United States Department of Agriculture

Food Safety and Inspection Service

Washington, D.C. 20250

NOV 5 2008

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

Dear Dr. González:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Spain's meat inspection system February 26 through March 14, 2008. Comments from Spain have been included as an attachment to the final 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 (202) 690-5646, by facsimile at (202) 720-0676, or electronic mail at donald.smart@fsis.usda.gov.

Sincerely,

Donald Smart
Director
International Audit Staff
Office of International Affairs

Enclosure

cc:

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Canice Nolan, First Secretary, EU Mission to the US, Washington, DC
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Final Audit Letter November 5, 2008

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

FEBRUARY 26 THROUGH MARCH 14, 2008

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

AC	Autonomous Community
CCA	Central Competent Authority [Ministry of Health and Consumer Affairs]
CCP	Critical Control Point
CFR	Code of Federal Regulations
E. coli	*Escherichia coli*
EC	European Commission
EU	European Union
FSA	Food Safety Agency
FSIS	Food Safety and Inspection Service
HD	Health Department
NOID	Notice of Intent to Delist
POE	Port of entry
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point
SSOP	Sanitation Standard Operating Procedure(s)
Salmonella	*Salmonella* species
VEA	European Community/United States Veterinary Equivalence Agreement

1. INTRODUCTION

The audit took place in Spain from February 26 through March 14, 2008.

An opening meeting was held on February 26 in Madrid with the Central Competent Authority (CCA). At this meeting, the auditors confirmed the audit itinerary and the objective and scope of the audit, and requested additional information needed to complete the audit of Spain's meat inspection system.

The auditors were accompanied during the entire audit by representatives from the CCA (the Ministry of Health and Consumer Affairs) and/or representatives from the regional and local inspection offices.

2. OBJECTIVE OF THE AUDIT

This was a routine annual audit, with special emphases on microbiology methodologies and humane handling of livestock. 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, two Autonomous Community inspection offices, one microbiology laboratory performing analytical testing on United States-destined product, one swine-slaughter establishment, and four pork-processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	Madrid
	Autonomous Communities	2	Castilla y León and Valencia
	Local	5	Establishment level
Laboratories		1	Majadahonda (Madrid)
Swine Slaughter Establishments		1	La Alberca
Pork Processing Establishments		4	Toledo, Valencia, Logroño, and Burgos

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 audits of a selection of records in the country's inspection headquarters and in two Autonomous Community offices. The third part involved on-site visits to five

establishments: One slaughter establishments and four processing establishments. The fourth part involved visits to one government-owned and operated microbiology laboratory. *Centro Nacionál De Alimentación* was conducting analyses of field samples for species verification and for the presence of *Salmonella* species *(Salmonella)* and *Listeria monocytogenes*. The residue section of the laboratory was also scheduled for audit; however, time constraints did not allow for its inclusion.

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 (SSOP), (2) animal disease controls, (3) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (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 auditors evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditors also assessed how inspection services are carried out by 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.

In the opening meeting, the auditors 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 Food Safety and Inspection Service (FSIS) auditors would audit the meat inspection system against European Commission (EC) 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 auditors would audit against FSIS requirements, which include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification, and requirements for HACCP, SSOP, and testing for generic *E. coli* and *Salmonella*.

Third, the auditors would audit against any equivalence determinations that have been made by FSIS for Spain under provisions of the Sanitary/Phytosanitary Agreement. The following alternative procedures have been determined by FSIS to be equivalent for Spain:

- Testing for Salmonella using PEE/LSPV/012
- Testing for *Enterobacteriaceae* and Total Viable Count in lieu of testing for generic *E. coli*
- The use of EN 45001 - laboratory quality control standards

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 (EC) Directives was also assessed:

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

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address:

http://www.fsis.usda.gov/Regulations_&_Policies/ Foreign_Audit_Reports/index.asp

The two most recent FSIS audits of Spain's meat inspection system were conducted:

- March 29 through April 26, 2006
- February 28 through March 21, 2007

<u>February-March 2007</u>

Four establishments (one slaughter and processing establishment and three processing establishments) were audited, one of which had been suspended by FSIS, but which was included in the audit schedule at Spain's request. No establishment was delisted, nor did any receive a Notice of Intent to Delist (NOID); however, one of the three processing establishments had been issued a NOID during the previous FSIS audit on March 31, 2006. Subsequently, this establishment's eligibility to export meat and meat products to the US was suspended on August 15, 2006, as a result of two POE violations for the presence of *Listeria monocytogenes*. At the time of the 2007 audit, this establishment remained under suspension. Had this establishment been certified for US export at that time, it would have been delisted, based upon failure to implement effective corrective actions, as required, to address the NOID received on March 31, 2006, and also upon additional deficiencies identified during the new on-site audit.

In the three establishments certified at the time of the audit, the following deficiencies were reported:

- In one establishment, the establishment management could not provide written documentation to support the frequency of the verification procedures for Critical Control Point (CCP) 2-B.

- In one establishment, the monitoring of the CCP for weight increase after the addition of nitrite was not being documented, as required according to the written HACCP plan.

In the suspended establishment, which was included in the audit schedule at the request of the CCA and subjected to a "routine" FSIS audit, the following deficiencies were noted:

- Numerous SSOP and other sanitation requirements were not met.
- Several HACCP deficiencies were identified.
- Inspection officials did not adequately describe, in their pre-operational and operational sanitation verification records, the deficiencies they had identified.
- Contaminated/suspect swine carcasses were retained for further post-mortem inspection by the veterinary inspector, but these carcasses were marked "Inspected and Passed" by an establishment employee before final inspection was completed.
- 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.
- Verification of the implementation of US and Council Directive 64/433 requirements by the CCA, the Autonomous Communities, and the districts was inadequate.
- The periodic supervisory audits performed by the CCA, the Autonomous Community officials, and the districts did not adequately verify the implementation of US and/or Council Directive 64/433 requirements for HACCP programs, SSOP, and other sanitation programs.
- Council Directive 64/433 was not adequately enforced: 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.

March-April 2006

Seven establishments (one slaughter and processing establishment and six processing establishments) were audited. No establishment was delisted; however, two establishments received NOIDs for non-compliance with HACCP, SSOP, and other sanitation requirements.

The following deficiencies were reported:

- The periodic supervisory reports did not reflect actual establishment conditions.

- In one establishment, documentation of verification procedures was not included in the records for corrective actions taken as a result of deficiencies identified during periodic supervisory reviews.

- Verification of implementation of US requirements by inspection service officials at the Autonomous Community and/or the district levels was inadequate.

- In six establishments, one or more HACCP and/or SSOP implementation deficiencies were reported.

- In three establishments, Council Directive 64/433 was not adequately enforced: In the slaughter establishment, the mesenteric lymph nodes of swine viscera were not being routinely palpated by the veterinary inspection officials during post-mortem inspection.

- In all seven establishments, the periodic supervisory audits performed by the CCA, Autonomous Communities, and/or districts did not adequately document the implementation of US and/or Council Directive 64/433 requirements, including the implementation of HACCP programs, SSOP, and other sanitation controls.

- In the slaughter establishment, veterinary inspection officials were not verifying, documenting, and enforcing the requirement of zero tolerance for visible contamination with 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 auditors were informed that the relevant EC Directives, determined equivalent under the VEA, had been transposed into Spain's legislation.

6.2 Government Oversight

6.2.1 CCA Control Systems

The responsibility for Spain's meat inspection control systems lies with two Ministries.

The chain of command begins with the Ministry of Health and Consumer Affairs, the Central Competent Authority (hereinafter called the Ministry of Health), which is responsible in general for matters of food safety, and in particular for the direct authorization and supervision of the export establishments, developing and implementing controls over the products they produce, and ensuring that the internal procedures in the establishments are safe from a health perspective. Ministry of Health responsibilities cover food products of animal and vegetable origin, all kinds of foods, drugs, chemical products, phytosanitary products for human use, and public health controls. The Ministry of Agriculture, Fisheries, and Food is responsible for animal health and welfare, animal feedstuffs, veterinary drugs, and traceability from the farms to the slaughterhouses.

There is also a Spanish Food Safety Agency (AESA) which is under the authority of the Health Minister but is an independent, self-managed body. Its responsibilities include the coordination of the competent authorities regarding national health control, the enactment

of food regulations, the preparation of scientific reports for food safety issues, and representation of the competent bodies before the EC regarding the development of European requirements, but it has no food inspection responsibilities.

The country is divided into 17 Autonomous Communities (ACs). There was a decentralization of government functions in the 1980s, as a result of which the central government transferred to the ACs the responsibilities for regulation and enforcement in the field of public health, including food control; the central government, however, maintains exclusive responsibilities for some aspects of public health, including import and export controls at Spain's borders. The Ministry of Health conducts coordination meetings three to four times per year between the ACs and the central government to ensure uniform application and implementation of the meat inspection programs and export requirements among the ACs that contain export establishments by harmonizing inspection criteria, standards, and procedures. All these meetings were documented. At the time of this audit, two such meetings had already been held since the beginning of the 2008 calendar year.

The ACs are considered to be "federal states," equivalent in their responsibilities to the national government. The General State Budget grants the ACs their own authority to establish their own regional budgets. Each AC designs and controls its own budget according to allocations provided to them from the central government. In the event of a lack of resources, there is a legal procedure to transfer resources and/or funding from one department to another within the same AC. Depending upon the amount required, the transfer is authorized by the Minister of Health or by the Health Counselor in the AC, and if a very large amount is required, it is authorized by the Council of Ministers. For emergencies, credit extension may be granted by the Council of Ministers. The public officials of the ACs (including in-plant inspection personnel) have the same status as public officials of the national government.

At the time of this audit, five of the ACs contained US-eligible establishments. The Ministry of Health has the absolute authority and responsibility to require uniform implementation of FSIS requirements in those ACs that contain US-eligible establishments. The Ministry of Health also conducts the initial equivalence determinations of establishments, in new ACs, whose management personnel wish to become eligible to export to the US, and has the sole authority to grant final certification of a new establishment and to permit an existing US-eligible establishment to maintain its eligibility to export to the United States.

6.2.2 Ultimate Control And Supervision

Within the Ministry of Health, the department with inspection and control responsibilities regarding exports and imports is the Public Health General Directorate and its General Subdirectorate for Foreign Health. The latter controls exports and imports, whereas domestic trade is controlled by the ACs on the basis of their own responsibilities. The Ministry of Health has exclusive responsibility regarding regulation and enforcement of imports and exports, and relies on the ACs for the enforcement of the health regulations regarding exports, specifically through the official veterinary services of the ACs. Since the previous FSIS audit, the Ministry of Health had undertaken to unify field inspection procedures and was in the process of developing a computer application intended to unify all the forms and procedures for the official veterinary services throughout the country.

In 2006-07, Spain (through an independent contractor) developed a new Auditor's Manual, specifying procedures for supervision of establishments for export, in two parts—procedures for the regulation of sanitary requirements and a specific audit form for inspectors to use; the program will ultimately incorporate a database that will provide full traceability of all US-eligible products. The program is based on Spanish national, EU, and FSIS regulations and, at the time of this audit, was operational in a pilot form, and was still under further development to include all relevant historical data. A new unified form for official supervisory auditing of official establishments was adopted in April 2007. It was in use at the time of this audit, and was being incorporated into the computer system; field inspectors were being provided with devices (similar to Personal Data Assistants) to enter inspection results directly into the system. It was anticipated to be completed by April-May 2008, and will include data regarding SSOP, HACCP programs, product and process control, Pre-Shipment Reviews, equipment, and hygiene controls regarding operations and personnel.

The details of the organization and structure of the meat inspection delivery programs is, as mentioned above, the responsibility of the ACs. At the time of this audit there were basically two general structures. One was unique to the AC of Castilla y León and the other four ACs that contained establishments eligible to export to the US fit into the second. Interviews were conducted in the ACs of Castilla y León and Valencia.

Castilla y León	Valencia
The AC was divided into 9 Provinces, each of which was subdivided into *Basic Health Areas*. Each Basic Health Area contained its own inspection services. The Castilla y León Food Safety Agency (FSA) was the competent authority for health issues, including managing and coordinating inspection activities regarding environment, food products, food establishments, and food services. The FSA in Castilla y León had three services: Alert Management and Risk Assessment, Health Planning and Certification (including meat inspection services), and Official Sanitary Vigilance and Control. Each Province had a Territorial Health Service with the following six Sections: Official Veterinary Services (responsible for all products of animal origin), Official Pharmaceutical Services, a Public Health Laboratory, Consumer Affairs, Public Health, and Food Hygiene & Environmental Health.	The AC was divided into three Provinces, which were subdivided into 22 public (animal and human) Health Departments (HDs). The highest health authority in this AC is the Health Council. Under the Health Council is the General Directorate for Public Health. The Valencia General Directorate for Public Health is the competent authority for all issues regarding public health, including managing and coordinating inspection activities regarding environment, food products, food establishments, and food services. The Provincial government had no responsibilities regarding official meat inspection control. There were no Basic Health Areas (these were unique to Castilla y León). Seventeen of the HDs had inspection services, located in Public Health Centers. Each Public Health Center had a Veterinary Coordinator, a Department Veterinarian, a Veterinary Inspector for Slaughterhouses, and a Food Hygiene Technical Specialist.

Castilla y León	Valencia
There were three levels of supervision over US-eligible establishments: The CCA (Ministry of Health), the Castilla y León FSA, and the Provincial Food Hygiene Sections. The Ministry of Health conducted at least one review in the US-eligible establishment per year; the AC carried out one per year, and the Provincial Food Hygiene Sections carried out the other 10 reviews per year.	There were three levels of supervision over US- eligible establishments: The CCA (Ministry of Health), the Valencia Health Council, and the 17 HDs. The Ministry of Health conducted at least one review in the US-eligible establishment per year; the AC carried out one per year, and the Veterinary Coordinator carried out the other 10 reviews per year.

6.2.3 Assignment of Competent, Qualified Inspectors

Hiring was accomplished through public competition; successful completion of both national and AC civil service exams was required. Both the central government (the Ministry of Health) and the ACs were involved in the continuing training procedures to ensure that inspection personnel maintained their competence. All official inspection personnel at all levels had attended multiple training sessions over the course of the past few years, covering a wide spectrum of topics from basic theory up to and including advanced application of export requirements. The ACs had also provided additional recent training courses for inspection personnel. Furthermore, Ministry of Health and AC personnel had attended FSIS courses in Puerto Rico (in May 2006 and May 2007) and Washington, DC (July 2007), as well as privately-organized professional HACCP courses that were held in Spain in April 2007 and an international symposium on meat safety in February 2007. Establishments were not charged for inspection services or laboratory analyses; the salaries of all in-plant inspection personnel were paid from taxes.

Supervisory reviews were conducted monthly. The same review form was used by the ACs (and also by the Provinces) as was used by the Ministry of Health; this form was based very closely on the FSIS Foreign Establishment Audit Report. The (at least) annual AC reviews included evaluations of the activities and performance of the in-plant inspection personnel and also of the supervision and verification activities of the Provincial inspection staff (who conducted 10 of the periodic reviews per year).

All internal review reports reflected follow-up evaluation of corrective actions taken as a result of deficiencies identified during previous reviews. Copies of the internal review reports were routinely provided to the General Subdirectorate for Foreign Health in Madrid for assessment

Castilla y León	Valencia
All inspection personnel in US-eligible establishments were veterinarians. There was a pool of qualified personnel who were available to be called upon to relieve inspection personnel on short notice. There were five official veterinarians assigned to the three US-eligible establishments, and they were not permitted to have simultaneous vacations.	One veterinarian was assigned to the US-eligible establishment. In case of sudden absence due to illness or for planned absence, the Veterinary Coordinator assumed the in-plant duties.

6.2.4 Authority and Responsibility to Enforce the Laws

The Ministry of Health maintains exclusive responsibility regarding the general principles of health and also for transposing the EC regulations into Spanish law to guarantee the consistency of the national inspection system. The general basic regulations regarding food safety are the responsibility of the Ministry of Health through the Spanish Food Safety Agency, which coordinates the consistency of the national system. The ACs develop and implement those regulations.

6.2.5 Adequate Administrative and Technical Support

One laboratory, the *Centro Nacionál De Alimentación,* performed all of the regulatory microbiological analyses of US-eligible product; all results were provided to the General Subdirectorate for Foreign Health. Reviews of this laboratory were conducted by Spain's National Accreditation Body (ENAC); the results were reviewed and verified by the General Subdirectorate for Foreign Health. The laboratory was owned and operated by the Ministry of Health and was also under the authority of the Spanish Food Safety Authority. All residue analyses for US-eligible product were performed in laboratories that were owned and operated by the ACs, and all of which had ENAC and ISO 17025 accreditation; the methods employed were recognized and approved by the EC.

6.3 Headquarters Audit

The auditors conducted a review of inspection system documents at the headquarters of the Ministry of Health. 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
- New laws and implementation documents such as regulations, notices, directives and guidelines
    - Sampling and laboratory analyses for residues
    - Sanitation, slaughter and processing inspection procedures and standards

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

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

6.3.1 Audits of Regional and Local Inspection Sites

The auditors conducted interviews in the head offices of the inspection services in the Autonomous Communities of Castilla y León (in the city of Valladolid) and Valencia (in the city of Valencia), and also interviewed the in-plant inspection personnel in the five establishments that were audited.

7. ESTABLISHMENT AUDITS

The FSIS auditors visited a total of five establishments. One was conducting both swine slaughter and pork processing; the other four were pork-processing establishments. None of the establishments was delisted. One establishment received a Notice of Intent to Delist from the Ministry of Health, primarily due to varying degrees of neglected maintenance of over-product structures. This establishment may retain its certification for export to the United States provided that the establishment management corrects all deficiencies noted during the audit within 30 days of the date when the establishment was audited.

In the establishment that had been suspend and re-listed, the newly-implemented heat treatment applied to post-lethality-exposed product was evaluated; no concerns arose as a result of this evaluation.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During the laboratory audit, emphasis was placed on the application of procedures and standards that are equivalent to the 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 auditors evaluated compliance with the criteria established for the use of private laboratories under the PR/HACCP requirements.

The microbiology section of the government-owned and -operated *Centro Nacionál De Alimentación* in Majadahonda, Madrid was audited. The following deficiencies were reported:

- The method being used for species verification was an alternative method that had been provided to FSIS for an equivalence determination, but equivalence had not yet been granted. A test intended for use with cooked products that was recommended by FSIS (Cooked Meat/Meat Products Species Identification Test Kit, manufactured by TEPNEL) had been used, but the products tested were not cooked, and the test did not meet the laboratory's quality control requirements. Exports of the products in question to the US were stopped until a suitable test (Raw Species Identification Test Kit, produced by the same manufacturer) was found. This test was currently in use pending a determination of equivalence by FSIS. In the meantime, the laboratory was also running validation tests on an FSIS-approved method, MLG 17-02.

- Illegible corrections were observed in the official media preparation register.

- The laboratory personnel were not routinely recording the condition or the temperature of samples received for analysis for microbiology and/or species verification.

As stated earlier in this report, the residue section of the laboratory was also scheduled for audit; however, time constraints did not allow for its inclusion.

9. SANITATION CONTROLS

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

Based on the on-site audits of the 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, 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 five establishments were found to meet the basic FSIS regulatory requirements, with no deficiencies reported.

9.2 Sanitation Performance Standards

Sanitation Performance Standards in all five establishments were found to meet the basic FSIS regulatory requirements, except as noted below. Some requirements were not adequately enforced in two of the five establishments audited:

- In one establishment, maintenance and cleaning of many over-product structures in numerous areas had been neglected to varying degrees. (No actual product contamination was observed.)

- In one establishment, during pre-operational sanitation inspection, product residues from the previous day's operations were observed on several non-product contact surfaces that were, however, very close to product-contact surfaces. (No actual product contamination was observed.)

- In one establishment, pull-ropes for opening hydraulic doors in various production areas were made of braided materials that were very difficult to clean and sanitize; some of these were discolored and caked with old product residues.

- In one establishment, malodorous material from the downstream portion of the inedible conveyor system had flowed back into the auger hopper that was employed to transport inedible and condemned soft tissues out of the main cutting/boning room at the end of the cutting/boning process.

9.3 EC Directive 64/433

In four of the five establishments audited, the provisions of EC Directive 64/433 were effectively implemented.

- In one establishment, maintenance and cleaning of over-product structures and pull-ropes for operating hydraulic doors had been neglected to varying degrees.

10. ANIMAL DISEASE CONTROLS

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

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 auditors 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* (or its recognized equivalent) in slaughter establishments.

11.1 Humane Handling and Humane Slaughter

The auditors evaluated the slaughter establishment's implementation of the requirements for humane handling and slaughter, employing a recently-developed checklist. No concerns arose as a result of this evaluation.

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 establishment audits. Deficiencies regarding HACCP implementation were reported in two of the five establishments audited:

- In two establishments, illegible corrections were observed in the monitoring documents for the CCPs.

- The management of one establishment was unable to provide documentation for the verification of calibration of equipment used to monitor the critical limits for two of the CCPs.

11.3 Testing for Generic *E. coli*

The swine slaughter establishment was conducting routine testing for generic *E. coli*, and also for *Enterobacteriaceae* and Total Viable Count according to EC policy, which has been recognized by FSIS as equivalent for EU Member States. The establishment was evaluated according to both FSIS regulations (for generic *E. coli*) and the relevant Annex to the Commission Decision, notified under document number C(2001) 1561 of 8 June, 2001 (for *Enterobacteriaceae* and Total Viable Count).

The testing programs for generic *E. coli*, *Enterobacteriaceae*, and Total Viable Count were properly conducted in the slaughter establishment.

11.4 Testing for *Listeria monocytogenes*

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

11.5 EC Directive 64/433

In all five establishments, except as noted above, the slaughter/processing provisions of EC Directive 64/433 were effectively implemented.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditors 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.

Residue controls at the establishment level were effectively implemented; no deficiencies were reported. Spain's national residue testing program for 2008 was being followed and was on schedule.

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 and was well-documented.

13.2 Testing for *Salmonella*

Spain has adopted the FSIS requirements for testing for *Salmonella* with the exception of the following equivalent measure:

- Testing for Salmonella using PEE/LSPV/012 (equivalence was granted March 12, 2008)

All of the five establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing and were evaluated according to the criteria employed in the United States' domestic inspection program. *Salmonella* testing was properly conducted in all five establishments.

13.3 Species Verification

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

There was one concern regarding the method being used for species verification in the microbiology laboratory that was audited (see Section 8).

13.4 Periodic 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.

13.5 Inspection System Controls

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

In addition, controls were in place for the importation of only eligible meat products from other counties for further processing.

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

- Deficiencies regarding enforcement by inspection personnel of some FSIS requirements were found in two of the five establishments audited and in the microbiology laboratory.

14. CLOSING MEETING

A closing meeting was held on May 14, 2008 in Madrid with the CCA. At this meeting, the primary findings, conclusions, and recommendations from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Gary D. Bolstad, DVM
Senior Program Auditor

16. ATTACHMENTS TO THE AUDIT REPORT

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

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Campofrio Alimentacion, S.A. Torrijos Toledo, Castilla-La Mancha	03/04/08	14	Spain
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Gary D. Bolstad, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Date: 03/04/08 Est #: 14 (Campofrio Alimentacion, S.A. [P]) (Toledo, Spain)

(Pork processing establishment)

19/51 The establishment was unable to provide documentation for the verification of calibration of equipment used to monitor the critical limits for two of the Critical Control Points. The Autonomous Community official who was leading the audit ordered immediate correction. [Regulatory reference: 9CFR §417.5(3) and §417.8]

22/51 Illegible corrections were observed in the monitoring documents for one of the CCPs. The inspection service officials instructed the establishment officials regarding the proper way to correct entry errors. [9CFR §417.5(3) and §417.8]

39/51/56 Varying degrees of neglected maintenance and cleaning of overhead structures and ceilings, over exposed-product-handling and -traffic areas, as well as in production areas (but not directly over exposed-product areas), were observed in numerous parts of the establishment. Observations included deteriorated conduit covers, rust, exposed insulation, and beaded condensation. No actual contamination or adulteration of product was observed. The Autonomous Community official who was leading the audit ordered retention of the product under the affected areas pending microbiological testing and reinspection and prompt scheduling of extensive repair and maintenance of the overhead structures and ceilings. [Regulatory references: 9CFR §416.2(b), §416.17, and European Commission Council Directive 64/433, Chapter III (3)]

46/51/56 Pull-ropes for opening hydraulic doors in various production areas were made of braided materials that were very difficult to clean and sanitize; some of these were discolored and caked with old product residues. The Autonomous Community official who was leading the audit ordered immediate corrective actions and replacement of the uncleanable pull-cords with others made of cleanable materials. [9CFR §416.4(b)), §416.17, and European Commission Council Directive 64/433, Chapter III (3)]

Note: The deficiencies reported as a result of the previous FSIS audit had been adequately addressed and corrected.

58 The Service Head of the Official Veterinary Health Services, Ministry of Health and Consumer Affairs issued to the establishment management a Notice of Intent to Delist. This establishment may retain its certification for export to the United States provided that the establishment management corrects all deficiencies noted during the audit within 30 days of the date when the establishment was audited.

61. NAME OF AUDITOR

Gary D. Bolstad DVM

62. AUDITOR SIGNATURE AND DATE

March 4/2008

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Palacios Alimentacion, S.A. Ctra de Logrono, s/n Logrono, La Rioja 0	03/11/08	16	Spain
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Gary D. Bolstad, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Date: 03/11/08 Est #: 16 (Palacios Alimentacion, S.A [P]) (Logrono, Spain)

(Pork processing establishment)

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

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE

March 11, 2008

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Redondo Iglesias S.A. Carreterra National 3, km 266 Utiel, Valencia 46300	03-06-2008	20	Spain
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Gary D. Bolstad DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Date: 03-06-2008 Est #: 20 (Redondo Iglesias S.A. [P]) (Utiel, Spain)

(Pork processing establishment)

22/51 Illegible corrections were observed in the monitoring documents for one of the CCPs. The inspection service officials instructed the establishment officials regarding the proper way to correct entry errors. [Regulatory references: 9CFR §417.5(3) and §417.8]

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE

GD Bolstad DVM March 6, 2008

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Campofrio Alimentacion, S.A. C/ La Bureba, s/n Burgos, Castilla y Leon	03/12/08	21	Spain
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Gary D. Bolstad, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Date: 03/12/08 Est #: 21 (Campofrio Alimentacion, S.A. [P]) (Burgos, Spain)

(Pork processing establishment)

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

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE

March 12, 2008

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Embutidos Fermin, S. L. La Alberca La Alberca, Salamanca 0	03/03/08	23	Spain
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Gary D. Bolstad, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Date: 03/03/08 Est #: 23 (Embutidos Fermin, S. L. [S/P]) (La Alberca, Spain)

(Swine slaughter/pork processing establishment)

45 During pre-operational sanitation inspection, product residues from the previous day's operations were observed on several non-product contact surfaces that were, however, very close to product-contact surfaces. No actual product was affected. The establishment management took immediate corrective actions. [Regulatory reference: 9CFR §416.4(a)]

46 Malodorous material from the downstream portion of the inedible conveyor system had flowed back into the auger hopper that was employed to transport inedible and condemned soft tissues out of the main cutting/boning room at the end of the cutting/boning process. The establishment management ordered thorough cleaning and disinfection of the interior surfaces of the auger unit and proposed modification of its construction to permit easy opening, cleaning, and disinfection of the internal surfaces on a regular basis. [9CFR §416.4(b)]

61. NAME OF AUDITOR

Gary D. Bolstad, DVM

62. AUDITOR SIGNATURE AND DATE

March 3, 2008

Brown, Yvonne

From: Bolstad, Gary
Sent: Tuesday, November 04, 2008 6:36 AM
To: Smart, Donald; Chaudry, Manzoor; Brown, Yvonne; Winters, Bonnie
Subject: FW: Est. 14 and Response to Draft Final Report

I have heard from Spain that there are no comments to the Draft Final Report from my Feb-Mar 08 audit, so we may consider the report Final. Here is Marta's response (below).

Gary D. Bolstad, DVM
Senior Program Auditor
Office of International Affairs, FSIS, USDA
Phone 202-205-4054, Fax 202-720-0676

From: mgarrido@msc.es [mailto:mgarrido@msc.es]
Sent: Tuesday, November 04, 2008 2:17 AM
To: Bolstad, Gary
Cc: jtroncoso@msc.es; ogonzalez@msc.es
Subject: RE: Est. 14 and Response to Draft Final Report

Hi, Gary,

You are right: I forgot to answer the second question. Relating to the Draft Final audit, Autonomous Region and Majadahonda Lab didn´t send any comments within the 60 days period after its reception. Therefore, it is supposed they are satisfied with the content. We are too. So you can close up this issue.

Thanks for everything.

Marta Garrido García
Jefa del Área de Gestión y Coordinación
Subdirección General de Sanidad Exterior
Ministerio de Sanidad y Consumo

Tfno: + 34 91 596 20 32
Fax: + 34 91 360 13 43
E mail: mgarrido@msc.es

> -----Mensaje original-----
> **De:** Bolstad, Gary [mailto:Gary.Bolstad@fsis.usda.gov]
> **Enviado el:** lunes, 03 de noviembre de 2008 21:15
> **Para:** Garrido García, Marta
> **CC:** Chaudry, Manzoor; Smart, Donald; Brown, Yvonne; Winters, Bonnie; Troncoso Ramón, Juan Manuel
> **Asunto:** RE: Est. 14 and Response to Draft Final Report
>
> Hello, Marta,
>
> Thank you very much for your updating us on the status of your providing us with the corrective actions taken for Establishment 14. We are looking forward to receiving the translation of the details from your Embassy here in Washington.

Please be so kind as to also answer the other question I asked in my communication of October 2: Have you sent a response to the Draft Final audit report that we sent to you on April 21? We are unable to find one in our files and are hoping that you will be able to send one in the very near future. If you have no comments and are satisfied with the content, please let us know at your very earliest convenience so that we may close out this open issue.

Best regards,
Gary

Gary D. Bolstad, DVM
Senior Program Auditor
Office of International Affairs, FSIS, USDA
Phone 202-205-4054, Fax 202-720-0676

From: mgarrido@msc.es [mailto:mgarrido@msc.es]
Sent: Monday, October 20, 2008 10:13 AM
To: Bolstad, Gary
Cc: Chaudry, Manzoor; Smart, Donald; Winters, Bonnie; jtroncoso@msc.es
Subject: RE: Est. 14 and Response to Draft Final Report

Hello, Gary,

Finally, after some changes in the staff of my Deputy - Directorate, we have news relating on this file.

For your information, I communicate you that Pedro Ángel García (former Deputy – Director) and Carlos Abellán (former Head of Service) left us, and they don´t work in this Unit any longer. Replacing them, we are lucky to count with Óscar González (new Deputy – Director) and Juan Manuel Troncoso (new Head of Service).

These changes, added to the change of General Director before last summer, are the main reasons for the delay in our response.

Anyway, I´ve got the pleasure to inform you that, last week, we sent the documents concerning the corrective measures adopted in establishment Nº 14. The information was sent in Spanish language to our Embassy in Washington for translation and further transmission to FSIS.

Best regards,

Marta Garrido García
Jefa del Área de Gestión y Coordinación
Subdirección General de Sanidad Exterior
Ministerio de Sanidad y Consumo

Tfno: + 34 91 596 20 32
Fax: + 34 91 360 13 43
E mail: mgarrido@msc.es

-----Mensaje original-----
De: Bolstad, Gary [mailto:Gary.Bolstad@fsis.usda.gov]
Enviado el: jueves, 02 de octubre de 2008 19:12
Para: Garrido García, Marta; Abellán García, Carlos; Steve.Hammond@fas.usda.gov
CC: Chaudry, Manzoor; Smart, Donald; Winters, Bonnie
Asunto: Est. 14 and Response to Draft Final Report

Hello again Marta,

I hope you're having a wonderful autumn. The leaves are starting to turn here and it's getting beautiful.

We have two items that we would like to close out, and would like to request your help.

1. Have you send a response to the Draft Final audit report that we sent to you on April 21? We are unable to find one in our files and are hoping that you will be able to send one in the very near future. If you have no comments and are happy with the content, please let us know.

2. In response to questions that I sent regarding the status of corrective actions that were taken by Establishment 14 in response to the NOID, you sent the following response on May 12, 1008:

> "Concerning the establishment 14, I inform you that, after receiving the NOID:
>
> - The enterprise supplied a plan with corrective actions,
> - The Regional Authorities visited the facilities on 13th March and 2nd April, and
> - Our Ministry visited them too on 10th April.
>
> "Everything was made within the period provided by FSIS legislation.
>
> "Nevertheless, we didn´t inform you yet because we´ve got a new General Director (2 or 3 weeks ago) and we need to let him know the situation for taking some decisions. I hope we will be able to inform you in some days. Sorry for the inconvenience."

We had the impression, from your response, that you would be sending additional information, and have been waiting to hear from you. I sent more requests for your follow-up information on July 8 and August 4. We still have heard nothing more from your side.

Will you please confirm for the nature and details of the corrective actions taken by the establishment, as well as the details of the results of the reviews by the Regional Authorities and by your Ministry, at your very earliest convenience?

Please provide copies of your responses (to both questions) to the people on the distribution list, above, as well.

Thanks, and best regards,

Gary

Gary D. Bolstad, DVM

Senior Program Auditor

Office of International Affairs, FSIS, USDA

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