



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

Dr. Jorge Amaya
Presidente
Servicio Nacional de Sanidad y Calidad Agroalimentaria
Secretaria de Agricultura, Ganaderia, Pesca y Alimentación
Paseo Colon 367-Piso 9
1063 Buenos Aires
Argentina

DEC 05 2007

Dear Dr. Amaya:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Argentina's meat inspection system July 13 to August 8, 2007. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (402) 344-5100, by facsimile at (402) 344-5169, or electronic mail at donald.smart@fsis.usda.gov.

Sincerely,

Donald Smart
Director
International Audit Staff
Office of International Affairs

Enclosure

FINAL

DEC - 5 2007

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

JULY 13 THROUGH AUGUST 8, 2007

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority: National Service for Animal Health and Agro-Food Quality (<i>Servicio Nacional de Sanidad y Calidad Agroalimentaria</i>) (SENASA)
DFPOA	Directorate for Products of Animal Origin and Inspection (<i>Dirección Fiscalización de Productos de Origen Animal</i>)
DNFA	National Directorate for Inspection of Foods and Agricultural Products (<i>Dirrección Nacional de Fiscalización Agroalimentaria</i>)
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
<i>Salmonella</i>	<i>Salmonella</i> species
SENASA	National Service for Animal Health and Agro-Food Quality (<i>Servicio Nacional de Sanidad y Calidad Agroalimentaria</i>)
SSOP	Sanitation Standard Operating Procedures
SPS	Sanitation Performance Standards
VIC	Veterinarian-In-Charge

1. INTRODUCTION

The audit took place in Argentina from July 13 through August 8, 2007.

An opening meeting was held on July 13, 2007, in Buenos Aires with the Central Competent Authority (CCA). In this meeting, the auditor confirmed the objective and scope of the audit, the auditor's itinerary, and requested additional information needed to complete the audit of Argentina's meat inspection system.

The auditor was accompanied during the entire audit activities by representatives from the CCA, the National Service for Animal Health and Agro-Food Quality (SENASA), and representatives from the provincial offices and local inspection offices.

2. OBJECTIVE OF THE AUDIT

This was a routine annual audit. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter and processing establishments certified by the CCA as eligible to export meat products to the United States.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, two provincial offices, two laboratories performing analytical testing on United States-eligible product, two slaughter and fabrication establishments, one slaughter, fabrication, and cooking establishment, one slaughter, fabrication, and canning establishment, one cooking establishment, and one slaughter, fabrication, cooking, canning, and extraction establishment.

Competent Authority Visits			Comments
Competent Authority	Central	1	Buenos Aires
	Provincial	2	Cordoba & La Pampa
	Local	6	Establishment level
Microbiological Laboratory		1	
Residue Laboratory		1	
Bovine Slaughter and Fabrication Establishments		2	
Bovine Slaughter, Fabrication, and Cooking Establishment		1	
Bovine Slaughter, Fabrication, and Canning Establishment		1	
Bovine Cooking Establishment		1	
Bovine Slaughter, Fabrication, Cooking, Canning, and Extraction Establishment		1	

3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in Argentina's inspection headquarters and in two provincial offices. The third part involved on-site visits to six establishments: Five slaughter/fabrication and/or further processing establishments and one cooking-only facility. The fourth part involved a visit to two private laboratories; Xenobioticos S.R.L. was conducting chemical analyses of field samples for residues and Mercolab was conducting microbiological analyses of field samples.

Program effectiveness determinations of Argentina'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 daily operation of HACCP programs and a testing program for generic *Escherichia coli* (*E. coli*), (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella* species (*Salmonella*). Argentina's inspection system was assessed by evaluating these five risk areas.

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

In the opening meeting, the auditor explained that Argentina's meat inspection system would be audited against two standards: (1) FSIS regulatory requirements and (2) any equivalence determinations made for Argentina. FSIS requirements include, among other things, daily inspection in all certified establishments, periodic supervisory visits to certified establishments, humane handling and slaughter of animals, ante-mortem inspection of animals and post-mortem inspection of carcasses and parts, the handling and disposal of inedible and condemned materials, sanitation of facilities and equipment, residue testing, species verification, testing programs for generic *E. coli* and *Salmonella* species, and requirements for HACCP, SSOP, SPS.

No special equivalence determinations have been made by FSIS for Argentina.

4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.

5. SUMMARY OF PREVIOUS 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 findings were reported in the September/October 2005 FSIS audit:

- SSOP- implementation deficiencies were found in four of the 12 establishments audited.
- HACCP- implementation deficiencies were found in seven of the 12 establishments audited.

The following findings were reported in the August/September 2006 FSIS audit:

- HACCP-implementation deficiencies were found in three of the six establishments audited.

All deficiencies noted during the last FSIS audit had been addressed and corrected.

6. MAIN FINDINGS

6.1 Government Oversight

There had been one major change in the CCA organizational structure since the last FSIS audit. The implementation of the Regional concept for more direct supervision of the establishments producing agricultural products had been almost completed. All but one Region was in operation. That one area still had direct supervision from Buenos Aires, as did the establishments in the Buenos Aires metropolitan area. Each Region had Thematic Coordinators which may either be the direct supervisors of the establishments or have supervisors under them. The Regional Directors report to a Regional Coordinator in the headquarters offices in Buenos Aires. The National Service of Animal Health and Agro-Food Quality (*Servicio Nacional de Sanidad y Calidad Agroalimentaria-SENASA*) has the responsibility for carrying out Argentina's meat inspection program, including oversight and enforcement of the FSIS regulatory requirements in establishments certified to export to the United States.

6.1.1 Ultimate Control and Supervision

SENASA has ultimate control and supervision over its inspection program.

6.1.2 Assignment of Competent, Qualified Inspectors

Approximately 73 veterinarians and 300 meat inspectors provided direct meat inspection service to those establishments that produce or store U.S. products. All official veterinarians and meat inspectors employed by Argentina's meat inspection program possessed the required educational degrees necessary to meet minimum qualifications. These inspection personnel went through introductory training as well as participation in

on-the-job training under the supervision of experienced veterinarians. Continual training was provided for all inspection personnel as needed. The individual training records of inspection personnel were maintained in the regional offices.

6.1.3 Authority and Responsibility to Enforce the Laws

SENASA has the legal authority and the responsibility to enforce U.S. requirements.

6.1.4 Adequate Administrative and Technical Support

SENASA has adequate administrative and technical support to operate its meat inspection program.

6.2 Headquarters Audit

The auditor conducted a review of inspection system documents in the Buenos Aires SENASA headquarters office and in one provincial office. The records reviews focused primarily on food safety hazards and included the following:

- Internal review reports;
- Supervisory visits to establishments that were certified to export to the United States;
- Training records for inspectors and laboratory personnel;
- New laws and implementation documents, such as regulations, notices, directives and guidelines;
- Sampling and laboratory analyses for residues;
- Sanitation, slaughter and processing inspection procedures and standards;
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials;
- Export product inspection and control including export certificates, and
- Enforcement records, including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

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

6.2.1 Audits of Regional and Local Inspection Sites

The auditor interviewed personnel in two Regional Offices, one in Cordoba for the Cordoba Province and one in Santa Rosa for the La Pampa and San Luis Provinces. No concerns arose as a result of those interviews.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of six establishments. Two were slaughter and fabrication establishments, one was a slaughter, fabrication, and cooking establishment, one was a slaughter, fabrication, and canning establishment, one was a cooking

establishment, and one was a slaughter, fabrication, cooking, canning, and extraction establishment. None of the establishments were delisted, nor did any receive a Notice of Intent to Delist (NOID).

Specific deficiencies are noted in the attached individual establishment audit checklists.

8. LABORATORY AUDITS

During the laboratory audits, emphasis was placed on the application of procedures and standards that are equivalent to the United States' requirements.

Residue laboratory audits focus on sample handling, sampling frequency, timely analysis, data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and written corrective action programs.

The following laboratory was audited:

- Xenobioticos S.R.L., located in Buenos Aires. This is a private laboratory which conducts residue testing for the National Residue Program.

No deficiencies were noted.

Microbiological 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 samples of U.S.-eligible products, the auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS Pathogen Reduction/HACCP requirements.

The following laboratory was reviewed:

- Mercolab, located in Santa Fe, Santa Fe. This is a private laboratory which conducts microbiological sampling for both SENASA-based samples and those sent by establishments.

No deficiencies were noted.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses on five areas of risk in assessing an exporting country's meat inspection system. The first of these risk areas that the FSIS auditor reviewed was Sanitation Controls.

Based on the on-site audits of establishments, except as noted below, Argentina's inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene practices, and good product handling and storage practices.

In addition, Argentina's inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

9.1 Sanitation Standard Operating Procedures

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the United States domestic inspection program. The SSOP in all audited establishments were found to meet the basic FSIS regulatory requirements.

- Four of six establishments audited had deficiencies in SSOP, primarily in implementation, maintenance, and recordkeeping.

9.2 Sanitation Performance Standards (SPS)

- Deficiencies involving SPS were identified in five of the six establishments audited. These included building maintenance, pest control, equipment and utensils, and ventilation.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, procedures for sanitary handling of returned and reconditioned product, and the implementation of the requirements for control of Bovine Spongiform Encephalopathy (BSE). The auditor determined that Argentina's inspection system had adequate controls in place.

No deficiencies were noted.

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. The controls include the following areas: humane handling and humane slaughter, ante-mortem inspection and disposition, post-mortem inspection and disposition, implementation of HACCP systems in establishments, and implementation of generic *E. coli* testing programs in slaughter establishments.

The controls also include ingredients identification, control of restricted ingredients, formulations, processing schedules, equipment and records, and processing controls of cured, dried, and cooked products.

Specific deficiencies are noted in the attached individual establishment audit checklists.

11.1 Humane Handling and Slaughter

No deficiencies were observed regarding humane handling or slaughter practices.

11.2 HACCP Implementation.

All establishments approved to export meat products to the United States are required to have developed and adequately implemented HACCP programs. 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 all six establishments.

- Deficiencies involving HACCP implementation, primarily in the areas of verification, corrective actions, and recordkeeping, were identified in all six of the establishments audited.

The specific deficiencies are noted in the attached individual establishment audit checklists.

11.3 Testing for Generic *E. coli*

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

Five of the six establishments audited were required to meet the basic FSIS regulatory requirements for testing for generic *E. coli* and were evaluated according to the criteria employed in the United States' domestic inspection program.

Testing for generic *E. coli* was properly conducted in four of the five slaughter establishments. Statistical process control techniques had been developed in all the slaughter establishments in order to evaluate the results.

- In one establishment, a deficiency was identified regarding the selection of carcasses for sampling for generic *E. coli*.

11.4 Testing for *Listeria monocytogenes* and *Salmonella* in Ready-to-Eat (RTE) Product

Four of the six establishments audited were producing RTE for export to the United States. Testing for *Listeria monocytogenes* (*Lm*) and *Salmonella* was being done for "tube" products four times per year. Testing for *Lm* and *Salmonella* for cooked, dried products was being done, at the request of the producing establishment, on every lot produced for export.

There was no national risk-based sampling program for ready-to-eat, post-lethality-exposed products.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviewed was Residue Controls. These controls include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

Argentina's National Residue Testing Plan for 2007 was being followed and was on schedule.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella* species.

13.1 Daily Inspection

Inspection was being conducted daily in all the establishments audited.

13.2 Testing for *Salmonella* species

Argentina has adopted the FSIS regulatory requirements for testing for *Salmonella* species.

Five of the six establishments audited were required to meet the basic FSIS regulatory requirements for testing for *Salmonella* species and were evaluated according to the criteria employed in the United States' domestic inspection program.

Testing for *Salmonella* species was properly conducted in all of the five establishments.

13.3 Species Verification

Species verification was being performed as required at four of six establishments. The two slaughter and fabrication only establishments were not scheduled for species verification.

13.4 Periodic Supervisory Reviews

In all establishments visited, periodic supervisory reviews were being performed and documented as required.

13.5 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying,

diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the United States with product intended for the domestic market.


No livestock or meat was imported from other countries for use in U.S.-eligible product.

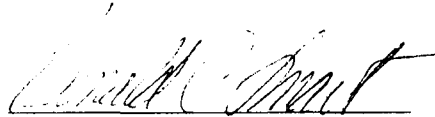
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on August 8, 2007, in Buenos Aires, with the CCA. At this meeting, the primary findings were presented by the auditor.

The CCA understood and accepted the findings.

Rori K. Craver, DVM 
Senior Program Auditor



15. ATTACHMENTS

Individual Foreign Establishment Audit Forms

Foreign Country Response to Draft Final Audit Report *(No comments received from the Government of Argentina)*

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Swift Armour S.A. Argentina Av. J. D. Peron S/N V. Godor. Galvez, Rosario, Santa Fe S2124IUA	2. AUDIT DATE 07/23&24/07	3. ESTABLISHMENT NO. 13	4. NAME OF COUNTRY Argentina
	5. NAME OF AUDITOR(S) Rori K. Craver, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

Date: 07/23&24/07 Est #: 13 (Swift Armour S.A. Argentina [S/P/CS]) (V. Godor. Galvez, Santa Fe, Argentina)

10. (A) The boots of an employee on the evisceration stand in the slaughter area extended beyond the edge of the platform and contacted carcasses and a rumen as the evisceration procedures were performed. [Regulatory Reference: 9 CFR § 416.13]

(B) There were a number of instances of actual and potential cross-contamination in the boning room. These included deficiencies such as close proximity of containers with edible products and products destined for industrial use, personal equipment and containers of product for industrial use, and personnel in close proximity to containers with specified risk materials. [Regulatory Reference: 9 CFR § 416.13]

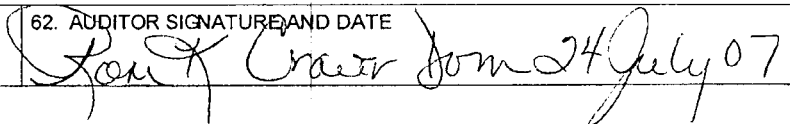
22/51. The entries on the HACCP monitoring record for CCP1 located in the slaughter plan did not have the time of the entry or the initials of the monitor. [9 CFR § 417.5(b), 417.8]

39/51. The floors in the cooking area had many broken and cracked tiles which would no longer be impervious to moisture and would inhibit complete cleaning. [9 CFR § 416.2(b)(2)]

61. NAME OF AUDITOR

Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

Handwritten signature of Rori K. Craver and date 24 July 07

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Mirab S.A. Calle 3 y del Canal, Parque Industrial Pilar Pilar Prov. Buenos Aires 1629	2. AUDIT DATE 07/16/07	3. ESTABLISHMENT NO. 1067	4. NAME OF COUNTRY Argentina
	5. NAME OF AUDITOR(S) Rori K. Craver, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	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 SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.	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.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park 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	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

Date: 07/16/07 Est #: 1067 (Mirab S.A. [P]) (Prov. Buenos Aires, Argentina)

13. Some entries on pre-operational and operational sanitation monitoring records did not contain sufficient detail in the observations, corrective actions, and/or preventive measures for the verification of the efficacy of the actions. [Regulatory Reference: 9 CFR § 416.16]

22/51. The HACCP plan for CCP1 at the cooking and water activity step mentions a possible reprocessing step as a corrective action but no reprocessing step is evident in the flow diagram or the hazard analysis. [9 CFR § 417.5 and 417.8.]

39/51. The floors in the post-cooking rooms had cracks and broken areas along the junctures to the walls, by the drains, and across the floors. The floors in the raw area were the same but did show evidence of some sealing of these cracks. [9 CFR § 416.2(b)(3)]

61. NAME OF AUDITOR
Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

Rori K. Craver 16 July 07

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Frigorifico Rioplatense Avda de los Constituyentes 2801 General Pacheco Pcia. Buenos Aires B1517AAN	2. AUDIT DATE 07/17/07	3. ESTABLISHMENT NO. 1920	4. NAME OF COUNTRY Argentina
	5. NAME OF AUDITOR(S) Rori K. Craver, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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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.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 07/17/07 Est #: 1920 (Frigorifico Rioplatense [S/P/CS]) (Pcia. Buenos Aires, Argentina)

19/51. The verification activities listed in the HACCP plan did not include direct observation of the monitor and records review. [Regulatory References: 9 CFR § 417.4(a)(2), 417.8]

22/51. HACCP monitoring records for the CCP addressing the contamination of carcasses and carcass parts by visible feces, ingesta, and milk (i.e., zero tolerance) did not include the time of entry and initials of the person for each carcass monitored. This establishment monitors 100% of the carcasses. [9 CFR § 417.5(b), 417.8]

61. NAME OF AUDITOR
Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

Rori K Craver 17 July 07

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Swift Armour S.A. Argentina Ave Mitre 2816 San Jose Entre Rios E3283CEX	2. AUDIT DATE 07/19/07	3. ESTABLISHMENT NO. 1930	4. NAME OF COUNTRY Argentina
	5. NAME OF AUDITOR(S) Rori K. Craver, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment


Date: 07/19/07 Est #: 1930 (Swift Armour S.A. Argentina [S/P]) (Entre Rios, Argentina)

22. Some of the HACCP monitoring records from CCP1 and CCP9 did not have the initials of the monitor and times recorded for each event. [Regulatory Reference: 9 CFR § 417.5(b)]

45/51. Many of the flat pans used in the cooking and canning areas had deep cracks on each corner, therefore allowing for the possibility of the formation of biofilms. Those in use were immediately removed from service and new pans replaced them. [9 CFR § 416.3(a)]

61. NAME OF AUDITOR
Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

 19 July 07

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Estancias del Sur S.A. Camino a Pajas Plancas Km. 22 Unquillo, Cordoba	2. AUDIT DATE 07/27/07	3. ESTABLISHMENT NO. 2065	4. NAME OF COUNTRY Argentina
	5. NAME OF AUDITOR(S) Rori K. Craver, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.	X	37. Import	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	X
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.	X	48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	X	56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 07/27/07 Est #: 2065 (Estancias del Sur S.A. [S/P/CS]) (Unquillo, Cordoba, Argentina)

11/51. The SSOP had not been revised in eight years. The sections of the SSOP for both pre-operational and operational sanitation monitoring stating the requirements for the temperatures for sterilizers stated that they should be at 82°C, with an acceptable range of 80-85°C. Both the establishment and SENASA said that this was a typo and action is taken at any temperature below 82°C, but the auditor was only able to partially confirm this. [Regulatory References: 9 CFR § 416.14 and 416.17]

13/51. There was no frequency for operational sanitation monitoring. Preventive measures were addressed in corrective action records, but not addressed in the SSOP plans for either pre-operational or operational sanitation. Actual values for temperatures were not recorded in the monitoring records for operational and pre-operational sanitation, only acceptable or not acceptable. [9 CFR § 416.16 and 416.17]

19/51. The thermometer calibration plan stated an action level of 10% for the difference between the certified standard thermometer and one being calibrated. Quality control said they used an action level of 0.5°C. [9 CFR § 417.4 ((a)(2)(i) and 417.8]

20/51. The corrective actions listed in the HACCP plan for CCP1 in slaughter, the CCP for zero tolerance of fecal material, ingesta, and/or milk, did not state that carcasses would be re-evaluated back to the last acceptable monitoring event. [9 CFR § 417.3(a)(4) and 417.8]

28/51. A second sample for analysis for generic *Escherichia coli* were not collected if the total number of animals slaughtered only exceeded 300 by up to 25 or 30 animals. The establishment did not understand that a slaughter count of 301 would require a second sample to be taken. [9 CFR § 310.25(a)(2)(iii)(A)]

38/39/51. Outside doors to the shipping area and the doors at the entrance to the secondary box storage room (which opened to the outside) did not close or seal properly which could allow for the possible entrance of insects or rodents. [9 CFR § 416.3]

51. SENASA personnel were reviewing records but were not reading either the SSOP or HACCP plans and therefore were not verifying that the establishment was doing what they had written that they would do. [9 CFR § 416.17 and 417.8]

61. NAME OF AUDITOR
Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

Rori K. Craver
27 July 07

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Exportaciones Agroindustriales Argentinas S.A. Ruta 5 Km. 598 Santa Rosa, L.P.	2. AUDIT DATE 08/01/07	3. ESTABLISHMENT NO. 2520	4. NAME OF COUNTRY Argentina
	5. NAME OF AUDITOR(S) Rori K. Craver, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	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	X
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.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	O
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment Date: 08/01/07 Est #: 2520 (Exportaciones Agroindustriales Argentinas S.A. [S/P/CS]) (Santa Rosa, L.P., Argentina)

12/51. SSOP plans for both operational and pre-operational sanitation did not mention corrective actions or preventive measures. Although the records call for recording of the temperatures of the sterilizers, there is no reference to this in the SSOP plans including that no reference temperature is listed. [Regulatory References: 9 CFR § 416.15 & 416.17]

13/51. Corrective actions did not include written preventive measures for deficiencies of product contact surfaces. [9 CFR § 416.16 & 416.17]

19/51 Verification procedures for the CCPs did not include direct observation of the monitor. [9 CFR § 417.4 & 417.8]

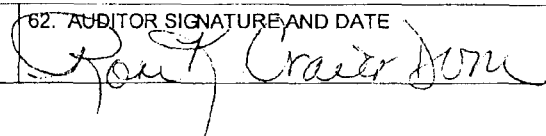
22/51. HACCP monitoring records for the CCP in secondary packaging had times recorded prior to the monitoring events. [9 CFR § 417.5 & 417.8]

39/51. The insides of the cisterns holding the well water that is used by the establishment had flaking paint. [9 CFR § 416.2(b)(1)]

41/51. Product freezer #9 was extremely overcrowded which decreased airflow and therefore caused frost around the outside of the doors. This frost and ice also extended along the floor for several feet outside the door. [9 CFR § 416.2(d)]

61. NAME OF AUDITOR
Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

 1 Aug 07

Country Response Not Received