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

DEC 26 2001

Dr. Satoshi Takaya, Director
Division of Export of Meat Products to the United States
Food Sanitation Department
Ministry of Health, Labor and Welfare
1-2-2 Kasumigaseki, Chiyoda-ku
Tokyo 100-8916, Japan

Dear Dr. Takaya:

The Food Safety and Inspection Service has completed an on-site audit of Japan's meat inspection system. The audit was conducted from August 20 – September 1, 2001.

Enclosed is a copy of the draft final audit report. You are invited to provide comments regarding the information in the audit report. Comments received from the Government of Japan will be included as an attachment to the final report. Comments must be provided within 60 days of the receipt of this letter.

During this audit, our auditor found that two of Japan's three certified establishments had deficiencies in sanitation controls (both pre-operational and operational sanitation), animal disease controls, and slaughter/processing controls. Because of these deficiencies, the establishments were rated as acceptable/re-review. During our next audit, these establishments will be rated either acceptable or unacceptable.

In addition, the following concerns were noted with regard to Japan's meat inspection system.

1. Condemned product was not properly denatured in all three establishments. Condemned products must be denatured or decharacterized with approved denaturants to preclude their use as human food.
2. Suspect animals were not adequately separated from non-suspect animals in all three establishments. Suspect animals must be kept in pens or other facilities that are completely separate from pens holding healthy-appearing animals.
3. Japan is using the sponge method for sampling of product for generic *E. coli* and is using the excision method criteria to evaluate test results. Since Japan is using the sponge method to collect samples (not the excision method), Japan will need to evaluate test results based on Table 1—Evaluation of *E. coli* Test Results (9 CFR 310.25(a)(5)). These are the criteria to use to evaluate test results when an establishment uses the sponge method to take samples for testing. I have enclosed a copy of Table 1 for your information.

Please advise FSIS of the specific actions taken or to be taken by the Government of Japan to correct the deficiencies noted in the draft final audit report and presented above.

If you have any questions regarding the audit or need additional information, please contact me at 202-720-3781. My fax number is 202-690-4040 and my email address is sally.stratmoen@usda.gov.

Sincerely,

/s/ Nancy Goodwin

Sally Stratmoen, Chief
Equivalence
International Policy Staff
Office of Policy, Program Development
and Evaluation

Enclosures

cc:
Suzanne Hale, Minister-Counselor, U.S. Embassy, Tokyo
Mr. Watanabe, First Secretary, Embassy of Japan, Washington, DC
Ross Kreamer, FAS Area Officer
John Prucha, ADA, OPPDE
Sally Stratmoen, Chief, ES, IPS, OPPDE
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Donald Smart, Director, Review Staff, OFO
Nancy Goodwin, ES, IPS, OPPDE
Amy Winton, State Department
Country File-Japan (Audit FY 2001—draft final audit to CVO)

FSIS:OPPDE:IPS:NGoodwin:bw:12/20/01:720-9187:Japan-FY2001 audit

Clearance:	Initial	Date
Sally Stratmoen, Chief, ES, FSIS, IPS	_____	_____
Clark Danford, Acting Director	_____	_____

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AUDIT REPORT FOR JAPAN

August 20 through September 1, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Japan's meat inspection system from August 20 through September 1, 2001. Three establishments were certified to export meat to the United States; all those were audited on-site. All three were slaughter establishments.

The last audit of the Japanese meat inspection system was conducted in February 2000. The same establishments were audited and all three were found acceptable. Four major concerns were reported at that time:

1. Lack of implementation and monitoring, in all establishments, of pre-shipment document reviews.

2. Contamination with hair on skinned carcasses.

3. Neglected maintenance and monitoring of over-product structures.

4. Reinspection criteria sheets had not been updated to reflect the zero-tolerance policy for visible contamination with ingesta.

Japan exports only beef to the United States; however, due to the presence of foot and mouth disease in cattle. No beef products were allowed into the U.S. from Japan at the time of this audit.

During calendar year 2001, Japanese establishments did not export any product to the U.S. due to the presence of foot and mouth disease.

PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with Japanese national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second was conducted by on-site visits to establishments. The third was a visit to four laboratories, one performing analytical testing of field samples for

the national residue testing program, and the others culturing field samples for the presence of microbiological contamination with *Salmonella* species and generic *E. coli*.

Japan's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the generic *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Effective inspection system controls were found to be in place in all three establishments audited; two of these (G1 and K1) were recommended for re-review. Details of the audit findings, including compliance with the requirements for HACCP systems, SSOPs, and testing programs for *Salmonella* species and generic *E. coli,* are discussed later in this report.

As stated above, four major concerns had been identified during the last audit of the Japanese meat inspection system. During this new audit, the auditor verified that all of the previous concerns had been addressed and corrected.

The HACCP programs were found to meet the basic FSIS regulatory requirements. Japanese establishments were not required to perform pre-shipment document reviews at the time of this audit, due to the ineligibility of Japanese meat for export to the U.S. The MHLW officials assured the Auditor, however, that the establishments were prepared to resume compliance with the requirement in the event that Japanese beef again becomes eligible for the U.S. market.

In addition, these were four new major concerns:

1. Pre-operational and operational sanitation deficiencies.

2. Inadequate separation of suspect animals from non-suspect animals.

3. Condemned product was not properly denatured in any of the three establishments.

4. In all three establishments, the sponge method was used for collecting samples for generic *E. coli* testing, while incision method criteria were used for the evaluation of the test results. Also, statistical process control procedures had not been developed.

Entrance Meeting

On August 22, an entrance meeting was held in the Tokyo offices of Japan's Ministry of Health, Labor and Welfare (MHLW), and was attended by Dr. Eiji Michino, Deputy Director, Division of Export of Meat Products to the United States; Dr. Makoto Kanie, Section Chief; Dr. Kazuko Ohno, Staff Veterinarian; Dr. Tesuo Hanamoto, Agricultural Specialist, U.S. Embassy; and Dr. Oto Urban, International Audit Staff Officer, FSIS, hereinafter called 'the Auditor". Topics of discussion included the following:

1. Itinerary and lodging arrangements for the Auditor were finalized.

2. The Auditor shared with the MHLW officials the data collection instruments for SSOPs, HACCP programs, and testing programs for generic *E. coli* and *Salmonella* species.

3. The name of the Division of Export of Meat Products to the United States had been changed to the Inspection and Safety Division.

4. There was a discussion with the inspection officials about the Foot-and-Mouth Disease situation in the country.

5. There was a discussion about the regulatory and enforcement information. Japan's, annual report of inspection and enforcement activities is made available to the public.

6. Information was provided to update FSIS's country profile of Japan.

7. Japan's responses to an FSIS questionnaire on residue control were discussed.

Headquarters Audit

There had been one change in the organizational structure since the last U.S. audit of Japan's inspection system in February 2000. There was a change of the name Veterinary Sanitation Division, Environmental Health Bureau, Ministry of Health and Welfare to Inspection and Safety Division, Department of Food Safety, Ministry of Health, Labor and Welfare.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor observed and evaluated the process.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Japan as eligible to export meat products to the United States were full-time MHLW employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

All three establishments certified to export meat products to the United States at the time this audit was conducted (Establishment numbers G-1, K-1, and M-1) were visited for on-site audits. In all these establishments, adequate MHLW inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products, except as otherwise noted below.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected about the risk areas of government oversight of accredited, approved, and private laboratories; intra-laboratory quality assurance procedures, including sample handling; and methodology.

The Japanese Food Research Laboratory in Nagoya was audited on August 23, 2001. Effective controls were in place for 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 methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency).

Japan's microbiological testing for *Salmonella* was being performed in government laboratories. One of these, the Gunma Prefectural Meat Inspection Laboratory, in the Prefecture of Gunma was audited.

On the same day as the audit of Establishment G-1, the auditor visited the private laboratory Syokuniku Kosya, owned and operated by the establishment, in which sponge samples were analyzed for the required testing for *E. coli*.

No concerns arose as a result of the laboratory audit.

Establishment Operations by Establishment Number

The three establishments (G-1, M-1 and K-1) were conducting beef slaughter and cutting operations. Each establishment received its livestock only from established contracted suppliers.

SANITATION CONTROLS

Based on the on-site audits of establishments, Japan's inspection system had controls in place for water potability records, chlorination procedures, back siphonage prevention, hand washing facilities, sanitizers, separation of establishments, pest control monitoring, temperature control, work space, ventilation, approval of facilities, product contact equipment, welfare facilities, personnel dress and habits, personal hygiene practices, cross-contamination prevention, product handling and storage, product reconditioning, product transportation, operational sanitation, and waste disposal.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements, with the exception that preventive measures were included as part of corrective actions in Ests. G1 and K1.

Over-Product Ceilings

1. In Est. G-1, flaking paint was observed over a product traffic area in the tongue-washing room during pre-operational sanitation inspection. *This deficiency was corrected immediately by the establishment management*.

2. Water was observed dripping from the ceiling in the offal wash area in Est. G-1. *This deficiency was corrected by the management.*

3. Flaking paint was observed over cartoons in the box room in Est. K-1. *No immediate corrective action was observed.*

Equipment Sanitizing

1. The employee performing bleeding failed to sanitize his knife after cutting through the skin in Est. G-1. *This deficiency was corrected by the establishment officials.*

2. The employee removing viscera cut through the intestine and continued to work without sanitizing his knife in Est. G-1. *This deficiency was corrected by the inspection service.*

Sanitary Dressing Procedures

1. The employee responsible for head washing did not wash the nostrils in Est.M-1. *The inspection personal took immediate corrective action.*

2. In Est. M-1, one carcass was contaminated by hair in the cooler. *This deficiency was immediately corrected by the establishment officials.*

Pre-Operational Sanitation

1. Paint on the conveyor belt and non-dripping condensation on the ceiling were observed in the deboning room during the pre-operational sanitation inspection in Est. G-1. *This deficiency was corrected immediately by the establishment management.*

2. In Est. G-1, dripping condensation was observed over production areas in the offal room during pre-operational sanitation inspection. *This deficiency was corrected by the establishment officials.*

3. Several holes were observed under doors in the product shipping area in Est. M-1. *This deficiency was scheduled for correction by the establishment management.*

4. In Est. M-1, non-dripping condensation was observed in the pre-chill and offal rooms during pre-operational sanitation inspection. *These deficiencies were corrected by the establishment management.*

5. Rusty supports in the packaging and pre-trim room, inadequate cleaning of a rolling combo bin, and rusty wheels on a conveyor belt were observed in the boning room in Est. K-1. *Some deficiencies were corrected immediately and some were scheduled for correction*.

Pest Control

1. Spider webs were observed on the slaughter floors in Ests. G-1 and M-1. *These deficiencies were corrected immediately by the establishment management*.

2. Flies were observed in the slaughterhouse during pre-operational sanitation inspection in Ests. G-1 and M-1. *These deficiencies were corrected immediately by the establishment management.*

3. Rodent poison was used in the carton storage room in Est. M-1. *This deficiency was scheduled for correction by the company officials*

4. There were no bait stations outside establishment Est. K-1. The pest control reports indicated a history of rodent activity in the establishment. *This deficiency was scheduled for correction by the company.*

Lighting

1. Light in the ante-mortem inspection area was inadequate in Est. G-1. *This deficiency was scheduled for correction by the establishment.*

2. Light in the ante-mortem and deboning room inspection areas was inadequate in Est. M-1. *This deficiency was corrected immediately by the establishment management.*

Ante-Mortem Facilities

Suspect animals were not physically separated from non-suspect animals in any of the establishments. *This deficiency was scheduled for prompt correction.*

Dry Storage Areas

Dirt and dust were observed on cartons and boxes in the box room in Est. K-1. *No immediate corrective action was observed.*

Maintenance

Several gaps were observed under doors in the product shipping area in Est. M-1. *This deficiency was scheduled for correction by the establishment management.*

Outside Premises

In Est. G-1, much discarded material was observed in the mechanical room (potential pest harborage). *This deficiency was scheduled for correction by the establishment.*

ANIMAL DISEASE CONTROLS

With the exceptions listed below, Japan's inspection system had controls in place to ensure adequate ante-mortem inspection procedures and dispositions, restricted product control, and procedures for sanitary handling of returned and rework product.

Animal Identification

No marks of inspection were visible on several carcasses in the carcass cooler in Est. K-1. *This deficiency was scheduled for correction by the establishment.*

Post-Mortem Inspection Procedures

The inspectors were observed to "chop" head and viscera lymph nodes rather than incising them carefully and observing the cut surfaces. *This deficiency was corrected by the inspection service in K-1.*

Condemned Product Control

1. Condemned product was not properly identified and denatured in Est. K-1 and M-1. *This deficiency was to be corrected by the establishment.*

2. Condemned product was not properly denatured in Est. G-1. *This deficiency was to be corrected by the establishment.*

There had been outbreaks of Foot-and Mouth disease since the previous U.S. audit, which were under control at the time of this audit.

RESIDUE CONTROLS

Japan's national residue testing plan for 2001 was being followed, and was on schedule. The Japanese inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals. The Auditor visited a farm that supplied cattle to Est. K-1. This farm and all residue-related questions were found to be satisfactory. No antibiotics were used on the farm.

SLAUGHTER/PROCESSING CONTROLS

The Japanese inspection system had controls in place to ensure adequate pre-boning trim and processed meat reinspection. All these establishments had adequate controls in place to prevent meat products intended for Japan domestic consumption from being commingled with products eligible for export to the U.S.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were found to meet the basic FSIS regulatory requirements. Japanese establishments were not required to perform pre-shipment document reviews at the time of this audit, due to the ineligibility of Japanese meat for export to the U.S. The MHLW officials assured the Auditor, however, that the establishments were prepared to resume compliance with the requirement in the event that Japanese beef again becomes eligible for the U.S. market.

Testing for Generic *E. coli*

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

The three establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The generic *E. coli* testing programs were found to meet the basic FSIS regulatory requirements except that, in all three establishments, the sponge method was used for collecting samples for testing, while incision method criteria were used for the evaluation of the test results. Also, baseline studies for generic *E. coli* had not been conducted, and statistical process control methods had not been developed to evaluate the results.

Control of *Listeria monocytogenes*

Information on *Listeria monocytogenes*, as well as on other food-borne illnesses, was collected on a national basis. Physicians are required to report cases of these illnesses to the health center of the local government, which then conducts epidemiological investigations and laboratory tests to determine the cause of infection. The health centers then reports the test results to MHLW.

All these establishments had adequate controls in place to prevent meat products intended for Japan domestic consumption from being commingled with products eligible for export to the U.S.

ENFORCEMENT CONTROLS

Inspection System Controls

The MHLW inspection system controls ante-mortem inspection procedures and dispositions; control of restricted product and inspection samples; boneless meat reinspection; shipment security, including shipment between establishments; monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans); inspection supervision and documentation] were in place and effective in ensuring that products produced by the establishments were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* Species

The three establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

Species Verification Testing

At the time of this audit, Japan was not exempt from the species verification requirement. The auditor verified that species verification was being conducted in accordance with FSIS requirements.

Monthly Reviews

These internal reviews were being performed by the Japan equivalent of Area Supervisors. All were veterinarians with several years of experience.

The internal review program was applied only to export establishments. Internal review visits were announced in advance to inspection personnel, but not to the establishment officials, and were conducted at least once monthly. The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the central MHLW offices in Tokyo, and were routinely maintained on file for a minimum of ten years.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, any product produced as of the start of business on the day of the audit would be ineligible for access to the U.S. market.

Enforcement Activities

Japan's compliance programs are governed by food sanitation laws that provide for regulation of meat production activities and for prosecution of fraud. Japan had legal provisions in place to prevent anyone convicted of food industry violations from holding positions of authority in export meat establishments for a period of two years following the conclusion of the legal proceedings.

Exit Meetings

An exit meeting was conducted in Tokyo on August 31, 2001. The participants included Dr. Eiji Michino, Deputy Director of Division Export of Meat Product to the U.S.; Dr. Kazuko Ohno, Staff Veterinarian; Dr. Tetsuo Hamamoto, Agricultural Specialist, U.S. Embassy; and Dr. Oto Urban, International Audit Staff Officer, FSIS. The following topics were discussed:

1. The details of the findings in the individual establishments were discussed. These included pre-operational sanitation deficiencies, neglected maintenance of over-product structures, condensation, inadequate separation of suspect animals from non-suspect animals, and inadequate sanitizing of skinning equipment. Some of these deficiencies were corrected during the on-site audits and some were scheduled for correction by the

establishment officials. Upper-level meat inspection officials gave assurances that field personnel would continue to monitor the establishments to ensure continued effective corrective actions.

2. Condemned product was not properly denatured in all three establishments. This procedure was to be corrected by the companies and monitored by the Japanese inspection officials.

3. The requirement for pre-shipment document reviews for any product eligible for export to the U.S. was discussed. None had been implemented yet since the restrictions had been placed on the eligibility of Japanese meat very shortly after the previous FSIS audit, but the Japanese officials gave assurances that they were well aware of the requirement, and that pre-shipment document reviews would be performed once Japanese meat is again eligible for U.S. export.

4. In all three establishments, the sponge method was used for collecting samples for testing, while incision method criteria were used for the evaluation of the test results. This deficiency will be corrected by establishment management.

CONCLUSION

The inspection system of Japan was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. Three establishments were audited: one was acceptable, and two were evaluated as acceptable/re-review. The deficiencies encountered during the on-site establishment audits, in those establishments which were found to be acceptable, were adequately addressed to the auditor's satisfaction.

Dr. Oto Urban
International Audit Staff Officer

(signed)Dr. Oto Urban

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Data collection instrument for generic *E. coli* testing
D. Data collection instrument testing for *Salmonella* species
E. Laboratory Audit Forms
F. Individual Foreign Establishment Audit Forms
G. Written foreign country's response to the draft final audit report

Attachment A

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respons-ible indiv. Identified	7. Docu-mentation done daily	8. Dated and signed
G-1	√	√	√	√	√	√	√*	√
M-1	√	√	√	√	√	√	√	√
K-1	√	√	√	√	√	√	√*	√

G-1 & K-1 Documentation of preventive measures was missing.

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing routine pre-shipment document reviews.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. Use & users included	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corr. actions are described	8. Plan validated	9. Adequate verific. Procedures	10.Adequate documentation	11. Dated and signed	12.Pre-shipmt. doc. review
G-1	√	√	√	√	√	√	√	√	√	√	√	N
M-1	√	√	√	√	√	√	√	√	√	√	√	N
K-1	√	√	√	√	√	√	√	√	√	√	√	N

The requirement for pre-shipment document reviews for any product eligible for export to the U.S. was discussed. None had been implemented yet, since the restrictions had been placed on the eligibility of Japanese meat very shortly after the previous FSIS audit, but the Japanese officials gave assurances that they were well aware of the requirement, and that pre-shipment document reviews would be performed once Japanese meat is again eligible for U.S. export.

Attachment C

Data Collection Instrument for Generic *E. coli* Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is/are being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
G-1	√	√	√	N/A	√	√	√	√	No	√
M-1	√	√	√	N/A	√	√	√	√	No	√
K-1	√	√	√	N/A	√	√	√	√	No	√

The sponge method was used for collecting samples for testing, while incision method criteria were used for the evaluation of the test results.

Attachment D

Data Collection Instrument for *Salmonella* species testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* species testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. Salmonella testing is being done in this establishment.

2. Carcasses are being sampled.

3. Ground product is being sampled.

4. The samples are being taken randomly.

5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is being used for sampling.

6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	*1. Testing as required*	*2. Carcasses are sampled*	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
G-1	√	√	N/A	√	√	√
M-1	√	√	N/A	√	√	√
K-1	√	√	N/A	√	√	√

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE	NAME OF FOREIGN LABORATORY
08-23-01	Nagoya Branch

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
MHLW (Ministry of Health,labor and welfare)	NAGOYA,JAPAN	Nagoya

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr.O.Urban	Dr.Kazoo Ohara

	Residue Code/Name ▶			200											
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE												
	Sample Handling	01		A											
	Sampling Frequency	02		A											
	Timely Analyses	03		A											
	Compositing Procedure	04		O											
	Interpret Comp Data	05		O											
	Data Reporting	06		A											
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A											
	Correct Tissue(s)	08		A											
	Equipment Operation	09		A											
	Instrument Printouts	10		A											
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	A											
	Recovery Frequency	12		A											
	Percent Recovery	13		A											
	Check Sample Frequency	14		A											
	All analyst w/Check Samples	15		A											
	Corrective Actions	16		A											
	International Check Samples	17		A											
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	O											
OTHER REVIEW		19	EVAL. CODE												
		20													

SIGNATURE OF REVIEWER

A.P. Smith for Dr. Urban

DATE

8/23/01

Designed on FormFlow Software

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE	NAME OF FOREIGN LABORATORY
08-28-2001	Syokuniku Kosya

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
MHLW	Sawa	Sawa

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr.O.Urban	Dr.Kazuko Ohno

	REVIEW ITEMS	ITEM #		Residue Code/Name ▶ E.C.											
SAMPLING PROCEDURES	Sample Handling	01	EVALUATION CODE	A											
	Sampling Frequency	02		A											
	Timely Analyses	03		A											
	Compositing Procedure	04		O											
	Interpret Comp Data	05		O											
	Data Reporting	06		A											
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A											
	Correct Tissue(s)	08		A											
	Equipment Operation	09		A											
	Instrument Printouts	10		O											
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	O											
	Recovery Frequency	12		O											
	Percent Recovery	13		O											
	Check Sample Frequency	14		O											
	All analyst w/Check Samples	15		O											
	Corrective Actions	16		A											
	International Check Samples	17		O											
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	A											
OTHER REVIEW	E.C. = E.coli generic	19	EVAL. CODE												
		20													

SIGNATURE OF REVIEWER: for Dr. Urban

DATE: 8/28/2001

Designed on FormFlow Software

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE	NAME OF FOREIGN LABORATORY
08-28-2001	Gunma Perfectral Meat Inspection Lab

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
MHLW	Gunma,Sawa,Japan	Sawa

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr.O.Urban	Dr.Kazuko Ohno

			Residue Code/Name ▶	SA											
	REVIEW ITEMS	ITEM #	EVALUATION CODE												
SAMPLING PROCEDURES	Sample Handling	01		A											
	Sampling Frequency	02		A											
	Timely Analyses	03		A											
	Compositing Procedure	04		O											
	Interpret Comp Data	05		O											
	Data Reporting	06		A											
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A											
	Correct Tissue(s)	08		A											
	Equipment Operation	09		A											
	Instrument Printouts	10		O											
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	O											
	Recovery Frequency	12		O											
	Percent Recovery	13		O											
	Check Sample Frequency	14		A											
	All analyst w/Check Samples	15		A											
	Corrective Actions	16		A											
	International Check Samples	17		A											
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	O											
OTHER REVIEW	SA=Salmonella	19	EVAL. CODE												
		20													

SIGNATURE OF REVIEWER

for Oka Ur Sa

DATE

8/25/01

Designed on FormFlow Software

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
8/24/01	G1 Gunma-Kon Shokuniku Oroshiuri Shijo. Co. LTD	Sawa
		COUNTRY: Japan

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Dr. Kazuko Ohno	☐ Acceptable ☒ Acceptable/ Re-review ☐ Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 O
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 U	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 N	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 O
Sanitizers	05 A	Effective maintenance program	33 M	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 O
Pest --no evidence	07 M	Operational sanitation	35 A	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 A	Container closure exam	66 O
Lighting	11 M	Antemortem inspec. procedures	38 A	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 A	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	71 O
Equipment approval	16 O	Condemned product control	43 M	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 M	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 A	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 A	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 M	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 M	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 O
Personal dress and habits	25 A	Boneless meat reinspection	52 A	SSOP	82 M
Personal hygiene practices	26 A	Ingredients identification	53 O	E. coli	83 M
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	8/24/01	G1 Gunma-Kon Shokuniku Oroshiuri Shijo. Co. LTD	Sawa
			COUNTRY Japan

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Dr. Kazuko Ohno	☐ Acceptable ☒ Acceptable/ Re-review ☐ Unacceptable

COMMENTS:

7 Flies and a large spider web were observed on the slaughter floor during preoperational sanitation inspection. These deficiencies were corrected immediately by the establishment management.

11 Light in the ante-mortem inspection area was inadequate. This was scheduled for correction by the establishment.

17 Flaking paint was observed over a product traffic area in the tongue-washing room during preoperational sanitation inspection. This was corrected immediately by the establishment management.

17 Water was observed dripping from the ceiling in the offal wash area. This was corrected by the management.

22 Suspect animals were not physically separated from non-suspect animals. This was scheduled for prompt correction.

24 Much discarded material was observed in the mechanical room (potential pest harborage). Correction was scheduled by the establishment.

29 The employee performing bleeding failed to sanitize his knife after cutting through the skin. This deficiency was corrected by the establishment officials.

29 The employee removing viscera cut through intestine and continue to work without sanitizing his knife. This was corrected by the inspection service.

34 Paint on the conveyor belt and non-dripping condensation on the ceiling were observed in the deboning room during the preoperational sanitation inspection. This was corrected immediately by the establishment management.

34 Dripping condensation was observed over production areas in the offal room during preoperational sanitation inspection. Corrected by the establishment officials.

43 Condemned product was not properly denatured. This procedure was to be corrected by the company.

82 Preventive action was missing in the SSOP program.

83 The sponge method was used for collecting E. coli samples for testing, while incision method criteria were used for evaluation of the test results.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
8/27/01	M1 MiyaTiku Co. LTD	Takasaki
		COUNTRY: Japan

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Dr. Kazuko Ohno	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 O
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 O
Sanitizers	05 A	Effective maintenance program	33 M	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 O
Pest --no evidence	07 M	Operational sanitation	35 A	Processing records	63 O
Pest control program	08 M	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 A	Container closure exam	66 O
Lighting	11 M	Antemortem inspec. procedures	38 A	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 A	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	71 O
Equipment approval	16 O	Condemned product control	43 M	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 A	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 A	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 M	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 O
Personal dress and habits	25 A	Boneless meat reinspection	52 A	SSOP	82 A
Personal hygiene practices	26 A	Ingredients identification	53 O	E. coli	83 M
Sanitary dressing procedures	27 M	Control of restricted ingredients	54 O		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY / COUNTRY
	8/27/01	M1 MiyaTiku Co. LTD	Takasaki / Japan

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Dr. Kazuko Ohno	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

COMMENTS:

7 A fly and a spider web were observed in the slaughter house during preoperational sanitation inspection. These deficiencies were corrected immediately by the establishment management.

8 Rodent poison was used in the cartoon storage room. This was scheduled for correction by the company officials.

11 Light in the ante-mortem and deboning room inspection areas was inadequate. This was corrected immediately by the establishment management.

22 Suspect animals were not physically separated from non-suspect animals. This was scheduled for prompt correction by the company.

27 The employee responsible for head washing did not wash the nostrils. The inspection personal took immediate corrective action.

27 One carcass was contaminated by hair in the cooler. This deficiency was immediately corrected by the establishment officials.

33 Several holes were observed under doors in the product shipping area. This deficiency was scheduled for correction by the establishment management.

34 Paint and dust were observed on a conveyor belt in the packaging room during preoperational sanitation inspection. This was corrected immediately by the company management.

34 Non-dripping condensation was observed in the pre-chill and offal rooms during preoperational sanitation inspection. These deficiencies were corrected by the establishment management.

43 Condemned product was not properly identified and denatured. This procedure was to be corrected by the company.

83 The sponge method was used for collecting E. coli samples for testing, while incision method criteria were used for evaluation of the test results.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
8/28/01	K1 Minamikyusyu Tchikusan Kogyo Co. LTD	Sueyoshi
		COUNTRY: Japan

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Oto Urban	Dr. Kazuko Ohno	☐ Acceptable ☒ Acceptable/ Re-review ☐ Unacceptable

CODES (Give an appropriate code for each review item listed below)
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Pest --no evidence	07 M	Operational sanitation	35 A	Processing records	63 O
Pest control program	08 M	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 M	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 A	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 M	Process. defect actions -- plant	70 O
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Equipment approval	16 O	Condemned product control	43 M	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
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Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 O
Personal dress and habits	25 A	Boneless meat reinspection	52 A	SSOP	82 N
Personal hygiene practices	26 A	Ingredients identification	53 O	E. coli	83 N
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 O		

Attachment G

Inspection and Safety Division
Department of Food Sanitation
Ministry of Health, Labour and Welfare, Japan

18 March 2002

Dr. Sally Stratmoen, Chief
Equivalence
International Policy Staff
OPPDE, FSIS, USDA

Dear Dr. Sally Stratmoen:

Thank you for your kind attention regarding beef exports to the United States.
I would like to provide our opinions to your draft report as follows:

We recommend to:
1) Add the name of Dr.Tesuo Hanamoto, Agricultural Specialist, U. S. Embassy as the participant in the Entrance Meeting. (page 3 of draft final)

2) Headquarters Audit : Change "Inspection and Safety Division to the Division of Export of Meat Products to the United States" to "Veterinary Sanitation Division, Environmental Health Bureau, Ministry of Health and Welfare to Inspection and Safety Division, Department of Food Safety, Ministry of Health, Labour and Welfare". (page 3)

3) Pest Control 1: Change "in all three establishments" to "in G-1 and M-1" of the first sentence, because it was not pointed out at K-1. (page 6)

4) Post-Mortem Inspection Procedures : Insert "in K-1" in the second sentence, because it was pointed out only at K-1. (page 7)

We would confirm that:
5) "Condemned Product" means dead bodies which died in a slaughterhouse before slaughter? (last sentence of page 2)

If you need further information, please do not hesitate to contact me.
Yours Sincerely,

Satoshi Takaya

Satoshi Takaya, DVM
Director
Inspection and Safety Division, Department of Food Safety
Ministry of Health, Labour and Welfare, Japan

Inspection and Safety Division Department of Food Sanitation Pharmaceutical and Medical Safety Bureau Ministry of Health, Labour and Welfare, Japan 1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-8916 phone:81-3-3595-2337 fax:81-3-3503-7964