USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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Dott. ssa Gaetana Ferri
Director General for Food Hygiene, Safety, and Nutrition
Ministry of Health
Directorate General for Veterinary Health and Food
(Direttore del Dipartimento de Sanita Pubblica Veterinaria, Nutrizione e Sicurezza degli Alimenti, Ministero della Salute)
Via Giorgio Ribotta, 5
00144 Rome, Italy

Dear Dott. Ferri,

The FSIS on-site audit conducted from September 10 through September 25, 2018, supports that Italy's 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.

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

ITALY

SEPTEMBER 10-25, 2018

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

RAW AND PROCESSED PORK PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

February 4, 2019

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from September 10-25, 2018. The purpose of the audit was to determine whether Italy's food safety inspection system governing pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Italy is eligible to export raw intact, raw non-intact, thermally processed-commercially sterile (TPCS), not heat treated-shelf stable, heat treated-shelf stable, and fully cooked-not shelf stable pork products.

The audit focused on six system equivalence components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following finding:

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling)

- The supervisory visit reports did not consistently document an assessment that all HACCP and official sampling requirements were compliant according to the CCA's written procedures. At one regional office, the periodic supervisory visit reports did not document review of all required elements over the course of one year including:
  - Reports reviewed did not include assessment of all HACCP requirements, and
  - Reports reviewed did not include assessment of official microbiologic sampling.

During the audit exit meeting, the Central Competent Authority (CCA) committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Italy's food safety inspection system from September 10-25, 2018. The audit began with an entrance meeting held on September 10, 2018, in Rome, Italy, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA), the Italian *Ministry of Health* (MOH).

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether the food safety system governing pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Italy currently exports the following categories of pork products to the United States: thermally processed commercially sterile (TPCS); ready-to-eat (RTE) salt-cured; RTE pork fully cooked without subsequent exposure to the environment; RTE fully cooked; RTE dried; RTE acidified/fermented (without cooking); raw intact; raw non-intact; and not ready-to-eat (NRTE) otherwise processed pork.

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Italy as free of Foot-and-Mouth Disease (with special restrictions), free of Swine Vesicular Disease within the regions of Emilia-Romagna, Fruili, Liguria, Lombardia, Marche, Piemonte, Valle d' Aosta, and Veneto, and the Autonomous Provinces of Trento and Bolzano (with special restrictions), and low risk for Classical Swine Fever (APHIS-defined European CSF region). For African Swine Fever, APHIS recognizes the status based on restricted zones in the European Union (EU) established by the EU or any EU Member State because of detection of African Swine Fever in domestic or feral swine.

FSIS applied a risk-based procedure that 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) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from the CCA through the self-reporting tool (SRT).

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

Administrative functions were reviewed at CCA headquarters, two regional offices, and 12 local inspection offices. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of 12 establishments was selected from a total of 120 establishments certified to export to the United States, comprised of three slaughter and nine processing establishments. During the establishment visits, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditors assessed the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §327.2.

Additionally, one government microbiological laboratory and one government residue laboratory were audited to verify their ability to provide adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• Ministry of Health, Rome
	Regional Offices	2	• Emilia-Romagna Regional Office, Bologna • Lombardia Regional Office, Milan
Laboratories		2	• Istituto Zooprofilattico Sperimentale Laboratory, (government microbiological), Brescia • Istituto Zooprofilattico Sperimentale Laboratory, (government residue), Brescia
Pork slaughter establishments		3	• Establishment 304 M, Marcaria • Establishment 404 M, Busseto • Establishment 361 M, Cremona
Pork processing establishments		9	• Establishment 2 L, Barzanò • Establishment 302 L, Correggio • Establishment 508 L, Biassono • Establishment 550 L, Felino • Establishment 670 L, Langhirano • Establishment 690 L, Langhirano • Establishment 757 L, Zola Predosa • Establishment 955 L, Lavezzola • Establishment H5H5G, Correggio

FSIS performed the audit to verify the food safety inspection system met requirements equivalent to those 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. 1901-1906); and
- The Meat Inspection Regulations (9 CFR Parts 301 to the end).

The audit standards applied during the review of Italy's inspection system for processed pork products included: (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the World Trade Organization's *Agreement on the Application of Sanitary and Phytosanitary Measures*. This also includes the following:

- Regulation European Commission (EC) No. 178/2002;
- Regulation (EC) No. 852/2004;
- Regulation (EC) No. 853/2004;
- Regulation (EC) No. 854/2004;
- Regulation (EC) No. 882/2004;
- Regulation (EC) No. 1/2005;
- Regulation (EC) No. 2073/2005;
- Regulation (EC) No. 1069/2009;
- Regulation (EC) No. 1099/2009;
- Regulation (EC) No. 142/2011;
- Council Directive No. 93/119/EC;
- Council Directive No. 96/22/EC; and
- Council Directive No. 96/23/EC.

III. BACKGROUND

From June 1, 2015, to May 31, 2018, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 47,111,294 pounds of RTE dried pork; 9,194,643 pounds of RTE fully cooked pork; 1,853,770 pounds of RTE acidified/fermented pork (without cooking); 699,172 pounds of TPCS pork; 312,486 pounds of RTE pork fully cooked without subsequent exposure to the environment; 61,827 pounds of RTE salt-cured pork; 11,488 pounds of raw non-intact pork; 7,425 pounds of NRTE otherwise processed pork, and 228 pounds of raw intact pork exported by Italy to the United States. Of these amounts, FSIS performed additional types of inspection on 9,743,114 pounds of pork, including testing for chemical residues and microbiological pathogens including *Listeria monocytogenes (Lm)* and *Salmonella* in RTE products. The additional types of inspection resulted in FSIS refusing entry on a total of 16,967 pounds of RTE pork for issues related to public health, including detection of *Lm* and off-condition RTE products.

The previous FSIS audit in 2016 identified systemic findings under the Government Sanitation component related to failure to ensure sanitary conditions of overhead structures and a lack of awareness by inspection officials regarding mandatory glove use in the post-lethality areas of RTE establishments. The audit also identified systemic findings under the Government HACCP component based on recordkeeping deficiencies that FSIS auditors observed in multiple establishments. Lastly, systemic findings in the Government Microbiological Testing Programs component included the incorrect identification of the post-lethality environment in two RTE establishments and the incorrect classification of some RTE Alternative 3 deli products. The FSIS auditors verified that the corrective actions for the previously reported findings had been completed.

Prior to the on-site equivalence verification audit, the FSIS auditors reviewed and analyzed Italy's SRT responses and supporting documentation. During the audit, the FSIS auditors conducted interviews, reviewed records, and observed operations to determine whether Italy's food safety inspection system governing processed pork products is being implemented as documented in the country's SRT responses and supporting documentation.

The FSIS final audit reports for Italy's food safety inspection 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 (E.G., ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components that the FSIS auditors reviewed was Government Oversight. FSIS import regulations require the foreign food safety inspection system to be organized by the national government in such a manner as to provide ultimate control and supervision over all official inspection activities; ensure 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 national government of Italy organizes and manages the meat inspection system as mandated by Italian statutes. The CCA is the Ministry of Health (MOH), established by *Law No. 172*. The MOH consists of a General Secretariat and 12 General Directorates with the Directorate General for Hygiene, Food Safety and Nutrition (*Direzione Generale per l'Igiene e la Sicurezza degli Alimenti e la Nutrizione*, DGISAN) responsible for oversight of 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 as well as training activities. *Legislative Decree No. 193/2007* designates the MOH, the Regions, the Autonomous Provinces of Trento and Bolzano as well as local health authorities as responsible for implementing the provisions of *Regulations (EC) No. 852/2004*, *No. 853/2004*, *No. 854/2004* and *No. 882/2004*.

In each region, the Regional Veterinary Service (RVS) is responsible for planning, coordination, guidance, authorization of establishments to operate, and verification of controls of the applicable Local Health Units (LHU). Cooperation between the central government and regions takes place during the State-Regions Conference. The LHUs are the third level and responsible for the implementation of official inspection activities by government inspectors. Within the LHUs, the Local Veterinary Services are responsible for animal health (Area A), food of animal origin (Area B), and animal welfare, hygiene of animal husbandry and of farming production (Area C). The LHUs provide direct oversight of establishments certified to export to the United States, by assignment of Official Veterinarians (OVs) under the supervision of LHU Directors.

The MOH has issued two new circulars since the last FSIS audit. Circular *DGISAN 10140 (3/17/2017)* provides instructions for general verification activities associated with food safety

requirements, including supervisory reviews and annual establishment certification, and is intended to harmonize the execution of official verification activities at the LHU level. Circular *DGISAN 31378 (07/31/2018)* provides instructions for verification activities in slaughter establishments. Both circulars represent updates to prior issuances.

The MOH has documented procedures for the certification of establishments requesting approval to export to the United States in circular *DGISAN 15012 (4/14/2016)*. Regional office personnel conduct the initial assessment of establishments and a central MOH task force audit is required prior to determining whether the establishment meets requirements for certification. The FSIS auditors reviewed documentation of the MOH audit for a slaughter establishment requesting initial certification for eligibility to export to the United States. The MOH audit identified several findings requiring corrective actions on the part of the establishment. The regional office supervision conducted a follow-up audit to verify that the findings were adequately resolved and informed the MOH of the outcome and suitability for certification. Only at that time did the MOH certify the establishment eligibility. This review indicated that the CCA implemented the initial certification process as described and intended.

Italy has electronic document management systems used to communicate requirements from the CCA headquarters level to the LHU level and government inspection personnel. The MOH transmits revised or new requirements directly to the regional offices. Each regional supervisor then transmits the information to the LHU directors who in turn transmit the information via email to official inspection personnel. In addition, the MOH publishes all relevant requirements on the MOH website. Each LHU has their own document management system for requirements, records, and other inspection system documentation. The periodic supervisory visits include assessing the official inspection personnel awareness of requirements.

In Italy, all personnel within the three levels comprising the food safety system (central, regional, local) are employees of the government. The Ministry of Economics and Finance directly pays the salaries of headquarters officials. Regional veterinarians are paid by the regional administrations, and the officials in the LHUs are paid by the LHU administrations; both out of funds also provided by the Ministry of Economics and Finance. Under Italian *Legislative Decree 194*, the Ministry of the Treasury charges fees to the establishments for the inspection services provided and transfers the appropriate funds to the Ministry of Health to fund the program. No official inspection personnel receive any compensation from the establishments they regulate. The FSIS auditors verified evidence that the government directly pays, through direct deposit, regional and local government inspection personnel.

Italy's inspection system requires that official inspection personnel are qualified and competent prior to assignment at establishments certified to export to the United States. The hiring and selection of official inspection personnel is regulated through Presidential *Decree No. 483*. In accordance with *Regulation (EC) No. 854/2004*, the CCA is required to ensure that OVs have the required degree in veterinary medicine (5 years) and carry out training for at least 200 hours under the supervision of an appointed OV. The CCA develops training covering United States requirements, including revised training whenever the CCA's official instructions change. In addition, the regional and LHU offices organize and conduct meetings and training activities regarding requirements for establishments certified to export to the United States.

Beginning in 2017, the CCA implemented an e-learning course covering the official circulars that implement requirements and verification activities for establishments certified to export to the United States. Also in 2017, the CCA organized training covering audits of establishments that included classroom sessions as well as on-site visits to certified establishments. In May 2018, the CCA conducted a one-day training session for supervisors and OVs covering the updated requirements for exports to the United States. The FSIS auditors verified that supervisors and OVs assigned to audited establishments had completed each of these training sessions.

The Veterinary Public Health Institutes (*Istituti Zooprofilattici Sperimentali,* IZS) provide technical laboratory support for microbiological and chemical residue testing and IZS laboratories conduct official analyses for the purpose of United States exports. The IZS is aligned in the Italian government's National Health Institute. Some IZS laboratories serve as a National Reference Laboratory (NRL) for one or more animal diseases or for food safety issues. Each laboratory within the IZS network is required to meet the International Organization for Standardization (ISO) 17025 - *General requirements for the competence of testing and calibration laboratories* standards. Accredia is the Italian national accreditation body responsible for conducting accreditation audits to verify ISO 17025 standards and issue accreditation certificates. In addition, the National Health Institute (*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 as well as conformity with ISO 17025 standards.

The IZS microbiologic laboratories participate in annual proficiency testing programs organized by IZS Teramo for *Salmonella* spp. and *Lm* as well as inter-laboratory ring trials. The FSIS auditors confirmed that the CCA ensures laboratories comply with ISO 17025 criteria through review of the Accredia issued accreditation certificates, review of the annual ISS audit reports, and review of internal audits conducted in accordance with ISO 17025 as well as on-site visits to the laboratories.

The FSIS auditors verified that the CCA's food safety inspection system has the organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements for this component.

V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (E.G., 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 each and every carcass and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift

inspection during processing operations; and periodic supervisory visits to official establishments.

The FSIS auditors verified that the CCA has developed circular *DGISAN 31378 (07/31/2018)*, *Official control at the abattoirs registered with the list of Italian plants authorized to export to the USA,* to ensure good slaughtering practices, humane handling, and ante-mortem and post-mortem inspection tasks in slaughter establishments. In addition, the CCA has developed *Guidelines on the Application of Regulation (EC) No. 1099/2009,* for humane handling and slaughter to ensure that all animals are protected from avoidable excitement, pain, or suffering during slaughter. Each certified slaughter establishment has an OV assigned to ante-mortem inspection that is also responsible for verification of humane handling and slaughter requirements according to *DGISAN 31378* and the above referenced guidelines. The FSIS auditors verified through observation and record review that OVs conduct humane handling and slaughter verification activities at least daily, and every time the establishment employee performing stunning was changed during the course of the day.

In accordance with *Regulation (EC) No. 854/2004* and *Directive 91/497/EEC*, the CCA has established procedures in *DGISAN 31378* for conducting ante-mortem inspection to ensure that all livestock presented for slaughter are eligible for human food. The assigned OV carries out an ante-mortem inspection of all livestock before slaughter. Ante-mortem procedures include checks on documentation and health certificates that accompany the livestock, examination of animal identification, assessment of animal cleanliness, and examination of the livestock to determine whether they are fit for slaughter for human food. The FSIS auditors observed OVs performing ante-mortem inspection including observation of the swine in motion and at rest, as well as verification of required documentation.

The official inspection team, comprised of OVs, performs post-mortem inspection of swine according to the instructions detailed in *DGISAN 31378, Annex 1.* Post-mortem inspection procedures include head inspection with mandibular lymph node incision, viscera inspection, and carcass inspection for each carcass. The FSIS auditors assessed post-mortem inspection through on-site record reviews, interviews, and observations of the inspection personnel performing these procedures in audited slaughter establishments.

The LHU Directors are responsible for developing staffing plans for each certified establishment. Circular *DGISAN 31378, Annex 1*, specifies the number of inspectors required for post-mortem inspection in slaughterhouses based on FSIS regulatory requirements. The LHU Director develops staffing plans for slaughter establishments to ensure ante-mortem, post-mortem, and other verification activities occur throughout every slaughter shift according to the specified requirements for numbers of head, viscera, and carcass inspectors based on line speed. In addition, circular *DGISAN 10140 (03/17/2017)* describes the requirements for inspection based on establishment activities, using FSIS policies as the framework, to ensure official inspection during every shift of production for products intended for export to the United States. In Italy, the establishments are required to provide advance notice, in writing, of their intent to produce product for export to the United States. The FSIS auditors verified, at multiple establishments, the records documenting official inspection during all slaughter and production periods when establishments produced product for export to the United States.

Supervisory officials conduct periodic supervisory visits at certified establishments according to procedures defined in circular *DGISAN 10140* to ensure compliance with requirements and to assess the verification activities and associated knowledge of the OVs. The minimum frequency for supervisory visits is quarterly in slaughter establishments and twice per year in processing establishments. In addition, the CCA task force conducts oversight audits of at least 10% of establishments certified to export to the United States annually to assess compliance with United States requirements and to assess the function of the official control system.

The supervisory reviews include assessment of ante-mortem and post-mortem inspection, humane handling, sanitation standard operating procedures (SOPs), sanitation performance standards (SPS) and HACCP, food defense, economic adulteration and labeling, sampling programs, export certification, import inspection, direct and continuous official supervision during slaughter and per shift processing inspection, complete separation of establishments, and official controls over condemned material. The FSIS auditors reviewed both CCA task force audit reports and supervisory visit reports at multiple regional and establishment offices. The FSIS auditors confirmed that supervisory visits occurred at the described frequency and were documented using the established form. However, the FSIS auditors identified the following finding:

- The supervisory visit reports did not consistently document an assessment that all HACCP and official sampling requirements were compliant according to the CCA's written procedures. At one regional office, the periodic supervisory visit reports did not document review of all required elements over the course of one year including:
  - Reports reviewed did not include assessment of all HACCP requirements, and
  - Reports reviewed did not include assessment of official microbiologic sampling.

The CCA has issued a revised circular *DGISAN 10140* to include Chapter 2 covering eligibility of products based on APHIS restrictions. The circular identifies establishment requirements including records the establishment must maintain to guarantee source materials and finished products are eligible for export. The FSIS auditors verified at audited establishments that OVs ensure compliance with APHIS requirements prior to export certification.

Establishments are required to maintain identity of products, and to control and segregate product destined for the United States from other products as applicable. The OVs are responsible for issuing transport (movement) certificates as well as export certificates. The regional or LHU office assigns unique export certificate numbers to the OVs at each establishment. The OV conducts a pre-shipment review that includes all associated traceability documents, including verification of the raw meat source used to produce products, and food safety records for each lot prior to applying the official stamp and signature on the export certificate. The FSIS auditors verified in each audited establishment the official inspection security of controls associated with the export process including certification records and official seals.

The CCA has legal authority to establish regulatory controls over certified meat establishments that export their products to the United States. However, the supervisory visit reports did not consistently document assessment that all requirements were compliant.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of 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 sanitation SOPs to prevent direct product contamination or insanitary conditions.

The CCA requires establishments certified to export to the United States to develop and adhere to written programs that prevent direct product contamination and operate in a manner that prevents the creation of insanitary conditions. Each certified establishment must develop procedures to address sanitary requirements including cleaning, facility construction and maintenance, equipment maintenance, and pest control consistent with the FSIS sanitation regulations. Official inspection personnel verify compliance with sanitation requirements on a daily basis by direct observation and reviewing records as described in *DGISAN 10140*.

The CCA requires official inspection personnel to document noncompliance with requirements and requires the establishment to implement adequate corrective actions. The FSIS auditors reviewed noncompliance reports and supervisory visit reports and verified records demonstrating establishment corrective actions and verification by the official inspection personnel that the corrective actions were implemented and effective. The CCA's enforcement program includes suspension and withdrawal of inspection for those establishments that fail to prevent product contamination or fail to take corrective actions.

The FSIS auditors verified the adequacy of official verification and inspection activities related to sanitation programs at establishments certified to export to the United States by observing official inspection personnel as they assessed the implementation of the establishments' sanitation procedures. The FSIS auditors assessed the adequacy of pre-operational sanitation by observing OVs conducting pre-operational verification of the establishment's sanitation program at two of the audited establishments. The OVs conducted this activity in accordance with the established procedures including an organoleptic inspection of food contact surfaces of facilities, equipment, and utensils. The FSIS auditors also reviewed inspection records and assessed the overall sanitary conditions of production areas and storage rooms, and auditors observed the production processes conducted in slaughter and processing establishments.

In addition to the basic requirements outlined above, the CCA has developed specific requirements for sanitation in establishments producing post-lethality exposed RTE product in *DGISAN 35655-P (9/16/2015)*. Establishments are required to verify sanitation by testing food contact surfaces for *Lm* or indicator organisms and develop a surveillance program for *Lm*, which must be included in the establishment's HACCP, sanitation SOP, or other prerequisite program.

The FSIS auditors evaluated official inspection personnel verification of sanitary dressing procedures in slaughter establishments. Official inspection personnel routinely verify establishment sanitary dressing and perform daily verification of zero tolerance for fecal material, ingesta, and milk on at least ten swine carcasses. Overall, the CCA has written

requirements and verification procedures sufficient to ensure that each slaughter establishment adheres to sanitary dressing principles.

The FSIS auditors verified that the CCA's actions in response to the prior FSIS audit findings in the Government Sanitation component were effective in resolving the issues. The FSIS auditors did not identify similar findings during this audit. The CCA's food safety inspection system continues to maintain sanitary regulatory requirements that meet the core requirements for this component.

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

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

The FSIS auditors verified that the CCA requires establishments to design, implement, and maintain HACCP systems in accordance with United States requirements. The CCA has issued *DGISAN 10140* detailing the HACCP requirements as well as official inspection verification activities. The official inspection team conducts daily verification activities for HACCP requirements through direct observation and hands-on activities as well as review of records. In addition, inspection personnel perform a hazard analysis verification (HAV) activity to ensure establishments consider and address the relevant hazards. The FSIS auditors reviewed programs and records maintained by inspection personnel and the audited establishments, and the auditors also observed the implementation of the HACCP systems.

The FSIS auditors verified that the audited establishments have developed flow charts and conducted hazard analyses for expected hazards. For specific hazards that are reasonably likely to occur, the establishments have instituted critical control points (CCPs) described in HACCP plans. The FSIS auditors also verified that official inspection personnel conduct daily HACCP verification activities. At slaughter establishments, the FSIS auditors verified that official inspection personnel also verify zero tolerance for fecal material, ingesta, and milk in swine slaughter establishments to ensure establishment compliance with sanitary dressing and the establishments' CCPs for zero tolerance.

At the audited 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 *DGISAN 35655-P*. The FSIS auditors noted that the CCA requires RTE establishments to maintain validated HACCP systems to support a 5-log reduction for *Salmonella* and stabilization of fully cooked and shelf-stable RTE products.

Lastly, in response to the prior FSIS audit findings, the CCA implemented revised requirements in *DGISAN 10140* and other actions. While the current audit identified isolated HACCP findings at multiple establishments, the auditors determined that these findings were not systemic findings because the CCA has implemented the appropriate requirements, training, verification, and supervisory activities for the Government HACCP component. The FSIS auditors verified that

the CCA requires establishments certified to export to the United States to develop and implement HACCP systems.

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 food safety inspection system is to present a chemical residue testing 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 inspection authorities or by FSIS as potential contaminants.

Prior to the on-site visit, FSIS' residue experts thoroughly reviewed Italy's 2018 *National Residue Monitoring Plan* (NRMP), results for 2017, associated methods of analysis, and additional SRT responses outlining the structure of Italy's chemical residue testing program. There have not been any POE violations related to this component since the last FSIS audit in 2016.

As required by equivalent provisions outlined in *Council Directive 96/23/EC, Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products*, the CCA publishes and implements an annual NRMP. The NRMP takes into account requirements of *Legislative Decree No. 158/2006* regarding official collection and handling of samples, in accordance with the instructions of *Commission Decision No. 98/179/EC* of February 23, 1998. The CCA defines the species, categories, points of sampling, substances for food safety interest, and test procedures according to the EC's legal provisions. The DGISAN Office 8 of the CCA develops the annual plan in collaboration with the IZS national reference laboratory in Brescia, the regional offices, and additional IZS sites involved in residue testing. The plan takes into account the previous year's results in order to implement appropriate modifications and possible targeted actions.

Once finalized, the regional office then forwards the plan to 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, official veterinarians take samples from live animals on farm and in slaughter plants in accordance with the following sub-plans:

1. *Routine Plan*. Animals or carcasses are not routinely detained during routine sampling unless the sampling is for prohibited substances.
2. *Suspect Plan*. Instituted in cases where there is evidence of illegal treatment, clinical symptoms, or suspected noncompliance with the withdrawal period for authorized veterinary drugs. When samples are collected the carcass, animal, or animal products are detained at the sampling point pending the analytical results.
3. *Extra Plan*. Includes monitoring plans arranged by the Ministry and regions to meet specific local or national requirements.

The regional offices receive results directly from the laboratories and if violative, they submit all follow-up events and results directly into the *National Veterinary Information System for Food*

Safety (SINVSA) database. The DGISAN Office 8, in the MOH headquarters, oversees the NRMP results and the actions in response to noncompliant results. The prior FSIS audit identified inconsistency with the use of a form used to document actions in the case of violative samples, but the process described above has replaced the prior questionnaire. The FSIS auditors reviewed records documenting actions in response to violative results and identified follow-up activities were conducted according to the NRMP including on-farm investigations, increased sampling of animals from specific suppliers, and enforcement actions including issuance of fines.

During the evaluation of ante-mortem inspection at three slaughter establishments, the FSIS auditors observed that OVs verify documentation that discloses the origin of every lot of swine and includes a signed declaration that attests that owners have adhered to veterinary pharmaceutical withdrawal periods. Through review of records at slaughter establishments and regional offices, the FSIS auditors verified that the LHUs and regional offices were implementing the 2018 NRMP as intended.

The audit of the IZS Reference Laboratory (Brescia) included interviews with the laboratory management, document reviews, and observations of the laboratory. This laboratory is ISO 17025 accredited by Accredia. The FSIS auditors reviewed the most recent accreditation audits of the laboratory and verified the laboratory's corrective action plans in response to the audits. The FSIS auditors verified that the Quality Manual included all expected chapters, including organization, staff qualifications, credentials, and training. The FSIS auditors also reviewed intra- and inter-laboratory proficiency testing associated with the methods, and they found the results to be acceptable. The FSIS auditors verified that the audited laboratory ensured traceability throughout sample receipt, analysis, and reporting.

The FSIS auditors' analysis and on-site audit verification indicated that the CCA continues to meet the core requirements for this component.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components that the FSIS auditors reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that meat products prepared for export to the United States are safe and wholesome.

The CCA has written procedures for the collection, analysis, and verification of *Enterobacteriaceae* and Total Viable Counts (TVC) as process control indicators according to *Regulation (EC) No. 2073/2005*. The slaughter establishment collects samples from five carcasses every two weeks using the sponge technique. Establishments are required to document results and verify the limits support process control of the slaughter process. In addition, Italy has adopted the FSIS *Salmonella* performance standards in swine slaughter establishments as described in *DGISAN 31378*. The official inspection team is responsible for collecting samples, or directly observing the establishment collect samples, from each carcass using the sponge technique. There are 55 samples collected on consecutive slaughter dates that comprise the annual *Salmonella* set from each slaughter establishment, and the acceptable limits are consistent

with those identified in 9 CFR §310.25. The CCA requires that official IZS laboratories analyze *Salmonella* performance standard samples using the ISO 6579-1:2017, *Microbiology of the food chain – Horizontal method for the detection, enumeration and serotyping of Salmonella – Part 1: Detection of Salmonella spp.* The FSIS auditors reviewed establishment and official inspection records at the three audited slaughter establishments and concluded that the process control sampling programs are implemented as described.

The CCA describes RTE requirements and official verification and sampling procedures in *DGISAN 35665*. Specifically, the requirements dictate zero tolerance for *Lm* and *Salmonella* in RTE products and require the same controls for *Lm* as 9 CFR §430. In addition, the CCA requires that each RTE establishment have validated support for *Salmonella* lethality ensuring at least a five-$\log_{10}$ reduction. The CCA also implements official verification sampling including risk-based RTE product sampling as well as non-risk based sampling for all RTE products, whether post-lethality exposed or not. Lastly, the CCA has implemented an official verification routine risk-based *Listeria monocytogenes* (RLm) sampling program that includes sampling of food contact surfaces (FCS) and non-contact surfaces (NFCS) as well as RTE product for *Lm* and *Salmonella* analysis. The CCA requires that all sampled RTE products be held pending analytical results.

The CCA requires that government IZS laboratories perform the analyses of official samples using FSIS MLG 8.10 for *Lm* and FSIS MLG 4.09 for *Salmonella*. The annual schedule for RLm testing targets 25% of the certified RTE establishments. Microbiologically independent lots of product are held during all phases of sampling (FCS, NFCS, and product) and restricted from distribution until acceptable results are confirmed. Inspection personnel at audited RTE establishments demonstrated the pre-shipment review and associated documentation in the official files that assure all products certified for export to the United States have acceptable microbiologic results, whether through establishment or official sampling and analysis. The FSIS auditors reviewed the sampling records at each audited RTE establishment, as well as the audited regional offices and verified that the CCA's has implemented the sampling programs as described.

The FSIS audit included a visit to the IZS microbiology laboratory in Brescia. Government personnel, including LHU technicians, collect all official samples and LHU couriers transport samples directly to the laboratory. The FSIS auditors verified that the laboratory utilized the defined methods for *Salmonella* carcass swabs and RTE product samples and surfaces. The FSIS auditors verified that the CCA's procedures for sample collection, transportation, and receipt by the laboratory ensure integrity of official samples. Test results are reported from the laboratory database into the CCA's SINVSA database and immediately accessible to official inspection personnel.

The 2016 FSIS audit identified systemic findings associated with the failure of two fully cooked RTE establishments to accurately identify the post-lethality areas of the process. In addition, the previous auditors identified that the CCA failed to correctly categorize "deli" products in the 2016 official sampling plan for RTE establishments. The current audit verified the effectiveness of the corrective actions in resolving the prior audit findings.

FSIS has identified one POE violation due to the presence of *Lm* since the last audit. The CCA delisted the producing establishment at the request of establishment management. In addition, FSIS identified two POE violations associated with off-condition fully cooked, not shelf stable RTE products produced by one establishment. The FSIS auditors audited the producing establishment and verified that the corrective actions described in the CCA's response were implemented and effective in preventing additional failures to meet FSIS requirements.

Within Italy, establishments producing TPCS products are required to address the hazards using HACCP principles according to *Regulation (EC) No. 852/2004,* requiring that hermetically sealed containers must be produced using a process that raises every part of the product treated to a given temperature for a given period and to prevent product contamination during the process. The FSIS audit included one establishment producing TPCS product.

The CCA organizes and administers microbiological testing programs to verify that meat products destined for export to the United States are unadulterated, safe, and wholesome in accordance with United States requirements. The CCA's meat inspection system continues to meet the core requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held with the MOH on September 25, 2018, in Rome, Italy. At this meeting, FSIS auditors presented the preliminary findings from the audit. An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following systemic finding:

Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling)

- The supervisory visit reports did not consistently document an assessment that all HACCP and official sampling requirements were compliant according to the CCA's written procedures. At one regional office, the periodic supervisory visit reports did not document review of all required elements over the course of one year including:
  - Reports reviewed did not include assessment of all HACCP requirements, and
  - Reports reviewed did not include assessment of official microbiologic sampling.

During the audit exit meeting, the CCA committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

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 F. LLI Beretta SPA Via Garibaldi 67 Barzano (LC)	09/14/2018	2L	Italy
	5. AUDIT STAFF OIEA 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 .	X
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	X
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	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. Periodic Supervisory Reviews	
58. Official RTE Sampling	X
59.	

60. Observation of the Establishment

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

14/51. The hazard analysis did not address *Listeria monocytogenes (Lm)* at the first post-lethality step of the process. The establishment verbally stated the casings were impermeable and prevented post-lethality exposure. However, the establishment lacked supporting documentation that the casings used are impermeable and prevent post-lethality exposure to *Lm* and therefore failed to support this decision in the hazard analysis. As a consequence, the determination that the establishment is exempt from the requirements of the *Listeria* rule (as defined in DGISAN 35665) is not supportable.

In addition, the establishment determined that biological hazards at the product cooling step post-lethality were prevented by a prerequisite program. However, the establishment was monitoring ambient air temperature in the cooler and failed to demonstrate any correlation between internal product and ambient temperatures sufficient to ensure the cooling requirements were met and that measuring ambient air temperature was reflective of the internal product temperature.

22/51. The records documenting the review of records ongoing verification activity for CCP 1B and CCP 2B did not include the results of the verification activity.

38/51. The meat storage freezer had product stored wall to wall with no access to visualize the wall/floor junctures nor space to walk down the center of the room to assess sanitary conditions throughout the room.

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

58/51. The CCA determined the establishment was subject to one RTE_RAND official sample per year to verify the effectiveness of the food safety system. However, the sample collected for initial analysis was not the same product produced for export to the United States and the smaller size and process parameters were not reflective of product produced for export to the United States.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/14/2018

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 S.C. . Correggio	09/20/2018	302 L	Italy
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch		[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. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

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

22/51:
-Some of the establishment’s HACCP monitoring and verification records did not document the time of the monitoring or verification activities for each entry.
-The establishment did not maintain calibration records for the instrument used to monitor the critical limits.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch	09/20/2018

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
Mec Carni S.P.A. . Marcaria	09/18/2018	304 M	Italy
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch		[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.	
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Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
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12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
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19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Periodic Supervisory Reviews	
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. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch	09/18/2018

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
Pro Sus S.P.A. Cremona	09/17/2018	361 M	Italy
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch		[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.	
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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	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	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

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

22/51. The establishment's HACCP records documenting review of records for ongoing verification did not include the time of the verification activity.

46/51. Swine carcasses present on the out rail for additional trimming were in direct contact with each other prior to trimming, that may result in cross-contamination between carcasses.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch	09/17/2018

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
Annoni S.P.A. . Localita Madonna Dei Prati Busseto (PR) Emilia Romagna	09/17/2018	404 M	Italy
	5. AUDIT STAFF OIEA 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.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
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Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	X
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	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	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

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

10/46/51. Establishment employees were using a gloved hand to grab the anus prior to dropping the bung but not washing their hands between carcasses. The observed procedures fail to ensure sanitary dressing sufficient to prevent contamination between carcasses.

38/51. In two separate freezers boxed products were stored in a manner that prevent access throughout the room to visualize the wall/floor junctures and assess sanitary conditions throughout the room.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/17/2018

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
Rovagnati S.P.A. Biassono	09/14/2018	508 L	Italy
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch		[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.	
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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	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	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. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

The following non-compliances were not identified by Italy's inspection officials during the establishment review:
22/51. The establishment did not document the annual reassessment of all of its HACCP plans.

41/51. Beaded condensate was observed over exposed product in the production area. No direct product contamination was observed.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch	09/14/2018

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
Casale S.P.A. Parma	09/13/2018	550 L	Italy
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch		[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	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	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. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

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

41/51. Beaded condensate was observed over exposed product in the production area. No direct product contamination was observed.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch	09/13/2018

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&G . Parma	09/19/2018	670 L	Italy
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch		[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. Periodic Supervisory Reviews	
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. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch	09/19/2018

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
Disossatura Langhiranese.Di Boschi & CSAS Langhirano Langhirano (PR)	09/19/2018	690L	Italy
	5. AUDIT STAFF OIEA 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 .	X
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	X
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	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. Periodic Supervisory Reviews	
58. RTE Listeria requirements	X
59.	

60. Observation of the Establishment

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

14/51. The establishment's hazard analysis demonstrated inconsistent decisionmaking and lack of support for some decisions in the hazard analysis:

- The establishment determined that *Lm/Salmonella/S. aureus* are not reasonably likely to occur at receiving but lacks support for the decision. The supporting document references shelf stability and sanitation at receiving as supporting the hazards are not likely to occur. However, these factors are not sufficient to demonstrate that the identified hazards are not reasonably likely to occur.
- At a subsequent step of the process the establishment then determined *Lm/Salmonella/S. aureus* are reasonably likely to occur due to potential contamination of product during the process. This decision undermines the effectiveness of the sanitation program that must be designed to prevent the hazards. Further, the validation documentation for effectiveness of off-site high-pressure processing (HPP) lacked reference to *Salmonella* reduction.

38/51. Product on racks was stored in the CCP 1B cooler from wall to wall preventing visualization of the wall/floor junctures and access to verify sanitary conditions throughout the room.

58/51. The establishment's written Listeria sampling program did not include food contact surfaces in the ham washing room, an area where received and exposed RTE hams are first handled during the deboning process.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/19/2018

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
Felsineo SPA Zola Predosa Zola Predosa	09/21/2018	757L	Italy
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA 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.	X
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	X
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	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. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

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

19/51. The establishment failed to perform the review of records ongoing verification activity at the frequency specified in the HACCP plan.

38/51. Boxed products were stored in the meat freezer in a manner to prevent visualization of the wall/floor juncture and prevent the ability to assess sanitary conditions throughout the room.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/21/2018

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
Golfera In Lavezzola SPA Conselice Conselice	09/20/2018	955L	Italy
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA 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 .	X
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	X
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	X
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. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

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

14/51. The establishment's thermally processed, commercially sterile (TPCS) HACCP system lacked supporting documentation associated with decisions in the hazard analysis:

- there was no process schedule identifying critical factors for the TPCS product
- there was a lack of documented process control to ensure the prevention of incipient spoilage prior to the thermal process
- immediate packages of TPCS product do not include permanent markings identifying the code mark and day/year of production
- the establishment is not measuring the internal temperature of the coldest container prior to the start of the thermal process

38/51. Boxed meat in the freezer was stored wall to wall preventing visualization of the wall/floor junctures and the ability to assess sanitary conditions throughout the room.

42/51. Opening the retort door resulted in the pooling of water across an area approximately 5 m in diameter due to the lack of sufficient plumbing and drainage. Accumulation of water on flooring results in insanitary conditions.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/20/2018

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
Certosa Salumi SPA .	09/18/2018	H5H5G	Italy
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA 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. Periodic Supervisory Reviews	
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. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/18/2018

Appendix B: Foreign Country Response to the Draft Final Audit Report

Ministero della Salute

DIREZIONE GENERALE PER L'IGIENE E LA SICUREZZA DEGLI ALIMENTI E LA NUTRIZIONE

Ufficio 2

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination
InternationalCoordination@fsis.usda.gov

c.c. Ambasciata d'Italia a Washington
Ufficio Commerciale
amb.washington@cert.esteri.it

Ambasciata degli Stati Uniti a Roma
Ufficio USDA - FAS
c.a Biasetti, Dana <Dana.Biasetti@fas.usda.gov>

On-site audit of Italy's meat inspection system - comment to the draft final audit report

Dear Dr. Catlin,

Reference is made to your letter of November 27th, 2018 and your invitation to provide comment to the draft of the final report of the on-site audit conducted in Italy by your Service last September.
With regards to the corrective action taken by Italy to address the audit findings, please find the attached circular (Annex1) sent by the General Directorate to the Regional and Local competent authorities as well as to the operators in order to cover the gap identified in the following topics

- **Supervisory visit report** (need to document the review of all required elements according to the CCA's procedures)
- **Operators findings**
  - SPS
  - SSOP
  - HACCP
- **Sampling and testing programs** (establishment deboning's ham washing area should be included in the area where the product is post lethality exposed)

Moreover, in order to cover all the gap identified for the **Thermally Processed-Commercially Sterile** products, in addition to the measures foresees by the specific circular (DGISAN n. 40602 October 24th 2018) already shared with your offices, please consider also the following action:

- On November 23th was performed the **training course** for the official veterinarians of the four establishments actually listed as eligible to export thermally processed/commercially sterile products
- The establishments' implementation of the additional requirements is going to be verified and the review process will be completed by this month in order to maintain the eligibility of the plant to export the above-mentioned products. This review is performed by the trained official veterinarians according to the DGISAN n. 40602 October 24th 2018 measures.

Please, do not hesitate to contact us for any further information needed.
Kind Regards.

THE DIRECTOR GENERAL
Dr. Gaetana Ferri

Ref:

Anna Beatrice Ciorba e-mail ab.ciorba@sanita.it
Nicola Santini e-mail: n.santini@sanita.it

Ministry of Health

DIRECTORATE-GENERAL FOR THE HIGIENE AND SAFETY OF FOOD AND NUTRITION
Department 2

Health Division
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Autonomous Regions and Provinces

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Trade associations (meat industry)

Subject: preliminary findings of the USDA-FSIS audit 10-25 September 2018

On September 25th, 2018 at the offices of viale Ribotta, the closing meeting of the audit was held. This was conducted by the USDA-FSIS inspectors in Italy in order to verify the continuation of the conditions of equivalence that allow Italy to export meat and pork products to the United States of America.

The preliminary results allow us to predict a positive conclusion of the assessment of the official control system in force in Italy. However, given that the US inspectors have highlighted certain aspects that need improvement, it is considered appropriate to call upon all the concerned parties to maintain a high level of attention in the processing plants authorized to export to this Third Country.

For this reason, the undersigned General Management wishes to anticipate the conclusions, not yet formalized, of the final audit report recalling the official Veterinarians, the Supervisors as well as the Food Industry Operators (OSA) to focus attention on compliance with all the measures envisaged and in particular those highlighted in the critical issues listed below.

1. **Supervisory reports** - Please note that this activity is aimed at verifying, not so much the activity of the OAS but the work of the official inspector and/or his delegates. In relation to the activity carried out by the inspector, and indirectly also on the OAS, it is however necessary to highlight the fact that, in the course of 1 calendar year, all the aspects listed in the audit report are verified.

2. **Sanitation Performance Standards (SPS)**
   A. in some processing plants, situations such as to determine the formation of condensation have been observed. It is recalled that this condition can determine the direct contamination of the product and therefore the causes that can lead to the formation of condensation must

be avoided as well as, the OSA, must prepare and implement a procedure for the management of such non-compliance;

B. in various plants, there were report of storage cells being too full, or in any case in conditions that make the rooms impossible to inspect, this situation in cells, warehouses, raw material stores, semi-finished products, food products, and auxiliary materials is considered non-compliant and the premises are therefore not adequately managed;
C. water drainage systems must be guaranteed at the plants premises to prevent water stagnation from causing unhealthy working conditions.

3. **Sanitation Standard Operating Procedures (SSOP)** - In some slaughterhouses, observations were made in relation to contact conditions of the carcasses to be subjected to grooming. This processing mode can determine cross contamination by contact of the carcasses. In general, all the manual operations that can lead to cross contamination situations must be avoided, including the operations carried out by the same official inspector when the post mortem inspection is performed.

4. **HACCP –**
   A. analysis of the dangers and documentation supporting the decisions taken: critical issues remain regarding the preparation of HACCP manuals regarding the construction of the Hazard Analysis. It should be noted that during the hazard analysis, all hazards must be considered here, which in a given process phase have a reasonable probability of occurring and that the consequent decision on how to handle any danger deemed probable must be taken on the basis of adequately documented scientific evidence. In a de-boning plant, a remark was made regarding the lack of motivation adopted at the basis of the decision not to consider the risk of Listeria and Salmonella as "reasonably possible" in the introduction phase of boned hams coming from other processing plants. It is therefore considered necessary that any de-boning plant, whether external or annexed, if de-boning products manufactured in a different recognized plant should:
      i. review their own risk analysis, at least in the receipt phase,
      ii. collect and record the documentation supporting the decisions taken,
      iii. document the methods for managing the reception phase.
   B. validation studies of the production process: the validation studies must be scientifically sound and must contain elements that allow the Official Inspection to be able to compare the results of the study with those obtained from the production process adopted by the individual company. Only in this way it will it be possible to demonstrate that the production process is able to respect critical limits adequate to achieve the final objective that is the correct management of pathogens potentially present in the food;
   C. failure to review the self-control manual every year;
   D. incorrect mode or failure to register on-site checks.

5. **Sampling and testing programs -** has been detected in the debris factories that the hams washing area is not considered as an area where the product is re-established after post-lethal treatment. This processing area must instead be considered in the area of exposure to the post-lethal environment and be included in the sampling plan for Listeria and Salmonella provided for the RTE products.

It is also reported that during the visit, US inspectors confirmed the need to fill in information gaps recently highlighted by USDA-FSIS as part of the annual document verification of the equivalence of the Italian System "System Recognition Tool". These shortcomings, which emerged following the adoption by the US of some amendments in the CFR that introduce more detailed requirements for health management, concern products defined as

"Thermally processed - Commercially sterile", impact on the equivalence of the production system and official controls of the aforementioned products.

Therefore, it is confirmed that soon the undersigned office shall issue an official letter with details of the measures that, in line with the US standard, will allow to maintain the equivalence of the Italian system for the production and control of the products in question exported to the US.

Further updates of the notes and ministerial letters relating to US exports may be issued following the formalization of the audit report from the US side and should the need arise to amend the existing measures.

We thank you for your cooperation Best regards.

THE GENERAL MANAGER

*Signed Gaetana Ferri

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** "The handwritten signature is replaced by a printed signature pursuant to Article 3, paragraph 2, of Legislative Decree no. 39/1993."*