



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

Dr. Óscar González Gutiérrez-Solana  
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Spain

MAY 3 2001

Dear Dr. Gutiérrez-Solana:

Enclosed is the Food Safety and Inspection Service (FSIS) final report of the June 12-24, 2000, on-site audit of Spain's meat inspection system. I apologize for the delay in sending this report to you. We have made the editorial changes suggested in your January 22, 2001, response to our draft final audit report, and have included that letter as an addendum to the enclosed final report.

We appreciate actions taken by the Government of Spain (GOS) to correct deficiencies identified during the June 2000 audit. We also understand the concerns expressed in your January 22, 2001, letter regarding current and past audit-related issues. Hopefully, this letter will clarify U.S. meat import requirements in the following areas: 1) Laboratory Quality Assurance Program; 2) Analysis of residue samples; 3) Laboratory Check Sample Program; 4) Monthly reviews; and 5) HACCP implementation.

#### *Laboratory Quality Assurance Program*

The FSIS auditor reported that Spain's laboratory quality assurance program did not meet FSIS requirements. You indicated in your January 22, 2001, letter that Spain was required by the European Union to implement a laboratory quality assurance program based on the EN45001 laboratory standards. FSIS has determined that these standards, which are mandated by the European Union for all Member States, are equivalent to those used by FSIS approved laboratories in the United States. Accordingly, FSIS will audit the laboratory quality assurance programs of EU Member States against the criteria stated by the EN45001 standards.

#### *Analysis of Residue Samples*

During the June 2000 audit of Spain's meat inspection system, the FSIS auditor reported that some residue samples were being analyzed on a quarterly basis instead of monthly. Your January 22, 2001, letter confirms that certain residues are being analyzed at the end of the quarter, which you stated complies with the quality assurance standards of EN45001.

As stated above, FSIS accepts as equivalent the EN45001 laboratory standards and therefore will audit Spain's national residue program against the criteria established by these standards.

#### *Laboratory Proficiency Testing Program*

The FSIS auditor reported that the GOS was not meeting FSIS requirements for a laboratory check sample program. We understand from your January 22, 2001, response that your laboratory check sample program complies with the criteria established in EN45001. As stated above, FSIS accepts as equivalent the EN45001 laboratory standards and, therefore, will in the future audit Spain's laboratory proficiency testing program against the criteria established by these standards.

#### *Monthly Supervisory Visits*

FSIS regulations (9 CFR Part 327.2 (a)(2)(iv)(A)) state that representatives of the foreign inspection system must conduct, at a minimum, one supervisory visit per month to each establishment that is certified for export to the United States. The purpose of these visits is to ensure that certified establishments maintain sanitary measures that meet U.S. import requirements. The FSIS auditor reported that reviews of establishments certified to export to the United States were being conducted by the GOS (two per year), Autonomous Governments (two per year), and the Provincial Government Delegation (six per year). While FSIS accepts reviews by national and local governments as official visits, the combined total of annual supervisory visits is less than one per month. Accordingly, we request that the GOS provide assurance that the FSIS requirement of monthly visits to each certified establishment is being met. Such visits are not required with respect to any establishment during a period when the establishment is not producing or exporting products to the United States.

#### *HACCP Implementation*

FSIS regulations require foreign inspection systems to implement an equivalent HACCP program whereby establishments certified for export to the United States identify and evaluate food safety hazards that can affect their products, institute controls to prevent those hazards from occurring or keep them within acceptable limits, monitor the performance of controls, and maintain records routinely. Additionally, foreign inspection systems must verify the effectiveness of exporting establishment HACCP plans and have an enforcement program to ensure HACCP compliance.

During the June 2000 audit of Spain's meat inspection system, the FSIS auditor reported several deficiencies in HACCP implementation by all four Spanish establishments certified to export meat to the United States. These included: (1) HACCP plans did not adequately establish critical limits and monitoring procedures; (2) HACCP plans did not adequately state the procedures establishments use to verify that the plan is being implemented and the frequencies with which these procedures will be performed; (3) HACCP plans did not adequately address corrective actions to be taken in response to a deviation; (4) Neither establishment nor GOS inspection personnel were aware of HACCP pre-shipment

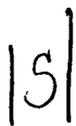
requirements mandating a review of all documentation pertaining to the monitoring of critical limits; and (5) GOS inspection officials were not adequately verifying establishments' HACCP plans.

In documentation, dated May 19, 1998; June 17, 1998; and March 24, 1999; GOS communicated to FSIS that all Spanish establishments certified to export meat to the United States had implemented HACCP procedures meeting the U.S. HACCP requirements. In these documents and in other correspondence, GOS further advised FSIS that Spain's meat inspection system had implemented equivalent measures to ensure full compliance with the U.S. HACCP requirements. In my letter of April 17, 2000, I informed GOS that FSIS had completed the document review process of Spain's HACCP program and determined that it was equivalent. I also stated that FSIS would follow-up with an on-site verification audit to evaluate how effectively Spain's inspection program had implemented the HACCP program described in your submitted documentation.

As I mentioned earlier, our June 2000 on-site audit identified several deficiencies in Spain's HACCP program. Your January 22, 2001, response provided assurances that all HACCP-related deficiencies have been corrected and that in some instances the information regarding HACCP implementation was contained in other supporting documents. It is important that the FSIS auditor have access to all relevant documents at the time of the audit in order to understand inspection system controls. Regardless of the program documentation issue, FSIS remains concerned that the June 2000 audit indicates that GOS is not exercising appropriate supervision of HACCP programs in establishments certified for export to the United States.

As you know, FSIS conducted another audit of Spain's meat inspection system from March 21-April 4, 2001. The FSIS auditor is currently preparing his draft audit report, and we will send it to you as soon as possible. If you have any questions concerning the information contained in this letter, please contact Mr. Steve McDermott, Equivalence Section, at telephone number (202) 720-6400, facsimile number (202) 720-7990, or email address ([steve.mcdermott@usda.gov](mailto:steve.mcdermott@usda.gov)).

Sincerely,



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Office of Policy, Program Development  
and Evaluation

Enclosure



## AUDIT REPORT FOR SPAIN JUNE 12 THROUGH JUNE 24, 2000

### INTRODUCTION

#### Background

This report reflects information that was obtained during an audit of Spain's meat inspection system from June 12 through June 24, 2000. All four establishments certified to export meat to the United States were audited. These establishments were conducting processing operations. Currently, Spain does not have any establishments that are certified to slaughter product for export to the United States.

In addition, the auditor reviewed Establishment 12 as a special request by the Government of Spain (GOS) and approved by FSIS' Office of Policy, Program Development and Evaluation (OPPDE). This establishment, Nestle Espana, S.A., expressed interest in retaining eligibility to export canned meat to the United States. A separate report concerning this review is available upon request.

The last audit of the Spanish meat inspection system was conducted in November 1997. Twelve establishments were audited. Of these, two establishments (11 and 15) were rated unacceptable and delisted at the time of the audit, and four others (10, 12, 18, and 26) were subsequently delisted. The remaining six establishments (13, 14, 16, 17, 19, and 20) were found acceptable. The serious deficiencies noted during the audit included: 1) failure to implement generic *Escherichia coli* (*E.coli*) testing program; 2) failure to implement and enforce adequate sanitation controls; 3) failure to implement a boneless meat reinspection program; 4) failure to provide adequate processing controls and records in canning establishments; and 5) failure to implement adequate GOS oversight of approved establishments.

The following were some of the specific concerns identified during the previous audit:

1. The daily pre-operational and operational sanitation monitoring record was not maintained by the inspection officials in Establishments 13, 14, and 16. *The new audit verified that this deficiency was corrected.*
2. Gaps at the bottom and sides of doors were not protected to prevent the entrance of rodents and other vermin in the processing and dry storage rooms. Dead flies and insects inside of light fixtures in the processing room and rodent droppings in the dry storage room observed in Establishment 14. *The new audit verified that this deficiency was corrected.*

3. Edible and inedible product containers were not identified in the boning room in Establishment 16. *The new audit verified that this deficiency was corrected.*
4. Either monthly supervisory reviews were not made or no written records of reviews were maintained in Establishments 13, 14, 16, and 20. *The new audit revealed that this deficiency had not been corrected. Please see comments under monthly reviews.*
5. Basic establishment facilities were not maintained as follows: overhead pipes and screens on air conditioning units were found with rust and dirt in the ham cut-up and salting rooms and flaking paint on walls and few panels were broken in the cooler in Establishment 13. All screens on air conditioning units were dirty in the processing room in Establishment 14. *The new audit verified that these deficiencies were corrected.*
6. Cross contamination: hams were contacting the dirty stand, platform and employee's boots in the curing room in Establishment 20. *The new audit verified that this deficiency was corrected.*
7. Laboratory's check samples program was inadequate. Residue samples were not analyzed within 14 days of collection in laboratory. *The new audit revealed that this deficiency had not been corrected. Please see laboratory audit.*

During this new audit, the auditor reviewed Establishments 13, 14, 16, and 20. Establishments 10, 11, 12, 15, 17, 18, 19, and 26 were not certified to export to the United States at this time.

Spain exports only cured pork products to the United States. Restrictions are placed on Spanish beef and fresh pork due to the presence of foot and mouth disease, Rinderpest, hog cholera and Scrapie. Spain is considered to have a substantial risk associated with BSE and swine vesicular disease. Spain is using raw pork slaughtered in U.S. approved establishments in Denmark and Netherlands. Poultry products are ineligible for export to the United States because FSIS does not recognize Spain's poultry inspection system as being equivalent. Spain is currently seeking eligibility to export poultry products to the United States.

During January 1 through April 30, 2000, Spanish establishments exported 84,019 pounds of cured pork to the U.S. There were no rejections at ports of entry.

## PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Spanish national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat inspection headquarters facilities preceding the on-site visits. The third was conducted by on-site visits to establishments. The fourth was a visit to one government laboratory *performing* analytical testing of field samples for the national residue testing program, and culturing field samples for the presence of microbiological contamination with *Listeria*.

Program effectiveness determinations focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems, and (5) enforcement controls, including the testing program for *Salmonella* species and *Listeria*. 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, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

## RESULTS AND DISCUSSION

### Summary

Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and *Listeria* are discussed later in this report.

As previously stated, five serious deficiencies were identified during the last audit of the Spanish meat inspection system, conducted in November 1997. The auditor has determined that these deficiencies had been adequately addressed and corrected by the establishments and GOS. Also, it was previously stated that two deficiencies noted during the November 1997 audit (monthly supervisory reviews and laboratory check sampling program) had not been corrected and still exist. In addition, during this new audit, implementation of the required HACCP programs was found to be deficient in all four establishments reviewed (13, 14, 16, and 20). Details are provided in the Slaughter/ Processing Controls section later in this report.

### Entrance Meeting

On June 14, an entrance meeting was held in the Madrid office of the Ministerio De Sanidad Y Consumo (MSC), and was attended by Dr. Oscar Gonzalez Gutierrez Solana, Subdirector General de Sanidad Exterior y Veterinaria; Dr. Jesus Martin Ruiz, Jefe de Area de Veterinaria de Salud Publica; Dr. Margritta Garzon Rigau, Jefe de Servicio Veterinaria Oficial; Dr. Julia Navarro Perales, Tecnica Superior; Dr. Arnaldo Cabello, Jefe de Area; Mr. Carlos Ucaz, Interpreter; Mr. Diego Pazos Moran, Senior Agricultural Specialist, American Embassy; and Dr. Faiz R. Choudry, International Audit Staff Officer, FSIS. Topics of discussion included the following:

1. Itinerary and lodging arrangements for the auditor were finalized.

2. The auditor shared with the MSC officials the updated data collection instruments for HACCP, *Salmonella* testing, and SSOPs.
3. The auditor provided the MSC officials with the latest FSIS Regulatory & Enforcement Report (from FSIS's Internet home page).

### Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of Spain's inspection system in November-December 1997.

Prior to the on-site audits of establishments, certain central documents were examined in the office of the meat/poultry inspection headquarters, including the results of the 1999 national residue testing program and the 2000 residue-testing plan

- Training records for inspectors and laboratory personnel.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Export product inspection and control including export certificates.
- Enforcement records including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

### Government Oversight

All inspection veterinarians and inspectors in establishments certified by Spain as eligible to export meat products to the United States were full-time either MSC or Autonomous Government Public-Health employees, receiving no remuneration from either industry or establishment personnel.

### Establishment Audits

Four establishments were certified to export meat products to the United States at the time this audit was conducted. All four Establishments (13, 14, 16, and 20) were visited for on-site audits.

## Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information about the following risk areas was also collected:

1. Government oversight of accredited, approved, and private laboratories.
2. Intra-laboratory quality assurance procedures, including sample handling.
3. Methodology.

The Instituto De Salud Carlos 111, Centro Nacional De Alimentacion Laboratory in Ctra. Majadahonda was audited on June 22, 2000. Except as noted below, effective controls were in place for 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 methods used for the analyses were acceptable.

Samples for chlorinated hydrocarbons, organophosphates, polychlorinated biphenyls, trace elements, hormones, chloramphenicol, sulfonamides, and ivermectin were collected every month and analyzed at the end of each quarter (between 2-3 months). Dr. Jose Juan Sanchez Saaz, subdirector, indicated that two-thirds of total samples were analyzed within 14 working days.

The check sample program did not meet FSIS requirements. Intra-laboratory check samples were performed quarterly for chlorinated hydrocarbons (CHC), organophosphates (OP), polychlorinated biphenyls (PCBs), trace elements (TE), hormones (H), chloramphenicol (CHLO), antibiotics (AB), sulfonamides (SULFA), ivermectin (IVER), Species, and *Listeria*, whereas FSIS require one check sample per month. Number of check samples performed during from January 1 through June 22, 2000, were as follows: CHC 8; OP 8; PCBs 8; TE 8; H 2; CHLO 2; AB 6; SULFAS 1; IVER 3; Species 7; and *Listeria* 2.

Laboratory Quality Assurance Program did not meet FSIS requirements. The record books were not signed and verified by the supervisor each time before the newly prepared solutions for trace elements, hormones, chloramphenicol, and ivermectin, were used by the technicians or chemists. According to Dr. Jose Juan Sanchez Saez, Subdirector General, the Centro Nacional de Alimentacion Laboratory (CNA), has been accredited by ENAC (quality-based system EN 45001) since July, 1999 and that, therefore, under the new Laboratory Quality Assurance Program, supervisors were not required to sign and verify record books. This alternative laboratory quality assurance program has not been submitted to FSIS for equivalence determination.

Spain's microbiological testing for *Listeria* was being performed in Centro Nacional de Alimentacion laboratory, which was audited. The auditor determined that the system met the criteria established for the use of private laboratories under FSIS's Pathogen Reduction/HACCP rule. These criteria are:

1. The laboratories were accredited/approved by the government, accredited by third party accrediting organization with oversight by the government, or a government contract laboratory.
2. The laboratories had properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities.
3. Results of analyses were being reported to the government or simultaneously to the government and establishment.

### Establishment Operations by Establishment Number

The following operations were being conducted in the four establishments:

Cured/dried pork products - four establishments (13, 14, 16, and 20)

### SANITATION CONTROLS

Based on the on-site audits of establishments, Spain's inspection system had controls in place for water potability records; chlorination procedures; back-siphonage prevention; hand washing facilities; sanitizers; separation of operations; pest control and monitoring; temperature control; lighting; work space; ventilation; maintenance and cleaning of over-product ceilings and equipment; dry storage areas; personal dress, habits, and hygiene; equipment sanitizing; and product handling and storage.

### Sanitation Standard Operating Procedures (SSOPs)

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 data collection instrument used accompanies this report (Attachment A).

### Cross-Contamination

Dripping condensate, from ceilings that were not cleaned/sanitized daily, was falling onto packaged product in the cooler in Establishment 14. Establishment officials were prompt in taking corrective actions and proposed preventive measures to GOS inspection officials. In addition, in Establishment 14, the ham cut-up room and the numerous plastic cutting boards that were in use were deeply scored. Establishment officials proposed corrective and preventive measures to Government of Spain (GOS) inspection officials.

## ANIMAL DISEASE CONTROLS

Spain's inspection system had controls in place to ensure adequate, condemned and restricted product control, and procedures for sanitary handling of returned and rework product. Spain does not have any approved slaughter establishment for export to the United States. All hams are imported from Denmark and the Netherlands.

Spain is considered to have a substantial risk associated with BSE and swine vesicular disease. No outbreaks of animal diseases with public-health significance have been reported since the November 1997 audit.

## RESIDUE CONTROLS

Spain's National Residue Testing Plan for 2000 was being followed and was on schedule. The Spanish inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

## SLAUGHTER/PROCESSING CONTROLS

The Spanish inspection system had controls in place to ensure adequate pre-boning trim, ingredients identification, control of restricted ingredients, formulations, packaging materials, processing schedules, processing equipment, and processing records.

Spain does not have any approved slaughter establishment for export to the United States.

## HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were audited and found to meet the basic FSIS regulatory requirements with the following exceptions:

1. The HACCP plan did not adequately specify critical limit, monitoring procedures and monitoring frequencies performed for each CCP in Establishments 13, 14, 16, and 20.
2. The HACCP plans did not state adequately the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequencies with which these procedures will be performed in all four establishments.
3. Corrective actions to be followed in response to a deviation from a critical limit not addressed adequately in the written HACCP plans in Establishments 13, 14, and 20.

4. Both establishment and inspection personnel had been unaware of the requirement for a final review of all documentation pertaining to the monitoring of critical limits for the product included in each shipment eligible for export to the U.S. The auditor explained the requirements for this pre-shipment review in detail and MSC ordered immediate implementation.

MSC inspection officials were not adequately verifying the establishments' HACCP plan for monitoring critical control points, corrective actions, and recordkeeping system and verification procedures. The auditor explained this requirement in detail and MSC agreed to comply with this requirement

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

All four of the establishments audited were not required to meet the basic FSIS regulatory requirements for generic *E. coli* testing because none of the establishments was a slaughter establishment. All hams intended for export to the U.S. were imported from Denmark and the Netherlands. Hog carcasses and/or hams received from domestic slaughter establishments were used for Spanish domestic consumption and/or exported to EU countries.

Additionally, establishments had adequate controls in place to prevent meat products intended for Spanish domestic consumption from being commingled with products eligible for export to the U.S.

#### Control of *Listeria monocytogenes*

In response to the auditor's inquiry regarding the Spanish establishment official's evaluation of their HACCP programs to address the risk of *Listeria monocytogenes*, the meat inspection officials provided this information. All four establishments reviewed did not conduct a hazard analysis for *Listeria monocytogenes* to determine the food safety hazards reasonably likely to occur in the production process for ready-to-eat products or none of the four establishments had scientific evidence to demonstrate that controls were not needed.

Official veterinarians were taking one sample per month from each establishment for *Listeria monocytogenes* testing on raw product only.

### ENFORCEMENT CONTROLS

#### Inspection System Controls

The MSC inspection system controls [control of restricted product and inspection samples, boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic

product, monitoring and verification of establishment programs and controls, inspection supervision and documentation, the importation of only eligible meat products from other countries (i.e., only from eligible countries and certified establishments within those countries) and the importation of only eligible meat and meat products from other countries for further processing] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

### Testing for *Salmonella* Species

None of the four establishments reviewed was required to meet the basic FSIS regulatory requirements for *Salmonella* testing, because none of the establishments was a slaughter facility. Establishments 13, 14, and 20 were producing dry-cured hams and Establishment 16 was producing dry-cured chorizos. *Salmonella* testing was being done on ready-to-eat products in Establishment 16. The data collection instrument used accompanies this report (Attachment D).

### Species Verification Testing

The auditor verified that species verification testing was being conducted in accordance with FSIS requirements. Spain submitted a March 1, 2000, letter to FSIS stating that, at the present time, Spain will not be requesting an exemption from Species Verification Testing.

### Monthly Reviews

The internal audits in Spain were being conducted in three parts as follows:

1. Administracion General, two audits per year by Drs. Margarita Garzon and Jesus Martin, staff officers, both of whom were veterinarians in the Ministerio de Sanidad y Consumo, under the direct supervision of the Subdirector General de Sanidad Exterior y Veterinaria, Dr. Oscar Gonzalez Gutierrez Solana. No specific method was used for selecting the review dates of the establishments, but the dates varied from year to year. The internal audit program was applied only to export establishments. The internal audits were conducted twice a year, and were announced to the inspection personnel about two weeks in advance. Copy of each internal audit report was kept in the headquarters of the Ministerio de Sanidad y Consumo in Madrid.
2. Autonomus Government Public Health, one audit per year by a Veterinarian during any time of the year. Copy of the audit report was kept in the Autonomus Government Public Health office and also in the establishment.
3. Provincial Government Delegation, six audits per year by a veterinarian. No specific method was used for selecting the review dates of the establishments, but the dates varied from each audit. One copy of each internal audit report was kept in the

Provincial headquarters and also in the establishments. They were being maintained on file for a minimum of 3 years.

The internal review program was applied only to export establishments. The internal audits were conducted mostly once in two months, and were announced to the inspection personnel, about two weeks in advance; the establishment officials were not informed in advance. The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the provincial office.

In the event that an establishment was found, during one of these internal reviews, to be out of compliance with U.S. requirements and is delisted for U.S. export, before it may again qualify for eligibility to be reinstated, an MSC meat inspection official from Madrid is empowered to conduct an in-depth review, and the results are reported to Dr. Oscar Gonzalez Gutierrez Solana, Subdirector General de Sanidad Exterior y Veterinaria, for evaluation; he formulates a plan for corrective actions and preventive measures.

### Enforcement Activities

Dr. Oscar Gonzalez Gutierrez Solana, Subdirector General, MSC, indicated that they had a decree # 1904 and 1993, to enforce noncompliance when they determine that an establishment had not met the regulatory requirements. Under this decree, MSC may temporarily withhold the marks of inspection from specific products, suspend inspection, or withdraw a grant of inspection if an establishment is not meeting crucial requirements.

### Exit Meetings

An exit meeting was conducted in Madrid on June 23. The participants were Dr. Oscar Gonzalez Gutierrez Solana, Subdirector General De Sanidad Exterior Y Veterinaria, MSC; Dr. Jesus Martin Ruiz, Jefe De Area De Veterinaria De Salud Publica ,MSC; Dr. Margaritta Garzon Rigau, Jefe De Servicio De Veterinaria Oficial, MSC; Dr. Julia Navarro Perales, Tecnica Superior, MSC; Dr. Antonio Garcia Jane, Jefe De Seccion De Higiene Alimentaria, Castilla-La Mancha; Dr. Juan Jose Martinez De Loza, La Rioja; Dr. Alicia Dimenez, Tecnica De Salud Publica, MSC; Dr. Ignacio Sanchez, Subdirector General De Sanidad Veterinaria , Ministerio De Agricultura, Pesca Y Alimentacion, (MAPA); Dr. Arnaldo Cabello, Jefe De Area, MAPA; Dr. Sonsoles Sanchez Trujillano, Jefe De Area, MAPA; Dr. Fernando Tovar, Director General, Instituto De Salud Carlos 111, Centro Nacional De Alimentacion(CNA); Dr. Jose Juan Sanchez, Subdirector General, CAN; Mr. Robert Wicks, Counselor for Agricultural Affairs, American Embassy; Mr. Diego Pazos Moran, Senior Agricultural Specialist, American Embassy; and Dr. Faiz R. Choudry, International Audit Staff Officer, FSIS.

The deficiencies identified were discussed in detail. The MSC inspection officials reinforced the assurances made by field personnel during and at the conclusions of the on-site audits of the establishments, and stated that they would ensure prompt compliance with the following items:

1. The HACCP plans did not specify critical limit, monitoring procedures and monitoring frequencies performed for each CCP adequately in Establishments 13, 14, 16, and 20.
2. The HACCP plans did not state adequately the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequencies with which these procedures will be performed in Establishments 13, 14, 16, and 20.
3. Corrective actions to be followed in response to a deviation from a critical limit not addressed adequately in the written HACCP plan in Establishments 13, 14, and 20.
4. Both establishment and inspection personnel had been unaware of the requirement for a final review of all documentation pertaining to the monitoring of critical limits for the product included in each shipment eligible for export to the U.S. The auditor explained the requirements for this pre-shipment review in detail; MSC ordered immediate implementation.
5. MSC inspection officials were not adequately verifying the establishments' HACCP plan for monitoring critical control points, corrective actions, and recordkeeping system and verification procedures. The auditor explained in detail; MSC indicated to comply with this requirement.

The following topics were also discussed at the exit meeting:

1. Samples for chlorinated hydrocarbons, organophosphates, polychlorinated biphenyls, trace elements, hormones, chloramphenicol, sulfonamides, and ivermectin were collected every month and analyzed at the end of each quarter (between 2-3 month). Dr. Jose Juan Sanchez Saez, Subdirector, indicated that two-third of total samples were analyzed within 14 days.
2. The frequency of intralaboratory check samples was quarterly for chlorinated hydrocarbons (CHC), organophosphates (OP), polychlorinated biphenyls (PCBs), trace elements (TE), hormones (H), chloramphenicol (CHLO), antibiotics (AB), sulfonamides (SULFA), ivermectin (IVER), Species, and listeria. FSIS requires one check sample per month. Number of check samples performed by June 22, 2000, as follows: CHC 8; OP 8; PCBs 8; TE 8; H 2; CHLO 2; AB 6; SULFAS 1; IVER 3; Species 7; and Listeria 2. Dr. Jose Juan Sanchez Saez, Subdirector General, indicated that no change would be made until they receive instructions in writing from FSIS, OPPDE, Washington, DC.
3. Laboratory Quality Assurance Program: The record books were not signed and verified by the supervisors each time before the newly prepared solutions for trace elements, hormones, chloramphenicol, and ivermectin were used by the technicians or chemists. According to Dr. Jose Juan Sanchez Saez, Subdirector General, the Centro Nacional de Alimentacion Laboratory (CNA), had been accredited by ENAC (quality-based system EN 45001) since July, 1999, and that, therefore, under the new Laboratory Quality Assurance Program, supervisors were not required to sign and verify record books.

## CONCLUSION

The inspection system of Spain was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments with the following exceptions. Four establishments were audited and all were acceptable. The deficiencies encountered during the on-site establishment reviews were adequately addressed to the auditor's satisfaction. The MSC inspection officials reinforced the assurances made by field personnel during and at the conclusions of the on-site audits of the establishments, and stated that they would ensure prompt compliance.

The major concerns were the following:

1. The HACCP plans did not adequately specify critical limit, monitoring procedures and monitoring frequencies performed for each CCP.
2. The HACCP plans did not state adequately the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequencies with which these procedures will be performed in all four establishments.
3. Corrective actions to be followed in response to a deviation from a critical limit not addressed adequately in the written HACCP plan in Establishments 13, 14, and 20.
4. Both establishment and inspection personnel had been unaware of the requirement for a final review of all documentation pertaining to the monitoring of critical limits for the product included in each shipment eligible for export to the U.S. The auditor explained the requirements for this pre-shipment review in detail and MSC ordered immediate implementation.
5. MSC inspection officials were not adequately verifying the establishments' HACCP plans for monitoring critical control points, corrective actions, and recordkeeping system and verification procedures. The auditor explained in detail and MSC indicated they would comply with this requirement.
6. Samples for chlorinated hydrocarbons, organophosphates, polychlorinated biphenyls, trace elements, hormones, chloramphenicol, sulfonamides, and ivermectin were collected every month and analyzed at the end of each quarter (between 2-3 month). Dr. Jose Juan Sanchez Saez, Subdirector, indicated that two-third of total samples were analyzed within 14 days.
7. The frequency of intralaboratory check samples was quarterly for chlorinated hydrocarbons (CHC), organophosphates (OP), polychlorinated biphenyls (PCBs), trace elements (TE), hormones (H), chloramphenicol (CHLO), antibiotics (AB), sulfonamides (SULFA), ivermectin (IVER), Species, and Listeria. FSIS requires one check sample per month. Number of check samples performed by June 22, 2000, as follows: CHC 8; OP 8; PCBs 8; TE 8; H 2; CHLO 2; AB 6; SULFAS 1; IVER 3; Species 7; and Listeria 2. Dr. Jose Juan Sanchez Saez, Subdirector General, indicated that no change would be made until they receive instructions in writing from FSIS, OPPDE, Washington, DC.

8. Laboratory Quality Assurance Program: The record books were not signed and verified by the supervisors each time before the newly prepared solutions for trace elements, hormones, chloramphenicol, and ivermectin were used by the technicians or chemists. According to Dr. Jose Juan Sanchez Saez, Subdirector General, the Centro Nacional de Alimentacion Laboratory (CNA), had been accredited by ENAC (quality-based system EN 45001) since July, 1999, and that, therefore, under the new Laboratory Quality Assurance Program, supervisors were not required to sign and verify record books.

Dr. Faizur R. Choudry  
International Audit Staff Officer

(signed) Dr. Faizur R. Choudry

## ATTACHMENTS

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs
- C. Data collection instrument for *E. coli* testing.
- D. Data collection instrument for *Salmonella* testing
- E. Laboratory audit form
- F. Individual Foreign Establishment Audit Forms
- G. Written Foreign Country's Response to the Draft Final Audit Report (when it becomes available)
- H. FSIS Response(s) to Foreign Country Comments (when it becomes available)
- I. Special review of Establishment 12.

Data Collection Instrument for SSOPs

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 data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1. Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible indiv. identified	7. Documentation done daily	8. Dated and signed
13	√	√	√	√	√	√	√	√
14	√	√	√	√	√	√	√	√
16	√	√	√	√	√	√	√	√
20	√	√	√	√	√	√	√	√

## Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
9. The HACCP plan was validated using multiple monitoring results.
10. *The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.*
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. All hazards identified	4. Use & users included	5. Plan for each hazard	6. CCPs for all hazards	7. Monitoring is specified	8. Corr. actions are described	9. Plan validated	10. Adequate verific. procedures	11. Adequate documentation	12. Dated and signed
13	√	√	√	√	√	√	√1	√2	√	√3	√	√
14	√	√	√	√	√	√	√1	√2	√	√3	√	√
16	√	√	√	√	√	√	√1	√	√	√3	√	√
20	√	√	√	√	√	√	√1	√2	√	√3	√	√

1. The HACCP plan did not specify critical limits, monitoring procedures and monitoring frequencies for each CCP adequately.
2. The HACCP plan did not state adequately the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequencies with which these procedures will be performed.
3. Corrective actions to be followed in response to a deviation from a critical limit not addressed adequately in the written HACCP plan.

Data Collection Instrument for Generic *E. coli* Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli*.
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1. Written procedure	2. Sampler designated	3. Sampling location given	4. Predominant species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
13	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
14	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
16	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
20	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

NOTE: Spain does not have any approved slaughter establishment for export to the United States.

Data Collection Instrument for *Salmonella* testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. *Salmonella* testing is being done in this establishment.
2. Carcasses are being sampled.
3. Ground product is being sampled.
4. The samples are being taken randomly.
5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is being used for sampling.
6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	1. Testing as required	2. Carcasses are sampled	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
13	N/A	N/A	N/A	N/A	N/A	N/A
14	N/A	N/A	N/A	N/A	N/A	N/A
16	N/A	N/A	N/A	N/A	N/A	N/A
20	N/A	N/A	N/A	N/A	N/A	N/A

NOTE: Establishments 13, 14, and 20 are producing dry-cured ham products only.

Establishment 16 is producing dry-cured chorizos and initiated *Salmonella* testing for ready to eat products only (5 samples out of 425 kilos products).

U.S. DEPARTMENT OF AGRICULTURE  
 FOOD SAFETY AND INSPECTION SERVICE  
 INTERNATIONAL PROGRAMS

REVIEW DATE  
 6/22/2000

NAME OF FOREIGN LABORATORY  
 Instituto de Salud Carlos III  
 Centro Nacional de Alimentacion

**FOREIGN COUNTRY LABORATORY REVIEW**

FOREIGN GOV'T AGENCY  
 Ministerio de Sanidad y Consumo

CITY & COUNTRY  
 Majadahonda, Madrid-SPAIN

ADDRESS OF LABORATORY  
 Ctra. Majadahonda a Pozuelo, km 2  
 28220 Majadahonda, Madrid-SPAIN

NAME OF REVIEWER  
 Faiz R. Choudry, DVM

NAME OF FOREIGN OFFICIAL  
 Fernando T. Hernandez, Director; Dr. Jose J. S. Saaz, Subdirector & Dr. Margaritta Garzon

Residue Code/Name

		100	111	300	400	500	200	203	800	923	List.	S/V		
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE											
	Sample Handling	01	A	A	A	A	A	A	A	A	A	A	A	
	Sampling Frequency	02	A	A	A	A	A	A	A	A	A	A	A	
	Timely Analyses	03	C	C	C	C	C	A	C	C	C	A	A	
	Compositing Procedure	04	O	O	O	O	O	O	O	O	O	O	O	
	Interpret Comp Data	05	O	O	O	O	O	O	O	O	O	O	O	
	Data Reporting	06	A	A	A	A	A	A	A	A	A	A	A	
ANALYTICAL PROCEDURES	Acceptable Method	07	A	A	A	A	A	A	A	A	A	A	A	
	Correct Tissue(s)	08	A	A	A	A	A	A	A	A	A	A	A	
	Equipment Operation	09	A	A	A	C	C	A	C	A	C	A	A	
	Instrument Printouts	10	A	A	A	A	A	O	O	O	A	O	O	
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	A	A	A	A	A	O	O	O	A	O	O	
	Recovery Frequency	12	A	A	A	A	A	O	O	O	A	O	O	
	Percent Recovery	13	A	A	A	A	A	O	O	O	A	O	O	
	Check Sample Frequency	14	A	A	A	A	A	A	A	A	A	A	A	
	All analyst w/Check Samples	15	C	C	C	C	C	C	C	C	C	C	C	
	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 PROCEDURES	Corrected Prior Deficiencies	18	C	C	C	C	C	C	C	C	A	C	C	
OTHER REVIEW		19												
		20												

SIGNATURE OF REVIEWER

DATE

<b>FOREIGN COUNTRY LABORATORY REVIEW</b> <i>(Comment Sheet)</i>		<b>REVIEW DATE</b> 6/22/2000	<b>NAME OF FOREIGN LABORATORY</b> Instituto de Salud Carlos III Centro Nacional de Alimentacion
<b>FOREIGN GOV'T AGENCY</b> Ministerio de Sanidad y Consumo		<b>CITY &amp; COUNTRY</b> Majadahonda, Madrid-SPAIN	<b>ADDRESS OF LABORATORY</b> Ctra. Majadahonda a Pozuelo, km 2 28220 Majadahonda, Madrid-SPAIN
<b>NAME OF REVIEWER</b> Faiz R. Choudry, DVM		<b>NAME OF FOREIGN OFFICIAL</b> Fernando T. Hernandez, Director; Dr. Jose J. S. Saaz, Subdirector & Dr. Margaritta Garzo	

RESIDUE	ITEM	COMMENTS
100,111, 300,400, 500,203, 800,923	3	Dr. Jose Juan Sanchez Saaz, Subdirector, indicated that two-third of total samples were analyzed within 14 working days for chlorinated hydrocarbons (CHC), polychlorinated biphenyls (PCBs), organophosphates (OP), trace elements (TE), hormones (H), chloramphenicol (CAP), sulfonamides (SULFA), and ivermectin (IVR). Samples were collected every month and analyzed at the end of each quarter.
400,500, 203, 923	9	Laboratory Quality Assurance Program: The record books were not signed and verified by the supervisors each time before the newly prepared solutions for trace elements, hormones, chloramphenicol, and ivermectin, were used by the technicians or chemists.
100,111, 300,400, 500,203, 200,800, 923, Listeria, Species Verifica- tion	14	The frequency of intralaboratory check samples was quarterly for each residue compound analyzed in this laboratory . FSIS requires one check sample per month.  During last FSIS audit in December 9, 1997, same deficiencies were reported but no corrections had been made for item 3, and 14. Dr. Jose Juan Sanchez Saaz, indicated that they did not receive any communication from FSIS since the last audit to make any changes.
100,111, 300,400, 500,203, 200,800, Listeria, Species Verifica- tion	3,14	

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS  <b>FOREIGN PLANT REVIEW FORM</b>	REVIEW DATE 6/16/2000	ESTABLISHMENT NO. AND NAME Est. 13 Navidul, S. A.	CITY Olias del Rey  COUNTRY SPAIN
NAME OF REVIEWER Faiz R. Choudry, DVM	NAME OF FOREIGN OFFICIAL Dr. Margaritta Garzon, & Dr. Javier Ariza		EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable

CODES (Give an appropriate code for each review item listed below)  
 A = Acceptable    M = Marginally Acceptable    U = Unacceptable    N = Not Reviewed    O = Does not apply

<b>1. CONTAMINATION CONTROL</b>	Cross contamination prevention	28 A	Formulations	55 A
<b>(a) BASIC ESTABLISHMENT FACILITIES</b>	Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	<b>(d) ESTABLISHMENT SANITATION PROGRAM</b>		Inspector monitoring	60 A
Sanitizers	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	Preoperational sanitation	34 A	Processing equipment	62 A
Pest --no evidence	Operational sanitation	35 A	Processing records	63 A
Pest control program	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	<b>2. DISEASE CONTROL</b>		Filling procedures	65 O
Temperature control	Animal identification	37 O	Container closure exam	66 O
Lighting	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	Condemned product control	43 O	<b>5. COMPLIANCE/ECON. FRAUD CONTROL</b>	
<b>(b) CONDITION OF FACILITIES EQUIPMENT</b>	Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	<b>3. RESIDUE CONTROL</b>		Export certificates	74 A
Product contact equipment	Residue program compliance	46 O	Single standard	75 A
Other product areas (inside)	Sampling procedures	47 O	Inspection supervision	76 M
Dry storage areas	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	<b>4. PROCESSED PRODUCT CONTROL</b>		"Equal to" status	80 A
<b>(c) PRODUCT PROTECTION &amp; HANDLING</b>	Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	Boneless meat reinspection	52 O		
Personal hygiene practices	Ingredients identification	53 A		
Sanitary dressing procedures	Control of restricted ingredients	54 A		

**FOREIGN PLANT REVIEW FORM**  
(reverse)

6/16/2000

Est. 13  
Navidul S. A.

CITY  
Olias del Rey  
COUNTRY  
SPAIN

NAME OF REVIEWER  
Faiz R. Choudry, DVM

NAME OF FOREIGN OFFICIAL  
Dr. Margaritta Garzon, & Dr. Javier Ariza

EVALUATION  
 Acceptable  Acceptable/  
Re-review  Unacceptat

COMMENTS:

76. Six bi-monthly audits were being conducted by the regional meat inspection officials.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS  <b>FOREIGN PLANT REVIEW FORM</b>	REVIEW DATE 6/21/2000	ESTABLISHMENT NO. AND NAME Est. 14 Navidul, S. A.	CITY Torrijos  COUNTRY SPAIN
NAME OF REVIEWER Faiz R. Choudry, DVM	NAME OF FOREIGN OFFICIAL Dr. Margaritta Garzon, & Dr. Javier Ariza		EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable

CODES (Give an appropriate code for each review item listed below)  
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<b>1. CONTAMINATION CONTROL</b>	Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES	Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	60 A
Sanitizers	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	Preoperational sanitation	34 A	Processing equipment	62 A
Pest --no evidence	Operational sanitation	35 A	Processing records	63 A
Pest control program	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	2. DISEASE CONTROL		Filling procedures	65 O
Temperature control	Animal identification	37 O	Container closure exam	66 O
Lighting	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	Condemned product control	43 O	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT	Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	3. RESIDUE CONTROL		Export certificates	74 A
Product contact equipment	Residue program compliance	46 O	Single standard	75 A
Other product areas (inside)	Sampling procedures	47 O	Inspection supervision	76 M
Dry storage areas	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING	Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	Boneless meat reinspection	52 O		
Personal hygiene practices	Ingredients identification	53 A		
Sanitary dressing procedures	Control of restricted ingredients	54 A		

<b>FOREIGN PLANT REVIEW FORM</b> (reverse)	6/21/2000	ESTABLISHMENT NO. AND NAME Est. 14 Navidul S. A.	CITY Torrijos <hr/> COUNTRY SPAIN
NAME OF REVIEWER Faiz R. Choudry, DVM	NAME OF FOREIGN OFFICIAL Dr. Margaritta Garzon, & Dr. Javier Ariza		EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptat

COMMENTS:

- 17. Dripping condensate, from ceilings that were not cleaned/sanitized daily, was falling onto packaged products in the cooler.
  
- 19. Numerous plastic cutting boards that were in use, were deeply scored in the ham cut-up room.
  
- 76. Six bi-monthly audits were being conducted by the regional meat inspection officials.

FOREIGN PLANT REVIEW FORM

REVIEW DATE

6/19/2000

ESTABLISHMENT NO. AND NAME

Est. 20  
Redondo Iglesias, S. A.

CITY  
Utiel

COUNTRY  
SPAIN

NAME OF REVIEWER  
Faiz R. Choudry, DVM

NAME OF FOREIGN OFFICIAL  
Dr. Margaritta Garzon, & Dr. Inmawlada

EVALUATION  
 Acceptable   
  Acceptable/ Re-review   
  Unacceptable

CODES (Give an appropriate code for each review item listed below)

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1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	2. DISEASE CONTROL		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 O	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 A	Inspector verification	73 A
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Product contact equipment	19 A	Residue program compliance	46 O	Single standard	75 A
Other product areas (inside)	20 A	Sampling procedures	47 O	Inspection supervision	76 M
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O		
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

**FOREIGN PLANT REVIEW FORM**  
(reverse)

6/19/2000

ESTABLISHMENT NO. AND NAME  
Est. 20  
Redondo Iglesias, S. A.

CITY  
Utiel

COUNTRY  
SPAIN

NAME OF REVIEWER  
Faiz R. Choudry, DVM

NAME OF FOREIGN OFFICIAL  
Dr. Margaritta Garzon, & Dr. Inmawlada

EVALUATION  
 Acceptable  Acceptable/  
Re-review  Unacceptab

COMMENTS:

76. Six bi-monthly audits were being conducted by the regional meat inspection officials.

FOREIGN PLANT REVIEW FORM

REVIEW DATE

6/15/2000

ESTABLISHMENT NO. AND NAME

Est. 16  
Embutidos Palacios, S. A.

CITY  
Albelda de Iregua

COUNTRY  
SPAIN

NAME OF REVIEWER  
Faiz R. Choudry, DVM

NAME OF FOREIGN OFFICIAL  
Dr. Margaritta Garzon, & Dr. Juan Jose Martinez

EVALUATION  
 Acceptable  Acceptable/  
Re-review  Unacceptable

CODES (Give an appropriate code for each review item listed below)

A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	2. DISEASE CONTROL		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 O	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	3. RESIDUE CONTROL		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 O	Single standard	75 A
Other product areas (inside)	20 A	Sampling procedures	47 O	Inspection supervision	76 M
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 A		
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

<b>FOREIGN PLANT REVIEW FORM</b> (reverse)	6/15/2000	ESTABLISHMENT NO. AND NAME Est. 16 Embutidos Placios, S. A.	CITY Albelda de Iregua COUNTRY SPAIN
NAME OF REVIEWER Faiz R. Choudry, DVM	NAME OF FOREIGN OFFICIAL Dr. Margaritta Garzon, & Dr. Juan Jose Martinez		EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unaccept:

COMMENTS:

76. Six bi-monthly audits were being conducted by the regional meat inspection officials.



*Embassy of the United States of America  
Office of Agricultural Affairs  
Madrid, Spain*

**FAX MEMORANDUM**

**Date:** March 26, 2001

**To:** Mark Manis/Director  
FSIS, Office of Policy, Program Development and Evaluation International Policy  
Development Division/Fax: (202) 720 7990

**From:** Leslie O'Connor/Agricultural Counselor, Madrid/Fax: 91-564 96 44

**Subject:** Comments on the U.S. on Foreign Plants Certified to Export Meat to the United States

Dear Mr. Manis:

Enclosed please find a letter from Ms. Maria Dolores Flores Cerdan, Director General in the Spanish Ministry of Health and a letter from Dr. J.J. Sanchez Saez, Head of Analytical Spanish Residues Program. The letters provide comments on "the on-site Audit of Spain's Meat Inspection System" carried out by Dr. Faizur Choudry, FSIS Inspector, during June 12-24, 2000 and on the Quality Assurance System in force in the Spanish Lab on charge of Residue Plan. The documents and the letter were forwarded to our office on March 20, 2001.

We have provide Dr. Faizur Choudry, FSIS Inspector with copies of the letters.

We will send the original documents by APO mail. In the meantime, please contact us if we can provide you with any further assistance.

Sincerely,



MINISTERIO  
DE SANIDAD  
Y CONSUMO

DIRECCION GENERAL  
DE SALUD PÚBLICA  
Y CONSUMO

María Dolores  
Flores Cerdán

DIRECTORA GENERAL

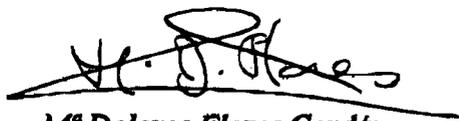
*Madrid, 15 de marzo de*

*Sra. D<sup>a</sup> Lesile O'CONNOR  
Consejera de Agricultura  
Embajada de EE. UU. en España  
Madrid*

*Estimada Sra.:*

*Adjunto, para su conocimiento y traslado al Sr. Mark Manis,  
escrito del Vicedirector del C.N.A., sobre las observaciones realizadas por el  
inspector del F.S.I.S. en la última visita de auditoria realizada en España, así  
como la aceptación del sistema de calidad EN45001.*

*Un cordial saludo,*

  
*M<sup>a</sup> Dolores Flores Cerdán*



Ministerio de Sanidad y Consumo

Instituto  
de Salud  
Carlos III

Centro Nacional  
de Alimentación

Mr. Mark Manis  
Director FSIS; Office of Policy,  
Program Development and Evaluation International Policy  
Development Division

Majadahonda, February 26, 2001

Dear Mr. Manis,

In the report concerning the last "on-site Audit of Spain's Meat Inspection System" carried out by Dr. Faizur Choudry, two topics were recorded that have not yet been clarified after the Spanish allegations were forwarded to you.

The first point is the maximum period that the characteristics of certain analytes are maintained when stored frozen until their analysis is carried out.

The second one refers to the Quality Assurance System applied in our Center.

We will be very grateful if you could send us your technical opinion before the next scheduled Audit of our Laboratory by Dr. Choudry to avoid the repetition of the controversies of the last time.

In relation to the maximum accepted period of deep frozen storage for certain analytes, we have adopted the system of accumulating the samples of a quarter because it is the less expensive way to perform the Residue Monitoring Program, except for *Listeria monocytogenes* testing and Antibiotics testing (Inhibition Biotest). This approach was accepted in a former Audit some years ago.

The second topic, namely our Quality Assurance System, is related to the European Union Rule that establishes the requirement of a Quality Assurance System based on EN 45001 for all Official Food Control Laboratories.

Until May 2000, we applied two systems simultaneously:

- a copy of your system close to GLP
- and
- the European Legislation EN 45001 system.

Ctra. Majadahonda a Pozuelo, Teléfono 91 5097912  
km 2.  
28220, Majadahonda- Madrid Fax 91 5097913  
ESPAÑA web: www.isciii.es



Ministerio de Sanidad y Consumo

Instituto  
de Salud  
Carlos III

Centro Nacional  
de Alimentación

This situation is very painful and expensive, starting with the efforts spent for the unequivocal identification of the samples coming from the Specific Monitoring Program of Residues for Export to USA, required to apply the correct system. According to the opinion of your inspector this is inadequate because the samples are not handled in the usual way of the ordinary samples.

On the other hand, our Lab is accredited by the Spanish National Accreditation Body ENAC (an external organization, independent of the Spanish Government Administration). This means that our analytical results are recognized by any European Official Lab as the EU Legislation establishes. The Accreditation by ENAC is based on an Audit of the Quality System as well as the technical proficiency of the analysts.

Our Quality System obliges to an Evaluation of the Quality of the Analytical Results different to the one proposed in your System, mainly in relation to the number of samples that the supervisor should introduce in the system for controlling the analysts.

In 1999 the Spanish Health Ministry sent an exhaustive dossier to the FSIS with global information on our Quality Assurance System and the Accreditation by ENAC.

In summary, we would like to receive your technical opinion so as to know the official viewpoint of the FSIS concerning the before-mentioned topics, since we consider there are enough scientific bases in our Quality Assurance System to guarantee the reliability of our analytical results.

Yours sincerely

Dr. J.J. Sánchez Sáez  
Vicedirector CNA.  
Head of Analytical Spanish Residues Program