



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

*Don Smart*

*12/2/04*

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

NOV 26 2004

Dear Dr. García González:

The Food Safety and Inspection Service (FSIS) conducted an audit of Spain's meat inspection system March 3 through April 7, 2004. Enclosed is a copy of the final audit report. Included in this report as attachments are copies of your letters dated June 17, 2004, and July 12, 2004, in which you provided comments to the FSIS audit findings.

If you have any questions regarding the final report or the audit, please contact me at telephone number (202) 720-3781, facsimile number (202) 690-4040, or my email address at [sally.white@fsis.usda.gov](mailto:sally.white@fsis.usda.gov).

Sincerely,

*Sally White JD*

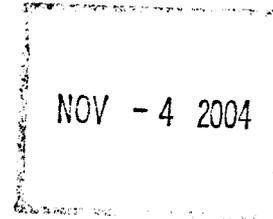
Sally White  
Director  
International Equivalence Staff  
Office of International Affairs

Enclosures

cc:

Samuel J. Juarez, Agricultural Counselor, Embassy of Spain, Washington, DC  
Stephen Hammond, Counselor, American Embassy, Madrid, Spain  
Tony Van der haegen, Agriculture, Fisheries, Food Safety and Consumer Affairs Section  
European Commission Delegation to the U.S., Washington, DC  
Norval Francis, Minister-Counselor, US Mission to the EU in Brussels  
Scott Bleggi, FAS Area Director  
Dave Young, ITP, FAS  
Amy Winton, State Department  
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William James, Deputy Assistant Administrator, FSIS  
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Linda Swacina, Executive Director – FSIA, OIA, FSIS  
Spain Country File (Audit FY 2004)

**FINAL**



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

March 3 through April 7, 2004

Food Safety and Inspection Service  
United States Department of Agriculture

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## ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority - Ministerio de Sanidad y Consumo- MSC (Ministry of Public Health) and Ministerio de Agricultura, Pesca y Alimentacion-MAPA (Ministry of Agriculture).
<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
VEA	European Community/United States Veterinary Equivalence Agreement

## 1. INTRODUCTION

The audit took place in Spain from March 3 through April 7, 2004.

An opening meeting was held on March 3, 2004, 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 Ministerio de Sanidad y Consumo (MSC) and representatives from the local inspection offices.

## 2. OBJECTIVE OF THE AUDIT

This 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, one autonomous district inspection office, one residue and one microbiology government laboratory performing analytical testing on United States-destined product, and four meat processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	Regional Offices	2	
	Autonomous Province	2	
	Local	6	Establishment level
Laboratories		2	
Meat Slaughter Establishments		0	
Meat Processing Establishments		6	
Cold Storage Facilities		0	

## 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 on-site visits to six processing establishments. The third part involved visits to two government laboratories: the Centro Nacional de Alimentacion (National Food Center) in Majadahonda (Agencia Espanola de Seguridad Alimentaria – AESA, (also a reference laboratory) and Red de Laboratorios de Salud Publica (Public Health Laboratory Network) in Valencia. The National Food Center was conducting

analyses of field samples for the presence of generic *E. coli* and *Listeria monocytogenes* for the establishments certified to export product to the United States. At the time of this audit, the Public Health Laboratory Network was not conducting analytical testing of pork products destined for the United States.

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, (4) residue controls, and (5) enforcement controls. 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 also determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated and properly labeled.

During the 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. These include daily inspection in all certified establishments, handling and disposal of inedible and condemned materials, species-verification testing, and FSIS requirements for HACCP, SSOP, testing for *Listeria monocytogenes*, and *E. coli* 0157:H7.

Third, the auditor would audit against any equivalence determinations that have been made by FSIS for Spain under provisions of the Sanitary/Phytosanitary Agreement.

#### 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://199.140.65.44/regulations\\_&\\_policies/Foreign\\_Audit\\_Reports/index.asp](http://199.140.65.44/regulations_&_policies/Foreign_Audit_Reports/index.asp)

The last two audits of Spain’s inspection system resulted in the following deficiencies.

During the December 2001 FSIS audit of Spain’s meat inspection system, the following deficiencies were identified:

- In two establishments, no hand washing facilities were available where exposed product was handled.
- Personnel hygiene deficiencies of workers were observed in one establishment.
- Unmarked chemicals were found in the production areas of two establishments.

All deficiencies noted during the December 2001 audit had been addressed and corrected.

During the May/June 2003 FSIS audit of Spain’s meat inspection system, the following deficiencies were identified:

- In one establishment, a ham was observed contacting the floor of a drying room
- Rusty ceiling protectors were observed in the slicing room of one establishment and, in another establishment, plastic boxes used for edible and inedible product were being used indiscriminately. In both cases, requirements of EC Directive 64/433 were not fully met.

## 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’s legislation.

## 6.2 Government Oversight

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

### 6.2.1 CCA Control Systems

The CCA has jurisdiction or direct authority over the 19 Autonomous Regions (ARs), 17 in mainland Spain and two more in North Africa (Ceuta and Melilla).

Some of these Autonomous Regions may have several Provinces. For examples, two of the establishments (Ests. 13 and 14) certified for U.S. export were in the Castilla La Mancha AR; one (Est. 16) was in the La Rioja AR, and one (Est. 20) was in the AR of Valencia.

Each Autonomous Health Administration of the autonomous communities has three administrative levels; Central Autonomous Administration, Province Autonomous Administration and Local Autonomous Administration, which is performing slaughterhouse and processing establishment inspection.

### 6.2.2 Ultimate Control and Supervision

Control and supervision of inspectors in certified establishments at Autonomous Regional and Local levels did not meet the FSIS requirements. Daily coverage was not being provided in three establishments.

### 6.2.3 Assignment of Competent, Qualified Inspectors.

In three out of six establishments, daily inspection coverage was not being provided. Inspectors visit these establishments from 1-3 days per week and no inspection coverage was provided on the daily night shift of a two-shift establishment

All veterinarians and inspection officials were full time employees of the government.

### 6.2.4 Authority and Responsibility to Enforce the Laws

The CCA was created by the Law 11/2001 and is assigned to the Ministry of Health and Consumer Affairs. The main objectives of the CCA are as follows:

1. Promote collaboration and coordination among public administrations in charge of food safety.
2. Favor collaboration between public administrations and the various interested sectors.
3. Act as a national reference organization with relation to food risk assessment, management and communication, particularly in crisis and emergency situations.

Its functions include:

- Coordinate administrative action.
- Program and coordinate actions related to the health aspects of the official food control.
- Urge the relevant authorities to take measures and prepare norms, particularly in crisis and emergency situations.
- Inform on the Spanish position with relation to food safety matters, and support it in front of the European Union and International organizations.
- Prepare the general action plan in food crisis and emergency situations.
- Coordinate the operation of the existing alert networks and their integration into the Community and International alert systems.
- Promote the simplification and harmonization of food safety legislation.

FSIS requirements were enforced on the days of inspector's visit. However, there was no enforcement by the CCA on other days and on the night shift of one establishment.

Inspectors were not aware of the FSIS requirements relating to *Listeria monocytogenes* testing for ready to eat products

#### 6.2.5 Adequate Administrative and Technical Support

The CCA, through the Local and Autonomous Regional Offices, 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 Regional and Local offices, and in the inspection offices at 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.
- Sampling and laboratory analyses for residues.
- Sanitation, and processing inspection procedures and standards.
- Export product inspection and control including export certificates.

The CCA was not aware of the FSIS requirements for *Listeria monocytogenes* testing for ready to eat products.

## 7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of six processing establishments. None of the six establishments were delisted by Spain. Four of the six establishments received a Notice of Intent to Delist (NOID).

## 8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

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

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

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

The following government laboratories were audited:

The Centro Nacional de Alimentacion laboratory in Majadahonda (Agencia Espanola de Seguridad Alimentaria-AESA) and the Red de Laboratorios de Salud Publica in Valencia.

No concerns arose as a result of these visits.

## 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 practices, and good product handling and storage practices.

In addition, and except as noted below, Spain inspection system had controls in place for light, ventilation, plumbing and sewage, water supply, dressing rooms/lavatories, equipment and utensils, sanitary operations, employee hygiene, and condemned product control.

- In one establishment, a frayed ham transportation belt was observed.

## 9.1 SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The SSOPs in all six establishments were found to meet the basic FSIS regulatory requirements.

## 9.2 EC Directive 64/433

In one establishment, all provisions of EC Directive 64/433 were not effectively implemented. The specific deficiencies are noted in the attached individual establishment reports.

## 10. ANIMAL DISEASE CONTROLS

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

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

## 11. SLAUGHTER/PROCESSING CONTROLS

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

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

### 11.1 Humane Handling and Humane Slaughter

There are presently no slaughter establishments in Spain that are certified for export to the U.S.

### 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. Following deficiencies were noted.

- The HACCP plan of one of the establishments did not meet FSIS requirements. Its hazard analysis was incomplete; there was no CCP verification frequency and corrective action did not comply with FSIS requirements. This establishment produces dry cured ham. It had changed ownership a couple of weeks prior to the FSIS visit and had no approved labels or U.S.-eligible product on hand.
- Three establishments did not comply with 9 CFR 430 regulations and were not aware of the FSIS requirements relating to testing for *Listeria monocytogenes* as explained in FSIS Directive 11240.4.

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

Spain does not have any certified slaughter establishments approved for export to the U.S.; therefore generic *E. coli* testing is not required.

### 11.4 Testing for *Listeria monocytogenes*

All six of the establishments audited were producing ready-to-eat products for export to the United States. Hazard analysis of three establishments had not been conducted properly. HACCP plans of these three establishments did not comply with *Listeria monocytogenes* testing for ready-to-eat products.

### 11.5 EC Directive 64/433

In one of the six establishments, all provisions of EC Directive 64/433 were not fully implemented relating equipment maintenance.

## 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 Red de Laboratorios de Salud Publica (Public Health Laboratory Network) was reviewed at the request of the government of Spain. This laboratory does not currently conduct analytical testing of pork products destined for the United States.

Additionally, the Centro Nacional de Alimentacion laboratory in Majadahonda (AESAL laboratory) was audited for *Listeria monocytogenes* and species-verification testing. No findings were observed during this audit.

### 12.1 EC Directive 96/22

In the Red de Laboratorios de Salud Publica, the provisions of EC Directive 96/22 were effectively implemented.

### 12.2 EC Directive 96/23

In the Red de Laboratorios de Salud Publica, the provisions of EC Directive 96/23 were effectively implemented.

### 12.3 FSIS Requirements

At the time of this audit, no Spanish slaughter establishments were certified to export to the United States. All raw product was obtained from approved slaughter establishments in Denmark, the Netherlands and Hungary.

## 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

Daily inspection coverage was not being provided in three establishments and on the night shift of one establishment.

### 13.2 Testing for *Salmonella* Species

Spain does not have any certified slaughter establishments approved for export to the U.S.; therefore *Salmonella* testing is not required.

### 13.3 Species Verification

At the time of this audit, Spain was required to test product for species verification. Species verification testing 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 does not have controls in place for during daily operations of the processing establishments. Inspectors visit establishments at less than daily frequency.

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. Inspectors are present during the arrival of shipments U.S.-eligible fresh meat at the establishment.

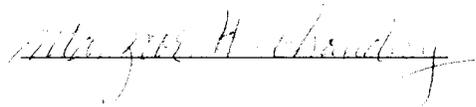
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

#### 14. CLOSING MEETING

A closing meeting was held on April 7, 2004 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. M. Ghias Mughal  
Deputy Director, Review Staff



## 15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms

Individual Foreign Laboratory Audit Forms

Foreign Country Response to Draft Final Audit Report

REVIEW DATE  
 Mar. 26, 2004

NAME OF FOREIGN LABORATORY  
 The Centro Nacional de Alimentacion, Laboratory

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY  
 Agencia Espanola de Seguridad Alimentaria

CITY & COUNTRY  
 Majadahonda, Spain

ADDRESS OF LABORATORY  
 Majadahonda (Madrid)

NAME OF REVIEWER  
 Dr. M. Ghias Mughals

NAME OF FOREIGN OFFICIAL

Residue Code/Name

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

Signature of reviewer *M. Ghias Mughals, DVM*

Date *4/26/04*



REVIEW DATE  
 Apr. 2, 2004

NAME OF FOREIGN LABORATORY  
 Laboratorio de Salud Publica de Valencia

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOVT AGENCY  
 Regional Health Council of  
 Valencia

CITY & COUNTRY  
 Albal, Spain

ADDRESS OF LABORATORY  
 Cami de la Marjai, S/N

NAME OF REVIEWER  
 Dr. M. Ghias Mughal

NAME OF FOREIGN OFFICIAL

Residue Code/Name			100	111	300	200	203	400	500	800	ive	lev				
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE													
	Sample Handling	01		A	A	A	A	A	A	A	A	A	A			
	Sample Frequency	02		A	A	A	A	A	A	A	A	A	A			
	Timely Analysis	03		A	A	A	A	A	A	A	A	A	A			
	Compositing Procedure	04		O	O	O	O	O	O	O	O	O	O			
	Interpret Comp Data	05		O	O	O	O	O	O	O	O	O	O			
	Data Reporting	06	A	A	A	A	A	A	A	A	A	A				
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	A	A	A	A	A	A	A	A	A				
	Correct Tissue(s)	08		A	A	A	A	A	A	A	A	A	A			
	Equipment Operation	09		A	A	A	A	A	A	A	A	A	A			
	Instrument Printouts	10		A	A	A	A	A	A	A	A	A	A			
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	A	A	A	A	A	A	A	A	A				
	Recovery Frequency	12		A	A	A	A	A	A	A	A	A	A			
	Percent Recovery	13		A	A	A	A	A	A	A	A	A	A			
	Check Sample Frequency	14		A	A	A	A	A	A	A	A	A	A			
	All Analyst W/Check Samples	15		A	A	A	A	A	A	A	A	A	A			
	Corrective Actions	16		A	A	A	A	A	A	A	A	A	A	A		
	International Check Samples	17		A	A	A	A	A	A	A	A	A	A	A		
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE	A	A	A	A	A	A	A	A	A				
OTHER REVIEW		19	EVAL. CODE													
		20														

Signature of reviewer *M. Ghias Mughal, DVM*

Date *4/26/04*



## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Secaderos De Almaguer, SA	2. AUDIT DATE April 1, 2004	3. ESTABLISHMENT NO. 13	4. NAME OF COUNTRY Spain
5. NAME OF AUDITOR(S) Dr. M. Ghias Mughal		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	O
<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.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
<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.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.	X	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	O	51. Enforcement	
24. Labeling - Net Weights	O	52. Humane Handling	O
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	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. <span style="border: 1px solid black; padding: 2px;">NOID</span>	X
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

## 60. Observation of the Establishment

SPAIN – Est. 13 April 1, 2004

This establishment was bought by the present owners within past few weeks. It plans to process dry cured hams. It has applied for new labels to FSIS. At the time of this visit, there were no approved labels and the establishment has not produced any U.S.-eligible product thus far and plans to start processing around June 1, 2004.

15. The HACCP plan did not address all the hazards and flow diagram was incomplete. Did not comply with FSIS Regulation 417.2(a) and requirements of 9 CFR 430.4(a) for *Listeria monocytogenes*.

19. The HACCP plan did not describe the frequency of CCP verification. Did not comply with FSIS Regulation 417.4(2)

20. Corrective actions written in the plan did not meet FSIS HACCP requirements. Did not comply with FSIS Regulation 417.3(a)(3)

58. The establishment was issued a Notice of Intent to Delist (NOID) by Spanish inspection officials to correct all deficiencies within 30 days of the date of the audit.

61. NAME OF AUDITOR

Dr. M. Ghias Mughal

62. AUDITOR SIGNATURE AND DATE

Shirazee H. Chaudhry 4/1/04

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Campofrio. 45500 Torrijos ( Toledo)	2. AUDIT DATE March 8, 2004	3. ESTABLISHMENT NO. 14	4. NAME OF COUNTRY Spain
5. NAME OF AUDITOR(S) Dr. M. Ghias Mughal		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	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.	X	37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	X
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	X
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins/Moisture)	O	54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

## 60. Observation of the Establishment

SPAIN - Est. 14 March 8, 2004

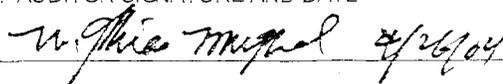
11. One plastic belt in the salting area used for transportation of hams was frayed on the edges. Did not comply with FSIS Regulation 416.14

49, 50 and 51. This establishment works five days per week and has two shifts. It produces dry cured hams. Inspection coverage is provided two to three days per week during the morning shift. There is no inspection coverage on the night shift.

61. NAME OF AUDITOR

Dr. M. Ghias Mughal

62. AUDITOR SIGNATURE AND DATE

Handwritten signature of Dr. M. Ghias Mughal dated 3/26/04.

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Redondo Iglesias S.A., Utiel	2. AUDIT DATE March 11, 04	3. ESTABLISHMENT NO. 20	4. NAME OF COUNTRY Spain
5. NAME OF AUDITOR(S) Dr. M. Ghias Mughal		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		O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements			Part E - Other Requirements		
10. Implementation of SSOP's, including monitoring of implementation.			36. Export		
11. Maintenance and evaluation of the effectiveness of SSOP's.			37. Import		
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.			38. Establishment Grounds and Pest Control		
13. Daily records document item 10, 11 and 12 above.			39. Establishment Construction/Maintenance		
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements			40. Light		
14. Developed and implemented a written HACCP plan.		X	41. Ventilation		
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.			42. Plumbing and Sewage		
16. Records documenting implementation and monitoring of the HACCP plan.			43. Water Supply		
17. The HACCP plan is signed and dated by the responsible establishment individual.			44. Dressing Rooms/Lavatories		
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements			45. Equipment and Utensils		
18. Monitoring of HACCP plan.			46. Sanitary Operations		
19. Verification and validation of HACCP plan.			47. Employee Hygiene		
20. Corrective action written in HACCP plan.			48. Condemned Product Control		
21. Reassessed adequacy of the HACCP plan.			Part F - Inspection Requirements		
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.			49. Government Staffing		X
Part C - Economic / Wholesomeness			50. Daily Inspection Coverage		X
23. Labeling - Product Standards			51. Enforcement		X
24. Labeling - Net Weights			52. Humane Handling		O
25. General Labeling			53. Animal Identification		
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		O	54. Ante Mortem Inspection		O
Part D - Sampling Generic E. coli Testing			55. Post Mortem Inspection		
27. Written Procedures		O	Part G - Other Regulatory Oversight Requirements		
28. Sample Collection/Analysis		O	56. European Community Directives		
29. Records		O	57. Monthly Review		
Salmonella Performance Standards - Basic Requirements			58.		
30. Corrective Actions		O	59.		
31. Reassessment		O			
32. Written Assurance		O			

## 60. Observation of the Establishment

SPAIN – Est. 20 March 11, 2004

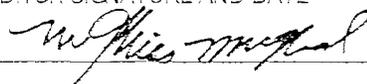
14. The HACCP plan did not comply with the requirements of 9 CFR 430.4 (a) relating to testing for *Listeria monocytogenes* as explained in FSIS Directive 11240.4

49, 50 and 51. Daily inspection coverage is not provided in this processing establishment. The Inspector visits this establishment one to three days per week. Inspection requirements are not enforced on the days the inspector is not present in the establishment.

61. NAME OF AUDITOR

Dr. M. Ghias Mughal

62. AUDITOR SIGNATURE AND DATE

 4/26/04

United States Department of Agriculture  
Food Safety and Inspection Service

**Foreign Establishment Audit Checklist**

1. ESTABLISHMENT NAME AND LOCATION Embutidos Palacios S.A. Alberda de Iregua Ctra. Logrono s.n. - 2620	2. AUDIT DATE 3-4 & 31, 2004	3. ESTABLISHMENT NO. 16	4. NAME OF COUNTRY Spain
5. NAME OF AUDITOR(S) Dr. M. Ghias Mughal		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	O
<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	X
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	X
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	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

SPAIN – Est. 16 March 4 & 31, 2004

49, 50, 51. Daily inspection coverage is not provided in this processing establishment. Inspection requirements are not enforced on the days inspector is not present in the establishment.

61. NAME OF AUDITOR

Dr. M. Ghias Mughal

62. AUDITOR SIGNATURE AND DATE

*Dr. Ghias Mughal* 4/26/04

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Campofrio Pol. Ind. Gamonal- Villimar Burgos	2. AUDIT DATE March 29, 04	3. ESTABLISHMENT NO. 21	4. NAME OF COUNTRY Spain
5. NAME OF AUDITOR(S) Dr. M. Ghias Mughal		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	O
<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 SSOPs 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	
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

SPAIN – Est. 21 March 29, 2004

There were no negative findings.

61. NAME OF AUDITOR

Dr. M. Ghias Mughal

62. AUDITOR SIGNATURE AND DATE

*m. ghias mughal 4/26/04*

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Jamones Burgales Calle de La Bureba s/n Burgos	2. AUDIT DATE March 30, 04	3. ESTABLISHMENT NO. 22	4. NAME OF COUNTRY Spain
5. NAME OF AUDITOR(S) Dr. M. Ghias Mughal		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	O
<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.	X	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	
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

SPAIN – Est. 22 March 30, 2004

14. The HACCP plan did not comply with the requirements of 9 CFR 430.4 (a) relating to testing for *Listeria monocytogenes* as explained in FSIS Directive 11240.4.

61. NAME OF AUDITOR

Dr. M. Ghias Mughal

62. AUDITOR SIGNATURE AND DATE

*M. Ghias Mughal* 4/26/04

[Coat of Arms of the Kingdom of Spain]  
MINISTRY OF HEALTH AND CONSUMPTION

GENERAL PUBLIC HEALTH ADMINISTRATION

Manuel Oñorbe de Torre

GENERAL DIRECTOR

Dr. Sally Stratmoen  
Acting Director  
International Equivalence Staff  
Office of International Affairs  
U.S. Department of Agriculture  
Food Safety and Inspection Service  
1400 Independence Avenue  
Washington, D.C. 202050

Madrid, June 17, 2004

After the three meetings held this past April 26th and 30th, to conclude and clarify the findings of the last audit carried out by Dr. Mughal, and one held this past June 15th, regarding the Control Plan of *L. monocytogenes*, I would like to inform you of the following:

First, note that establishment **Number 13** has changed its name: before, it was called CAMPOFRIO ALIMENTACION, S.A., its new name now is **SECADEROS DE ALMAGUER, S.A.**

This establishment, which was visited as part of the last audit, and which, due to the previously mentioned name change, was without any activity, and as a result, did not have any type of production, according to the results of the audit it showed deficiencies relative to the Normalized Plan for Hygiene Control (PNCH, acronym in Spanish) and the Plan for the Analysis of Dangers and Critical Control Points (APPCC, acronym in Spanish).

In this regard, we have received a document from the General Public Health Administration of the communities of Castilla-La Mancha indicating that the pertinent corrective measures have been taken and that these have been verified by official veterinary services responsible for the control and official supervision of the establishment.

In contrast and relative to the **Plan of Corrective Actions** indicated in the April 30th meeting, I notify you that we have been awaiting the developments of the last meeting this past June 15th, with the objective of issuing said plan.

PASEO DEL PRADO, 18-20  
28071 MADRID  
TEL: 91 596 20 63  
FAX: 91 596 44 08

[Coat of Arms of the Kingdom of Spain]  
MINISTRY OF HEALTH AND CONSUMPTION

GENERAL PUBLIC HEALTH ADMINISTRATION

Manuel Oñorbe de Torre

GENERAL DIRECTOR

Moreover, regarding the daily presence of an official veterinarian in the establishments indicates that the Competent Authorities of La Rioja and Valencia, for establishments Numbers 16 and 20, respectively, have provisionally accepted said requirement, and that currently in these establishments the presence of an official veterinarian is on a daily basis, during all the work shifts of the companies, and said presence and the activities undertaken are recorded in writing.

The Competent Authority of Castilla-La Mancha, with respect to establishment Number 13, which needed to cover the afternoon shift, and establishment Number 14, which is still inactive, is evaluating this possibility and will shortly inform us of their decision in this regard.

In this sense, we inform you that, not only in our opinion and view, but also in that expressed by the Competent Authorities of the Autonomous Commonwealths (CC.AA., Spanish acronym), this requirement for the establishments which make cured raw meat products, such as hams and chorizo sausages, should remain circumscribed to the time period in which products destined for the U.S. market are handled.

Moreover, we would like to point out that during the curing phase of the products, which in the case of hams, may surpass 400 days without interruption and is carried out in closed chambers set aside for that purpose, without any product handling during that period, we consider that official control is permanent and that daily presence of a veterinarian is not necessary, since the only variations and controls which are applied to these products during this phase relate to temperature, time and humidity; furthermore, we should consider that these variations do not impact hygienic quality nor product safety, but rather commercial quality. These curing parameters are strictly controlled and recorded by means of computer systems and may be monitored and verified at all times during the curing process. Evidently, when the product has completed this phase and is taken out of the chamber, veterinary intervention continues *in situ* until it is shipped.

Last, regarding the requirement of compliance with 9CFR 430 over control of *L. monocytogenes* in ready-to-eat (RTE) meat and fowl products, I inform you that the six authorized establishments and the competent authorities of the four Autonomous Commonwealths involved, as well as this Department, with the support of the Spanish Agency for Food Safety and the National Foodstuffs Center, are working intensively to try to apply said regulation with the greatest accuracy possible in order to ensure correct compliance. However, I would like to remind you that we did not receive the aforementioned regulation until this past April 15th, when the U.S. Embassy in Madrid sent us Dr. Karen Stuck's document dated July 29, 2003 informing of said regulation.

E-MAIL

PASEO DEL PRADO, 18-20  
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[Coat of Arms of the Kingdom of Spain]  
MINISTRY OF HEALTH AND CONSUMPTION

GENERAL PUBLIC HEALTH ADMINISTRATION

Manuel Oñorbe de Torre

GENERAL DIRECTOR

It has been necessary to translate this new regulation into Spanish, and once translated, to remit it to the Competent Authorities of the Autonomous Commonwealths, the companies involved and other agencies in order to be able to conduct a detailed analysis and study for its interpretation and be able to make the corresponding decisions for its appropriate application.

After the last meeting with FSIS technicians on this subject, our levels of knowledge and interpretation have improved, however, in spite of making good progress relative to the alternatives to be applied for each product from each one of the establishments, we are still missing details and documentation which the companies need to provide, in order to accurately evaluate the effectiveness of the treatments, agents or anti-microbial processes involved, so that we can consider the alternatives chosen as appropriate and in compliance with the regulation, as in the case of the use of high hydrostatic pressures (HHP).

In this last case, we expect to have all the documentation shortly in order to be able to send you an appropriate and complete plan of corrective actions in this regard.

Moreover, we consider that in certain measure, we have given a response to the plan of corrective actions requested, which will be completed once we receive the relevant replies and complementary documentation from the Competent Authorities of the Autonomous Commonwealths.

We await your observations, remarks and any suggestions you consider relevant and timely.

Without any further particulars, please receive my kind regards,

[illegible signature]  
Manuel Oñorbe de Torre

E-MAIL

PASEO DEL PRADO, 18-20  
28071 MADRID  
TEL: 91 596 20 63  
FAX: 91 596 44 08

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

Madrid, July 12, 2004

Dear Ms Stratmoen:

As a follow-up to my letter of June 17, after having received pertinent answers from proper health authorities of the Autonomous Communities, by means of this letter I am sending the plan for corrective actions that complete the actions and measures indicated in the previous letter.

With regard to the daily presence of an official veterinarian in the plants, it was already reported to you that the proper authorities of Rioja and Valencia have accepted that measure provisionally for plants number 16 and 20, respectively. Currently the official veterinarian is present daily in those plants during all company work shifts and his presence and activity carried out is recorded in writing.

The proper authority of Castilla-La Mancha have communicated to us their decision regarding plants number 13 and 14 and indicated that for inspection of the two plants authorized for export to the U.S.A., a work protocol has been established such that handling of products is done exclusively during morning shifts Monday through Friday. Official inspection activities are strengthened when products intend for the U.S.A. are handled. They have given reason and justification for that decision. (See attached answer.)

In this sense, our criterion and posture was already communicated to you, reiterating the position of the Castilla-La Mancha answer.

Finally, regarding the demand for compliance with 9 CFR 430 on the control of L. monocytogenes in ready-to-eat (RTE) meat and poultry products, in the attached documentation are mentioned the different alternatives that each plant has decided are more appropriate according to the type of process for each product. As a summary, you are being sent a table on "L. MONOCYTOGENES CONTROL MEASURES FOR U.S.A.-BOUND MEAT PRODUCTS."

E-MAIL

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FAX: 91 596 44 09

MINISTRY  
OF HEALTH  
AND CONSUMER AFFAIRS

PUBLIC HEALTH  
ADMINISTRATION

Manuel Oñorbe de Torre

DIRECTOR GENERAL

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In light of this, we consider that with our previous letter and definitively with this letter and the documentation submitted, we have given you the final answer to the requested plan of corrective actions.

We await any observations, comments and suggestions that you consider timely.

There being nothing else to discuss, I send my greetings.

*[Signature]*

Manuel Oñorbe de Torre

E-MAIL

PASEO DEL PRADO, 18-20  
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