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

3/15/04

MAR 8 2004

Dr. Pedro Ángel García González
Chief of the Spanish Inspection Service
Subdirection General de Sanidad
Exterior y Veterinaria
Ministerio de Sanidad
Paseo del Prado, 18
28014 Madrid
Spain

Dear Dr. Ángel García:

Enclosed is the final report of the Food Safety and Inspection Service (FSIS) on-site audit of Spain's meat inspection system. This audit was conducted May 21 through June 5, 2003. Comments received from the government of Spain have been included as an attachment to the final report.

We have reviewed the comments and made the appropriate changes to the final report. For clarification, FSIS does not authorize foreign laboratories to conduct analyses on meat products for export to the United States. Once FSIS has determined that a country has an equivalent meat inspection system, we rely on the foreign government to sanction laboratories as meeting the FSIS requirements.

In regard to your comment that the relevant EU legislation is Directive 77/99/ECC instead of Directive 64/433/EEC, under the EU/US Veterinary Equivalence Agreement, only three EU directives, i.e., 64/433/ECC, 96/22/EC, and 96/23/EC, have been determined equivalent by FSIS. Accordingly, we will continue to reference these three EU directives as the legal basis under which FSIS audits the meat inspection systems of EU countries.

If you have any questions regarding the enclosed report or the FSIS audit, please contact me at telephone number (202) 720-3781 or facsimile number (202) 690-4040. You may also reach me by email at sally.stratmoen@fsis.usda.gov.

Sincerely,

Sally Stratmoen JD

Sally Stratmoen, Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc: Samuel J. Juárez, Agricultural Counselor, Embassy of Spain, Washington, DC
Lloyd Fleck, Minister Counselor, American Embassy, Madrid
Agriculture, Fisheries, Food Safety and Consumer Affairs Section, EU Mission to the US, Washington, DC
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Country File-Spain (FY03 Audit)

# FINAL



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

May 21 through June 5, 2003

Food Safety and Inspection Service
United States Department of Agriculture

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14. CLOSING MEETING

15. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

| | |
|---|---|
| CCA | Central Competent Authority - Ministerio de Sanidad y Consumo-MSC (Ministry of Public Health) and Ministerio de Agricultura, Pesca y Alimentacion-MAPA (Ministry of Agriculture). |
| *E. coli* | *Escherichia coli* |
| FSIS | Food Safety and Inspection Service |
| PR/HACCP | Pathogen Reduction/Hazard Analysis and Critical Control Point Systems |
| SSOP | Sanitation Standard Operating Procedures |
| *Salmonella* | *Salmonella* species |
| VEA | European Community/United States Veterinary Equivalence Agreement |

## 1. INTRODUCTION

The audit took place in Spain from May 21 through June 5, 2003.

An opening meeting was held on May 21 in Madrid with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit, the auditor's itinerary, and requested additional information needed to complete the audit of Spain's meat inspection system.

The auditor was accompanied during the entire audit by representatives from the CCA, the MSC and MAPA, and representatives from the local inspection offices.

## 2. OBJECTIVE OF THE AUDIT

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

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, one autonomous district inspection office, one residue and one microbiology government laboratory performing analytical testing on United States-destined product, and four meat processing establishments.

| Competent Authority Visits | | | Comments |
|---|---|---|---|
| Competent Authority | Central | 1 | |
| | Autonomous Province | 1 | |
| | Local | 4 | Establishment level |
| Laboratories | | 2 | |
| Meat Slaughter Establishments | | 0 | |
| Meat Processing Establishments | | 4 | |
| Cold Storage Facilities | | 0 | |

## 3. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved on-site visits to four processing establishments. The third part involved visits to two government laboratories: the Centro Nacional de Alimentacion (National Food Center) in Majadahonda (Agencia Espanola de Seguridad Alimentaria – AESA, (also a reference laboratory) and Red de Laboratorios de Salud Publica (Public Health Laboratory Network) in Valencia. The National Food Center was conducting

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

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

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

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

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

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

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

## 4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).

- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.

In addition, compliance with the following European Community Directives was also assessed:

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

## 5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address: http://www.fsis.usda.gov/OPPDE/FAR/index/htm.

The last two audits of Spain's inspection system have shown some problems. During the audit of March/April 2001, the following deficiencies were identified:

- The HACCP plans in all four establishments had not adequately stated the procedures that the establishments would use to verify that the plans were being effectively implemented and the frequencies with which these procedures would be performed.

- Spain inspection officials in three establishments had not been adequately verifying the establishments' monitoring of critical control points and plant verification procedures.

- Inadequate pre-operational sanitation had been found in two establishments.

- Cross contamination and insanitary handling of product had been observed in two establishments.

- Containers for edible and inedible product had not been identified in three establishments.

- Condemned product was not being denatured in three establishments.

All deficiencies noted during the March/April 2001 audit had been addressed and corrected.

During the audit of December 2001, the following deficiencies were identified:

- No presence of hand washing facilities where exposed product was handled was observed in two establishments.

- Personnel hygiene deficiencies of workers were observed in one establishment.

- Unmarked chemicals found in production areas of two establishments.

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

## 6. MAIN FINDINGS

### 6.1 Legislation

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

### 6.2 Government Oversight

The CCA Ministerio de Sanidad y Consumo, Spanish Food Safety Agency (AESA) and Ministerio de Agricultura, Pesca y Alimentacion, have the organizational structure and staffing to ensure uniform implementation of U.S. requirements.

#### 6.2.1 CCA Control Systems

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

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

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

#### 6.2.2 Ultimate Control and Supervision

Control and supervision of inspectors in certified establishments was demonstrated at Autonomous Regional and Local levels.

#### 6.2.3 Assignment of Competent, Qualified Inspectors

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

#### 6.2.4 Authority and Responsibility to Enforce the Laws

The CCA, Spanish Food Safety Agency was created by the Law 11/2001 and is assigned to the Ministry of Health and Consumer Affairs. AESA main objectives are the following:

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

Its functions include:

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

6.2.5 Adequate Administrative and Technical Support

The CCA, through the Local and Autonomous Regional Offices, has the ability to support a third-party audit.

6.3 Headquarters Audit

The auditor conducted a review of inspection system documents at the Headquarters, Autonomous Regional and Local offices, and in the inspection offices at the audited establishments. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors and laboratory personnel.
- Label approval records such as generic labels, and animal raising claims.
- Sampling and laboratory analyses for residues.
- Sanitation, and processing inspection procedures and standards.
- Export product inspection and control including export certificates.

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

## 7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of four processing establishments. None of the four establishments were delisted by Spain. None of the four establishments received a notice of intent to delist (NOID).

## 8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

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

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

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

The following government laboratories were audited:

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

The findings in these laboratories will be discussed in Section 11.3 (Testing for Generic *E. coli*), Section 12 (RESIDUE CONTROLS), or Section 13.2 (Testing for *Salmonella* species) of this report.

## 9. SANITATION CONTROLS

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

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

In addition, and except as noted below, Spain inspection system had controls in place for light, ventilation, plumbing and sewage, water supply, dressing rooms/lavatories,

equipment and utensils, sanitary operations, employee hygiene, and condemned product control.

- In one establishment, rusty ceiling protectors were observed in the slicing room.
- In one establishment, toxic product was used for rodent control inside of the establishment.
- In one establishment, insectocutors were observed over the product area in the deboning room.
- In one establishment, plastic boxes used for edible and inedible product were used indiscriminately for both.

9.1 SSOP

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

- In one establishment, one ham was observed contacting the floor in the drying room.

9.2 EC Directive 64/433

In one establishment, the provisions of EC Directive 64/433 were effectively implemented. Deficiencies were identified in three establishments. The specific deficiencies are noted in the attached individual establishment reports.

10. ANIMAL DISEASE CONTROLS

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

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

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviews is Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures, ante-mortem disposition, humane handling and humane slaughter, post-mortem

inspection procedures, post-mortem disposition, ingredients identification, control of restricted ingredients, formulations, processing schedules, equipment and records, and processing controls of cured, dried, and cooked products.

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

11.1 Humane Handling and Humane Slaughter

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

11.2 HACCP Implementation

All establishments approved to export meat products to the United States are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program.

The HACCP programs were reviewed during the on-site audits of the four establishments. All four establishments had adequately implemented the PR/HACCP requirements.

11.3 Testing for Generic *E. coli*

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

11.4 Testing for *Listeria monocytogenes*

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

11.5 EC Directive 64/433

In one of the four establishments, the provisions of EC Directive 64/433 were effectively implemented and deficiencies in the following categories were noted in three establishments:

- Establishment grounds and pest control
- Establishment construction/maintenance
- Condemned product control.

## 12. RESIDUE CONTROLS

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

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

- DES recovery was on the level of 8% and 19%. The lab informed auditor that this method is in the validation period.
- Urine was used as a tissue for analysis of DES.

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

### 12.1 EC Directive 96/22

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

### 12.2 EC Directive 96/23

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

### 12.3 FSIS Requirements

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

## 13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviews is 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 processing establishments.

13.2 Testing for *Salmonella* Species

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

13.3 Species Verification

At the time of this audit, Spain was required to test product for species verification. Species verification was being conducted in those establishments in which it was required.

13.4 Monthly Reviews

During this audit it was found that in all establishments visited, monthly supervisory reviews of certified establishments were being performed and documented as required.

13.5 Inspection System Controls

The CCA had controls in place for prevention of commingling of product intended for export to the U.S. with product intended for the domestic market.

In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other counties for further processing.

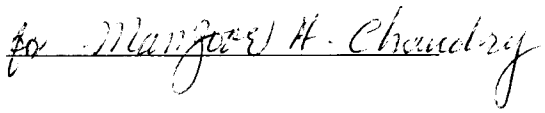
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on June 5 in Madrid with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Dr. Oto Urban
International Audit Staff Officer



## 15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms
Individual Foreign Laboratory Audit Forms
Foreign Country Response to Draft Final Audit Report (when it becomes available)

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

# FOREIGN COUNTRY LABORATORY REVIEW

| REVIEW DATE | NAME OF FOREIGN LABORATORY |
|---|---|
| 5/23/03 | The Centro Nacional de Alimentacion laboratory |

| FOREIGN GOV'T AGENCY | CITY & COUNTRY | ADDRESS OF LABORATORY |
|---|---|---|
| Agencia Espanola de Seguridad Alimentaria | Majadahonda, Spain | Majadahonda (Madrid) |

| NAME OF REVIEWER | NAME OF FOREIGN OFFICIAL |
|---|---|
| Dr. Oto Urban | Dr. Luis Familiar Martin |

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

SIGNATURE OF REVIEWER: Donald C Mott (for Oto Urban) DATE: 7/17/03

FSIS FORM 9530-4 (6/96) Designed on FormFlow Software

| FOREIGN COUNTRY LABORATORY REVIEW *(Comment Sheet)* | REVIEW DATE | NAME OF FOREIGN LABORATORY |
|---|---|---|
| | 5/23/03 | The Centro Nacional de Alimentacion laboratory |

| FOREIGN GOV'T AGENCY | CITY & COUNTRY | ADDRESS OF LABORATORY |
|---|---|---|
| Agencia Espanola de Seguridad Alimentaria | Majadahonda, Spain | Majadahonda (Madrid) |

| NAME OF REVIEWER | NAME OF FOREIGN OFFICIAL |
|---|---|
| Dr. Oto Urban | Dr. Luis Familiar Martin |

| RESIDUE | ITEM NO. | COMMENTS |
|---|---|---|
| | | * Method used for detection of Listeria monocytogenes: PNT/CNA/BA-1-6 |
| | | * Method used for species verification: PNT/CNA/1B-1-4 |

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

**FOREIGN COUNTRY LABORATORY REVIEW**

| REVIEW DATE | NAME OF FOREIGN LABORATORY |
|---|---|
| 5/30/03 | Laboratorio De Salud Publica De Valencia |

| FOREIGN GOV'T AGENCY | CITY & COUNTRY | ADDRESS OF LABORATORY |
|---|---|---|
| Regional Health Counsil of Valencia | Albal, Spain | Cami De La Marjal, S/N |

| NAME OF REVIEWER | NAME OF FOREIGN OFFICIAL |
|---|---|
| Dr. Oto Urban | Dr. Pedro Marti Requena |

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

SIGNATURE OF REVIEWER: (for Oto Urban)

DATE: 7/17/03

**FOREIGN COUNTRY LABORATORY REVIEW**

*(Comment Sheet)*

| REVIEW DATE | NAME OF FOREIGN LABORATORY |
|---|---|
| 5/30/03 | Laboratorio De Salud Publica De Valencia |

| FOREIGN GOV'T AGENCY | CITY & COUNTRY | ADDRESS OF LABORATORY |
|---|---|---|
| Regional Health Counsil of Valencia | Albal, Spain | Cami De La Marjal, S/N |

| NAME OF REVIEWER | NAME OF FOREIGN OFFICIAL |
|---|---|
| Dr. Oto Urban | Dr. Pedro Marti Requena |

| RESIDUE | ITEM NO. | COMMENTS |
|---|---|---|
| 500 | 13 | DES recovery was found to be 8% and 19%. Laboratory officials explained that this method is in the validation period. |
| 500 | 8 | Urine was used as the matrix for detection of DES. |

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 |
|---|---|---|---|
| Navidul Toledo, Olias del Rey | 05 - 26 - 03 | 13 | Spain |
| | 5. NAME OF AUDITOR(S) | | 6. TYPE OF AUDIT |
| | Dr. Oto Urban | | [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT |

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

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

| Part D - Continued Economic Sampling | Audit Results |
|---|---|
| 33. Scheduled Sample | |
| 34. Species Testing | |
| 35. Residue | |
| **Part E - Other Requirements** | |
| 36. Export | |
| 37. Import | |
| 38. Establishment Grounds and Pest Control | |
| 39. Establishment Construction/Maintenance | |
| 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 | |
| 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

Spain Est. 13 05-26-03

61. NAME OF AUDITOR
Dr. Oto Urban for

62. AUDITOR SIGNATURE AND DATE
Donald C Smart 7/17/03

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 |
|---|---|---|---|
| Navidul S.A.<br>Torrijos | 05 - 27 - 03 | 14 | Spain |
| | 5. NAME OF AUDITOR(S) | | 6. TYPE OF AUDIT |
| | Dr. Oto Urban | | [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. | X |
| 11. Maintenance and evaluation of the effectiveness of SSOP's. | |
| 12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration. | |
| 13. Daily records document item 10, 11 and 12 above. | |
| **Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements** | |
| 14. Developed and implemented a written HACCP plan . | |
| 15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions. | |
| 16. Records documenting implementation and monitoring of the HACCP plan. | |
| 17. The HACCP plan is signed and dated by the responsible establishment individual. | |
| **Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements** | |
| 18. Monitoring of HACCP plan. | |
| 19. Verification and validation of HACCP plan. | |
| 20. Corrective action written in HACCP plan. | |
| 21. Reassessed adequacy of the HACCP plan. | |
| 22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. | |
| **Part C - Economic / Wholesomeness** | |
| 23. Labeling - Product Standards | |
| 24. Labeling - Net Weights | |
| 25. General Labeling | |
| 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture) | |
| **Part D - Sampling Generic *E. coli* Testing** | |
| 27. Written Procedures | |
| 28. Sample Collection/Analysis | |
| 29. Records | |
| **Salmonella Performance Standards - Basic Requirements** | |
| 30. Corrective Actions | |
| 31. Reassessment | |
| 32. Written Assurance | |

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

60. Observation of the Establishment

Spain Est. 14 05-27-03

10 Product (ham) was observed to contact the floor in the drying room. This was corrected immediately by the establishment management.

39 Rusty ceiling protectors were observed in the slicing room. This was scheduled for correction by the establishment officials.

56 European Community Directives 64/433

61. NAME OF AUDITOR
Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE
7/17/03

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 Palacios S.A.<br>Alberda de Iregua<br>Ctra. Logrono s.n. - 2620 | 05 - 22 - 03 | 16 | Spain |
| | 5. NAME OF AUDITOR(S) | 6. TYPE OF AUDIT | |
| | Dr. Oto Urban | [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT | |

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

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

| Part D - Continued Economic Sampling | Audit Results |
|---|---|
| 33. Scheduled Sample | |
| 34. Species Testing | |
| 35. Residue | |
| **Part E - Other Requirements** | |
| 36. Export | |
| 37. Import | |
| 38. Establishment Grounds and Pest Control | X |
| 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 | X |
| **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 | X |
| 57. Monthly Review | |
| 58. | |
| 59. | |

60. Observation of the Establishment

Spain Est. 16 05-22-03

38 Insectocutors were observed over the product way area in the deboning room. This was scheduled for correction by the establishment management.

48 Plastic boxes used for edible and inedible product were used indiscriminately for both. This was corrected immediately by the inspection officials.

56 European Community Directive 64/433.

61. NAME OF AUDITOR
Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE
7/7/03

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., Utiel | 05 - 29 - 03 | 20 | Spain |
| | 5. NAME OF AUDITOR(S) | | 6. TYPE OF AUDIT |
| | Dr. Oto Urban | | [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT |

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

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

| Part D - Continued Economic Sampling | Audit Results |
|---|---|
| 33. Scheduled Sample | |
| 34. Species Testing | |
| 35. Residue | |
| **Part E - Other Requirements** | |
| 36. Export | |
| 37. Import | |
| 38. Establishment Grounds and Pest Control | X |
| 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 | |
| 53. Animal Identification | |
| 54. Ante Mortem Inspection | |
| 55. Post Mortem Inspection | |
| **Part G - Other Regulatory Oversight Requirements** | |
| 56. European Community Directives | X |
| 57. Monthly Review | |
| 58. | |
| 59. | |

60. Observation of the Establishment

Spain Est.20 05-29-03

38 Toxic product was used for the rodent control inside of the establishment. This was corrected immediately by the establishment management.

56 European Community Directive 64/433.

61. NAME OF AUDITOR
Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE
7/17/03

EMBASSY OF SPAIN
Office of Agriculture, Fisheries and Food
2375 Pennsylvania Ave., N.W.
Washington, D.C. 20037

Phone (202) 728 2339
(202) 452 0100
Fax (202) 728 2320
info@mapausa.org

*UNOFFICIAL TRANSLATION*

Madrid, January 20, 2004

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

Dear Dr. Stratmoen,

This answers your letter of September 25, 2003, to which you attached the report on the audit performed by Dr. Otto Urban between May 21 and June 5, 2003. I am pleased to inform you that the mentioned report, received on October 8, 2003 through the U.S. Embassy in Madrid, was translated into Spanish and forwarded to the Spanish Food Safety Agency, to the Ministry of Agriculture, Fisheries and Food, and the General Directorate of Health Services of the three Autonomous Communities involved, so that all stakeholders had the chance to review it and make the relevant observations.

I am now enclosing the comments and observations to the report, so that they can be considered for the final report.

Regarding observations 2 and 3 in the enclosed document, I would like to point out that the Public Health Laboratory in Valencia does not perform any analysis on meat products for export to the United States. During Dr. Urban's visit, we suggested the possibility that FSIS accept and authorize this laboratory to perform analysis of *L. monocytogenes* for products processed by establishment no. 20 (Redondo Iglesias, S.A.) in Valencia. We are looking forward to FSIS' response to our suggestion.

Sincerely,

Pedro Ángel García González

EMBASSY OF SPAIN
Office of Agriculture, Fisheries and Food

# OBSERVATIONS AND COMMENTS TO FSIS' DRAFT REPORT OF JULY 17, 2003, ON THE SPANISH MEAT INSPECTION SYSTEM

Once review the report, we have the following observations:

1. In several places in the report there are mentions to Directive 64/433/EEC, the scope of which is exclusively fresh meat. Considering that currently all establishments certified for export to the United States process only meat-based products, the relevant legislation is Directive 77/99/EEC, instead of the mentioned 64/433/EEC. We suggest that the final version of the report replaces mentions of Directive 64/433/EEC with Directive 77/99/EEC.

2. Pages 5-6, point 3, "Protocol"

   The first paragraph states that the laboratory of the *Centro Nacional de Alimentación* (National Food Center) in Majadahonda and the *Red de Laboratorios de Salud Pública* (Public Health Laboratory Network) of Valencia are the institutions that perform analysis for the detection of generic *E. coli* and *L. monocitogenes* in establishments authorized for export to the U.S. Please note that the only laboratory in Spain that perform such analysis in products from the authorized establishments is the *Centro Nacional de Alimentación.*

3. Page 13, point 12.

   The second paragraph reiterates that the *Laboratorio de Salud Pública* (Public Health Laboratory) of Valencia performs analysis in products from establishments authorized for export to the U.S.

   Also in point 12, and regarding the mentioned laboratory, it is mentioned that the matrix used for the detection of DES is urine. We do not consider this a deficiency, since the National Residue Research Plan of Spain, approved by the European Commission, as it is in all Member States, the use of urine as matrix is accepted. Also, Spain sends FSIS its annual report on the implementation of the National Residue Research Plan, and FSIS has never shown any concerns in that respect.

Madrid, January 20, 2004