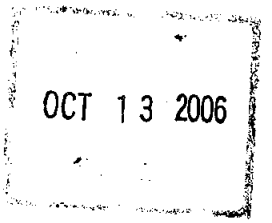
United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250



Dr. Pedro Ángel García González
Subdirector General de Sanidad Exterior
Ministerio de Sanidad y Consumo
Paseo del Prado, 18 y 20
28014 Madrid
Spain

Dear Dr. García:

This letter transmits the Food Safety and Inspection Service final report of a meat inspection system audit conducted in Spain March 29 through April 26, 2006. Comments from Spain have been included as an attachment to the final report. Enclosed is a copy of the final report.

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

Sincerely,

Sally White JD

Sally White
Director
International Equivalence Staff
Office of International Affairs

Enclosure

FINAL

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

MARCH 29 THROUGH APRIL 26, 2006

Food Safety and Inspection Service
United States Department of Agriculture

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14. CLOSING MEETING

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority [Ministry of Health and Consumer Affairs]
FSIS	Food Safety and Inspection Service
VEA	European Community/United States Veterinary Equivalence Agreement
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
SSOP	Sanitation Standard Operating Procedures
E. coli	*Escherichia coli*
Salmonella	*Salmonella* species
SPS	Sanitation Performance Standard
CCP	Critical Control Point
CL	Critical Limit

1. INTRODUCTION

The audit took place in Spain from March 29 through April 26, 2006.

An opening meeting was held on March 29, 2006, in Madrid with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit, the auditor's itinerary, and requested additional information needed to complete the audit of Spain's meat inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA, the Ministry of Health and Consumer Affairs, Spanish Food Safety Agency and representatives from Spain's Regional Autonomous Communities inspection offices.

2. OBJECTIVE OF THE AUDIT

This audit 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, four Regional Autonomous Communities inspection offices, six pork processing establishments, one swine slaughter and processing establishment, and one laboratory conducting microbiological testing on United States-destined product.

Competent Authority Visits			Comments
Competent Authority	Central	1	Ministry of Health and Consumer Affairs
	Regional	4	Autonomous Communities
	Local	7	Establishment level
Laboratories		1	
Meat Slaughter and processing Establishment		1	
Meat Processing Establishments		6	

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 the country's inspection headquarters and regional autonomous communities offices. The third part involved on-site visits to seven establishments: one slaughter and processing establishment and six processing establishments. The fourth part involved a visit to one government laboratory. The Centro Nacional de Alimentacion reference laboratory in Majadahonda, Madrid was conducting analyses of field samples for the presence of *Salmonella, Listeria monocytogenes* and *Salmonella* in ready-to-eat (RTE) products.

Program effectiveness determinations of Spain's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures, (2) animal disease controls, (3) slaughter/processing controls, including the implementation and operation of HACCP programs and a testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella*. Spain'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 Spain and determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated and properly labeled.

At the opening meeting, the auditor explained to the CCA that their inspection system would be audited in accordance with three areas of focus. First, under provisions of the European Community/United States Veterinary Equivalence Agreement (VEA), the FSIS auditor would audit the meat inspection system against European Commission Directive 64/433/EEC of June 1964; European Commission Directive 96/22/EC of April 1996; and European Commission Directive 96/23/EC of April 1996. These directives have been declared equivalent under the VEA.

Second, in areas not covered by these directives, the auditor would audit against FSIS requirements. FSIS requirements 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 requirements for HACCP, SSOP, testing for generic *E. coli* and *Salmonella*.

Third, the auditor would audit against any equivalence determinations that have been made by FSIS for Spain under provisions of the Sanitary/Phytosanitary Agreement. Currently, Spain has an equivalence determination from FSIS regarding the use of EN 45001 (quality control standards used for accrediting laboratories)

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.

In addition, compliance with the following European Community Directives was also assessed:

- Council Directive 64/433/EEC of June 1964 entitled Health Problems Affecting Intra-Community Trade in Fresh Meat

- Council Directive 96/23/EC of 29 April 1996 entitled Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products
- Council Directive 96/22/EC of 29 April 1996 entitled Prohibition on the Use in Stockfarming of Certain Substances Having a Hormonal or Thyrostatic Action and of B-agonists

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 last two FSIS audits of Spain's meat inspection system were conducted in November/December 2004 and March/April 2005.

During the November/December 2004 FSIS audit of Spain's inspection system:

- Five certified establishments and two laboratories were reviewed.
- One non-certified pork slaughter establishment was reviewed.
- Three establishments were cited for inadequate HACCP implementation.
- Three establishments were cited for inadequate SSOP implementation.
- One establishment was cited for inadequate implementation of Sanitation Performance Standards (SPS).
- Three establishments were cited for inadequate RTE product testing.
- *Salmonella* Performance Standards was not being followed by the government in the slaughter establishment.
- The government's Central National laboratory was not using the FSIS laboratory testing methods for the detection of *Listeria monocytogenes*.
- The government's Central National laboratory was not using the FSIS laboratory testing methods for the detection of *Salmonella.*
- All six establishments, as well as government's Central National Laboratory, were cited for inadequate government enforcement.

During the March/April 2005 FSIS audit of Spain's inspection system:

- Two establishments were cited for inadequate implementation of other sanitation requirements.
- Three establishments had not adequately implemented the HACCP requirements.

6. MAIN FINDINGS

6.1 Government Oversight

There are three levels of supervision over the official activities of all government employees in certified establishments:

- o Ministry of Health and Consumer affairs (MHCA), General Office of Public Health (CCA) in Madrid.

- Four Autonomous Communities Regions where all seven establishments are located.
- The Province and/or District Autonomous Administrations.

The responsibility of monthly reviews is shared as follows:

- The Central Competent Authority (CCA) conducts one audit per year.
- The Autonomous Communities Regions conducts one audit per year.
- The Province and/or District Autonomous Administrations conduct ten audits per year.

6.1.1 CCA Control Systems

The CCA has jurisdiction over Spain's 17 Autonomous Communities. Each Autonomous Community has two departments: Public Health Department and Animal Health Veterinary Services Department. Public Health Departments within the Autonomous Communities are directly responsible for official control, inspection, and certification throughout the food production chain and it has three administrative levels.

6.1.2 Ultimate Control and Supervision

Each establishment is under the direct authority of the applicable Autonomous Community. The Autonomous Communities i.e., regional governments, have sufficient personnel to provide government oversight of the establishments within its region. All seven establishments reviewed had daily inspection coverage. The inspection officials assigned to the establishments were full time employees of the Autonomous Communities.

The Ministry of Health has sufficient number of personnel to ensure effective oversight of all U.S. import inspection requirements. However, the Ministry of Health needs to strengthen its government oversight of the Autonomous Communities.

The following deficiencies were observed:

- The "monthly" supervisory reports did not reflect actual establishment conditions.
- In one establishment, the verification documentation was not included in the records for corrective actions taken as a result of observations made during "monthly" supervisory visits.
- There was inadequate verification of the implementation of U.S. requirements by the province and/or district.

6.1.3 Assignment of Competent, Qualified Inspectors

According to Autonomous Communities Legislation:

1) An Official Veterinarian must be present during the ante- and post-mortem inspection in the slaughterhouse.

2) Routine veterinary supervision in the rest of the establishments, at times required by the legislation, or according to the establishment size and/or types of manufactured products.

All seven establishments audited had daily inspection coverage. The inspection officials assigned to certified establishments were full time employees of the Spanish government.

The following deficiencies were observed:

- The findings demonstrated that government veterinary meat inspectors were not fully trained in FSIS requirements.

6.1.4 Authority and Responsibility to Enforce the Laws

Autonomous Communities have legal authority and responsibility to enforce and implement food safety legislation over the exporting establishments and government laboratories within their region.

The main functions of the Autonomous Communities Health Department are as follows:

1) The implementation of hygiene regulations in fresh meat establishments.
2) The implementation of hygiene controls in meat products, minced meat and other production establishments.
3) The supervision of the recall and mark of the specified risk materials.
4) Sampling for microbiological analysis, collection of zoonotic agents residues, etc.

The Ministry of Health and Consumer Affairs, although not having legislative authority over the exporting establishments, does have legal authority to certify and decertify approved establishments. The Ministry of Health and Consumer Affairs also has legislative authority over the National Government Laboratory (CNA), which is the only laboratory currently conducting microbiological testing of samples for *Salmonella* and *Listeria monocytogenes* in ready-to-eat meat products being exported to the United States.

6.1.5 Adequate Administrative and Technical Support

The authorization/certification of red meat establishments, wishing to export to the United States of America, has several steps as follows. First, it requires the separate authorization of each establishment, which is granted jointly by the General Directorate of Public Health (within the Ministry of Health and Consumer Affairs) and the General Directorate of Livestock (within the Ministry of Agriculture, Fishing, and Food). Second, the authorization is given after the appropriate validation inspections have been carried out by the relevant authority of the Autonomous Community. Third, after the inspection visit by the relevant Services of the above mentioned General Directorates, health certification of foods to be exported is carried out by the Official Veterinary Services of the Autonomous Communities, which are responsible for establishment control.

The CCA, through the Autonomous communities (Central, Regional, and Local offices), has administrative and technical support to operate its inspection service and has the ability to support a third-party audit.

6.2 Headquarters Audit

The auditor conducted a review of inspection system documents at the headquarters, Autonomous Communities Regions, and local inspection offices of the audited establishments. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- 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, and of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records, including examples of 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.

The following concerns arose as a result the examination of these documents.

- The "monthly" supervisory reports did not reflect actual establishment conditions.
- In one establishment, the verification documentation was not included in the records for corrective actions taken as a result of observations made during "monthly" supervisory visits.
- There was inadequate verification of the implementation of U.S. requirements by the province and/or district.

6.2.1 Audit of Central, Regional, and Local Inspection Sites

The following offices were audited for government oversight functions:

- The Central Competent Authority (CCA) [Ministry of Health and Consumer Affairs (MHCA)] headquarters in Madrid.

Four Health Authority Offices at the Autonomous Communities:

- Office of Castilla-La Mancha Region in Toledo
- Office of Castilla y Leon Region in Valladolid
- Office of Valencia Region in Valencia
- Office of Rioja Region in Logrono

- o Seven local offices at the establishment level

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of seven establishments. One was a slaughter and processing establishment and six were processing establishments. No establishments were delisted by Spain. Two establishments received a Notice of Intent to Delist from Spain inspection officials for inadequate implementation of SSOP, other Sanitation, and HACCP requirements. These establishments may retain their certification for export to the United States provided that they correct all deficiencies noted during the audit within 30 days of the date the establishment was reviewed.

The following deficiencies were observed:

- Two establishments received Notices of Intent to Delist (NOIDs) for inadequate implementation of SSOP, other Sanitation, and HACCP requirements.
- In six establishments, one or more SSOP implementation deficiencies were identified.
- In six establishments, one or more deficiencies were identified concerning on-going HACCP requirements regarding corrective actions and recordkeeping.
- In four establishments, other sanitation (EU Directive 64/433) requirements were not met.
- In six establishments, veterinary meat inspection officials were not specifying the identified deficiencies and were not verifying the corrective actions taken for pre-operational and operational sanitation deficiencies to ensure appropriate disposition of products that might be contaminated or to prevent the recurrence of direct product contamination.
- In one establishment, the operational sanitation monitoring for the 2nd and 3rd shift operations was not carried out either by the establishment or by Government of Spain (GOS) inspection officials. All FSIS requirements must be implemented in all shifts of a certified establishment.
- In one establishment, EU Directive 64/433 was not adequately enforced. For example, the mesenteric lymph nodes of viscera were not palpated by the veterinary inspection officials during post-mortem inspection of swine carcasses.
- In one establishment, verification documentation was not included in the records for corrective actions taken as a result of observations made during "monthly" supervisory visits.
- In all seven establishments, the monthly supervisory audits performed by the CCA, Autonomous Community province, and/or district did not adequately verify the implementation of U.S. and/or Council Directive 64/433 requirements such as: SSOP, other sanitation, and HACCP noncompliance.
- In the only slaughter establishment, veterinary inspection officials were not verifying, documenting, and enforcing the requirements that there be no visible fecal material or ingesta on hog carcasses at or immediately after the final rail as required by FSIS Directive 6420.2
- The Province Autonomous supervisor had provided the FSIS Directive to veterinary inspection officials in the establishment but it was not enforced.

Specific deficiencies are noted on the attached individual establishment reports.

8. LABORATORY AUDITS

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

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples.

The following laboratory was reviewed:

The National Laboratory (Centro Nacional de Alimentacion) a reference laboratory in Majadahonda, Madrid, was audited.

No deficiencies were observed.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses on five areas of risk to assess 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, and except as noted below, Spain'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 and practices, and good product handling and storage practices.

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

9.1 SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the United States' domestic inspection program. The SSOP in the seven establishments were found to meet the basic FSIS regulatory requirements, with the following deficiencies:

- In six establishments, SSOP on-going requirements were not effectively implemented such as:
    - Corrective actions did not address preventive measures or procedures to ensure the appropriate disposition of products that could be contaminated.

- In three of the six establishments, the daily pre-operational and operational sanitation monitoring records did not document the identified deficiencies.

9.2 EC Directive 64/433

In four of the seven establishments, the provisions of EC Directive 64/433 were not effectively implemented.

The following deficiencies were observed:

- In two establishments, employees working in contact with product did not adhere to hygienic practices to prevent cross-contamination of product, and in another establishment, fat residue from the previous day's operation was observed on employee's metal protective aprons in the de-boning room.
- In two establishments, containers for edible and inedible products were cross utilized and were not identified to prevent contamination.
- In one establishment, deteriorated insulation and beaded condensation on one pipe over product was observed in the ham drying room, and condensation from ceilings was dripping in the corridor where the packaged product was passing through to the shipping room.
- In two establishments, facilities were not properly maintained either to prevent conditions that could lead to insanitary conditions or to preclude the entrance of flies, rodents, and other vermin.
- In one establishment, the packaging materials were stored on racks against the walls and numerous boxes were kept directly on the floor, which prevented monitoring of pest control and sanitation programs in the dry storage room. Cobwebs were observed in the dry storage room.

Specific deficiencies are noted in the attached individual establishment reports.

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, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that Spain'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: ante-mortem inspection procedures, ante-mortem disposition, humane handling and humane slaughter, post-mortem inspection procedures, post-mortem disposition, ingredients identification, control of

restricted ingredients, formulations, processing schedules, equipment and records, and processing controls of cured, dried, and cooked products.

The controls also include the implementation of HACCP systems in all establishments and implementation of a testing program for generic *E. coli* in slaughter establishments.

11.1 Humane Handling and Humane Slaughter

No deficiencies were noted.

11.2 HACCP Implementation

All establishments approved to export meat products to the United States are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program.

The HACCP programs were reviewed during the on-site audits of the seven establishments. All seven establishments had not adequately implemented the HACCP requirements.

- In six establishments, on-going verification procedures did not include direct observation of monitoring activities, corrective actions and/or calibration of process instruments.
- In six establishments, HACCP records documenting the monitoring of Critical Control Points (CCP) and/or on-going verification activities did not include the time, initials or signature of the person performing the monitoring or the recording of the actual values observed during the monitoring process.
- In two establishments, deviations from critical limits occurred, but the establishment did not adequately document corrective actions taken in response. They failed to:
    - Identify and eliminate the cause of deviation.
    - Include measures to ensure that the CCP was brought under control.
    - Include measures to prevent the deviation from recurring.
    - Include the appropriate disposition of the product
- In five establishments, in the written HACCP plans, the establishments did not identify all four parts of corrective actions to be taken in response to a deviation from a critical limit such as:
    - Identify and eliminate the cause of deviation.
    - Includes measures to ensure that the CCP will be under control after the corrective action is taken.
    - Include measures to prevent the deviation from recurring.
    - No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.
- In one establishment, the Critical Limit (CL) associated with the Critical Control Points (CCP) for the product temperature was not monitored. The establishment was monitoring the room temperature which was not an identified Critical Limit (CL) in hazard analysis in their HACCP plan.

- In one establishment, monitoring procedures and the frequency with which those procedures will be performed were not clearly described in the written HACCP plans.
- In the only slaughter establishment, veterinary inspection officials were not verifying, documenting, and enforcing the requirements that there be no visible fecal material, or ingesta on hog carcasses at or immediately after the final rail as required by FSIS Directive 6420.2
- The Province Autonomous supervisor had provided the FSIS Directive to veterinary inspection officials in the establishment but it was not enforced.

Specific HACCP deficiencies are noted in the attached individual establishment reports.

11.3 Testing for Generic *E. coli*

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

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

Testing for generic *E. coli* was properly conducted in the slaughter establishment.

11.4 Testing for *Listeria monocytogenes*

All seven establishments audited were producing ready-to-eat products for export to the United States. In accordance with FSIS requirements, the HACCP plans in these establishments had been reassessed to include *Listeria monocytogenes* as a hazard reasonably likely to exist.

No deficiencies concerning government sampling were observed.

11.5 EC Directive 64/433

In one of the seven establishments, the provisions of EC Directive 64/433 were not effectively implemented.

- In the only slaughter establishment, EU Directive 64/433 was not adequately enforced. For example, the mesenteric lymph nodes of viscera were not palpated by the veterinary inspection officials during post mortem inspection of swine carcasses.

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.

No residue laboratory was reviewed during this audit.

Spain's National Residue Control Program for 2006 was being followed and was on schedule.

12.1 EC Directive 96/22

No residue laboratory was reviewed during this audit.

12.2 EC Directive 96/23

No residue laboratory was reviewed during this audit.

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.*

13.1 Daily Inspection in Establishments

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

13.2 Testing for *Salmonella*

Spain has adopted the FSIS regulatory requirements for testing for *Salmonella*

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

Salmonella species testing was implemented in both the slaughter establishment (carcass testing) and processing establishments (producing RTE products).

13.3 Species Verification

Species verification was being conducted in those establishments in which it was required.

13.4 Monthly Reviews

During this audit it was found that in all establishments visited, monthly supervisory reviews of certified establishments were being performed and documented as required with the following exceptions:

- In all seven establishments, the monthly reports did not accurately reflect the conditions of the establishments.

- In one establishment, the inspection officials did not verify the corrective actions taken by the establishment for the identified deficiencies in the monthly reviews.

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 with the following exception:

- In all seven establishments, veterinary inspectors failed to enforce all of the FSIS inspection requirements.

- The mesenteric lymph nodes of viscera were not palpated by the veterinary inspection officials during post mortem inspection of swine carcasses.

In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other counties for further processing.

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

14. CLOSING MEETING

A closing meeting was held on April 26, 2006, in Madrid, Spain with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

The CCA understood and accepted the findings.

for Faizur R. Choudry, DVM
Senior Program Auditor

Faizur H. Choudry

15. ATTACHMENTS TO THE AUDIT REPORT

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

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Campofrio Alimentacion, S.A. Torrijos Toledo	03/31/2006	0014	SPAIN
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Establishment: 0014 Date of Audit: 03/31/2006 Processing Operation

10/51. a) Pieces of fat and fat residue from the previous day's operations were observed on food-contact surfaces of plastic conveyor belt and tables ready for use in the raw ham receiving room. **b)** Rust and salt residue was observed on food-contact surfaces in the salt chutes. **c)** Metal tables and other equipment with open seams and fat residue on food contact surfaces were observed in the ham salting and de-boning rooms. **d)** The plastic curtains which were broken and had turned black because of residue build-up, fat, and pieces of papers were observed on food-contact surfaces, ready for use, in the ham washing machine. **e)** Pieces of meat and fat were observed on-food contact surfaces in the ham molding equipments. The Government of Spain (GOS) inspection officials took corrective actions immediately. 9 CFR 416.13

13/51. The establishment did not document the daily pre-operational and operational sanitation deficiencies identified in the monitoring records and had no documentation to verify the appropriate disposition of the product involved (if any) and/or to verify the preventive measures for recurrence of direct product contamination or adulteration 9 CFR 416.16 and 416.17

15/51. The Critical Limit (CL) associated with the Critical Control Point (CCP 3) for the product temperature was not monitored. The establishment was monitoring the room temperature which was not identified CL in the hazard analysis in their HACCP plan. 9 CFR 417.2(c)

19/51. The written HACCP plan did not address the ongoing verification activities such as: (i) The calibration of process-monitoring instruments; (ii) Direct observation of monitoring activities and corrective actions.

22/51. The records documenting monitoring of Critical Limits were not initialed or signed by the person performing the monitoring. 9 CFR 417.5

39/56/51. a) Gaps at the bottom of one door in the product shipping room and emergency exit door in the dry storage room for the packaging materials were not sealed to prevent the entry of rodents and other vermin. **b)** The packaging materials were stored on racks against the walls and numerous boxes were kept directly on the floor that prevented monitoring of pest control and sanitation programs in the dry storage room. Cobwebs were observed in the dry storage room. **c)** The door between packaged product storage room and shipping room had loose plastic panels. The upper part of door frame had loose panel with flaking paint. CFR 416.2(b) and EEC C/D 64/433 Annex 1 Chapter II

41/56/51. a) Deteriorated insulation and beaded condensation on one pipe over product was observed in one ham drying room. b) Condensation from ceilings was dripping in the corridor where the packaged product was passing through to shipping room. CFR 416.2(d) and EEC C/D 64/433 Annex 1 Chapter II

47/56/51. Fat residue from the previous day's operation was observed on employee's metal protective aprons in the de-boning room. 9 CFR 416.5 and EEC Council Directive 64/433 Annex 1 Chapter III

51. Meat inspection officials did not verify the corrective actions taken, to prevent recurrence of direct product contamination or adulteration, in their documentation of pre-operational and operational sanitation inspection. 9 CFR 416.17

51/56/57. The supervisory audits were conducted monthly but there was no indication of any findings in the supervisory monthly records concerning the aforementioned SSOP, other sanitation and HACCP non-compliances. 9 CFR 416.17; 417.8; and EEC Council Directive 64/433 Annex 1 Chapter II

58 Following a review of the findings by FSIS, this establishment was served with a Notice of Intent to Delist. Consequently, the Central Competent Authority must conduct an in-depth review within 30 days of the date of the audit, to determine whether corrective actions were taken and, if the corrective actions taken were not effective, to remove the establishment from the list of establishments certified as eligible to export to the United States.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Faizur R. Choudry, DVM	Faizur R. Choudry 05/11/06

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Palacios Alimentacion, S.A. Ctra. Logroño S.N. - 26120 Albelda de Iregua La Rioja	04/04/2006	0016	SPAIN
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Establishment: 0016 Date of Audit: 04/03/2006 Processing

10/51. Fat residue from previous day's operation was observed on food-contact surfaces of metal containers and employees' metal mesh gloves in de-boning room and on metal sticks for hanging chorizos in the processing room. 9 CFR 416.13

13/51. The daily pre-operational and operational sanitation monitoring records did not verify the corrective actions taken to ensure appropriate disposition of products that could be contaminated or to prevent the recurrence of direct product contamination or adulteration. 9 CFR 416.16

48/51. Metal containers for edible and inedible product were cross utilized and were not identified to prevent product contamination in the ham de-boning room. 9 CFR 416.3(c)

51. Government of Spain (GOS) meat inspection officials were not verifying the monitoring of HACCP plan by direct observation or measurement at a Critical Control Points (CCP). 9 CFR 417.8(f)

51/57. The supervisory audits were conducted monthly but there was no indication of any findings in the supervisory monthly records concerning the aforementioned SSOP and HACCP non-compliances. 9 CFR 416.17 & 417.8

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Faizur R. Choudry, DVM	Faiz R Choudry 05/11/06

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Redondo Iglesias S.A. Utiel Valencia	04/20/2006	0020	SPAIN
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Establishment: 0020 Date of Audit: 04/20/2006 Processing Operation

13/51. The daily pre-operational and operational sanitation monitoring records did not include documentation of the corrective actions taken to ensure appropriate disposition of products that could be contaminated and/or to prevent the recurrence of direct product contamination or adulteration. 9 CFR 416.16

19/51. Ongoing verification activities did not include the calibration of process-monitoring instruments and corrective actions. 9 CFR 417.4(a)(2)(i)(ii)

20/51. The HACCP plan did not describe the all parts of corrective actions to be taken in response to a deviation from a Critical Limit (CL) such as: 1) Identify and eliminate the cause of the deviation; 2) Include measures to ensure that the CCP was brought under control and; 3) Include measures to prevent the deviation from recurring. 9 CFR 417. 3(a)(4)

22/51. The monitoring records of Critical Limits did not include the time by the person performing the monitoring. 9 CFR 417.5

51. a) Meat Inspection Officials did not verify the corrective actions taken for the identified deficiencies, to prevent recurrence of direct product contamination or adulteration, in their documentation of pre-operational and operational sanitation inspection. **b)** Government of Spain (GOS) meat inspection officials were not verifying the monitoring of HACCP plan by direct observation or measurement at a Critical Control Points (CCP). 9 CFR 417.8 (f) and 416.17

51/57. The supervisory audits were conducted monthly but there was no indication of any findings in the supervisory monthly records concerning the aforementioned SSOP and HACCP non-compliances. 9 CFR 416.17 & 417.8

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Faizur R. Choudry, DVM	Faiz R Choudry 05/11/06

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Campofrio Alimentacion, S.A. Burgos	04/17/2006	0021	SPAIN
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Establishment: 0021 Date of Audit: 04/17/2006 Processing Operation

18/51. The procedures to monitor Critical Limit (CL) for sodium nitrite (50ppm) at the Critical Control Point (CCP2) was not followed as described in the HACCP plan such as each formulation batch will be weighed to control sodium nitrite in the product. 9 CFR 417.2(c)(4)

19/51. The written HACCP plan did not address the ongoing verification activities such as: (i) The calibration of process-monitoring instruments and; (ii) corrective actions. 9 CFR 417.4(a)(2)(i)(ii)

22/51. A) In response to a deviation from the Critical Limit for (High pressure pasteurization "5,000 bare for 8 minutes") for Critical Control Point (CCP 5), corrective actions taken did not: 1) identify and eliminate cause of deviation; 2) include measures to ensure that the CCP was brought under control; 3) include measures to prevent the deviation from recurring and; 4) include the appropriate disposition of the product. **B)** The records documenting monitoring of Critical Limits (CL) did not include time, initial or signature by the person performing the monitoring. 9 CFR 417.3(a)(1)(2)(3)(4) and 9 CFR 417.5

39/56/51. Gaps at the bottom of few doors in the product shipping room were not sealed to prevent the entry of rodents and other vermin. 9 CFR 416.2(b) and EEC C/D 64/433 Annex1 Chapter II

47/56/51. One employee picked up sliced ham consumer size package from the floor and placed it into the edible product container and without washing his hands, handling edible product. The packaged product was not handled in a sanitary manner to maintain the integrity of packaged product. 9 CFR 416.5(a) and EEC C/D 64/433 Annex1 Chapter III

48/51. Red and white color plastic containers for edible and inedible product were cross utilized and were not identified to prevent product contamination in the processing room. 9CFR 416.3(c)

51/56/57. The supervisory audits were conducted monthly but there was no indication of any findings in the supervisory monthly records concerning the aforementioned other sanitation and HACCP non-compliances. 9 CFR 416.17 & 417.8 and EEC C/D 64/433 Annex1

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Faizur R. Choudry, DVM	05/11/06

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Jamones Burgaleses, S.A. Burgos	04/18/2006	0022	SPAIN
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Establishment: 0022 Date of Audit: 04/18/2006 Processing Operation

10/51. The operational sanitation monitoring for the 2nd and 3rd shift operations were not carried out either by the establishment or by the Government of Spain (GOS) inspection officials. Although, the establishment officials stated that they are not producing any product for export to the U.S. during these shifts. 9 CFR 416.13 (b)

13/51. The establishment did not specify the daily pre-operational and operational sanitation deficiencies in the monitoring records and did not include documentation of the corrective actions taken to ensure appropriate disposition of products that could be contaminated and/or to prevent the recurrence of direct product contamination or adulteration. 9 CFR 416.16

15/51. The Critical Limit (CL) temperature for the initial salt room 4C and for the post salt room 10C, were being monitored as written in the HACCP plan but the establishment officials did not conduct co-relation study between room temperature and product temperature in their hazard analysis or provide justification. 9 CFR 417.2

19/51. The written HACCP plan did not address the ongoing verification activities such as: (i) The calibration of process-monitoring instruments; (ii) Direct observation of monitoring activities and corrective actions. 9 CFR 417.5

20/51. The HACCP plan did not describe the all four parts of corrective actions to be taken in response to a deviation from a critical limit (CL) such as: 1) identify and eliminate cause of deviation; 2) include measures to ensure that the CCP was brought under control and; 3) include measures to prevent the deviation from recurring. 9 CFR 417.3(a (1)(2)(3)

22/51. The records documenting monitoring of CL did not include time by the person performing the monitoring. 9 CFR 417.5

51. Meat inspection officials did not perform: a) Reviewing the HACCP plan; b) Reviewing and determining the adequacy of corrective actions taken; and c) Direct observation or measurement at a Critical Control Point (CCP). 417.8. (a)(c)(f)

51/57. The supervisory audits were conducted monthly but there was no indication of any findings in the supervisory monthly records concerning the aforementioned SSOP and HACCP non-compliances. 9 CFR 416.17 & 417.8

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Faizur R. Choudry, DVM	Faizur R Choudry 05/11/06

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Embutidos Fermin, S.L. La Alberca	04/11/2006	0023	SPAIN
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Establishment: 0023 **Date of Audit: 04/11/2006** **Slaughter/Processing**

10/51. Grease, dried blood, and/or fat were observed on food-contact surfaces of plastic containers and metal chains for hanging carcass in the slaughter room and on metal hooks in the processing room. Heavy accumulation of fat on the ham salt washing machine was observed in the processing room. 9 CFR 416.13

13/51. The establishment did not specify the daily pre-operational and operational sanitation deficiencies in the monitoring records and had no documentation to verify the appropriate disposition of the product involved (if any) and/or to verify the preventive measures for recurrence of direct product contamination or adulteration 9 CFR 416.16 and 416.17

22/51. 1) The monitoring records for Critical Limits (CL) did not include the entries for the actual observations; e.g., the monitor was documenting one entry for observation of 50 carcasses when according to the HACCP plan, it was required to record entries for all the carcasses monitored at the zero tolerance for CCP 1-B. (100%) 2) In response to a deviation from the Critical Limit (CL) for zero tolerance (visible fecal), the corrective actions taken did not: a) identify and eliminate the cause of the deviation; b) include measures to ensure that the CCP was brought under control; c) include measures to prevent the deviation from recurring, and d) include the appropriate disposition of the product such as it was not verified if the contamination was removed from carcasses (with fecal contamination) either by the establishment or by the meat inspection officials. 3) The monitoring records of Critical Limits were not initialed or signed by the persons performing the monitoring and on-going verification activities. 9 CFR 417.3(a (1)(2)(3)(4) and 417.5

47/51. One employee in the hog slaughter room was observed picking-up piece of meat from the floor and, without washing his hands, handling edible product. 9 CFR 416.5(a) and Council Directive 64/433/EEC/ Annex1 Chapter III

51. A) Meat inspection officials did not specify the deficiencies identified and did not verify the corrective actions taken, either to ensure the appropriate disposition of products that could be contaminated or to prevent recurrence of direct product contamination or adulteration, in their documentation of pre-operational and operational sanitation inspection. **B)** In the monthly supervisory reviews, the deficiencies identified were not verified by the inspection officials for corrective actions taken by the establishment. **C)** Meat inspection officials did not perform direct observation or measurement at a Critical Control Point (CCP) to verify the adequacy of the HACCP plan. 9 CFR 416.17 and 417.8(f)

55, 56,51. The mesenteric lymph nodes of viscera were not palpated by the veterinary inspection officials during post mortem inspection of swine carcasses. Council Directive 64/433 of June 26, 1964, Annex 1, Chapter VI 25(g) was not met.

57. The supervisory audits were conducted monthly but there was no indication of any findings in the supervisory monthly records concerning the aforementioned Sanitation Standard Operating Procedures (SSOP), other sanitation requirements, and Hazard Analysis and Critical Control Points (HACCP) non-compliances. 9 CFR 416.17 & 417.8

58 Following a review of the findings by FSIS, this establishment was served with a Notice of Intent to Delist. Consequently, the Central Competent Authority must conduct an in-depth review within 30 days of the date of the audit, to determine whether corrective actions were taken and, if the corrective actions taken were not effective, to remove the establishment from the list of establishments certified as eligible to export to the United States.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Faizur R. Choudry, DVM	Faizur R Choudry 05/11/06

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Industrias carnicas El Rasillo. S.A. Calle C/San Mames S.A 26124 El Rasillo, La Rioja	04/05/2006	0024	SPAIN
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Faizur R. Choudry, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Establishment: 0024 Date of Audit. 04/05/2006 Processing Operation

13/51. The daily pre-operational and operational sanitation monitoring records did not include documentation of the corrective actions taken to ensure appropriate disposition of products that could be contaminated and/or to prevent the recurrence of direct product contamination or adulteration. 9 CFR 416.16

15/51. Monitoring of the Critical Limit (CL) for water activity in cured Serrano ham was performed, but the procedures and frequency were not clearly described for the monitoring in the HACCP plan. 9 CFR 417.2(c)

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

20/51. The HACCP plan did not describe the all parts of corrective actions to be taken in response to a deviation from a Critical Limit (CL) such as: appropriate disposition of the product or otherwise adulterated as a result of the deviation enters commerce. 9 CFR 417. 3(a)(4)

51. Government of Spain (GOS) meat inspection officials were not verifying the monitoring of HACCP plan by direct observation or measurement at a Critical Control Points (CCP). 9 CFR 417.8(f)

51/57. The supervisory audits were conducted monthly but there was no indication of any findings in the supervisory monthly records concerning the aforementioned SSOP and HACCP non-compliances. 9 CFR 416.17 & 417.8

61. NAME OF AUDITOR

Faizur R. Choudry, DVM

62. AUDITOR SIGNATURE AND DATE

Faiz R Choudry 05/11/06

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EMBASSY OF SPAIN
Office of Agriculture, Fisheries and Food
2375 Pennsylvania Ave., N.W.
Washington, D.C. 20037

[UNOFFICIAL TRANSLATION]

In response to your letter of June 9, 2006, which accompanied the draft final report of the audit to the Spanish meat inspection system conducted between March 29 and April 26, 2006, I am enclosing a list of observations and corrective actions, for your consideration in the final report.

Madrid, Agust 18, 2006

The Under Director General

The Head of Management and Coordination

Ana Rodríguez Castaño

Sally White, Acting Director, International Equivalence Staff, Office of International Affairs. U.S. Department of Agriculture/Food Safety and Inspection Service

EMBASSY OF SPAIN
Office of Agriculture, Fisheries and Food

OBSERVATIONS TO THE DRAFT FINAL REPORT OF THE AUDIT CONDUCTED ON THE SPANISH MEAT INSPECTION SYSTEM (March 29 to April 26, 2006) **AND CORRECTIVE ACTIONS ADOPTED**

In response to the mentioned draft final report we detail the following observations and corrective actions implemented, as verified by the relevant official veterinary services in charge of the supervision of establishments authorized for export to the United States of America.

OBSERVATIONS

1. Page 5, item 1, par. 3: Where it reads "Food Safety Agency" it should read "Spanish Food Safety Agency."
2. Page 9, item 6.1.4, last paragraph, last subparagraph would be clearer with the following text:

   "Within the scope of this audit, the national government laboratory is the National Food Center (*Centro Nacional de Alimentación*) which depends administratively and functionally from the Spanish Food Safety Agency, an agency integrated within the Ministry of Health and Consumer Affairs. The Laboratory is involved in the export of meat products to the United States, being the only Center currently performing species determination analyses and microbiological analyses for the detection of *Salmonella* and *Listeria Monocytogenes* in those products destined for export to the United States."
3. Page 9, item 6.1.5, where it reads "..the General Directorate of Agrarian Production Health" should read "General Directorate of Livestock."
4. Page 10, item 6.2.1, where it reads "Audit of Regional and Local Inspection Sites" should read "Audit of Central, Regional, and Local Inspection Sites."

CORRECTIVE ACTIONS IMPLEMENTED

1. In a letter issued May 22, 2006, and as a follow up of the teleconference held May 4, 2006, we sent a copy of the "Enhanced Comprehensive Program for the Implementation and Verification of FSIS Requirements," which is based on three pillars:
   a. Enhancement of the verification of the implementation of FSIS requirements;
   b. Unification of the criteria governing the inspections of authorized establishments performed by the SVO.
   c. Training
2. In regards to the NOID issued to establishment 14, Campofrío Alimentación, we attached to our April 21 letter the following documentation:
   a. Verification Report, which concludes with a result of "Acceptable" after verification of all the actions and corrective measures adopted, both on the structural and equipment side (SPS) and on the SSOP and HACCP side.

b. At the same time we submitted a report issued by the company documenting the corrective actions performed.

3. Regarding the NOID to establishment 23, Embutidos Fermín, S.R.L., enclosed in our letter of June 7, we submitted the following documentation:

   a. Verification Report, which concludes with a result of "Acceptable" after verification of all the actions and corrective measures adopted, both on the structural and equipment side (SPS) and on the SSOP and HACCP side.

   b. At the same time we submitted a report issued by the company documenting the corrective actions performed.

   c. Documenting the actions and follow-up performed by this Department and by the the Food Safety and Health Protection Agency (*Agencia de Protección de la Salud y Seguridad Alimentaria*, APSSA) in response to the NOID and the deficiencies detected in the establishment's Official Veterinary Services, we submitted the following documentation:

      - April 12 letter from APPSA Director informing of the deficiencies detected and the intention of immediately addressing those deficiencies;
      - April 12 letter from APPSA Director informing of the deficiencies detected in the establishment and of the NOID, giving the company 30 days to correct those deficiencies;
      - April 21 letter from the General Director of Public Health of this Ministry to APSSA Director analyzing the situation to find an effective and satisfactory response.
      - April 12 report from the Chief Staff Veterinarian of my department, which was annexed to the April 12 letter to APSSA Director.
      - Report from the Head of Regulation and Health Authorization of APSSA regarding the verification and corrective actions on the Official Control. Annexes I, II, and III of this report are the recording forms created for the verification by the Official Veterinary Services of the "Procedure for Control of Fecal Matter, Directive FSIS 6420.2," "Preoperative and Operative for SSOP," and "CCPs."

Madrid, August 18, 2006