



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

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

OCT 05 2007

Dear Dr. García González:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Spain's meat inspection system February 28 to March 22, 2007. Comments from Spain have been included in the final audit report. Enclosed is a copy of the final audit report.

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

Sincerely,

Donald Smart  
Director  
International Audit Staff  
Office of International Affairs

Enclosure

**FINAL**

OCT - 3 2007

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

**FEBRUARY 28 THROUGH MARCH 21, 2007**

**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 [Agencia Española de Seguridad Alimentaria y Nutrición]
CCP	Critical Control Point
CL	Critical Limit
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
SSOP	Sanitation Standard Operating Procedures
<i>Salmonella</i>	<i>Salmonella</i> species
SPS	Sanitation Performance Standard
VEA	European Community/United States Veterinary Equivalence Agreement

## 1. INTRODUCTION

The audit took place in Spain from February 28 through March 21, 2007.

An opening meeting was held on February 28, 2007, 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 periodically during the audit by representatives from the CCA, the Agencia Española de Seguridad Alimentaria y Nutrición and representatives from Spain's Regional Autonomous Communities inspection offices.

## 2. OBJECTIVE OF THE AUDIT

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

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, three Regional Autonomous Communities inspection offices, three pork processing establishments, one swine slaughter and processing establishment, and two laboratories conducting microbiological testing on United States-destined product.

Competent Authority Visits			Comments
Competent Authority	Central	1	Ministry of Health and Consumer Affairs
	Regional	3	Autonomous Communities
Laboratories		2	One establishment was suspended by the CCA at the time of the audit.
Meat Slaughter and processing Establishment		1	
Meat Processing Establishments		3	

## 3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection headquarters and regional autonomous community offices. The third part involved on-site visits to four establishments: one slaughter and processing establishment and three processing establishments. The fourth part involved a visit to two government laboratories. The Centro Nacional de Alimentacion reference laboratory in Majadahonda, Madrid was conducting analyses of field samples for the presence of *Salmonella*, *Listeria monocytogenes* and *Salmonella* in ready-to-eat (RTE) products. The Microbiology Laboratory, Laboratorio de Salud Publica de Zamora, Junta de Castilla y

Leon, Zamora was conducting analyses for the presence of *Listeria monocytogenes* and *Salmonella* in ready-to-eat (RTE) products (This laboratory processes establishment samples only).

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

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

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

Second, in areas not covered by these directives, the auditor would audit against FSIS requirements. FSIS requirements include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification testing, and requirements for HACCP, SSOP, testing for generic *E. coli* and *Salmonella*.

Third, the auditor would audit against any equivalence determinations that have been made by FSIS for Spain under provisions of the Sanitary/Phytosanitary Agreement. Currently, Spain has an equivalence determination from FSIS regarding the use of EN 45001- laboratory quality control standards and the use of *Enterobacteriaceae* and Total Viable Count in lieu of Generic *E. coli* testing.

#### 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](http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp).

The last two FSIS audits of Spain's meat inspection system were conducted in March/April 2005 and March/April 2006.

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

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

During the March/April 2006 FSIS audit of Spain's inspection system:

- The periodic supervisory reports did not reflect actual establishment conditions.
- In one establishment, the verification documentation was not included in the records for corrective actions taken as a result of observations made during periodic supervisory reviews.
- There was inadequate verification of the implementation of U.S. requirements by the province and/or district.
- Two establishments received Notices of Intent to Delist (NOIDs) for inadequate implementation of HACCP, SSOP, and other Sanitation requirements.
- In six establishments, one or more HACCP, SSOP implementation deficiencies were identified.
- In one establishment, EU Directive 64/433 was not adequately enforced. For example, the mesenteric lymph nodes of viscera were not palpated by the veterinary inspection officials during post-mortem inspection of swine carcasses.
- In all seven establishments, the periodic supervisory audits performed by the CCA, Autonomous Community province, and/or district did not adequately verify the implementation of U.S. and/or Council Directive 64/433 requirements such as: HACCP, SSOP, and other sanitation noncompliance.
- In the only slaughter establishment, veterinary inspection officials were not verifying, documenting, and enforcing the requirements that there be no visible fecal material/ingesta or milk on hog carcasses at or immediately after the final rail as required by FSIS Directive 6420.2



## 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

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

- Ministry of Health and Consumer affairs (MHCA), General Office of Public Health (CCA) in Madrid.
- Four Autonomous Communities Regions.
- The Province and/or District Autonomous Administrations.

The responsibility of periodic supervisory reviews is shared as follows:

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

#### 6.2.1 CCA Control Systems

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

#### 6.2.2 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. Four establishments audited 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.

The following deficiencies were observed:

- In one establishment, the periodic supervisory review reports did not reflect actual establishment condition.

- There was inadequate verification of the implementation of U.S. requirements by one province.

### 6.2.3 Assignment of Competent, Qualified Inspectors

According to Autonomous Communities Legislation:

- An Official Veterinarian must be present during ante- and post-mortem inspection.
- Routine veterinary supervision is provided in the establishments, as required by the legislation, or according to the establishment size and/or types of manufactured products.

Four 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

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

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

- The implementation of hygiene regulations in fresh meat establishments.
- The implementation of hygiene controls in meat products, minced meat and other production establishments.
- The supervision of the recall and identification of the specified risk materials.
- Sampling for microbiological analysis, collection of zoonotic agents and residues.

The MHCA, although not having legislative authority over the exporting establishments, does have legal authority to certify and decertify establishments eligible to export to the US. Within the scope of this audit, the laboratory of the General Administration is the Agencia Española de Alimentación, which constitutionally belongs to the Agencia Española de Seguridad Alimentaria y Nutrición, is also an autonomous organization appointed to the Ministry of Health and Consumer Affairs. Such laboratory participate in matters of meat products exportations to the United States since it is the only center that performs microbiological analysis to detect *Salmonella* and *Listeria monocytogenes* in products to be exported to the United States.

### 6.2.5 Adequate Administrative and Technical Support

The certification of red meat establishments for the export to the U.S. has several steps as follow: First, it requires the separate certification of each establishment, which is granted jointly by the General Directorate of Public Health, MHCA and the General Directorate of Agrarian Production Health, the Ministry of Agriculture, Fishing, and Food. Second, after the appropriate validation inspections have been carried out by the relevant authority of the Autonomous Community. Third, the Official Veterinary Services of the

Autonomous Communities are responsible for providing daily inspection of establishment control.

The CCA, through the Autonomous communities (Central, Regional, Provincial, and Local offices), provides 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 Regions, and local inspection offices of the audited establishments. The records review focused primarily on food safety hazards and included the following:

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

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

- In one establishment, the periodic supervisory review reports did not reflect actual establishment conditions observed.
- In the same establishment, the verification of the implementation of U.S. requirements by the province and/or region was inadequate.

#### 6.3.1 Audit of Regional and Local Inspection Sites

Three Health Authority Offices at the Autonomous Communities:

- Office of Castilla-La Mancha Region in Toledo
- Office of Castilla y Leon Region in Valladolid
- Office of Valencia Region in Valencia
- Four local offices at the establishment level

## 7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of four establishments. One was a slaughter and processing establishment and three were processing establishments. One of three processing establishments had been issued a Notice of Intent to Delist (NOID) during the previous FSIS audit on March 31, 2006. Subsequently, this establishment's eligibility to export meat and meat products to the U.S. was suspended on August 15, 2006 after two *Listeria monocytogenes* Port of Entry violations. At the time of the present audit, this establishment remained under suspension. Had this establishment been certified for US export, this establishment would have been delisted based on current audit findings and for the failure to implement effective corrective actions, as required, to address the NOID received on March 31, 2006.

The following deficiencies were observed:

- In one establishment, numerous SSOP and other sanitation requirements were not met.
- In two establishments, one or more HACCP deficiencies were identified.
- In one establishment, inspection officials did not adequately describe the deficiencies identified in their pre-operational and operational sanitation verification records.
- In one establishment, contaminated/suspect swine carcasses were retained for further post-mortem inspection by the veterinary inspector. But these carcasses were marked "Inspected and Passed" by the plant employee before the final inspection was completed.
- In one establishment, receptacles used for storing inedible products were not marked as such and were cross-utilized for both edible and inedible product in the slaughter, cut-up, and processing rooms.
- In one establishment, there was inadequate verification of the implementation of U.S. and Council Directive 64/433/EEC requirements by the CCA, Autonomous Community Region and Province.
- In one establishment, the periodic supervisory audits performed by the CCA, Autonomous Community Region, and Province did not adequately verify the implementation of U.S. and/or Council Directive 64/433 requirements such as: HACCP, SSOP, and other sanitation requirements.
- In one establishment, EU Directive 64/433 was not adequately enforced, for example, fat residue from the previous day's operations was observed on employees' metal protective aprons, mesh gloves, and plastic aprons in the cut-up room.

Specific deficiencies are noted on the attached individual establishment reports.

## 8. LABORATORY AUDITS

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

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

The following laboratories were reviewed:

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

- No deficiencies were observed.

The Microbiology Laboratory “Laboratorio de Salud Publica de Zamora, Junta de Castilla y Leon” was audited (This laboratory processes establishment samples only).

## 9. SANITATION CONTROLS

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

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

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

### 9.1 SSOP

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

- In one establishment, officials were not routinely evaluating the adequacy and effectiveness of the Sanitation Standard Operating Procedures (SSOP) to prevent direct product contamination.
- In one establishment, product residues from previous day’s operations were observed on many food-contact surfaces in the swine slaughter, cut-up, and processing rooms.

### 9.2 EC Directive 64/433

In one of the four establishments, the provisions of EC Directive 64/433 and/or other sanitation requirements were not effectively implemented.

In one establishment, the following deficiencies were observed:

- An opening in the outside wall of the dry cure sausages and Serrano ham room was not sealed; four dead flies were observed at the bottom of the window frame.
- Rusty hooks were observed directly above exposed products in the dry curing room.
- Loose metal panels with large gaps were observed on one wall in the processing room.
- An accumulation of fat residue from the previous day's operations was observed on a metal frame over a conveyor belt in the cut-up room.
- Accumulation of fat residue from previous day's operations was observed inside of a metal protective covering for a conveyor belt in the boning room.
- Pieces of fat and grease were observed inside a metal cabinet used for keeping quality control verification records in the cut-up room.
- Salted hams were kept on plastic racks between two to three inches above the floor in the first ham salting room. An accumulation of water was observed in the walkway area that was not properly drained to prevent splashing of product from floor water.
- Receptacles used for storing inedible products were not marked as such and were cross-utilized for both edible and inedible product in the slaughter, cut-up, and processing rooms.
- Fat residue from the previous day's operations was observed on employees' metal protective aprons, mesh gloves, and plastic aprons in the boning room.

Specific deficiencies are noted in the attached individual establishment reports.

## 10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that Spain's inspection system had adequate controls in place. No deficiencies were noted

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

## 11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures, ante-mortem disposition, humane handling and humane slaughter, post-mortem inspection procedures, post-mortem disposition, ingredients identification, control of restricted ingredients, formulations, processing schedules, equipment and records, and processing controls of cured, dried, and cooked products.

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

In the slaughter establishment the following deficiencies were observed.

- Contaminated/suspect swine carcasses were diverted to a congested retain rail for disposition and were in direct contact with other suspect or contaminated carcasses.
- Hair was found on carcasses in the cooler and boning room.
- Numerous hairs were observed on the cut-up tables during boning operations. Veterinary inspection officials did not take corrective actions.

### 11.1 Humane Handling and Humane Slaughter

No deficiencies were observed.

### 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 four establishments. Two of the four establishments audited had not adequately implemented the HACCP requirements.

- In one establishment, the written HACCP plan did not address procedures and frequencies for the review of records generated and maintained and corrective actions for the Critical Control Point (CCP).
- In one establishment, the monitoring of the CCP for zero tolerance for visible feces/ingesta/milk detected numerous daily deviations from the Critical Limit (CL); the establishment was documenting corrective actions but the measures established to prevent recurrence were not effective.
- In one establishment, the establishment management could not provide written documentation to support the frequency of the verification procedures for CCP 2-B.
- In one establishment, the establishment was not documenting the monitoring of the CCP for weight increase after the addition of nitrite as described in the written HACCP plan.

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

### 11.3 Testing for Generic *E. coli*

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

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

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

#### 11.4 Testing for *Listeria monocytogenes*

All four 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 verification sampling were observed.

#### 11.5 EC Directive 64/433

In one of the four establishments, the provisions of EC Directive 64/433 were not effectively implemented. For example:

- In one establishment, contaminated/suspect swine carcasses were retained for further post-mortem inspection by the veterinary inspector. But these carcasses were marked “Inspected and Passed” by the plant employee before the final inspection was completed.

### 12. RESIDUE CONTROLS

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

- No residue laboratories were reviewed during this audit.

Spain’s National Residue Control Program for 2007 was being followed and was on schedule.

#### 12.1 EC Directive 96/22

No residue laboratory was reviewed during this audit.

#### 12.2 EC Directive 96/23

No residue laboratory was reviewed during this audit.

### 13. ENFORCEMENT CONTROLS

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



### 13.1 Daily Inspection in Establishments

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

### 13.2 Testing for *Salmonella*

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

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

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

### 13.3 Species Verification

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

### 13.4 Periodic Supervisory Reviews

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

- In one of the four establishments audited, the periodic supervisory reviews were routinely conducted by the Provincial Autonomous Administration but they did not verify and document any findings on their reports for the HACCP, SSOP, and SPS non-compliances.

### 13.5 Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the United States with product intended for the domestic market with the following exceptions:

- In one establishment, numerous SSOP implementation deficiencies were identified.
- In two establishments, one or more HACCP deficiencies were identified.
- In one establishment, contaminated/suspect swine carcasses were retained for further post-mortem inspection by the veterinary inspector. But these carcasses were marked "Inspected and Passed" by the plant employee before the final inspection was completed.

- In one establishment, receptacles used for storing inedible products were not marked as such and were cross-utilized for both edible and inedible product in the slaughter, cut-up, and processing rooms.
- In one establishment, EU Directive 64/433 was not adequately enforced, for example, fat residue from the previous day's operations was observed on employees' metal protective aprons, mesh gloves, and plastic aprons in the cut-up room.
- In one establishment, contaminated/suspect swine carcasses were diverted to a congested retain rail for disposition and were in direct contact with other suspect or contaminated carcasses. In the same establishment, hair was found on carcasses in the cooler and cut-up room and numerous hairs were observed on boning tables.
- One establishment had been issued a Notice of Intent to Delist (NOID) during the previous FSIS audit on March 31, 2006. Subsequently, this establishment's eligibility to export meat and meat products to the U.S. was suspended on August 15, 2006 after two *Listeria monocytogenes* Port of Entry violations. At the time of the present audit, this establishment remained under suspension. Had this been a routine audit, this establishment would have been delisted based on current audit findings and for the failure to implement effective corrective actions as required to address the NOID received on March 31, 2006.

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 March 21, 2007, in Madrid, Spain with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Faizur R. Choudry, DVM  
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 Campofrio Alimentacion, S.A. Torrijos, Toledo	2. AUDIT DATE 03/05/07	3. ESTABLISHMENT NO. 14	4. NAME OF COUNTRY Spain
5. NAME OF AUDITOR(S) Faizur R. Choudrv, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

## 60. Observation of the Establishment

March 5, 2007: Establishment 14; Campofrio Alimentacion, S.A., Torrijos, Toledo, Spain; Processing dry cured ham, Chorizo

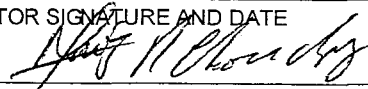
16/51: The establishment management could not provide written documentation to support the frequency of the verification procedures for Critical Control Point (CCP) B-1. [Regulatory references: 9 CFR 417.2 (c)(7), 417.5(a)(2), and 417.8]

22/51: The establishment was not documenting the monitoring of the CCP for weight increase after the addition of nitrite as described in the written HACCP plan. [9 CFR 417.5 (a)(3) and 417.8]

61. NAME OF AUDITOR

Faizur Choudry, DVM.

62. AUDITOR SIGNATURE AND DATE

 3/27/07

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION  Redondo Iglesias S.A. Utiel, Valencia	2. AUDIT DATE March 7, 2007	3. ESTABLISHMENT NO. 20	4. NAME OF COUNTRY Spain
		5. NAME OF AUDITOR(S) Faizur R. Choudry, DVM	6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
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
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

Establishment 20: Redondo iglesias S.A., Utiel, Valencia, Spain; March 7, 2007, Processing dry cured Serrano ham

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

61. NAME OF AUDITOR  
Faizur R. Choudry, DVM

62. AUDITOR SIGNATURE AND DATE

*Faizur R. Choudry* 3/27/07

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Camporfio Alimentacion, S.A. Burgos	2. AUDIT DATE 03/16/07	3. ESTABLISHMENT NO. 21	4. NAME OF COUNTRY Spain
	5. NAME OF AUDITOR(S) Faizur R. Choudrv. DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		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.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
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
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	O
27. Written Procedures	O	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		



## 60. Observation of the Establishment

March 16, 2007: Establishment 21; Camporfio Alimentacion, S.A., Burgos, Spain; Processing dry cured Serrano ham, Chorizo, and Salami

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

61. NAME OF AUDITOR  
Faizur R. Choudry, DVM.

62. AUDITOR SIGNATURE AND DATE

*Faizur R. Choudry* 3/27/07

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Embutidos Fermin, S.L. La Alberca, Spain	2. AUDIT DATE 03/13,14/07	3. ESTABLISHMENT NO. 23	4. NAME OF COUNTRY Spain
5. NAME OF AUDITOR(S) Faizur R. Choudry, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.	X	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.	X	38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	X
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	X
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	X
<b>Salmonella Performance Standards - Basic Requirements</b>		58. Under Suspension by Government of Spain (GOS)	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

## 60. Observation of the Establishment

March 13-14/2007: Est. 23; Embutidos Fermin, S.L., La Alberca, Spain; Slaughter/processing: Serrano ham, Chorizo

**10/51.** Product residues from the previous day's operations were observed on many food-contact surfaces in the swine slaughter room, the cut-up room, and processing rooms. Establishment officials took corrective actions in some cases. [Regulatory references: 9CFR 416.13 and 416.17]

**11/51.** Establishment officials were not routinely evaluating the adequacy and effectiveness of the Sanitation Standard Operating Procedures (SSOP) to prevent direct product contamination. [9CFR 416.14 and 417.17]

**12/51. a)** Contaminated/suspect swine carcasses were diverted to a congested retain rail for disposition and were in direct contact with other suspect or contaminated carcasses. **b)** Hair was found on carcasses in the cooler and boning room. **c)** Numerous hairs were observed on the cut-up tables during boning operations. Veterinary inspection officials did not take corrective actions. [9CFR 310.18(a), 416.15, and 416.17]

**19/51. a)** The written HACCP plan did not address procedures and frequencies for the review of records generated and maintained and corrective actions for Critical Control Point (CCP) 2-B. [9CFR 417.2 (c) (7), 417.5(a)(3) and 417.8] **b)** The monitoring of the CCP 1-B for zero tolerance for visible feces/ingesta/milk detected numerous daily deviations from the Critical Limit (CL); the establishment was documenting corrective actions but the measures established to prevent recurrence were not effective. [9CFR 417.3(a)(3) and 417.8]

**38/51/56.** An opening in the outside wall of the dry cure sausages and Serrano ham room was not sealed; four dead flies were observed at the bottom of the window frame. [9 CFR 416.2(a)(b) and EEC C/D 64/433, Annex 1, Chapter II.2(m)]

**39/51. a)** Rusty hooks were observed directly above exposed products in the dry curing room. **b)** Loose metal panels with large gaps were observed on one wall in the processing room. **c)** An accumulation of fat residue from the previous day's operations was observed on a metal frame over a conveyor belt in the cut-up room. **d)** Accumulation of fat residue from previous day's operations was observed inside of metal protective covering for conveyor belt in the boning room. **e)** Pieces of fat and grease were observed inside a metal cabinet used for keeping the records for the verification of quality control in the cut-up room. **f)** Salted hams were kept on plastic racks between two to three inches above the floor in the first ham salting room. An accumulation of water was observed in the walkway area that was not properly drained to prevent splashing of product from floor water. [9 CFR 416.2(b) and 416.17 and C/D 64/433/EEC Annex 1 Chapter II(2)]

**45/51.** Receptacles used for storing inedible products were not marked as such and were cross-utilized for both edible and inedible product in the slaughter, cut-up, and processing rooms. [9 CFR 416.3(c) and 416.17]

**47/51/56.** Fat residue from the previous day's operations was observed on employees' metal protective aprons, mesh gloves, and plastic aprons in the boning room. [9 CFR 416.5(b) and EEC C/D 64/433, Annex 1, Chapter III]

**51.** Inspection officials did not adequately describe the deficiencies identified in their pre-operational and operational sanitation verification records. [9 CFR 416.17]

**51/57.** Periodic supervisory audits were routinely conducted by the Provincial Autonomous Administration but there was no indication of any findings concerning the aforementioned, HACCP, SSOP, and SPS non-compliances. [9 CFR 416.17 and EEC C/D 64/433, Annex 1, Chapter III]

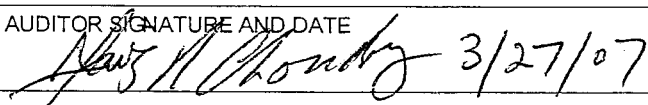
**55/51.** Contaminated/suspect swine carcasses were retained for further post mortem inspection by the Veterinary Inspector. These carcasses were marked "Inspected and Passed" by a plant employee before the final inspection was completed by the Veterinary Inspector. [9 CFR 310.3 and 8 and C/D 64/433, Annex 1, Chapter VII.27]

**58.** Establishment 23 had been issued a Notice of Intent to Delist (NOID) during the previous FSIS audit on March 31, 2006. Subsequently, this establishment's eligibility to export meat and meat products to the U.S. was suspended on August 15, 2006 after two *Listeria monocytogenes* Port of Entry violations. At the time of the present audit, this establishment remained under suspension. Had this been a routine audit, this establishment would have been delisted based on current audit findings and for the failure to implement effective corrective actions as required to address the NOID received on March 31, 2006.

61. NAME OF AUDITOR

Faizur R. Choudrv. DVM

62. AUDITOR SIGNATURE AND DATE





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]

August 22, 2007

Dr. Donald Smart  
Director International Audit Staff  
Office of International Affairs  
Food Safety and Inspection Service  
Washington, DC 20250-3700

Dear Dr. Smart,

I am writing you in reference to your letter dated May 24, 2007, in which you provided us with the draft of the final report on the audit performed by the FSIS in Spain on February 28 to March 22, 2007 in regards to the Spanish system meat inspection, please find attached some observations elaborated by the *Agencia Española de Seguridad Alimentaria y Nutrición* that belongs to the Under Directorate of Foreign Health in order to be taken into consideration at the final report.

Signed by Under Directorate  
PP Ana Rodríguez Castaño  
Jefa de Área de Gestión y Coordinación

(\*)Observations to the draft of the final report in regards to the audit performed by FSIS to the Spanish meat audit system (February 28 to March 21, 2007)

Page 5, Item 1.3, 3<sup>rd</sup> paragraph The name of "*Agencia de Seguridad Alimentaria*" should be replaced by the current name of "*Agencia Española de Seguridad Alimentaria y Nutrición*", as stipulated in the eighth disposition of Law 44/2006 of December 29 about consumers and users.

In addition, the Agency considers necessary to point out that there were not representatives from this agency at all the time at the moment of the inspection performed by FSIS.

Page 9, Item 6.2.4., last paragraph. The last sentence should be stated in the following way: "Within the scope of this audit, the laboratory of the General Administration is the *Agencia Española de Alimentación*, which constitutionally belongs to the *Agencia Española de Seguridad Alimentaria y Nutrición*, which it is also an autonomous organization appointed to the Ministry of Health and Consumer Affairs. Such laboratory participate in matters of meat products exportations to the United States since it is the only center that performs microbiological analysis to detect *Salmonella* and *Listeria monocytogenes* in products to be exported to the United States."

Page 9, Item 6.2.5. First paragraph. "*Dirección General de Sanidad de la Producción Agraria*" should be replaced by "*Dirección General de Ganadería*" according to the organization chart of the Ministry of Agriculture, Fisheries and Food.

Page 10, Item 6.3.1, first paragraph. The general services of the Ministry of Health and Consumer Affairs are not responsible for local and regional inspection, therefore, the title of point 6.3.1 should be changed.

Madrid August 22, 2007

(\*)Observations made by the Agencia Española de Seguridad y Nutrición.



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EMBASSY OF SPAIN  
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Washington, D.C. 20037

Dr. Donald Smart  
Director International Audit Staff  
Office of International Affairs  
Food Safety and Inspection Service  
1400 Independence Ave.  
Washington, D.C. 20250

September 7, 2007

Dear Dr. Smart,

Please find enclosed letter from the Under Directorate of the Ministry of Health and Consumer Affairs in response to you letter of May 24, 2007 in regards to the recent audit performed by FSIS to the Spanish meat audit system. I am also enclosing un official translation for your convenience.

If you need more information, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Juárez', written over the word 'Sincerely,'.

Samuel J. Juárez  
Counselor of Agriculture, Fisheries and Food



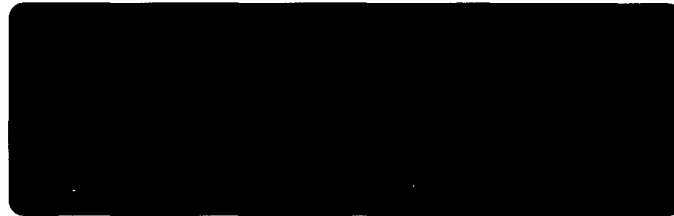
MINISTERIO  
DE SANIDAD  
Y CONSUMO

SECRETARIA GENERAL  
SANIDAD

DIRECCIÓN GENERAL D  
SALUD PÚBLICA

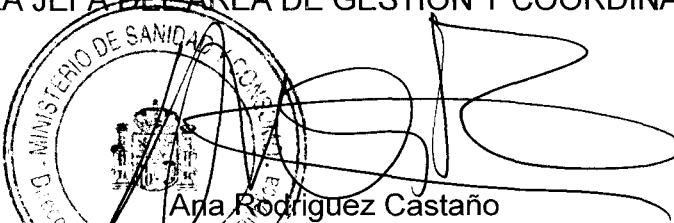
SUBDIRECCIÓN GENERAL  
DE SANIDAD EXTERIOR

30 CA/MM



Como respuesta a su escrito de 24 de mayo de 2007, por el que nos remite el borrador del informe final de la auditoría realizada en España, del 28 de febrero al 22 de marzo de 2007, sobre el sistema español de inspección de carnes, adjunto se remiten las observaciones que la Agencia Española de Seguridad Alimentaria y Nutrición de este Departamento nos ha trasladado, para que sean tenidas en cuenta en el correspondiente informe final.

Madrid, 22 de agosto de 2007  
EL SUBDIRECTOR GENERAL,  
P. A. LA JEFA DEL AREA DE GESTIÓN Y COORDINACIÓN

  
Ana Rodríguez Castaño

SUBDIRECCIÓN GENERAL DE SANIDAD EXTERIOR  
MINISTERIO DE SANIDAD Y CONSUMO

SR. D. DONALD SMART. DIRECTOR INTERNATIONAL AUDIT STAFF.OFFICE  
OF INTERNATIONAL AFFAIRS. USDA. FSIS.  
**WASHINGTON**



**(\*)OBSERVACIONES AL BORRADOR DEL INFORME FINAL DE LA AUDITORÍA DEL  
FSIS REALIZADA EN ESPAÑA SOBRE EL SISTEMA ESPAÑOL DE INSPECCIÓN DE  
CARNES (28 de febrero al 21 de marzo de 2007)**

1) **Página 5, Punto 1, 3<sup>er</sup> párrafo.** Se debería sustituir la denominación de “*Agencia de Seguridad Alimentaria*” por el nombre actual de “*Agencia Española de Seguridad Alimentaria y Nutrición*”, tal como se estipula en la disposición final octava de la ley 44/2006, de 29 de diciembre de los consumidores y usuarios.

Asimismo, la Agencia considera necesario señalar que no hubo representantes de la misma acompañando toda la auditoría al auditor del FSIS.

2) **Página 9, Punto 6.2.4, último párrafo, última frase.** Debería ser redactada de la siguiente forma: “*En el ámbito de esta auditoría el laboratorio de la Administración General del Estado es el Centro Nacional de Alimentación, el cual pertenece orgánica y funcionalmente a la Agencia Española de Seguridad Alimentaria y Nutrición, la cual a su vez es un organismo autónomo adscrito al Ministerio de Sanidad y Consumo. Dicho Laboratorio participa en el tema de las exportaciones de productos cárnicos a Estados Unidos al ser el único centro que actualmente realiza los análisis microbiológicos para detección de Salmonella y Listeria monocytógenas en aquellos productos que se exportan a Estados Unidos*”.

3) **Página 9, Punto 6.2.5, primer párrafo.** Se debería sustituir “*Dirección General de Sanidad de la Producción Agraria*” por “***Dirección General de Ganadería***”, conforme al organigrama actual del Ministerio de Agricultura, Pesca y Alimentación.

4) **Página 10, Punto 6.3.1, primer párrafo, primer ítem.** Los servicios generales del Ministerio de Sanidad y Consumo no son responsables de la inspección local y regional, por lo que se debería cambiar el título del punto 6.3.1.

Madrid, 22 de agosto de 2007