver DVM

Date: 1-7-05

Designed on Form Flow Software

FOREIGN COUNTRY LABORATORY REVIEW (Comment Sheet)	REVIEW DATE Jan. 7,2005	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 Rori K. Craver, DVM	NAME OF FOREIGN OFFICIAL Drs. Yutaka Konishi, MHL;, Tetsuo Hamamoto, FAS; Yoshiaki Hirata, Tatsuko Yamakawa, Kitahara Yumi, Iwata Hitoshi, Tomoko Tsubosak, Tama Lab; Shigeru Sugimoto, Tsutomu Nishimura JFR Labs	

RESIDUE	ITEM NO.	COMMENTS
Iver		Ivermectin
Sulf		Sulfonamides
Chlo		Chloramphenicol
Thia		Thiamphenicol
As		Arsenic
Hg		Mercury
Pb		Lead
Cd		Cadmium
CHC		Chlorinated Hydrocarbons
HCB		Hydrochlorinated Biphenyls
Car		Carbamates
Org		Organophosphates
Orc		Organochlorides
Pyr		Pyrethroides
Thio		Thiocarbamates
Sp		Species test

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOVT AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Miyazaki Prefecture MHLW	Takasaki-cho, Miyazaki 889-4505 Japan	4268-1 Omuta, Kitamoroke-gun

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Rori K. Craver, DVM	Drs. Shinya Tokoro, Kyushu Region, Makio Mizobe, Nobeoka Animal Hygiene Center (acting as interpreter)

	REVIEW ITEMS	ITEM #	EVLUATION CODE	Sal	ECO	gen	BSE								
	Residue Code/Name ▶														
SAMPLING PROCEDURES	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	EVLUATION CODE	A	A	A	A								
	Correct Tissue(s)	08		A	A	A	A								
	Equipment Operation	09		A	A	A	A								
	Instrument Printouts	10		O	O	O	A								
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVLUATION CODE	O	O	O	A								
	Recovery Frequency	12		O	O	O	O								
	Percent Recovery	13		O	O	O	O								
	Check Sample Frequency	14		A	A	A	O								
	All Analyst W/Check Samples	15		A	A	A	O								
	Corrective Actions	16		A	A	A	A								
	International Check Samples	17		O	O	O	O								
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE	O	O	O	O								
OTHER REVIEW		19	EVAL. CODE												
		20													

Signature of reviewer: Rori K. Craver DVM Date: 1-17-05

FSIS FORM 9920-4 (8/98) Designed in Form Flow Software

FOREIGN COUNTRY LABORATORY REVIEW (Comment Sheet)	REVIEW DATE	NAME OF FOREIGN LABORATORY
	Jan. 17, 2005	Takasaki (Miyazaki) Meat Inspection Center Laboratory

FOREIGN GOVT AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Miyazaki Prefecture MHLW	Takasaki-cho, Miyazaki 889-4505 Japan	4268-1 Omuta, Kitamoroka-gun

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Rori K. Craver, DVM	Drs. Shinya Tokoro, Kyushu Region, Makio Mizobe, Nobeoka Animal Hygiene Center (acting as interpreter)

RESIDUE	ITEM NO.	COMMENTS
Sal		Salmonella species
EC O		Escherichia coli O157:H7
gen		generic Escherichia coli
BSE		Bovine Spongiform Encephalopathy

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
Miyachiku Co Ltd. Takasaki Plant 4268-1 Oomuta Takasaki-Cho Miyazaki-ken 889-4505 Japan	14 Jan. 2005	M-1	Japan
	5. NAME OF AUDITOR(S) Rori K. Craver, DVM	6. TYPE OF AUDIT [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 SSOPs have failed to prevent direct product contamination or adulteration.	
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.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
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.	
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	
40. Light	
41. Ventilation	
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*	
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

Est. M-1 Japan
14 January 2005

46. 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. 9 CFR 416.4(b).

61. NAME OF AUDITOR
Rudi N. Crocker, DVM

62. AUDITOR SIGNATURE AND DATE
1-14-05

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-gun, Kagoshima, Japan	12 Jan. 2005	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 SSOPs have failed to prevent direct product contamination or adulteration.	
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.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
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.	
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	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils.	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
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

Est. K-1 Japan
January 12, 2005

61. NAME OF AUDITOR
Robert K. Craver DVM

62. AUDITOR SIGNATURE AND DATE
Robert K. Craver DVM 1-12-05

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
SANKYO MEAT Ltd. Ariake Meat Plant II 6965, Noikura, Ariake-cho so-gun, Kagoshima, Japan	11 Jan. 2005	K-2	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 SSOPs have failed to prevent direct product contamination or adulteration.	
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.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
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.	
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	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
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

Est. K-2 Japan
January 11, 2005

61. NAME OF AUDITOR
Brent R. Crocker DVM

62. AUDITOR SIGNATURE AND DATE
1-11-05

60. Observation of the Establishment

Est. G-1 Japan
18 January 2005

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. 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. 9 CFR 416.13(c)

61. NAME OF AUDITOR
Rod K. Fraser DVM

62. AUDITOR SIGNATURE AND DATE

Country Response Not Received