USDA

United States Department of Agriculture

Food Safety and
Inspection Service

1400 Independence
Avenue, SW.
Washington, D.C.
20250

OCT 13 2016

Dr. Giuseppe Ruocco
Director General for Food Hygiene, Safety and Nutrition
Ministry of Health
Directorate General for Veterinary Health and Food
Via Giorgio Ribotta, 5
00144 Rome, Italy

Dear Dr. Ruocco,

The Food Safety and Inspection Service onsite audit conducted from May 16 through June, 3, 2016, supports that Italy's processed meat inspection system continues to remain equivalent to that of the United States. Enclosed is a copy of the final audit report. The comments received from the Government of Italy are included as an attachment to the report.

If you have any questions, please feel free to contact me directly.

Sincerely,

Jane H. Doherty

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

ITALY

MAY 16 TO JUNE 3, 2016

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from May 16 to June 3, 2016. The purpose of the audit was to determine whether Italy's food safety system governing meat products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and accurately labeled and packaged. Italy is eligible to export processed pork products to the United States.

The audit focused on six system equivalence components: Government Oversight (Organization and Administration), Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (Inspection System Operation, Product Standards and Labeling, and Humane Handling), Government Sanitation, Government Hazard Analysis and Critical Control Points (HACCP) Systems, Government Chemical Residue Control Programs, and Government Microbiological Testing Programs.

During the audit, the following findings were identified:

- At one processing establishment, inspection officials were not aware of the mandatory glove use requirements in the final packaging and shipping area for bone-in, dry-cured ham. This area is considered a post-lethality environment of the establishment. Circular *DGISAN 35655-P (9/16/2015)* requires that gloves be worn in the post-lethality environment of the establishment by employees who are directly handling product.
- FSIS identified systemic deficiencies related to the maintenance of overhead structures in five of the 13 establishments audited. Additionally, isolated sanitation findings are included in the individual establishment checklists which are attached to this report.
- FSIS identified systemic deficiencies related to HACCP recordkeeping in four of the 13 establishments audited. Additionally, isolated HACCP findings are included in the individual establishment checklists which are attached to this report.
- Two processing establishments had incorrectly identified the post-lethality environment for cooked products as the point at which they exit the cooler after chilling, rather than the point where they exit the oven after cooking (lethality).
- The 2016 official surveillance plan for monitoring *Listeria monocytogenes* and *Salmonella* in pork products to be exported to the United States (*DGISAN 445)* incorrectly identified some of the Alternative 3 deli products. For example, the current plan identifies bone-in, dry-cured prosciutto as a "non-deli" product as it is typically sent for deboning. However, based on the definition found in 9 CFR 430.1, FSIS considers this type of product a "deli product," i.e., *a product that is typically sliced, either in an official establishment or after distribution from an official establishment, and assembled in a sandwich for consumption*.

An analysis of the findings within each component did not identify any deficiencies which represented an immediate threat to public health. During the audit exit meeting, the Central Competent Authority (CCA) was made aware of all the FSIS concerns and noted that it had already begun to address the audit findings by implementing immediate corrective actions. FSIS received a written response from the CCA addressing all outstanding concerns within 60 days of communication of the draft final audit report.

TABLE OF CONTENTS

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of Italy's food safety system from May 16 to June 3, 2016. The audit began with an entrance meeting held on May 16, in Rome, Italy with representatives from the Ministry of Health (MOH), and two FSIS auditors. The MOH is Italy's Central Competent Authority (CCA) for the export of meat products to the United States.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to ensure the food safety system governing meat products maintains equivalence to that of the United States, with the ability to export products which are safe, wholesome, unadulterated, and correctly labeled and packaged.

This audit also included verification of corrective actions implemented by the CCA in response to the previous FSIS audit which occurred in July 2014, with special emphasis on the control of *Listeria monocytogenes* (*Lm*) in dry-cured hams.

In pursuit of these objectives, FSIS applied a risk-based procedure which included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process included an analysis of data collected by FSIS over a three-year timeframe, in addition to information obtained directly from the CCA through a self-reporting process.

The FSIS auditors were accompanied throughout the entire audit by representatives from the CCA and representatives from the regional and local inspection offices. Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (Organization and Administration), (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (Inspection System Operation, Product Standards and Labeling, and Humane Handling), (3) Government Sanitation, (4) Government Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Government Chemical Residue Control Programs, and (6) Government Microbiological Testing Programs.

Administrative functions were reviewed at CCA headquarters, two regional offices, and 13 local inspection offices, during which the FSIS auditors evaluated the implementation of control systems in place which ensure that the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of 13 establishments was selected from a total of 101 establishments certified to export to the United States. During the establishment visits, particular attention was paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) § 327.2 (i.e., the FSIS regulations addressing equivalency determinations for foreign country inspection systems).

Additionally, two government laboratories were audited to verify their ability to provide adequate technical support to the inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• CCA (MOH) – Rome
	Regional	2	• Friuli Regional Office – Udine • Emilia Romagna Regional Office – Bologna
Government Laboratories		2	• Istituto Zooprofilattico Sperimentale (Microbiology and Residue) – Brescia • Istituto Zooprofilattico Sperimentale (Microbiology only) – Parma
Pork Slaughter and Processing Establishments		2	Dosolo and Migliarina
Pork Processing Establishments		11	Colà di Lazise, Langhirano, Sala Baganza, San Candido, San Daniele del Friuli (two locations), San Gimignano (two locations), Silandro, Trieste, and Villafranca Di Verona

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

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] 601, et seq.),
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901, et seq.), and
- The Federal Meat Inspection Regulations for Imported Products (9 CFR Part 327).

The audit standards applied during the review of Italy's inspection system for meat products included: (1) All applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) the following subsequent equivalence determinations that have been made by FSIS under provisions of the Sanitary/Phytosanitary Agreement.

Currently, Italy has equivalence determinations in place for the following:

- European Commission (EC) Regulation 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, and
- Council Directive 2004/41/EC.
- Testing for *Enterobacteriaceae* and Total Viable Count in lieu of generic *Escherichia coli* (*E. coli)* is acceptable for all European Union (EU) Member States exporting meat products to the United States.
- Government laboratories use International Organization for Standardization (ISO) 6579 and Association of Official Analytical Chemists (AOAC) 967.25 to analyze samples for *Salmonella*.

III. BACKGROUND

Italy is eligible to export processed pork products to the United States. From October 1, 2012 to September 30, 2015, FSIS import inspectors performed 100% re-inspection for labeling and certification on 47,575,020 pounds of meat products exported by Italy to the United States. FSIS also performed re-inspection on 31,891,726 pounds at POE for additional types of inspection, of which a total of 166,774 pounds were rejected for food safety-related reasons. Since the last FSIS audit in July 2014, the United States rejected a total of 31,143 pounds for the following food safety-related reasons: two lots of ready-to-eat (RTE) pork products tested positive for *Lm,* one lot of unsliced ham was identified as being "off-condition," and found to contain mold.

The audit included visits to the establishments implicated in these POE violations for which FSIS concluded that the Italian government had satisfactorily worked with food business operators to identify the root causes of the problems and institute appropriate corrective actions. Specific details regarding these follow-up activities are included in the subsequent sections of the audit report where appropriate.

The FSIS final audit reports for Italy's food safety system are available on the FSIS website at:
http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components that the auditors reviewed was Government Oversight. FSIS import regulations require the foreign inspection system to be organized by the national government in such manner to provide ultimate control and supervision over all official inspection activities; insure the uniform enforcement of requisite laws; provide sufficient administrative technical support; and assign competent qualified inspection personnel at establishments where products are prepared for export to the United States.

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 onsite record reviews, interviews, and observations made by the FSIS auditors at government offices and in the audited establishments.

In accordance with the requirements outlined in *Legislative Decree No. 193/2007*, Italy's meat inspection system is organized on three levels: national, regional, and local. At the national level, the MOH *Office of the Secretariat* coordinates the activities of nine *General Directorates*, for which that of primary interest to FSIS is the *General Directorate for Hygiene, Safety and Nutrition* [Italian: *Direzione Generale per l'Igiene e la Sicurezza degli Alimenti e la Nutrizione* (DGISAN)]. The DGISAN provides oversight to eight offices involved in products of animal origin and the export of food products. Of these, the *Food Hygiene and Export Office* (Office 2) is responsible for coordinating the lower levels of the inspection system in activities related to the export of meat products to the United States.

Ultimate control of establishments certified to export to the United States is achieved through the remaining two intermediate levels. The MOH provides oversight through 21 second-level *Regional Health Service Offices* (RHSOs) [19 regional and two autonomous provincial offices—Trento and Bolzano]; their responsibilities include planning, coordination, guidance, authorization of establishments to operate, and verification of controls of their underlying *Local Health Units* (LHUs). Each RHSO has a number of third-level LHUs. The LHUs are responsible, at the local level, for the organization and management of all public health services. The establishments certified to export to the United States are overseen by these LHUs, and the assigned veterinarians (designated as Official Veterinarians) are paid directly by the LHUs. There are two services within the LHUs: 1) the *Food Hygiene and Nutrition Service* and 2) the *Local Veterinary Services*; the latter of which is responsible for animal health (Area A), inspection and control of foods of animal origin (Area B), and animal welfare, hygiene of animal husbandry and of farming production (Area C).

The MOH has issued an updated process for the certification of establishments requesting approval for United States export in circular *DGISAN 15012 (4/14/2016)*. A *National Sanitary Service Training* course on USDA food law is now compulsory for LHU veterinarians and establishment quality managers at establishments eligible to export to the United States. Establishment application for United States-export can be submitted only after a preliminary audit conducted by the RHSO. Upon satisfactory outcome of the audit of the requesting establishment, final certification is granted by the MOH. While onsite, the FSIS auditors reviewed documents specifically associated for the approval of establishment (CE IT 745) which was certified to export products to the United States under the revised procedure. This review indicated that the above-referenced approval process was implemented as intended.

As per *EC Regulations 178/2002, 854/2004,* and *882/2004*, inspection controls at meat establishments are performed by official employees hired by the General Directorate for Health Professions and Human Resources of the National Health Service. Consequently, all inspection personnel assigned to establishments eligible to export to the United States are employees of the Italian Government. This is verifiable through internet systems maintained by each LHU. Through these portals the FSIS auditors were able to identify individuals assigned to United States-eligible establishments by name and confirm their national employment and payment status.

Technical laboratory support for microbiological and chemical residue testing within the CCA's meat inspection system is provided through the government's *Veterinary Public Health Institutes* [Italian: *Istituti Zooprofilattici Sperimentali* (IZS)]. There are 10 IZS, for which each institute covers one or more regions. Some of the IZS serve as a National Reference Laboratory (NRL) for one on more animal diseases or for food safety issues. Each laboratory within the IZS network is ISO 17025 accredited through Accredia, the Italian national accreditation body appointed by the State to perform accreditation activity.

FSIS identified the following areas needing improvement within the ISO 17025 recordkeeping system at the audited residue laboratory:

- Laboratory personnel were routinely documenting negative freezer temperatures with positive values (e.g., -22º C was being recorded as "22º C").
- The laboratory did not maintain records during the incubation of matrices associated with anabolic steroid and stilbene testing sufficient to ensure the process was occurring as intended.

In addition to the certification provided through Accredia, the *National Health Institute* [Italian: *Istituto Superiore di Sanità* (ISS)] conducts annual audits of the IZS laboratories performing microbiological analyses of products destined for export to the United States. These audits focus on application of approved *FSIS Microbiology Laboratory Guidebook (MLG)* methods; calibration of equipment; internal audits; traceability of samples and sample analysis; facility maintenance; quality manual and procedures; analyst training; and verification of corrective actions from previous audit findings. While onsite, the FSIS auditors confirmed that the 2015 audits had been conducted at all IZS laboratories as intended, and that the schedule for 2016 was being adhered to.

The CCA continues to provide written instructions and ongoing training to its inspection force, of which a portion of these coordinating activities were undertaken in response to the 2014 FSIS audit findings:

- *Circular DGISAN 15012 (4/14/2016):* Updated procedure for listing establishments.
- *Circular DGISAN 35655-P (9/16/2015):* Updates to the requirements for the control of *Lm* in the post-lethality environment.
- *Circular DGISAN 14971 (4/16/2015):* Revision of export certificates.
- *Circular DGISAN 24076 (6/12/2014):* Food defense guidelines.
- *Circular DGISAN 26639 (4/30/2014):* Updated inspection manual. Describes the responsibilities of the Italian official control bodies and the procedures for product

and process control to be applied during inspections in the establishments eligible to export meat products to the United States.

- *Circular DGISAN 36882 (9/29/2014):* Guidance on the use of high-pressure processing (HPP) as a post-lethality treatment.
- *Circular DGISAN 2627 (1/29/2016):* Registration of official *Salmonella* and *Enterobacteriaceae* testing in the electronic information system.
- *Circular DGI0053AN 445 (1/11/2016):* 2016 official sampling plan for *Lm.*
- Training on December 10, 2014 (Milan): *Exercising Specific Controls for Lm and Salmonella*
- Training on October 8, 2015 (Siena): *Exercising Official Control in United States-eligible Establishments*
- Training on October 13-14, 2015 (Gemona): *Use of the National Veterinary Information System for Food Safety (SINVSA)*
- Training on November 27, 2015 (Parma): *Export Requirements for the United States*
- Training on January 12-14 and 15-17, 2016 (Brescia): *Conducting Supervisory Reviews at United States-eligible Export Establishments*

FSIS concluded that the CCA continues to organize and administer its meat inspection system in a manner which meets the core requirements for this component. However, additional training regarding the oversight of RTE product may be necessary based on findings identified in subsequent sections of this report. Areas needing improvement include: identification of the post-lethality environment and classification of Alternative 3 deli products in accordance with 9 CFR 430.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

The second of six equivalence components that the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; daily inspection; and periodic supervisory visits to official establishments.

The FSIS auditors verified that the livestock (swine) brought to slaughter are receiving ante-mortem examination in accordance with the requirements in *Regulation (EC) 854/2004*. The FSIS auditors further verified that in-plant inspection personnel conduct ante-mortem inspection on the day of slaughter by observing all animals at rest and in motion prior to slaughter.

The FSIS auditors 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. This included verification that all animals have access to water

in all holding pens (including the pens used for suspect animals), and that if animals are held overnight, feed and water are provided.

The FSIS auditors also assessed post-mortem inspection examinations through onsite record reviews, interviews, and observations of in-plant inspection personnel performing post-mortem examinations. The FSIS auditors 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 auditors observed the performance of the inspection personnel examining the heads, viscera, and carcasses in order to ensure that the proper incision, observation, and palpation of required organs and lymph nodes were made in accordance with relevant EC regulations.

- At one slaughter establishment visited, the FSIS auditors noted that the post-mortem viscera inspector was not conducting adequate palpation of the mesenteric lymph nodes (swine) as required by *Regulation (EC) No. 854/2004* Section IV (determined equivalent by FSIS). Only a portion of the lymph node chain was being palpated.

The various frequencies and scope of periodic supervisory visits at United States-eligible establishments are outlined in ministerial circular *DGISAN 26639 (6/30/2014)*. These visits occur on two levels:

1. Documented reviews conducted by the LHU Supervising Veterinarian.
    - Every 3 months (four times a year) in establishments that have at least one slaughtering line;
    - Every 6 months (twice a year) in all establishments that produce processed meat products;
    - Once every year in establishments that do 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 necessary to address issues at noncompliant establishments.

2. National supervision of 25% of establishments eligible to export to the United States (annually). This activity is carried out by a group of national experts appointed by the MOH. In order to perform its monitoring activities, these experts collaborate with IZS technicians and LHU inspection personnel.

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 certified establishments from those establishments not certified for export to the United States; requirements for sanitation; official controls over condemned material; and HACCP system. The FSIS auditors determined that these reviews were being implemented as intended. However, the above-referenced finding related to post-mortem inspection

indicates a need for greater surveillance on the part of supervising officials to ensure that these procedures are conducted as expected.

There are no regulatory changes associated with the export of meat products to the United States since the last FSIS audit that would have required changes by the CCA. Italy's meat inspection system continues to maintain the legal authority and a regulatory framework to implement requirements equivalent to those governing meat inspection in the United States, although there was some need for improvement of oversight related to post-mortem inspection procedures.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of the six equivalence components that the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the CCA requires each official establishment to develop, implement, and maintain written standard operating procedures to prevent direct product contamination or insanitary conditions.

The FSIS auditors verified that the MOH uses its legal authority to require that certified establishments develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions. Furthermore, the FSIS auditors verified that inspection personnel exercise their official authority as prescribed by the regulations of the system and follow the requirements outlined in Section A of *DGISAN 26639 (6/30/2014): Official control in the establishments listed among the Italian establishments eligible to export meat products to the USA* to verify that the establishments adequately implement pre-requisite programs such as Sanitation Standard Operating Procedures (SSOP), Good Manufacturing Practices (GMP), and Sanitation Performance Standards (SPS).

The FSIS auditors observed in-plant inspection verification of operational sanitation procedures at all establishments visited. Pre-operational verification activities were also reviewed at one location. Audit evidence was gathered through direct observation of establishment operations and a review of the establishments' associated records. The FSIS auditors noted that, for the most part, the inspection and establishment records mirrored the actual sanitary conditions of the establishment. The audited establishments maintain sanitation records sufficient to document the implementation and monitoring of the SSOP and any corrective actions taken. The establishment employees responsible for the implementation and monitoring of the SSOP correctly authenticate these records with initials or signatures and the date. No concerns arose as the result of these document reviews.

However, the FSIS auditors reported the following findings concerning the CCA's ability to exercise official controls for sanitary operations, although no direct product adulteration was observed in any of these cases.

- Systemic deficiencies related to the maintenance of overhead structures were identified in five of the 13 establishments audited:

    - At one processing establishment, several production areas presented overhead structures with corroded valves and leaking pipes. Although the establishment had instituted short-term procedures to ensure that product would not be placed in these areas, FSIS determined that these maintenance issues had not been adequately addressed as they were of such extent and nature to warrant an immediate and permanent long-term solution.
    - Deficiencies related to the maintenance of overhead structures in the remaining four facilities:
        - Presence of rust and cobwebs.
        - Gaps between the ceiling and protruding metal bars above exposed product and food-contact surfaces in production areas.
        - Small holes in the ceiling over exposed product in several production areas.
- An isolated finding was identified at a processing establishment where pooling red-tinged liquid was observed on the floor of a storage cooler, originating from draining racks of raw product. This caused concern in that the wheels of hand trucks transiting through this area could cause splashing and result in product contamination.

In addition to the basic requirements outlined above, the MOH has developed specific requirements for sanitation in establishments producing post-lethality exposed RTE product in ministerial circular *DGISAN 35655-P (9/16/2015)*. 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 other 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 document also contains specific requirements concerning handling of product, appropriate use of paper towels in the post-lethality environment, and steps to be taken when product, food-contact surface (FCS), or non-food contact surface (NFCS) samples test positive for *Lm* or indicator organism.

- At one establishment, inspection officials were not aware of the mandatory glove use requirements in the final packaging and shipping area (Italian: *area di spedizione*) for bone-in, dry-cured ham. This area is considered a post-lethality environment of the establishment. Circular *DGISAN 35655-P (9/16/2015)* requires that gloves be worn in the post-lethality environment of the establishment by employees who are directly handling product. This establishment was under new ownership and had not yet begun packaging and shipping product to the United States (inventory of product destined for export was still undergoing the aging process). While in this instance the impact on final product was minimal, it is FSIS' expectation that official inspection personnel be familiar with requirements set forth by the CCA prior to certifying product for export to the United States. Similarly, while this finding can be considered isolated in nature as it was identified at only one facility, the CCA will need to take the necessary precautions to ensure that the requirements outlined in *DGISAN 35655-P (9/16/2015)* are implemented as intended at United States-eligible establishments throughout Italy.

At the audit exit conference, the CCA provided the FSIS auditors with evidence that the facility sanitation non-compliances had been corrected. FSIS' ongoing assessment of Italy's inspection system indicated that it maintains clearly defined requirements and controls that meet the core equivalence requirements for this component; however, there is a need to improve sanitation verification and enforcement activity, especially at it relates to the maintenance of the overhead structures in the production areas establishments certified for export to the United States.

VII. COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM

The fourth of six equivalence components that the FSIS auditors reviewed was Government HACCP System. The inspection system is to require that each official establishment develop, implement, and maintain a HACCP plan.

The evaluation of this component included a review and analysis of the information provided by the CCA in the updated self-reporting tool (SRT) and observations during the onsite audit. The ministerial circular *DGISAN 26639 (6/30/2014)* requires establishments exporting to the United States to develop and implement a HACCP program consistent with 9 CFR Part 417. Furthermore, paragraph D of this document requires all establishments that export meat products to the United States must implement and apply *Lm* management procedures for RTE products in accordance with 9 CFR Part 430.

At the 13 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. The FSIS auditors reviewed zero tolerance (e.g., feces, ingesta, and milk) Critical Control Point (CCP) records and noted that the two slaughter establishments were conducting 100% monitoring. The auditors also verified the physical CCP locations by observing inspection personnel conducting HACCP hands-on verification activities.

At the 11 establishments producing RTE products, the FSIS auditors reviewed the HACCP programs for these processes with a special emphasis on lethality for *Salmonella* and other relevant pathogens in accordance with Section C of *DGISAN 35655-P (9/16/2015).* The FSIS auditors noted that the establishments producing dry-cured pork products maintained validated HACCP programs to support a 5-log reduction for *Salmonella* in these products. Establishments producing cooked pork products were adhering to the lethality and stabilization performance standards outlined in Appendixes A and B of the *FSIS Compliance Guidelines for Cooking/Cooling Meat and Poultry Products*.

The onsite audit identified the following findings concerning government enforcement of HACCP requirements:

- Systemic deficiencies related to HACCP recordkeeping were identified in four of the 13 establishments audited, these included:

- Missing time entries (monitoring or verification records)
- Missing ongoing verification results (verification of records, calibration of process-monitoring instruments)

Specific details regarding these deficiencies can be found on the individual establishment checklists attached to this report.

- At one establishment, the written HACCP monitoring procedure (CCP1) related to the preparation of brine solution did not accurately identify the amount of the nitrite mixture (50% nitrite) which was actually being used. While the mixing charts used in the production areas called for the addition of 170 grams (nitrite mixture) /100 liters (water), the HACCP plan specified a quantity of 110 grams (nitrite mixture) / 100 liters (water). Ultimately, FSIS was able to verify the safety of product being produced (review of production records, analytical testing of product). A review of analytical product testing results demonstrated that products typically contained less than 2 parts per million (ppm) for both nitrites and nitrates. However, the failure of the establishment to accurately describe its HACCP monitoring procedures does not meet the requirements outlined in Section 5.3.3.3-4 (Monitoring) of circular *DGISAN 26639 (6/30/2014).*

- Two establishments had incorrectly identified the post-lethality environment for cooked products as the point at which they exit the cooler after chilling, rather than the point where they exit the oven after cooking (lethality). This included an establishment which was using aluminum molds during cooking/chilling to give the product its form. However, as the aluminum molds do not provide an impermeable seal (as evidenced by product protruding from the seams due to thermal expansion), these products should also be considered post-lethality exposed after cooking.

- At one establishment, the inclusion of pistachio nuts (an ingredient in mortadella) had not been identified as a potential hazard (allergen) within the establishment's hazard analysis. A subsequent review of the product label indicated that this ingredient was included in the product formulation. However, the failure for the establishment to address this potential food-safety hazard within the context of its hazard analysis does not meet the requirements outlined in Section 5.3.2 (Hazard Analysis) of circular *DGISAN 26639 (6/30/2014).*

During the exit meeting, the MOH presented evidence that they had taken immediate measures to resolve the non-compliances identified at the above-referenced locations, including issuance of non-compliance reports and verification that food business operators had modified their HACCP programs accordingly. FSIS requests that the MOH provide a description of long-term measures taken to improve the manner in which in-plant officials verify the implementation of establishment HACCP systems, particularly as it pertains to the correct identification of the post-lethality environment for cooked products.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that the FSIS auditors reviewed was Government Chemical Residue Testing Programs. The inspection system is to present a chemical residue control program, organized and administered by the national government, which includes random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified by the exporting country's meat and poultry inspection authorities or by FSIS as potential contaminants.

Prior to the onsite visit, FSIS' residue experts thoroughly reviewed the 2016 residue sampling plan, associated methods of analysis, and additional SRT responses outlining the structure of Italy's chemical testing program. It was also noted that there have not been any POE violations related to this component since the last FSIS audit.

As required by equivalent provisions outlined in *EC Directive 96/23, Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products*, the MOH publishes and implements an annual *National Residue Monitoring Plan* (NRMP) for Italy. 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 No. 98/179/EC* of February 23, 1998. The MOH defines the species, categories, points of sampling, substances for food safety interest, test procedures according to the EC's legal provisions, and indications. The plan is developed annually by the MOH in collaboration with the RHSO, the IZS national reference laboratory in Brescia, and additional IZS sites involved in residue testing. In addition, the plan takes into account the previous year's results in order to implement appropriate modifications and possible targeted actions. Once finalized, the RHSO then forwards the plan onto the individual LHUs, which are responsible for its implementation. The NRMP goes into effect each year on January 1, and ends December 31.

Under Italy's NRMP, samples are taken from live animals and slaughter plants in accordance with the following sub-plans:

1. *Routine Plan*. Takes place at various sampling points as documented in the NRMP. When a positive result is obtained, the result is recorded by the laboratory on the official sampling and analysis form. Animals or carcasses are not routinely detained during routine sampling.
2. *Suspect Plan*. Instituted in cases where there is evidence of illegal treatment, clinical symptoms, or suspected non-compliance with the withdrawal period for authorized veterinary drugs. When samples are taken, the carcass, animal, or animal product is detained at the sampling point pending the analysis results.
3. *Extra Plan*. Includes monitoring plans arranged by the Ministry and Regions to meet specific local or National requirements.

In the case of violative samples, inspection officials transmit a questionnaire [Italian: *Questionario Sull Attività Conseguente a Non Conformità*] to the MOH with the details summarizing the follow-up activities.

- However, the FSIS auditors identified the following concerns during its review of the documentation submitted in response to residue violations. In some instances, completed questionnaires did not indicate whether follow-up sampling or on-farm investigations occurred, as directed by Italian residue enforcement guidelines. In other cases, unexpected modifications were made to the form template by the user. Ultimately, the FSIS auditors were able to verify that the appropriate follow-up procedures were performed in conjunction with all violative samples identified through implementation of the NRMP since the last FSIS audit. However, these deficiencies can impact the CCA's ability to demonstrate that the national residue plan is operating as intended.

During the evaluation of ante-mortem inspection at two slaughter establishments, the FSIS auditors observed that government inspectors verify that all lots of animals are accompanied by documentation that discloses their origin and includes a signed declaration that attests that owners have adhered to veterinary pharmaceutical withdrawal periods. A review of the sampling records maintained at the two local inspection offices audited indicated that the 2016 sampling program was being adhered to as scheduled.

During the audit of the IZS Reference Laboratory (Brescia) laboratory, FSIS reviewed the training records and certifications associated with the qualifications of the analysts. The documents reviewed made evident that analysts had successfully participated in intra- and inter-laboratory evaluations administered by the laboratory manager and accrediting bodies. Furthermore, records and past internal laboratory audit reports showed that laboratory managers readily respond to correct non-conformities identified during internal and external audits. The documentation on file also showed that the analysts possess the academic qualifications, technical credentials, and accreditations required to conduct analyses within their accreditation scope.

FSIS determined that the chemical residue control program as described is consistent with the criteria established for this component, although some weaknesses which could ultimately impact its effective implementation were observed. Nevertheless, the result of the onsite audit activities indicate that Italy continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in the tissues of swine slaughtered for meat and meat products for human consumption.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component that the FSIS auditors reviewed was Government Microbiological Testing Programs. The system is to implement certain sampling and testing programs to ensure that meat products produced for export to the United States are safe and wholesome.

The CCA has developed a *Salmonella* testing program for chilled livestock carcasses (swine) within its *DGISAN 5107-P (3/14/2008)* that is equivalent with FSIS regulatory requirements outlined in 9 CFR Part 310.25(b). *Enterobacteriaceae* and aerobic plate count (APC) testing is carried out in accordance with *Regulation (EC) 2073/2005* on microbiological criteria for foodstuffs. All documents reviewed in relation to these microbiological testing programs led the FSIS auditors to conclude that adequate process control was being maintained in the two swine slaughter establishments visited.

The CCA considers *Lm* to be a hazard of concern in the production of RTE products that are post-lethality exposed to the environment. Specific requirements related to *Lm* control are contained in *DGISAN 35655-P (9/16/2015)*, replicating the controls in 9 CFR 430.4 by providing the same three alternative controls to prevent post-lethality *Lm* adulteration in exposed RTE product. *Section A.4.1.* of this document prohibits the export of any RTE product to the United States which is either contaminated with *Lm* or has come into direct contact with a food contact surface that is contaminated with *Lm*. Furthermore, this document requires all United States-eligible establishments to operate under a single microbiological standard (zero-tolerance) for *Lm* on product and product contact surfaces regardless of whether they are actively producing for the United States market at a given time.

Section C of *DGISAN 35655-P (9/16/2015)* outlines specific requirements for official verification of establishment RTE control programs. *Section C.1.b.* addresses verification of the post-lethality treatments and processes used to eliminate or suppress the growth of *Lm* in RTE products in conjunction with specific risk alternatives chosen by the establishment; *Section C.1.c* outlines procedures for the verification of sanitation and HACCP requirements, with special emphasis on the control of *Lm* in RTE products and verification of establishment RTE sampling plans; and *Section C.1.1.d* specifies enforcement actions to be undertaken in the face of positive results identified either through establishment or government verification testing.

The FSIS auditors verified that the CCA implemented the 2016 official surveillance plan for monitoring *Lm* and *Salmonella* in pork products to be exported to the United States as outlined in *DGISAN 445 (1/11/2016)*. This plan includes the random and risk-based sampling of all RTE products for *Lm* and *Salmonella*; and a plan that includes the monitoring of FCS and NFCS in 25% of RTE establishments eligible to export to the United States annually. Microbiologically independent lots of product are held during all phases of sampling (FCS, NFCS, product), and results of these surveillance programs are uploaded in the SINVSA database. As per Attachment 4 of *DGISAN 35655-P (9/16/2015)*, all official analyses are conducted using *USDA/FSIS MLG 8.09 Isolation and identification of Listeria monocytogenes from Red Meat, Poultry, Egg and Environmental samples*.

- The FSIS auditors noted that the 2016 official surveillance plan incorrectly identified some Alternative 3 deli products. For example, the current plan identifies bone-in, dry-cured prosciutto as a “non-deli” product as it is typically

sent for deboning. However, based on the definition found in 9 CFR 430.1, FSIS considers this type of product a "deli product," i.e., *a product that is typically sliced, either in an official establishment or after distribution from an official establishment, and assembled in a sandwich for consumption.*

The FSIS auditors noted that the industry testing of FCS, NFCS, and product were conducted at frequencies outlined in *Section A.4.2.d.* of *DGISAN 35655-P (9/16/2015).* Establishment records indicated that product is routinely held until all (FCS, NFCS, product) testing results are received. Furthermore, it was noted that establishment testing results were routinely verified by representatives of the LHU, as well as during periodic supervisory reviews. No concerns arose from the review of these programs.

While onsite, the FSIS auditors conducted follow-up activities to verify responses provided by the CCA in response to the following violations for *Lm* identified at POE:

- One lot of product received on December 4, 2014, for which 30 pounds of RTE, dry-cured, sliced ham was refused entry into the United States.
- One lot of product received on December 22, 2014, for which 16 pounds of RTE, deboned, dry-cured, unsliced ham was refused entry into the United States.

In both cases, the FSIS auditors were provided with sufficient evidence to demonstrate:

- Timely notification of the event throughout the inspection system.
- Segregation of product, with a focus on microbiological independence of the lots in question, and immediate suspension of export of all similar products to the United States. As per Annex 3 of *DGISAN 35655-P (9/16/2015),* the MOH defines the production lot as the quantity of product that has to be taken into consideration if a positive finding is obtained on a product or food contact surface. If a product or food contact surface is identified as positive for *Lm*, the production lot must be recalled if it has already been placed on sale. For this purpose, production lots are generally identified as the quantity of product processed between two complete clean-up operations (clean-up to clean-up), unless the plant is able to manage smaller lots. Lot sizes may be reduced if the plant is able to implement a complete action of clean-up and sanitizing between two lots (based on its SSOP cleaning and sanitizing procedures). To determine the lot sizes, it is necessary to consider various factors including the origin of the materials used for RTE production, the frequency of cleaning and sanitizing and the production stages. In any case, the processes must be recognized suitable (validated) to restore generally sanitary hygienic conditions and, specifically, to guarantee the elimination of the environmental pathogens and the microbiological independence between two production lots.
- Documented activities conducted by industry to identify the source of the contamination.
- Intensified industry sampling, in accordance with *DGISAN 35655-P (9/16/2015)*, *Section A.4.2.f.*
- Intensified government sampling in accordance with *DGISAN 35655-P (9/16/2015)*, *Section A.4.2.f., Section C.2.b.*

- Performance of a documented supervisory review performed by an assigned task force of government officials.

Additional verification activities conducted by the FSIS auditors included a review of trend data compiled by the CCA from 2014 to the early part of 2016, which demonstrated a trending decline in positive results in recent years. The FSIS auditors also verified that the CCA maintained documentation to demonstrate that appropriate corrective actions outlined in *DGISAN 445 (1/11/2016)* were taken in response to positive results.

Year	Contact surfaces		Non contact surfaces		Products	
	Tested samples	Positive samples for *Lm*	Tested samples	Positive samples for *Lm*	Tested samples	Positive samples for *Lm*
2014	4,450	8	1,249	11	542	4
2015	5,594	0	1,010	1	293	1
2016 (partial)	1,550	1	340	0	79	0
Total	**11,594**	**9**	**2,599**	**12**	**914**	**5**

During the visit to the microbiological laboratories, the FSIS auditors noted that FSIS MLG methods were used to analyze United States export samples (both for *Lm* and *Salmonella*). Verification of activities related to sample receiving and traceability was also performed. Samples are hand-delivered to the laboratory in cooling bags by trained technicians. Laboratories maintain appropriate discard criteria to ensure the integrity of the sample and testing results.

FSIS concludes that the CCA continues to meet the core equivalence requirements for this component. While the identified finding is unlikely to have a significant impact on the CCA's ability to ensure the export of safe product, it is important that the CCA correctly distinguish deli products under Alternative 3 in order to provide an effective implementation of the government risk-based sampling program for post-lethality exposed RTE products. Furthermore, based on the findings identified under component 4 (HACCP), the CCA will need to ensure that establishments have accurately identified the post-lethality environment for RTE product, and that government verification sampling of FCS and NFCS occurs within the redefined post-lethality environment of the facility.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on June 3, 2016, in Rome, Italy with the MOH. At this meeting, the FSIS auditors presented the preliminary findings from the audit. The CCA understood and accepted the findings.

During the audit, the following findings were identified:

- At one processing establishment, inspection officials were not aware of the mandatory glove use requirements in the final packaging and shipping area for bone-in, dry-cured ham. This area is considered a post-lethality environment of the establishment. Circular *DGISAN 35655-P (9/16/2015)* requires that gloves be worn in the post-lethality environment of the establishment by employees who are directly handling product.
- FSIS identified systemic deficiencies related to the maintenance of overhead structures in five of the 13 establishments audited. Additionally, isolated sanitation findings are included in the individual establishment checklists which are attached to this report.
- FSIS identified systemic deficiencies related to HACCP recordkeeping in four of the 13 establishments audited. Additionally, isolated HACCP findings are included in the individual establishment checklists which are attached to this report.
- Two processing establishments had incorrectly identified the post-lethality environment for cooked products as the point at which they exit the cooler after chilling, rather than the point where they exit the oven after cooking (lethality).
- The 2016 official surveillance plan for monitoring *Listeria monocytogenes* and *Salmonella* in pork products to be exported to the United States (*DGISAN 445)* incorrectly identified some of the Alternative 3 deli products. For example, the current plan identifies bone-in, dry-cured prosciutto as a "non-deli" product as it is typically sent for deboning. However, based on the definition found in 9 CFR 430.1, FSIS considers this type of product a "deli product," i.e., *a product that is typically sliced, either in an official establishment or after distribution from an official establishment, and assembled in a sandwich for consumption.*

An analysis of the findings within each component did not identify any deficiencies which represented an immediate threat to public health. During the audit exit meeting, the CCA was made aware of all the FSIS concerns and noted that it had already begun to address the audit findings by implementing immediate corrective actions.

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	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Fontana Ermes SPA Sala Baganza (PR)	05/26/2016	100L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
International Audit Staff (IAS)	

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Leoncini SRL VIA CONFINE, 4 LAZISE	05/24/2016	169L	Italy
	5. NAME OF AUDITOR(S) International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The following non-compliances were not identified by Italian inspection officials during the establishment review:

15/51. The inclusion of pistachio nuts (an ingredient in mortadella) had not been identified as a potential hazard (allergen) within the establishment's hazard analysis. A subsequent review of the product label indicated that this ingredient was included in the product formulation. However, the failure for the establishment to address this potential food-safety hazard within the context of its hazard analysis does not meet the regulatory requirements of 9 CFR 417.2(a)(1).

58/51. The establishment had incorrectly identified the post-lethality environment for cooked hams as the point which the aluminum cooking molds are opened after chilling. However, as the aluminum molds do not provide an impermeable seal (as evidenced by protruding product at the seams), these products should also be considered post-lethality exposed after cooking.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
International Audit Staff (IAS)	

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Principe Di San Daniele SPA	5. NAME OF AUDITOR(S) 05/19/2016	205L	6. TYPE OF AUDIT Italy ON-SITE AUDIT DOCUMENT AUDIT

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

International Audit Staff (IAS) X

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

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

60. Observation of the Establishment

The following non-compliances were not identified by Italian inspection officials during the establishment review:

39/51. The FSIS auditor observed numerous gaps between the ceiling and protruding metal bars holding attached structures in the ceiling above exposed products and food contact surfaces in the production areas. The auditor did not observe any direct product contamination.

22/51. The establishment HACCP ongoing verification records documenting the *calibration of process-monitoring instruments* did not include the time at which the verification activity occurred.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
International Audit Staff (IAS)	

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Agricola Tre Valli Soc. Coop, A R.L. Villafranca Di Verona	05/24/2016	363L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The following non-compliances were not identified by Italian inspection officials during the establishment review:

22/51. The establishment HACCP ongoing verification records documenting the *calibration of process-monitoring instruments* did not include the time at which the verification activity occurred. In addition, the ongoing verification records for the component of *records review* did not include the results of the activity.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
International Audit Staff (IAS)	

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Principe Di San Daniele SPA J. Ressel, 1 San Dorligo della Valle	05/20/2016	478L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	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	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
International Audit Staff (IAS)	

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Recla GmBH - s.r.l. I-39028 Schlanders Silandro	05/18/2016	621L	Italy
	5. NAME OF AUDITOR(S) International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The following non-compliance was not identified by Italian inspection officials during the establishment review:

39/51. Some of the overhead structures in the product smoking areas presented unclean surfaces (rust, cobwebs). No direct product contamination was observed.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
International Audit Staff (IAS)	

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Martelli F. LLI SPA VIA CANTONE 22/24 Dosol	05/25/2016	643M	Italy
	5. NAME OF AUDITOR(S) International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	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	
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

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
International Audit Staff (IAS)	

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Prosciutti Doc E G. Langhirano (PR)	05/26/2016	670L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	International Audit Staff (IAS)		X ON-SITE AUDIT ☐ DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The following non-compliances were not identified by Italian inspection officials during the establishment review:

39/51. The FSIS auditor observed numerous gaps between the ceiling and protruding metal bars holding attached structures in the ceiling above exposed products and food contact surfaces in the production areas. The auditor did not observe any direct product contamination.

22/51. The HACCP ongoing verification records for the component of *records review* did not include the results of the verification activity.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
International Audit Staff (IAS)	

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Grandi Salmuific Italiani APA S. Candido Via Pizach 11 39038	05/18/2016	675L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The following non-compliances were not identified by Italian inspection officials during the establishment review:

39/51. The FSIS auditor observed several small holes on the ceiling and on the overhead structures in the production areas and over exposed products. No direct product contamination observed by the FSIS auditor at this time.

22/51. The establishment's HACCP verification records for direct observation component did not document the time of the ongoing verification activities conducted by the establishment's personnel.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
International Audit Staff (IAS)	

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Filiera Uno Prosciutti Srl. Via Jiacopo Pirona 15 3303 San Daniele del Friuli	05/19/2016	683L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	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	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

46/51. Inspection officials were not enforcing the mandatory use of gloves in the final packaging and shipping area (*spedizione*) for bone-in, dry-cured ham (*prosciutto crudo con osso*). This area is considered a post-lethality area of the facility. *DGSAN 0035655-P-16/09/2015* requires that gloves be worn in the post-lethality areas of the facility by employees who are directly handling product.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
International Audit Staff (IAS)	

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Salumificio Piacenti S.r.L. VIA DEL PONTE, 4 San Gimignano (SI)	05/30/2016	718L	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The following non-compliances were not identified by Italian inspection officials during the establishment review:

15/51. The written HACCP monitoring procedure (CCP1) related to the preparation of brine solution did not accurately identify the amount of the nitrite mixture (50% nitrite) which was actually being used. While the mixing charts used in the production areas called for the addition of 170 grams (nitrite mixture) /100 liters (water), the HACCP plan specified a quantity of 110 grams (nitrite mixture) / 100 liters (water). A detailed review of the production records and discussions with establishment and inspection personnel conducted by FSIS upon identification of this error indicated that the values on the production charts were correct (and those within the HACCP plan were in error), for which the safety of product currently in the facility and previously exported could be demonstrated. Furthermore, a review of analytical product testing results demonstrated that products typically contained less than 2 ppm for both nitrites and nitrates. However, the failure for the establishment to accurately describe its HACCP monitoring procedures does not meet the regulatory requirements of 9 CFR 417.2(c)(2).

39/51. Several production areas of the facility presented overhead structures with corroded valves and leaking pipes. Although the establishment had instituted short-term procedures to ensure that product would not be placed in these areas, FSIS determined that these deficiencies had not been adequately addressed as they were of such extent and nature to warrant an immediate and permanent long-term solution. No product adulteration was observed.

46/51. Pooling blood was observed in the storage cooler containing racks of raw product. This caused concern in that the wheels of hand trucks transiting through this area could cause splashing and result in product contamination. No evidence of product contamination was observed at this time.

58/51. The establishment had incorrectly identified the post-lethality environment for exposed cooked hams (and other similar cooked pork products) as the point at which they exit the cooler after chilling, rather than the point where they exit the oven.

58/51. Within the context of its control program for *Listeria monocytogenes* (Alternative 3) for ready-to-eat products, the establishment identified “deli products” as only those products sliced onsite, rather than a product that *is typically sliced, either in an official establishment or after distribution from an official establishment, and assembled in a sandwich for consumption* (as per 9 CFR 430.1). Consequently, some products (e.g., whole roasted hams) which should have classified as “deli” were incorrectly identified as “non-deli.”

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
International Audit Staff (IAS)	

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Italcarni Societa Cooperativa Agricola Via Per Guastalla 21/a Migliarina di Carpi	05/25/2016	791M	Italy
	5. NAME OF AUDITOR(S) International Audit Staff (IAS)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The following non-compliance was not identified by Italian inspection officials during the establishment review:

22/51. The establishment HACCP ongoing verification records for *document review* (CCP1: "zero tolerance") did not include the time at which the verification activity occurred.

In addition, the FSIS auditor noted the following findings related to implementation of Italy's meat inspection system:

55. The post-mortem viscera inspector was not conducting adequate palpation of the mesenteric lymph nodes (swine) as required by *Regulation (EC) No 854/2004 Section IV* (determined equivalent by FSIS). Only a portion of the lymph node chain was being palpated.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
International Audit Staff (IAS)	

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Salumificio Piacenti S.r.L. San Gimignano (SI)	05/30/2016	D9C5P	Italy
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
International Audit Staff (IAS)	

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 2

Jane Doherty
International Coordination Executive

p.c. Ambasciata degli Stati Uniti a Roma
Ufficio USDA

Ambasciata Italiana a Washington
Ufficio Economico-Commerciale

Consigliere diplomatico
Dr. Luigi Ferrari

Dear Dr. Doherty,

We are in receipt of the Draft Final Report of the audit of the Italian food safety system conducted by FSIS last May.

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 25752 of June 22nd, 2016 (Annex 1 - English translation), which reflect changes related to the non compliance results gathered from the exit meeting and on the draft final report;
2. verified, through the official veterinary services, that all the non compliances pointed out by the inspectors during the on site visits were solved.
3. Is working in a e-learning course specific for US export that will be available for the official veterinarians by the next year

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

[C[1]] Supervision of the Government

A) As regards the non compliance related to the way in which the non compliances reports (in case of non compliances) are filled, we would like to add that in Italy, in the near future, an informatics system to collect the data is going to be implemented.

B) All the inspection personnel of the slaughtering plant participate to training events regarding the inspection method. The official veterinarian at the post mortem inspection is no more working in the same field and was assigned to other non US export establishments.

Component Six [C^6]: Residues Testing

Recordkeeping to be performed during the incubation of samples: As during the test run quality controls are inserted (positive controls to the CCß), and depending on the outcome of the test it is decided if it is necessary to repeat or not the test itself, it is believed that the non-registration of incubation times and temperatures during the execution of test methods for the detection of stilbene and anabolic steroid does not undermine in any way the result. The method provides that, if the outcome of the positive controls is not compliant the test run must be repeated.

Finally, please find here after some minor concerns regarding the draft:

1. Pag. 3, Background, 6° line – it is said that after the Audit of 2014, 2 batches of products where refused because tested positive for Lm. One was referred to a sliced dry cured ham and the other one was not a "fully cooked" product as reported at page 15 but a deboned dry cured ham.
2. Pag. 3, Background, last phrase, - "*...one lot of unsliced ham was identified as being "off-condition" and one lot of dried, unsliced ham was found to contain mold".* Based on the information we have, the two non compliances ("off-condition" and "mold") should be refered to the same ham. We propose to modify as following : "*...~~one lot~~ **one ham** of unsliced ham was identified as being "off-condition" and ~~one lot of dried, unsliced ham~~ **the same ham** was found to contain mold".*
3. Report of establishment 683L: the correct name of the plant is not "B e B", but FILIERA UNO PROSCIUTTI SRL.

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)

Referente
Anna Beatrice Ciorba – 0659946937
E-mail: ab.ciorba@sanita.it

Annex 1 – English text of the note DGISAN 25752 of June 22nd, 2016

Object: Audit USDA - FSIS year 2016 - preliminary outcomes

By the following Note we would like to inform all the organizations in address regarding the preliminary outcomes resulted from the audit activity conducted by FSIS from May, 16th to June, 3rd 2016.

Audit activity was performed in the following structures:

- Ministry of Health
- 2 Regional Services (Friuli V.G. and Emilia Romagna)
- 2 Zooprophilactic Institutes for the microbiological criteria (Brescia e and Parma)
- 1 Zooprophilactic Institute for the chemical criteria (Brescia)
- 13 establishments (2 slaughterhouses included)

During the exit meeting held in Rome June 3, 2016, were highlighted the following non-compliances divided by topic area:

[C[1]] Supervision of the Government

A) chemical residues lab and National Plan for Residues

1. temperatures freezer records must always report punctual values and the sign + or - depending on the temperatures that are to be referred to positive or negative values;
2. The labs' documentation should highlight the processing activities of the samples (ex. Recording the time and the sample incubation activities if this is applicable)

We would like to remind to the Official Veterinary Services that during the document review carried out within the CCA and with regard to non-compliances related to the Residues National Plan (*Questionnaire On Resulting Activities in Non-Conformity*), FSIS underlined what follows:

- In some cases, the reports did not provide complete information regarding the follow-up activities to the notification of non-compliance (**follow-up sampling or on-farm investigations**)
- In other cases, the non compliance questionnaires were modified by the users .

Consequently, it was not easy to prove by the CCA that the Residues National Plan in case of non compliances was being implemented as required. It is therefore necessary to pay maximum attention regarding the necessity of strict compliance with the procedures laid down in the Residues National Plan which, in case of follow-up activities as a result of non-compliance, schedules the inclusion of the non-compliance questionnaire in the NSIS / PNR system ~~of~~, duly completed in all its parts, in particular for what concerns the indication of all the corrective actions taken.

B) inspection at slaughterhouse

It brings the attention of the official veterinary services to comply with the Regulation (EC) No 854/2004 Section IV - recognized as equivalent by FSIS before the change which provides the only visual inspection post mortem to the slaughter.

[C[3]] Sanifications (SSOP)

It is recalled that according to the ministerial note (DGSAN 0035655-P-16/09/2015) all the operators working in the post lethality areas of the establishments must wear gloves.
More generally, it is an expectation that all operators in the sector as well as the official control are familiar with all the current regulations regarding the export of meat products to the United States.

[C⁴] HACCP

The official control requires and verifies that at all establishments develop an HACCP plan in accordance with the provisions of the ministerial note DGISAN 26639 of 30/06/2014 and subsequent amendments and with US regulations.
Given that it is necessary, ensure that:

- All documents related to the CCPs monitoring and verification activity clearly specify the outcome of the performed control as well as the data, the time and the signature;
- Corrective actions always include: the identification of batches of the product involved and the consequent actions; the identification and elimination of the cause of the deviation; the restoration of the state of compliance; preventive actions able to ensure that the deviation does not occur further.
- Please remember that the CCP verification activities always include: calibration of measuring instruments; Onsite verification and document review.
- Hazard analysis must always include all the hazards that may reasonably occur (such hazards should be listed individually for each identified step). The hazards to be identified also include the use of allergens that must be indicated on the label and should also be reported in the product formula.

[C⁶] Microbiological controls

DRY CURED PRODUCTS

According to the definition of "deli" products and as specified in the Ministerial note *DGSAN 0035655-P-16/09/2015 and in* 9 CFR 430.1 "*As only those products sliced onsite, rather than a product that is typically sliced, either in an official establishment or after distribution from an official establishment, and assembled in a sandwich for consumption*", all products of Italian delicatessens are "deli" products.
Given that, all the establishments producing only bone-in dry cured hams that were collocated in alternative 3 "not-deli", by the date of this note will be collocate in alternative 3 DELI as specified in the Ministerial note DGISAN 441 of 11/01/2016.

We kindly ask the official veterinary services:

1. to verify that all the establishments modify their procedures and sampling plan accordingly to this alternative.
2. to perform during this year at least one additional official sampling on product for each establishment involved in this change (Plan RTE PROD RAND).

COOKED PRODUCTS - Post Lethality Areas definitions

For enforcement of the existing legislation on the export of RTE food products, a product is considered RTE when is submitted to a lethality treatment.
Following the application of the lethality treatment, the environment where the products is exposed again - "post lethality area" - should be identified.
For the cooked RTE products cooked in grids or in cook-out method, such environment must be referred to all areas of the plant where the product passes and / or is stored following the exit from the oven.

Finally, in order to make more evident the post lethality area, it is desirable that all establishments highlight in their flowchart and Flow diagram the post lethality areas.