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

Dr. Nelmon Oliveira da Costa
Director, Department of Inspection
for Products of Animal Origin
Ministry of Agriculture and Provisions
Division of International Commerce Control
Ministry of Agriculture Annex
Block D, 4th Floor, Room 436A
70043-900 Brasilia DF, Brazil

AUG 15 2005

Dear Dr. Costa:

The Food Safety and Inspection Service (FSIS) conducted an on-site enforcement audit of Brazil's meat inspection system March 10 to April 14, 2005. Comments from Brazil have been included as an attachment to the final report. Enclosed is a copy of the final report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-3781, at (202) 690-4040 or electronic mail at sally.white@fsis.usda.gov.

Sincerely,

Sally White

Sally White
Director
International Equivalence Staff
Office of International Affairs

Enclosure

Cc:
William Westman, Agricultural Counselor, US Embassy, Brasilia
Colleen Magro, Trade Specialist, Embassy of Brazil
Robert Macke, Assistant Deputy Administrator, ITP, FAS
Jeanne Bailey, FAS Area Officer
Barbara Masters, Administrator, FSIS
Linda Swacina, Executive Director, FSIA, OIA
Amy Winton, State Department
Karen Stuck, Assistant Administrator, OIA
William James, Deputy Asst. Administrator, OIA
Donald Smart, Director, Program Review, OPEER
Sally White, Director, IES, OIA
Clark Danford, Director, IEPS, OIA
Mary Stanley, Director, IID, OIA
Armia Tawadrous, Director, FSIS Codex Staff, OIA, FSIS
AJ Ogundipe, IES, OIA
Nancy Goodwin, IES, OIA
Country File

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

March 10 through April 14, 2005

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

BSE	Bovine Spongiform Encephalopathy
CCA	Central Competent Authority
DFA	Delegate for Federal Agriculture Office at State Level (Delegacia Federal de Agricultura do Estado)
DIPOA	Department of Animal Product Inspection
E. coli	*Escherichia coli*
FSIS	Food Safety and Inspection Service
MAPA	Ministry of Agriculture, Livestock and Supply (Ministério da Agricultura, Pecuária e Abastecimento)
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
Salmonella	*Salmonella* species
SDA	Agriculture and Livestock Defense Secretariat (Secretaria de Defesa Agropecuária)
SIPA	Animal Product Inspection Service (Serviço de Inspeção de Produtos de Origem Animal)
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures
U.S.	United States
VMO	Veterinary Medical Officer

1. INTRODUCTION

The audit took place in Brazil from March 10 through April 14, 2005.

An opening meeting was held on March 10, 2005, in Brasilia with the Central Competent Authority (CCA), which is the Department of Animal Product Inspection (Departamento de Inspeção de Produtos de Origem) (DIPOA). At this meeting, the Food Safety and Inspection Service (FSIS) audit team confirmed the objective and scope of the audit, the audit itinerary, and requested additional information needed to complete the audit of Brazil's meat inspection system.

The audit team was accompanied during the entire audit by representatives from DIPOA and/or representatives from the Animal Product Inspection Service (Serviço de Inspeção de Produtos de Origem Animal) (SIPA).

2. OBJECTIVE OF THE AUDIT

This audit was an enforcement audit. The objective of the audit was to determine whether Brazil was maintaining an equivalent meat inspection system and may continue to export meat products to the United States (U.S.).

In pursuit of the objective, the following sites were visited: the headquarters of DIPOA located in Brasilia, nine SIPA offices located in different Federal Agriculture Offices at State Level in various parts of Brazil, 11 establishments (audit for payment of inspectors), seven (four government and three private) residue testing laboratories, ten (one government and nine private) microbiological testing laboratories, one cold storage facility, six meat processing establishments, and eight slaughter and processing establishments.

Competent Authority Visits			**Comments**
Competent Authority Visit	Headquarters	1	Brasilia
	SIPA	9	Federal Agric Offices at State level
	Establishments	11	Establishment level for payment of inspector issue.
Residue Laboratories		7	
Microbiology Laboratories		10	
Cold Storage		1	
Processing Establishments		6	
Slaughter and Processing Establishments		8	

3. PROTOCOL

This on-site audit was conducted in five parts. One part involved visits with DIPOA (both at headquarters and SIPA offices) officials to discuss oversight inspection programs including enforcement activities, policies, communication process, organizational structure, and delivery of inspection programs. The second part involved an audit of a selection of records at DIPOA headquarters and nine SIPA offices. The third part involved an audit of eleven establishments for payment of inspectors. The fourth part involved on-site visits to fifteen establishments: eight slaughter and processing establishments, six processing establishments, and one cold storage facility. The fifth part involved visits to seven (four government and three private) residue laboratories, and ten (one government and nine private) microbiology laboratories. All laboratories conduct tests on meat products destined for U.S. export.

Program effectiveness determinations of Brazil's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP) and Sanitation Performance Standards (SPS), (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) programs, and a testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella*, daily inspection, monthly reviews, Bovine Spongiform Encephalopathy (BSE), and inspection system controls. Brazil's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the audit team evaluated the nature, extent and degree to which findings impacted on food safety and public health. The audit team also assessed how inspection services are carried out by the government of Brazil and determined if establishment and inspection system controls were in place to ensure that the meat product exports to the U.S. are safe, unadulterated and properly labeled.

At the opening meeting, the audit team explained to the DIPOA officials that Brazil's meat inspection system would be audited against two standards: (1) FSIS regulatory requirements and (2) any equivalence determinations made for Brazil. 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, Salmonella*, and government oversight/enforcement activities.

Equivalence determinations are those that have been made by FSIS for Brazil under provisions of the Sanitary/Phytosanitary Agreement. Brazil has adopted the FSIS regulatory requirement for *Salmonella* testing with the exception of the following equivalent measures:

1. Establishment employees collect samples.
2. Private laboratories analyze samples.

3. An establishment is suspended the first time it fails to meet a *Salmonella* performance standard.

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 U.S. import requirements listed in 9 CFR 327 and the Pathogen Reduction/HACCP regulations.

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address: http:/www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp

The following deficiencies were identified during the August 2003 audit:

Sanitation Controls

- In eleven establishments audited, SSOP were not effectively implemented.

Slaughter/Processing Controls

- In seven out of eleven establishments, the HACCP requirements were not effectively implemented.
- Carcass brands were not legible on approximately 40% of the carcasses in one establishment.
- No provision for drinking water was available in the suspect pen in one establishment.

Residue Controls

- Brazil was not following their 2003 residue plan.
- No nitrofurazon was being analyzed.
- No iveromectine was being analyzed.
- No chloramphenicol was being analyzed.
- No sulfonamide samples had been collected for 6 months.

- No maintenance records for sample holding temperature were found.

- Recordkeeping in the Porto Alegre laboratory with respect to trace back to standards for TE was incomplete.

- Brazil is not using the FSIS method for Diethylstilbestrol (DES) analysis.

- Brazil is not using the appropriate method for antibiotic testing.

Enforcement Controls

- In more than half the establishments audited, DIPOA inspection personnel were not enforcing FSIS requirements.

- In August 2003, it was found that it was possible for DIPOA to use the services of establishment-paid inspection personnel in the "extreme" situation. In an extreme situation, employees paid by the establishments can be used for inspection purposes.

The following deficiencies were identified during the September 2004 routine audit:

Sanitation Controls

In six establishments, SSOP requirements were not effectively implemented:

- Several small pieces of rail dust on two carcasses were observed at the final trim in the boning room.

- Boxed product had holes punctured in it from a forklift. The product inside had been contaminated.

- Product was contacting the floor in the restricted area of the frozen cooked beef cooler.

- Dripping and beaded condensate from the refrigeration unit, not cleaned and sanitized, was dripping on partially covered exposed product in the cooler.

- Food product contact surface of utensil (shovel) was in contact with the floor in the processing area.

- Plastic bags with edible product had a hole punctured in it from a forklift. The product inside had been contaminated. There was not a process in place to control the product.

- Employee who was assigned to work with edible product was contaminating carcasses by handling product that had been in contact with the floor and with an inedible product container without washing his hands.

In seven establishments, SPS requirements such as sanitary operations, maintenance of equipments and facilities, and pest control were not effectively implemented:

- Walls within the facility were damaged or had holes in them from forklifts.
- Boxed product within the facility was covered with frozen condensate or ice.
- Unidentified plastic wrapped poultry product was stored on top of boxes.
- Heavily beaded condensate was observed over boxed product way.
- No sanitizers were available in the inspection room to sanitize the knife or saw used for inspection.
- Gaps were observed at the bottoms and sides of doors in the shipping room.

Residue Controls

- In both government laboratories, there was no calibration of equipment and no inter-laboratory check sample program.
- Brazil is not using the FSIS method for DES analysis.

Enforcement Controls

- Auditor was informed that payment of inspectors is handled by Federal Agriculture Offices at State level.

6. MAIN FINDINGS

6.1 Government Oversight

The office of DIPOA in Brasilia is under the umbrella of the Ministry of Agriculture, Livestock and Supply (Ministério da Agricultura, Pecuária e Abastecimento (MAPA)). The Director, DIPOA reports to the office of Agriculture and Livestock Defense Secretariat (Secretaria de Defesa Agropecuária (SDA)) which is equivalent to USDA, office of Under Secretary for Food Safety. DIPOA, Brazil's CCA, is responsible for providing government oversight of Brazil's meat inspection programs. The International Export and Import Programs Coordnation Division is one of the offices in DIPOA and it has broad responsibility: develop and manage export and import programs and policies inluding auditing procedures and certification of new establishments; manage regulation and rule making process; develop and manage field implementation strategies for FSIS food safety requirements; and coordinate field inspection activities nationwide.

Each state in Brazil has a Delegate for Federal Agriculture Office at State Level (Delegacia Federal de Agricultura do Estado (DFA)). Federal Delegates, also referred to as Federal Superintendents, are polical appointees of Minister of Agriculture. SIPA is located in the office of DFA. The Chief of SIPA is responsible for direct implementation

of U.S. requirements and inspection oversight activities over establishments certified for U.S. export.

6.1.1 CCA Control Systems

The Chief of SIPA reports directly to DFA in the states. DFA reports to the Minister of Agriculture. DFA controls budget inluding appropriation of funds for various programs and makes decision about which programs are to be funded.

It appeared that organizational structure did not facilitate the effective supervision of inspection activities at the establishment levels. SIPA organizational structure varies from one office of DFA to another depending on size and strength of the mission. Some SIPA offices do not have regional offices and the Chief of SIPA only needs approval of DFA to establish regional offices. SIPA with regional offices have regional coordinators with no supervisory authority to officially rate job performances and provide feedback to inspectors.

DIPOA did not have direct oversight of the laboratories. The national residue coordinator, who is responsible to develop, plan, and direct Brazil residue programs, does not report to DIPOA. The national laboratory coordinator, who is responsible for oversight of all laboratories including microbiology and residue laboratories, does not report to DIPOA.

6.1.2 Ultimate Control and Supervision

DIPOA and SIPA officials did not demonstrate that they have effective oversight that would facilitate accountability of SIPA inspection officials and effective supervision of inspection activities. DIPOA auditing procedures in place were not effective. Audit reports for the establishments that were delisted or received an NOID did not reflect actual establishment condition. DIPOA was unable to demonstrate how they use audit information or findings to improve its meat inspection system. SIPA did not demonstrate effective supervision of inspectors. Regional coordinators did not have supervisory authority to officially rate job performances and provide feedback to inspectors.

6.1.3 Assignment of Competent, Qualified Inspectors

Although DIPOA demonstrated that it had training programs for newly hired official Veterinary Medical Officers (VMO), it did not have a national training policy for all inspectors. DIPOA and SIPA were unable to demonstrate the existence of effective training programs to ensure continued inspector skills and competency. DIPOA and SIPA did not have training programs for auxiliary inspectors (both official and non-official). DIPOA and SIPA were unable to demonstrate it had a mechanism in place to determine the training needs of inspectors.

6.1.4 Authority and Responsibility to Enforce the Laws

The sanitation, slaughter and processing inspection procedures and standards, and legal authority to enforce these requirements, are outlined and specified in Brazil inspection law referred to as RIISPOA in section 1.283, article 876. DIPOA and SIPA have the

authority and responsibility to enforce the inspection laws. However, fourteen establishments audited had inadequate enforcement of U.S. inspection requirements. DIPOA inspection officials and establishment officials relied on the FSIS auditor to identify non-compliance with U.S. requirements. DIPOA inspection officials were not proactively identifying non-compliances with HACCP, SSOP, and SPS requirements and verifying the HACCP and SSOP records.

6.1.5 Adequate Administrative and Technical Support

It does not appear that Brazil has adequate technical support for its inspection program, as evidenced by the serious deficiencies noted in the residue and microbiological laboratories.

6.2 Headquarters Audit

The audit team conducted a review of the headquarters to determine whether DIPOA has effective government oversight and enforcement strategies such as program development, policies, delivery of inspection and implementation strategies, auditing process, and communication process in place to support and operate Brazil's meat inspection system. In pursuit of this, FSIS interviewed seven key officials from DIPOA and MAPA. Various supporting records and documents related to inspection programs and policies were examined and verified to confirm DIPOA officials' responses and claims.

6.3. Audit of SIPA and Local Inspection Sites

SIPA offices are responsible for direct implementation of U.S. requirements and inspection oversight activities over establishments certified for U.S. export. The audit team conducted reviews of nine SIPA offices to determine the effectiveness of delivery of inspection programs and policies and implementation strategies. In pursuit of this, FSIS inverviewed twenty-one key officials in nine SIPA offices. The following SIPA offices were audited:
Office in Porto Alegre, Rio Grande do Sul State
Office in Florianpolis, Santa Catarina State
Office in Sao Paulo, Sao Paulo State
Office in Curitiba, Parana State
Office in Campo Grande, Mato Grasso do Sul State
Office in Cuiaba, Mato Grosso State
Office in Goiania, Goias State
Office in Belo Horizonte, Minas Gerais State
Office in Rio de Janerio, Rio de Janerio State
Various supporting records and documents related to field inspection oversight activities were examined and verified to confirm SIPA officials' responses and claims.

In addition, FSIS interviewed thirty-four Meat Inspectors (Veterinary Medical Officers and Auxiliary Inspectors) assigned to eleven different establishments in nine SIPA offices to determine the effectiveness of government oversight of payment of inspectors. Various supporting records and documents such as employment, payroll, time and attendance, budget, benefits, and applicable law and regulations were examined and verified to confirm inspection officials' responses and claims. Specific audit findings

related to payment of inspectors are described in section 13.5 "Inspection System Controls".

7. ESTABLISHMENT AUDITS

The FSIS audit team reviewed a total of 15 establishments; eight beef slaughter and processing establishments, six beef processing establishments, and one cold storage facility. Three establishments were delisted for failure to meet U.S. requirements. Ten establishments received a NOID for not effectively implementing HACCP, SSOP and SPS requirements.

Specific deficiencies are noted in the attached Foreign Establishment Audit Checklists.

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.

8.1 RESIDUE LABORATORY AUDIT

Seven (four government and three private) residue testing laboratories that conduct residue tests on meat products destined for U.S. export were audited. 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.

The following deficiencies were noted:

- Five laboratories had multiple deficiencies in meeting FSIS requirements.
- Five laboratories were deficient in analytical procedures by not using acceptable FSIS methods to analyze samples.
- Five laboratories were deficient in quality assurance procedures.
- Internal check samples for analytical methods within the laboratories were not performed.
- Three laboratories did not implement corrective actions to address previously identified deficiencies.
- No procedures to audit private laboratory analyses.
- Private laboratories used unapproved methods for DES detection.
- Unapproved screen test was being used for antibiotic detection.

The specific deficiencies are noted in the attached Foreign Country Laboratory Review report (FSIS Form 9520-4).

8.2 MICROBIOLOGY LABORATORY AUDIT

Ten (one government and nine private) microbiological testing laboratories that conduct tests on meat products destined for U.S. export were audited. 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 U.S. samples, then FSIS evaluates compliance with the criteria established for the use of private laboratories under the FSIS PR/HACCP requirements.

The following deficiencies were noted:

- Two private laboratories that conduct microbiological testing on U.S.-destined product were suspended for not being certified by the government of Brazil.
- All ten microbiological laboratories audited had multiple deficiencies in meeting FSIS requirements.
- Sample integrity was not maintained throughout the process in all the laboratories.
- Chain of custody for handling and storage of samples was not effective.
- Internal check samples within the laboratories were not performed.
- No procedure was in place to identify and separate U.S. product samples from other samples.
- No training procedures were in place for analysts to enhance their skills and competency.
- Laboratories were not adequately staffed.

9. SANITATION CONTROLS

As stated earlier, the FSIS focused on five areas of risk to assess Brazil's meat inspection system. The first of these risk areas that the audit team reviewed was Sanitation Controls.

Based on the on-site audits of establishments, Brazil's inspection system did not have effective sanitation controls.

9.1 Sanitation Standard Operating Procedures

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the United States' domestic inspection program. In fourteen establishments, SSOP requirements were not effectively implemented:

- Establishment officials did not maintain daily SSOP records sufficient to document the implementation and monitoring of SSOP and corrective actions.
- For identified SSOP non-compliances, establishment officials did not properly address and document corrective actions.
- Dripping condensate from overhead structures was falling on exposed products, on product contact surfaces, and on areas where exposed products were handled.
- Establishments' corrective actions did not address preventive measures and procedures to ensure appropriate disposition of products that may be contaminated.
- Contaminated water was dripping directly on exposed beef carcasses in different locations during slaughter operations.
- During slaughter operations, exposed beef carcasses were in contact with different non-food contact equipment, utensils, ladders, and inedible containers. In addition, exposed beef carcasses were in contact with the floor, not cleaned and sanitized, in different production areas.

- No records to demonstrate that establishments had been routinely evaluating the effectiveness of SSOP in preventing direct contamination or adulteration of products.
- No documentation records for non-compliance with SSOP.
- Establishment officials were not performing daily pre-operational sanitation in ready-to-eat (RTE) processing room as required by SSOP.
- Product residues from previous days' operations were observed on food product contact surfaces and various equipments in different production areas.

9.2 Sanitation Performance Standards

Each establishment was evaluated to determine if the FSIS regulatory requirements for SPS were met according to the criteria employed in the United States' domestic inspection program. Seven establishments did not meet SPS requirements:

- Facilities were not properly maintained to prevent conditions that could lead to insanitary conditions and to preclude entrance of flies and vermin such as mice.
- Beef washing cabinet was not maintained to prevent insanitary conditions and adulteration of product.
- Employees working in contact with product did not adhere to hygienic practices to prevent cross contamination of product.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS audit team reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. No deficiencies were observed.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS audit team reviewed was Slaughter/Processing Controls. The controls include the following areas: humane handling and slaughter of animals, 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 Procedure

DIPOA inspection officials did not fully implement the FSIS requirements regarding post-mortem inspection slaughter procedures in seven establishments:

- DIPOA inspection officials were not properly performing post-mortem inspection activities such as head and beef lung inspection.
- During slaughter operations, establishment officials were not maintaining adequate temperature of sanitizers.

- Ineffective sanitizers were being used in slaughter operations to sanitize knives, creating a cross contamination hazard.

11.2 HACCP Implementation.

Fourteen establishments approved to export meat products to the United States were required to have developed and adequately implemented a HACCP program. The one cold storage establishment reviewed was not required to implement HACCP systems. 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 14 establishments. In 14 establishments, HACCP requirements were not effectively implemented:

- HACCP plans did not adequately specify monitoring procedures for each critical control point (CCP) to ensure compliance with critical limits.
- HACCP plans did not specify verification procedures and the frequency those procedures will be performed.
- Establishment officials were not performing verification procedures.
- HACCP plans did not address all the elements of corrective actions specified in the HACCP requirements including cause of deviations and preventive measures to prevent recurrence.
- HACCP records documenting the monitoring of CCP's and verification did not include the recording of actual values, critical limits, time, initials or signature.

11.3 Testing for Generic *E. coli*

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

Eight of the 15 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. No deficiencies were observed.

11.4 Testing for *Listeria monocytogenes*

Eleven establishments audited were producing ready-to-eat products including commercially sterile products for export to the U.S. Six establishments were producing commercially sterile products, which are not subject to the testing requirements for *Listeria monocytogenes*. Specific deficiencies regarding *Listeria monocytogenes* are noted in the attached Foreign Establishment Audit Checklists.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS audit team 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. Specific audit

findings related to residue controls are described in section 8.1 "Residue Laboratory Audit".

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS audit team reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements, the testing program for *Salmonella*, daily inspection, monthly reviews, and inspection system controls (Bovine Spongiform Encephalopathy (BSE) and payment of inspectors)

13.1 Daily Inspection in Establishments

In one establishment, DIPOA did not conduct government inspection oversight activities for the products produced during second and third shifts.

13.2 Testing for *Salmonella*

Brazil has adopted the FSIS requirements for testing for *Salmonella* with the exception of the following equivalent measures:

- Establishment employees collect *Salmonella* samples.
- Samples are analyzed in private laboratories.
- Brazil suspends an establishment the first time it fails to meet a *Salmonella* performance standard.

Establishments audited were required to meet the above FSIS approved Sanitary and Phytosanitary equivalent measures for *Salmonella* testing and were evaluated according to the above criteria. The following deficiencies were observed:

- In eight establishments, DIPOA did not follow FSIS approved equivalence standard for *Salmonella* testing.
    - DIPOA inspection officials collected Salmonella samples, instead of establishment personnel.
    - DIPOA did not suspend establishments for the first time they failed to meet the *Salmonella* Performance Standard, as specified in the approved equivalence standard.

13.3 Species Verification

Brazil is exempt from species verification testing and is following all controls to maintain the exemption.

13.4 Monthly Reviews

Supervisory monthly review procedures were not effective:

- Supervisory monthly reviews did not adequately address inspection oversight activities of inspectors at the establishment level.

- Supervisory monthly review for the establishments that were delisted or received an NOID did not reflect actual establishment conditions.
- DIPOA did not have adequate oversight of supervisory monthly reviews.
- No procedure in place for trend analysis of supervisory monthly reviews to determine enforcement action options for recurring non-compliances.
- Non-supervisory staffs at SIPA that conduct supervisory monthly reviews had no training to perform these activities.

13.5 Inspection System Controls

Eight of the 15 establishments audited were required to meet the basic FSIS regulatory requirements by implementing preventive procedures for Bovine Spongiform Encephalopathy (BSE). They were evaluated according to the criteria employed in the United States' domestic inspection program. The BSE preventive procedures were reviewed during the on-site audits of the eight establishments. In eight establishments, DIPOA inspection officials did not effectively implement BSE requirements:

- DIPOA inspection officials did not collect a brain sample for BSE analysis of a cow that died once it arrived at the establishment.
- There were no procedures to remove, segregate, and dispose of "specified risk materials" (SRM).
- Establishments were not maintaining daily records to document monitoring and verification procedures.
- DIPOA inspection officials were unable to demonstrate they were performing verification inspection activities of BSE procedures.

Government of Brazil (GOB) was required to demonstrate that all government inspectors assigned to establishments certified for U.S. exports to perform inspection duties were being paid by government. In pursuit of this, FSIS interviewed thirty-four Meat Inspectors (Veterinary Medical Officers and Auxiliary Inspectors) assigned to eleven different establishments in nine SIPA offices to determine the effectiveness of government oversight over payment of inspectors. DIPOA and SIPA did not demonstrate that they have control and oversight over the payment of non- federal inspectors (inspectors loaned from municipal government) working in certified establishments:

- There was no uniform method of hiring and providing salaries for contracted inspection officials in establishments.
- All employees (both permanent and contracted) are allowed to eat free or at a subsidized rate at the establishment cafeteria/restaurant and most official inspectors take advantage of this benefit.
- A few official inspectors receive free transportation and either free or subsidized housing from some establishments.
- All official inspectors were getting free medical check ups, initial medical treatment and advice from the establishment physicians.
- Establishment physicians are authorized to recommend placing inspectors on sick leave and DIPOA had to honor recommendations of the establishment physician.

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.

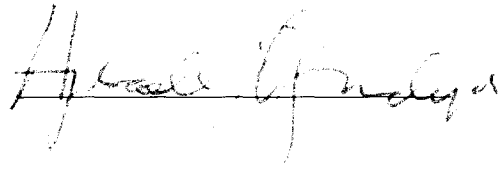
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on April 14, 2005, in Brasilia with the CCA. At this meeting, the preliminary findings and conclusions from the audit were presented by the lead auditor.

The CCA understood the findings and responded that they will provide comments at later date.

AJ Ogundipe
Lead Auditor



15. ATTACHMENTS

Individual Foreign Establishment Audit Forms
Foreign Country Response to Draft Final Audit Report

FEDERAL REPUBLIC OF BRAZIL
MINISTERIO DA AGRICULTURA PECUÁRIA E ABASTECIMENTO – MAPA [FEDERAL DEPARTMENT OF LIVESTOCK AND SUPPLY]
SECRETARIA DE DEFESA AGROPECUÁRIA – SDA [OFFICE OF THE SECRETARY FOR FARMING/RANCHING DEFENSE]
DEPARTAMENTO DE INSPEÇÃO DE PRODUTOS DE ORIGEM ANIMAL – DIPOA [DEPARTMENT FOR INSPECTION OF PRODUCTS OF ANIMAL ORIGIN]
COORDENAÇÃO GERAL DE PROGRAMAS ESPECIAIS –CGPE [COORDINATING OFFICE FOR SPECIAL PROGRAMS]

NOTICE No. 187/**CGPE/DIPOA/05** **Brasilia,** 02 August **2005**

Dear Advisor:

I am happy to send greetings and at the same time to request your help in the sense of forwarding to Ms. Sally White, Director of International Equivalence of the USDA/FSIS, the following comments, in relation to the *"DRAFT FINAL REPORT OF AN AUDIT CARRIED OUT IN BRAZIL COVERING BRAZIL'S MEAT INSPECTION SYSTEM – March 10 through April 14, 2005"*.

The DIPOA understands that the matter was [?scrutinized?] in the letter of 5 May 2005, from Dr. Gabriel Alves Macini, Secretary for Farming/Ranching Defense of the MAPA, to Dra. Vierie D. Pierson, communicating therein the decision of the DIPOA to suspend, voluntarily, exports of meat products to the United States of America until the review of the inspection system to achieve equivalence with American legislation.

Finally, we understand that, after the performance of two other audits carried out by American technicians with satisfactory results and the consequent normalizing of exports of meat products to the United States, there is nothing to add.

Sincerely,

[signature]
Nelmon Oliveira da Costa
Director of the DIPOA/SDA/MAPA

To:
Mr. William Westman
Agricultural Affairs Advisor
Embassy of the United States of America
SES – Avenida das Nações, Quadra 801, lote 3
70403-900 Brasilia, DF

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
Ferreria International Ltd. Tres Rios Rio de Janeiro	04/04/2005	SIF 0013	BRAZIL
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	X
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.	X
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	X
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	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	O
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	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	X
58. Notice of Intend to Delist (NOID)	X
59.	

60. Observation of the Establishment

Establishment # SIF 0013 Date: 04/04/2005 Processing Operation

12/51. Dripping condensate, from overhead exhaust system directly connected to blancher that was not cleaned/sanitized daily, was falling into the product. Establishment officials stopped the blanching operation to restore sanitary conditions and to prevent the recurrence of direct contamination or adulteration of products but neither Government of Brazil (GOB) officials nor Establishment personnel took corrective actions to ensure appropriate disposition of products. 9 CFR 416.15
13/51.a) The daily pre-operational and operational sanitation SSOP deficiencies were not specified and the corrective actions did not include: 1) to ensure appropriate disposition of products that may be contaminated; 2) to prevent recurrence of direct product contamination or adulteration. 9 CFR 416.16
18/51. Procedures to monitor Critical Control Point (CCP 1B) were not described in the HACCP plan how to monitor the CCP to ensure compliance with the critical limits. 9 CFR 417.2(c)(4)
19/51. Establishment ongoing verification activities did not include: a) direct observations of monitoring activities and corrective actions. 9 CFR 417.4(a)(2)(ii)
20/51. Corrective actions to be followed in response to a deviation from a critical limit did not include in the HACCP plan such as: 1) the cause of deviation is identified and eliminated; 2) measures to prevent recurrence are established; and (3) no product that is injurious to health or otherwise adulterated as a result of deviation enters commerce. 9 CFR 417.3(a)(1)(3)(4)
51. a) GOB meat inspection officials verification did not include verifying monitoring and corrective actions of the HACCP plan(s) for the 1st shift operation such as: 1) reviewing and determining the adequacy of corrective actions taken when a deviation occurs; 2) direct observation or measurement at a CCP. 9 CFR 417.8 (c)(f).
b) GOB meat inspection officials were not verifying the monitoring, corrective actions, record keeping, and plant verification of the HACCP plan(s) for the second shift operation such as: a) reviewing the HACCP plan; b) reviewing the CCP records; c) reviewing and determining the adequacy of corrective actions taken when a deviation occurs; d) reviewing the critical limits; e) reviewing other records pertaining to the HACCP plan or system; f) direct observation or measurement at a CCP; g) sample collection and analysis to determine the product meets all safety standards; and h) on-site observations and record review. 9 CFR 417.8
c) GOB inspection officials did not follow-up the preventive measures (to prevent the recurrence of direct contamination or adulteration of product) to be taken by the establishment for the identified deficiencies in the pre-operational and operational sanitation SSOP verification. CFR 416.17
57/51. In the monthly supervisory review GOB inspection officials did not address the above deficiencies. 9 CFR 416.17 and 417.8
58. GOB meat inspection officials gave a Notice of Intend to Delist (NOID) to Establishment SIF 0013 regarding the inadequate implementation requirements for SSOP, HACCP, and Government Oversight Enforcement, effective April 4, 2005. GOB inspection official is to evaluate the adequacy of corrective actions and provide a full report to FSIS.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Faizur R. Choudry, DVM	4/18/05

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
FRIBOI Ltda. Barretoes, Sao Paulo	03/14/2005	SIF 0076	Brazil
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faizur R. Choudry, 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.	X
13. Daily records document item 10, 11 and 12 above.	X
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.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

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

60. Observation of the Establishment

Establishment # SIF 0076 Date: 03/14/2005 Processing Operation

12/51. a) Product (meat) residue was observed on food-contact surfaces of two mixers ready-for-use for 6 pound can corned beef and pipes from previous day's operation. 9 CFR 416.15
b) Numerous metal containers with open gaps and rough cracked edges had product residues from previous day's operation in the processing room. Build-up of rust, dirt and product residue from previous day's operation was observed on numerous baskets and racks in the processing room. Neither establishment nor Government of Brazil (GOB) inspection officials took corrective actions. 9 CFR 416.15
13/51. The daily pre-operational and operational Sanitation Standard Operational Procedure (SSOP) records did not document the corrective actions properly for identified deficiencies such as: to ensure appropriate disposition of products that may be contaminated and prevent recurrence of direct product contamination or adulteration. 9 CFR 416.16
22/51. The establishment failed to record appropriate corrective actions in response to a deviation from a critical limit (biological contamination in seaming can CCP # 3), establishment did not follow written procedure(s) in HACCP plan such as: records document corrective actions taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. 9 CFR 417.3(a (1)(2)(3)(4)
39/51. Gaps at the bottoms and sides of doors and open seams between wall panels in two storage rooms for can corned beef were not sealed properly to prevent the entry of rodents and other vermin. Numerous ants were observed. 9 CFR 416.2(b)(3)
41/51. Gaps at the junction of walls and ceilings were not sealed properly to prevent the entry of rodents and other vermin in the potable water tank. 9 CFR 416.2(g)(1)
43/51. Dripping condensate, from overhead lift for beef carcasses ready for use, was falling in the carcass receiving room. Establishment officials took corrective actions immediately. 9 CFR 416.2
47/51. One employee did not observe good hygienic work habits to prevent direct product contamination such as: collecting rubbish from the floor and without washing hands, handled edible product in the processing room. Neither establishment nor GOB inspection officials took corrective actions. 9 CFR 416.5(a)
51. a) GOB meat inspection officials verification did not include verifying the monitoring and corrective actions of the HACCP plan(s) for the 1st shift operation such as: 1) reviewing and determining the adequacy of corrective actions taken when a deviation occurs; 2) direct observation or measurement at a CCP. 9 CFR 417.8 (c)(f).
b) GOB meat inspection officials were not verifying the monitoring, corrective actions, record keeping, and plant verification of the HACCP plan(s) for the second shift operation such as: a) reviewing the HACCP plan; b) reviewing the CCP records; c) reviewing and determining the adequacy of corrective actions taken when a deviation occurs; d) reviewing the critical limits; e) reviewing other records pertaining to the HACCP plan or system; f) direct observation or measurement at a CCP; g) sample collection and analysis to determine the product meets all safety standards; and h) on-site observations and record review. 9 CFR 417.8
c) GOB inspection officials did not specify the identified deficiencies and corrective actions taken were not verified for pre-operational and operational sanitation SSOP. CFR 416.17
57/51. In the monthly supervisory review GOB inspection officials did not address the above deficiencies. 9 CFR 416.17 and 417.8
58. GOB meat inspection officials gave a Notice of Intend to Delist (NOID) to Establishment SIF 0076 regarding the inadequate implementation requirements for SSOP, SPS, HACCP, and Government Oversight Enforcement, effective March 14, 2005. GOB inspection official is to evaluate the adequacy of corrective actions and provide a full report to FSIS.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Faizur R. Choudry, DVM	4/18/05

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
Pampeano Alimentos S/A Fabricas de Conservas Hulha Negras, Rio Grande do Sul	03/31/2005	SIF 0226	Brazil
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	O
35. Residue	O
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	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	X
58. Delisted	X
59.	

60. Observation of the Establishment

Establishment # SIF 0226 Date: 03/31/2005 Processing Operation

12/51. Product (meat) residue, grease, and black particles were observed on food-contact surfaces of one can corned filling machine and pipe from previous day's operation in the processing room. Neither establishment nor Government of Brazil (GOB) inspection officials took corrective actions. 9 CFR 416.15

13/51. The daily pre-operational and operational Sanitation Standard Operational Procedures (SSOP) records did not document the corrective actions properly for identified deficiencies such as: to ensure appropriate disposition of products that may be contaminated and prevent recurrence of direct product contamination or adulteration. 9 CFR 416.16

18/51. The Critical Limits (CL) identified in the hazard analysis for physical hazards (plastic, wood, glass, etc), and biological hazards (fecal materials) were not controlled under separate Critical Control Points (CCP) to prevent, eliminate or to reduce to an acceptable levels. The physical and biological hazards were controlled under a single CCP 1B. 9 CFR 417.2(c)(3)

19/51. Establishment officials were not performing ongoing verification activities at the frequency written in the Hazard Analyses Critical Control Points (HACCP) for CCP 2B. 9 CFR 417.4(a) 2

20/51. The corrective actions to be followed in response to a deviation from a critical limit did not include: 1) the cause of deviation is identified and eliminated; 2) the CCP will be under control after the corrective action is taken; and 3) measures to prevent recurrence are established. 9 CFR 417.3(a)(1)(2)(3)

22/51. Records documenting the monitoring and ongoing verification of critical control points did not include the actual values, critical limits, time, and initial or signature. 9 CFR 417.5

51. a) GOB meat inspection officials verification did not include verifying monitoring and corrective actions of the HACCP plan(s) for the 1st shift operation such as: 1) reviewing and determining the adequacy of corrective actions taken when a deviation occurs; 2) direct observation or measurement at a CCP. 9 CFR 417.8 (c)(f).

b) GOB meat inspection officials were not verifying the monitoring, corrective actions, record keeping, and plant verification of the HACCP plan(s) for the second shift operation such as: a) reviewing the HACCP plan; b) reviewing the CCP records; c) reviewing and determining the adequacy of corrective actions taken when a deviation occurs; d) reviewing the critical limits; e) reviewing other records pertaining to the HACCP plan or system; f) direct observation or measurement at a CCP; g) sample collection and analysis to determine the product meets all safety standards; and h) on-site observations and record review. 9 CFR 417.8

c) GOB meat inspection officials were not verifying the effectiveness of the sanitation SSOP for the second shift operation. 9 CFR 416.17

d) GOB inspection officials were not specifying the identified deficiencies and were not verifying the corrective actions taken to ensure appropriate disposition of products that may be contaminated and prevent recurrence of direct product contamination or adulteration for pre-operational and operational sanitation SSOP. 9 CFR 416.16

57/51. In the monthly supervisory review GOB inspection officials did not address the above deficiencies. 9 CFR 416.17 and 417.8

58. Due to noncompliance with implementation of SSOP, HACCP, and lack of enforcement requirements by the GOB meat inspection officials and the status of this establishment is not equivalent to that required in the U.S. program. Establishment SIF 0226 was given a Notice of Indent to Delist (NOID) during the last audit in 2004. All the above deficiencies were discussed with GOB meat inspection officials and they agreed to remove Establishment SIF 0226 from the list of establishments eligible to export meat and meat products to the United States, effective March 31, 2005.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Faizur R. Choudry, DVM	4/18/05

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
Bertin Ltda, Lins, Sao Paulo	03/22. 23/2005	SIF 0337	Brazil
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	X
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.	X
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.	X
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	X
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	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	X
58. *Listeria monocytogenes (LM)* & BSE	X
59. Notice of Intend to Delist (NOID)	X

60. Observation of the Establishment

Establishment # SIF 0337 Date: 03/22, 23/2005 Slaughter/Processing Operations

13/51. The daily pre-operational and operational SSOP records did not document the corrective actions properly for identified deficiencies such as: to ensure appropriate disposition of products that may be contaminated and prevent recurrence of direct product contamination or adulteration. 9 CFR 416.16

21/51/58. Government of Brazil (GOB) did not verify that the establishment has reassessed its hazard analysis to determine what steps, if any, are necessary to ensure that its products are free of Specific Risk Materials (SRMs) and DIPOA did not instruct the Veterinarian-in-Charge to verify Bovine Spongiform Encephalopathy (BSE) program. b) Tonsils were being removed by the GOB inspectors and there were no verification records of proper removal of SRMs. 9 CFR 417.4(a)(3)

c) GOB was not documenting any records for the verification and noncompliance of establishment written procedures for the complete and proper removal of SRMs. d) SRMs go to inedible rendering but sometime spinal card and brain are used as human food for the domestic or overseas market. Establishment does not have documented procedures (spinal card and brain when saved for human food) for the identification, segregation, and prevention of commingling with edible products. 9 CFR 310.22(d)(1)(2)

e) All non-ambulatory animals are condemned at ante-mortem but Veterinarian-in-Charge is not required to sample for BSE except for Central Nervous System (CNS) animals. 9 CFR 309.4 and13

30/51 FSIS has granted Brazil an equivalence determination allowing them to use establishment employees collect *Salmonella* samples and Brazil suspends an establishment the first time it fails to meet a *Salmonella* performance standard. GOB has changed the equivalence determination criteria on March 13, 2002, under the Circular 113/2002 DCI/ DIPOA. It was not submitted to OIA, Washington, D.C, for equivalence determination prior to change. Brazil suspends an establishment the third time it fails to meet a *Salmonella* performance standard and the government inspectors collect the sample. 9 CFR 310.25

46/51. Rubber seal deteriorated and with black discoloration was observed in the beef carcass washing cabinet during pre-operational sanitation. Establishment official took corrective actions immediately. 9 CFR 416.4(b)

51. a) GOB meat inspection officials verification did not include verifying monitoring and corrective actions of the HACCP plan(s) for the 1st shift operation such as: 1) reviewing and determining the adequacy of corrective actions taken when a deviation occurs; 2) direct observation or measurement at a CCP. 9 CFR 417.8 (c)(f).

b) GOB meat inspection officials were not verifying the monitoring, corrective actions, record keeping, and plant verification of the HACCP plan(s) for the second shift operation such as: a) reviewing the HACCP plan; b) reviewing the CCP records; c) reviewing and determining the adequacy of corrective actions taken when a deviation occurs; d) reviewing the critical limits; e) reviewing other records pertaining to the HACCP plan or system; f) direct observation or measurement at a CCP; g) sample collection and analysis to determine the product meets all safety standards; and h) on-site observations and record review. 9 CFR 417.8

c) GOB inspection officials did not follow-up the preventive measures (to prevent the recurrence of direct contamination or adulteration of product) to be taken by the establishment for the identified deficiencies in the pre-operational and operational sanitation SSOP verification. CFR 416.17

55/51. The middle and anterior mediastinal lymph nodes of lungs were not incised during post-mortem inspection. 9 CFR 310

57/51. In the monthly supervisory review GOB inspection officials did not address the above deficiencies. 9 CFR 416.17 and 417.8

58/51. Establishment is producing Ready-to-Eat (RTE) product (beef jerky and cooked and frozen beef) and *Listeria monocytogenes* (*LM*) was not addressed in its HACCP plan hazard reasonably likely to occur. However, establishment is analyzing *LM* samples for testing of food contact surfaces in the post-lethality processing environment to ensure the surfaces are sanitary and free of *L. monocytogenes* and for the RTE product. FSIS Directive 10,240.4

59. GOB meat inspection officials gave a Notice of Intend to Delist and suspended Establishment SIF 0337 regarding the inadequate implementation requirements for SSOP, HACCP, BSE, and Government Oversight Enforcement, effective April 13, 2005. GOB inspection official is to evaluate the adequacy of corrective actions and provide a full report to FSIS.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Faizur R. Choudry, DVM	4/18/05

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
Friboi Ltda, Andradina, Sao Paulo	03/16/2005	SIF 0385	BRAZIL
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faizur R. Choudry, 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.	X
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	X
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.	X
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	X
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	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	X
58. BSE	X
59. Delisted	X

60. Observation of the Establishment

Establishment # SIF 0385 Date: 03/16/2005 Slaughter/Processing Operation

11/51. Establishment officials were not routinely evaluating the adequacy and effectiveness of the Sanitation Standard Operating Procedures (SSOP) to prevent direct product contamination. There were no records of any deficiencies concerning SSOP for a few weeks. 9 CFR 416.14.

12/51. a) Numerous sanitizers were not maintained at the required temperature (82°C) in the slaughter room. The Government of Brazil (GOB) inspection officials took corrective actions immediately and stopped the slaughter operation approximately for ½ an hour. b) Dripping condensate, from overhead pipes, beams, carcass rails, and ceilings that was not cleaned/sanitized daily, was falling onto beef carcasses in cooler # 7 and 10. GOB inspection officials took corrective actions immediately. c) Meat hooks were found with black discoloration and grease ready for use in the beef hook cleaning room. d) Dripping condensate, from overhead exhaust system that was not cleaned/sanitized daily, was falling onto one continuous cooker and into the product. GOB inspection officials took corrective actions immediately. e) Pieces of meat and product residue from previous day's operation were observed on food-contact surfaces of mixer paddles in two mixers used for can corned beef. Dark colored product residue inside of pipes from previous day's operation which was connecting the mixer to a can filling hopper was observed. FSIS had received a consumer complaint that a 12 oz can of corned beef contents were found dark in color and with a putrid off odor. f) The skinned beef heads and tails were contacting dirty hide puller chain at the hide removal station. The establishment officials took corrective actions temporarily. 9 CFR 416.15

13/51. The daily pre-operational and operational SSOP corrective actions did not include: 1) to ensure appropriate disposition of products that may be contaminated; 2) to prevent recurrence of direct product contamination or adulteration. 9 CFR 416.16

21/51/58. The GOB inspection officials did not verify that the establishment has reassessed its hazard analysis to determine what steps, if any, are necessary to ensure that its products are free of Specific Risk Materials (SRMs) and GOB did not instruct the Veterinarian-in-Charge to verify Bovine Spongiform Encephalopathy (BSE) program. b) Tonsils were being removed by the GOB inspectors and there were no verification records of proper removal of SRMs. 9 CFR 417.4(a)(3)

c) GOB inspection officials were not documenting any records for the verification and noncompliance of establishment written procedures for the complete and proper removal of SRMs. d) SRMs go to inedible rendering but sometime spinal card and brain are used as human food for the domestic or overseas market. Establishment does not have documented procedures (spinal card and brain when saved for human food) for the identification, segregation, and prevention of commingling with edible products. 9 CFR 310.22(d)(1)(2)

e) All non-ambulatory animals are condemned at ante-mortem but GOB inspection officials are not required to sample for BSE except for Central Nervous System (CNS) animals. 9 CFR 309.4 and13

30/51. FSIS has granted Brazil an equivalence determination allowing them to use establishment employees collect *Salmonella* samples and Brazil suspends an establishment the first time it fails to meet a *Salmonella* performance standard. GOB has changed the equivalence determination criteria on March 13, 2002, under the Circular 113/2002 DCI/ DIPOA. It was not submitted to OIA, Washington, D.C, for equivalence determination prior to change. Brazil suspends an establishment the third time it fails to meet a *Salmonella* performance standard and the government inspectors collect the sample. 9 CFR 310.25

51.a) GOB meat inspection officials verification did not include verifying monitoring and corrective actions of the HACCP plan(s) for the 1st shift operation such as: 1) reviewing and determining the adequacy of corrective actions taken when a deviation occurs; 2) direct observation or measurement at a CCP. 9 CFR 417.8 (c)(f).

b) GOB meat inspection officials were not verifying the monitoring, corrective actions, record keeping, and plant verification of the HACCP plan(s) for the second shift operation such as: a) reviewing the HACCP plan; b) reviewing the CCP records; c) reviewing and determining the adequacy of corrective actions taken when a deviation occurs; d) reviewing the critical limits; e) reviewing other records pertaining to the HACCP plan or system; f) direct observation or measurement at a CCP; g) sample collection and analysis to determine the product meets all safety standards; and h) on-site observations and record review. 9 CFR 417.8

55/51.a) The middle and anterior mediastinal lymph nodes of lungs were not incised during post-mortem inspection. b) The lymph nodes of beef heads were only partially incised and were not observed properly. 9 CFR 310

57/51. In the monthly supervisory review GOB inspection officials did not address the above deficiencies. 9 CFR 416.17 and 417.8

59. Due to noncompliance with implementation of SSOP, HACCP, BSE, & lack of enforcement requirements by the GOB meat inspection officials and the status of this establishment is not equivalent to that required in the U.S. program. All the above deficiencies were discussed with GOB meat inspection officials and they agreed to remove Establishment SIF 385 from the list of establishments eligible to export meat and meat products to the United States, effective March 16, 2005.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Faizur R. Choudry, DVM	4/18/05

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
FRIBOI Ltda. Presidente Epitacio Sao Paulo	03/17/2005	SIF 0458	Brazil
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faizur R. Choudry, 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.	X
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	X
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.	X
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	X
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
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	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	X
58. BSE Sample	X
59. Notice of Intend to Delist (NOID)	X

60. Observation of the Establishment

Establishment # 458 Date: 03/17/2005 Slaughter & Processing Operations

11/51. Establishment officials were not routinely evaluating the adequacy and effectiveness of the Sanitation Standard Operating Procedure (SSOP) to prevent direct product contamination. There were no records of any deficiencies concerning SSOP for a few weeks. 9 CFR 416.14.

12/51. Automatic continuous viscera and offal conveyor pans were found with pieces of meat, fat, and blood after cleaning and sanitizing in the cattle slaughter room. The Government of Brazil (GOB) inspection officials took corrective actions immediately and stopped the slaughter operation. 9 CFR 416.15

13/51. The daily pre-operational and operational SSOP records did not document the corrective actions properly for identified deficiencies such as: to ensure appropriate disposition of products that may be contaminated and prevent recurrence of direct product contamination or adulteration. 9 CFR 416.16

21/51/58.a) GOB inspection officials did not verify that the establishment has reassessed its hazard analysis to determine what steps, if any, are necessary to ensure that its products are free of Specific Risk Materials (SRMs) and GOB did not instruct the inspection officials to verify Bovine Spongiform Encephalopathy (BSE) program. b) Tonsils were being removed by the GOB inspectors and there were no verification records of proper removal of SRMs. 9 CFR 417.4(a)(3)

c) GOB inspection officials were not documenting any records for the verification and noncompliance of establishment written procedures for the complete and proper removal of SRMs. d) SRMs go to inedible rendering but sometime spinal card and brain are used as human food for the domestic or overseas market. Establishment does not have documented procedures (spinal card and brain when saved for human food) for the identification, segregation, and prevention of commingling with edible products. 9 CFR 310.22(d)(1)(2)

30/51 FSIS has granted Brazil an equivalence determination allowing them to use establishment employees collect *Salmonella* samples and Brazil suspends an establishment the first time it fails to meet a *Salmonella* performance standard. GOB has changed the equivalence determination criteria on March 13, 2002, under the Circular 113/2002 DCI/ DIPOA. It was not submitted to OIA, Washington, D.C, for equivalence determination prior to change. Brazil suspends an establishment the third time it fails to meet a *Salmonella* performance standard and the government inspectors collect the sample. 9 CFR 310.25

51. a) GOB meat inspection officials verification did not include verifying monitoring and corrective actions of the HACCP plan(s) for the 1st shift operation such as: 1) reviewing and determining the adequacy of corrective actions taken when a deviation occurs; 2) direct observation or measurement at a CCP. 9 CFR 417.8 (c)(f).

b) GOB meat inspection officials were not verifying the monitoring, corrective actions, record keeping, and plant verification of the HACCP plan(s) for the second shift operation such as: a) reviewing the HACCP plan; b) reviewing the CCP records; c) reviewing and determining the adequacy of corrective actions taken when a deviation occurs; d) reviewing the critical limits; e) reviewing other records pertaining to the HACCP plan or system; f) direct observation or measurement at a CCP; g) sample collection and analysis to determine the product meets all safety standards; and h) on-site observations and record review. 9 CFR 417.8

55/51. The middle and anterior mediastinal lymph nodes of lungs were not incised during post-mortem inspection. 9 CFR 310

57/51. 57/51. In the monthly supervisory review GOB inspection officials did not address the above deficiencies. 9 CFR 416.17 and 417.8

58/51. One cattle arrived on dead on March 14, 2005, and GOB officials did not take a sample of brain for testing of Bovine Spongiform Encephalopathy (BSE). 9 CFR 310.22(d)(1)(2)

59. GOB meat inspection officials gave a Notice of Intend to Delist and suspended Establishment SIF 0458 regarding the inadequate implementation requirements for SSOP, HACCP, BSE, and Government Oversight Enforcement, effective April 13, 2005. GOB inspection official is to evaluate the adequacy of corrective actions and provide a full report to FSIS.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Faizur R. Choudry, DVM	4/18/05

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
Kerry Do Brasil Ltda Tres Coracoes, Minas Gerais	03/29/2005	SIF 0471	Brazil
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

60. Observation of the Establishment

Establishment # SIF 0471 Date: 03/29/2005 Processing Operation

12/51. A) Dripping condensate, from overhead pipes, that was not cleaned/sanitized daily, was falling onto product mixer, ready for use in processing room. 9 CFR 416.15
B) Product residue from previous day's operation was observed on food-contact surfaces of mixer paddles in the processing room. 9 CFR 416.15
C) Product residue from previous day's operation was observed on food-contact surfaces of sieves and open seams were sealed with silicone in the processing room. 9 CFR 416.15
13/51. The daily pre-operational and operational SSOP records did not document the corrective actions properly for identified deficiencies such as: to ensure appropriate disposition of products that may be contaminated and prevent recurrence of direct product contamination or adulteration. 9 CFR 416.16
19/51. Establishment ongoing verification activities did not include: a) direct observations of monitoring activities and corrective actions; b) the review of records. 9 CFR 417.4(a)(2)(ii)(iii)
39/51. Flaking paint was observed in the processing and rusty pipe, flaking paint and cobwebs were observed in the hallway. 9 CFR 416.2 (b)
50/51. There was no government inspection coverage as records indicated for the 2nd and 3rd shift operations. 9 CFR 327.2 (ii)(D)
51. a) a) GOB meat inspection officials verification did not include verifying monitoring and corrective actions of the HACCP plan(s) for the 1st shift operation such as: 1) reviewing and determining the adequacy of corrective actions taken when a deviation occurs; 2) direct observation or measurement at a CCP. 9 CFR 417.8 (c)(f).
b) GOB meat inspection officials were not verifying the monitoring, corrective actions, record keeping, and plant verification of the HACCP plan(s) for the second and third shift operations such as: a) reviewing the HACCP plan; b) reviewing the CCP records; c) reviewing and determining the adequacy of corrective actions taken when a deviation occurs; d) reviewing the critical limits; e) reviewing other records pertaining to the HACCP plan or system; f) direct observation or measurement at a CCP; g) sample collection and analysis to determine the product meets all safety standards; and h) on-site observations and record review. 9 CFR 417.8
c) GOB meat inspection officials were not verifying the effectiveness of pre-operational Sanitation Standard Operating Procedures (SSOP). The operational sanitation was limited to Sanitation Performance Standards (SPS). Records indicated that there were no deficiencies were observed by the GOB inspection officials concerning SSOP for the last two months. 9 CFR 416.17
57/51. In the monthly supervisory review GOB inspection officials did not address the above deficiencies. 9 CFR 416.17 and 417.8
58. Due to noncompliance with implementation of SSOP, HACCP, and lack of enforcement requirements and daily inspection coverage by the GOB meat inspection officials and the status of this establishment is not equivalent to that required in the U.S. program. All the above deficiencies were discussed with GOB meat inspection officials and they agreed to remove Establishment SIF 0471 from the list of establishments eligible to export dried beef extract in powder form to the United States, effective March 29, 2005.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Faizur R. Choudry, DVM	Faiz R Choudry 4/18/05

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
Friboi Ltda. Goiania Goias	04/08/2005	SIF 0862	Brazil
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faizur R. Choudry, 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.	X
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)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	X
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
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	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	X
58. BSE	X
59. Notice of Intend to Delist (NOID)	X

60. Observation of the Establishment

Establishment # 862 Date: 04/08/2005 Slaughter & Processing Operations

21/51/58. The Government of Brazil (GOB) inspection officials did not verify that the establishment has reassessed its hazard analysis to determine what steps, if any, are necessary to ensure that its products are free of Specific Risk Materials (SRMs) and GOB did not instruct the Veterinarian-in-Charge to verify Bovine Spongiform Encephalopathy (BSE) program.
b) Tonsils were being removed by the GOB inspectors and there were no verification records of proper removal of SRMs. 9 CFR 417.4(a)(3)
c) GOB inspection officials were not documenting any records for the verification and noncompliance of establishment written procedures for the complete and proper removal of SRMs. d) SRMs go to inedible rendering but sometime spinal card and brain are used as human food for the domestic or overseas market. Establishment does not have documented procedures (spinal card and brain when saved for human food) for the identification, segregation, and prevention of commingling with edible products. 9 CFR 310.22(d)(1)(2)
e) All non-ambulatory animals are condemned at ante-mortem but GOB inspection officials are not required to sample for BSE except for Central Nervous System (CNS) animals. 9 CFR 309.4 and13
30/51 FSIS has granted Brazil an equivalence determination allowing them to use establishment employees collect *Salmonella* samples and Brazil suspends an establishment the first time it fails to meet a *Salmonella* performance standard. GOB has changed the equivalence determination criteria on March 13, 2002, under the Circular 113/2002 DCI/ DIPOA. It was not submitted to OIA, Washington, D.C, for equivalence determination prior to change. Brazil suspends an establishment the third time it fails to meet a *Salmonella* performance standard and the government inspectors collect the sample. 9 CFR 310.25
51. a) GOB meat inspection officials verification did not include verifying monitoring and corrective actions of the HACCP plan(s) for the 1st shift operation such as: 1) reviewing and determining the adequacy of corrective actions taken when a deviation occurs; 2) direct observation or measurement at a CCP. 9 CFR 417.8 (c)(f).
b) GOB meat inspection officials were not verifying the monitoring, corrective actions, record keeping, and plant verification of the HACCP plan(s) for the second shift operation such as: a) reviewing the HACCP plan; b) reviewing the CCP records; c) reviewing and determining the adequacy of corrective actions taken when a deviation occurs; d) reviewing the critical limits; e) reviewing other records pertaining to the HACCP plan or system; f) direct observation or measurement at a CCP; g) sample collection and analysis to determine the product meets all safety standards; and h) on-site observations and record review. 9 CFR 417.8
c) GOB inspection officials did not follow-up the preventive measures (to prevent the recurrence of direct contamination or adulteration of product) to be taken by the establishment for the identified deficiencies in the pre-operational and operational sanitation SSOP verification. CFR 416.17
57/51. 57/51. In the monthly supervisory review GOB inspection officials did not address the above deficiencies. 9 CFR 416.17 and 417.8
59. GOB meat inspection officials gave a Notice of Intend to Delist (NOID) to Establishment SIF 0862 regarding the inadequate implementation requirements for HACCP, BSE, and Government Oversight Enforcement, effective April 13, 2005. GOB inspection official is to evaluate the adequacy of corrective actions and provide a full report to FSIS.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Faizur R. Choudry, DVM	Faizur R Choudry 4/18/05

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
Frigorifico Extremo Sul S/A. Capao do Leao Rio Grande do Sul	04/01/2005	SIF 1651	Brazil
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faizur R. Choudry, 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.	X
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	X
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.	X
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	X
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	X
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
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	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	X
58. BSE	X
59. Notice of Intend to Delist (NOID)	X

60. Observation of the Establishment

Establishment # SIF 1651 Date: 04/01/2005 Slaughter/Processing Operations

11/51. Establishment officials were not routinely evaluating the adequacy and effectiveness of the Sanitation Standard Operating Procedures (SSOP) to prevent direct product contamination. There were no records of any identified deficiencies concerning operational sanitation SSOP for the last 4 weeks. 9 CFR 416.14

12/51. a) The skinned beef heads were contacting dirty hide puller chain at the hide removal station. Establishment officials took corrective action immediately. b) Contaminated water was falling from employee's working platform onto exposed area of fore-shanks and beef heads at the bung dropping station. c) Contaminated water was falling from employee's working platform onto exposed skinned beef heads at the hindquarter skinning operation. d) Sanitizer was not maintained at the required temperature (82°C) at pre-boning trim station in the boning room. The Government of Brazil (GOB) inspection officials took corrective actions immediately and stopped the operation for ½ an hour approximately. 9 CFR 416.15

13/51. a) The daily pre-operational and operational SSOP records did not document the corrective actions taken for identified deficiencies such as: to ensure appropriate disposition of products that may be contaminated and prevent recurrence of direct product contamination or adulteration. 9 CFR 416.16

b) Corrective actions taken for identified SSOP deficiencies were not verified in the record keeping. 9 CFR 416.16(a)

19/51. Establishment ongoing verification activities did not include: a) direct observations of monitoring activities and corrective actions. 9 CFR 417.4(a)(2)(ii)

20/51. Corrective actions to be followed in response to a deviation from a critical limit did not include in the HACCP plan such as: 1) the cause of deviation is identified and eliminated; 2) measures to prevent recurrence are established; and (3) no product that is injurious to health or otherwise adulterated as a result of deviation enters commerce. 9 CFR 417.3(a)(1)(3)(4)

21/51/58.a) The Government of Brazil (GOB) inspection officials did not verify that the establishment has reassessed its hazard analysis to determine what steps, if any, are necessary to ensure that its products are free of Specific Risk Materials (SRMs) and GOB did not instruct the Veterinary Inspector to verify Bovine Spongiform Encephalopathy (BSE) program. b) Tonsils were being removed by the GOB inspectors and there were no verification records of proper removal of SRMs. 9 CFR 417.4(a)(3)

c) GOB inspection officials were not documenting any records for the verification and noncompliance of establishment written procedures for the complete and proper removal of SRMs. d) SRMs go to inedible rendering but sometime spinal card and brain are used as human food for the domestic or overseas market. Establishment does not have documented procedures (spinal card and brain when saved for human food) for the identification, segregation, and prevention of commingling with edible products. 9 CFR 310.22(d)(1)(2)

e) All non-ambulatory animals are condemned at ante-mortem but GOB inspection officials are not required to sample for BSE except for Central Nervous System (CNS) animals. 9 CFR 309.4 and13

22/51. The records to document monitoring of Critical Control Points (CCP) and plant verification did not include the recording of the actual values, critical limits, time, and initial or signature. 9 CFR 417.5

30/51 FSIS has granted Brazil an equivalence determination allowing them to use establishment employees collect *Salmonella* samples and Brazil suspends an establishment the first time it fails to meet a *Salmonella* performance standard. GOB has changed the equivalence determination criteria on March 13, 2002, under the Circular 113/2002 DCI/ DIPOA. It was not submitted to OIA, Washington, D.C, for equivalence determination prior to change. Brazil suspends an establishment the third time it fails to meet a *Salmonella* performance standard and the government inspectors collect the sample. 9 CFR 310.25

51. a) GOB meat inspection officials verification did not include verifying monitoring and corrective actions of the HACCP plan(s) for the 1st shift operation such as: 1) reviewing and determining the adequacy of corrective actions taken when a deviation occurs; 2) direct observation or measurement at a CCP. 9 CFR 417.8 (c)(f).

b) Product that contacted the floor (drop meat) was being trimmed (reconditioned) by the GOB inspection officials instead of verifying the adequacy and effectiveness of handling and reconditioning of drop meat in a sanitary manner before being added into the edible product by the establishment personnel. 9 CFR 416.17(c)

55/51. a) The middle and anterior mediastinal lymph nodes of lungs were not incised and the masticatory muscles (cheek muscles) of beef heads were not properly incised during post-mortem inspection. 9 CFR 310

57/51. In the monthly supervisory review GOB inspection officials did not address the above deficiencies. 9 CFR 416.17 and 417.8

59. GOB meat inspection officials gave a Notice of Intend to Delist (NOID) to Establishment SIF 1651 regarding the inadequate implementation requirements for SSOP, HACCP, BSE, and Government Enforcement, effective April 01, 2005. GOB inspection official is to evaluate the adequacy of corrective actions and provide a full report to FSIS.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Faizur R. Choudry, DVM	Faiz R Choudry 4/18/05

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
Friboi Ltda Compo Grande Mato Grosso do Sul	03/24/2005	SIF 1662	Brazil
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faizur R. Choudry, 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.	X
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	X
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.	X
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	X
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

Establishment # SIF 1662 Date: 03/24/2005 Slaughter & Cut-up/Boning Room

11/51. Establishment officials were not routinely evaluating the adequacy and effectiveness of the Sanitation Standard Operating Procedures (SSOP) to prevent direct product contamination. 9 CFR 416.14

12/51. a) Contaminated water was falling from employee's working platform onto skinned fore-shanks at the second leg skinning operation. b) Skinned fore-shanks of beef carcasses were contacting employee's working platform and leader at the horn removal station. c) Contaminated water was falling from employee's working platform onto exposed skinned beef heads at the hind part of carcass skinning operation. d) Automatic beef head conveyor hooks were found with pieces of fat after washing/sanitizing in the slaughter room. Establishment officials took corrective actions immediately. e) Automatic beef viscera conveyor pans were found with pieces of fat, meat, intestine, and blood after washing/sanitizing in the slaughter room. Establishment officials took corrective actions immediately. f) Long pieces of beef hind quarters were contacting inedible product and container for inedible product at the hindquarter trimming station in the boning room. 9 CFR 416.15 g) Pieces of fat and meat from previous day's operation were observed on food-contact surfaces of containers used for edible product in the boning room. 9 CFR 416.15

13/51. The daily pre-operational and operational SSOP records did not document the corrective actions properly for identified deficiencies to prevent recurrence of direct product contamination or adulteration. Records indicated that there were no deficiencies were observed by the establishment concerning SSOP for the last 4 weeks. 9 CFR 416.16

21/51/58.a) The Government of Brazil (GOB) inspection officials did not verify that the establishment has reassessed its hazard analysis to determine what steps, if any, are necessary to ensure that its products are free of Specific Risk Materials (SRMs) and GOB did not instruct the Veterinary meat inspection officials to verify Bovine Spongiform Encephalopathy (BSE) program. b) Tonsils were being removed by the GOB inspectors and there were no verification records of proper removal of SRMs. 9 CFR 417.4(a)(3); c) GOB inspection officials were not documenting any records for the verification and noncompliance of establishment written procedures for the complete and proper removal of SRMs. d) SRMs go to inedible rendering but sometime spinal card and brain are used as human food for the domestic or overseas market. Establishment does not have documented procedures (spinal card and brain when saved for human food) for the identification, segregation, and prevention of commingling with edible products. 9 CFR 310.22(d)(1)(2)

22/51. The records to document monitoring of Critical Control Points (CCP) and plant verification did not include the recording of time and initial or signature at the time the specific event occur. 9 CFR 417.3(a (1)(2)(3)(4)

30/51 FSIS has granted Brazil an equivalence determination allowing them to use establishment employees collect *Salmonella* samples and Brazil suspends an establishment the first time it fails to meet a *Salmonella* performance standard. GOB has changed the equivalence determination criteria on March 13, 2002, under the Circular 113/2002 DCI/ DIPOA. It was not submitted to OIA, Washington, D.C, for equivalence determination prior to change. Brazil suspends an establishment the third time it fails to meet a *Salmonella* performance standard and the government inspectors collect the sample. 9 CFR 310.25

39/51. a) Broken and loose screens at the junction of walls and ceilings and a few holes in the roof were not maintained properly to prevent the entry of rodents and other vermin in the dry storage room. b) Loose plastics, black discoloration, and missing panels were observed over ceilings in three coolers. c) A build-up of dust and debris observed in the storage area was being used for storing wooden pallets, unclean plastic containers for edible product, racks, and plastic rolls. This area was partially covered with ceilings and drains were not protected to prevent the creation of insanitary conditions.9 CFR 416.2

47/51. One employee did not observe good hygienic work habits to prevent direct product contamination such as: collecting pieces of meat from the floor and added into the edible product without washing/trimming and washing hands over the working table in the offal room. Establishment officials took corrective actions immediately. 9 CFR 416.5(a)

51. a) Government Of Brazil (GOB) meat inspection officials verification did not include verifying monitoring and corrective actions of the HACCP plan(s) such as: 1) reviewing and determining the adequacy of corrective actions taken when a deviation occurs; 2) direct observation or measurement at a CCP. 9 CFR 417.8 (c)(f). b) Inspection officials did not follow-up the preventive measures (to prevent the recurrence of direct contamination or adulteration of product) to be taken by the establishment for the identified deficiencies in the pre-operational and operational sanitation SSOP for the last 4 weeks. 9 CFR 416.17 **55/51**.a) The middle and anterior mediastinal lymph nodes of lungs were not incised and the masticatory muscles (cheek muscles) of beef heads were not properly incised during post-mortem inspection. 9 CFR 310

57/51. In the monthly supervisory review GOB inspection officials did not address the above deficiencies. 9 CFR 416.17 417.8

59. GOB meat inspection officials gave a Notice of Intend to Delist and suspended Establishment SIF 1662 regarding the inadequate implementation requirements for SSOP, HACCP, and Government Oversight Enforcement, effective March 24, 2005. GOB inspection official is to evaluate the adequacy of corrective actions and provide a full report to FSIS.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Faizur R. Choudry, DVM	4/18/05

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
Bertin Ltda Votuporanga, Sao Paulo	03/15/2005	SIF 2023	Brazil
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
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.	X
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	X
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	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	X
58.	
59.	

60. Observation of the Establishment

Establishment # 2023 Date: 03/15/2005 Processing Operation

19/51. The calibration of process monitoring instruments and the frequency with which those procedures are being performed not included in HACCP plan such as CCP at the seaming of cans. . However, the calibration of process monitoring equipment was being performed. 9 CFR 417.4(a)(2)(i)
22/51. The monitoring records of critical control points did not include the initial or signature of the monitor. 9 CFR 417.5(b)
41/51. Beaded condensation was observed on ceilings in the equipment washing room. There was no washing/cleaning of equipment activity at the time of audit. 9 CFR 416.2(d)
51. a) GOB meat inspection officials verification did not include verifying monitoring and corrective actions of the HACCP plan(s) for the 1st shift operation such as: 1) reviewing and determining the adequacy of corrective actions taken when a deviation occurs; 2) direct observation or measurement at a CCP. 9 CFR 417.8 (c)(f).
b) GOB meat inspection officials were not verifying the monitoring, corrective actions, record keeping, and plant verification of the HACCP plan(s) for the second shift operation such as: a) reviewing the HACCP plan; b) reviewing the CCP records; c) reviewing and determining the adequacy of corrective actions taken when a deviation occurs; d) reviewing the critical limits; e) reviewing other records pertaining to the HACCP plan or system; f) direct observation or measurement at a CCP; g) sample collection and analysis to determine the product meets all safety standards; and h) on-site observations and record review. 9 CFR 417.8
57/51. In the monthly supervisory review GOB inspection officials did not address the above deficiencies. 9 CFR 416.17 and 417.8

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Faizur R. Choudry, DVM	Faiz R Choudry 4/18/05

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
Frisa Frigorifico Rio Doce S/A Nanuque Minas Gerais	04/06/2005	SIF 2051	Brazil
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	X
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	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	X
58. BSE	X
59. Notice of Intend to Delist (NOID)	X

60. Observation of the Establishment

Establishment # 2051 Date: 04/06/2005 Slaughter & Processing Operations

12/51. a) Beef carcasses were contacting the employee's working platform at the bung dropping station. 9 CFR 416.15
b) Fore-shanks of beef carcasses were contacting sanitizer after carcass splitting station. 9 CFR 416.15
c) Beef carcasses were contacting dirty plastic hose at the carcass splitting station. 9 CFR 416.15
d) Automatic beef head conveyor hooks were found with dried fat, blood, and grease after washing/sanitizing in the slaughter room. Establishment officials took corrective actions immediately. 9 CFR 416.15
13/51. The daily pre-operational and operational SSOP records did not document the corrective actions properly for identified deficiencies such as: to ensure appropriate disposition of products that may be contaminated and prevent recurrence of direct product contamination or adulteration. 9 CFR 416.16
20/51. Corrective actions to be followed in response to a deviation from a critical limit did not include all four parts such as: 3) measures to prevent recurrence are established; and (4) no product that is injurious to health or otherwise adulterated as a result of deviation enters commerce. 9 CFR 417.3(a)(3)(4)
21/51/58.a) Government of Brazil inspection officials did not verify that the establishment has reassessed its hazard analysis to ensure that its products are free of Specific Risk Materials (SRMs) and GOB did not instruct the Veterinarian in Charge to verify Bovine Spongiform Encephalopathy (BSE) program. 9 CFR 417.4(a)(3). b) Tonsils were being removed by the GOB inspectors and there were no verification records of proper removal of SRMs. The Inspectors were not removing tonsils in a sanitary manner and GOB inspection officials did not take appropriate action. 9 CFR 417.4(a)(3)
c) GOB inspection officials were not documenting any records for the verification and noncompliance of establishment written procedures for the complete and proper removal of SRMs. d) SRMs go to inedible rendering but sometime spinal card and brain are used as human food for the domestic or overseas market. Establishment does not have documented procedures (spinal card and brain when saved for human food) for the identification, segregation, and prevention of commingling with edible products. 9 CFR 310.22(d)(1)(2)
e) All non-ambulatory animals are condemned at ante-mortem but GOB inspection officials are not required to sample for BSE except for Central Nervous System (CNS) animals. 9 CFR 309.4 and13
b) Specified Risk Materials (SRM) tonsils were not being removed in a sanitary manner by the GOB inspector and no appropriate action was taken by the VIC. 9 CFR 417.4(a)(3)
22/51. The records to document monitoring of critical control points and ongoing verification did not include the recording of quantifiable values, actual time, initial or signature. 9 CFR 417.3(a (1)(2)(3)(4)
30/51 FSIS has granted Brazil an equivalence determination allowing them to use establishment employees collect *Salmonella* samples and Brazil suspends an establishment the first time it fails to meet a *Salmonella* performance standard. GOB has changed the equivalence determination criteria on March 13, 2002, under the Circular 113/2002 DCI/ DIPOA. It was not submitted to OIA, Washington, D.C, for equivalence determination prior to change. Brazil suspends an establishment the third time it fails to meet a *Salmonella* performance standard and the government inspectors collect the sample. 9 CFR 310.25
38/51. Numerous flies were observed on exposed carcasses in the slaughter room. 9 CFR 416.2(a)
51. a)) GOB meat inspection officials verification did not include verifying monitoring and corrective actions of the HACCP plan(s) for the 1st shift operation such as: 1) reviewing and determining the adequacy of corrective actions taken when a deviation occurs; 2) direct observation or measurement at a CCP. 9 CFR 417.8 (c)(f).
b) GOB inspection officials did not follow-up the preventive measures (to prevent the recurrence of direct contamination or adulteration of product) to be taken by the establishment for the identified deficiencies in the pre-operational and operational sanitation SSOP verification. CFR 416.17
c) In the monthly audit reports the supervisor had identified deficiencies but neither VIC nor supervisor in its follow-up audit reports verified any corrective actions taken by the establishment officials. CFR 416.17
55/51. The masticatory muscles (cheek muscles) of beef heads were not incised properly. 9 CFR 310
57/51. In the monthly supervisory review GOB inspection officials did not address the above deficiencies. 9 CFR 416.17 and 417.8
59. GOB meat inspection officials gave a Notice of Intend to Delist (NOID) to Establishment SIF 2051 regarding the inadequate implementation requirements for SSOP, HACCP, BSE, and Government Oversight Enforcement, effective April 06, 2005. GOB inspection official is to evaluate the adequacy of corrective actions and provide a full report to FSIS.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Faizur R. Choudry, DVM	Faiz R Choudry 4/18/05

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
Marfrig frigorificos e Comercio de Alimentos Ltda. Sao Paulo, Sao Paulo	03/21/2005	SIF 2543	Brazil
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faizur R. Choudry, 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.	X
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	X
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.	X
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	X
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
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	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	X
58. BSE	X
59. Notice of Intend to Delist (NOID)	X

60. Observation of the Establishment

Establishment # 2543 Date: 03/21/2005 Slaughter & Processing Operations

11/51. Establishment officials were not routinely evaluating the adequacy and effectiveness of the Sanitation Standard Operating Procedures (SSOP) to prevent direct product contamination. There were no records of any deficiencies concerning SSOP for the last 4 weeks. 9 CFR 416.14

12/51. a) The skinned beef heads were contacting dirty hide puller wheel at the hide removal station. 9 CFR 416.15

b) Fore-shanks of beef carcasses were contacting platform and the evisceration station. 9 CFR 416.15

c) Beef carcasses were contacting dirty plastic hose at the carcass splitting station. 9 CFR 416.15

d) Neck and fore-shanks of beef carcasses were contacting dirty cover over chute for condemned carcasses at the retained carcass post-mortem inspection station. 9 CFR 416.15

e) Fore-shanks of beef carcasses were contacting the floor after final washing. 9 CFR 416.15

13/51. The daily pre-operational and operational SSOP records did not document the corrective actions properly for identified deficiencies such as: to ensure appropriate disposition of products that may be contaminated and prevent recurrence of direct product contamination or adulteration. 9 CFR 416.16

21/51/58.a) Government of Brazil (GOB) inspection officials did not verify that the establishment has reassessed its hazard analysis to determine what steps, if any, are necessary to ensure that its products are free of Specific Risk Materials (SRMs) and GOB did not instruct the Veterinarian in Charge of meat inspection to verify Bovine Spongiform Encephalopathy (BSE) program. b) Tonsils were being removed by the GOB inspectors and there were no verification records of proper removal of SRMs. 9 CFR 417.4(a)(3)

c) GOB inspection officials were not documenting any records for the verification and noncompliance of establishment written procedures for the complete and proper removal of SRMs. d) SRMs go to inedible rendering but sometime spinal card and brain are used as human food for the domestic or overseas market. Establishment does not have documented procedures (spinal card and brain when saved for human food) for the identification, segregation, and prevention of commingling with edible products. 9 CFR 310.22(d)(1)(2)

22/51.a) Records for corrective action in response to a deviation from a critical limit were not adequately documenting the corrective actions and preventive measures. For example, there were no records that: measures to prevent recurrence were established and no product that was adulterated as a result of the deviation enters commerce.

9 CFR 417.3(a) regulatory requirements were not adequately met.

b) The records to document monitoring of critical control points did not include the recording of time, initial or signature. 9 CFR 417.3(a (1)(2)(3)(4)

30/51 FSIS has granted Brazil an equivalence determination allowing them to use establishment employees collect *Salmonella* samples and Brazil suspends an establishment the first time it fails to meet a *Salmonella* performance standard. GOB has changed the equivalence determination criteria on March 13, 2002, under the Circular 113/2002 DCI/ DIPOA. It was not submitted to OIA, Washington, D.C, for equivalence determination prior to change. Brazil suspends an establishment the third time it fails to meet a *Salmonella* performance standard and the government inspectors collect the sample. 9 CFR 310.25

51. a) GOB meat inspection officials verification did not include verifying the monitoring and corrective actions of the HACCP plan(s) such as: 1) reviewing and determining the adequacy of corrective actions taken when a deviation occurs; 2) direct observation or measurement at a CCP. 9 CFR 417.8 (c)(f).

b) GOB inspection officials did not have any findings during pre-operational and operational sanitation SSOP in the slaughter room for the last 4 weeks. CFR 416.17

c) Product that contacted the floor (drop meat) was being trimmed (reconditioned) by the GOB inspection officials instead of verifying the adequacy and effectiveness of handling and reconditioning of drop meat in a sanitary manner before being added into the edible product by the establishment personnel. 9 CFR 416.17(c)

55/51. a) The middle and anterior mediastinal lymph nodes of lungs were not incised during post-mortem inspection. 9 CFR 310

57/51. In the monthly supervisory review GOB inspection officials did not address the above deficiencies. 9 CFR 416.17 and 417.8

59. GOB meat inspection officials gave a Notice of Intend to Delist (NOID) to Establishment SIF 2543 regarding the inadequate implementation requirements for SSOP, HACCP, BSE, and Government Oversight Enforcement, effective March 21, 2005. GOB inspection official is to evaluate the adequacy of corrective actions and provide a full report to FSIS.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Faizur R. Choudry, DVM	Faiz R Choudry 4/18/05

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
LOcalfrio S/A-Armazens Gerais Frigorificos Ltda Guaruja, Sao Paulo	03/28/2005	SIF 3155	Brazil
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faizur R. Choudry, 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.	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	O
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	O
16. Records documenting implementation and monitoring of the HACCP plan.	O
17. The HACCP plan is signed and dated by the responsible establishment individual.	O
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	O
19. Verification and validation of HACCP plan.	O
20. Corrective action written in HACCP plan.	O
21. Reassessed adequacy of the HACCP plan.	O
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	O
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)	O
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	O
35. Residue	O
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	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Establishment # 3155 Date: 03/28/2005 Cold Store

13/51. The daily operational sanitation SSOP deficiencies were not specified and corrective actions did not prevent the recurrence of direct contamination or adulteration of product(s).

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Faizur R. Choudry, DVM	Faiz R Choudry 4/18/05

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
Jack Link's Do brasil Ltda.Bertin Ltda Itopeva, Sao Paulo	03/18/2005	SIF 3673	Brazil
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X
13. Daily records document item 10, 11 and 12 above.	X
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.	X
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	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	O
35. Residue	O
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	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	O
57. Monthly Review	X
58. *Listeria Monocytogenes*	X
59. Notice of Intend to Delist (NOID)	X

60. Observation of the Establishment

Establishment # SIF 3673 Date: 03/18/2005 Processing Operation

12/51. a) Product (meat) residue was observed on food-contact surfaces of plastic conveyor belt from previous day's operation in Ready-to-Eat (RTE) beef jerky room. Establishment officials took corrective actions immediately.
b) Establishment was not performing pre-operational Sanitation Standard Operating Procedures (SSOP) daily in the RTE processing room and was washed once a week. Establishment was using pressured air to blow any contaminants on food-contact-surfaces and then applying "All-Clean Gel) for sanitizing equipment. 9 CFR 416.15
13/51. The daily pre-operational and operational Sanitation Standard Operational Procedures (SSOP) records did not document the corrective actions properly for identified deficiencies such as: to ensure appropriate disposition of products that may be contaminated and prevent recurrence of direct product contamination or adulteration. 9 CFR 416.16
20/51. The establishment failed to take appropriate corrective actions in response to a deviation from a critical limit (70 C temperature CCP 1), establishment did not follow procedure(s) in plan such as: records document corrective actions taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. 9 CFR 417.3(a (1)(2)(3)(4)
51. a) GOB meat inspection officials verification did not include verifying the monitoring and corrective actions of the HACCP plan(s) such as: 1) reviewing and determining the adequacy of corrective actions taken when a deviation occurs; 2) direct measurement at a CCP. 9 CFR 417.8 (c)(f).
b) GOB meat inspection officials were not verifying the adequacy of the HACCP plan(s) for the second and third shift operations. 9 CFR 417.8
c) GOB inspection officials were not verifying the corrective actions taken for the identified deficiencies in the monthly supervisory reviews. 9 CFR 416.17
57/51. In the monthly supervisory review GOB inspection officials did not address the above deficiencies. 9 CFR 416.17 and 417.8
58/51. Establishment is producing Ready-to-Eat (RTE) product (beef jerky) and *Listeria monocytogenes* (*LM*) was not addressed in its HACCP plan hazard reasonably likely to occur. Establishment is analyzing one *LM* sample per month for RTE product. FSIS Directive 10,240.4
59. GOB meat inspection officials gave a Notice of Intend to Delist (NOID) to Establishment SIF 3673 regarding the inadequate implementation requirements for SSOP and HACCP, effective April 01, 2005. GOB inspection official is to evaluate the adequacy of corrective actions and provide a full report to FSIS.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Dr. Faizur R. Choudry, DVM	Faiz R Choudry 4/18/05