

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

Dr. Yayo Vicente Director, Servicio Nacional de Salud Animal (SENASA) Ministerio de Agricultura y Ganaderia (MAG) Apartado 3-3006 Cenada Heredia, Costa Rica

Dear Dr. Vicente:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Costa Rica's meat inspection system September 14 to September 25, 2009. You were invited to provide comments regarding the information in the draft final audit report. No comments were received from the government of Costa Rica within 60 days. 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 (202) 205-3969, by facsimile at (202) 720-0676, or electronic mail at james.adams5@fsis.usda.gov.

Sincerely,

James Adams, DVM

Director International Audit Staff Office of International Affairs

Enclosure

EQUAL OPPORTUNITY IN EMPLOYMENT AND SERVICES

<u>cc:</u>

Kevin N. Smith, Ag Counselor, US Embassy, San Jose Laura Dachner, Minister Counselor, Embassy of Costa Rica **OSTA/FAS** Hugh Maginnis, FAS Area Officer Ann Ryan, State Department Alfred Almanza, Administrator, FSIS Ron Jones, Assistant Administrator, OIA James Adams, Director, IAS, OIA Andreas Keller, Director, IES, OIA Rick Harries, Director, EPS Jerry Elliot, Director, IID, OIA Stephen Hawkins, Acting Director, FSIS Codex Lisa Wallenda Picard, OA David Smith, IES, OIA Phil Derfler, FSIS, OPPD Dan Engeljohn, FSIS, OPPD Clark Danford, Director, IPD, OPPD **Country File** 

## FINAL REPORT OF AN AUDIT CARRIED OUT IN COSTA RICA COVERING COSTA RICA'S MEAT INSPECTION SYSTEM

## SEPTEMBER 14 THROUGH SEPTEMBER 25, 2009

Food Safety and Inspection Service United States Department of Agriculture

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## ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

AI	Auxiliary Inspector
CCA	Central Competent Authority
CVO	Chief Veterinary Officer
DIPAO	Direccion de Inocuidad Productos Origen Animal, Direction of Safety of Product of Animal Origin
E. coli	Generic Escherichia coli
FSIS	Food Safety and Inspection Service
LANASEVE	Laboratorio Nacional de Servicios Veterinarios, National Residue and Microbiology Veterinary Laboratory
MAG	<i>Ministerio de Agricultura y Ganaderia</i> , Ministry of Agriculture and Livestock
NOID	Notice of Intent to Delist
PBIS	Performance Based Inspection System
PR/HACCP	Pathogen Reduction/ Hazard Analysis and Critical Control Point Systems
Salmonella	Salmonella species
SENASA	Servicio Nacional de Salud Animal or National Service of Animal Health
SPS	Sanitation Performance Standards
SRM	Specified Risk Material
SSOP	Sanitation Standard Operating Procedures
VIC	Veterinarian-In-Charge

#### 1. SUMMARY

#### 1.1 Description/Eligibility

This report summarizes the outcome of the audit conducted in Costa Rica from September 14 through September 25, 2009. This was a routine audit. Costa Rica is currently eligible to export fresh beef and beef products to the United States. At the time of the audit, three establishments were eligible to export to the United States. During calendar year 2008 Costa Rica exported 14,229,944 pounds of fresh beef to the United States. Activities of the current audit appear in the table below.

The findings of the previous audit during April 17 through April 28, 2008, resulted in no restrictions of any Costa Rica establishment ability to export fresh beef and beef products to the United States.

	CURRENT AUDIT DATES: September 14 through September 25, 2009	PREVIOUS AUDIT DATES: April 17 through April 28, 2008
Levels of Government Oversight Audited		
Headquarters		1
Regional	0	0
Establishment Level	3	3
Laboratories Audited		
Microbiology	0	1
Residue	1	1
Establishments Audited		
Slaughter/processing	2	2
Processing only	1	1
Enforcement Actions Initiated		
NOID	0	0
Delistment	0	0
Risk Area Findings		
Sanitation Controls (SSOP, SPS)	5	3
Animal Disease Controls	0	0
Slaughter/Processing (PR/HACCP)	5	0
Residue Controls	0	0
Microbiology Controls	0	0
Inspection/Enforcement Controls	8	2
Special Emphasis (HH, O157:H7)	0	0

1.2 Comparison of the Current Audit and the Previous Audit

#### 1.3 Summary Comments for the Current Audit

The results of this audit reflected increased non-compliance in Sanitation Controls, Slaughter/Processing Controls and Inspection/Enforcement Controls. Specific non-compliances are noted on the attached establishment reports and in sections 10, 12 and 14 of this report.

#### 2. INTRODUCTION

The audit took place in Costa Rica from September 14 through September 25, 2009.

An entrance meeting was held on September 14 in Lagunilla, Heredia with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit, the details of the audit itinerary, and requested additional information needed to complete the audit of Costa Rica's meat inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA, the *Servicio Nacional de Salud Animal* (SENASA) National Service of Animal Health and its Division Direction of Safety of Product of Animal Origin, *Direccion de Inocuidad Productos Origen Animal* (DIPOA) and, when appropriate, representatives from the local inspection offices.

#### 3. OBJECTIVE OF THE AUDIT

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

In pursuit of the objective, the Senior Program Auditor visited the following sites: the headquarters of the CCA, one government laboratory performing analytical testing on United States-destined product, and two beef slaughter/processing and one processing establishments eligible to export to the U.S.

#### 4. PROTOCOL

The official 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 Costa Rica's inspection headquarters offices. The third part involved on-site visits to the two beef slaughter/ processing and one processing establishments certified by Costa Rica as eligible to export to the United States. The fourth part involved visit to one government-owned and - operated laboratory. The *Laboratorio Nacional de Servicios Veterinarios* (LANASEVE), National Residue and Microbiology Veterinary Laboratory was conducting analyses of field samples for Costa Rica's national residue control program and the pathogen reduction program for *Salmonella* species.

Program effectiveness determinations of Costa Rica's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP); (2) animal disease controls;
(3) slaughter/processing controls, including the implementation and operation of Hazard Analysis/Critical Control Point (HACCP) programs and the testing program for generic *E. coli*; (4) residue controls; and (5) enforcement controls, including the testing program for *Salmonella* species. Costa Rica's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditor also assessed how inspection services are carried out by Costa Rica 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.

During the entrance meeting, the auditor explained that Costa Rica's inspection system would be audited in accordance with two areas of focus. First, the auditor would audit against FSIS requirements. These include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification testing, and FSIS' requirements for HACCP, SSOP, testing for generic *E. coli* and *Salmonella* species.

Second, the auditor would audit against any equivalence determinations that have been made by FSIS for Costa Rica under provisions of the Sanitary/Phytosanitary Agreement. Currently, Costa Rica has one equivalence determinations, which was issued in February 2005. Establishment personnel collect samples of product for generic *E. coli* testing and analysis is conducted in official government laboratories.

#### 5. 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.) and
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.
- 6. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at: http://www.fsis.usda.gov/Regulations & Policies/ Foreign Audit Reports/index.asp.

The last two FSIS audits of Costa Rica's inspection system were conducted in February 2007 and April 2008.

The following deficiency was observed during the FSIS audit in February 2007:

• Samples for analysis of organophosphates and DES were sent to the University of San Jose laboratory and to the Panama's government laboratory due to the temporary malfunctioning equipment.

This specific deficiency was verified as having been corrected during the April 2008 FSIS audit.

The following non-compliances were observed during the FSIS audit in April 2008:

- During operational sanitation inspection in the boning room, conveyor belt was observed with several cracks in the contact surface, which made it difficult to clean.
- While condensation was being removed from a rail in the cooler, it was observed that carcasses were not moved from beneath of rail to avoid contamination.
- During the pre-operational sanitation inspection in the frozen patties processing room, a conveyor belt was observed with several wires missing, which made it difficult to clean.

These specific non-compliances were verified as having been corrected during the September 2009 FSIS audit.

#### 7. MAIN FINDINGS

#### 7.1 Government Oversight

Meat inspection activities are centrally located in Heredia and are administered by the office of the *Servicio Nacional de Salud Animal* or Nacional Service (SENASA) of Animal Health and its subdivision, *Direccion de Inocuidad Productos Origen Animal* Direction of Safety of Product of Animal Origin. SENASA is under the umbrella of the *Ministerio de Agricultura y Ganaderia*, Ministry of Agriculture and Livestock. The Division of Direction of Safety of Product of Regional Origin has the direct oversight of the local inspection offices. The function of Regional Offices is for animal health only.

The DIPOA is Costa Rica's Central Competent Authority and is responsible for providing government oversight of Costa Rica's meat inspection programs. The SENASA has direct authority over the National Laboratory of Residue and Micro Analysis in Heredia, the official government laboratory of Costa Rica. This official government laboratory performs chemical and microbiological analytical testing of meat products exported to the US.

The official guidelines and regulations are issued by the CCA headquarters in Heredia.

All inspection personnel assigned to establishments certified to export meat to the United States are full-time government employees receiving no compensation from either industry or establishment personnel. Inspection personnel can hold outside employment provided it does not serve as a conflict of interest with their inspection duties.

Meat export certificates are controlled by the Chief Veterinary Officer (CVO) and are signed and distributed on an as-needed basis to the official inspection personnel stationed at the certified establishments. Additionally, the CVO maintains documented control of all official government seals and stamps. The Veterinarians-in-Charge (VICs) in the three establishments certified as eligible to export to the United States maintain physical control of all assigned government seals and stamps.

Verification activities are performed through periodic supervisory audit and inspection verification of establishment activities. Suspension and withdrawal of inspection is authorized by the Chief of DIPOA.

7.1.1 CCA Control Systems

The DIPOA is headed by a CVO who has the responsibility for oversight of Costa Rica's meat and poultry establishments. During this audit, the CVO accompanied the FSIS auditor and served as an audit leader for the three establishment audits. Additionally, the DIPOA has authority over live animal issues in Costa Rica relative to livestock and poultry movements and disease.

7.1.2 Ultimate Control and Supervision

At each certified establishment, the VIC has the authority to cease the establishment's production operations any time the wholesomeness and safety of the product is jeopardized. The VIC reports directly to the CVO regarding enforcement activities. The CCA has direct supervision over inspection personnel at establishments certified to export to the US. Costa Rica is using a system similar to the FSIS Performance Based Inspection System (PBIS) with weekly assignments for inspection personnel. Additionally, periodic supervisory audits are performed. A decision to suspend the operations of an establishment for non-compliance or to delist an establishment from exporting to the United States is authorized by the Head of the DIPOA.

The VIC has direct supervision over other inspection personnel assigned to certified establishments. In the three establishments certified to export meat to the United States, the DIPOA has the inspection personnel to carry out the FSIS requirements.

The government of Costa Rica has the organizational structure and staffing to ensure uniform implementation of US import requirements.

7.1.3 Assignment of Competent, Qualified Inspectors

All inspection personnel assigned to certified establishments undergo initial and continuing training, as well as participation in practical on-the-job training under the combined supervision of the CVO, VIC, also training in Puerto Rico and US.

All official veterinarians are qualified veterinarians who have obtained their veterinary degree from accredited veterinary colleges in Mexico, Brazil, and Costa Rica. Inspectors are required to have a high school diploma with major in livestock or agriculture.

The government of Costa Rica has competent inspection personnel in all three certified establishments.

#### 7.1.4 Authority and Responsibility to Enforce the Laws

The official inspection personnel are authorized to enforce the government of Costa Rica' meat inspection legislation and US import requirements including animal health and welfare, control of animal disease, veterinary medicines, and the production of safe foods of animal origin. The CVO of DIPOA has the legal authority to delist certified establishments and the VIC at each certified establishment to suspend operations to prevent the export of unsafe meat to the United States.

7.1.5 Adequate Administrative and Technical Support

The DIPOA has adequate administrative and technical support to operate Costa Rica's meat inspection system and to ensure its compliance with U.S. requirements. The CCA has the ability to support a third party audit.

7.2 Headquarters Audits

The auditor conducted a review of inspection system documents at the headquarters of the inspection service in Heredia, Costa Rica. The records review focused primarily on food safety hazards and included the following:

- Methods of payment to inspection personnel.
- Proper distribution of relevant legislation to inspection personnel.
- Process of hiring, qualification and assignment of inspection personnel to the US certified establishments.
- Internal review reports.
- Other supervisory visits to establishments that were certified to export to the US.
- New laws and implementation of documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Sampling and laboratory analyses for microbiology.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as cysticercosis.
- Control of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records, including examples of criminal prosecution and seizure and control of noncompliant product.

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

#### 8. ESTABLISHMENT AUDITS

The FSIS auditor visited the two beef slaughter/processing and one processing establishments that have been certified by SENASA as eligible to export to the U.S. None were delisted or issued a Notice of Intent to Delist (NOID) by Inspection Officials of Costa Rica because of failure to meet basic US requirements.

### 9. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

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

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

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. If private laboratories are used to test United States samples, the auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS Pathogen Reduction/HACCP requirements. (Two private laboratories were used in Costa Rica for analyses of generic *E. coli*.)

The following laboratory was audited:

The SENASA *Laboratorio Nacional de Servicios Veterinarios*, (LANASEVE), The National Residue Laboratory.

No deficiencies were reported during the audit of government residue laboratory.

**10. SANITATION CONTROLS** 

As stated earlier, the FSIS auditor focuses on five areas of risk to assess Costa Rica'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, Costa Rica's inspection system had controls in place for SSOP programs, good personal hygiene practices, and good product handling and storage practices.

10.1 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 U.S. domestic inspection program.

The following non-compliances were reported:

- It was noticed during the review of written meat rework procedure for the debonning room that meat will be picked up from the floor, taken to the rework table, dipped in peroxyacids solution which has concentration of 180 to 220 PPM. The outer surface which has touched the floor is not being trimmed by knife to remove the potential contamination. This non-compliance was never noticed by the inspector in-charge and during the supervisory periodic reviews by the CCA, and failed to take appropriate corrective actions.
- In the evisceration room, there was no hand wash facility available for the employee who was removing the spinal cord from the bovine carcass at the spinal cord removal station, except the sanitizing facility for utensils (hook, knife). The employee's gloves were observed with excessive blood and potential source of cross contamination during handling of carcasses. The inspection personnel and CCA official of periodic supervisory visits were failed to observe this non-compliance.

#### 10.2 Sanitation Performance Standards

In addition, Costa Rica'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.

The following non-compliances were reported:

- In the debonning room, it was observed that meat rework table, meat moving cart and meat table had irregular and rough welding on the meat contact surfaces which made difficult to clean. There was no indication of such non-compliance during the records review of inspection and periodic supervisory visits. The CCA had failed to take enforcement actions for such non-compliance.
- In the processing room, two hand wash facilities were observed without a supply of water with suitable temperature (hot/warm). Cold water was available at both hand wash facilities at the time of audit. Also it was noted during the inspection records review of the same day, this finding was not observed by the inspection official.

#### 11. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditors 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. The auditor determined that Costa Rica's inspection system had adequate controls in place.

No non-compliances were reported during the audit concerning Animal Disease Control.

There had been no outbreaks of animal diseases with public health significance since the last FY 2008 FSIS audit.

#### 12. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures; ante-mortem disposition; humane handling and humane slaughter; post-mortem inspection procedures; post-mortem disposition; specified risk materials (SRM) controls; 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 testing program for generic *E. coli* in slaughter establishments.

12.1 Humane Handling and Humane Slaughter

No non-compliances were reported.

12.2 HACCP Implementation

Both beef slaughter/processing and one processing 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 following non-compliances were reported:

- In the processing room, beef patties operation was stopped by the establishment's employee due to malfunction of metal detector system which was a Critical Control Point (CCP1). The operation was resumed after the repair of metal detector system. I asked the government officials to verify the function of metal detector system (CCP1), it was observed that metal detector system did not function properly as intended and beef patties with metal chip were kicked off from the conveyer belt by a stopper (divider) rather than allows the patties to go in the tubs under the belt at the end of conveyer belt.
- The establishment had not incorporated appropriate procedures and controls for the handling of non-ambulatory disabled cattle into HACCP, SSOP, or prerequisite programs as required by FSIS regulations, although establishment personnel and government officials had told verbally that non-ambulatory disable cattle had not enter into the food chain since FSIS regulatory requirements regarding the non-ambulatory disabled cattle. The inspection officials and periodic supervisory visits conducted by CCA official could not identify this non compliance.
- The establishment had not addressed in HACCP, SSOP, or prerequisite programs that all cattle would be considered 30 months or older for the removal, segregation, and disposition of the SRMs, although it was verified during the on-site audit that the establishment had considered all cattle as 30 months or older for the removal,

segregation, and disposition of the SRMs. The CCA did not take enforcement actions if establishment did not address that all cattle would be considered 30 months or older in HACCP, SSOP, or prerequisite programs.

#### 12.3 Testing for Generic E. coli

Costa Rica has adopted the FSIS regulatory requirements for testing for generic *E. coli*. Both establishments 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 both establishments.

#### 12.4 Testing for Listeria monocytogenes

None of the establishments audited were producing any ready-to-eat products, either for the U.S. or for any other domestic or foreign markets, so the requirements for testing for *Listeria monocytogenes* according to the Final Rule of June 6, 2003, did not apply to these establishments.

#### **13. RESIDUE CONTROLS**

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

The government owned and operated *Laboratorio Nacional Servicio Veterinario*, National Residue Laboratory was audited.

No non-compliances were reported.

#### 14. 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*.

14.1 Daily Inspection in Establishments

Documented daily inspection was provided in all three establishments on days during which U.S.-eligible product was produced.

14.2 Testing for Salmonella Species

Costa Rica has adopted the FSIS regulatory requirements for testing for *Salmonella* species. Both slaughter establishments were evaluated according to the criteria employed in the United States' domestic inspection program.

No non-compliances were reported.

14.3 Testing for E. coli O157:H7

No non-compliances were reported.

14.4 Species Verification

At the time of this audit, Costa Rica was required to test product for species verification. Species verification was being conducted in both slaughter/processing establishments as required.

14.5 Periodic Reviews

Periodic supervisory reviews of all three certified establishments were being performed and documented.

The following deficiencies were reported:

- It was noticed during the review of written meat rework procedure for the debonning room that meat will be picked up from the floor, taken to the rework table, dipped in peroxyacids solution which has concentration of 180 to 220 PPM. The outer surface which has touched the floor is not being trimmed by knife to remove the potential contamination. This non-compliance was never noticed by the inspector in-charge and during the supervisory periodic reviews by the CCA, and failed to take appropriate corrective actions.
- In the evisceration room, there was no hand wash facility available for the employee who was removing the spinal cord from the bovine carcass at the spinal cord removal station, except the sanitizing facility for utensils (hook, knife). The employee's gloves were observed with excessive blood and potential source of cross contamination during handling of carcasses. The inspection personnel and CCA official of periodic supervisory visits were failed to observe this non-compliance.
- In the debonning room, it was observed that meat rework table, meat moving cart and meat table had irregular and rough welding on the meat contact surfaces which made difficult to clean. There was no indication of such non-compliance during the records review of inspection and periodic supervisory visits. The CCA had failed to take enforcement actions for such non-compliance.
- The establishment had not incorporated appropriate procedures and controls for the handling of non-ambulatory disabled cattle into HACCP, SSOP, or prerequisite programs as required by FSIS regulations, although establishment personnel and government officials had told verbally that non-ambulatory disable cattle had not enter into the food chain since FSIS regulatory requirements regarding the non-ambulatory disabled cattle. The inspection officials and periodic supervisory visits conducted by CCA official could not identify this non compliance.

#### 14.6 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; and prevention of commingling of product intended for export to the United States with product intended for the domestic market.

The following deficiencies were reported:

- It was noticed during the review of written meat rework procedure for the debonning room that meat will be picked up from the floor, taken to the rework table, dipped in peroxyacids solution which has concentration of 180 to 220 PPM. The outer surface which has touched the floor is not being trimmed by knife to remove the potential contamination. This non-compliance was never noticed by the inspector in-charge and during the supervisory periodic reviews by the CCA, and failed to take appropriate corrective actions.
- In the evisceration room, there was no hand wash facility available for the employee who was removing the spinal cord from the bovine carcass at the spinal cord removal station, except the sanitizing facility for utensils (hook, knife). The employee's gloves were observed with excessive blood and potential source of cross contamination during handling of carcasses. The inspection personnel and CCA official of periodic supervisory visits were failed to observe this non-compliance.
- In the debonning room, it was observed that meat rework table, meat moving cart and meat table had irregular and rough welding on the meat contact surfaces which made difficult to clean. There was no indication of such non-compliance during the records review of inspection and periodic supervisory visits. The CCA had failed to take enforcement actions for such non-compliance.
- The establishment had not incorporated appropriate procedures and controls for the handling of non-ambulatory disabled cattle into HACCP, SSOP, or prerequisite programs as required by FSIS regulations, although establishment personnel and government officials had told verbally that non-ambulatory disable cattle had not enter into the food chain since FSIS regulatory requirements regarding the non-ambulatory disabled cattle. The inspection officials and periodic supervisory visits conducted by CCA official could not identify this non compliance.

#### **15. EXIT MEETING**

An exit meeting was held on September 25 with the CCA. At this meeting, the preliminary findings from the audit were presented by the auditor.

The CCA understood and accepted the finding.

Farooq Ahmad, DVM Senior Program Auditor

for Manzvor H. Chaudury

## 16. ATTACHMENTS

Individual Foreign Establishment Audit Forms Foreign country response to Draft Final Audit Report (when available)

ι	Inited	States	Depart	tment	of A	\gricul	ture
-	Food	l Safety	and Ir	nspec	tion	Servio	æ

## Foreign Establishment Audit Checklist

Foreign	Estabili	Sinne	ni Aduli Checkis	51		
1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT D	ATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY		
COOPEMONTECILLOS R.L. # 8 9/17/20		)9	8	Costa Rica		
Contigua al MOPT Alajuela 5. NAME OF		AUDITO	01TOR(S) 6. TYPE OF AUDIT			
Alajuela, Montecillos		A 1				
Costa Rica Farooc			Ahmad, DVM			
Place an X in the Audit Results block to ind	icate non	compl	ance with requirem	ents. Use O if not applicable.		
Part A - Sanitation Standard Operating Procedures (S	SOP)	Audit		rt D - Continued	Audit	
Basic Requirements	<i></i>	Results	Ecc	onomic Sampling	Results	
7. Written SSOP	1. A.		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)			Part E -	Other Requirements		
Ongoing Requirements			36. Export			
<ol> <li>Implementation of SSOP's, including monitoring of implementation</li> <li>Maintenance and evaluation of the effectiveness of SSOP's.</li> </ol>	lation,					
12. Corrective action when the SSOP's have failed to prevent dire	ect	x	<ol> <li>37. Import</li> <li>38. Establishment Grounds</li> </ol>	and Pest Control	0	
product contamination or adulteration. 13. Daily records document item 10, 11 and 12 above.			39. Establishment Construc	tion/Maintenance		
Part B - Hazard Analysis and Critical Control			40. Light			
Point (HACCP) Systems - Basic Requirements	- - -		41. Ventilation	· · ·		
14. Developed and implemented a written HACCP plan .           15. Contents of the HACCP list the food safety hazards,		x	42. Plumbing and Sewage	· · · · · · · · · · · · · · · · · · ·		
critical control points, critical limits, procedures, corrective act 16. Records documenting implementation and monitoring of the	ions.		43. Water Supply	······································		
			44. Dressing Rooms/Lavatories			
17. The HACCP plan is signed and dated by the responsible establishment individual.			45. Equipment and Utensits			
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements			46. Sanitary Operations			
18. Monitoring of HACCP plan.				· · · · · · · · · · · · · · · · · · ·		
19. Verification and validation of HACCP plan.			47. Employee Hygiene			
20. Corrective action written in HACCP plan.	-		48. Condemned Product Co	ontrol		
21. Reassessed adequacy of the HACCP plan.			Part F - Inspection Requirements			
22. Records documenting: the written HACCP plan, monitoring of critical control points, dates and times of specific event occur	the		49, Government Staffing			
Part C - Economic / Wholesomeness	ieices.		F0 D-14 1		· ·	
23. Labeling - Product Standards			50. Daily Inspection Covera	ge		
24. Labeling - Net Weights			51. Enforcement		x	
25. General Labeling			52. Humane Handling	· · · · · ·		
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Mois	sture)		53. Animal Identification			
	oturo,				· · · · · · · · · · · · · · · · · · ·	
Part D - Sampling Generic <i>E. coli</i> Testing			54. Ante Mortem Inspection		x	
27. Written Procedures		1	55. Post Mortem Inspection			
28. Sample Collection/Analysis						
29. Records			Part G - Other Regu	latory Oversight Requirements		
Salmonella Performance Standards - Basic Requir	ements		56. European Community Di	rectives	0	
30. Corrective Actions			57. Monthly Review			
31. Reassessment			58. SRM		x	
32. Written Assurance			59.			

FSIS- 5000-6 (04/04/2002)

60. Observation of the Establishment

Date: 09/17/09 Est #: 8 (Montecillos [S/P]) (Alajuela, Costa Rica)

12/51 It was noticed during the review of written meat rework procedure for the debonning room that meat will be picked up from the floor, taken to the rework table, dipped in peroxyacids solution which has concentration of 180 to 220 PPM. The outer surface which has touched the floor is not being trimmed by knife to remove the potential contamination. This non-compliance was never noticed by the inspector in-charge and during the supervisory periodic reviews by the CCA, and failed to take appropriate corrective actions. The government officials assured corrective actions by the establishment to revise meat rework procedure. [Regulatory references: 9 CFR 416.4(d), 416.15 and 416.17]

15/54/51 The establishment had not incorporated appropriate procedures and controls for the handling of non-ambulatory disabled cattle into HACCP, SSOP, or prerequisite programs as required by FSIS regulations, although establishment personnel and government officials had told verbally that non-ambulatory disable cattle had not enter into the food chain since FSIS regulatory requirements regarding the non-ambulatory disabled cattle. The inspection officials and periodic supervisory visits conducted by CCA official could not identify this non compliance. The inspection officials assured appropriate corrective actions by the establishment to reassess their HACCP plan to meet FSIS regulatory requirements. [9 CFR 309.3(e) and 417.8]

15/58/51 The establishment had not addressed in HACCP, SSOP, or prerequisite programs that all cattle would be considered 30 months or older for the removal, segregation, and disposition of the SRMs, although it was verified during the on-site audit that the establishment had considered all cattle as 30 months or older for the removal, segregation, and disposition of the SRMs. The CCA did not take enforcement actions if establishment did not address that all cattle would be considered 30 months or older in HACCP, SSOP, or prerequisite programs. The inspection officials assured appropriate corrective actions by the establishment to reassess their HACCP plan to meet FSIS regulatory requirement. [9 CFR 310.22(d) and 417.8]

61. NAME OF AUDITOR Faroog Ahmad. DVM

62. AUDITOR SIGNATURE AND DATE Mangood H. Chaudry 3/14/10

# United States Department of Agriculture Food Safety and Inspection Service

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Fore	ign Establi	ishme	nt Audit Checkli	st	
1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT D	DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY	
Heredia		09	12	Costa Rica	
		F AUDITO	R(S)	6. TYPE OF AUDIT	
		Farooq Ahmad, DVM			NT AUDIT
Place an X in the Audit Results block to	indicate noi	ncompl	iance with requirem	ents. Use O if not applicable	
Part A - Sanitation Standard Operating Procedu	res (SSOP)	Audit		rt D - Continued	Audit
Basic Requirements		Results		onomic Sampling	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 (S Ongoing Requirements	SOP)		Part E	Other Requirements	
10. Implementation of SSOP's, including monitoring of imp	lementation	_	36. Export		
11. Maintenance and evaluation of the effectiveness of SS			37. Import		
12. Corrective action when the SSOP's have falled to prev product contamination or adulteration.	ent direct	x	38. Establishment Grounds	and Pest Control	
13. Daily records document item 10, 11 and 12 above.			39. Establishment Construc	ction/Maintenance	
Part B - Hazard Analysis and Critical Contro Point (HACCP) Systems - Basic Requiremen			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, correc	tive actions.		42. Plumbing and Sewage		
16. Records documenting implementation and monitoring HACCP plan.	of the		43. Water Supply		
17. The HACCP plan is signed and dated by the responsi	ble		44. Dressing Rcoms/Lavati	ories	
establishment individual. Hazard Analysis and Critical Control Point			45. Equipment and Utensil	S	x
(HACCP) Systems - Ongoing Requirements			46. Sanitary Operations		X
18. Monitoring of HACCP plan.			47. Employee Hygiene		
19. Verification and validation of HACCP plan.			48. Condemned Product C	ontrol	
20. Corrective action written in HACCP plan.			· · · · · · · · · · · · · · · · · · ·		
21. Reassessed adequacy of the HACCP plan.			Part F - I	nspection Requirements	
22. Records documenting: the written HACCP plan, monit critical control points, dates and times of specific even	oring of the nt occurrences.		49. Government Staffing		
Part C - Economic / Wholesomeness	•		50. Daily Inspection Cover	age	
23. Labeling - Product Standards			51. Enforcement		x
24. Labeling - Net Weights	· · · · · · · · · · · · · · · · · · ·		52. Humane Handling		
25. General Labeling 7				·	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Sk	ins/Moisture)		53. Animal Identification		
Part D - Sampling Generic <i>E. coli</i> Testing			54. Ante Mortem Inspection	n	ľ
27. Written Procedures	·		55, Post Mortem Inspection	n	
28, Sample Collection/Analysis		1	<u> </u>		
29. Records			Part G - Other Reg	ulatory Oversight Requirements	
Salmonella Performance Standards - Basic F	Requirements		56. European Community Σ	Directives	0
30. Corrective Actions	·		57. Monthly Review		· .
31. Reassessment			58. SRM		Х
32. Written Assurance		"	59.		

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60. Observation of the Establishment

12/58/51 In the evisceration room, there was no hand wash facility available for the employee who was removing the spinal cord from the bovine carcass at the spinal cord removal station, except the sanitizing facility for utensils (hook, knife). The employee's gloves were observed with excessive blood and potential source of cross contamination during handling of carcasses. The inspection personnel and CCA official of periodic supervisory visits were failed to observe this non-compliance. The government officials assured corrective action by establishment to install hand washing facility at this location. [9 CFR 310.22, 416.15, and 416.17]

45/46/51 In the debonning room, it was observed that meat rework table, meat moving cart and meat table had irregular and rough welding on the meat contact surfaces which made difficult to clean. There was no indication of such non-compliance during the records review of inspection and periodic supervisory visits. The CCA had failed to take enforcement actions for such non-compliance. Government officials assured corrective actions by establishment to replace or repair such equipment which would be easy to clean. [Regulatory reference: 9 CFR 416.3(a), 416.4(a)]

61. NAME OF AUDITOR Faroog Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE Joy Manzood H. Chaudry 3/4/10

United States Department of Agriculture
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

				· · · · · · · · · · · · · · · · ·	
		ATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY	
Procesadora de Carnes del Rey Belen - Heredia	09/21/09		19 Costa Rica		
Heredia 0		5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT	
		Ahmad, D	VM	X ON-SITE AUDIT DOCUMEN	
Place an X in the Audit Results block to inc	dicate nor	ncompl	iance with requirem	ents. Use O if not applicable.	 ,
Part A - Sanitation Standard Operating Procedures (SSOP)		Audit	Part D - Continued		Audit
Basic Requirements		Results		onomic Sampling	Results
7. Written SSOP			33. Scheduled Sample		
8. Records documenting implementation.			34. Species Testing		0
9. Signed and dated SSOP, by on-site or overall authority. Sanitation Standard Operating Procedures (SSOP)			35. Residue		
Ongoing Requirements			Part E -	Other Requirements	
10. Implementation of SSOP's, including monitoring of impleme	ntation.		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 di product contamination or adulteration.	irect		38. Establishment Grounds	and Pest Control	
13. Daily records document item 10, 11 and 12 above.	· .		39. Establishment Construct	tion/Maintenance	
Part B - Hazard Analysis and Critical Control			40. Light		
Point (HACCP) Systems - Basic Requirements 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 an	ctions.	x	42. Plumbing and Sewage		
<ol> <li>Records documenting implementation and monitoring of the HACCP plan.</li> </ol>	)		43. Water Supply		X
17. The HACCP plan is signed and dated by the responsible		-	44. Dressing Rooms/Lavato	ries	
establishment individual. Hazard Analysis and Critical Control Point			45. Equipment and Utensils	;	<u> </u>
(HACCP) Systems - Ongoing Requirements			46. Sanitary Operations	·	
18. Monitoring of HACCP plan.			47. Employee Hygiene		
19. Verification and validation of HACCP plan.	· · ·		48. Condemned Product Co	ontrol	
20. Corrective action written in HACCP plan.			Dort E. Ju	nspection Requirements	
21. Reassessed adequacy of the HACCP plan.			Part F - 11		
<ol> <li>Records documenting: the written HACCP plan, monitoring critical control points, dates and times of specific event occ</li> </ol>			49. Government Staffing		
Part C - Economic / Wholesomeness			50. Daily Inspection Covera	age	
23. Labeling - Product Standards			51. Enforcement		
24. Labeling - Net Weights			52. Humane Handling		0
25. General Labeling 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Mo	oisture)		53. Animal Identification		0
····					
Part D - Sampling Generic <i>E. coli</i> Testing			54. Ante Mortem Inspection	) 	0
27. Written Procedures		0	55. Post Mortem Inspection	1	0
28. Sample Collection/Analysis		0	Dect C. Other Dec	latan ( Ovorpight Bagwimmant)	
29. Records		0	Part G - Other Kegt	latory Oversight Requirements	
Salmonella Performance Standards - Basic Requ	irements		56. European Community D	rectives	O,
30. Corrective Actions		0	57. Monthly Review		
31. Reassessment			58. SRM		
32. Written Assurance		0	59.		

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60. Observation of the Establishment

Page 2 of 2

15 In the processing room, beef patties operation was stopped due to malfunction of metal detector system which was a Critical Control Point (CCP1). The operation was resumed after the repair of metal detector system. I asked the government officials to verify the function of metal detector system (CCP1), it was observed that metal detector system did not function properly as intended and beef patties with metal chip were kicked off from the conveyer belt by a stopper (divider) rather than allows the patties to go in the tubs under the belt at the end of conveyer belt. The operation was stopped for repair and before start of operation establishment officials performed monitoring of metal detector system (CCP1) which functioned as it was intended. [Regulatory reference: 9 CFR 417.3]

43 In the processing room, two hand wash facilities were observed without a supply of water with suitable temperature (hot/warm). Cold water was available at both hand wash facilities at the time of audit. Also it was noted during the inspection records review of the same day, this finding was not observed by the inspection official. Government officials assured immediate corrective actions and water supply with suitable temperature was available at both hand wash facilities. [9 CFR 416.2(g)]

61. NAME OF AUDITOR Faroog Ahmad, DVM

62. AUDITOR SIGNATURE AND DATE Mon2vor H. Chaudery 3/4/10