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

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

AUG 12 2005

Dear Dr. Ángel García:

This letter transmits the Food Safety and Inspection Service final report of the meat inspection system audit conducted in Spain March 30 through April 21, 2005. Enclosed is a copy of the final report, which includes comments received from the government of Spain concerning the draft final report of the same audit.

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,

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
Canice Nolan, 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
James Dever, FAS Area Director
Amy Winton, State Department
Barbara Masters, Administrator, FSIS
Donald Smart, Director, Review Staff, FSIS
Karen Stuck, Assistant Administrator, OIA, FSIS
William James, Deputy Assistant Administrator, OIA, FSIS
Sally White, Director, IES, OIA, FSIS
Clark Danford, Director, IEPS, OIA, FSIS
Steve McDermott, IES, OIA, FSIS
Mary Stanley, Director, IID, OIA, FSIS
Armia Tawadouras, Director, Codex Programs Staff, OIA, FSIS
Linda Swacina, Executive Director – FSIA, OIA, FSIS
Country File (Spain Audit File - FY 2005)

FINAL

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

MARCH 30 THROUGH APRIL 21, 2005

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

14. CLOSING MEETING

15 ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority [Ministerio de Sanidad y Consumo or Ministry of Health and Consumer Affairs]
E. coli	*Escherichia coli*
FSIS	Food Safety and Inspection Service
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
RTE	Ready-to-Eat
Salmonella	*Salmonella* species
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures
VEA	European Community/United States Veterinary Equivalence Agreement

1. INTRODUCTION

The audit took place in Spain from March 30 through April 21, 2005.

An opening meeting was held on March 30, 2005, 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, Food Safety Agency (Agencia Espanola de Seguridad Alimentaria), and representatives from Spain's Regional Autonomous Communities.

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, three Autonomous Communities, five pork processing establishments, one swine slaughter establishment, and two laboratories conducting microbiological and residue testing of meat samples.

Competent Authority Visits			Comments
Competent Authority	Central	1	Ministry of Health and Consumer Affairs
	Regional	3	Autonomous Communities
	Local	6	Establishment level
Laboratories		2	Microbiology and Residue Laboratories
Meat Slaughter Establishments		1	Pork Producing Establishments
Meat Processing Establishments		5	

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 or regional offices. The third part involved on-site visits to six establishments: one slaughter establishment and five processing establishments. The slaughter establishment was not certified to export product to the United States but presented as fully meeting the FSIS inspection requirements. The fourth part involved visits to two government laboratories.

The Centro National de Alimentacion (CNA) laboratory was conducting analyses of field samples for the presence of *Listeria monocytogenes* and *Salmonella* for Ready-to-Eat (RTE) products. The Centre de Salut Publica de Valencia was conducting analyses of field samples for Spain's national residue control program.

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*, *Listeria monocytogenes*, 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, there are no equivalences determinations in effect for Spain.

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

<u>During the March/April 2004 FSIS audit of Spain's inspection system:</u>

- 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.)

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

- 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 Standard was not conducted 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*.
- All six establishments, as well as the government's Central National Laboratory, were cited for inadequate government enforcement.

6. MAIN FINDINGS

6.1 Legislation

The auditor was informed that the relevant EC Directives, determined equivalent under the VEA, had been transposed into Spain legislation.

6.2 Government Oversight

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

6.2.1 CCA Control Systems

The CCA has jurisdiction over Spain's 17 Autonomous Communities. Each Autonomous Community has two departments: the Public Health Department and the Animal Health Veterinary Services Department. The 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 (Central, Province, and Local). Local Autonomous Administration is responsible for carrying out the inspection activities in slaughter and processing establishments.

6.2.2 Ultimate Control and Supervision

Official control of inspection activities is under direct supervision of the Autonomous Communities which have received public health competencies through the Ministry of Health which in turn oversees the entire process annually. The Autonomous Communities perform the functions needed to fulfill the FSIS inspection requirements. These functions are based on instructions issued by the CCA and in accordance with the criteria agreed upon in the different coordinating meetings between the CCA and the Autonomous Communities.

6.2.3 Assignment of Competent, Qualified Inspectors

According to Autonomous Communities Legislations:

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 is, at times, required by the legislation, or according to the establishment size and/or types of manufactured products.

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

6.2.4 Authority and Responsibility to Enforce the Laws

The Autonomous Communities possess delegated health authority for executing 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 follow:

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, and etc.

The Ministry of Health and Consumer Affairs has legislative authority over the exporting establishments and therefore has 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 RTE meat products being exported to the United States.

6.2.5 Adequate Administrative and Technical Support

The authorization/certification of red meat establishments wishing to export to the United States of America has several steps which brought together in the April 4, 1995, Decree. First, the application must be filled out by the establishment and addressed to the General Office of Public Health (DGSP) of the Ministry of Health and Consumer affairs. Second, in accordance with the general procedures for authorization of establishments for the export of meat and meat products to the United States, the DGSP requests the competent authority of the Autonomous Communities for the corresponding report on compliance with the demands to be met for that authorization. Third, once the favorable report on such compliance has been received, MSC and MAPA officials make the verification visit to assure that such compliance meets the requirements established by FSIS. Finally, when it is favorable, both departments make the authorization jointly on the establishment and notify FSIS. Health certification of foods that are going to be exported is performed by the Official Veterinary Services of the Autonomous Communities, which are responsible for routine monitoring of the establishments.

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.

6.3 Headquarters Audit

The auditor conducted a review of inspection system documents at the headquarters, Autonomous Communities, 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.
- Label approval records such as generic labels and animal raising claims.
- 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.

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

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

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of six establishments. One was a slaughter establishment that was not certified but presented to FSIS as fully meeting the U.S. inspection requirements and five were processing establishments. None of the six establishments were delisted or received a Notice of Intent to Delist the establishment from Spanish inspection officials.

Specific deficiencies are noted on the attached individual establishment report checklists.

8. LABORATORY AUDITS

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

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

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

The following laboratories were reviewed:

The Centre de Salut Publica de Valencia, a government residue laboratory located in Valencia Autonomous Community. No deficiencies were noted.

The Centro Nacional de Alimentacion, the Central National Laboratory, located in Majadahonda. This laboratory has been certified under the requirements of ISO 17025. This is the only lab in Spain currently conducting microbiological testing for both *Listeria monocytogenes* and *Salmonella* in RTE meat products being exported to the United States. The testing methods used for the detection of *Listeria monocytogenes* and *Salmonella* were not FSIS-approved methods. Spain has been submitted its alternative testing methods to FSIS for equivalence determination. Meanwhile, Spain may continue using its methods until further notification by FSIS.

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 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. The SSOP in the six establishments were found to meet the basic FSIS regulatory requirements with no deficiencies.

9.2 EC Directive 64/433

In all establishments, the provisions of EC Directive 64/433 were effectively implemented. As for the SPS requirements, there was inadequate implementation of these requirements in two establishments.

Specific SPS 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 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 six establishments. Three establishments had not fully implemented the HACCP requirements.

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

11.3 Testing for Generic *E. coli*

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

11.4 Testing for *Listeria monocytogenes*

Five of the six 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 occur.

No deficiencies concerning government sampling were noted.

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.

The Centre de Salut Publica de Valencia, a government residue laboratory located in Valencia Autonomous Community, was reviewed. No deficiencies were noted.

Spain's National Residue Control Program for 2005 was being followed and was on schedule.

12.1 EC Directive 96/22

In the Centre de Salut Publica de Valencia, the provisions of EC Directive 96/22 were effectively implemented.

12.2 EC Directive 96/23

In the Centre de Salut Publica de Valencia, the provisions of EC Directive 96/23 were effectively implemented.

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*

Salmonella species testing was implemented in the slaughter establishment (carcass testing) and the 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.

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.

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 21, 2005 in Madrid 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.

Dr. Nader Memarian
Senior Program Auditor

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
Jamones Burgalesses Pol. Ind Gamonal-Villimar C/La Bureba, S/N- Apdo.84 09007 Burgos	April 05, 2005	22	Spain
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Nader Memarian		[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.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
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	O
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Establishment: 22 Audit Date: April 05, 2005 Processing Operation

15/51 The written HACCP plan did not list the verification procedures (direct observation of monitoring activities and review of the records) and the frequency with which those procedures should be performed {9CFR part 417.2(c)(7)}.

61. NAME OF AUDITOR

Dr. Nader Memarian

62. AUDITOR SIGNATURE AND DATE

8/5/05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Campofrio Ctra. Toledo 45500 Torrijos	April 01, 2005	14	Spain
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Nader Memarian		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
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24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	O
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	X
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55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Establishment: 14 Audit Date: April 01, 2005 Processing Operation

39/51 Condensation from an overhead pipe was dripping onto one side of a working table in which exposed products were being packed on the other side of the same table.

45/51 Rough, interrupted, and uneven welds were observed on the food contact surfaces of:
A) one of the ham molding equipment B) one stainless steel table
which may prevent the adequate removal of product residue and could become a source of product contamination.

61. NAME OF AUDITOR

Dr. Nader Memarian

62. AUDITOR SIGNATURE AND DATE

(for Dr. Memarian) 5/5/05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Palacious Alimentacios Ctra. De Logrono, S/N 26120 Albelda De Iregua La Rioja	April 07, 2005	16	Spain
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Nader Memarian		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

60. Observation of the Establishment

Establishment: 16 Audit Date: April 07, 2005 Processing Operation

15/51 The written HACCP plan did not include direct observation of monitoring activities as part of its verification procedures {9CFR part 417.2(c)(7)}.

22/51 Records documenting monitoring and verification activities did not include the time the specific event occurs {9 CFR part 417.5(b)}.

61. NAME OF AUDITOR

Dr. Nader Memarian

62. AUDITOR SIGNATURE AND DATE

8/8/05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Redondo Iglesias Ctr. N 111, Km 266 Utiel 46300	April 13, 2005	20	Spain
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Nader Memarian		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOPs have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
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	O
34. Species Testing	O
35. Residue	O
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
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	
58.	
59.	

60. Observation of the Establishment

Establishment: 20 Audit Date: April 13, 2005 Processing Operation

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. NAME OF AUDITOR

Dr. Nader Memarian

62. AUDITOR SIGNATURE AND DATE

8/8/05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Campofrio Pol. Ind Gamonal-Villimar 09007 Burgos	April 06, 2005	21	Spain
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Nader Memarian		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Establishment: 21 Audit Date: April 06, 2005 Processing Operation

15/51 The written HACCP plan did not include direct observation of monitoring activities in its verification procedures {9CFR part 417.2(c)(7)}.

22/51 Verification records did not include time/initial {9 CFR part 417.5 (b)}.

61. NAME OF AUDITOR

Dr. Nader Memarian

62. AUDITOR SIGNATURE AND DATE

(for Dr. Memarian) 8/8/05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Fermin Embutidos Y Jamones 37624 La Alberca	April 11, 2005	10.04664/SA	Spain
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Nader Memarian		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
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	
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	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	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Establishment: 10.04664/SA Audit Date: April 11, 2005 Slaughter/cut-up Operation

39/51 1) A build up of rust was observed on the overhead structure (rails and hangers) in the ham storage room.
2) Heavy beaded condensation was observed over products in two cooling rooms.
3) There were two areas of exposed insulation on the overhead of the (a) ham storage and (b) cooling room.
{ 9 CFR part 416.2}

This establishment was not certified to export product to the United States but was presented as fully meeting the FSIS inspection requirements.

61. NAME OF AUDITOR
for Dr. Nader Memarian

62. AUDITOR SIGNATURE AND DATE
manzoor # - Chaudry 8/10/05

[logo] MINISTRY
OF HEALTH
AND CONSUMPTION

GENERAL DIVISION OF FOREIGN HEALTH

[illegible]

Mrs. Sally White
Acting Director
International Equivalence Staff
Office of International Affairs
US Department of Agriculture
Food Safety and Inspection Service
1400 Independence Avenue
Washington DC 20250

Madrid, July 14, 2005

Dear Sally,

We have received your June 1, 2005 letter through which you send the final report of the audit carried out in Spain on the Spanish meat inspection system, from December 1 to 10, 2004, which incorporates the observations and comments that we sent you at the proper time.

I am hereby attaching the observations on the draft of the final report on the audit performed in Spain of the Spanish meat inspection system from March 30 to April 21, 2005, and the corrective actions taken, so that they can be taken into account in the corresponding final report.

With nothing further to consider, best wishes.

[signature]

Pedro Angel García González

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GENERAL OFFICE OF
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OBSERVATIONS ON THE DRAFT OF THE FINAL REPORT OF THE AUDIT CARRIED OUT IN SPAIN ON THE SPANISH MEAT INSPECTION SYSTEM (March 30, to April 21, 2005) AND CORRECTIVE ACTIONS TAKEN

Below are listed observations on the draft of the aforementioned report, along with corrective actions carried out and verified by the corresponding official veterinary services responsible for overseeing establishments authorized for export to the United States of America.

OBSERVATIONS

1. Section "6.2.2. Final monitoring and oversight."

In this section it is stated that *"Official monitoring of inspection activities is under the direct supervision of the Autonomous Communities which have been given powers in the realm of public health through the Ministry of Health." After ["] Ministry of Health,["] the following should be added, "**which in turn oversees the entire process annually.**"*

In this same section, it is stated that "The autonomous Communities determine all the final decisions in relation to complying with FSIS inspection requirements."

Really that is not exactly the case. The correct expression would be: "***Following the instructions issued by the Central Competent authority (ACC)*** and in accordance with the criteria agreed upon in the different coordinating meetings between the AACs and the and the Autonomous Competent Authorities, the Autonomous Communities perform the functions needed to fulfill the FSIS inspection requirements."*

2. Section "6.2.4 Authority and responsibility for executing legislation."

In the first paragraph of this section which reads: *"The Autonomous Communities have legal authority and responsibility for carrying out and ..."* it should read: "***The Autonomous Communities possess delegated health authority for executing and ....***"

---

* [Translation retains Spanish acronyms]

In the last section of this paragraph it is stated that *"The Ministry of Health and Consumption, although it does not have legislative authority over export establishments ..."*

This statement is not correct, because specifically *"Foreign health is solely the competency of the state,"* flowing from article 149 1-16 of the Spanish Constitution, and specifically of the Ministry of Health and Consumption, because, *"Foreign health activities are all those that are performed in the area of oversight and monitoring of possible risks to health derived from the import, export, or transit of goods and of international traffic of foreigners."* That competency is granted by article 38.2 of the General Law on Health (14/1986).

Therefore the Ministry of Health and Consumption does indeed have legislative authority over export establishments, and provision is made for that effect in national legislation, such as:

- Royal Decree 218/1999, establishing the health conditions of production and sale of fresh meats, meat products and other specified products of animal origin to **third countries**.

- April 4, 1995 Decree establishing the technical health conditions for authorization of meat and meat product establishments for their export to the United States.

- Bulletins USA Nº 1/995, 2/95, 3/96, 5/97 which develop that Decree as further development of FSIS legislation.

Hence, this paragraph should read, "***The Ministry of Health has legislative authority over export establishments, and therefore has legal authority to certify ....***"

3. **Section "6.2.5 Adequate technical and administrative assistance."**

The first paragraph on authorization/certification of red meat establishments wishing to export to the United States of America, in which various stages are indicated, should read as follows:

"***Authorization/certification of red meat establishments wishing to export to the United States entails various stages which are brought together in the April 4, 1995 Decree. First, the application must be filled out by the establishment and addressed to the General Office of Public Health (DGSP) of the Ministry of Health and Consumption. Second, in accordance with the General Procedure for***

Authorization of establishments for export of meat and meat products to the USA, the DGSP asks the Competent Authority of the Autonomous Community for the corresponding report on compliance with the demands to be met for that authorization. Third, once the favorable report on such compliance has been received, MSC and MAPA officials make the verification visit to assure that such compliance meets the requirements established by the FSIS. Finally, when it is favorable, both Departments make the authorization jointly on the establishment and notify the FSIS. Health certification of foods that are going to be exported is performed by the Official Veterinary Services of the Autonomous Communities, which are responsible for routine monitoring of the establishment."

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CORRECTIVE ACTIONS TAKEN

\With regard to the deficiencies indicated on the draft of the final auditing report, the following is noted:

A. On the Slaughterhouse

In the attachment for the individual report on the establishment, the following deficiencies are listed:

39/51

1) The development of rust incrustations on the upper structure was noted (rails and racks) in the ham storage room.
2) Condensation was noted and drops had formed on products in the refrigeration chambers.
3) There are two exposed isolation zones in the upper structure of (a) the ham storage chamber and (b) the chilling room.

(9 CFR part 416.2)

With regard to these deficiencies it is noted that the Agency for Health Protection and Food Safety of the Council of Castilla y Leon has sent guarantees of the following corrective actions carried out at that establishment:

1) All the rusty parts and rails have been removed.
2) A specific program has been set up with a system for monitoring and eliminating condensations in all chambers and facilities where they are likely to be produced.
3) Those areas where insulation was exposed have been repaired.

B. With regard to establishment number 14 (Campofrio).

39/51

There was condensation coming from a pipe up above which was dripping onto a side of the work table on which products exposed were being packed on another side of that same table.

Creased, broken, and uneven welds were observed on the contact surfaces with foods of:

a) One of the ham-shaping machines; b) a stainless steel table that could prevent adequate removal of product wastes and that could become a source of product contamination.

With regard to these deficiencies, we wish to point out that:

The condensation that was dripping onto a work table, when this flaw was discovered, after having been pointed out by the official veterinarian of the establishment during the auditing visit,* the work was immediately halted and orders were given for setting up the work table elsewhere, preventing that condensation from falling onto the work area. This circumstance that was causing dripping was corrected the same day as the audit, and the veterinarian assigned to the establishment verified that it had been corrected.

With regard to the deficiencies in the welds, it is noted that, just as in the previous case, upon discovery of this deficiency after it was pointed out during the auditing visit by the official veterinarian of the establishment, a "REMOVED" label was placed on the molding equipment and another on the stainless steel table so that they would not be used. A Registry of Deficiencies was opened on both deficiencies (Registry of non-conformity "NR"), after they were verified by the veterinarian assigned to the establishment and subsequently by the next higher level, the District Chief, and they have been corrected.

Hence, in view of these deficiencies described, immediate corrective actions were taken while the audit was taking place in the presence of the auditor himself.

They have all been corrected, and confirmation that the correction has been verified has been received from the Castilla-La Mancha Health Advisory Office.

C. On establishment number 16 (Palacios Alimentación)

In the attachment for the individual report on the establishment the following deficiencies are noted:

* [Sentence structure poor in the Spanish text]

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With regard to these deficiencies listed for establishments 21 and 22, we note that the Health Protection and Food Safety Agency of the Council of Castilla y Leon has sent a notice that the corresponding verification visits have been made by the Official Veterinary Services assigned to monitoring those plants and by the Technicians of the Food Hygiene And Environmental health Section of the province of Burgos, as well as by staff from this Agency. It has been established that those deficiencies have been remedied.

The foregoing makes it clear that all the deficiencies described in this report have been properly corrected and their correction has been verified, and hence in the final report the corresponding sections should reflect that these corrections have been made.

Madrid, July 13, 2005