



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

JUN - 1 2005

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

Dear Dr. Ángel García:

The Food Safety and Inspection Service (FSIS) conducted an on-site enforcement audit of Spain's meat inspection system December 1 through 10, 2004. Enclosed is a copy of the final report, which includes comments received from the government of Spain. In regard to your question about individual microbiology laboratory review forms, we currently do not include any microbiology laboratory form as part of the FSIS audit report.

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

Sincerely,

Steven A. McDermott

for

Sally White, Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc: Stephen Hammond, Counselor, American Embassy, Madrid
Samuel Juarez, Agricultural Counselor, Embassy of Spain, Washington, DC
Tony Van der haegen, Agric./Consumer Affairs, EU Mission to the U.S.,
Washington, DC
Bernard Van Goethem, Director, Directorate E, European Commission, Brussels
Norval Francis, Minister-Counselor, US Mission to the EU, Brussels
Robert Macke, International Trade Policy, FAS
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Linda Swacina, Executive Director – FSIA, OIA, FSIS
Country File (Spain Audit File - FY 2005)

FSIS:OIA:IES. S. McDermott:690-0297: 5/4/2005

MAY 31 2005

FINAL

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

DECEMBER 1 THROUGH DECEMBER 10, 2004

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

| | |
|----------------|---|
| CCA | Central Competent Authority [Ministerio de Sanidad y Consumo (Ministry of Health and Consumer Affairs)] |
| CFR | U.S. Code of Federal Regulations |
| CVO | Chief Veterinary Officer |
| <i>E. coli</i> | <i>Escherichia coli</i> |
| EC | European Community |
| FSIS | Food Safety and Inspection Service |
| NOID | Notice of Intent to Delist |
| PR/HACCP | Pathogen Reduction/Hazard Analysis and Critical Control Point System |
| RTE | Ready-to-Eat |
| SSOP | Sanitation Standard Operating Procedures |
| Salmonella | Salmonella species |
| US | United States |

1. INTRODUCTION

The audit took place in Spain from December 1 through 10, 2004.

An opening meeting was held on December 1 in Madrid with the Central Competent Authority (CCA). At this meeting, the audit team confirmed the objective and scope of the audit, the audit team's itinerary, and requested additional information needed to complete the audit of Spain's meat inspection system.

The audit team members were accompanied during the entire audit by representatives from the central office of the Ministry of Health and Consumer Affairs (hereon referred to as the Ministry of Health) and/or representatives from four of Spain's regional governments, i.e., Autonomous Communities.

2. OBJECTIVE OF THE AUDIT

This audit was an enforcement audit. The objective of the audit was to determine whether Spain was maintaining an equivalent inspection system and, therefore, retain eligibility to export meat and meat products to the United States.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, four Autonomous Communities, five pork processing establishments, one swine slaughter establishment, and 4 laboratories conducting microbiological testing of meat samples.

| Competent Authority Visits | | | Comments |
|-----------------------------------|------------------------|---|--|
| Competent Authority | Central | 1 | Ministry of Health |
| | Autonomous Communities | 4 | Regional Governments |
| Microbiological Laboratories | | 4 | Establishments Producing Pork Products |
| Meat Slaughter Establishments | | 1 | |
| Meat Processing Establishments | | 5 | |

3. PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with Ministry of Health inspection officials at the central office and Autonomous Communities offices 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 or Autonomous Communities. The third part involved on-site visits to 5 certified establishments and one non-certified establishment that was presented to FSIS as fully meeting the U.S. import requirements.

Government oversight was evaluated using the five FSIS government oversight requirements stipulated in FSIS regulations (9 CFR 327). 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*.

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

At the opening meeting, the audit team explained to the CCA that their inspection system would be audited in accordance with three areas of focus. First, under provisions of the EC/US Veterinary Equivalence Agreement, the FSIS audit team would normally audit Spain's meat inspection system against EC Directives:

- 64/433/EEC, of June 1964, entitled "Health Problems Affecting Intra-Community Trade in Fresh Meat"
- 96/22/EC, 29 April 1996, entitled "Prohibition on the Use in Stockfarming of Certain Substances Having a Hormonal or Thyrostatic Action of B-agonists"
- 96/23/EC, 29 April 1996, entitled "Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products"

However, since this audit did not include a review of Spain's residue program, EC Directives 96/22 and 96/23 were not relevant to this audit.

Second, in areas not covered by EC Directive 64/433, the FSIS audit team would audit against the FSIS inspection 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*, *Salmonella* species, and *Listeria monocytogenes*.

Third, the audit team would audit against any equivalence determinations that have been made by FSIS for Spain under provisions of the Sanitary/Phytosanitary Agreement. Currently, no equivalences determinations are in affect.

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 300 to end), which include the Pathogen Reduction/HACCP regulations.

In addition, compliance with EC Directive 64/433 was also assessed by the FSIS audit team.

5. SUMMARY OF PREVIOUS AUDIT

Final audit reports are available on FSIS' website at:

http://199.140.65.44/regulations_&_policies/Foreign_Audit_Reports/index.asp.

FSIS audit of Spain's inspection system conducted in March/April 2004.

- Six certified establishments and two laboratories reviewed.
- Four establishments received an NOID.
- Inadequate HACCP implementation in one establishment.
- No daily inspection in three establishments.
- Inadequate implementation of *Listeria* regulations.
- *Salmonella* testing for RTE products was not implemented. (This deficiency was not cited during the audit but determined later.)

6. MAIN FINDINGS

6.1 Legislation

The legislative responsibility of Spanish establishments certified to export meat to the United States is co-shared by Spain's Ministry of Health and the regional governments, i.e., Autonomous Communities. Each Autonomous Community is the government Spanish body that has legislative authority over the exporting establishments and regional government laboratories. The Ministry of Health, although not having legislative authority over the exporting establishments, does have legal authority to certify and decertify these establishments. The Ministry of Health also has legislative authority of the National Government Laboratory that currently conducts all microbiological testing of samples of meat products being exported to the United States.

6.2 Government Oversight

The CCA has the organizational structure and staffing to ensure uniform implementation of the U.S. import inspection requirements.

6.1.1 CCA Control Systems

Primary government oversight of certified establishments falls under the Autonomous Communities, which is Spain's regional governments. The country of Spain is divided into 17 Autonomous Communities. In regard to the six establishments reviewed during this audit, they are located within the following four Autonomous Communities:

- Castilla y Leon
- Castilla-La Mancha

- La Rioja
- Valencia

Within each Autonomous Community, the region is subdivided into Provincial and District governments, which also play a role in providing government enforcement and oversight of establishments certified to export meat to the United States. Each Autonomous Community determines the amount of shared responsibility to Provinces and Districts and it varies slightly for each Autonomous Community. Regardless of the distribution of enforcement and oversight responsibility of certified establishments, the Autonomous Community determines all final decisions regarding compliance with FSIS inspection requirements. All three governing bodies have daily coordination with one another.

Audit of the CCA control systems included the following document reviews during on-site visits to headquarters, regional offices, and local inspection offices (establishments):

- Supervisory visits to establishments that were certified to export to the U.S.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Label approval records.
- Sampling and analyses for residues and water supply.
- Pathogen reduction and other food safety initiatives such as SSOP and HACCP programs, generic *E. coli*, *Salmonella* species, and *Listeria monocytogenes* testing.
- Sanitation, slaughter and processing inspection procedures and standards.
- Export product inspection and control including export certificates.
- National residue control program and monitoring results.
- Enforcement records including examples of criminal prosecutions, consumer complaints, recalls, seizures and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

No concerns arose as a result of the examination of these documents with the exception of the following:

- Salmonella testing by the government was not being conducted as required.

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 six 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.

6.1.3 Assignment of Competent, Qualified Inspectors

Upon entering government employment as an official inspector, new employees undergo induction training as well as participate in on-the-job practical training under the supervision of experienced veterinarians. Training is supplemented by refresher courses on inspection requirements and participation in US government training seminars. The Autonomous Communities determine the amount of training for its inspection personnel. In addition, the Ministry of Health can recommend training for inspection personnel.

FSIS inspection requirements are distributed from the Ministry of Health to the Autonomous Communities, which provides these requirements to the Provinces, Districts, and applicable establishments. The deficiencies noted during the audit in regard to HACCP and SSOP would suggest that additional training in FSIS HACCP and SSOP is needed for inspection personnel.

6.1.4 Authority and Responsibility to Enforce the Laws

The Autonomous Communities have the authority and responsibility to enforce the applicable laws relevant to establishments producing product for export to the United States. However, the audit findings demonstrate that the Ministry of Health needs to take strengthen its oversight of the Autonomous Communities to ensure complete compliance with the U.S. import inspection requirements. Accordingly:

- *Salmonella* testing by the government was not implemented in the slaughter establishment. Although this establishment was not certified to export to the United States, it was presented to FSIS as fully meeting the U.S. import inspection requirements.
- *Salmonella* testing by the government was not implemented in the five processing establishments for RTE products. In addition, in one processing establishment, a second RTE product was not being tested for *Listeria monocytogenes*.

6.1.5 Adequate Administrative and Technical Support

During the audit, the audit team found that the Ministry of Health has administrative and technical support to operate Spain's inspection system and has the ability to support a third-party audit.

6.2 Headquarters / Regional Offices / Local Inspection Offices

The audit team conducted a review of inspection documents that included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the United States.
- Training records for inspectors.
- New laws and implementation documents such as regulations, notices, directives and guidelines.

- Export product inspection and control including export certificates.
- Enforcement records, including examples of recalls, control of noncompliance product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

With the exception of the finding that has been previously reported, no serious concerns arose as a result the examination of these documents.

7. ESTABLISHMENT AUDITS

The FSIS audit team reviewed five certified pork processing establishments and one porcine slaughter establishment that was not certified but presented to FSIS as fully meeting the U.S. import requirements.

The review of the non-certified slaughter establishment was in connection with the government of Spain seeking to have its authority returned from FSIS to certify slaughter establishments for export to the United States. This authority was removed as the result of serious concerns regarding inadequate implementation of PR/HACCP identified during a 1997 FSIS audit of Spain's meat inspection system.

Specific deficiencies are noted on the attached individual establishment check lists.

8. LABORATORY AUDITS

One residue laboratory was reviewed. There were no concerns.

During reviews of microbiology laboratories, emphasis was placed on the methods, standards, and analytical control procedures relative to the testing of meat products for Species Verification and the presence of *Listeria monocytogenes* and *Salmonella*. Three of the four laboratories reviewed were public laboratories located in the cities of Burgos, Salamanca, and Toledo. None of the three laboratories were testing samples of meat products being exported to the United States.

The fourth laboratory reviewed was the government of Spain's Central National Laboratory located in Majadahonda. This laboratory has been certified under the requirements for ISO 17025. In addition, this laboratory is the only lab currently conducting microbiological testing of samples of meat products being exported to the United States. As the result of the review of this laboratory, the testing methods being used for the detection of *Listeria monocytogenes* and *Salmonella* were not FSIS-approved methods. The Central National Laboratory has sent alternative laboratory testing methods to FSIS for an equivalence determination.

9. SANITATION CONTROLS

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

Based on the on-site reviews of the six establishments, 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, 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. Of the six establishments reviewed, there was inadequate implementation of SSOP requirements in 10 establishments. The degree of non-compliance varied.

SSOP implementation deficiencies are noted on the attached individual establishment reports.

9.2 EC Directive 64/433

All provisions of EC Directive 64/433 were being met in the six establishments reviewed.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS audit team reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. 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 audit team reviewed was Slaughter/Processing Controls. Controls reviewed included the following areas: ante-mortem and post-mortem inspection procedures and 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.

Review of controls also included the implementation of HACCP systems in all establishments and implementation of testing programs for generic *E. coli* and *Listeria monocytogenes*.

11.1 Humane Handling and Humane Slaughter

No deficiencies were noted

11.2 HACCP Implementation

All establishments certified to export meat products to the United States are required to have developed and adequately implemented a HACCP program. This requirement also applied to the one non-certified slaughter establishment, which was presented to FSIS as fully meeting the U.S. import inspection requirements. 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 reviews of six establishments. Of these establishments, there was inadequate implementation of HACCP requirements in 2 establishments.

HACCP implementation deficiencies are noted on the attached establishment checklists.

11.3 Testing for Generic *E. coli*

The slaughter establishment had effectively implemented testing for generic *E. coli*.

11.4 Testing for *Listeria monocytogenes*

The five processing establishments reviewed were producing RTE pork products for export to the United States. All five establishments had conducted a hazard analysis and reassessed their HACCP plans to include testing of RTE products for *Listeria monocytogenes* with the exception of the following:

- In one processing establishment, *Listeria* testing was not being conducted on a second RTE product being produced and exported to the United States.

Deficiencies regarding *Listeria* implementation are noted on the attached establishment checklists.

12. RESIDUE CONTROLS

The fourth of the five risk areas normally reviewed by FSIS is Residue Controls. For this audit, FSIS did not review Spain's residue controls.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS audit team reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing programs for *Salmonella* and Species Verification.

13.1 Daily Inspection in Establishments

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

13.2 Testing for *Salmonella*

- Slaughter establishment. The government of Spain had not implemented a testing program for *Salmonella* species.
- Processing establishments. The government of Spain had not implemented a testing program for *Salmonella* species for RTE products.

13.3 Species Verification

At the time of this audit, Spain was required to test meat products for species verification. Species verification testing was being conducted as 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.

13.5 Inspection System Controls

The CCA had controls in place for ante-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.

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 countries 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 December 10, 2004 in Madrid with the CCA. At this meeting, the primary findings from the audit were presented by the FSIS audit team.

The CCA understood and accepted the findings.

STEVEN A. MCDERMOTT
Team Leader
International Equivalence Staff
Office of International Affairs

A handwritten signature in black ink, appearing to read "Steven A. McDermott", with a long horizontal flourish extending to the right.

15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms

Foreign Country Response to Draft Final Audit Report (when it becomes available)

Foreign Establishment Audit Checklist

| | | | |
|---|-----------------------------|---|-----------------------------|
| 1. ESTABLISHMENT NAME AND LOCATION Campofrio Ctra. Toledo 45500 Torrijos | 2. AUDIT DATE 12/07/2004 | 3. ESTABLISHMENT NO 14 | 4. NAME OF COUNTRY Spain |
| 5. NAME OF AUDITOR(S) Dr. Nader Memarian | | 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT | |

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

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

60. Observation of the Establishment

Establishment: 14

Audit Date: 12/07/2004

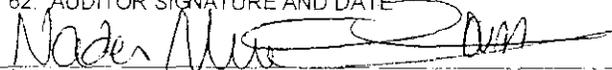
Processing Operation

51 Spanish Government did not perform monthly Salmonella testing on Ready-to-Eat product.

61. NAME OF AUDITOR

Dr. Nader Memarian

62. AUDITOR SIGNATURE AND DATE



12-14-04

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|---|-----------------------------|---|-----------------------------|
| 1. ESTABLISHMENT NAME AND LOCATION Embutidos Palacios S.A. Alberda de Iregua Ctra. Logrono s.n. - 2620 | 2. AUDIT DATE 12/03/2004 | 3. ESTABLISHMENT NO. 16 | 4. NAME OF COUNTRY Spain |
| 5. NAME OF AUDITOR(S) Dr. Farooq Ahmad | | 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT | |

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

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

60. Observation of the Establishment

Spain Est. # 16 (processing only) Date of audit = Dec 3rd 2004

Note: - The previous deficiency noted during the last audit in March 2004 has been corrected.

12/51 = Preventive measures are not included in the pre-op sanitation and operational sanitation program after the corrective actions are taken and verified, neither in establishment's records nor in official's records. (9CFR 416.15(b))

38/51 = (1) Receiving door used to receive raw frozen pork has opening from outside on both side of the platform. (9CFR 416.2(3))

(2) In the dry storage room the packaging material is stored against the wall leaving no room for inspection of this Facility. (9CFR 416.2(a))

51 = (1) The government officials are not taking finished product samples for *Salmonella* at this establishment.

(2) The government officials are not taking finished product samples of ^(ready-to-eat) pork loins for *Listeria monocytogenes* at this establishment.

61. NAME OF AUDITOR

Dr. Farooq Ahmad

62. AUDITOR SIGNATURE AND DATE



12/14/2004

Foreign Establishment Audit Checklist

| | | | |
|---|-----------------------------|---|-----------------------------|
| 1. ESTABLISHMENT NAME AND LOCATION Redondo Iglesias Ctr. N 111, Km 266 Utiel 46300 | 2. AUDIT DATE 12/03/2004 | 3. ESTABLISHMENT NO. 20 | 4. NAME OF COUNTRY Spain |
| 5. NAME OF AUDITOR(S) Dr. Nader Memarian | | 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT | |

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

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

60. Observation of the Establishment

Establishment: 20

Audit Date: 12/03/2004

Processing Operation

51 Spanish Government did not perform monthly Salmonella testing on Ready-to-Eat product.

61. NAME OF AUDITOR

Dr. Nader Memarian

62. AUDITOR SIGNATURE AND DATE

Nader Memarian  12-14-04

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|---|---------------------|---|-----------------------------|
| 1. ESTABLISHMENT NAME AND LOCATION Campofrio Pol. Ind. Gamonal-Villimar Burgos | 2. AUDIT DATE 21 | 3. ESTABLISHMENT NO. | 4. NAME OF COUNTRY Spain |
| 5. NAME OF AUDITOR(S) Dr. Farooq Ahmad | | 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT | |

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

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

60. Observation of the Establishment

Spain Est. # 21 (processing only) Date of audit = Dec. 2nd 2004

Note: - There was no deficiency noted during the last audit in March 2004.

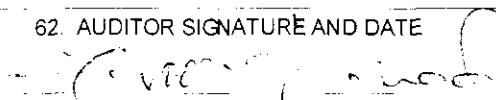
11/51 = It was observed during the Pre-op-sanitation that paper towels are being used to dry the processing equipment and small pieces of paper towels were left attached to the meat contact surfaces of the processing equipment. (9CFR 416.14)

16/51 = It was noted during the pre-shipment review documents that establishment's responsible employee did not signed these documents. (9CFR 417.5)

61. NAME OF AUDITOR

Dr. Farooq Ahmad

62. AUDITOR SIGNATURE AND DATE

 12/14/2004

Foreign Establishment Audit Checklist

| | | | |
|--|-----------------------------|---|-----------------------------|
| 1. ESTABLISHMENT NAME AND LOCATION Jamones Burgalas Calle de La Bureba s/n Burgos | 2. AUDIT DATE 12/01/2004 | 3. ESTABLISHMENT NO. 22 | 4. NAME OF COUNTRY Spain |
| 5. NAME OF AUDITOR(S) Dr. Farooq Ahmad | | 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT | |

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

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

60. Observation of the Establishment

Spain Est. # 22 (processing only) Date of audit = Dec. 1st 2004

Note: - The previous deficiency noted during the last audit in March 2004 has been corrected.

15/51 = HACCP/Hazards analysis.

- 1) It was noted during the review of establishment's hazard analysis documents that there is no physical and chemical hazard during the processing without any reference for this justification. (9CFR 417.2)
- 2) It was noted that there was no indication of how much product (lbs) will be treated with 20 kg of Nitrite and 100kg of Salt at their PCC 2 location. (9 CFR 417.2)

61. NAME OF AUDITOR

Dr. Farooq Ahmad

62. AUDITOR SIGNATURE AND DATE

Farooq Ahmad 12/14/2004

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

| | | | |
|--|---------------------------|---|-----------------------------|
| 1. ESTABLISHMENT NAME AND LOCATION Fermin Embutidos Y Jamones 37624 La Alberca | 2. AUDIT DATE 12/01/04 | 3. ESTABLISHMENT NO 10.04664/SA | 4. NAME OF COUNTRY Spain |
| 5. NAME OF AUDITOR(S) Dr. Nader Memarian | | 6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT | |

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

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

60. Observation of the Establishment

Establishment: 10.04664 SA

Audit Date: 12/01/2004

Slaughter/cut-up Operation

- 13/51 SSOP records did not document all three parts of the corrective action (9CFR part 416.15 and 416.16).
- 22/51 A) HACCP records documenting corrective actions to be followed in response to a deviation from a critical limit did not address all four parts of the corrective action (9CFR part 417.3(a) and 417.5(a)3).
B) HACCP monitoring and verification records did not include time/initial for each entry (9CFR part 417.5(b)).
C) Pre-shipment record was not available for review (9CFR part 417.5(c)).
- 51 Salmonella performance standards was conducted by the establishment (9CFR part 310.25(b)).

61. NAME OF AUDITOR

Dr. Nader Memarian

62. AUDITOR SIGNATURE AND DATE

Nader Memarian DVM → 12-14-04

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE
 12/09/2004

NAME OF FOREIGN LABORATORY
 Laboratorio De Salud Publica

FOREIGN GOV'T AGENCY
 Junta de Castilla y Leon

CITY & COUNTRY
 Valladolid, Spain

ADDRESS OF LABORATORY
 Adva. Ramon y Cajal, 6

NAME OF REVIEWER
 Dr. Farooq Ahmad

NAME OF FOREIGN OFFICIAL

| Residue Code/Name | | | 105 | 108 | 117 | 200 | 305 | 310 | 800 | | | | | | |
|------------------------------|------------------------------|--------|-----------------|-----|-----|-----|-----|-----|-----|---|--|--|--|--|--|
| SAMPLING PROCEDURES | REVIEW ITEMS | ITEM # | EVALUATION CODE | | | | | | | | | | | | |
| | Sample Handling | 01 | | A | A | A | A | A | A | A | | | | | |
| | Sample Frequency | 02 | | A | A | A | A | A | A | A | | | | | |
| | Timely Analysis | 03 | | A | A | A | A | A | A | A | | | | | |
| | Compositing Procedure | 04 | | O | O | O | O | O | O | O | | | | | |
| | Interpret Comp Data | 05 | | O | O | O | O | O | O | O | | | | | |
| | Data Reporting | 06 | A | A | A | A | A | A | A | | | | | | |
| ANALYTICAL PROCEDURES | Acceptable Method | 07 | A | A | A | A | A | A | A | | | | | | |
| | Correct Tissue(s) | 08 | A | A | A | A | A | A | A | | | | | | |
| | Equipment Operation | 09 | A | A | A | A | A | A | A | | | | | | |
| | Instrument Printouts | 10 | A | A | A | A | A | A | A | | | | | | |
| QUALITY ASSURANCE PROCEDURES | Minimum Detection Levels | 11 | A | A | A | A | A | A | A | | | | | | |
| | Recovery Frequency | 12 | A | A | A | A | A | A | A | | | | | | |
| | Percent Recovery | 13 | A | A | A | A | A | A | A | | | | | | |
| | Check Sample Frequency | 14 | A | A | A | A | A | A | A | | | | | | |
| | All Analyst W/Check Samples | 15 | A | A | A | A | A | A | A | | | | | | |
| | Corrective Actions | 16 | A | A | A | A | A | A | A | A | | | | | |
| | International Check Samples | 17 | A | A | A | A | A | A | A | | | | | | |
| REVIEW | Corrected Prior Deficiencies | 18 | EVAL. CODE | O | O | O | O | O | O | | | | | | |
| OTHER REVIEW | | 19 | EVAL. CODE | | | | | | | | | | | | |
| | | 20 | EVAL. CODE | | | | | | | | | | | | |

Signature of reviewer *Farooq Ahmad*

Date 12/15/04



Phone (202) 728 2339
(202) 452 0100
Fax (202) 728 2320
info@mapausa.org

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

UNOFFICIAL TRANSLATION

Sally White
Acting Director
International Equivalence Staff
Office of International Affairs
U.S. Department of Agriculture
Food Safety and Inspection Service
1400 Independence Avenue
Washington, D.C. 20250

Madrid, April 8, 2005

Dear Sally,

In reference to your February 7 letter received through the United States Embassy in Madrid accompanying the Final Draft of the Report on the Audit of the Spanish Meat Inspection System, performed December 1-10, 2004, please be informed that we have distributed the mentioned document to the four relevant Autonomous Communities and the Spanish Food Safety Agency for their comments, which I am enclosing.

Best regards,

[Signed]

Pedro Ángel García González

COMMENTS TO THE DRAFT REPORT ON THE AUDIT PERFORMED BY FSIS DECEMBER 1-10, 2004

Upon reading the draft, the following comments have been suggested:

- Page 9, item 8, second paragraph: the paragraph indicates that three laboratories were visited, but the Annex does not include detailed reports on the visits.
- Page 9, item 8, third paragraph: it should be added that the National Food Center has sent FSIS a description of its analysis methods for an evaluation of their equivalence. In addition, the Annex does not include a detailed report on the visit.
- Page 13: Annexes to the draft report: There are no detailed reports on the four visited laboratories: Burgos, Salamanca, Toledo, and the National Food Center.
- Report on Establishment #21: the first page mentions deficiencies in points 11,22, and 51, whereas the second page details deficiencies on points 11, 16, and 51. This needs clarification, since it may be a typo.
- Last page of the Annex: it includes the report on the residue analysis laboratory in Valladolid, but in page 9, item 8, first paragraph, the report indicates that no residue analysis lab was visited.