



United States Department of Agriculture

MAY 13 2015

Food Safety and
Inspection Service

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Dr. Giuseppe Ruocco
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Ministry of Health
Directorate General for Veterinary Health and Food
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Dear Dr. Ruocco:

The United States Department of Agriculture's Food Safety and Inspection Service (FSIS) is pleased to update you on our comprehensive review of Italy's meat inspection system.

First, I want to share with you the final report from our July 2014 audit of your national meat inspection program. I have enclosed a copy of the final audit report. You will note that the comments received from the Government of Italy are included as an attachment to the document.

Second, as we have previously discussed, our delay in issuing a final decision with regards to your equivalence determination was the result of two point-of-entry (POE) violations for *Listeria monocytogenes* (*Lm*) in prosciutto from establishments 100L (Fontana Hermes) and 718L (Salumificio Piacenti) in December 2014. Earlier this year, FSIS notified your Ministry of each of the two violations. FSIS reviewed the subsequent Ministry of Health (MOH) response and had additional questions and concerns regarding the corrective action responses. FSIS sent a follow-up letter on March 6, 2015, that identified these concerns and requested clarification regarding several specific questions. FSIS received the MOH response dated April 2, 2015. After evaluation of the submitted documentation, FSIS determined, based on the information provided, that the measures put in place for establishments 100L and 718L, including sanitation procedures, equipment maintenance, employee training, and testing, which were verified by the Local Health Unit, address the identified causes of the violations. Therefore, FSIS considers the POE violations for these establishments to be resolved based on the current information provided. This conclusion is not a determination as to whether these establishments meet Italy's new *Lm* zero tolerance policy, as described below.

Dr. Giuseppe Ruocco

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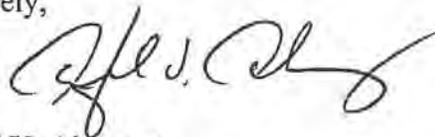
Thirdly, based on our discussions and your data submissions, we understand that MOH is transitioning to a new *Lm* zero tolerance policy for establishments exporting ready-to-eat product to the U.S. We have analyzed Italy's response and believe your national program to prevent *Lm* in post-lethality exposed ready to eat (RTE) products, once implemented, will meet the appropriate U.S. levels of protection, in accordance with our international obligations.

As you know, domestically, FSIS allows *Lm* to be controlled in post-lethality exposed RTE product via a HACCP plan, Sanitation SOP, or other prerequisite program. Therefore, it has been determined that the intent of the Italian program is to accomplish an equivalent food safety objective as the FSIS inspection verification system. To maintain this determination, the Italian Central Competent Authority (CCA) must ensure that: 1) *Lm* is prevented, and 2) that the RTE product is non-detectable for *Lm* when using a detection method equivalent to the FSIS laboratory methodology. FSIS cautions that the Italian CCA control programs would not be deemed equivalent if the RTE product is contaminated with *Lm* but at a level of less than 100 cfu/g. FSIS will verify the effective implementation of these corrective actions, as well as documented oversight by Italy's CCA during its next audit.

Therefore, FSIS requests that MOH provide an updated list of certified establishments operating under the control program that prevents *Lm* from adulterating post-lethality exposed RTE products. This revised list should include newly certified establishments as well as those that are presently certified. Once this revised list is received, FSIS will post it to its webpage for export eligible foreign country establishments. Because of the significance of your commitment to transition to a zero tolerance policy, FSIS will reduce the port-of-entry testing from 100% to 50%. The 50% POE testing will remain in effect for at least 45 days. At that time, if there are been no port of entry *Lm* positives, FSIS will resume its normal level of reinspection where randomly selected lots will be sampled for *Lm* based on the FSIS annual sampling plan.

I hope this information is helpful. I want to thank you and the Ministry for your personal attention to this important public health concern. If you have any questions regarding our determinations, please feel free to contact me at your earliest convenience.

Sincerely,



Alfred V. Almanza
Deputy Under Secretary, Office of Food Safety
Acting Administrator, FSIS

FINAL REPORT OF AN AUDIT CONDUCTED IN
ITALY

July 7 – 18, 2014

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING
THE PRODUCTION OF MEAT PRODUCTS
INTENDED FOR EXPORT TO
THE UNITED STATES OF AMERICA

April 27, 2015

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from July 7 to July 18, 2014, to determine whether Italy’s food safety system governing the production of meat remains equivalent to that of the United States, with the ability to produce products that are safe, wholesome, unadulterated, and properly labeled.

The audit was designed to determine the equivalence of Italy’s meat inspection system and focused on six main system components: (1) Government Oversight; (2) Statutory Authority and Food-Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Chemical Residue Control Programs; and (6) Microbiological Testing Programs. In addition, the audit conducted a detailed verification of Italy’s Ready-to-Eat (RTE) program and government control measures applied in response to eleven concerns related to the Central Competent Authority’s (CCA) ability to meet FSIS’ equivalence criteria pertaining to FSIS import regulations (9 CFR Part 327.2) and its effectiveness in preventing additional United States-Point-of-Entry (POE) *Listeria monocytogenes* (*Lm*) violations in RTE products exported to the United States. These concerns were communicated to the CCA by FSIS in a letter dated January 13, 2014. Italy currently exports only processed pork products to the United States.

The current audit findings related to Government oversight, Sanitation, HACCP, and the Microbiological components are summarized in the table below and are further addressed in the respective sections of the report.

	Equivalence Component	Audit Findings
1	<i>Government Oversight</i>	The audit findings in Government Oversight, Sanitation, HACCP System, and the Microbiological Testing Program components indicate a need to improve the CCA’s oversight functions and supervisory reviews. Inadequate support documents detailing how the CCA provides guidance to establishments on attaining at least a 5-Log ₁₀ reduction of <i>Salmonella</i> in dried cured ham products were also found.
2	<i>Statutory Authority and Food-Safety Regulations</i>	No concerns to report
3	<i>Sanitation</i>	The nature and extent of findings related to this component observed at the audited establishment raises concerns about Italy’s ability to maintain equivalent sanitation measures. Example of the finding include: Worn gasket on multiple oven doors, workers in RTE deboning area not wearing gloves, paper towels being used to clean food contact surfaces after sanitizing the surface, harvested offal not being chilled and washed immediately,
4	<i>HACCP</i>	FSIS Auditors noted serious findings related to HACCP component that indicate ineffective verification conducted by Italy’s meat inspection system. The audit findings are related to inaccuracies in flow diagram and hazard analysis of some processing steps.
5	<i>Chemical Residues Control Programs</i>	No concerns were noted related to the CCA’s HQ, Regional and Local inspections for Chemical Residues Control Program.
6	<i>Microbiological Testing Program</i>	The audit found inadequate support documents regarding how the CCA provides guidance to establishments on attaining at least a 5-Log ₁₀ reduction of <i>Salmonella</i> in dried cured ham products.

On and prior to the exit meeting, the CCA provided the FSIS auditors with evidence of immediate corrective action addressing most of the findings identified above. After the on-site audit, the CCA proffered additional corrective action committing to update its circular 2731_P_02_03_2014 before the end of 2014, to reflect program changes related to sanitation and microbiological sampling. The auditors concluded that the system is operating at an “adequate” level; however, the CCA needs to improve its oversight functions in Sanitation, HACCP, and Microbiological Testing Program components. FSIS needs a response from Italy within 60 days of issuance to this report and provide FSIS how it would ensure that its oversight functions and proffered corrective actions will prevent future adulteration of RTE product with *Lm*.

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I. BACKGROUND

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site equivalence verification audit of Italy's meat inspection system from July 7 to July 18, 2014.

Italy is eligible to export processed pork product to the United States. Italy has exported a total of 15,520,451 pounds of processed pork product to the United States during the period beginning from August 5, 2013 to July 31, 2014. All shipments of product were re-inspected at the United States-Point-of-Entry (POE) and a total of 88,422 pounds of this volume were rejected for public health reasons.

This audit of the inspection system was originally planned to occur in September 2013. Because of the government shut down in the United States, the audit was rescheduled to July of 2014. In addition, FSIS was also concerned about numerous United States-POE violations because of *Lm* in imported Italian dry cured ham products. Because of eleven POE violations since March 2012, including a recent POE violation in June 2014, RTE product imported from Italy has been under 100 percent testing in accordance with FSIS' policy on imported products implicated in United States-POE violations posing health risks to the public. While Italy's proffered corrective actions failed to prevent new cases of *Lm* violations, FSIS requested the Italian Ministry of Health (MOH) to update the information in the Self Reporting Tool (SRT) specific to RTE and HACCP criteria. FSIS delayed the audit further, to allow MOH to complete the request for the SRT update and provide corrective actions for the new cases of *Lm*.

To determine whether Italy's *Listeria* control measures are effective, the audit included visits to four of the five establishments implicated in the United States-POE violations for the presence of *Lm* in the dry cured ham products imported from Italy. One of the five processing establishments audited was ineligible to export to the United States, as the CCA had delisted the establishment because it was the source of product that was found to contain *Lm* when examined at POE.

On November 25 to 26, 2013, a two-day technical meeting was held at FSIS' Headquarters in Washington, DC. The Italian delegation headed by Dr. Silvio Borrello, Director General for Hygiene, Food Safety and Nutrition, Ministry of Health, included representatives from the food export office, regional food inspection directorate, laboratories, and information technology directorate, members from Experimental Zooprohylactic Institute. The counselor of Economic, Commercial and Scientific Affairs Office and Scientific Attaché from Italian Embassy in Washington, DC attended. The FSIS technical team was comprised of members from the Office of Investigations, Enforcement and Audit (OIEA), Office of Field Operations (OFO), Office of Policy and Program Development (OPPD), and Office of Data Integration and Food Protection (ODIFP).

Among other items on the agenda, the talks sought to help both countries develop a better understanding of each other's inspection systems. In closing remarks, both sides committed to continuing collaboration to achieve common goals of protecting public health and ensuring that the highest standards of food safety are maintained. Italy proposed the following actions to strengthen its inspection system:

- Revise the list of Italian plants approved for export of meat products to the United States as of January 2014;
- Revise its technical guidance documents related the official control of *Lm* with respect to the sampling of food contact surfaces and non-contact surfaces and prepare a guidance document for the official control of *Lm* in RTE products;

- Create a task force made up of representatives from Local Health Units (LHU), officials from Regional Directorate, representatives from laboratories and MOH. The task force will be responsible for conducting an investigation in response to product contamination. The investigation will focus on the identification and source of the contamination as well as mitigation strategies;
- Develop courses for the training of inspectors and supervisors, specifically designed to implement FSIS regulations in the United States-eligible establishments; and
- Establish a database for cataloguing strains, typing/identification and genetic characterization of *Lm* to be used by central and local authorities.

At the closing meeting, FSIS informed the Italian delegation that it would not be closing any pending issues related to POE violations implicating Italian dry cured ham adulterated with *listeria monocytogenes* on a multiple occasions. The agency made it clear to the delegation that RTE product imported from Italy will continue to be subjected to intensified testing at the United States-POE will continue to occur in accordance with the FSIS policy to protect public health.

On January 13, 2014, FSIS sent a letter to MOH, which outlined eleven issues that were still pending. The issues were related to *Lm* policies in RTE products, sanitation, lethality and stabilization requirements, supervisory reviews, daily inspection, food safety assessments, effective verification sampling programs and effective implementation of HACCP, Standard Sanitation Operating Procedures (SSOP), and pre-requisite programs to destroy pathogens of concern. In a series of subsequent communications between FSIS and MOH, nine of the eleven issues were resolved, contingent upon verification during the on-site audit. Two issues related to daily inspection and supervisory reviews at establishments exporting products to the United States were still pending and were to be verified during the audit. FSIS notified Italy of its decision to conduct an on-site audit of Italy's meat inspection system from July 7 to 18, 2014, to verify it proffered corrective actions identified above.

II. INTRODUCTION

This audit was conducted pursuant to the specific provisions of the United States laws (United States Code, U.S.C.), regulations (Code of Federal Regulations, CFR) and European Commission's (EC) Regulations, in particular:

- Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
- Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901-1906), and
- Federal Meat Inspection Regulations (9 CFR Parts 301 to end)
- Regulation (EC) No. 852/2004
- Regulation (EC) No. 853/2004
- Regulation (EC) No. 854/2004
- Regulation (EC) No. 2073/2005
- Council Directive 96/22/EC
- Council Directive 96/23/EC
- Council Directive 2004/41/EC

The audit standards applied included all applicable legislation and procedures originally determined by FSIS to be equivalent as part of the initial equivalence process for Italy and any subsequent equivalence determinations that have been made under provisions of the Sanitary/Phytosanitary Agreement and the European Community/United States Veterinary Equivalence Agreement were also applied.

III. AUDIT GOAL AND OBJECTIVES

FSIS' main objective of the audit was to verify how the MOH implemented the control measures proposed during the FSIS-MOH technical meeting held in Washington, D.C. on November 25-26, 2013, and whether the MOH had effectively addressed each of the eleven concerns pertaining to its RTE program as it applies to dry cured ham products. As stated above, these concerns were communicated to MOH in a letter dated January 13, 2014.

Additional verification activities focused on determining whether Italy's overall food safety inspection system governing meat products continues to be equivalent to that of the United States, with the ability to produce and export products that are safe, unadulterated, wholesome, and properly labeled.

FSIS auditors reviewed available documentation, conducted interviews and gathered objective evidence during the audit at the CCA's headquarter in Rome, a regional office in Emilia Romagna, the Parma LHU, and at seven local inspection offices located in slaughter and processing establishments that were audited

The audit focused on six equivalence components to determine whether each component continues to be equivalent to that of the United States: (1) Government Oversight, (2) SAFSR, (3) Sanitation, (4) HACCP Systems, (5) Chemical Residue Control Programs, and (6) Microbiological Testing Programs. FSIS auditors also verified that Italy's RTE program and government control measures implemented in response to the eleven concerns raised by FSIS in the January 13, 2014, letter to MOH, were effective in supporting the CCA's ability to meet FSIS' equivalence criteria pertaining to FSIS import regulations (9 CFR Part 327.2) and its effectiveness in preventing additional United States-POE violations in RTE products exported to the United States. Two slaughter establishments and five processing establishments eligible to export to the United States were audited.

IV. AUDIT METHODOLOGY

FSIS utilized its established four-phase process to conduct this equivalence verification audit: planning, execution (on-site), evaluation, and feedback. Each phase is described below.

The first phase involves document and data review and analysis of previous audit findings and other available information. Therefore, prior to conducting the July 2014 on-site audit, FSIS examined the CCA's MOH performance within the six equivalence components, data on exported product types and volumes, available United States-POE testing results, and other data recently collected from MOH.

The FSIS auditors reviewed information obtained directly from the CCA through the SRT, outlining the structure of the inspection system and identifying any significant changes that have occurred recently. FSIS had requested that Italy update its RTE and HACCP portions of the SRT and submit any required documents necessary to oversee the RTE program by the MOH. Prior to the July 2014 audit, a team of

FSIS reviewers evaluated Italy's RTE program and assessed the CCA controls and its ability to maintain equivalence regarding the production of RTE products. The review team concluded that the MOH met the equivalence criteria on nine of the eleven issues that were raised in the January 13, 2014, letter to the MOH, contingent upon verification during the on-site audit. They also found that the MOH did not meet the equivalence criteria for daily inspection and supervisory reviews, respectively, since the MOH did not clearly document how these activities were being conducted. Documentation from the MOH on conducting daily inspections and periodic supervisory reviews were also to be verified during the on-site audit. FSIS made the following determinations:

- FSIS should conduct an on-site verification audit of Italy's inspection system as soon as possible. The on-site audit will provide an opportunity to verify the effectiveness of the control program employed by MOH.
- FSIS should continue to conduct 100 percent POE re-inspection of RTE products lots until the on-site audit determines that Italy's MOH is employing effective control measures to prevent additional United States-POE violations in RTE product exported to the United States.
- FSIS should not list any new establishments until objective evidence is gathered to suggest that Italy's MOH is meeting all the applicable equivalence criteria and other food safety requirements.
- FSIS should not close any of the cases of United States-POE violations due to the presence of *Lm* in Italian dry cured ham product. FSIS should review updated Italian response and take appropriate action based on the review of Italy's response of all United States-POE violations and proffered corrective action plan.

The second phase was an on-site audit or execution phase. FSIS conducted this on-site audit to verify the CCA's oversight activities as they relate to each equivalence component. The auditors gathered data on all six components through document reviews, interviews, observations, and site visits. The FSIS auditors were accompanied throughout the audit by representatives from the CCA, Regional offices, and Local Health Unit (LHU).

The FSIS auditor reviewed management, supervision, and administrative functions at the CCA headquarters, one regional office, one LHU, and local inspection offices located at each audited establishment to determine whether the national system of inspection, verification, and enforcement is being implemented as required to maintain equivalence. The auditors verified that the CCA has implemented the following three new documents as part of its commitment to FSIS to strengthen its verification controls and oversight over the United States-eligible establishments:

DGISAN 1122-P-17/01/2014 -This ministerial note is on the subject of the government surveillance testing plan for *Listeria monocytogenes* and *Salmonella spp.* The requirements of this ministerial note are already in effect in all United States-eligible establishments. The sampling plan applied to an establishment is based on the plant's production process and the associated risk classification. In this ministerial note, the MOH has provided the information on sampling and testing of food contact surfaces and non-contact surfaces and product. This plan includes the monitoring of products and processing environment (food contact and non-food contact surfaces) for the presence of *Lm* that is similar to information in FSIS Directive 10,240.5 (Verification Procedures for Enforcement, Investigations and Analysis Officers (EIAOs) for the *Lm* Regulation and Routine Risk-Based *Lm* (RLm) Sampling Program - Revision 3.) As indicated in DGISAN 1122-P-17/01/2014, at least 25 percent of establishments eligible to export to the United States are audited annually. In 2014, 33 percent were

audited. As noted in this document, all deboning and slicing plants, as well as all plants with internal deboning or slicing facilities, are producing RTE products under Alternative 3, deli (sanitation only). Under the *Listeria* rule (9 CFR Part 430), products produced under Alternative 3 and the processing environment are likely to be subject to more frequent verification testing by FSIS than products and the processing environment when Alternative 1 or 2 is employed. In addition to meeting the sanitation requirements, establishments that produce deli or hotdog products under Alternative 3 must verify that the corrective actions taken after an initial positive test for *Lm* or its indicator organisms on a food contact surface (FCS) in the post-lethality processing environment are effective. This verification is achieved by performing follow-up testing for *Lm* or an indicator organism after the FCS positive test that includes a targeted test of the specific site on the FCS that is the most likely the source of contamination and additional tests on the surrounding FCS area.

If follow-up testing yields a second positive result, products that may be contaminated must be sampled using a sampling method and frequency that will provide a level of statistical confidence that will ensure that lots are not adulterated, and the sampled lots must be held by the establishment until test results are received. An establishment in Alternative 3 that produces deli meat or hotdog products will be subject to more frequent FSIS verification testing than one that does not produce such products because deli and hotdog products were ranked as higher risks for *Lm* contamination in the 2003 Food and Drug Administration/FSIS risk assessment.

On February 3, 2014, the MOH issued circular 2731_P_02_03_2014 to be effective within 60 days of issuance. The 2731_P_02_03_2014, titled “*Internal self-monitoring and official monitoring in the establishments listed among the Italian establishments eligible to export meat products to the United States of America and surveillance plan for the detection of Listeria monocytogenes and Salmonella spp. in pork products to be exported to the United States of America – Rev 0,*” outlines the requirements for establishments’ sampling plans. Additionally, the document outlines the official surveillance testing that will be done to verify the efficacy of RTE programs at United States-eligible establishments. The document has been developed in line with FSIS’ *Lm* Compliance Guideline (*FSIS Compliance Guideline: Controlling Listeria monocytogenes in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products, published in January 2014*). During the onsite audit, the auditors verified the implementation of this document by both the LHU and establishments. Sampling plans and the outcome of the sampling activity were also verified. The auditors further verified that the CCA, in accordance with the DGISAN note 2731_P_02_03_2014 (issued on February 3, 2014), elevated the frequency of CCA audits to 25 percent from the previous 10 percent of establishments audited.

The MOH issued the ministerial note DGISAN 26639 30_6_14 as indicated to FSIS in response to addressing the issues in the January 13, 2014, letter. This note went into effect for immediate implementation on June 30, 2014. This comprehensive guidance on official controls to be enforced in establishments eligible to export meat products to the United States requires that United States-exporting establishments producing post lethality exposed product comply with the provisions of the regulations in 9 CFR Parts 416, 417, and 430.

The third phase is an evaluation of all data collected on-site to determine whether the CCA’s performance is consistent with the information provided to FSIS in the SRT and other submitted documents.

The final phase is the feedback phase that begins with providing the CCA a draft audit report with an opportunity for comment. After reviewing the CCA's comments and responses to all findings, FSIS will prepare a final report.

V. COMPONENT ONE: GOVERNMENT OVERSIGHT

The first of the six equivalence components reviewed was Government Oversight. The FSIS import eligibility requirements state that an equivalent foreign inspection system must be designed and administered by the national government of the foreign country with standards equivalent to those of the United States' meat inspection system. The evaluation of this component included a review of documentation submitted by the CCA as support for the responses and corrective actions, as well as on-site record reviews, interviews, and observations made by the FSIS auditors at government offices and in the audited establishment.

The CCA has revised the manner in which supervisory reviews are conducted and outlined these changes in the ministerial circular DGISAN 26639 30_6_14. During these supervisory visits to the establishments, in addition to the review of SPS, SSOP, HACCP, and sampling related documents, product samples are also collected and tested for *Lm* and *Salmonella*, and food contact and non-food contact surface samples are also collected and tested for *Lm*. All reports of supervisory reviews and official sampling records are uploaded into SINVSA. Supervisors and veterinarians at the establishments are rotated once every 5 years.

There is daily inspection at the establishments, and an inspector is always present when the establishment is producing products meant for United States export. The establishment is expected to notify the LHU at least 3 days in advance, before producing products for the United States export, to ensure an inspector will be present during the processing of products meant to be exported to the United States. A list of the daily functions of the inspector is outlined in the DGISAN 26639 30_6_14, and it includes at least one verification activity for SPS, SSOP, and HACCP each day.

While verifying government oversight and verification procedures that the CCA had put in place to prevent future contamination of dry cured ham with *Listeria monocytogenes*, the FSIS auditors focused on the implementation of instructions contained in three Ministerial circulars (discussed in the next component) issued in early 2014 and one in late June 2014. Although, through these circulars, the Ministry and its other inspection components implemented new measures to address FSIS concerns identified in the letter of January 13, 2014, the auditors observed weaknesses in the delivery of oversight and supervisory reviews as evident from the concerns noted below:

- At the two slaughter and five processing establishments audited, the auditors reviewed the periodic supervisory reviews. Based on the extent and nature of the findings the FSIS auditors conclude that these reviews are not being conducted in accordance with the instruction provided in recently issued ministerial circulars: DGISAN 26639_30_6_14 and DGISAN 2731_P_02_03_2014.
- In one slaughter establishment, during sanitation verification, the FSIS auditor observed that, in the hot boning room, pork feet with residual hair tufts and extraneous material attached were being removed on a conveyor belt moving across the boning room past a point where meat was being cut and boned. This situation poses an insanitary condition and creates a potential for direct product contamination with the extraneous material on the feet. The establishment

corrected the situation by removing the pork hind-feet at the carcasses' point of entry in the hot deboning room. Additionally, a new sterilizer was placed at this point for employee to sanitize apron and equipment, to maintain sanitary conditions at all time.

The FSIS auditors reviewed the official legislation, official circulars, and official instructions, which provided regulatory authority by the CCA for microbiology testing programs. Controls were in place to grant the Regional and LHU offices the regulatory authority to enforce microbiological testing program requirements. One Regional office and one LHU were visited to determine whether the Regions and LHUs are maintaining adequate government oversight at the United States-certified establishments in the implementation of the CCA's food inspection system microbiological sampling and testing program requirements. In addition, five processing and two slaughter establishments were audited. The FSIS auditors reviewed the food safety programs of the establishments and records maintained by the LHUs, which had regulatory oversight over these establishments. In addition, one laboratory was audited.

In reviewing the CCA's program to control *Lm* and *Salmonella spp.* in RTE products, the auditors noted that:

- The CCA had not demonstrated how it provides guidance to establishments on attaining at least a 5-Log₁₀ reduction of *Salmonella* in dried cured products to ensure safety and absence of *Salmonella* in RTE products. The CCA provided general guidance on the use of parameters in scientific studies and challenge studies to support lethality.

The CCA's national plan of monitoring for *Listeria monocytogenes* and *Salmonella spp.* (RTE PROD_RAND and RTE PROD_RISK) also serves to ascertain that the lethality step has been adequately reached, as stated in the DGISAN 2731_P_02_03_2014 note issued February 3, 2014. The CCA conducts end product testing for *Salmonella* to verify that lethality and stabilization requirements are met. FSIS considers that a 5-Log₁₀ reduction of *Salmonella* in RTE meat products would produce a product safe for consumption. Lethality treatments can be supported by challenge studies indicating the specific log reduction achieved by the process, and why it results in a similar level of safety as a 5-Log₁₀ reduction of *Salmonella*. The CCA indicated it was updating the 2731_P_02_03_2014 note issued February 3, 2014, with information requiring that establishments producing both post lethality exposed and non-post lethality RTE products meet a lethality of at least 5-Log₁₀ reduction of *Salmonella*. MOH plans to issue the updated circular before the end of 2014.

The FSIS auditor's analysis and on-site verification activities indicate that the CCA continues to maintain equivalence and is operating at an "adequate" level for this component. However, as mentioned earlier, FSIS has concerns in the areas the CCA's oversight controls over Sanitation, HACCP and Microbiological Testing Program.

VI. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS auditors reviewed was Statutory Authority and Food Safety Regulations. The inspection system must provide an appropriate regulatory framework to demonstrate equivalence with FSIS' requirements, including but not limited to HACCP, sanitation, chemical residue and microbiological sampling, humane handling, slaughter, ante-mortem inspection, post-mortem inspection, establishment construction, facilities, equipment, daily inspection, and periodic supervisory visits to the establishments certified eligible to export to the United States. The evaluation

of this component included an analysis of information provided by the CCA in the SRT, interviews, and observations during the on-site portion of the audit.

The legislative decree 193/2007 appointed the MOH, the Regions and autonomous provinces of Trento and Bolzano, and LHU as competent authorities for food safety in order to implement Regulations (EC) No 852/2004, 853/2004, 854/2004 and 882/2004. The responsibility of animal health, food and feed safety, animal welfare, risk assessment in the food chain, and guidance to producers and consumers resides within the Department of Veterinary Public Health, Nutrition, and Food Safety (DVPHNFD). The DVPHNFD is one of the four Departments under the MOH. The DVPHNFD is further divided into three branches, which include two General Directorates. Of the two General Directorates, the General Directorate for Food Safety and Nutrition (DGISAN) is the entity that is predominantly responsible for the enforcement of those requirements that are of interest to FSIS. This General Directorate provides oversight to nine offices addressing products of animal origin and the export of food products. The office IX (Foodstuffs Export) is responsible for the export of meat products to the United States.

The ministerial circular DGISAN 26639_30_6_14, that came into effect first week of July 2014. The circular which distinctly outlines the enhanced oversight functions aimed at correcting concerns identified by FSIS. It develops tools to ensure the implementation of United States requirements and issues specific to *Listeria* control in RTE product. The circular delineates those United States requirements that go beyond EU legislation and how to verify compliance in the establishment eligible to export to the United States. Some of the audit findings noted in the government oversight indicates that requirement of the circular are not being implemented as described.

The ministry develops guidance documents as necessary. The MOH recently issued three documents with intent to strengthen and improve coordination among the three levels of inspection. Other functions critical to the delivery of the effective inspection system include official controls, microbiological sampling and testing, and development and delivery of training, to name few. In the context of United States export, the following functions are managed at the central level:

- Managing the list of establishments eligible to export to the United States;
- Suspending/revoking eligibility of a noncompliant establishments to export to the United States when recommended by Local Health Unit and Regional Directorate;
- Monitoring and ensuring that the official control data and the sampling-related information is being uploaded on the National Veterinary Information System for Food Safety information system (SINVSA).

In 19 regions and 2 autonomous provinces in Italy, the responsibility for animal health, food of animal origin, and feed safety and animal welfare is assigned to the Regional Veterinary Services (RVS), which are part of the Regional Public Health Service (RPHS). In one of the two autonomous provinces, veterinary service is part of the Provincial Agriculture Authority. The RPHS has a coordination function, while implementation of controls is carried out at local level by inspectors employed at LHU.

Pertaining to the role of RVS, the ministerial note DGISAN 26639_30_6_14 outlined those specific functions delivered at the RPHS in relation to the oversight at the United States-eligible establishments. These include:

- Acting as conduit between the MOH and LHU to ensure the government controls are in place as intended and the establishments are in compliance with the United States requirements;

- Playing a pivotal role being a part of multilevel “Task Force” and other operational working groups organized by the of the MOH;
- Providing the oversight in their respective regions and ensuring the receipt of MOH circulars, and regulations including FSIS requirements; and
- Collaborating with MOH to organize training.

The operational implementation of controls in the area of public health and food derived from an animal is handled by 146 LHUs in Italy. The LHUs are local government bodies that are responsible at the local level for the organization and management of all public health services. The LHUs are equipped with a high degree of managerial, administrative, financial and technical autonomy and are organized in sanitary districts within the Department of Prevention (DP). The DP branches into two programs, one of which is Food Hygiene and Nutrition Service and the other is Local Veterinary Services. The inspection activities are shared between the two services. For purposes of this report, inspection at the local level will be identified as Local Health Unit and the acronym LHU is being used elsewhere in the report. It is the LHU that provides the inspection staff as well as the immediate supervisory staff in the United States-eligible establishments. The inspection staffs in these establishments are local government employees and are paid from local government funds.

The ministerial note DGISAN 26639_30_6_14 identifies some crucial functions conducted by the inspection staff employed at this level of inspection. The main activities include:

- Performing the official control activities and verifying the compliance of establishments eligible to export to the United States with all applicable requirements;
- Implementing sampling plan as appropriate. Testing for *Salmonella* performance standards at slaughtering establishments;
- Implementing a sampling program under RTE_PROD, RTE_RISK, *RLm*, and IVT testing programs at establishments; and
- Conducting periodic supervisory visits to all United States -eligible establishments at the frequencies dictated by the MOH. LHUs’ supervisory chain of command ensures that the official veterinarian assigned to a United States-eligible establishment has knowledge, training, skills, and ability to enforce United States’ requirements.

The auditors noted that the collaboration between the three levels has increased in recent months, particularly after the FSIS-MOH technical meeting. An example of such collaboration is establishment of the Task Force. The MOH utilizes senior experienced staff from each level to form the Task Force. The functions and responsibility of the Task Force are analogues to FSIS-Enforcement, Investigation, and Analysis Officer. The auditors reviewed the report generated by the Task Force at the United States-eligible establishments.

Prior to the FSIS audit, the CCA organized a training course in accordance with the MOH proposed commitment in a February 12, 2014, to FSIS. The participation of officials from the CCA, Regions, and LHUs was mandatory. At least one representative from each establishment exporting to the United States was also in attendance. The training covered topics such as management of *Listeria* in the food processing establishment, management of positive results, and performance of investigative sampling. The auditors reviewed the presentation and other materials to confirm that the MOH delivered the

training in accordance with the commitment made in the above-mentioned letter. The training for the inspection staff is to be completed by the end of 2014.

The auditors and the FSIS review team mentioned above also assessed Italy's microbiological testing program. More on Italy's microbiological testing program is covered in the microbiological testing component of the report. During the on-site audit, the auditors conducted interviews at the CCA, Region, and local inspection offices to verify that the establishments that produce cured ham product or sliced RTE meat products are all producing products under Alternative 3, deli, and had implemented the requirements for the alternative.

The auditor verified that the livestock brought to slaughter are receiving ante-mortem examination in accordance with the requirements in Regulation (EC) 854/2004. The auditor further verified that in-plant inspection personnel conduct ante-mortem inspection on the day of slaughter by reviewing the receiving logs and the pen cards. The inspection personnel observed all animals at rest and in motion in designated holding pens prior to slaughter in order to determine whether they are fit for slaughter and for human food purposes. The designated holding pens for sick or suspect animals were maintained for further examination of these animals as needed.

The auditor confirmed that the CCA applies relevant provisions of EU Directive 93/119 and Regulations EC 854/2004 and 1099/2009 pertaining to humane handling and slaughtering legislation. The MOH has provided the ministerial note DGSAN/IX/34788/P on national guidance regarding the requirement of ante-mortem and post-mortem examination. The national guidance document provides information on how LHU needs to verify the implementation of EU regulations and ensure that standards are being maintained.

Regarding the approval procedures for the new certification, the MOH has issued guidance in the circular DGVA/IX/26665 of July 19, 2006, for establishments wishing to be approved for United States export. During the initial audit of the facility requesting approval, an LHU supervisor makes an on-site visit to verify that the applying establishment meets the importing country's requirement. Upon satisfactory outcome of the audit of a requesting establishment, recommendation is made to the Regional Veterinarian who in turn forwards the request to MOH for final approval. Requests for slaughter establishments are also verified for the establishments' ability to comply with applicable humane handling and slaughter regulations.

With regards to post-mortem requirements, the auditor verified that LHU-hired inspectors were conducting post-mortem inspection on each carcass and viscera in accordance with the regulatory requirement specified in relevant Regulations (EC) 854/2004. The ministry has issued its national guidance for slaughter establishments on application of proper procedure to facilitate ante-mortem and post-mortem examination by the LHU inspectors. The guidance document provides instructions to inspectors on how to conduct ante-mortem and post-mortem examination.

The various frequencies, scope of periodic supervisory visits and type of additional supervisions -- other than delivered through LHU -- have been discussed in recently issued ministerial circulars: DGISAN 26639_30_6_14 and DGISAN 2731_P_02_03_2014. The minimum frequency of each audit type is given below:

- Every 3 months (four times a year) in the establishments that have at least one slaughtering line ;

- Every 6 months (twice a year) in all the establishments that produce processed meat products;
- Once every year in the establishments, that does not actively export to the United States, but are on the list of establishments eligible to export to the United States.

If warranted, the supervising veterinarians can increase the stated frequency as may be necessary to address issues at noncompliant establishments. The review of these circulars indicates that the CCA has increased its frequency of audits at United States-eligible establishments from a previously enforced 10 percent to at least 25 percent annually. In 2014, this frequency was increased to 33 percent. During these supervisory visits to the establishments, in addition to the review of SPS, SSOP, HACCP, and sampling related documents, product samples are also collected and tested for *Lm* and *Salmonella*, and food contact and non-food contact surface samples are also collected and tested for *Lm*. This decision to increase the frequency of supervisory visits was proposed to FSIS as a corrective action after a string of United States-POE violations in which dry cured ham product imported from Italy tested positive for the presence of *Lm*. The CCA's audit provides the LHU auditor or Task Force Team the opportunity to collect additional samples for analysis.

On each visit, these reviews routinely verify (where appropriate) the following: ante-mortem inspection; post-mortem inspection; official controls by the national government over establishment construction, facilities, and equipment; direct and continuous official supervision of slaughtering and preparation of product; complete separation of establishments; requirements for sanitation; official controls over condemned material; and HACCP system. The attachments in annex 4 of DGISAN 2731_P_02_03_2014 are samples of all the forms used by inspectors, including those used by supervisors or the CCA. The sample forms reviewed include: Record of Periodic Inspection Record, Record of Non-Compliance form and Instructions for completing each record form. Establishments failing official testing for *Lm/Salmonella* in RTE are subjected to investigative audit by the Task Force team. The reports on these supervisory reviews and investigative sampling are uploaded in SINVSA, and CCA has access to and can review the reports through this system.

One important feature of the ministerial circulars: DGISAN 26639_30_6_14 is the audit conducted by the Task Force are designed after Food Safety Assessment (FSA) type of evaluation of the food safety system of the establishment. FSA conducted at by FSIS' EIAO requires a five weeks comprehensive training in multi-disciplinary food safety based curriculum prior to conducting any such assessment. The FSIS auditors however noted that Task Force did not acquire such training.

Through record reviews of establishments' internal control and the verification of inspection records, the auditors verified the official controls exercised over condemned material at all establishments intending to export to the United States. Italy has implemented the specific provisions of Regulations (EC) 1774/02, 852/04, and 853/04 on requirements concerning the official control on condemned material.

The FSIS auditor also assessed post-mortem inspection examinations through on-site record reviews, interviews, and observations of in-plant inspection personnel performing post-mortem examinations. The FSIS auditor observed and verified that proper presentation, identification, examination, and disposition of carcasses and parts are being implemented and concluded that in-plant inspection personnel are adequately trained in performing their on-line post-mortem inspection duties. The FSIS auditor observed the performance of the inspection personnel examining the heads, viscera, and carcasses in which the proper incision, observation, and palpation of required organs and lymph nodes

are made in accordance with EU regulations that have been deemed equivalent by FSIS. The design of the post-mortem inspection stations, including proper lighting, meets regulatory requirements.

The FSIS auditor also observed the functions of the Official Veterinarian (OV) and off line inspectors who conduct daily inspection verification activities. These daily verification activities include direct observation and review of establishment records of HACCP, SSOP, and Sanitation Performance Standards (SPS) activities, generic *E. coli/Enterobacteriaceae* sampling techniques, and *Salmonella* sampling and testing for the Pathogen Reduction Program. In RTE establishments, the OV also oversees the collection and submission of samples to the laboratory for *Lm* and *Salmonella* analysis and reviews the results as part of daily verification activity. Samples may be collected by a trained technician, who is part of the LHU. The sampling results are documented in the “Control Record Form,” and are in the LHU’s electronic record system, SINCER (Information System for Food Safety), for review

Lastly, during the audit of Headquarters, region, LHU and local inspection offices the auditors verified that the CCA has system in place whereby new FSIS requirements (including new legislation, regulation, guideline, etc.) are disseminated to the field through Official Ministerial Notes. Headquarters sends these Ministerial Notes to the Regional officials and the latter provide them to the LHUs. Several examples were demonstrated, including the distribution of information about United States-POE violations. Inspectors frequently access USDA-FSIS homepage to stay abreast with the new happenings in the realm of food safety, and in particularly within FSIS.

Based on the auditors’ review of the aforementioned circulars, they determined that the documents provide guidance to industry and inspection officials similar to FSIS’ Compliance Guidelines for Controlling *Lm* in Post-lethality Exposed RTE Meat and Poultry Product, FSIS’ Directives 10,300.1 (*Intensified Verification Testing (IVT) Protocol for Sampling of Product, Food Contact Surfaces and Environmental Surfaces for Listeria monocytogenes - Revision 1*) and 10,240.4 (*Verification Activities for the Listeria monocytogenes (Lm) Regulation and the Ready-to-Eat (RTE) Sampling Program - Revision 3*). The auditors further determined that if the information contained in the documents was implemented and verified as intended, Italy should be able to overcome difficulties in controlling and preventing the presence of *Lm* in dry cured ham products. The CCA has implemented a program for managing *Lm* strains isolated during their surveillance programs. *Lm* isolates are sent to the Experimental Zooprophyllactic Institute (IZS), where the genetic profile of the isolate is determined using pulsed-field gel electrophoresis (PFGE) analysis. PFGE information is shared with the LUH and establishments, and is used as a tool in identifying niches in the production environment, harborage, and cross-contamination in RTE establishments. Other salient features of this circular include:

- Recommended Frequencies for Cleaning and Sanitizing Procedures;
- Correct use of Sanitizers in alternation, and in accordance with concentrations permissible in Part 178, section 178.1010 of 21 CFR;
- Operational Sanitation Procedures to Prevent Cross Contamination between Raw and RTE Post-Lethality Environment;
- Sanitation during Construction;
- Intensified cleaning and sanitation following a “Positive *Listeria* Sample” and
- Evaluation of the Effectiveness of the Sanitation Program.

The auditor's assessment of this component indicate, that the CCA has made significant changes in the inspection system by issuing four circulars at the central level to address the concerns identified in the FSIS letter of January 13, 2014. However, based on nature and extent of the finding in this and other component auditors indicate that implementation of these programs require strong oversight and further training to the supervisory chain of command and the inspectors assigned to the United States- certified establishment. One of the proffered corrective actions was to provide each inspector training by the end of year 2014. As proffered corrective action to the audit findings the CCA has committed to amend its DGISAN 2731_P_02_03_2014 by the end of this year.

Based on the overall assessment of this component the auditors conclude that the CCA continues to maintain equivalence and is operating at an "adequate" level for this component.

VII. COMPONENT THREE: SANITATION

The third of the six equivalence components that the FSIS auditors reviewed was Sanitation. An equivalent inspection system must provide requirements for all areas of sanitation, sanitary handling of products, and SSOP. Prior to the on-site audit, the auditors reviewed documentation provided in the SRT by the CCA. The document or references found in the Sanitation component of the SRT included references to EU regulations, and ministerial Circulars concerning compliance with FSIS' criteria for sanitation.

Italy applies FSIS' sanitation requirements in all United States-certified establishments without any prejudice to compliance with EU regulations. In order to implement the United States specific sanitation measures, the CCA issued ministerial circular DGISAN 26639 30_6_14 titled "Official control in the establishments listed among the Italian establishments eligible to export meat products to the USA."

The attachment A of the aforementioned circular is a "Manual on Official Controls" for inspectors assigned to all United States-certified establishments on how to attain compliance of the establishments with the United States' regulations. Per this circular, the FSIS' Sanitation and HACCP requirements as specified in 9 CFR Parts 416 and 417, respectively, meet the sanitation design requirements in their entirety. Section 3 of the circular is a guide on how to use the manual, particularly during on-site inspection in the processing establishments. Section 4 of the aforesaid circular describes the criteria for the assessment of compliance and the management of noncompliance. FSIS regulatory requirements for SPS and the applicable corresponding CCA's criteria for official controls are compared side by side in tabulated format in section 5.1 of the document. The CCA's criteria for official controls regarding SSOP and HACCP can be found in sections 5.2 and 5.3, respectively. The attachment B of this circular provides all those procedural forms that are used to document the application of the criteria and compliance thereof.

With respect to sanitation programs in RTE establishments processing product in the post lethality environment, the CCA has provided additional guidance in Annex 2 of DGISAN 2731_P_02_03_2014 titled "*Internal self-monitoring and official monitoring in the establishments listed among the Italian establishments eligible to export meat products to the United States of America and surveillance plan for the detection of L. monocytogenes and Salmonella spp. in pork products to be exported to the United States of America – Rev 0.*" The guidance expounds on the effective application of 9 CFR Part 416 with respect to *Listeria* control in the RTE establishments where the products are exposed to post lethality

environment. Among the requirements included in the document, the CCA emphasized that all RTE establishments must maintain sanitation in their environment according to 9 CFR Part 416. Establishments are required to verify sanitation by testing food contact surfaces for *Lm* or indicator organisms, and also develop a surveillance program for *Lm*, which must be included in the establishment's HACCP, SSOP, or Prerequisite Program. If a product or food contact surface tests positive for *Lm*, the product is considered adulterated and must be reprocessed or destroyed. The guidance also provides information on additional steps to be taken when product, food contact surface, or non-food contact surface sample test positive for *Lm* or indicator organism.

The circular DGISAN 2731_P_02_03_2014 also establishes the definition and composition of a "Production Lot" in the context of when product tests positive for the presence of pathogens. As stated in the document and for all practical purposes, a production lot is identified as the quantity of product processed between two complete clean-up cycles (clean-up to clean-up). Thus, a production lot is the quantity of product that is to be taken into consideration in the event of either a product or a food contact surface testing positive for *Lm*. If a product or food contact surface is identified as positive for *Lm* and the implicated Product Lot has entered commerce, the Lot is subject to a recall. The auditors verified this definition of a lot during the on-site audit.

During the on-site visit to the two slaughter and five processing establishments audited, the FSIS auditors conducted interviews with inspection officials at all sectors audited, reviewed sanitation plans and records related to the design and implementation of sanitation programs in accordance with the MOH issued circulars. The auditors confirmed that the written procedures related to sanitation were developed and were implemented in pursuant to the circulars discussed above.

The auditors' verification of the sanitation component also included actual pre-operational verification at two of the five processing establishments and one of the two slaughter establishments audited. With some exceptions as noted below, the auditors observed that the official veterinarians were conducting these verification and other hands-on activities and were following the procedures established in the circulars referenced above. The in-plant inspection personnel's hands-on verification procedures began after the establishment personnel conducted their pre-operational sanitation checks and determined that the facility is ready for in-plant inspector pre-operational sanitation verification activities.

At each establishment audited, the FSIS auditors followed and observed the OV conducting verification of operational sanitation procedures. These verification activities included direct observation of operations and review of the establishments' associated records. Reports of the supervisory reviews were examined in all audited establishments. The FSIS auditors also reviewed the establishment's sanitation monitoring and corresponding inspection verification records. With some exceptions noted below, the auditors noted that the inspection and establishment records mirrored the actual sanitary conditions of the establishment. In order to correlate the audit findings with the supervisory reviews, the auditors evaluated these reviews for the same period as selected for inspectors' and establishment's record. With some exceptions as noted below, the audited establishment maintained sanitation records sufficient to document the implementation and monitoring of the SSOPs and any corrective actions taken. The establishments' employees responsible for the implementation and monitoring of the SSOP procedures correctly authenticated these records with initials or signatures and the date.

The FSIS auditors reported the following findings concerning the CCA's ability to exercise official controls over some aspects of SPS and SSOP implementation in the audited establishments:

- In one processing establishment, the gasket on the doors of a couple of cooking ovens were deteriorating and detaching from the frame. This condition permits heat to escape from the oven and can result in under processing of product. The CCA verified the establishment's corrective actions and forwarded pictures to the FSIS auditors as evidence of implementing the corrective action.
- In one of the five processing establishments audited, the employees in the deboning area were not wearing gloves. Product was being handled with bare hands. Handling of products with bare hands is a potential source of cross contamination. The CCA did indicate during the exit meeting that it had verbally communicated with establishments on the requirement to wear gloves when handling RTE products and was updating the 2731_P_02_03_2014 circular to include information on mandatory use of gloves when handling RTE products.
- In four of the five processing establishments audited, the auditors observed during operational sanitation in the deboning area that paper towels were being used to clean the food contact surface after the second application of sanitizer on the FCS, while one establishment allowed the sanitizer to evaporate from the surface. The use of paper towels after sanitizing the surface could be a potential source of cross contamination. The CCA indicated during the exit meeting that it was updating the 2731_P_02_03_2014 circular to include information on the appropriate use of paper towels to clean food contact surfaces during hourly sanitation.
- In one slaughter establishment, the auditor noted that the harvested offal were not being chilled and washed immediately. The establishment did not have any procedures or documentation to monitor the time and temperature for chilling and sanitary handling of the offal. The establishment implemented immediate corrective actions, by updating the procedure and providing specific reference to the time by which harvests shall be chilled to a temperature of 3°C (37.4°F) within an hour of harvesting or -18°C (-0.4°F) for immediate freezing. The CCA provided evidence of compliance.
- In one establishment, there was continuous operation which did not allow employees to thoroughly clean the kill area until the end of the shift. As a result, blood and slaughter waste was accumulating on the kill floor, thereby creating insanitary conditions. The corrective action implemented by the establishment included a specific operative instruction displayed in the working areas instructing workers responsible for sanitation in the kill area that floors shall be cleaned hourly or even more frequently as necessary. The CCA verified the implementation of corrective action and provided evidence to the FSIS auditor.
- During the pre-operational sanitation verification in one establishment, the auditor observed that the scalding had clumps of hair and slimy material clinging to some sections of the pipes. The veterinarian in-charge rejected the scalding and required immediate corrective action prior to the start of kill operation. The veterinarian in-charge provided the evidence of corrective action and future cleaning procedures to prevent recurrence of the conditions.
- In one slaughter establishment, foreign material was observed adhered on the jars containing metal seals to attach on hams. This observation creates the potential for indirect contamination of the ham. The official veterinarian rejected the jars and provided evidence that the establishment had replaced the old jars with new ones.

The FSIS auditors did not observe any direct evidence of product contamination related to these findings. As indicated above, all findings related to the sanitation component were addressed

immediately and in some instances, written evidence was provided to the auditors while the audit of Italy's meat inspection system was still in progress. The CCA committed to updating the DGISAN 2731-P circular issued on February 3, 2014, by the end of 2014, to include information requiring the use of gloves when handling RTE products, and also the appropriate use of paper towels and sanitizer during the hourly cleaning of food contact surfaces during the processing of RTE products. The FSIS auditors determined that the CCA's inspection system provides requirements similar to those of the FSIS system for sanitary handling of products, as well as development and implementation of SSOP.

Considering the nature and extent of the findings in the Sanitation component the auditors determined that the CCA has to strengthen its oversight and the supervisory reviews over sanitation. One of the CCA corrective actions outlined in their letter dated February 12, 2014, committed to provide refresher training for FSIS requirements to all personnel by the end of year 2014. FSIS expects that the CCA complete the training to supervisors and the inspectors assigned to the United States-certified establishments. As proffered corrective action to the audit findings the CCA has committed to amend its DGISAN 2731_P_02_03_2014 by the end of this year.

The on-site verification activities indicate that the CCA continues to maintain equivalence and is operating at an "adequate" level for this component. The FSIS auditors noted multiple deficiencies that require corrective actions. The CCA proffered during the on-site audit to complete several immediate and longer-termed corrective actions, including the reissuance of DGISAN 2731-P.

VIII. COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. The inspection system needs to require a HACCP plan or similar type of preventive control plan to maintain equivalence.

The evaluation of this component included a review and analysis of the information provided by the CCA in the updated SRT and observations during the on-site audit. The ministerial circular DGSAN/20775/P issued July 11, 2008, requires establishments exporting to the United States to develop and implement a HACCP program consistent with 9 CFR Part 417. This requirement is to be met without any prejudice to HACCP requirements stipulated in EU regulations. The most recently issued ministerial circular DGISAN 26639 30_6_14 superseded the previously implemented DGSAN/20775/P July 11, 2008.

The Paragraph D of ministerial circular DGISAN 26639 30_6_14 requires all establishments that export meat products to the United States must implement and apply:

- Sanitation Performance Standard per 9 CFR Part 416
- Standard Sanitation Operating Procedures per 9 CFR Part 416
- Hazard Analysis Critical Control Program per 9 CFR Part 417
- *Listeria monocytogenes* management procedures for RTE products per 9 CFR Part 430

The section 5.3 (attachment A) of DGISAN 26639 30_6_14 provides guidance to establishments on how to meet regulatory requirements specified in 9 CFR Part 417. The section also provides a side-by-side guidance to inspectors on how to verify each requirement of HACCP per 9 CFR Part 417. The

inspectors need to refer to FSIS Directive 5000.1, Revision 4, and follow the methodology described and applied by the United States inspection system when verifying an establishment's food safety system. The circular directs inspectors that they should be guided by FSIS Directive 5100.6, Revision 1, when conducting verification activities related to an establishment's hazard analysis.

The results of routine HACCP verification are recorded on a routine control form identified as a Control Record. The Control Record provides a pre-printed list of all the activities that must be carried out to satisfy United States' regulatory requirements in 9 CFR Parts 416 and 417. The control form has a section on verification of sampling plan and a field for inspector's notation if a noncompliance is observed during the verification activities. A noncompliance is documented on a noncompliance record. The aforesaid circular also provides the Control Form as a way to document the outcome of supervisory reviews conducted by the CCA based auditors. The CCA based audits conducted by the Task Force at the United States-certified establishments are in addition to supervisory reviews conducted by the LHU supervisors. A step-by-step guidance on the CCA's supervisory reviews and how to document them is also appended in the circular.

At the two slaughter and five processing establishments audited, the FSIS auditors verified through record reviews and observations that the in-plant inspection personnel conducted daily verification of HACCP plans in accordance with the methodology described in the above mentioned circular, regulations, and directive, which includes the evaluation of written HACCP programs, monitoring, verification, review of corrective actions, recordkeeping, and hands-on verification inspection. The in-plant daily inspection verification also included Critical Control Points (CCP) verification with results entered in in-plant inspection records.

The FSIS auditors noted that:

- In one establishment the flow chart and hazard analysis did not identify the bagging of ham. The establishment corrected the flow diagram and identified the missing step. The CCA verified the correction and provided evidence to the auditor.
- In the aforementioned establishment, the auditor determined that no hazard analysis was conducted for the Smoking, Chilling and Returns steps, as shown on the flow diagram. The establishment corrected the inaccuracies identified during the document review pertaining to HACCP system. The veterinarian in-charge verified that the finding had been accurately remedied and provided evidence to the FSIS auditor.
- The auditor also observed that the hazards associated with the cooking step are controlled through CCP with the Critical Limit established as time/temperature, but the time limit for this CCP was not identified. The establishment corrected this finding by establishing the time limit as "instantly," and the CCA verified the correction and provided evidence of the corrective action to the auditor.
- In one slaughter establishment, the HACCP plan indicates the frequency of verification of a Critical Limit at a CCP for zero tolerance as 20 carcasses. However, the review of verification record indicated that only 10 carcasses were being verified during observation. The establishment immediately corrected the verification frequency, and the CCA verified that the establishment's HACCP plan had been corrected to reflect the correct verification frequency.

The FSIS auditors determined that weak government oversight and supervisory reviews resulted in an inadequate implementation of the United States import requirements as specified in 9 CFR Part 327.2

by the inspectors at the establishments. The gaps in the inspection and verification activities might have contributed to the contaminated dry cured ham with *Listeria monocytogenes* being exported to the United States at multiple occasions. Since the MOH-FSIS technical meeting Italy has made significant changes in its inspection system including issuance of four new circulars aimed at addressing all FSIS concerns. These circulars provide a combination of instruction and guidance to inspectors and industry on how to implement procedures to achieve FSIS regulatory requirements of SSOP, HACCP and Listeria Rule as specified in 9 CFR Parts 416, 417, and 430. These circulars could be effective in preventing the product contamination provided that if implemented as planned.

Although the audit identified some significant findings related to HACCP component, the auditors' analysis and on-site verification activities including training of inspectors and updating DGISAN 2731_P_02_03_2014 determines that the CCA continues to maintain equivalence and is operating at an "adequate" level for this component.

IX. COMPONENT FIVE: CHEMICAL RESIDUES CONTROL PROGRAM

The FSIS auditors reviewed the Chemical Residues Control Programs as the fifth of the six equivalence components. The FSIS criteria for this component include the design and implementation of a program managed by the CCA that carries out effective regulatory activities to prevent chemical residue contamination of food products. To be considered equivalent to FSIS' residue control program, the CCA's program needs to include random sampling of internal organs, muscle, and fat of carcasses for chemical residues identified by the exporting countries and FSIS as potential contaminants. In addition, the CCA needs to identify the laws, regulations, or other decrees that serve as the legal authority for the implementation of the program; provide a description of its residue sampling and testing plan and the process used to design the plan; describe the actual operation of its residue plan and actions taken to deal with unsafe residues as they occur; and provide oversight of laboratory capabilities and analytical methodologies to ensure the validity and reliability of test data.

FSIS' residue experts thoroughly reviewed documentation pertaining to the design and implementation of the CCA's National Residue Monitoring Program (NRMP) prior to this audit, which is part of the European Commission's (EC) annual residue sampling plan. The in-depth review included an analysis of the 2014 residue monitoring plan as well as additional responses outlining the structure of Italy's chemical testing program provided in the SRT.

The NRMP takes into account requirements of Legislative Decree No. 158 of March 16, 2006, regarding official collection and handling of samples, in accordance with the instructions of Commission Decision n.98/179/EC of February 23, 1998. The auditors did verify that Italy's MOH has a national plan that is part of the European Commission's annual residue sampling plan. The MOH defines the species, categories, points of sampling, substances for food safety interest, test procedures according to EC's legal provisions, and indications. The plan is reviewed annually by the MOH in collaboration with the Regions, The National Reference Laboratory for Residue Analysis (NRL) and the Istituti Zooprofilattici Sperimentali – IZZSS (Experimental Animal Health Research Institutes). In addition, the plan takes into account the previous year's results in order to implement appropriate modifications and possible targeted actions. The MOH provides the plan to the Regions. The Regions forward this plan to the LHU. The LHU is responsible for implementing the plan (when to sample; what to sample; monitoring of sampling results). A veterinarian at the LHU is responsible for executing the residue plan

at the local level and the scope of responsibility is limited to his or her local health unit– e.g., heavy metals and residue in muscle samples and the number of samples to be collected annually. Residue testing is done in the laboratory in Bologna (Emilia Romagna Region) and results of the National Residue Sampling plan are sent to the MOH. The annual audit of the lab is organized and carried out by the Central Quality Unit in Brescia. The NRMP goes into effect each year on January 1st, and ends December 31st. The auditor did not conduct an on-site audit of the residue laboratories.

Based on the limited scope of the residue component audit, FSIS determined that the Chemical Residue Control Programs as described is consistent with the criteria established for this component. It includes a national program managed by the CCA. The inspection system has appropriate laws, circulars, and other decrees that serve as the legal authority for the implementation of this program. The auditors could not verify that the CCA has access to and supervises the activities of analytical laboratories that have testing capabilities to ensure the validity and reliability of test data, since on-site audit of the chemical residue laboratory was not included in the scope of the 2014 audit.

FSIS determined that the Chemical Residue Control Programs as described is consistent with the criteria established for this component. It includes a national program managed by the CCA. The inspection system has appropriate laws, circulars, and other decrees that serve as the legal authority for the implementation of this program. The CCA has access to and supervises the activities of analytical laboratories that have testing capabilities to ensure the validity and reliability of test data.

X. COMPONENT SIX: MICROBIOLOGICAL TESTING PROGRAMS

The sixth equivalence component that the FSIS auditors reviewed was Microbiological Testing Programs. This component pertains to regulatory requirement for the inspection system to have a microbiological testing program organized and administered by the national government to verify that products destined for export to the United States are safe, wholesome, and meet all equivalence criteria. Both the CCA and establishments certified for export to the United States are to employ control measures to prevent adulteration of both post-lethality exposed and non-exposed RTE products by *Lm* and *Salmonella spp.* Furthermore, the CCA must conduct verification sampling and testing for *Lm* and *Salmonella spp.* in post-lethality exposed RTE products, and testing for *Lm* on product contact surfaces, and environmental surfaces to verify that an establishment's control measures are effective in controlling these pathogens.

The auditors verified that the CCA implemented the 2014 official surveillance plan for monitoring *Listeria monocytogenes* and *Salmonella spp.* in pork products to be exported to the United States (DGISAN 1122-P issued on January 17, 2014), an outcome of the technical meeting held in Washington, DC in November 2013. This plan includes the random and risk-based sampling of all RTE products for *Listeria monocytogenes* and *Salmonella spp.* (RTE PROD_RAND and RTE PROD_RISK, respectively); and a plan that includes the monitoring of product contact surfaces and processing environment (both food contact surface and non-food contact surface) for *Lm* (*RLm*) in 33 percent of RTE establishments eligible to export to the United States annually, similar to instructions provided by FSIS in Directives 10,240.4 and 10,240.5. Results of these surveillance programs are uploaded in the SINVSA database, that the MOH has access to and is available for review in real time.

The auditors were able to verify that CCA's Note DGISAN 2731_P_02_03_2014 on "*Internal self-monitoring and official monitoring in the establishments listed among the Italian establishments eligible to export meat products to the United States of America and surveillance plan for the detection of Listeria monocytogenes (Lm) and Salmonella spp. in pork products to be exported to the United States of America – Rev 0*" has been implemented at the Regional, LHU, and establishments level.

Establishments have determined in their HACCP plans that *Lm* and *Salmonella* species are biologically hazardous pathogens that are reasonably likely to occur. The elimination of *Lm* is addressed in the establishments' SSOPs and prerequisite programs. There are written sanitation and microbiological verification sampling programs, including conditions under which products are held, pending the availability of test results (test and hold). The CCA has a structure whereby an annual monitoring plan is developed by the Regions and shared with the LHU. The LHU implements the plan that includes sampling and verification activities at the establishment, after which a report is developed and uploaded in the electronic database (SINVSA) that the CCA accesses. Training of the local inspectors and technicians on how to aseptically collect product and environmental samples is organized by the Region and LHU. Supervisory reviews occur at least twice a year and reports are uploaded into SINVSA.

Based on the guidance provided by the CCA on identifying critical operating parameter in scientific support (DGISAN 2731_P_02_03_2014), establishments are using FSIS Appendix A as guidance for supporting lethality in heat treated products and FSIS Appendix B for the cooling/stabilization requirement to control growth of spore formers such as *Staphylococcus aureus* and *Clostridium perfringens*.

The CCA's accreditation body, "Accredia," conducts annual audits of the government microbiology laboratories that conduct analysis of products destined for export to the United States. The audits focus on application of approved FSIS Microbiology Laboratory Guidebook (MLG) methods; calibration of equipment; internal audits; traceability of samples and sample analysis; traceability of data; test kits; facility maintenance; quality manual and procedures; training, and equipment calibration; general requirements for the competence of testing calibration laboratories of the International Organizations Standards (ISO 17025 requirements); and verification of corrective actions for previous findings.

The laboratory has an annual sampling plan, which anticipates the samples will be collected and analyzed annually. Verification of information collected on sample at sample receiving for traceability of sample was also performed. Samples are hand delivered to the laboratory in cooling bags by the technicians. Technicians are trained on sample collection. The temperature of samples is taken on arrival. Sample discard criteria included: samples above acceptable temperature range; delivered more than 24 hours after collection. At sample receiving and in cold room, there is a dedicated area for the United States export samples.

The FSIS method is used to analyze United States export samples (both for *Listeria* and *Salmonella*). Positive and negative controls are used when analyzing samples. Laboratory media is prepared by the central lab in Brescia and shipped weekly to the laboratory in Parma. The laboratory communicates results with LHU in real-time. The auditor visited one microbiological testing laboratory in Parma.

The CCA has an annual monitoring plan and has clearly documented procedures to be followed by the LHU when there is a positive *Lm* or *Salmonella spp.* sample from self-monitoring, official monitoring, or United States-POE violation (DGISAN 2731_P_02_03_2014). Establishments that are added to the

list of RTE establishments authorized to export to the United States during the year are subject to official sampling, starting a month after they have been included in the United States export list. The CCA implements a national monitoring plan for *Lm* and *Salmonella spp.* in RTE products at establishments certified to export RTE products to the United States. Monitoring is designed to ascertain that the lethality step during production has been adequately reached, to achieve the critical operating parameters from scientific support or challenge study.

When the LHU obtains a positive *Lm* or *Salmonella spp.* result from either product or food contact surface (from the official monitoring sampling plan, similar to FSIS *RLm*), or from the routine or risk-based monitoring programs at establishments (RTE PROD_RAND and RTE PROD_RISK sampling programs), a non-compliance report is created and the guidance provided by the MOH in circular DGISAN 02731-P-03/02/2014 is followed. The LHU also informs the establishment of this finding, and the establishment is required to address the finding by reassessing their SSOP, performing intensified sanitation and verification testing to identify the problem, and implementing corrective and preventive actions to eliminate the problem. The circular also contains information on handling a United States-POE *Lm* or *Salmonella* violation.

The LHU initiate intensified sampling at the establishment involved and informs the establishment of the intensified sampling before it is conducted, to be certain that the specific product in question will be produced when sampling is conducted. At the end of the investigation, a report is written and all data collected is uploaded in SINVSA. The results of LHU investigation must be in conformance before the establishment can continue to process products for United States export.

If the positive *Lm* or *Salmonella spp.* is as a result of self-monitoring by the establishment as required by the CCA, the plant is required to identify the source of contamination, intensify its sanitation program, and test the environment until it is able to demonstrate that the situation has returned to normal. The LHU then performs an intensified sampling, and the non-conformance can only be considered resolved after sampling results of the LUH are negative for *Lm* or *Salmonella spp.* In the case where positive results are obtained, additional corrective actions will be assigned to the establishment by the LHU. The establishment will have to demonstrate it is in conformity with CCA's requirements by obtaining negative results, after which the LHU will perform verification testing.

In the event of a positive result for either the self-or official monitoring program, production at the establishment is limited. The plant cannot ship products to the United States until all corrective and preventive actions have been implemented, the non-conformance closed by the LHU, and the report uploaded into SINVSA for the MOH's review and concurrence, as stated in DGISAN 2731_P_02_03_2014 issued February 3, 2014.

In the case of positive *Lm* result on non-food contact surfaces, the establishment is required to perform corrective actions and intensified sampling until it can demonstrate negative results on both food contact and non-food contact surfaces. During this time, the LHU would make a determination if the establishment can continue to export to the United States or if further investigation is needed.

In the case of a United States-POE *Lm* or *Salmonella* violation, the CCA informs the Region and LHU where the establishment in question is located, and the LHU will follow the guidance from MOH in DGISAN 2731_P_02_03_2014 , similar to procedures followed when a positive is obtained during

official monitoring sampling. The CCA also suspends all export to the United States from the establishment until the issue is resolved as discussed above. Once the LHU considers the issue resolved by obtaining negative results from its own verification sampling, a report is sent through the Regional Office to the MOH, and the MOH reports back to the United States on the results of the investigation within 30 days of the United States-POE violation. Restoration of export activity by the establishment is at the discretion of the MOH. If the MOH does not concur with the investigation or does not have assurance that the non-compliance has been resolved after 30 days from receiving the notice of the POE violation, the MOH will proceed with deleting the establishment from the list of establishments authorized to export to the United States.

Once a product or food contact surface is found to be *Lm* positive at an establishment, export activity to the United States is suspended. The establishment is expected to perform an investigation, take corrective actions, and implement preventive actions, after which a report is sent to LHU that the corrective action was effective in controlling *Lm* and preventive measures have been put in place. The LHU then goes back to the establishment to perform a verification activity/official sampling and monitors the establishment for 6 months, before processing for the United States market can be resumed. For non-food contact surface *Lm* or *Listeria spp.* positive, a non-conformance report is written and the establishment is expected to take corrective actions, including intensified sanitation and cleaning, after which results are reported to LHU. Depending on whether a trend is observed or not, additional enforcement action may be taken, such as the LHU stopping the plant from exporting to the United States. The non-conformance report is closed by LHU based on the establishment's report, and all information is uploaded in the SINVSA.

Reports of the United States-POE violation are sent to MOH. Reports/results of annual sampling plans are maintained at the LHU and uploaded in SINVSA, where it can be reviewed by the MOH. The LHU in Parma also has the SICER system (information system for food safety – active in Parma and Modena), that is used to report results of laboratory testing. The system also contains a report of corrective actions proffered by the establishment and verification activities conducted by the LHU. Non-conformance recorded by the veterinarian and daily inspection records are also captured in the SICER system.

Guidance provided by the CCA to establishments on controlling *Lm* in the post-lethality exposed environment and product to ensure product safety, is similar to FSIS requirements in 9 CFR Part 430. A list of training provided to veterinarians and technicians within the last year was provided. After training, a written assessment of the information covered is conducted to assess the competency of the participants. In addition to the written assessment provided, the trainee is accompanied by a trained inspector, who observes him/her for 6 months on the activity they were trained for – e.g., HACCP, SSOP, etc.

A review of the results of the self-monitoring and official sampling programs implemented to control *Lm* and *Salmonella* in RTE products and the processing environment in United States eligible establishments led the auditors to conclude that the CCA had made significant improvements in their *Lm* control program, that are similar to the FSIS *RLm* and IVT sampling programs, in addition to the RTE PROD_RAND and RTE PROD_RISK, that if followed diligently, should be able to control *Lm* and *Salmonella* in RTE products and the processing environment.

The FSIS auditor accompanied veterinarian in-charge and observed the in-plant inspection verification activities for *Salmonella*, *Enterobacteriaceae*, and Aerobic Plate Count (APC) sample collection in two of the slaughter establishments audited. The CCA has a *Salmonella* testing program for chilled livestock (swine) carcass sampling that is consistent with the FSIS *Salmonella* Performance standards in 9 CFR Part 310.25(b). Per decision EU 471/2001 which is considered equivalent to EU 2073 (annex 1 chapter 2), the first set of *Salmonella* testing is conducted in the same manner as the FSIS *Salmonella* testing conducted under PR/HACCP. Based on the establishment's meeting the performance on the first *Salmonella* set, the MOH allows the establishment to continue its own *Salmonella* testing of the first five samples per week for 30 weeks. Upon obtaining good results, this frequency can be reduced to five samples every 2 weeks instead of weekly. *Enterobacteriaceae* and APC testing is carried out in accordance with Regulation (EC) No 2073/2005 (annex I chapter 2) on microbiological criteria for foodstuffs. For *Enterobacteriaceae*, five swabs are collected every 2 weeks; and five swabs every 2 weeks for APC. All documents reviewed in relation to establishment Microbiological Verification Testing Program led the auditor to conclude that the establishments had sound verification programs utilizing sampling for sanitary dressing in accordance with Regulation (EC) No 2073/2005 (annex I chapter 2) on microbiological criteria for foodstuffs, which FSIS recognizes as equivalent to generic *E. coli* testing.

Additionally, CCA requires establishments producing both non-post lethality exposed and post lethality exposed products to meet applicable lethality and cooling requirements for these products and to ensure that product is not re-contaminated in the post-lethality environment. The CCA provided guidance to establishments in the DGISAN 2731_P_02_03_2014 circular, requesting to establishments to identify critical operating parameters in their processes and be able to demonstrate the lethality step of its process by means of scientific support or specific challenge study. This guidance from the CCA did not specifically request that establishments attain at least a 5-Log₁₀ reduction of *Salmonella* in dried cured products to ensure safety and absence of *Salmonella*. FSIS had recommended to the CCA during the November 2013 technical meeting in Washington D. C. that they provided clear guidance to establishments on attaining at least a 5-Log₁₀ reduction of *Salmonella* in dried cured products to ensure safety and absence of *Salmonella*. FSIS considers that a 5-Log₁₀ reduction of *Salmonella* in meat products would produce a product safe for consumption. The CCA indicated to the auditors that guidance on attaining at least a 5-Log₁₀ reduction of *Salmonella* in dried cured products will be provided in the revised DGISAN 2731_P_02_03_2014 to be issued by the end of 2014.

The CCA also indicated to the FSIS auditors that it had verbally communicated with the LHU and establishments on the mandatory use of gloves in RTE establishments, the appropriate use of paper towels to clean food contact surfaces, and that these corrective actions will be included in the revised DGISAN 2731_P_02_03_2014 circular which is being updated and should be issued by the end of 2014.

Italy's microbiology testing laboratory is well-equipped to provide technical support to the meat inspection system. The analytical methods, integrity of samples, accuracy of testing results, laboratory capacities, analysts' competency, equipment capabilities, and quality assurance programs are adequate.

Based on the assessment of the microbiological component, the corrective actions implemented in response to the FSIS January 13, 2014, letter, and corrective actions proffered during the audit, the FSIS auditors conclude that Italy's meat inspection system continues to be operating at an "adequate" level.

However, the FSIS expects that the CCA must implement all the corrective actions proffered during the audit, including the reissuance of DGISAN 2731_P_02_03_2014.

XI. CONCLUSIONS AND NEXT STEPS

The current audit findings related to Government oversight, Sanitation, HACCP, and the Microbiological components are summarized in the table below.

	Equivalence Component	Audit Findings
1	<i>Government Oversight</i>	The audit findings in Government Oversight, Sanitation, HACCP System, and the Microbiological Testing Program components indicate a need to improve the CCA’s oversight functions and supervisory reviews. Inadequate support documents detailing how the CCA provides guidance to establishments on attaining at least a 5-Log ₁₀ reduction of Salmonella in dried cured ham products were also found.
2	<i>Statutory Authority and Food-Safety Regulations</i>	No concerns to report
3	<i>Sanitation</i>	The nature and extent of findings related to this component observed at the audited establishment raises concerns about Italy’s ability to maintain equivalent sanitation measures. Examples of the finding include: Worn gasket on multiple oven doors, workers in RTE deboning area not wearing gloves, paper towels being used to clean food contact surfaces after sanitizing the surface, harvested offal not being chilled and washed immediately,
4	<i>HACCP</i>	FSIS auditors noted serious findings related to HACCP component that indicate ineffective verification conducted by Italy’s meat inspection system. The audit findings are related to inaccuracies in flow diagram and hazard analysis of some processing steps.
5	<i>Chemical Residue Control Programs</i>	No concerns were noted related to the CCA’s HQ, Regional, and Local inspections for Chemical Residue Control Program.
6	<i>Microbiological Testing Program</i>	The audit found inadequate support documents regarding how the CCA provides guidance to establishments on attaining at least a 5-Log 10 reduction of Salmonella in dried cured ham products.

On and prior to the exit meeting, the CCA provided the FSIS auditors with evidence of immediate corrective action addressing most of the findings identified above. After the on-site audit, the CCA proffered additional corrective action committing to update its circular DGISAN 2731_P_02_03_2014 before the end of 2014, to reflect program changes related to sanitation and microbiological sampling. The auditors concluded that the system is operating at an “adequate” level; however, the CCA needs to improve its oversight functions in Sanitation, HACCP, and Microbiological Testing Program components. FSIS needs a response from Italy within 60 days of issuance to this report and provide FSIS how it would ensure that its oversight functions and proffered corrective actions will prevent future adulteration of RTE product with Lm.

APPENDICES

APPENDIX A: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Alcica Via Roma, 73 Predosa, Italy	2. AUDIT DATE 07/9/2014	3. ESTABLISHMENT NO. 41L	4. NAME OF COUNTRY Italy
	5. NAME OF AUDITOR(S) Evelyne Mbandi PhD/Alam Khan,		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

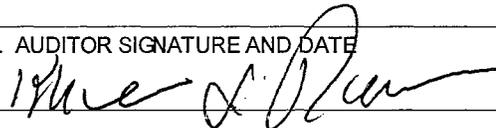
Date: 07/9/2014 Est. 41L a processing establishment

45/51 The gasket on the doors of a couple of cooking ovens were deteriorating and detaching from the frame. This condition permits heat to escape from the oven and can result in under processing of product. The establishment corrected the noncompliance while the audit was in progress.

61. NAME OF AUDITOR

AlamKhan. DVM

62. AUDITOR SIGNATURE AND DATE

 Alam Khan 7/9/2014

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Mec Carni Mercaria (Lombardia) Montova Italy	2. AUDIT DATE 07/10/2014	3. ESTABLISHMENT NO. 304M	4. NAME OF COUNTRY Italy
	5. NAME OF AUDITOR(S) Alam Khan DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 07/10/2014 Est. 304M a slaughter- cutting establishment

10/51 During on-site sanitation verification the auditor noted that in the hot boning room the pork feet with residual hair tuft and extraneous material attached to the feet were being removed on the conveyor belt moving across the boning room where meat was being cut and boned. This finding poses an insanitary condition and a potential for direct product contamination with extraneous material on the feet.

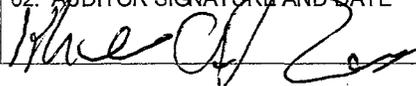
46/51/56 The jars containing metal seals to attach on hams (an APHIS requirement) were collecting dirt on them. This observation was creating potential for contamination of ham.

The first finding CCA gave assurance that they would resolve the issue as soon as possible. The second finding was corrected while the audit was still in progress.

61. NAME OF AUDITOR

AlamKhan. DVM

62. AUDITOR SIGNATURE AND DATE

 DVM 7/10/2014

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Disosso San Carlo, Langhirano, Parma, Italy	2. AUDIT DATE 07/11/2014	3. ESTABLISHMENT NO. 732L	4. NAME OF COUNTRY Italy
5. NAME OF AUDITOR(S) Evelyne Mbandi, PhD		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 07/11/2014 Est. 732L a processing establishment

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

61. NAME OF AUDITOR
Evelvne Mbandi. PhD

62. AUDITOR SIGNATURE AND DATE

Evelvne Mbandi Dan 7/11/2014

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Martelli Salumi Boara Pisani (BD) Italy	2. AUDIT DATE 07/112014	3. ESTABLISHMENT NO. 1820M	4. NAME OF COUNTRY Italy
	5. NAME OF AUDITOR(S) Alam Khan, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 07/11/2014 Est. 1820L a processing establishment

- 15/46/51 1) The flow chart and hazard analysis did not identify the bagging of ham.
2) The auditor verified that no hazard analysis was conducted for the smoking, Chilling and Returns steps, as shown on the flow diagram.
3) The auditor also observed that the hazards associated with the cooking step is controlled through CCP with the Critical Limit established as time/temperature, but the time limit for this CCP was not identified.

The CCA's representatives present at the establishment gave assurance that findings will be corrected as soon as possible.

61. NAME OF AUDITOR

AlamKhan. DVM

62. AUDITOR SIGNATURE AND DATE

 Alam Khan DVM 7/11/2014

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION M Cooperiti Vescovato, Italy	2. AUDIT DATE 07/14/2014	3. ESTABLISHMENT NO. 361M	4. NAME OF COUNTRY Italy
	5. NAME OF AUDITOR(S) Alam Khan, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 07/14/2014 Est. 361M a slaughter-cutting establishment

10/51 The harvested offal were not being chilled and washed immediately. The establishment did not have any procedures or documentation to monitor the time and temperature for chilling and sanitary handling of t offal.

19/51 The HACCP plan indicates the frequency of verification of a Critical Limit at a CCP for zero tolerance as 20 carcasses. However, the review of verification record indicated that only 10 carcasses were being verified during observation. This finding has already been corrected by official veterinarian.

46/51 1) The establishment operates on uninterrupted shift which does not allow employees to thoroughly clean the kill area until the end of the shift. As a result, blood and slaughter waste was accumulating on the kill floor, thereby creating insanitary conditions.

2) During the pre-operational sanitation verification in one establishment, the auditor noted that the scalding had clumps of hair and slimy material clung along some sections of the pipes.

61. NAME OF AUDITOR

AlamKhan. DVM

62. AUDITOR SIGNATURE AND DATE

 DVM 7/14/2014

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Disosso San Carlo, Langhirano, Parma, Italy	2. AUDIT DATE 07/14/2014	3. ESTABLISHMENT NO. 513L	4. NAME OF COUNTRY Italy
5. NAME OF AUDITOR(S) Evelyne Mbandi, PhD		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Date: 07/14/2014 Est. 513L a processing establishment

10/51 The employees in the deboning area were not wearing gloves. Product was being handled with bare hands. Handling products with bare hands is a potential source for cross contamination. The CCA gave assurance that a recommendation will be made to the establishment to start wearing gloves in the deboning area.

61. NAME OF AUDITOR
Evelvne Mbandi, PhD

62. AUDITOR SIGNATURE AND DATE

for Mbandi Dum 7/14/2014

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Langhiranese Prosciutti SRL, Langhirano, Parma, Italy	2. AUDIT DATE 07/15/2014	3. ESTABLISHMENT NO. 758L	4. NAME OF COUNTRY Italy
	5. NAME OF AUDITOR(S) Alam Khan, DVM, and Evelyne Mbandi, PhD		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection,	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

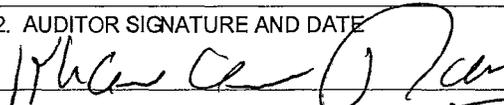
Date: 07/15/2014 Est. 758L a processing establishment

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

61. NAME OF AUDITOR

AlamKhan. DVM

62. AUDITOR SIGNATURE AND DATE

 Alam Khan DVM 7/15/2014

APPENDIX B: Foreign Country Response to Draft Final Audit Report



Ministero della Salute

DIREZIONE GENERALE PER L'IGIENE E LA SICUREZZA DEGLI ALIMENTI E DELLA
NUTRIZIONE
Ufficio IX-ex DGSAN

Dr. Shaukat H. Syed, Director
International Audit Staff
Office of Investigation, Enforcement and Audit
Food Safety and Inspection Service
1400 Independence Avenue, SW.
Washington, D.C. 00250

Ministero della Salute
DGSAN
0000352-P-09/01/2015



p.c. Al Almanza
Deputy Under Secretary for Food Safety

Jane Doherty
International Coordination Executive

Ambasciata Italiana a Washington
Ufficio Economico-commerciale

DGAP - Unita' Paesi America settentrionale

Capo di Gabinetto
Dr. Giuseppe Chinè

Consigliere diplomatico
Dr. Luigi Ferrari

Segretariato Generale - Ufficio III
SEDE

DG SANCO Dr Lorenzo Terzi

Dear Dr. Sayed,

We are in receipt of the Draft Final Report of the audit of the Italian food safety system conducted by FSIS last July. The Ministry of Health (MoH) is pleased that the report documents and acknowledges the "significant improvements" in the Italian food safety system over the last year. With reference to the concerns expressed by FSIS in the draft report and in addition to the immediate corrective actions already provided by the CCA to FSIS auditors as acknowledged by the report itself, MoH:

1. published a new circular, DGISAN 44986 of December 3rd, 2014, which updates Circular 2731 of February 3rd, 2014 to reflect program changes related to sanitation and microbiological sampling (Annex 1);
2. organized on December 10, 2014 a training course on FSIS requirements involving supervisors and inspectors assigned to U.S.-certified plants. The training was attended by nearly 200 people. US-certified plant personnel were also invited. Documentation concerning the training is attached in Annex 2.
3. conducted in its capacity as CCA intensified monitoring activities, including inspections of 10 plants, 7 ASLs (Local Health Units) and 4 Regions to certify that the findings raised during the exit meeting and the related corrective actions have been fully implemented (reports of this activity are available upon request).

As an on going verification activity of the performance of the inspection system the CCA is collecting the data gather from the sampling activity and from the inspection activity conducted on 2014 on the certified establishments. The data will be revised within the Regional Services in order to program the inspection monitoring plan and the official sampling activity for 2015.

On the specific concerns reported by FSIS draft, MoH would like to underline the following:

Component One: Government Oversight

- a. "Need to improve the CCA's oversight functions and supervisory reviews"

First of all, MoH updated and published Circular 2731 of February 3rd, 2014 to reflect program changes related to sanitation and microbiological sampling. An English translation of the new circular - DGISAN 44986 of December 3rd, 2014 - is attached to this letter. Furthermore, after FSIS audit, the CCA conducted intensified activities, including inspections of 10 plants, 7 ASLs (Local Health Units) and 4 Regions. These activities certified that all corrective actions requested by FSIS auditors have been fully implemented.

- b. "Supervisory reviews were not being conducted in accordance with DGISAN 26639_30_6_14 and DGISAN 2731_P_03_02_2014"

The significant changes introduced in the inspection service by the Circular DGISAN 26639_30_6_14 were still under implementation at the time when the audit was conducted (July 7-18). All changes are now effective and the Circular is fully implemented as certified by the MoH

inspections conducted after the audit. The content of the circular is compatible with FSIS Directive 5000.1.

- c. "CCA had not demonstrated how it provides guidance to establishments on attaining at least a 5-log₁₀ reduction of Salmonella in dried cured products. Even though the CCA had not provided such guidance, it is not clear as to whether the establishments had implemented a program for attaining a 5-log₁₀ reduction of Salmonella."

EU regulation 2073/2005 mandates the absence of this pathogen from RTE products. Furthermore, with Circular DGISAN 44986/P of December 3rd, 2014 MoH formally required establishments to comply with the requirement of achieving the 5 log₁₀ reduction for Salmonella. In this regard, the inspection activity performed by the CCA after the audit verified the full compliance and implementation of this requirement by ASLs and establishments. In addition, training course held on December 10th, 2014 stressed once again the need to meet this requirement.

MoH would like to underline that none of the POE tests were positive for Salmonella. This confirms that CCA and individual establishments have full control and have adequate Salmonella testing verification in place to ensure that RTE products exported to the U.S. are free of Salmonella. Furthermore, MoH would like to stress the scientific results of the attached study (Annex 3) performed on dry-cured ham demonstrating that this reduction is already achieved through the aging process.

Component Three: Sanitation

- a. "Worn gaskets on oven doors".

Worn gaskets were replaced. Official documents attesting the solution of this concern were given to the auditors at the exit meeting.

- b. "Workers in RTE deboning areas not wearing gloves".

Circular DGISAN 44986/P of December 3rd, 2014 formally requires that all establishments comply with the requirement of wearing gloves. The full implementation of this requirement was certified by MoH inspection conducted following the recent audit. In addition, during the training course on December 10th, 2014 this requirement was thoroughly highlighted.

- c. "Paper towels being used to clean food contact surfaces".

By Circular DGISAN 44986/P of December 3rd, 2014 MoH has formally forbidden establishments from using paper in the last phase of operational cleaning. The implementation of this requirement was verified during the recent MoH audit. The requirement was also stressed during the December 10th, 2014 training.

- d. "Harvested offal not being chilled and washed immediately".

As acknowledged by FSIS draft report, immediate corrective action was taken to solve this issue by the adopting a specific procedure implemented at the establishment level.

- e. "Blood and slaughter waste was accumulating on the kill floor".

As acknowledged by FSIS draft report, immediate corrective action was performed immediately and the CCA verified the implementation of correction action and provided evidence to the FSIS auditors.

- f. "Scalder had clumps of hair and slimy material clinging to sections of pipes".

As acknowledged by FSIS draft report, immediate corrective action was performed immediately and the CCA verified the implementation of correction action and provided evidence to the FSIS auditors.

- g. "Foreign material adhered on the jars containing metal seals to attach on hams".

As acknowledged by FSIS draft report, immediate corrective action was performed immediately and the CCA verified the implementation of correction action and provided evidence to the FSIS auditors.

Component Four: HACCP

- a. "Ineffective verification conducted by Italy's meat inspection system. Inaccuracies in flow diagram and hazard analysis of some processing steps".

As acknowledged by FSIS draft report, since MoH-FSIS technical meeting Italy has made significant changes in its inspection system including issuance of four new circular aimed at addressing all FSIS concerns. MoH would like to stress once again that after FSIS audit, the CCA conducted intensified monitoring activities, including inspections of 10 plants, 7 ASLs and 4 Regions. The inspections performed by the CCA strongly stressed the importance of establishments and inspectors focusing on HACCP plans, the need for in-depth verification of the hazard analysis, and the correspondence of the flow chart with the layout of establishments. These same issues were highlighted during the December 10th, 2014 training course. MoH empathizes the importance to overview the HACCP programs at the establishments and accuracy on this review will be persecute during the CCA monitoring activity in 2015.

- b. "Flow chart and hazard analysis did not identify the bagging of the ham".

As acknowledged by FSIS draft report, the establishment corrected this non-compliance and evidence was provided to the auditors at the exit meeting.

- c. "No hazard analysis was conducted on smoking, chilling and returned product."

As acknowledged by FSIS draft report, the establishment corrected this non-compliance and evidence was furnished to the auditors at the exit meeting.

- d. "Hazards connected to the cooking step had a CCP for time and temperature but the time was not identified."

As acknowledged by FSIS draft report, the establishment corrected this non-compliance and evidence was furnished to the auditors at the exit meeting.

- e. "Written frequency of verification of the CCP for zero tolerance did not match what are being done by the govt. 20 carcasses versus 10."

As acknowledged by FSIS draft report, the establishment corrected this non-compliance and evidence was furnished to the auditors at the exit meeting.

Component Six: Microbiological Testing

- a. The same issue as discussed in Component One (5-log₁₀ reduction of Salmonella).

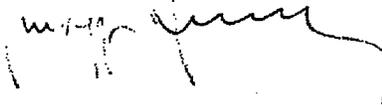
MoH would like to stress once again what highlighted in its comments about Component One. In particular, Circular DGISAN 44986/P of December 3rd, 2014 formally required establishments to comply with the requirement of achieving the 5 log₁₀ reduction for Salmonella and the inspection activity performed by the CCA after the audit verified the full compliance and implementation of this requirement by ASLs and establishments.

While referring to Annex 4 for additional detailed technical analysis of the draft report, in light of the above mentioned comments MoH considers that the continuation of measures such as 100% reinspection and restriction against certifying new plants, are not justified. In particular, MoH would like to stress that some of the new facilities in the waiting list have significantly invested in high-pressure processing (HPP), in line with FSIS recommendations.

Based on the information provided above, the Ministry of Health warmly encourages FSIS to quickly finalize the Audit Report, move forward with lifting 100% reinspection and the restriction against certifying new establishments for export to the U.S., as well as with the reassessment of the three establishments currently under bilateral review (732 L; 412 L; 167 L).

While considering the final report certainly crucial, the Ministry of Health would like to take this opportunity to reaffirm its firm intent to further develop cooperation and transparent dialogue with FSIS on strengthening food safety programs and consumer protection.

THE GENERAL DIRECTOR
(Dr. Giuseppe Ruocco)



01/30/2015

FSIS technical Team's Review and Conclusion on Italy's Response on FSIS' Audit Finding

On January 28, 2015, a multidisciplinary team consisting of members from IES, RMITAS, IAS and the Italy audit team held a meeting to review Italy's response package on the draft of the Final Italy audit report. The following participants were in attendance:

- Shaukat Syed, Director, IAS/OIEA
- Alam Khan, IAS/OIEA/Member -Italy Audit Team
- Evelyne Mbandi, RIMS/OPPD/Member -Italy Audit Team
- Alex Lauro, IAS/OIEA/Lead Auditor for FY 2015 Italy Audit Team
- David Smith, IES/OPPD
- Nick Bauer, RMTAS/OFO
- Angela Glodowske, RMTAS/OFO
- Martin Drew, RMTAS/OFO

The team reviewed a package of documents sent to FSIS by the competent authority; the Italian Ministry of Health (MOH). The following document were reviewed to arrive at the conclusion summarized in the table below:

- 
 Annex_1_DGISAN_4
 4986_P_03_12_2014
 - 
 Annex_2_TRAINING
 _OFFICIAL_CONTRO
 - 
 Annex_3.pdf
 - 
 Annex-4_MOH_TECH
 NICAL_COMMENTS_1
 - 
 DGISAN 352 of
 Jen2015.pdf
- 
 (IT0033) Italy - NC
 closure.pp...

Audit Findings	Italy's Proffered Corrective Action	Review Team's Conclusion
Government Oversight:		
<p>Need to improve the CCA's oversight functions and supervisory reviews regarding <i>Listeria monocytogenes (Lm)</i> and <i>Salmonella</i> Control.</p>	<p>Ministry of Health (MOH) updated its Circular 2731 into a new circular DGISAN 44986-P-03/12/2014 to employ following measures in sanitation and microbiological components:</p> <ul style="list-style-type: none"> • Use of disposable gloves in post lethality areas where RTE products are handled is now mandatory • Use of paper is prohibited, only sanitizer can be used during the 	<p>The review team concluded that the MOH has adequately addressed the audit finding, and the proffered corrective actions can be verified during subsequent FSIS audit slated to be audited in September 14-October 2, 2015</p>

	<p>last phase of operational sanitation</p> <ul style="list-style-type: none"> RTE establishments producing RTE products have to obtain supporting documentation for their process from scientific studies which demonstrate that the process guarantees a 5 log₁₀ reduction of <i>Salmonella</i>. For proper compliance establishment needs to refer to FSIS' <i>Salmonella</i> Compliance guidelines for small and very small meat and poultry establishments. Implementation of specific official controls for <i>Lm</i> in accordance with FSIS Directive 10.240.4. 	
Supervisory reviews were not being conducted in accordance with DGISAN 26639_30_6_14 and DGISAN 2731_P_03_02_2014"	MOH stresses the fact that at the time Italy's inspection audit of July 7 th to the 18 th , the inspection service was still phasing in the changes mandated by ministerial circular DGISAN 26639 30_6_14. These changes have now been fully implemented.	The review team concluded that next audit is not until September of this year that gives MOH enough time to implement all the proffered corrective action or strengthen its oversight at US-eligible establishments. The next audit can verify these controls measures.
Statutory Authority and Food Safety Regulations		
No concerns reported		
Sanitation		
<ul style="list-style-type: none"> Use of paper towels to clean food contact surfaces in RTE establishments Employees handling processed meat with bare hands in RTE establishments Insanitary condition in slaughter establishments 	<p>Findings identified in the RTE establishments were addressed in government oversight and control measures applied through issuance of a new circular DGISAN 44986-P-03/12/2014</p> <p>Findings related to slaughter establishments were addressed immediately on or before the exit meeting</p>	The review team concluded that the MOH adequately addressed the audit finding, and the proffered corrective actions can be verified during next FSIS audit scheduled to be conducted from September 14 thru October 2, 2015
HACCP		
<ul style="list-style-type: none"> The audit findings were related to inaccuracies in flow diagram and hazard analysis of some processing steps 	These findings were corrected and evidence was provided to the auditors on or before exit meeting.	These findings are considered addressed adequately.
Chemical Residues Control Programs		
No concerns reported		
Microbiological Testing Program		
<ul style="list-style-type: none"> The audit found inadequate support documents regarding how the CCA provides guidance to establishments on attaining at least a 5-Log₁₀ reduction of <i>Salmonella</i> in dried cured ham 	The MOH has addressed the findings in its updated Circular 2731. This circular now has been replaced by a new circular DGISAN 44986-P-03/12/2014. The details on the proffered corrective action are	The review team concluded that the MOH adequately addressed the audit finding. The proffered corrective actions can be verified during the subsequent FSIS audit slated to be audited in September 14-October 2,

products.	captured in GOS component in the table.	2015
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In addition to the review of corrective action the team also took a serious look at Italy's persistent failure in preventing new cases of product adulteration with *Lm* detected at US-POE despite adoption of US regulations, directives and guidelines, and implementing new ministerial circulars.

Based on the team's collective concurrence accepting Italy's proffered corrective actions in response to the audit findings and the concurrent implication of Italy in new POE violations the reviewers would like to make the following recommendations on closing and finalizing the Italy's Draft Final Audit Report:

- The team agreed that the recent or future *Lm* detections in Italian product at POE continue to be pursued in accordance with established RMTAS standards with close cooperation with the review team for their input on the corrective actions.
- IAS using its own protocol for finalizing the Audit Report will incorporate the comments from the audited country in appendix B at the end of report.
- A cover letter similar to the one attached with the draft final audit report be sent with a courtesy copy of the final audit report to the Italian CVO. This letter would express FSIS' concern that in light of the recent and past failure of Italian dry cured ham products from *Lms* testing, FSIS has decided to leave in place the current testing regime at POE until Italy is able to demonstrate that its corrective actions would be effective in guaranteeing public health safety in practicality.