United States Department of Agriculture

Food Safety and
Inspection Service

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

September 29, 2023

Dott. Ugo Della Marta
Direzione Generale per l'Igiene e la Sicurezza degli Alimenti e la Nutrizione
Ministero della Salute
Via Giorgio Ribotta, 5
00144 Rome, Italy

Dear Dott. Ugo Della Marta,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an onsite verification audit of Italy's inspection system March 13–April 4, 2023. 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
Digitally signed by MICHELLE CATLIN
Date: 2023.09.29 07:29:04 -04'00'

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED OF

ITALY

MARCH 13–APRIL 4, 2023

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING

PORK PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

September 26, 2023

Food Safety and Inspection Service
U. S. Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit of Italy conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) from March 13–April 4, 2023. The purpose of the audit was to verify 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 properly labeled and packaged. Italy currently exports pork products under the following process categories to the United States: Raw-Intact, Thermally Processed-Commercially Sterile, Heat Treated-Shelf Stable, Not Heat Treated-Shelf Stable, Fully Cooked-Not Shelf Stable, Heat Treated-Not Fully Cooked-Not Shelf Stable, and Products with Secondary Inhibitors-Not Shelf Stable.

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 audit 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 HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM

- Official veterinarians assigned to certified establishments that export to the United States were not verifying that the establishments met certain HACCP requirements set by the Ministry of Health (MOH) (Ministero della Salute), Italy's Central Competent Authority, regarding the design of the hazard analysis and HACCP plan, implementation of monitoring, verification and corrective actions procedures, and maintenance of records and supporting documents for the HACCP system.

During the audit exit meeting, MOH committed to address the preliminary finding as presented. FSIS will evaluate the adequacy of MOH'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 U.S. Department of Agriculture (USDA) conducted an onsite audit of Italy's food safety inspection system March 13–April 4, 2023. The audit began with an entrance meeting March 13, 2023, in Rome, Italy, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from Italy's Central Competent Authority (CCA)—the Ministry of Health (MOH) (Ministero della Salute). Representatives from MOH accompanied FSIS auditors throughout the entire audit. The audit concluded with an exit meeting conducted remotely via videoconference April 4, 2023.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to verify 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 properly labeled and packaged. Italy is eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products[1]
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Pork	Pork - All Products Eligible except Mechanically Separated and Advanced Meat Recovery Product (AMR)
Raw - Intact	Raw Intact Pork	Pork - All Products Eligible
Thermally Processed - Commercially Sterile (TPCS)	Thermally Processed, Commercially Sterile	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	Not Ready-to-Eat (NRTE) Otherwise Processed Meat	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	Ready-to-Eat (RTE) Acidified / Fermented Meat (without cooking)	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	RTE Dried Meat	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	RTE Salt-Cured Meat	Pork - All Products Eligible
Heat Treated - Shelf Stable	RTE Dried Meat	Pork - All Products Eligible
Heat Treated - Shelf Stable	RTE Acidified / Fermented Meat (without cooking)	Pork - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE Fully-Cooked Meat	Pork - All Products Eligible

[1] All source meat used to produce products must originate from eligible countries and establishments certified to export to the United States.

Process Category	Product Category	Eligible Products[1]
Fully Cooked - Not Shelf Stable	RTE Meat Fully-Cooked Without Subsequent Exposure to the Environment	Pork - All Products Eligible
Heat Treated - Not Fully Cooked - Not Shelf Stable	NRTE Otherwise Processed Meat	Pork - All Products Eligible
Products with Secondary Inhibitors - Not Shelf Stable	RTE Salt-Cured Meat	Pork - All Products Eligible

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, Veneto, and the Autonomous Provinces of Trento and Bolzano (with special restrictions), and low risk for classical swine fever (with restrictions). APHIS recognizes the status for African swine fever (ASF) based on restricted zones established by the European Union (EU) or any EU member state because of detection of ASF in domestic or feral swine (with special restrictions).

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed Italy's Self-Reporting Tool (SRT) responses and supporting documentation, including official chemical residue and microbiological sampling plans and results. During the audit, the FSIS auditors conducted interviews, reviewed records, and made observations to verify whether Italy's food safety inspection system governing pork products is being implemented as documented in the country's SRT responses and supporting documentation.

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 3-year period, in addition to information obtained directly from the MOH through the SRT.

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.

The FSIS auditors reviewed administrative functions at MOH headquarters, 2 regional offices, 2 local health units (LHU), and 12 local inspection offices within the establishments. 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 140 establishments certified to export to the United States. This included 2 pork slaughter and processing establishments and 10 pork

processing establishments. The products these establishments produce and export to the United States include raw intact pork, RTE acidified/fermented pork (without cooking), RTE dried pork, RTE fully cooked pork, RTE fully cooked pork without subsequent exposure to the environment, RTE salt-cured pork, NRTE otherwise processed pork, and TPCS pork.

During the establishment visits, the FSIS auditors paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliances that threatens food safety. The FSIS auditors assessed MOH'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.

The FSIS auditors also visited one government laboratory conducting microbiological and chemical residue testing and a second government laboratory conducting microbiological testing to verify that these laboratories can 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, Bologna • Tuscany, Florence
	Local Health Units	2	• Parma, Langhirano • Siena, Colle di Val d'Elsa
Laboratories		2	• Instituto Zooprofilattico Sperimentale Della Lombardia e dell' Emilia Romagna (IZSLER) (government) (microbiological and chemical residue testing), Brescia • IZSLER (government) (microbiological), Parma
Pork slaughter and processing establishments		2	• Establishment No. IT 207M, Agricola Tre Valli Società Cooperativa, Magreta di Formigine • Establishment No. IT 643M, Martelli F.LLI S.P.A., Dosolo
Pork processing establishments		10	• Establishment No. IT 5L, Levoni S.P.A., Castellucchio • Establishment No. IT 55L, Devodier Prosciutti S.R.L., Lesignano de' Bagni • Establishment No. IT 205L, Principe Di San Daniele S.P.A., San Daniele del Friuli • Establishment No. IT 498L, S. Nicola Prosciutti Del Sole S.P.A., Corniglio • Establishment No. IT 718L, Salumificio Toscano Piacenti S.P.A., San Gimignano • Establishment No. IT 955L, Golfera In Lavezzola S.P.A., Conselice

		• Establishment No. IT 1558L, Italpizza S.P.A., Modena • Establishment No. IT 1620L, Saor Italia S.R.L., Gioiosa Ionica • Establishment No. IT D627X, Giuseppe Citterio Salumificio S.P.A., Santo Stefano Ticino • Establishment No. IT F2M1W, Prosciuttificio San Michele - S.R.L., Traversetolo

FSIS performed the audit to verify that Italy's food safety inspection system meets 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.) Section 601 *et seq.*);
- The Humane Methods of Slaughter Act (7 U.S.C. Sections 1901–1906); and
- The Meat Inspection Regulations (9 CFR parts 301 to the end).

The audit standards applied during the review of Italy's food safety inspection system for 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.

III. BACKGROUND

From September 1, 2019, to August 31, 2022, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 96,263,399 pounds of pork products from Italy. This included 707,404 pounds of TPCS pork; 848,384 pounds of RTE salt-cured pork; 424,078 pounds of RTE pork fully cooked without subsequent exposure to the environment; 12,386,680 pounds of RTE fully cooked pork; 65,648,775 pounds of RTE dried pork; 12,313,154 pounds of RTE acidified/fermented pork (without cooking); 84,238 pounds of raw intact pork; and 3,850,686 pounds of NRTE otherwise processed pork exported by Italy to the United States. Of these amounts, additional types of inspection were performed on 12,063,407 pounds of pork (42,861 pounds of thermally processed, commercially sterile pork; 113,743 pounds of RTE salt-cured pork; 54,226 pounds of RTE pork fully-cooked without subsequent exposure to the environment; 1,559,493 pounds of RTE fully-cooked pork; 8,390,184 pounds of RTE dried pork; 1,573,716 pounds of RTE acidified/fermented pork (without cooking); and 329,184 pounds of NRTE otherwise processed pork). These additional types of inspection included physical examination, condition of container examination for TPCS products, chemical residue analysis, and testing for microbiological pathogens (*Listeria monocytogenes* [*Lm*] and *Salmonella* in RTE products). As a result of the reinspection, FSIS rejected 22,680 pounds of RTE dried, unsliced ham due to public health POE violations from testing positive for *Lm* or because the product was associated with lots that tested positive for *Lm*. FSIS evaluated MOH's corrective action responses, found them sufficient, and closed the POE violations.

The previous FSIS audit in 2021 did not identify any systemic findings.

Recent FSIS final audit reports for Italy's food safety inspection system are available on the FSIS website at: www.fsis.usda.gov/foreign-audit-reports.

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

The first equivalence component 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.

MOH is the central body of the National Health Service. Legislative Decree No. 193/07 designates MOH at the central level, 19 Regions and 2 autonomous Provinces (Trento and Bolzano) at the regional level, and 123 LHUs at the local level as competent authorities for food safety. Throughout this report, reference to regional offices includes the two autonomous provinces of Trento and Bolzano. MOH has sole responsibility for import and export controls of animals, food, and feed, and shares responsibility with Regional Health Services for animal health and welfare, and food and feed safety. LHUs are the third level of government authority and are responsible for the localized implementation of official inspection activities by government inspectors. The State-Regions Conference is a committee which represents the central level (state) and regions and autonomous provinces on issues that affect more than one region. Within MOH, the Directorate General for Food Hygiene, Food Safety and Nutrition (Direzione generale per l'igiene e la sicurezza degli alimenti e la nutrizione [DGISAN]) is responsible for oversight of the offices involved in products of animal origin and export of food products. Of these, the Food Hygiene and Export Office is responsible for coordinating lower levels of the inspection system in activities related to the export of pork products to the United States, as well as training activities. MOH established an export taskforce to reinforce cooperation between MOH and Regional Health Services. The export taskforce is managed by DGISAN and includes experts from Regional Health Services.

Each region has a Regional Veterinary Service, which is responsible for planning, coordination, guidance, and authorization of establishments to operate, as well as verification of controls of the applicable LHU. Within LHUs, Local Veterinary Services are responsible for animal health, inspection, and control of food of animal origin, and hygiene of animal husbandry and of farming production. LHUs provide direct oversight of establishments certified to export to the United States, by assignment of an Official Veterinarian (OV) under the supervision of LHU Directors.

MOH issued Ministerial Circular DGISAN 25342 (6/22/2021), USDA-FSIS Audit of Pork Meat and Pork Meat Products Exports to the United States, Preliminary Findings and Recommendations. This circular provides guidance for addressing noncompliances that cannot be resolved immediately. MOH has the option to either temporarily suspend the introduction of raw materials to be processed into products eligible for export to the United States, temporarily

suspend production processes of products for export to the United States, or temporarily suspend export certification while the establishment resolves the noncompliances. The temporary suspension may not exceed 6 months. If the establishment cannot resolve the noncompliances within 6 months, the OV is to notify the regional office to propose delisting the establishment from being eligible to export to the United States. The FSIS auditors reviewed two examples of establishments that were suspended until noncompliances were resolved and verified these requirements are being implemented as described.

MOH disseminates information through a cascade system to inspection personnel. MOH uses a certified email program called Posta Elettronica Certificata (PEC) to disseminate information to regional offices and LHUs. The OVs do not have access to the PEC program. The FSIS auditors reviewed the dissemination of Ministerial Circular DGISAN 25342. The FSIS auditors also reviewed PEC receipts confirming the information was transmitted from MOH headquarters to regional offices and then to LHUs. The regional offices provide this information to OVs via regular email. The FSIS auditors also reviewed dissemination of the official 2023 surveillance plan for *Lm* and *Salmonella* in RTE products. The FSIS auditors verified the surveillance plan was disseminated from MOH headquarters to regional offices and then to LHUs and OVs.

MOH's export certification process is designed to ensure that pork products intended for export to the United States are not adulterated or misbranded and that only eligible pork products are certified for export to the United States. Only OVs that have received training on the export process can issue export certificates for the United States. The OV assigned to an eligible slaughter establishment is responsible for issuing pre-export certificates for pork sent intra-country from slaughter to processing establishments. The OV assigned to the exporting establishment conducts a pre-shipment review that includes review of the pre-export certificate to verify eligibility of source materials used to produce processed products, food safety records for each lot, and test results from all samples of products tested for adulterants prior to issuing the export certificate. According to Ministerial Circular No. 19561 (27/05/2020), all RTE products destined for export to the United States are held pending results of microbiological analyses and swine carcasses and parts subject to official chemical residue testing are required to be held pending results. The establishments eligible to export to the United States have chosen to exclude livestock carcasses and parts subject to chemical residue testing from being eligible for export to the United States. The OV performs physical inspection of the packages including the label and integrity of primary and secondary packaging. The OV obtains a unique certificate number from the regional electronic system. Each region has a specific letter they use before the certificate number. The export certificate is printed on simple paper in a single copy and the OV applies the official seal of the regional office and the official stamp with their name and title and provides a wet signature. The OVs are responsible for securing the regional stamp in the locked government office and each OV is responsible for securing the stamps with their name and title. The FSIS auditors reviewed export certificates, associated documents, and the documentation of the export verification task and verified that OVs are performing export certification procedures sufficient to ensure FSIS import requirements are met prior to certifying product for export to the United States.

MOH has the legal authority to certify and decertify establishments that are eligible to export to the United States. The procedures for certification of establishments requesting approval to

export to the United States are described in Ministerial Circular DGISAN 15012 (4/14/2016). LHUs perform an onsite verification of requirements for eligibility and submit verification records along with a recommendation to the regional office. Regional office personnel perform a document review and forward the application to MOH. The establishment must then operate for a period of not less than 3 months while implementing eligibility requirements for export to the United States. After the 3-month pre-registration period, the establishment must validate its controls. MOH then performs a document review followed by an onsite verification audit. The FSIS auditors reviewed records associated with an establishment that was recently added to the certified list of establishments eligible to export pork products to the United States. The FSIS auditors also verified that MOH followed documented procedures for the establishment certification process as described.

Official personnel within central, regional, and local levels of the food safety inspection system are public employees and are selected through a competitive process. Salaries of headquarters officials are paid directly by the Ministry of Economy and Finance. Regional personnel are either paid by the regional office or LHU, and LHU officials, OVs, and prevention technicians are paid by the LHU with funds provided by the Ministry of Economy and Finance. The Department of the Treasury, under the Ministry of Economy and Finance, charges fees to establishments for the inspection services provided and transfers the appropriate funds to MOH to fund the program. The FSIS auditors reviewed an earnings statement for a central veterinarian and verified payment by the Ministry of Economy and Finance. The FSIS auditors also reviewed earning statements for a regional veterinarian and an OV and verified payment by the LHU. All public employees must sign a conflict-of-interest affidavit annually, which is verified by the LHU for local level officials at the end of each year. The FSIS auditors reviewed an LHU report from 2022 confirming that all local level officials signed the required annual conflict-of-interest affidavit.

Ministerial Circular DGISAN 10140-P (3/17/2017) describes requirements for inspection based on establishment activities, to ensure official inspection during every shift of production for products intended for export to the United States. Official inspection occurs continuously during slaughter operations and at least once per production shift during processing of pork products intended for export to the United States. Establishments are required to provide written advanced notice to the LHU of their intent to produce product for export to the United States. LHUs are responsible for developing staffing plans, including providing inspection coverage for planned and unplanned absences. OVs can be pulled from other establishments or from another LHU; however, the OV must be trained in FSIS import requirements. Ministerial Circular DGISAN 25342 specifies the number of inspectors required for post-mortem inspection in slaughterhouses certified for export to the United States, consistent with FSIS regulatory requirements. The FSIS auditors verified that the slaughter establishments included in the audit utilized the number of post-mortem inspectors for the number of animals slaughtered per hour in accordance with Ministerial Circular DGISAN 25342.

Italy's inspection system requires official inspection personnel to be qualified and competent prior to assignment at establishments eligible to export to the United States. OVs are required to have a degree in veterinary medicine and 3 years of post-graduate studies. OVs are also required to complete 150 hours of continuing education for veterinarians every 3 years. Prevention technicians are required to have a prevention technician degree from a university. Training

courses for OVs and prevention technicians can be conducted at central, regional, or local levels. MOH is responsible for coordinating training related to new requirements and exports. Regional offices coordinate ongoing training for LHUs. LHUs are responsible for conducting local inspection training. The FSIS auditors reviewed the Tuscany regional office training for 2022, which included modules for labeling of food products and official controls in the production of pork products. The FSIS auditors also reviewed documentation for training provided by the Siena LHU in 2021 related to verification of control of *Lm* and *Salmonella* in RTE pork products.

The Experimental Zooprophylactic Institutes (Istituti Zooprofilattici Sperimentali [IZS]) are a network of laboratories across Italy that are responsible for conducting official microbiological and chemical residue testing. Each IZS has peripheral branches. The National Institute of Health (Istituto Superiore di Sanità [ISS]), which is the leading technical and scientific body of the National Health Service, maintains oversight of IZS laboratories. IZS laboratories must implement general quality assurance and control procedures consistent with International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 standards. The National Independent Authority for Laboratories (L'Ente Italiano di Accreditamento [ACCREDIA]) is the national accreditation body responsible for accreditation and annual audits of IZS laboratories to verify compliance with ISO/IEC 17025 standards.

The Experimental Zooprophylactic Institute of Lombardy and Emilia Romagna (Istituto Zooprofilattico Sperimentale della Lombardia e Dell'Emilia Romagna [IZSLER]) headquarters laboratory is in Brescia. IZSLER has 18 peripheral branches. Only the IZSLER branches located in Brescia and Parma perform microbiological testing on RTE products intended for export to the United States. Other IZSLER branches, in addition to the IZSLER branches in Brescia and Parma, perform microbiological and chemical residue testing on carcasses and parts. The current audit included the microbiological and chemical residue testing sections of the IZSLER branch in Brescia and the microbiological section of IZSLER branch in Parma. The audit of the laboratories included interviews with the laboratory officials and analysts and document reviews, including documentation of internal and extemal laboratory audits. The FSIS auditors reviewed the report for the 2022 audit of the IZSLER network of laboratories by ACCREDIA and verified that IZSLER implemented corrective actions in response to the audit findings. In addition to the ACCREDIA audits, the laboratory is also subjected to internal audits by IZSLER and ISS (for FSIS methods). The FSIS auditors also reviewed the reports from internal audits conducted by ISS and IZSLER and verified that the laboratory implemented corrective actions to the audit findings.

IZSLER laboratory technicians that conduct testing according to FSIS laboratory methods in the Brescia and Parma laboratories must participate in an annual proficiency testing program organized and administered by the Experimental Zooprophylactic Institute of Abruzzo and Molise (Istituto Zooprofilattico Sperimentale della Abruzzo e Molise [IZSAM]). The proficiency testing schemes administered by IZSLER alternate between *Salmonella* and *Lm* each year. The FSIS auditors verified that all IZSLER technicians in Brescia and Parma that conduct testing according to FSIS laboratory methods participated in proficiency testing for *Lm* in 2021 and *Salmonella* in 2022 and that the results were deemed to be acceptable.

During the visits to the laboratories, the FSIS auditors reviewed records for sample receipt and registration, calibration of equipment, analyst worksheets, supervisory checks on analyst performance, analyst training, sample rejection, and reporting of results. Laboratories receive five portions for each chemical residue sample, of which one is analyzed, and the remaining four are stored for different reasons, including retesting if a result is appealed by the industry through judicial inquiry. However, MOH also includes instructions in Ministerial Circular 19561 (27/05/2020) stating that retesting cannot be used to assess the conformity of consignments intended for export to the United States. The FSIS auditors also reviewed implementation of the laboratory's information systems, DarWin, which is used to manage sampling and other data, and SiSi, which is used mainly for digital signing of test results. Digitally signed sample results are automatically distributed to the official in charge of sampling and to the LHU with oversight of the establishment where the sample was collected. The LHU official downloads the results from the regional information system and uploads it into the national database, SINVSA. Additionally, if the sample result is noncompliant, an IZSLER official directly contacts the LHU to notify them. The FSIS auditors reviewed an *Lm*-positive result from 2022 and verified that the laboratory immediately notified the LHU. If a sample is rejected because it does not comply with the established laboratory acceptance criteria, the laboratory contacts the LHU and requests that the sample be collected again. The FSIS auditors reviewed documentation for a sample that was rejected in 2020 because it did not arrive at the laboratory within the required timeframe after sample collection. The FSIS auditors verified that the laboratory followed notification procedures and requested a replacement sample be collected. The FSIS auditors also confirmed the replacement sample was collected and submitted to the laboratory for analysis.

The FSIS auditors verified that MOH'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 equivalence component 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 every carcass and its 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.

Ministerial Circular DGISAN 25342 provides requirements for animal welfare and humane handling during transport and slaughter. Establishment operators that handle the animals must obtain a certificate of competence for training on animal welfare provided by MOH. OVs are responsible for verification of humane handling and slaughter requirements once per day in each certified slaughter establishment. OVs identify injured animals that need to be slaughtered on the truck or in the pens to ease suffering and these animals are excluded from export to the United States. The FSIS auditors verified through record review that OVs conduct humane handling and slaughter verification activities as required by MOH.

OVs assigned to each certified slaughter establishment perform ante-mortem inspection to ensure that all livestock presented for slaughter are fit for human food. Ante-mortem inspection is carried out on every animal prior to slaughter and includes 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 animals arrive with a health certificate from the farm of origin certifying the health of the animals. The animals also arrive with a veterinary attestation of the animals' suitability to be transported to the slaughterhouse. OVs verify that condemned animals are destroyed. Suspect animals identified during ante-mortem are segregated and slaughtered separately, followed by a thorough post-mortem examination. The FSIS auditors verified through interviews and record review that OVs conduct ante-mortem inspection for every lot of animals as required by MOH.

OVs perform post-mortem inspection of swine according to instructions detailed in Ministerial Circular DGISAN 25342. Post-mortem inspection procedures of carcasses for export to the United States require visual inspection, palpation, and incision. Post-mortem inspection also includes head inspection with mandibular lymph node incision, viscera inspection with incision of the heart, and carcass inspection. The FSIS auditors verified through direct observation that OVs were performing post-mortem inspection as required by MOH.

The LHU performs supervisory reviews once a quarter at slaughter establishments and twice a year at processing establishments eligible to export to the United States, in accordance with Ministerial Circular DGISAN 10140-P. Supervisory reviews include establishment document review, onsite evaluation of the establishment, and evaluation of the verification activities and associated knowledge of the OV in charge of control. Supervisory reviews must cover all required elements over the course of the year. The FSIS auditors examined supervisory reviews related to official control conducted by the LHUs at multiple establishments. When deficiencies were noted, the FSIS auditors ascertained that the LHU verified compliance during the follow-up supervisory review. The FSIS auditors confirmed that supervisory visits occurred at the described frequency, were documented using the established form, and covered all required elements over the course of the year.

Ministerial Circular DGISAN 10140-P contains requirements that establishments certified to export to the United States must maintain identity of products and control and segregate product destined for the United States from other products, as applicable. The FSIS auditors verified at all visited establishments that products eligible to be certified for export to the United States were separated from products ineligible to be certified for export to the United States either through time, space, or identifying marks.

MOH requires species verification testing once per year at establishments eligible to export to the United States. The IZSLER laboratory in Brescia performs species identification testing in a specialized bacteriology laboratory. The FSIS auditors reviewed species testing conducted in 2022 and confirmed sampling was conducted at the required frequency in audited establishments and that testing only identified the presence of pork meat, as expected.

Circular DGISAN 15012 (14/04/2016) requires products destined to the United States to comply with FSIS labeling requirements. MOH verify labels for products eligible for export to the United States during the initial establishment certification and once a year during annual recertification. LHUs perform label review at least three times per year. The OV performs label verification anytime there is a change to the label. The FSIS auditors reviewed labels at the audited establishment and verified that mandatory label requirements were met. The FSIS auditors also reviewed label approvals received from FSIS and verified that establishments were complying with FSIS labelling requirements. The FSIS auditors also verified allergens were accurately declared on the labels when included in the formulation.

MOH receives information regarding changes to APHIS restrictions from the EU central office. This information is relayed to the LHU via the Regional Health Service. OVs are responsible for verifying that establishments authorized to export dry-cured pork products have a valid agreement with APHIS. All pork source materials must arrive at the processing establishment accompanied by a health certificate that includes health attestations for eligibility for export to the United States. The FSIS auditors verified that OVs are reviewing the official health certificates as part of their pre-shipment review verification task to ensure the raw materials are not restricted by APHIS.

Ministerial Circular DGISAN 10140-P contains procedures for inspection personnel to verify establishments certified to export to the United States identify, handle, and control condemned and inedible materials in accordance with Regulation (EC) No. 1069/2009, Commission Regulation (EU) No. 142/2011, and subsequent amendments. The FSIS auditors verified through observation and record review that OVs ensure condemned and inedible materials are controlled and not used to produce human food for export to the United States.

The FSIS auditors verified that MOH has the legal authority to establish regulatory controls over pork establishments that are eligible to export their products to the United States.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component the FSIS auditors reviewed was Government Sanitation. The FSIS auditor verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation standard operating procedures (Sanitation SOP) to prevent direct product contamination or insanitary conditions, and to maintain requirements for sanitation performance standards (SPS) and sanitary dressing.

MOH requires establishments certified as eligible to export to the United States to operate in a manner that prevents the creation of insanitary conditions. OVs verify the establishments' sanitary dressing procedures through several inspection verification tasks. During ante-mortem verification, OVs verify that animals with excessive contamination go through a live animal wash procedure in the pens prior to slaughter. The OV performs one of the five daily activities to verify zero tolerance for the presence of fecal material, ingesta, and milk on carcasses: 1) observe sanitary dressing procedures, 2) review zero-tolerance records, 3) observe the employee performing zero-tolerance monitoring, 4) observe the employee performing verification of zero-tolerance monitoring, or 5) hands-on verification of zero tolerance before the final carcass wash.

The OV also verifies sanitary conditions when conducting the daily SPS and Sanitation SOP verification tasks. The FSIS auditors confirmed through direct observation, interviews and records review that OVs perform daily verification tasks to ensure livestock are slaughtered and processed in a sanitary manner.

MOH requires that establishments eligible to export to the United States develop procedures consistent with FSIS sanitation regulations in 9 CFR part 416 to address SPS, including cleaning, facility construction and maintenance, equipment maintenance, and pest control. On days that products are being processed for export to the United States, OVs verify compliance with SPS daily by direct observation and records review, as described in Ministerial Circular DGISAN 10140-P. The FSIS auditors verified that OVs are performing at least one SPS task on days that products are being processed for export to the United States as well as ensuring that all aspects of SPS are being verified over time. The FSIS auditors also verified through records review that OVs are identifying and documenting SPS noncompliances and are verifying corrective actions.

MOH requires establishments certified as eligible for export to the United States to develop and adhere to written programs that prevent direct product contamination. MOH's enforcement program includes suspension and withdrawal of inspection for those establishments that fail to prevent product contamination or fail to take corrective actions. On the days that products are being processed for export to the United States, OVs verify compliance with Sanitation SOP daily by direct observation or through records review, as described in Ministerial Circular DGISAN 10140-P. The FSIS auditors verified that OVs are performing one Sanitation SOP task on days that products are being processed for export to the United States. The FSIS auditors reviewed reports of pre-operational and operational Sanitation SOP noncompliances and records demonstrating the establishments' corrective actions were implemented and effective, as verified by official inspection personnel. The FSIS auditor observed pre-operational sanitation verification tasks conducted by OVs at the two audited establishments. The FSIS auditors also verified that OVs review the establishments' pre-operational documentation before releasing the establishment to begin production. The FSIS auditors did not identify any issues.

FSIS analysis and onsite audit verification activities indicate that MOH's pork inspection system maintains sanitation programs that are consistent with criteria established for this component. The FSIS auditors identified isolated noncompliances related to inspection verification of sanitation requirements. These are noted in the individual establishment checklists provided in Appendix A of this report.

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

The fourth equivalence component 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 MOH requires establishments to design, implement, and maintain HACCP systems in accordance with EU and FSIS requirements. Ministerial Circular DGISAN 10140-P describes MOH's HACCP requirements. MOH requires establishments to develop

HACCP systems that include written hazard analyses, flow charts, and HACCP plans that identify, evaluate, and prevent or control food safety hazards throughout the production process. MOH requires establishments' HACCP plans to include activities designed to validate adequacy of controls, monitoring and verification procedures, records for documenting results of monitoring and verification activities, and corrective actions in response to deviations from critical limits. The FSIS auditors reviewed required documentation associated with HACCP systems at each audited establishment. The FSIS auditors conducted onsite observations of critical control point (CCP) monitoring and reviewed records associated with the establishments' design and implementation of their HACCP systems, including their hazard analyses, flow charts, CCPs, critical limits, monitoring procedures and frequencies, initial validation, ongoing verification, reassessment, records, and pre-shipment review. The FSIS auditors identified the following finding:

- OVs assigned to certified establishments that export to the United States were not verifying that the establishments met certain HACCP requirements set by the MOH regarding the design of the hazard analysis and HACCP plan, implementation of monitoring, verification and corrective actions procedures, and maintenance of records and supporting documents for the HACCP system.

Ministerial Circular DGISAN 10140-P describes MOH's required verification activities conducted by OVs. OVs perform a hazard analysis verification (HAV) task to verify establishments consider and address the relevant hazards. The HAV task is conducted by inspection personnel on each product type annually and when changes, such as implementation of new technologies, changes due to the annual reassessment, emergence of an unforeseen hazard, and addition or removal of a CCP, are made to the HACCP system. MOH requires the OV to conduct daily verification activities for HACCP requirements through direct observation, hands-on activities, or records review when product is being produced for export to the United States. Although the FSIS auditors verified that OVs are performing HAV tasks and daily HACCP verification tasks, OVs were not effectively identifying noncompliances when performing these tasks, as described in the preceding paragraph.

FSIS analysis and onsite audit verification activities indicate that MOH requires establishments to develop, implement, and maintain a HACCP system that is consistent with criteria established for this component; however, MOH is not ensuring that OVs verify the HACCP systems fully comply with their requirements. Observations related to this finding are noted in the individual establishment checklists provided in Appendix A of this report.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth equivalence component the FSIS auditor 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, or muscle of carcasses for chemical residues identified by the exporting country's meat products inspection authorities or by FSIS as potential contaminants.

Italy's National Residue Monitoring Plan (NRMP) is issued annually by DGISAN pursuant to specific provisions related to monitoring of chemical residues found in Regulation (EU) 2017/625 and Regulation (EC) No. 178/2002 on food law and food safety. DGISAN has issued Legislative Decree Nos. 27/2021, 32/2021, and 158/2006 to implement EU regulations and directives pertaining to chemical residue monitoring, sampling, and testing on livestock and other species. The NRMP goes into effect each year on January 1, and ends December 31. The NRMP plan is developed in collaboration with regions and autonomous provinces, national reference laboratories, and IZS. As required under the EU regulations stated above, MOH submits its NRMP for the current year and chemical residue test results for the previous year to the European Commission by March 31. Information provided to the commission must also contain changes and measures adopted based on evaluation of the results from the previous year's testing. Italy's NRMP is evaluated each year by the European Commission and chemical residue test results for the previous year are evaluated by the European Food Safety Authority.

The NRMP includes animal species tested, classes of drugs, pesticides, and environmental contaminants included in testing, methods of analysis for each of the compounds tested, points of sampling (e.g., slaughterhouses and livestock farms), and a description of samples that may be collected through targeted sampling. When the plan is developed each year it takes into consideration the results of the previous years, including trends of new emerging chemical residue hazards, such as newly approved or banned drugs, in the EU or in the United States.

The FSIS auditors verified that once the NRMP is finalized, the regional offices coordinate the plan with their respective LHUs, which are the ultimate entities responsible for the implementation of the plan. A statistically based number of samples are allocated to each LHU depending on several factors, including the number of slaughter establishments and the volume of slaughter attributable to that LHU. The slaughter establishment samples are collected under one of the three sampling sub-plans: 1) the routine plan; 2) the suspect plan; or 3) the extra (other) plan. While samples collected under the routine plan are based on production volume, the suspect plan allows OVs to collect samples when the animals offered for slaughter are suspected of receiving unauthorized or banned drugs, present clinical symptoms, or when there is suspected noncompliance with the withdrawal period for veterinary drugs. Sampling conducted within the extra (other) plan includes monitoring plans arranged by the Ministry and regions to meet specific local or national requirements. The NRMP also allocates a percentage of samples to be collected by veterinarians in the field from live animals at farms under routine surveillance. MOH requirements described in Ministerial Circular No. 19561 (27/05/2020) indicate that swine carcasses and parts subject to official chemical residue testing are required to be held pending results. The establishments eligible to export to the United States have chosen to exclude livestock carcasses and parts subject to chemical residue testing from being eligible for export to the United States.

The FSIS analysis and remote verification activities indicate that MOH continues to maintain overall authority for a chemical residue testing program which is designed and implemented to prevent and control the presence of veterinary drugs and contaminants in pork products exported to the United States.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component 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. This component also addresses requirements for TPCS meat products.

The FSIS auditors verified that MOH requires that all slaughter establishments certified to export to the United States implement an indicator organism swine carcass testing program using two-point sampling (pre-evisceration and post-chill) to monitor the effectiveness of the process control for enteric pathogens. The FSIS auditors confirmed that carcass samples are collected and analyzed for Enterobacteriaceae, and aerobic plate count pre-evisceration and after the final wash in one audited slaughter establishment processing hot-boned carcasses and that another audited slaughter establishment's two-point testing was being conducted at pre-evisceration and post-chill locations. If a sample exceeds an established limit, a nonconformance is documented, describing the cause of the nonconforming results and any adjustments in the process to prevent recurrence. The FSIS auditors reviewed a recent nonconformance in testing results that exceeded the critical limit in one of the audited establishments and verified that the establishment identified the cause and subsequently implemented appropriate corrective actions. The FSIS auditors review of MOH's requirements for indicator testing in swine slaughter establishments did not raise any concerns.

Additionally, although no longer required by FSIS for equivalence, MOH requires sampling for *Salmonella* in swine carcasses. MOH's requirements for testing chilled swine carcasses for *Salmonella* are described in Ministerial Circular DGISAN 25342. The FSIS auditors reviewed official inspection records and verified that the *Salmonella* verification sampling is being implemented as described in Ministerial Circular DGISAN 25342.

MOH enforces a zero-tolerance policy for *Lm* and *Salmonella* in RTE pork products as described in DGISAN Ministerial Note 37041(21/10/ 2020) and DGISAN Ministerial Circular 10140-P. According to DGISAN Ministerial Note 37041, each RTE establishment must have validated support for *Salmonella* lethality, ensuring at least a 5-$\log_{10}$ reduction. The FSIS auditors noted that audited RTE establishments producing post-lethality exposed (PLE) products are controlling hazards of *Listeria* contamination by adopting measures consistent with one of the three alternatives defined in FSIS' regulation 9 CFR part 430.

The establishment's self-control measures for verifying control of *Lm* include microbiological testing of product, direct and indirect food contact surfaces (FCS), and testing of non-food contact surfaces (NFCS) in the production environment. The frequencies of testing vary by the alternatives implemented by the establishment to control *Listeria* contamination in PLE RTE products. The FSIS auditors reviewed the testing programs at each audited RTE establishment and confirmed that the testing plan and frequencies complied with the requirements in DGISAN Ministerial Note 37041. The FSIS auditors further reviewed the establishments' self-verification testing program for products not covered under 9 CFR 430 and noted that the establishment testing also included analyses for staphylococci, generic *Escherichia coli*, and coliforms. Dried

products are monitored for either pH or water activity requirements, or both, as supported by validated scientific studies or as described in FSIS' guidelines for RTE products. DGISAN Ministerial Note 37041 provides the web links for industry and inspection staff to access FSIS' guideline, Controlling *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products (January 2014), and the newly revised FSIS guidelines for cooking and stabilization, FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A) (December 2021) and FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B) (December 2021).

The FSIS auditors noted that the audited establishments implement self-monitoring testing programs using ISO/IEC 17025-accredited laboratories that implement ISO/IEC methods of analysis for detection of *Lm* and *Salmonella*. Although there were no recent examples of *Lm* or *Salmonella*-positive results for RTE products, the FSIS auditors reviewed an older example at one audited establishment and verified that MOH's intensified follow-up testing protocol in response to an *Lm*-positive result was implemented until all results of the follow-up testing for *Lm* were negative. Establishments hold batches of product destined for the United States are held until all test results, whether from official or establishment self-control testing, are reported as negative for *Lm* and *Salmonella*. OVs assigned to certified establishments routinely verify test results prior to releasing the lots for export to the United States. Any lots testing positive are excluded from export certification.

MOH performs official verification sampling for *Lm* and *Salmonella* in RTE pork products exported to the United States as described in DGISAN Ministerial Note 37041. Official verification consists of random and risk-based components, including testing of RTE product for *Lm* and *Salmonella* and testing of FCS and NFCS for *Lm*. Microbiologically independent lots of products are held pending receipt of acceptable results and results of these surveillance programs are reported to the SINVSA database. The FSIS auditors reviewed the records related to official testing programs for *Salmonella* and *Lm* in RTE products and the production environment. The FSIS auditors verified that MOH requires official laboratories to implement testing according to FSIS' Microbiology Laboratory Guidebook (MLG) methods for detection of *Salmonella* and *Lm* in RTE products. FSIS' MLG 8.13 method is implemented for detection of *Lm* in a 25g test portion, and FSIS' MLG 4.12 method is implemented for detection of *Salmonella* in a 325g test portion.

The FSIS auditors verified that MOH requires certified establishments producing TPCS products to implement procedures as described in DGISAN Official Note 40602 (24/10/2018) for TPCS pork products intended for export to the United States. The requirements in the above-mentioned circular are consistent with the FSIS' requirements in 9 CFR part 431. The FSIS auditors noted that the audited establishments producing these products had taken all microbiological hazards associated with TPCS products into consideration in their hazard analysis and addressed them appropriately in their HACCP plan. In these audited establishments, time, temperature, and pressure associated with sterilization process were addressed through a CCP meeting MOH requirements.

The FSIS auditors examined process schedules and all associated critical factors for the products exported to the United States. The data reviewed related to the critical factors linked with the

process schedule for a TPCS product indicated that the establishments were monitoring initial temperatures, venting, vacuum and head space, and control instruments (e.g., temperature recorders, indicator thermometers). The FSIS auditors' document review also included an evaluation of establishments' procedures to ensure proper closure of containers, including training of closure technicians, incubation records, retort traffic controls and inspection verification data. The FSIS auditors' review identified isolated findings at both audited establishments and are captured in their respective establishment checklist in Appendix A of this report.

The FSIS auditors determined that MOH maintains the overall authority to implement its microbiological sampling and testing programs to ensure that pork products exported to the United States are unadulterated, safe, and wholesome.

X. CONCLUSIONS AND NEXT STEPS

A remote exit meeting was held on April 4, 2023, with MOH officials. At this meeting, the FSIS auditors presented the preliminary finding 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 finding:

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM

- OVs assigned to certified establishments that export to the United States were not verifying that the establishments met certain HACCP requirements set by the MOH regarding the design of the hazard analysis and HACCP plan, implementation of monitoring, verification and corrective actions procedures, and maintenance of records and supporting documents for the HACCP system.

During the exit meeting, MOH committed to address the preliminary finding as presented. FSIS will evaluate the adequacy of MOH's documentation of proposed corrective actions once received 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
LEVONI S.P.A. Via Matteotti 23, Castellucchio (MN) Mantua	3/15/2023	5L	Italy
	5. NAME OF AUDITOR(S)		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	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	O
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Pork processing.
Prepared Products:	RTE – Multiple Product Categories including TPCS/ NRTE otherwise processed pork meat

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)	03/20/2023

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
Devodier Prosciutti SRL Via Ponticella 4, Lesignano De' Bagni (PR)	3/23/2023	55L	Italy
	5. NAME(S) OF AUDITOR(S) 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	
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. Periodic Supervisory Reviews	
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.	
58.	
59.	

Establishment Operations:	Pork processing.
Prepared Products:	RTE – Dried and Fully Cooked pork meat

60. Observation of the Establishment

10. In the post lethality area, the auditor observed multiple bins ready to be used to store packaged deboned product that had not undergone cleaning and sanitation as was evidenced by the presence of dirt and moisture in them.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/28/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
PRINCIPE DI SAN DANIELE SPA VIALE VENEZIA 222/224, SAN DANIELE DEL FRIULI (UD)	3/28/2023	205L	Italy
	5. NAME(S) OF AUDITOR(S) 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.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	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.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
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.	
58.	
59.	

Establishment Operations:	Processing
Prepared Products:	Processed Pork Products

60. Observation of the Establishment

14 The establishment's hazard analysis states water activity (Aw) less than or equal to 0.92 does not allow the growth of pathogens. Auditor reviewed one sample from 2022 that exceeded Aw 0.92 and the establishment did not perform corrective actions. The establishment stated the actual limit is Aw less than 0.93 which is not consistent with what is stated in the hazard analysis.

15/22 CCP1 is for the ambient temperature of the salting chamber. The critical limit is for greater than 6°C for max of 24 hours. There is an internal probe that continuously monitors the ambient temperature using an automatic computer monitoring system, however, the HACCP plan states that monitoring is performed once a day by observing the temperature on the computer. The establishment stated that monitoring also includes a review of the previous 24 hours of records to verify the temperature did not exceed 6°C but this is not stated in the HACCP plan nor documented on the monitoring record.

19 The establishment's validation documentation states that product should remain in a salting chamber that is 4.5°C for 168 hours which doesn't support their established critical limit of greater than 6°C for max of 24 hours; however, the establishment has an SOP that requires the ambient temperatures to be in range with their validation documentation.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/28/2023

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 Societa Cooperativa, Via Mazzacavallo 47 – Magreta di Formigine (MO)	3/20/2023	207M	Italy
	5. NAME OF AUDITOR(S) 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	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures	O	**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

Establishment Operations:	Pork slaughter processing.
Prepared Products:	Raw Intact Pork Products

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)	03/21/2023

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
S. Nicola Prosciutti Del Sole SPA Corniglio Corniglio (PR)	3/22/2023	498L	Italy
	5. NAME OF AUDITOR(S)		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	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

Establishment Operations:	Pork processing.
Prepared Products:	RTE- Dried and Acidified/Fermented Pork Meat

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)	03/21/2023

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
MARTELLI F.LLI SPA . VIA FRATELLI MARTELLI 2/4 , DOSOLO (MN)	3/15/2023	643M	Italy
	5. NAME OF AUDITOR(S) 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	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .	X	41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	

60. Observation of the Establishment

10. During the walk through, the FSIS auditor twice observed food contact surfaces contacting contaminated surfaces. No product was affected and in both cases the establishment took immediate corrective actions to restore sanitary conditions.

14. Establishment's HACCP plan and correct actions record considers the CCP under control before identification of the cause of the deviation.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/15/2023

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 TOSCANO PIACENTI S.P.A. VIA DEL PONTE, LOC. CANONICA. 4, SAN GIMIGNANO (SI)	3/21/2023	718L	Italy
	5. NAME OF AUDITOR(S) 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 .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	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. Periodic Supervisory Reviews	
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.	
58.	
59.	

Establishment Operations:	Pork processing.
Prepared Products:	Processed Pork

60. Observation of the Establishment

15. HACCP plans do not specify the food safety hazards being controlled; however, this information is provided in the hazard analysis.

15. CCP1 in the roasted meat HACCP plan and the cured products HACCP plan does not accurately state the critical limit.

15. CCP1 in the roasted meat HACCP plan and the cured products HACCP plan states monitoring is performed by continuous automated monitoring of the room temperatures; however, the actual monitoring takes place once a day by an operator who verifies the temperature on the automated monitoring machine, but this information is not included in the HACCP plan.

15. HACCP plan references product temperature monitoring, however, the documentation does not comply with HACCP record keeping requirements. The establishment explained that product temperature monitoring is actually a prerequisite program and should not have been included in the HACCP plan.

22. CCP1 in the roasted meat HACCP plan and the cured products HACCP plan states monitoring is performed by continuous automated monitoring of the room temperatures, however, this information is not recorded so it does not comply with HACCP record keeping requirements. Monitoring records does not comply with HACCP record keeping requirements.

22. Hands-on verification records for CCP1 in the roasted meat HACCP plan does not include the outcome of the verification.

22. CP1 in the roasted meat HACCP plan and cured products HACCP plan does not reference the verification of monitoring instruments but they are performing calibrations once a year. CCP2 in the roasted meat HACCP plan does not include calibration of scales as a verification activity.

22. Monitoring records for CCP3 in the roasted meat HACCP plan did not include initials at the time the event occurred for all monitoring activities.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/21/2023

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
LAVEZZOLA SPA VIA DELL`INDUSTRIA 6/8 - LOC. LAVEZZOLA ., CONSELICE (RA)	03/23/2023	955L	Italy
	5. NAME OF AUDITOR(S) 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	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .	X	41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

Establishment Operations:	Pork processing.
Prepared Products:	Processed Pork

60. Observation of the Establishment

14. The thermally processed commercially sterile (TPCS) HACCP plan identifies critical limits for time, temperature, and pressure but the establishment only performs CCP monitoring and verification on the temperature.

15. There were inconsistencies in the sterilization temperature between the electronic TPCS process schedule, the HACCP plan, and the HACCP monitoring records. The establishment's validation of their process schedule states that the sterilization set point is 116°C for 110 minutes but the product is considered shelf stable at 115.5°C. for 110 minutes, but the establishment's HACCP monitoring records states stabilization is achieved at >115.0°C for 110 minutes and the HACCP plan indicates 116°C. The establishment stated their thermometer reads to 0.5°C so greater than 115.0°C is equal to 115.5°C.

19. The FSIS auditor noted some inconsistencies between the establishment's validated TPCS process schedule and the electronic process schedule. The validated process schedule stated the come-up time is 9 minutes, but the electronic process schedule states the come-up time is 6 minutes. The process authority stated the temperature must reach 116°C before the start of process timing regardless of the posted come-up time.

46. The FSIS auditor observed water droplets directly over salami in the washing area. The FSIS auditor did not observe droplets falling on product. The establishment took immediate corrective actions.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/24/2023

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
ITALPIZZA SPA VIA GHERBELLA 454/A - MODENA (MO) EMILIA ROMAGNA	3/24/2023	1558L	Italy
	5. NAME OF AUDITOR(S) 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.	X
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. Periodic Supervisory Reviews	
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.	
58.	
59.	

Establishment Operations:	Pork processing.
Prepared Products:	

60. Observation of the Establishment

14. The establishment's hazard analysis and flow chart does not include all steps in the process. Specifically, it does not identify slicing of salami as a processing step or consider the physical hazards associated with slicing equipment. However, in subsequent steps, all pizzas go through a metal detector.

14. The establishment's hazard analysis and flow chart identify a step for applying pizza toppings, which includes three different types of meats (salami, sausage, bacon), cheese, veggies, and tomato sauce but it doesn't consider hazards associated with each type of product and it doesn't identify any hazards that need to be prevented or controlled at that step. However, the establishment does have standard operating procedures that limit the amount of meat products that can enter the warm processing room at any given time, but it doesn't state anywhere that these standard operating procedures are to prevent the growth of biological hazards.

14. The flow chart does not accurately reflect the flow for all products. The flow chart shows all frozen meat products going from the freezer to a refrigerator, however it is only the frozen salami that follows this pathway and the other frozen meat ingredients (sausage/ bacon) go straight to the pizza topping step.

16. The on-site verification and record review verification of monitoring of the metal detector CCP does not comply with HACCP record keeping requirements.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/24/2023

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
Saor Italia SRL Contrada Palma SNC Gioiosa Ionica (RC)	3/28/2023	1620L	Italy
	5. NAME OF AUDITOR(S) 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 .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	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	
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. Periodic Supervisory Reviews	
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.	
58.	
59.	

Establishment Operations:	Pork processing.
Prepared Products:	TPCS

60. Observation of the Establishment

15. Neither the establishment's process flow chart nor its hazards analysis indicated a cooling step for product exiting the retort after receiving thermal application. However, during the tour of the facility the auditor observed the glass jars exiting from the retort, undergoing a brief drying phase, then entering a cooling phase where they were subjected to a cooling process with chlorinated water.

15. The establishment did not identify specific potential biological or chemical hazards associated with steps in the hazard analysis. In some instances, the biological hazard was just identified as microbial flora. The HACCP plan and programs associated with control points did refer to the specific pathogens.

15. The auditor noted that the HACCP plan for cooking and cooling steps with different hazard profiles for each step have been addressed in a single step as the cooking phase. Since the potential hazards associated with each step require different control hazards, the establishment could not justify as to how the two steps with different hazard characteristics would be sufficiently addressed in a single cooking phase. This raise concerns as cooking and cooling are different steps and pose different hazards.

15. The establishment's supporting documents for the sterilization step addressed acidified foods rather than the low acid canned foods which the establishment produces. Additionally, the critical parameters contained in the document were not being implemented by the establishment.

19. The establishment's HACCP plan did not state the verification frequency or verification procedures. The procedures were however described in the establishment's SOP.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/28/2023

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
GIUSEPPE CITTERIO SALUMIFICIO SPA VIA TICINO 105 SANTO STEFANO TICINO (MI)	3/17/2023	D627X	Italy
	5. NAME OF AUDITOR(S) 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	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .	X	41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

Establishment Operations:	Pork processing.
Prepared Products:	Processed Pork

60. Observation of the Establishment

14. CCP2B and CCP5B in the salami HACCP plans describes monitoring before and after seasoning of two pieces to determine weight loss; however, the establishment is monitoring 20 pieces before and selecting 2 of the 20 pieces to measure the after weight, therefore the monitoring activities are not being implemented as described in the HACCP plan.

19. CCP1B in the cooking HACCP plan is monitored using a portable thermometer; however, verification is performed by reviewing a thermal graph produced from the stove thermometer rather than verification of monitoring of the CCP, therefore ongoing verification activities do not include direct observation of monitoring activities.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/17/2023

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
Prosciuttificio San Michele SRL Via Carbognani 6, Traversetolo (PR)	3/21/2023	F2M1W	Italy
	5. NAME OF AUDITOR(S)		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	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

Establishment Operations:	Pork processing.
Prepared Products:	Applies High Pressure Process to incoming RTE-PLE products form the US Certified Establishments in Italy.

60. Observation of the Establishment

46. During the tour of the facility, the FSIS auditor observed multiple plastic bins containing packed ham products received for HPP treatment were in poor maintenance and had broken edges and rough surfaces at multiple places around them. One of these bins had collected visible dirt at more than one place. The condition observed jeopardizes the sanitary operation despite the use of liners in the containers. The establishment immediately transfer the product to cleaned bins and would further require their clients to inspect sanitation of containers prior to shipping product for the HPP treatment.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/22/2023

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
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Object: 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 June 30th, 2023 and your invitation to provide comment to the final draft report of the verification audit of Italy's meat inspection system conducted by FSIS from March 13th to 19th, 2023.

With regards to the content of the report of the audit conducted, no significant inconsistencies have been noticed regarding the documented review.

Non compliances related to the establishments inspected were solved and verification of the implementation of the corrective actions have been evaluated by the Official Competent Authority.

Regarding the need to develop, implement, and maintain a HACCP system that is consistent with criteria established by MOH, we recognize the need of an improvement that has been identified by your team. For this reason, the MOH established a working group to review the circular DGISAN 10140 of 2017.

Even thought a final text is not yet finalized, we will share it with you as soon as this review will be completed. Once the new measures would be adopted, the MOH will organize a specific training

course and on site verification of the implementation of the new rule in the exporting establishments' through the inspection activity.

In order to organize the training course in the most effective way, we will be grateful to receive information to evaluate the possibility that personnel of this MOH could participate to training course held by FSIS in U.S. for its staff.

I would like to share my truly appreciation for the work that has been conducted, to you and your team for the proactive cooperation. We take into serious consideration the safety of the products that Italy exports to the United States of America.

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

Kind Regards.

THE DIRECTOR GENERAL

Dr. Ugo Della Marta

UGO DELLA MARTA
22.09.2023
14:38:57
UTC

Ref:

Nicola Santini e-mail: n.santini@sanita.it