



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

JUL 15 2011

Dr. Óscar González Gutiérrez-Solana  
Deputy – Director of Foreign Health  
Ministry of Health and Social Policy  
Paseo del Prado, 18-20  
28014 Madrid  
Spain

Dear Dr. Gutierrez-Solana:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Spain's meat inspection system January 7 to February 3, 2010. Comments received from the government of Spain have been included as an attachment to the final report. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 205-3969, by facsimile at (202) 720-0676, or electronic mail at [andreas.keller@fsis.usda.gov](mailto:andreas.keller@fsis.usda.gov).

Sincerely,

*Andreas Keller*  
Andreas Keller, PhD  
Acting Director  
International Audit Staff  
Office of International Affairs

Enclosure

cc:

Margaret Peg Thursland, Attaché, US Embassy, Madrid, Spain  
Almudena Rodriguez Sanchez- Beato, Agricultural Counselor, Embassy of Spain  
Carlos Alvarez-Antolinez, Counselor, Food Safety and Consumer Affairs, EC  
Bernard Van Goethem, Director, Directorate E  
Ghislain Marechal, EC, DG SANCO - Directorate General for Health and Consumers  
Debra Henke, Minister-Counselor, US Mission to the EU in Brussels  
Cecilia Choi, EB, State Dept.  
Michael Conlon, Europe Area Director, FAS  
Office of Science and Technical Affairs, FAS  
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Mary Stanley, Director, IPD, OPPD  
Ronald Jones, Assistant Administrator, OIA, FSIS  
Steve McDermott, Sr. Director, OIA  
James Adams, Director, IAS, OIA  
Oto Urban, IAS, OIA  
Manzoor Chaudry, IAS, OIA  
Andreas Keller, Director, IES, OIA  
Jerry Elliott, Director, IID, OIA  
Rick Harries, Director, EPS, OIA  
Harry Walker, IES, OIA  
Yolande Mitchell, IES, OIA  
John K. Greifer, APHIS  
Country File

JUL 15 2010

DRAFT FINAL REPORT OF AN AUDIT CONDUCTED IN  
SPAIN

JANUARY 7 - FEBRUARY 12, 2010

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING  
THE PRODUCTION OF MEAT  
PRODUCT INTENDED FOR EXPORT TO  
THE UNITED STATES OF AMERICA

Food Safety and Inspection Service  
United States Department of Agriculture

## *Executive Summary*

This audit report describes the outcome of an on-site audit of Spain's meat inspection system conducted by the Food Safety and Inspection Service (FSIS) from January 7 through February 12, 2010.

This was a routine on-going equivalence verification audit. The audit objective was to ensure that Spain continues to maintain a food safety system for meat slaughter and meat processing equivalent to that of the United States, with the resultant capacity to produce products that are safe, unadulterated, and properly labeled. Between January 1 and December 31, 2009, Spain exported 1,531,355 pounds of processed pork meat products to the United States.

The Central Competent Authority (CCA) maintains the legal authority and the responsibility to enforce all applicable meat inspection system laws and regulations governing Spain and third country requirements. However, the auditor concluded that these requirements were not consistently applied throughout the food safety system, which resulted in the CCA initiating an enforcement action in one of the five establishments audited.

The auditor reviewed and analyzed five risk areas within Spain's food safety inspection system. The two risk areas revealed potential weakness in Sanitation Controls and Enforcement. These weaknesses were not determined to have a significant impact on the food safety inspection system, but did require action.

The audit also detected a potential weakness in Government Oversight, as laboratory reviews were not being conducted by the CCA. During the audit the CCA proffered corrective actions, which were later verified by the auditor.

Although several areas of concern were identified, the FSIS concluded that Spain continues to operate a food safety system equivalent to that of the United States.

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## ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

AC	Autonomous Community
CCA	Central Competent Authority
CFR	Code of Federal Regulations
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
<i>Lm</i>	<i>Listeria monocytogenes</i>
MSPS	Ministry of Public Health and Social Policy
NOID	Notice of Intent to Delist
POE	Port of Entry
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point
RTE	Ready-To-Eat
<i>Salmonella</i>	<i>Salmonella</i> species
SSOP	Sanitation Standard Operating Procedures

## 1. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture conducted an audit of Spain's meat food safety system from January 7 through February 12, 2010.

The audit began with an entrance meeting held on January 7, 2010, in Madrid with the participation of representatives from the Ministry of Public Health and Social Policy (MSPS), and the auditor from the FSIS, Office of International Affairs (OIA), International Audit Staff (IAS). The MSPS is the Central Competent Authority (CCA) for Spain. In addition to the MSPS representatives, a representative of the Ministry of Environment and Rural and Marine Affairs was present at this meeting.

## 2. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

The audit objective was to verify that Spain's food safety system governing meat products continues to be equivalent to that of the U.S. system, with the resultant capacity to produce products which are safe, unadulterated, and properly labeled.

The FSIS auditor was accompanied throughout the entire audit by representatives from the CCA and /or representatives from the regional and local inspection offices. Program effectiveness determinations focused on government controls and oversight within five risk areas (1) Sanitation Controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP), (2) Animal Disease Controls, (3) Slaughter/Processing Controls, including the implementation and operation of Hazard Analysis Critical Control Point (HACCP) programs, and a testing program for generic *Escherichia coli* (*E. coli*), (4) Residue Controls, and (5) Enforcement Controls, including a government verification testing program for *Salmonella* species.

Administrative functions were reviewed at the CCA headquarters, four autonomous regional offices, one provincial office, two district offices and five local inspection offices, during which the auditor evaluated the implementation of those management control systems in place which ensure that the national system of inspection, verification, and enforcement was being implemented as intended.

A sample of five establishments was selected from a total of ten establishments certified to export meat products to the U.S. During the establishment visits, particular attention was paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with 9 CFR 327.2.

Additionally, two microbiology laboratories and one residue laboratory were audited to verify their ability to provide adequate technical support to the inspection system.

### Audit Scope Summary

Competent Authority Visits		Locations	
Competent Authority	Central	1	MSPS Madrid
	Regional	4	Four regional inspection offices in the Autonomous Communities (AC) of Castilla-La Mancha, Castilla y León, Valencia, and La Rioja.
		1	One Provincial office in Castilla y Leon.
Microbiological Laboratories		2	<ul style="list-style-type: none"> <li>• Centro Nacional De Alimentacion, Mahadohonda, Madrid (also audited for residue)</li> <li>• Public Health Laboratory, Laboratorio de Salud Publica, Valencia</li> </ul>
Residue Laboratory		1	Laboratory for Residue Control, Lab de Salud Publica de Castilla y Leon, Salamanca
Meat Slaughter/Processing Establishments		1	Salamanca
Meat Processing Establishments		4	Burgos, Utiel, Toledo, Logrono

### 3. LEGAL BASIS FOR THE AUDIT AND AUDIT STANDARDS

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

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.), and
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) regulations.

The audit standards applied during the review of Spain's meat inspection system included: (1) All applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) Any subsequent equivalence determinations that have been made under provisions of the World Trade Organization's Sanitary/Phytosanitary Agreement, which include the use of the following laboratory methods and processes:

- Testing for *Salmonella* species using PEE/LSPV/012 (equivalence granted March 12, 2008),
- Testing for *Listeria monocytogenes (Lm)* in Ready- to -Eat (RTE) product, PEE/LSPV/068,
- Testing for *Enterobacteriaceae* and Total Viable Count in lieu of testing for generic *E. coli*,
- EN 45001 - laboratory quality control standards

- PNTCNA\_IB023 method for species verification (equivalence granted April 1, 2008)
- CAN/AESA\_BA001\_02 *Listeria monocytogenes* method (equivalence granted December 11, 2008), and
- CAN-AESA *Salmonella* method (equivalence granted December 11, 2008)

#### **4. BACKGROUND**

Spain is eligible to export raw and processed meat products, including pork, to the U.S. Between January 1 and December 31, 2009, Spain exported 1,531,355 pounds of processed pork meat products to the U.S., of which 486,597 pounds were re-inspected at U.S. Ports of Entry (POE). No products were rejected.

Spain's food safety system was last audited in February/March of 2008. The findings of the 2008 audit resulted in seven observations of non-compliance by the auditor, and one enforcement action taken by the CCA, which was a Notice of Intended Delistment (NOID). No enforcement actions resulted in any establishment being prohibited from exporting meat to the U.S. This was a routine verification audit which identified significant deficiencies. The audit findings included the lack of government oversight of laboratories, and a weakness in the Sanitation Controls risk area, which included a failure to implement and verify sanitation programs consistently throughout the system.

An analysis of these prior systemic deficiencies if found not to be fully corrected or repeat findings within the context of the current audit findings indicates a potential weakness in the CCA's ability to provide adequate oversight for the implementation of a sanitation program within its inspection system.

#### **5. GOVERNMENT OVERSIGHT**

FSIS import eligibility requirements dictate that a foreign country's inspection system be organized and administered by the national government of the foreign country and provide standards equivalent to those of the Federal system of meat inspection of the U.S. For Spain, the MPHS maintains exclusive responsibility regarding the general principles of health and also for transposing the European Community regulations into Spanish law to guarantee the consistency of the national inspection system. The Spanish Food Safety and Nutrition Agency coordinates the consistency of the national system. Each AC implements those regulations.

The CCA maintains the legal authority and the responsibility to enforce all meat inspection system laws and regulations governing Spain's food safety system and third country requirements. However, during the course of the audit of Spain's meat inspection system it was observed that these requirements were not consistently applied throughout the system. This conclusion was evidenced by the enforcement action (NOID) taken by the CCA in one of the five establishments audited.

An NOID action indicates conditions within an establishment were not immediately rectifiable, but did not pose an imminent threat to public health and would warrant decertification if not corrected within thirty days from the time of issuance. A failure to implement the inspection laws and regulations could result in the production and the export of unwholesome, adulterated, or mislabeled product to the U.S.

When a foreign CCA certified establishment is issued an NOID or is delisted, it is because there has been a fundamental failure of process control or basic sanitation within the facility. While FSIS expects these actions to occur in relation to the CCA's ongoing responsibilities for inspection and for oversight of its inspection personnel, these events carry a different significance when they occur within the context of an FSIS audit, as it calls into question why the conditions within a particular establishment have gone unchecked and escalated to the level where an enforcement action is necessary during the audit.

An important subcomponent of FSIS' eligibility requirements includes the need for the direct oversight of government laboratories. The audit also detected a potential weakness in Government Oversight, relative to laboratory oversight. The audit findings revealed that periodic laboratory reviews were not being conducted by the CCA. The CCA oversight of laboratories is important to verify that laboratories implement and maintain U.S. requirements.

FSIS expects that documented reviews be performed of all microbiological laboratories that are eligible to perform microbiological analyses of official samples of product eligible for export to the U.S. These reviews serve as a fundamental layer of oversight to ensure the standards are being met. A failure to provide direct oversight of these laboratories may result in the inconsistent application of U.S. requirements and the export of unwholesome, adulterated product to the U.S.

## **6. SANITATION CONTROLS**

The first of the five risk areas that the FSIS auditor reviewed was Sanitation Controls. The inspection system must contain requirements for sanitation, for sanitary handling of products, and for the development and implementation of SSOP.

The establishment audits indicated that some in-plant government inspection personnel were not effectively carrying out the procedures as described in MSPS's meat inspection laws and regulations governing the food safety system.

The auditor observed several failures by both establishment and inspection personnel to identify contaminated product and product-contact surfaces, and other insanitary conditions which may lead to product contamination and adulteration. Additionally, in the establishment issued the NOID enforcement action, the auditor observed all inspection personnel were performing only on-line slaughter activities, which consumed their total inspection time. As a result, other inspection oversight activities appeared to be neglected.

Supervisory reviews of establishments and inspector performance are conducted and documented by the CCA and by the AC authorities. The auditor analyzed the supervisory review documents,

and observed many of the deficiencies identified in the supervisory reviews, were also present during the audit. The enforcement action taken by the CCA during the current audit related to sanitation deficiencies, indicating the need for a more consistent application of controls, as well as better government oversight.

## **7. ANIMAL DISEASE CONTROLS**

The second of the five risk areas that the FSIS auditor evaluated was Animal Disease Controls, including a review of the mechanisms for animal identification, control of condemned and restricted product, and for the sanitary handling of returned and reconditioned product. No findings were identified as a result of this review.

## **8. SLAUGHTER/PROCESSING CONTROLS**

The third of the five risk areas the FSIS auditor reviewed was Slaughter/Processing Controls, which included ante-mortem inspection procedures, ante-mortem disposition, humane handling and humane slaughter, post-mortem inspection procedures, post-mortem disposition, implementation of HACCP systems in all establishments, and implementation of a generic *E. coli* testing program in slaughter establishments.

The review of applicable legislation and procedures indicated that the MSPS continues to maintain sufficient written controls with respect to this risk area. The auditor observed the implementation of MSPS's Slaughter/Processing controls and these observations resulted in no findings.

## **9. RESIDUE CONTROLS**

The fourth of the five risk areas that the FSIS auditor reviewed was Residue Controls. The inspection system must have a chemical residue control program, organized and administered by the national government, which includes random sampling of internal organs and fat of carcasses for chemical residues identified by the exporting country's meat inspection authority or by FSIS as contaminants. Prior to the on-site audit, the auditor reviewed FSIS' POE testing results and did not identify any concerns in this risk area.

During the audit, one government residue laboratory was reviewed and no deficiencies were observed. In addition, interviews with CCA personnel and the review of relevant records indicated that Spain's residue control plan was being appropriately implemented.

## **10. ENFORCEMENT CONTROLS**

The last of the five risk areas that the FSIS auditor reviewed was Enforcement Controls. These controls included the enforcement of inspection requirements and the testing programs for *Salmonella* spp; *Lm*, species verification, and verification of corrective action by the CCA.

While no deficiencies were identified concerning the testing programs for the relevant pathogens, weaknesses associated with the enforcement of sanitation standards and the

performance of laboratory oversight reviews have been duly noted in previous portions of this report (Government Oversight and Sanitation Controls).

## 11. EXIT MEETING

An exit conference was held on February 11, 2010 with the MSPS. At this meeting, the preliminary findings from the audit were presented by the FSIS auditor.

## 12. CONCLUSIONS AND CORRECTIVE ACTIONS

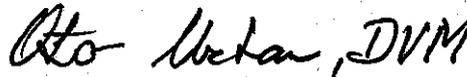
Non-compliances involving the enforcement of FSIS requirements were identified in three of five establishments audited. Inadequate CCA controls contributed to the issuance of one NOID for SSOP and other sanitation non-compliances. No non-compliances were reported in two of five establishments audited.

The FSIS auditor evaluated the nature, extent, and degree to which inadequate CCA controls impacted the food safety system and public health. Inadequate CCA controls relate to the lack of CCA oversight of some in-plant government officials, and plant staffing.

The FSIS auditor concluded that although not all FSIS requirements were enforced, MSPS has adequate controls in place, resulting in an effective food safety system.

During the on-site audit, the CCA made a verbal commitment to conduct annual oversight audits of all government laboratories which test U.S. eligible product. Subsequent to the audit, the CCA provided responses to FSIS's Self Reporting Tool, which indicated the annual laboratory audits were being implemented as committed. FSIS intends to request specific laboratory audit documents verifying the corrective actions are adequate and effective.

Oto Urban, DVM  
Senior Program Auditor

  
\_\_\_\_\_

## 13. ATTACHMENTS

Foreign Country Response to the Draft Final Audit Report (when it becomes available)

Received 1/1/11 MJC



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(202) 452 0100  
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EMBASSY OF SPAIN  
Office of Environment and Rural and Marine Affairs  
2375 Pennsylvania Ave., N.W.  
Washington, D.C. 20037

Mr. James Adams, DVM  
Director,  
FSIS/USDA  
International Audit Staff  
Office on International Affairs  
1400 Independence Ave. S.W.  
Washington, DC. 20250

July 6, 2011

Dear Mr. James Adams,

On June 10, we sent you copy of comments on draft of Final Report of the audit undertaken in Spain from January 7 to February 12, 2010 to evaluate the food safety security applied to the production of meat products susceptible to be exported to the United States. I also sent you an unofficial translation in later days. Now I am sending you the original documents and again a complimentary unofficial translation.

Should you have any question, do not hesitate to contact my office.

Sincerely,

A handwritten signature in black ink, consisting of a stylized, cursive script.

Almudena Rodríguez Sánchez-Beato  
Counselor

Equality), as Central Authority Competent (ACC), has visited the two laboratories authorized to analyze microorganism of Official samples of products that can be exported to the United States.

Food National Center (CNA): The supervision was undertaken on March 22, 2010. As it is indicated in point 3 of audit report (which copy it is attached), since the following day of the final meeting of the FSIS audit, the CNA attaches a copy of "Testing report" to the information that already was being sent to the Ministry of Health, Social Policy and Equality with the results of the analysis. In the testing report is, among others, the description and status of the sample received in the laboratory, as the methodology used.

As evidence, it is provided both communications on analytical results that correspond to one establishment: one is from January 21, 2010 (only with results) and the other is from February 15, 2010 (in which also it is included the testing report).

Laboratory of Public Health of Valencia (LSPV): the supervision of the ACC was undertaken in November 17, 2010, since this laboratory did not start its participation in the "Program of Verification of Microbiological of RTE products" until the third trimester of 2010.

It is attached a copy of the report of the visit with the results of it, also a note from the laboratory, as an example, which also has attached two analysis bulletins correspondents to the analyzed sample.

The ACC has planned to undertake at least one annual supervision to each laboratory in order to determine a sufficient application of the requirements to the United States.

June 9, 2011

## UNOFFICIAL TRANSLATION

### OBSERVATIONS TO THE FINAL DRAFT TO THE AUDIT UNDERTAKEN JANUARY 7 TO FEBRUARY 12, 2010 TO EVALUATE THE SECURITY OF THE FOOD SAFETY APPLIED IN THE PRODUCTION OF MEAT PRODUCTS SUSCEPTIBLES TO BE EXPORTED TO THE UNITED STATES.

#### 1. INTRODUCTION

- 2° Paragraph, 5 line: Where it says "Ministry of Environment" it should say "Ministry of Environment **and Rural and Marine Affairs**"

#### 2. AUDIT OBJECTIVE, SCOPE AND METHODOLOGY

- 2° Paragraph, 2° line: add "and" before the "or representatives" being the correct one "from the CCA **and** /or representatives from the regional and local inspection offices" since the FSIS inspector was accompanied all the time by the representative of the Central Authority.
- Table "Audit Scope Summary":
  - Microbiological Laboratories:
    - It should omit "Public Health Laboratory" before the "Centro Nacional de Alimentación"
    - Where it says "Majadohonda" it should say "Mahadahonda"
    - Where it says "Laboratorio de Salvo Pública, Valencia," it should say "Laboratorio de Salud Pública, Valencia,"
  - Residue Laboratory: where it says "Castilla León" it should say "Castilla y León".

#### 3. LEGAL BASIS FOR THE AUDIT AND AUDIT STANDARDS

In the summary of methodology and procedures of the laboratories, it should be included the one applied by the "*Centro Nacional de Alimentación*" for what the FSIS has determined the equivalence.

- PNTCNA\_IB023 method for species verification (equivalence granted April 1, 2008)
- CAN/AESA\_BA001\_02 *Listeria nomocytogenes* method (equivalence granted December 11, 2008), and
- CAN-AESA *Salmonella* method (equivalence granted December 11, 2008)

#### 5. GOVERNMENT OVERSIGHT

- 1<sup>ST</sup> paragraph, the line before the last one: where it says "Spanish Food Safety Agency" it should say "Spanish Food Safety **and Nutrition** Agency"

As a consequence of the observations made by the FSIS inspector in regards to the direct governmental supervision of the laboratories, during year 2010 the Ministry of Public Health and Social Policy (since October 2010, Ministry of Health, Social Policy and

**NATIONAL FOOD CENTER – YEAR 2010**  
**MARCH 22, 2010 – MAJADAHONDA (MADRID)**

**Attendees**

**National Food Center (CNA)**

- Fernando Tovar Hernández – Director
- María Teresa López Esteban – Acting Deputy Director
- María Carmen Blanco Vidal – Chief of the Food Microbiology Service
- Isidoro Ruíz-Ramos García Tenorio – Chief of Technical Management Service
- Joaquín Berenguer Soler – Chief of Quality Assurance Service.

**General Subdirectorate for Foreign Health**

- Marta Garrido García – Chief of Management and Coordination Area
- Juan Manuel Troncoso Ramón – Chief of Health and Hygiene Control Service

**1. Purpose of the meeting**

It celebrates the meeting as a result of the recommendations made by Dr. Oto Urban in the last audit held by the FSIS in our country from January 7<sup>th</sup> to February 11, 2010 as well as for the necessity of completing the corresponding part to such laboratory of “Self-reporting” elaborated by FSIS.

Likewise, we take the opportunity to discuss other topics related to the official control program for meat and meat-products’ s export to the USA.

**2. Completing of FSIS “Self-Reporting”**

The greater part of the meeting is dedicated to review the questions that arose by the FSIS in the “Self-reporting”, checking all

the documents supporting the lab answers (Quality Manual, General Operative Procedures – POGs, Lab worksheets, etc.)

**3. Supervision, by the ACC, of the methods used by CAN for meat and meat products analysis susceptible of been exported to the USA.**

In response to the respecting observation by the FSIS auditor, and from the following day to the final audit meeting, CAN attaches a copy of the "Test report" to the info sent to the SGSE with the results of analysis.

The test report contains, in addition to other data, the description and state of the sampling received from the lab, as well as the methodology used.

**4. Analytic method for *Salmonella* presence determination.**

In previous meeting, CAN and SGSE detected the necessity to convene the Autonomous Communities with authorized establishments to export to the USA; during this meeting, CNA will clarify doubts that would exist about the applying FSIS method MGL.04.C02 for the investigation of *Salmonella* in 325 g.

After discussing the details, it reaches the agreement that the SGSE, as a competent central authority, will convene to the meeting the responsible employees for the inspection official services at the Autonomous Communities (CCAA) and their lab officials with authorized establishments or underway of authorization to export their products to the USA.

Previously, the SGSE will send to the same CCAA the method MGL.04.C02 for its revision and study, in the way that the labs can expound their doubts in the cited meeting. The CNA offered to respond to those questions, due to its dilated experience in the RTE products analysis for meat and meat products export to the USA.

In this regard, all the labs will be at the same level, without assuming, neither one, the role of coordinator of the official control analysis program for the export of meat and meat products to the USA.

**5. New model of sampling minutes.**

During the meeting object of this summary, it reviews the new model of sampling minutes established through the

COURTESY UNOFFICIAL TRANSLATION

"sampling procedure (Official Microbiologic verification program in RTE product)." The CNA makes its observations during this meeting that the SGSE will add to the cited Procedure.

**6. Seminars for laboratories personnel organized by the FSIS.**

The SGSE handed to the CNA FSIS information related to three courses for official laboratories personnel about "Microbiology," "Antibiotics residues" and "Pesticides residues," that such Service is scheduled to hold during the present year.

Likewise, the deadline is indicated to send the compulsory applications, in case of the CNA has interest to participate in some of the seminars; it will be on Wednesday March 31, 2010.

Madrid, April 26, 2010

CHIEF OF MANAGEMENT AND  
COORDINATION AREA

CHIEF OF HEALTH AND  
HYGIENE CONTROL SERVICE

Marta Garrido García

Juan Manuel Troncoso Ramón

Ministry of Health and Consumption  
Spanish Agency of Food and Nutrition

Food National Center

Ministry of Health and Social Policy  
Internal Registry  
Assistant Director General for Foreign Health  
Entry  
Registry # 381  
Date 01/22/2010. 09:24:26

FOOD NATIONAL CENTER
FEB 15, 2010
EXIT # 77

Related to the samples included in the previous sending for the first semester, corresponding to "Residues, determination of species, Listeria and Salmonella Program for the USA", from the establishment Campofrío Food Group, S.A. (Burgos) and received on February 2, this year. Attached find the corresponding official "Sampling sheet" that accompanied it, as well as the obtained analytic results from the samples sent for the study on "Listeria" and "Salmonella" record # 10/00252.

Such results have not shown any abnormality.

Majadahonda, January 21, 2010

THE TECHNICAL SECRETARY

Isidoro Ruíz-Ramos

C/C: Official Veterinary Services. C/ La Bureba, s/n – 09007 – Burgos

Assistant General Director of Coordination and Alerts and AESAN Official Control Programming. c/ Alcalá, 56 – 28014 – Madrid.

ASSISTANT GENERAL DIRECTOR OF FOREIGN HEALTH – MINISTRY OF HEALTH AND SOCIAL POLICY. Paseo Del Prado, 18-20. 28014-MADRID

Ministry of Health and Consumption  
General Direction of Public Health

Sampling Sheet  
**06388**

Plan of Residues and Determination of Species for the USA

	SAMPLING OWNER AND SOURCE NAME AND ADDRESS: CAMPOFRIO FOOD GROUP, S.A. C/ La Bureba, 13 09007-BURGOS		OTHER IDENTIFICATIVE DATA Red seal - 174677
SPECIE: PIGS	AUTONOMOUS COMMUNITY: CASTILLE AND LEON	ESTABLISHMENT NUMBER: U.S.A. 21	Batch SIZE: 5,000 units
TISSUE OR SAMPLIN TO ANALIZE CODE G H R M <del>PROD.CARN.</del>	INSPECTION SERVICES' SAMPLING SHEET OUTPUT DATE: 02/01/2010		U.S.A. RESIDUES PROGRAM, AUTHORIZED LABORATORY <b>C.N.A.</b>
VETERINARY SERVICES INSPECTOR SIGNATURE	DATE OF COLLECTION OF SAMPLES 02/01/2010	COLLECTION TIME: 8:00	DATE OF SAMPLES SHIPMENT TO THE LABORATORY: 02/01/2010

Codes object of analysis (mark with an X):

PCB'S + ORGANOCHLORINE (OC) ( ); ORGANOPHOSPHORATE (OP) ( ); HEAVY METAL ( ); CHLORANPHENICOL ( ); ANTIBIOTICS ( );  
SULFAMIDES ( ); D.E.S. + HORMONES ( ); DETERMINATION OF ANIMAL SPECIES ( ); LISTERIAS (X); IVERMECTINE ( )

**SALMONELLA (X)**

FOR THE EXCLUSIVE USE OF THE LAB

ANALITIC REPORT # 10/00252 (# M.100167)								
SAMPLES CONDITION AT RECEPTION. Room temp	TISSUE OR SAMPLE CODE *MEAT PRODUCTOS		TISSUE OR SAMPLE CODE		TISSUE OR SAMPLE CODE		TISSUE OR SAMPLE CODE	
	DETERM. CODE	DETERM. RESULT	DETERM. CODE	DETERM. RESULT	DETERM. CODE	DETERM. RESULT	DETERM. CODE	DETERM. RESULT
LAB RECEPTION DATE 02/02/2010	LIST	ABSENCE/25g						
	SALM	ABSENCE/325g						
USA PROGRAM DIRECTOR'S SIGNATURE								
DOCUMENT SUPERVISOR'S SIGNATURE								
NOTES: *CHORIZO LIST—LISTERIA Monocytogenes SALM—SALMONELLA								

FOR THE EXCLUSIVE USE OF THE OFFICIAL VETERIANARIES

TISSUE OR SAMPLE AMOUNT SENT TO THE LABORATORY					DATA OF MEAT OR MEAT PRODUCT SAMPLES. FOREIGN SOURCE			
FAT	LIVER	MUSCLE	KIDNEY	MEAT PRODUCT 600+600 GR	FOREIGN ESTABLISHMENT NAME AND ADDRESS			COUNTRY
OTHER ESPECIAL DIRECTIONS FOR TAKING SAMPLES					ESTABLISHMENT ID #	BATCH ID #	BATCH SIZE	OTHER IDENTIFICATIVE DATA

Sample # 100167

TEST REPORT # 10/002 52

Service of Food Microbiology

SAMPLE NAME: MEAT PRODUCT (CHORIZO)

## TEST REPORT

### SAMPLE DENOMINATION, DESCRIPTION AND IDENTIFICATION, ACCORDING PETITIONER OR OTHERS

MEAT PRODUCT (CHORIZO)

The sample is formed by two chorizos, vacuumed and sealed by thermo heat, in the interior of an official sealed bag.

Sample from CAMPOFRIO FOOD GROUP, S.A. (Burgos)

Residues Program, species determination, Listeria and Salmonella for USA

Seal number: 000174677 red color.

Sample page #: 06388

Batch #: 695844

Type of Analysis: Informative

### PETITIONER:

AUTONOMOUS COMMUNITY OF CASTILLE AND LEON – OFFICIAL VETERINARY SERVICES –  
CAMPOFRIO FOOD GROUP, S.A.  
c/ La Bureba, 13  
09007 BURGOS

### SAMPLE RECEPTION DATE AT CNA:

February 2, 2010

Page 1 of 3

Testing Laboratory accredited by ENAC with accreditation # 178/LE397.

NOTE: This report only affects to the object undergoing test and it must not partially reproduce itself without the testing laboratory written approval.

Ctra. Pozuelo – Majadahonda Km. 6,100  
28220 MAJADAHONDA (Madrid)  
Phone: 91 822 3000  
Facsimile: 91 609 7913

Sample # 100167

TEST REPORT # 10/002 52

Service of Food Microbiology

**SAMPLE NAME:** MEAT PRODUCT (CHORIZO)

**SAMPLING PROCEDURE:**

Sample sent by the petitioner.

**ANALYZED PARAMETERS AND RESULTS:**

PARAMETER	RESULTS
#Salmonella	Absence /325 g.

# the marked tests are not included in the object of accreditation.

**Analytic methodology:**

Method (PCR-BAX) USDA-MLG 4C

PARAMETER	RESULTS
Listeria monocytogenes	Absence /25 g

**Analytic methodology:**  
PNTCNA\_BA001

**Test start date:** February 2, 2010

**Test end date:** February 12, 2010

Page 2 of 3

Testing Laboratory accredited by ENAC with accreditation # 178/LE397.

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Facsimile: 91 609 7913

FPOGCNA\_16\_04\_02



**AUTONOMOUS COMMUNITY  
OF VALENCIA**

Chancellery of Health  
Direction General of Public Health  
Center of Public Health of Valencia  
Departments 4,5 and 6

Public Health Laboratory  
Avda. Cataluña, 21  
96 1925890 Phone  
96 1925704 Fax  
46020 VALENCIA

MINISTRY OF HEALTH AND SOCIAL POLICY GENERAL REGISTRY  <b>DEC 21 2010</b>  ENTRY - 86556	AUTONOMOUS COMMUNITY OF VALENCIA CHANCELLERY OF HEALTH PUBLIC HEALTH CENTER 12/15/10 012022 REGISTRY OF EXIT VALENCIA
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Valencia,  
December 10, 2010

Privates

Attached please find the analysis tab bulletins detailed as follows:

APPLICATION	DATE	EXTERNAL REF.	SAMPLE	SAMPLE INFORMATION
08-10-15214	11/24/2010	07092	Chorizo	Population: Source:
08-10-15215	11/24/2010	07091	Chorizo	Population: Source:

The Director of Public Health

José Luis Fabedo Agustí

**AUTONOMOUS COMMUNITY  
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Electronic signature. Decree 87/2002, Valencia Government

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46020 VALENCIA

**ANALYSIS REPORT**

Report # 071210 15214	Sample # 08-10-15214 Record # 07092	Sample entry date: 11/24/2010 Sample date: 11/23/2010
Sample: Chorizo Sample description: CURED MEAT PRODUCT		Analysis type: Regulatory sample
Asked by: Privates ID #: C.A. DE LA RIOJA Plan: Especimen: City Establishment: PALACIOS ALIMENTACION, S.A.U.		Address:  Batch:

**Analysis requested:** Microbiology

End date: 12/02/2010

**Results:**

Parameter	Value Found	Incert. (±)	L.C.	Value of Reference	Method	Test Start date
Inv. <i>Listeria monocytogenes</i> (/25g)	It is not detected			Absence	PEE/LSPV/063	11/30/2010

**ALIQUOT'S OBSERVATIONS:**

**OBSERVATIONS:**

**NOTES:**

The column that expresses the value of reference is not included in the subject of the accreditation.

L.D.: Limit of detection

L.C.: Limit of quantification.

Parameters marked (#) does not match the reference established by:  
Regulation 2073/2005; RD 142/2002

Laboratory accredited by ENAC. Accreditation # 234/LE371

Valencia, December 7, 2010

Laboratory Section Chief  
This document has been validated  
Electronically according to what establishes  
Decree 87/2002, Valencia Government.

Pedro Marti Requena

The results in this report only are referred to the sample object of testing.  
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96 1925704 Fax  
46020 VALENCIA

**ANALYSIS REPORT**

Report # <b>071210 15215</b>	Sample # <b>08-10-15215</b> Record # <b>07091</b>	Sample entry date: <b>11/24/2010</b> Sample date: <b>11/23/2010</b>
Sample: <b>Chorizo</b> Sample description: <b>CURED MEAT PRODUCT</b>		Analysis type: <b>Regulatory sample</b>
Asked by: <b>Privates</b> ID #: <b>C.A. DE LA RIOJA</b> Plan: Especimen: City Establishment: <b>PALACIOS ALIMENTACION, S.A.U.</b>		Address:  Batch:

**Analysis requested:** Microbiology

End date: 12/03/2010

**Results:**

Parameter	Value Found	Incert. ( $\pm$ )	L.C.	Value of Reference	Method	Test Start date
Inv. Salmonella (/325g)	It is not detected			Absence	PEE/LSPV/063	11/30/2010
Inv. Salmonella (/325g)	It is not detected			Absence	PEE/LSPV/012	12/30/2010

**ALIQUOT'S OBSERVATIONS:**

**OBSERVATIONS:**

**NOTES:**

The column that expresses the value of reference is not included in the subject of the accreditation.

L.D.: Limit of detection

L.C.: Limit of quantification.

Parameters marked (#) does not match the reference established by:

Regulation 2073/2005; RD 142/2002

Laboratory accredited by ENAC. Accreditation # 234/LE371

Valencia, December 7, 2010  
Laboratory Section Chief  
This document has been validated  
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Pedro Marti Requena

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## Unofficial Translation

### LABORATORY REPORT ON PUBLIC HEALTH OF VALENCIA-year 2010

On November 17, 2010, as established by the Food Safety and Inspection Service (FSIS) of Department of Agriculture of the United States, it was undertaken an audit visit to the Public Health Laboratory of Valencia (LSPV).

The designated technical expert by the Directorate General of Public Health and Foreign Health (DGSPSE): Marta Garrido García.

#### Information of the laboratory:

Name of the Laboratory: Public Health Laboratory of Valencia

Address: Avda. de Cataluña, 21-46020 Valencia

Telephone 96 192 5890

#### Goals

- Verify analytical methodology undertaken within the frame of control program for the exportation of ready to eat products (RTE) to the United States.
- Comply with Self-Reporting Tool of FSIS

Subject: *Salmonella* and *Listeria monocytogenes*

#### Criterion:

- Analytical Methodologies PEE/LSPV/068 (*Listeria monocytogenes*) and PEE/LSPV/012 (*Salmonella*)
- Self-Reporting Tool

The verification activities were undertaken following the structure established in previous notification.

### BACKGROUND

The LSPV was authorized to undertake *Salmonella* and *Listeria monocytogenes* within the program of analysis of both microorganisms in RTE products to export to the United States, through Resolution of DGSPSE on November 20, 2008.

However, it has not been until this present year 2010 when the LSPV has started to participate in the "Microorganism Verification of RTE Program" and in the "Performing procedure when positive results appeared in the Official Control in RTE Products"

After the last audit by FSIS that took place in our country from January 7- February 11, 2010, it is required that the Central Government authority (DGSPSE) visit the implicated laboratories in the meat analysis and/or meat products to export to the United States.

## SUMMARY RESULTS

The supervision activities were performed according to the following structure:

Facilities: In the itinerary it was verified the area of culture, the food laboratory, the water laboratory, the identification laboratory, the heater room, the storage room, the molecular microbiological laboratory and the dioxin laboratory. The audit of the facilities ended at the contaminated material area.

Documentations and Records:

- Quality Manual (Rev.17, 13/01/2010, January 13, 2010)
- Procedure PG/LSPV/03 for the control, calibration/verification and maintenance of internal equipments (Rev. 3, 25/06/2004 June 25, 2004).
- Procedure PG/LSPV/013 for qualifications of staff (Rev. 1, 19/02/2007, February 19, 2007).
- Procedure PG/LSPV/14 for the elaboration and evaluation of the capacity plan for the LSVP (Rev.0/31/03/2006, March 31, 2006).
- Procedure PEM/LSPV/013: Reception, identification and records of the samplings (Rev.6, 11/02/2008, February 11, 2008)
- Work Sheet (No. record 8127 and 14027)
- Individual folder of equipment (heater 2160024)
- Resolution of November 20, 2008 of DGSPSE

In accordance to the areas of revision, the following considerations were undertaken:

### 1. FACILITIES OF THE LABORATORIES

The laboratory was moved to the main building (new building, to be used for first time) two years ago. In the visit, there were verified the evidences of the procedures collected in the Self Reporting Tool that have been collected in Annex 1.

### 2. DOCUMENTATION AND RECORDS

In the review of LSPV procedures, it was verified the one established in the Self-Reporting Tool, which such questionnaire was completed.

In regards to the documentation review, it was observed that some of the analytical reports submitted to the DGSPSE indicated that only the PEE/LSPV/096 methodology was used for the research of Salmonella, when the equivalent methodology by FSIS is PEE/LSPV/012.

During the visit the file of one of the reports (no. 08127) was revised and according to the work sheet, it was obtained the evidence that that both methodologies were undertaking although due to an error, the 012 was not included in the results of the reports.

On the other hand, it was affirmed that the laboratory does not have a copy of Resolution of November 20, 2008 of DGSPSE in which the LSPV is authorized to perform an analysis of *Salmonella* and *Listeria monocytogenes* within the frame of the Analysis Program of both microorganism in RTE products to export to the United States.

### 3. RESEARCH METHODOLOGY OF *SALMONELLA* AND *LISTERIA MONOCYTOGENES*

In the RTE products samples to export to the United States, the laboratory uses the recognized methodology as equivalent to the FSIS.

- PEE/LSPV/068 to research *Listeria monocytogenes* and
- PEE/LSVP/012 to research *Salmonella*

In regards to the investigation of the *Listeria monocytogenes* there is not any remarkable characteristics.

In regards to the research of *Salmonella*, the LSPV is undertaking in all the samples as the PEE/LSVP/012 Methodology (ISO 6579:2000, similar to FSIS MLG.4.04) as PEE/LSPV/096 (VIDAS). In addition, it is wanted to apply the PEE/LSPV/226 (screening PCR BAX, accredited in June 2010, similar to the FSIS MLG 4C.02).

In this sense, it is informed that the LSPV will have to send the methodology PEE/LSPV/096 and PEE/LSPV/226 to the DGSPSE for its submission to the FSIS, in order to submit to the recognized procedure equivalent by such authorities.

### 4. CONCLUSIONS

1. Requirements comply since the research of the *Salmonella* and *Listeria monocytogenes* in RTE products has used the recognized equivalent by the FSIS.
2. We have to make sure that all the analytical reports embrace the methodology PEE/LSPV/012 for the research for *Salmonella*, independently that the LSPV uses another analytical methodology.

Madrid, November 23, 2010

Signed by Chief of Management and Coordination, Marta Garrido Gardía.

Ministry of Health and Consumption  
Spanish Agency of Food and Nutrition

Food National Center

CNA, January 21, 2010

Ministry of Health and Social Policy  
Internal Registry  
Assistant Director General for Foreign Health  
Entry  
Registry # 381  
Date 01/22/2010. 09:24:26

FOOD NATIONAL CENTER
JAN 21, 2010
EXIT # 15

Related to the samples included in the previous sending for the first semester, corresponding to "Residues, determination of species, Listeria and Salmonella Program for the USA", from the establishment Campofrío Food Group, S.A. (Burgos) and received on January 5, this year, find attached the corresponding official "Sampling sheet" that accompanied the obtained analytic results from the samples sent for the study on "Listeria" and "Salmonella" (Number of Analysis: 10/00060.)

Such results have not shown any abnormality.

Majadahonda, January 21, 2010

THE TECHNICAL SECRETARY

Isidoro Ruíz-Ramos

C/C: Official Veterinary Services. C/ La Bureba, s/n - 09007 - Burgos

Assistant General Director of Coordination and Alerts and AESAN Official Control Programming. c/ Alcalá, 56 - 28014 - Madrid.

ASSISTANT GENERAL DIRECTOR OF FOREIGN HEALTH - MINISTRY OF HEALTH AND SOCIAL POLICY. Paseo Del Prado, 18-20. 28014-MADRID

Plan of Residues and Determination of Species for the USA

	SAMPLING OWNER AND SOURCE NAME AND ADDRESS CAMPOFRIO FOOD GROUP, S.A. C/ La Bureba, 13 09007-BURGOS		OTHER IDENTIFICATIVE DATA Blue seal - 174682
SPECIE: PIGS	AUTONOMOUS COMMUNITY: CASTILE AND LEON	ESTABLISHMENT NUMBER: U.S.A. 21	Batch SIZE: 10,000 Kg.
TISSUE OR SAMPLIN TO ANALYZE CODE  G H R M meat product <sub>i</sub>	INSPECTION SERVICES' SAMPLING SHEET OUTPUT DATE:  01/04/2010		U.S.A. RESIDUES PROGRAM, AUTHORIZED LABORATORY  <b>C.N.A.</b>
VEETERINARY SERVICES INSPECTOR'S SIGNATURE	DATE OF COLLECTION OF SAMPLES  01/04/2010	COLLECTION TIME:  8:10	DATE OF SAMPLES SHIPMENT TO THE LABORATORY: 01/04/2010

Codes object of analysis (mark with an X):

PCB'S + ORGANOCHLORINE (OC) ( ); ORGANOPHOSPHORATE (OP) ( ); HEAVY METAL ( ); CHLORANPHENICOL ( ); ANTIBIOTICS ( );  
SULFAMIDES ( ); D.E.S. + HORMONES ( ); DETERMINATION OF ANIMAL SPECIES ( ); LISTERIAS (X); IVERMECTINE ( )

**SALMONELLA (X)**

FOR THE EXCLUSIVE USE OF THE LAB

ANALITIC REPORT # 10/00060 N° sample.100005								
SAMPLES CONDITION AT RECEPTION. Room temp	TISSUE OR SAMPLE CODE *MEAT PRODUCTOS		TISSUE OR SAMPLE CODE		TISSUE OR SAMPLE CODE		TISSUE OR SAMPLE CODE	
	DETERM. CODE	DETERM. RESULT	DETERM. CODE	DETERM. RESULT	DETERM. CODE	DETERM. RESULT	DETERM. CODE	DETERM. RESULT
LAB RECEPTION DATE 01/04/2010	LIST	ABSENCE/25g						
	SALM	ABSENCE/325g						
USA PROGRAM DIRECTOR'S SIGNATURE								
DOCUMENT SUPERVISOR'S SIGNATURE								
NOTES: *CHORIZO LIST--LISTERIA Monocytogenes SALM--SALMONELLA								

FOR THE EXCLUSIVE USE OF THE OFFICIAL VETERINARY SERVICES

TISSUE OR SAMPLE AMOUNT SENT TO THE LABORATORY					DATA OF MEAT OR MEAT PRODUCT SAMPLES. FOREIGN SOURCE			
FAT	LIVER	MUSCLE	KIDNEY	MEAT PRODUCT 600+600 GR	FOREIGN ESTABLISHMENT NAME AND ADDRESS			COUNTRY
OTHER ESPECIAL DIRECTIONS FOR TAKING SAMPLES					ESTABLISHMENT ID #	BATCH ID #	BATCH SIZE	OTHER IDENTIFICATIVE DATA