



United States Department of Agriculture

Food Safety and
Inspection Service

April 15, 2025

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Washington, D.C.
20250

Dr. Alexandru Nicolae Bociu
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President – Secretary of State
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Dear Dr. Bociu,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an onsite verification audit of Romania's meat inspection system October 21–November 14, 2024. Enclosed is a copy of the final audit report. The comments received from the Government of Romania are included as an attachment to the report.

Sincerely,

PARRISH ENDY

Digitally signed by PARRISH
ENDY

Date: 2025.04.15 06:13:00 -04'00'

On behalf of
Margaret Burns Rath, JD, MPH
Assistant Administrator
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED OF
ROMANIA

OCTOBER 21–NOVEMBER 14, 2024

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING
PROCESSED PORK PRODUCTS
EXPORTED TO THE UNITED STATES OF AMERICA

April 14, 2025

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

Executive Summary

This report describes the outcome of an onsite equivalence verification audit of Romania conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) October 21–November 14, 2024. The purpose of the audit was to verify whether Romania's food safety inspection system governing raw and processed pork products remains equivalent to that of the United States, with the ability to export processed pork products that are safe, wholesome, unadulterated, and properly labeled and packaged. Romania is eligible to export ready-to-eat (RTE) and thermally processed - commercially sterile pork products to the United States.

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

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

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION and ADMINISTRATION)

- The Institute of Hygiene and Veterinarian Public Health, an official government microbiological reference laboratory, was not properly documenting the sample analysis procedures for detection of *Salmonella* and *Listeria monocytogenes* in RTE pork products in accordance with International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025 standards for traceability. The laboratory was not documenting the start and end times that samples were entering and leaving the incubators during various phases of analysis.

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

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) conducted an onsite audit of Romania’s food safety inspection system October 21–November 14, 2024. The audit began with an entrance meeting held October 21, 2024, in Bucharest, Romania, to discuss the audit objective, scope, and methodology. The participants included representatives from the National Sanitary Veterinary and Food Safety Authority (NSVFSA) — the Central Competent Authority (CCA). The FSIS auditor was accompanied by NSVFSA inspection officials throughout the entire audit. The audit concluded with an exit meeting conducted remotely via videoconference November 14, 2024.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to verify whether the food safety inspection system governing raw and processed pork remains equivalent to that of the United States, with the ability to export processed pork products that are safe, wholesome, unadulterated, and properly labeled and packaged. Romania is eligible to export the following categories of products to the United States.

Process Category	Product Category	Eligible Products ¹
Thermally Processed - Commercially Sterile	Thermally Processed - Commercially Sterile (TPCS)	Pork - All Products Eligible
Not Heat Treated – Shelf Stable	Ready-to-Eat (RTE) Dried Meat	Pork - All Products Eligible

The USDA’s Animal and Plant Health Inspection Service (APHIS) recognizes Romania as free of swine vesicular disease with no special restrictions but considers Romania to be affected with African swine fever (ASF), classical swine fever (CSF), and foot-and-mouth disease (FMD). Pork imported from Romania is subjected to ASF requirements specified in Title 9 of the United States Code of Federal Regulations (9 CFR) 94.8, CSF requirements specified in 9 CFR 94.9, and FMD requirements specified in 9 CFR 94.4.

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

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

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 capabilities 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 NSVFSA 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 auditor reviewed administrative functions at NSVFSA's headquarters, three regional offices, and five local inspection offices within the establishments. The FSIS auditor evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as documented in the country's SRT responses and supporting documentation.

All five establishments certified to export to the United States were selected for audit. This included four pork processing establishments and one swine slaughter establishment that provide raw source materials used for production of processed pork products intended for export to the United States. During the establishment visits, the FSIS auditor paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditor assessed NSVFSA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in 9 CFR 327.2.

The FSIS auditor also visited one official microbiological laboratory and one official chemical residue laboratory to verify that these government laboratories are capable of providing adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> • NSVFSA, Bucharest
	Regional Offices	3	<ul style="list-style-type: none"> • County Sanitary Veterinary and Food Safety Directorate (CSVFSD), Timișoara • CSVFSD, Sibiu • CSVFSD, Bacău

Laboratories	2	<ul style="list-style-type: none"> • Institute of Hygiene and Veterinarian Public Health, Bucharest • Sanitary Veterinary and Food Safety Chemical Residue Laboratory, Timișoara
Swine slaughter establishment	1	<ul style="list-style-type: none"> • Establishment No. 6 S.C. Smithfield Prod S.R.L. (Comtim Romania S.R.L.), Timișoara
Pork processing establishments	4	<ul style="list-style-type: none"> • Establishment No. 43 S.C. Vascar S.A., Vaslui • Establishment No. 46 S.C. Salbac S.A., Bacău • Establishment No. 84 S.C. Aldis S.R.L, Călărași • Establishment No. 400 S.C. Scandia Food S.R.L., Sibiu

FSIS performed the audit to verify that Romania’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 1901-1907); and
- The Meat Inspection Regulations (9 CFR Parts 301 to the end).

The audit standards applied during the review of Romania’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 May 2, 2023, to August 8, 2024, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 9,905 pounds of RTE dried pork products exported by Romania to the United States. FSIS also performed reinspection on 9,905 pounds at POE for additional types of inspection, including condition of container, product examination, and chemical residue analysis. No product was refused entry for issues related to public health.

The previous FSIS audit in 2021 did not identify any systemic findings representing an immediate threat to public health.

The most recent FSIS final audit reports for Romania’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 auditor 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 government inspection personnel at establishments where products are prepared for export to the United States.

Romania's meat inspection system is organized into three levels: central, regional, and local. At the central level, NSVFSA is Romania's CCA. NSVFSA is responsible for implementing and enforcing European Union (EU) regulations, Romanian national regulations, and third country import regulations, including oversight and enforcement of FSIS' import requirements for products intended for export to the United States. NSVFSA is comprised of three general directorates: (1) General Directorate of Animal Health and Animal Welfare, (2) General Directorate of Food Safety, (3) General Directorate for Inspection and Control. At the regional level, there are 42 Sanitary Veterinary and Food Safety Directorates (SVFSD) that provide supervision over local inspection offices within meat producing establishments for the control of products of animal origin. At the local level, Sanitary Veterinary and Food Safety Circumscription provide direct supervision over official inspection activities of veterinarians who are responsible for conducting and documenting the results of government ante-mortem and post-mortem inspection procedures verification of establishment implementation of sanitation standard operating procedures (Sanitation SOP), sanitation performance standards (SPS), HACCP, and other inspection verification activities in certified establishments.

The FSIS auditor verified that in-plant government inspection personnel consist of official veterinarians (OV) and official auxiliaries (hereinafter government inspection personnel) who are government employees paid by the Romanian government. The FSIS auditor reviewed government inspection personnel educational credentials and training records concerning humane handling and slaughter verification, ante-mortem and post-mortem inspection procedures, Sanitation SOPs, SPS, HACCP, chemical residue and microbiological sampling methodology, and FSIS import requirements. There were no concerns noted with the educational credentials or the training records.

The FSIS auditor verified that government inspection personnel are required to review product labels on shipping boxes and individual packages as part of their export certification task to verify compliance with FSIS labeling requirements. All export certification items, including blank export health certificates and stamps, are stored in the secure government inspection office at each certified establishment. The FSIS auditor verified that government inspection personnel conduct a pre-shipment review to verify establishment's traceability programs, associated establishment and inspection verification records for each lot, and review of testing results from either an establishment's self-control monitoring sampling or official inspection verification

sampling prior to signing an export health certificate. NSVFSA Service Note No. 29469/2016, further supported by NSVFSA Service Notes No. 26217/2017 and 26775/2019, requires government inspection personnel to ensure and verify that raw and processed pork products subject to chemical residue and microbiological analyses are held pending their test results. The FSIS auditor review of the export certification process did not raise any concerns.

NSVFSA Order No. 57/2010 provides inspection requirements applicable in all meat producing establishments, including those that are certified as eligible to export to the United States. The order outlines inspection enforcement procedures to certify, suspend, delist, or relist a certified establishment. NSVFSA has the authority to approve or reject an establishment's certification based on the outcome of its record reviews and onsite inspection verification of compliance with FSIS import requirements. The FSIS auditor reviewed the newly certified establishment's approval process which included government inspection personnel's evaluation of establishment written programs and onsite verification audits to determine the establishment's compliance with NSVFSA and FSIS import requirements. The FSIS auditor verified that government inspection personnel were following NSVFSA requirements.

Regulation (EC) No. 178/2002 and Regulation (EU) 2017/625 provide NSVFSA with the legal authority and enforcement responsibility to ensure that adulterated or misbranded products are not exported to the United States. NSVFSA provided regulatory definitions for adulterated and misbranded products that are consistent with FSIS requirements. The FSIS auditor verified that government inspection personnel have proper legal authority to enforce regulatory control actions by applying reject or retain tags on equipment, utensils, rooms, or compartments in accordance with NSVFSA requirements. The FSIS auditor verified that each audited establishment had written recall and traceability programs, and government inspection personnel verify establishment's adherence to these programs. NSVFSA also has recall procedures in place that include notifying EU and the United States of the recall. The FSIS auditor reviewed the export certification process and confirmed that government inspection personnel followed the export certification process in accordance with NSVFSA requirements.

The FSIS auditor verified that NSVFSA has provided instructions to government inspection personnel to identify and document any noncompliance findings on a noncompliance record, also known as a control note (CN). The FSIS auditor reviewed inspection-generated CNs and verified that government inspection personnel closed CNs after verifying the adequacy and effectiveness of the establishment's actions addressing noncompliance findings. The FSIS auditor confirmed that there have not been any elevated enforcement actions associated with certified establishments since the previous FSIS audit in 2021.

Government Ordinance No. 42/2004 provides NSVFSA with its legal authority and responsibility to approve and disapprove laboratories conducting testing of official verification samples. NSVFSA is also responsible for providing oversight of government laboratories that perform analyses for official verification sampling and testing programs for pork products intended for export to the United States, including oversight to ensure that government

laboratories conducting official analyses implement general quality assurance and control criteria consistent with International Organization for Standardization (ISO)/International Electrotechnical Commission Guide (IEC) 17025 standards. The FSIS auditor visited two government laboratories: the Institute for Hygiene and Veterinary Public Health (IHVPH) in Bucharest and the Sanitary Veterinary and Food Safety Chemical Residue Laboratory in Timisoara. The IHVPH is the national reference laboratory that conducts testing for *Salmonella* and *Listeria monocytogenes* (*Lm*) in RTE products or in environmental samples, including food contact and non-food contact surfaces. This laboratory conducts analyses for all official microbiological samples, including analysis of RTE pork products intended for export to the United States. The Sanitary Veterinary and Food Safety Chemical Residue Laboratory is a regional laboratory that conducts chemical residue testing on official samples originating from slaughter establishments. These government laboratories are accredited by the Romanian Accreditation Association in accordance with ISO/IEC 17025 standards. The FSIS audit scope in each audited laboratory included review of sample receipt, timely analysis, analytical methodologies, analytical controls, analyst qualifications and trainings, proficiency testing, and recording and reporting of results. The FSIS auditor reviewed the most recent accreditation audits, the laboratories' staff training records, and the results of their proficiency testing. In addition to reviewing documentation, the FSIS auditor interviewed laboratory personnel and reviewed records of analyses. The following systemic finding was identified:

- IHVPH was not properly documenting the sample analysis procedures for detection of *Salmonella* and *Lm* in RTE pork products in accordance with ISO/IEC 17025 standards for traceability. The laboratory was not documenting the start and end times that samples were entering and leaving the incubators during various phases of analysis.

Apart from the finding, the FSIS auditor verified that Romania's food safety inspection system governing raw and processed pork products has the organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements.

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 auditor 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.

The FSIS auditor verified that government inspection personnel are required to conduct humane handling and slaughter verification procedures in accordance with NSVFSA requirements that

are consistent with the procedures described in FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock. This included verification of proper repair and maintenance of holding pens and alleyways, verification of proper handling of animals prior to slaughter, and evaluation of the stunning and sticking procedures. Currently, Romania has one swine slaughter establishment certified as eligible to produce raw source material for processed pork products intended for export the United States.

The FSIS auditor confirmed that all swine presented for slaughter receive ante-mortem examination in accordance with Articles 17–18 of Regulation (EU) 2017/625; and Article 11 of Commission Implementing Regulation (EU) 2019/627. The FSIS auditor verified that government inspection personnel conduct ante-mortem inspection procedures prior to slaughter and document their examination results in accordance with NSVFSA requirements. Ante-mortem inspection procedures include observations of all live animals and verification of the incoming registrations, including animal health attestation and traceability documents.

The FSIS auditor verified that the audited swine slaughter establishment is staffed with a sufficient number of government inspection personnel to conduct post-mortem inspection procedures. This includes government inspection personnel verification of proper presentation and identification of all carcasses and parts; examination of heads, viscera, and carcasses; and disposition of affected carcasses and parts in accordance with NSVFSA requirements, which are consistent with the procedures described in FSIS Directive 6100.2, Post-mortem Livestock Inspection. The FSIS auditor confirmed that humane handling and slaughter verification procedures, ante-mortem inspection procedures, and post-mortem inspection procedures are conducted and documented in accordance with NSVFSA requirements.

The FSIS auditor verified that NSVFSA requires certified establishments to separate and appropriately dispose of condemned or inedible pork products. This included government inspection personnel verification of certified establishments' procedures to identify, segregate, and dispose of condemned and inedible materials. The FSIS auditor confirmed that government inspection personnel conduct weekly inspection verification activities to verify proper collection, segregation, storage, and disposal of condemned and inedible pork products in accordance with NSVFSA requirements.

The FSIS auditor verified that NSVFSA has a system in place to notify its government inspection personnel concerning animal disease status, including APHIS import requirements in regard to ASF, CSF, and FMD. NSVFSA provided specific technical instructions to government inspection personnel for implementation and verification of APHIS requirements in certified establishments.

The FSIS auditor verified that each audited establishment has a system in place to identify and segregate pork products intended for export to the United States from those that are produced for other markets during all stages of production, storage, and shipment. NSVFSA Service Note No. 29469/2016, further supported by NSVFSA Service Note No. 26775/01.08.2019, specifies that

certified pork processing establishments are required to ensure that raw source materials originate from slaughter establishments certified as eligible to export to the United States. The FSIS auditor verified that all certified processing establishments are required to maintain traceability mechanisms to ensure source materials originate from certified slaughter establishments in countries eligible to export to the United States.

The FSIS auditor verified that government inspection personnel from NSVFSA and CSVFSD conduct periodic supervisory visits at certified slaughter and processing establishments eligible to export to the United States. The risk-based periodic supervisory visits include assessment and verification of inspection requirements for ante-mortem inspection, animal welfare, post-mortem inspection, Sanitation SOPs, SPS, HACCP, labeling, establishment self-control monitoring and official inspection verification sampling programs, separation and identification of eligible source material, establishment construction and maintenance, controls over condemned and inedible material, species testing, APHIS disease restriction requirements, and export certification process. The FSIS auditor review of periodic supervisory reviews process and records did not raise any concerns.

FSIS onsite audit verification activities indicate that NSVFSA continues to maintain the legal authority, a regulatory framework, and adequate verification procedures to ensure sufficient official regulatory control over raw source materials and processed pork products intended for export to the United States.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component the FSIS auditor reviewed was Government Sanitation. The food safety inspection system is to require that each official establishment develop, implement, and maintain written Sanitation SOPs to prevent direct product contamination or insanitary conditions, and to maintain requirements for SPS and sanitary dressing.

The FSIS auditor verified that NSVFSA requires certified slaughter and processing establishments to develop, implement, and maintain written Sanitation SOPs, SPS, and implement sanitary dressing procedures to prevent direct product contamination or the creation of insanitary conditions consistent with FSIS requirements in 9 CFR Part 416. The FSIS auditor verified that each audited establishment maintains a written sanitation program to include cleanliness of the food contact surfaces prior to the start of operations and to maintain sanitary conditions during operations to prevent product adulteration or creation of insanitary conditions. Each audited establishment's Sanitation SOPs included maintenance and improvement of sanitary conditions through ongoing evaluation of the establishment's hygienic practices. The FSIS auditor confirmed that government inspection personnel conduct daily verification of sanitation requirements in accordance with NSVFSA Service Note No. 1618/2006 requirements. These verification activities consist of a combination of document review, observation, and hands-on inspection verification.

The FSIS auditor confirmed that government inspection personnel conduct pre-operational sanitation verification prior to production of product intended for export to the United States. This included both hands-on inspection verification and review of daily pre-operational records generated by establishments personnel. The FSIS auditor observed government inspection personnel perform hands-on operational sanitation verification in all audited establishments. The FSIS auditor noted that the inspection verification activities included direct observation of the actual operations and review of the establishments' associated records. The FSIS auditor's onsite observations and record reviews of establishments' sanitation monitoring, verification, and corrective action records showed no systemic concerns. The FSIS auditor also reviewed government inspection personnel's records documenting daily inspection verification results and periodic supervisory visits and verified that government inspection personnel took regulatory enforcement control actions sufficient to ensure that sanitary conditions were restored, and product was protected from contamination.

NSVFSA requires slaughter establishments to develop, implement, and maintain written sanitary procedures to prevent contamination of carcasses, organs, and other parts throughout the slaughter and dressing process. NSVFSA Service Note No. 27053/2023 requires slaughter establishments to have trained employees who conduct the sticking, skinning, bunging, eviscerating, and splitting carcass. The FSIS auditor evaluated government inspection personnel verification of establishment sanitary dressing procedures in the certified swine slaughter establishment. Government inspection personnel conduct daily verification of the establishment's sanitary dressing procedures including verification of zero tolerance for fecal material, ingesta, and milk. The FSIS auditor's observations and record reviews of inspection verification activities regarding these requirements did not raise any concerns.

FSIS onsite audit verification activities indicate that NSVFSA's food safety inspection system governing raw and processed pork products maintains sanitation programs that are consistent with criteria established for this component. The FSIS auditor identified isolated findings related to the 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 auditor 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 auditor verified that NSVFSA requires certified slaughter and processing establishments to develop, implement, and maintain a HACCP system consistent with FSIS requirements in 9 CFR Part 417. The FSIS auditor conducted interviews and reviewed documents in conjunction with direct observation at five audited certified establishments to verify whether NSVFSA continues to maintain and implement HACCP requirements. The FSIS

auditor verified that audited establishments' HACCP programs include written hazard analysis; flow charts; supporting documentation for hazard analysis decisions and critical limits, monitoring, and verification activities for critical control points (CCP); documentation of validation and reassessments; and records supporting the implementation of the HACCP system. The FSIS auditor reviewed establishments' generated records for monitoring, verification, corrective actions, and validation. The FSIS auditor reviewed records and assessed the effectiveness of government inspection personnel daily verification procedures in ensuring that HACCP requirements are properly implemented in each certified establishment.

The FSIS auditor verified that government inspection personnel conduct daily HACCP verification activities when a certified establishment intends to produce product for export to the United States. Government inspection personnel verification activities consist of a combination of document review, observation, and hands-on inspection verification. At the swine slaughter establishment, the FSIS auditor verified that government inspection personnel perform daily verification for zero tolerance of fecal material, ingesta, and milk to ensure establishment compliance with zero tolerance CCP requirements. The FSIS auditor verified that audited establishments took appropriate corrective actions in response to any critical limit deviations and government inspection personnel verified and documented the effectiveness of the establishments' corrective actions.

FSIS onsite audit verification activities indicate that NSVFSA requires certified establishments to develop, implement, and maintain a HACCP system that is consistent with criteria established for this component. The FSIS auditor identified isolated findings related to the inspection verification of HACCP recordkeeping requirements. These 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.

The FSIS auditor verified that NSVFSA is responsible for annual planning, coordination, and monitoring of the implementation of the National Residue Control Plan (NRCP) in accordance with Regulation (EU) 2017/625 and NSVFSA Order No. 95/2007. The NRCP is issued each year based on an evaluation of the number of animals slaughtered and the sampling results from the previous year. The NRCP contains the sampling protocol, the number of samples to be taken per year, the species to be sampled, the tissues to be collected, the target compounds, testing methods, action levels (i.e., maximum residue levels (MRL)), and the enforcement strategy when

violative results are identified. Samples for the NRCP are collected from both swine farms and swine slaughter establishments.

The FSIS auditor verified that trained government inspection personnel collect, prepare, seal and ship required samples to designated government laboratories in accordance with NSVFSA instructions. During the evaluation of ante-mortem inspection procedures at the only certified swine slaughter establishment, the FSIS auditor observed that government inspection personnel verify the origin of every lot of animals and the declaration by the animal owner attesting that they have adhered to veterinary pharmaceutical withdrawal periods prior to shipping animals for slaughter. In addition to the NRCP routine chemical residue sampling plan, NSVFSA Service Note No. 22873/2010 authorizes government inspection personnel to perform additional targeted sampling of any animal identified as suspect during ante-mortem or post-mortem inspection. Government Decision No. 984/2005 establishes sanctions and provisions to penalize chemical residue violators.

The acceptability of test results is based on EU requirements and FSIS identified banned substances with zero tolerance levels and substances with established MRLs permitted in pork products. NSVFSA ensures that products exported to the United States do not contain a chemical residue that exceeds an established United States tolerance or contain a chemical compound with no approved use in the production class tested.

FSIS onsite audit verification activities indicate that NSVFSA has overall authority of a chemical residue sampling program designed and implemented to prevent and control the presence of veterinary drugs, pesticides and other chemical contaminants in pork products intended for export to the United States. There have not been any POE violations related to this component since the previous FSIS audit in 2021. FSIS concludes that NSVFSA continues to meet the core requirements for this component.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth equivalence component the FSIS auditor 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 auditor verified that NSVFSA requires slaughter establishments implement sampling and testing in accordance with requirements in Commission Regulation (EC) No. 2073/2005 to verify process hygiene for swine carcasses. In addition to those requirements, NSVFSA Service Note No. 26146/2020 requires certified establishments eligible to export to the United States to conduct swine carcass sampling at pre- and at post-evisceration locations, consistent with FSIS requirements in 9 CFR 310.18(c). The FSIS auditor reviewed the establishment's written program, observed sample collection methodology at pre- and post-evisceration stations, verified

frequency of sample collection per NSVFSA requirements, and reviewed the use of statistical process control to evaluate swine carcass sampling results. The FSIS auditor confirmed that government inspection personnel conduct monitoring for process hygiene in accordance with NSVFSA requirements.

The FSIS auditor verified that NSVFSA requires establishments producing TPCS products to address potential hazards using HACCP principles and to comply with EU requirements, including Regulation (EC) No. 1935/2004 regarding suitability of food contact materials, Regulation (EC) No. 852/2004 regarding food hygiene and HACCP, and Regulation (EC) No. 853/2004 for foods placed on the market in hermetically sealed containers. NVSFSA Service Note No. 1618/2006 and Service Note No. 25047/2017 specify verification procedures for government inspection personnel to ensure TPCS products meet requirements consistent with FSIS requirements in 9 CFR Part 431. The FSIS auditor interviewed government inspection personnel regarding verification activities and reviewed related documentation addressing process schedules for products intended for export to the United States; procedures to address operations (e.g., posting of processes, retort traffic control, initial temperature) in thermal processing areas; incubation records; retort heat-distribution tests; and procedures to ensure proper closure of containers, including training of closure technicians. No concerns were identified.

The FSIS auditor confirmed that NSVFSA has adopted a zero tolerance approach for *Lm* and *Salmonella* in RTE pork products and RTE pork products that come into direct contact with food contact surfaces (FCS) contaminated with *Lm*. NSVFSA Service Note No. 26217/2017 and the addendum to Service Note No. 29469/2016 contain inspection instructions regarding official verification procedures to assess certified establishments compliance with FSIS import requirements. These Service Notes require certified establishments to identify and address pathogens of concern in RTE products and to include requirements for lethality and stabilization steps to address foodborne pathogens. Further, NSVFSA requires that certified establishments producing post-lethality exposed RTE products to control hazards by adopting measures consistent with one of the three alternatives in FSIS regulation 9 CFR Part 430.

NSVFSA requires that certified processing establishments implement sampling and testing programs for RTE products, FCS, and non-food contact surface (NFCS). In addition, government inspection personnel are required to verify establishments' food safety controls through official verification sampling and testing of RTE products, FCS, and NFCS. According to NSVFSA Order No. 35/2016, RTE pork product is considered adulterated if it contains *Lm* or *Salmonella*, or if it comes into direct contact with a food contact surface that is contaminated with *Lm*. In the event of positive results for *Lm* or *Salmonella* in product or *Lm* in FCS sampling, the affected pork products would not be eligible for export to the United States, as indicated in NSVFSA Service Note 26217/2017.

The FSIS auditor confirmed that NSVFSA requires certified establishments to test each batch of RTE pork products intended for export to the United States for *Lm* and *Salmonella* and to

conduct species verification testing. These batches of RTE pork products are held until all results are confirmed to be acceptable. Additionally, the FSIS auditor confirmed that government inspection personnel were verifying that the establishment personnel were collecting the samples appropriately as per the establishments' procedures and reviewing the test results for each batch of RTE pork products intended for export to the United States. The official verification testing for *Lm* is in accordance with the ISO 11290-1:2017 analytical method for a 25-gram test portion and testing for *Salmonella* is in accordance with the FSIS Microbiology Laboratory Guidebook Chapter 4 analytical method for detection of *Salmonella* in a 325-gram test portion. All official verification samples are collected by government inspection personnel and analyzed at designated government laboratories. The FSIS auditor verified that government inspection personnel collected official verification RTE samples and reviewed the acceptable test results prior to issuance of export health certificate in accordance with NSVFSA requirements.

FSIS onsite audit verification activities indicate that NSVFSA conducts microbiological sampling and testing programs to ensure that pork products intended for export to the United States are safe and wholesome. There have not been any POE violations related to this component since the previous FSIS audit in 2021. FSIS concludes that NSVFSA continues to meet the core requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held November 14, 2024, by videoconference with NSVFSA. The FSIS auditor presented the preliminary findings from the audit. An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditor identified the following systemic finding:

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION and ADMINISTRATION)

- IHVPH was not properly documenting the sample analysis procedures for detection of *Salmonella* and *Lm* in RTE pork products in accordance with ISO/IEC 17025 standards for traceability. The laboratory was not documenting the start and end times that samples were entering and leaving the incubators during various phases of analysis.

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

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION S.C. Smithfield Prod S.R.L. (Comtim Romania S.R.L.) Timisoara	2. AUDIT DATE 10/24/2024	3. ESTABLISHMENT NO. 6	4. NAME OF COUNTRY Romania
	5. AUDIT STAFF OIEA State and International Audit Staff		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	X
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.	X	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:	Swine Slaughter
Prepared Products:	Raw Products

60. Observation of the Establishment

- 22-The establishment’s HACCP ongoing verification records did not include the times of the verification activities.
- 41-Presence of beaded condensate on the overhead structures above exposed products in the swine carcass coolers.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA State and International Audit Staff (SIAS)	10/24/2024

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION S.C. Vascar S.A. Vaslui	2. AUDIT DATE 10/30/2024	3. ESTABLISHMENT NO. 43	4. NAME OF COUNTRY Romania
	5. AUDIT STAFF OIEA State and International Audit Staff		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. 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:	Thermally Processed Commercially Sterile

60. Observation of the Establishment

There were no findings after consideration of extent, degree, and nature of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA State and International Audit Staff (SIAS)	10/30/2024

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION S.C. Salbac S.A. Bacau	2. AUDIT DATE 11/01/2024	3. ESTABLISHMENT NO. 46	4. NAME OF COUNTRY Romania
	5. AUDIT STAFF OIEA State and International Audit Staff		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X	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:	Not Heat Treated-Shelf Stable

60. Observation of the Establishment

22-The establishment’s HACCP records for calibration of monitoring instruments did not include the times of the verification activities.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION S.C. Aldis S.R.L. Călărăsi	2. AUDIT DATE 11/04/2024	3. ESTABLISHMENT NO. 84	4. NAME OF COUNTRY Romania
	5. AUDIT STAFF OIEA State and International Audit Staff		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X	38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.	X	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.	X	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:	Not Heat Treated-Shelf Stable

60. Observation of the Establishment

- 12-The establishment's written Sanitation SOPs did not include all three parts of corrective actions when either the establishment or inspection personnel determines that the establishment's Sanitation SOPs may have failed to prevent direct contamination or adulteration of products.
- 15-The establishment's hazard analysis did not address physical, chemical, or biological hazards in some steps of its production process.
- 20-The establishment's written HACCP plan did not include all four parts of corrective actions to be followed in response to a deviation from a critical limit.
- 22-The establishment's HACCP verification records for calibration of monitoring instruments did not include the signature or initial of the person responsible for performing the verification activity.
- 38-Presence of deteriorated seals above an exterior shipping door could not provide a tight seal when the door was closed. This could create insanitary condition and facilitate the entrance of vermin to the production areas.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION S.C. Scandia Food S.R.L. Sibiu	2. AUDIT DATE 10/28/2024	3. ESTABLISHMENT NO. 400	4. NAME OF COUNTRY Romania
	5. AUDIT STAFF OIEA State and International Audit Staff		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
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:	Thermally Processed Commercially Sterile

60. Observation of the Establishment

39-Presence of numerous holes in the ceiling above exposed products and food contact surfaces in the production areas.

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



**AUTORITATEA NAȚIONALĂ SANITARĂ VETERINARĂ
ȘI PENTRU SIGURANȚA ALIMENTELOR**



**UNITED STATES DEPARTMENT OF AGRICULTURE (USDA)
FOOD SAFETY AND INSPECTION SERVICE (FSIS)
Mrs. Margaret BURNS RATH, JD, MPH, Assistant Administrator
Office of International Coordination**

Subject: Draft final audit report of an audit on the Romanian inspection system for processed pork products performed by the United States Department of Agriculture (USDA) - Food Safety and Inspection Service (FSIS), in the period 21st October - 14th November 2024, on site and remotely

Dear Mrs. Margaret BURNS RATH,

Thank you for the Draft final audit report, which was sent by your letter dated 4-th of February 2025, regarding the FSIS audit mission conducted in Romania between October 21st - November 14th, 2024, remote and onsite, in order to evaluate Romania's meat inspection system

According to your request, we send the NSVFSA corrective actions taken to address the deficiencies observed during the mission, registered in the draft final audit report.

I. Systemic finding:

GOVERNMENT OVERSIGHT (e.g., ORGANIZATION and ADMINISTRATION)

- The Institute of Hygiene and Veterinary Public Health (IHVPH) was not properly documenting the sample analysis procedures for detection of *Salmonella* and *Listeria monocytogenes* (Lm) in RTE pork products in accordance with ISO/IEC 17025 standards for traceability. The laboratory was not documenting the start and end times that samples were entering and leaving the incubators during various phases of analysis.

a) The Institute of Veterinary Hygiene and Public Health (IHVPH), National Reference Laboratory for *Salmonella* and *Listeria monocytogenes* has undertaken corrective actions to remedy the systemic error identified during the audit, respectively the failure to register the period for thermostating samples on the working sheets, during different analytical phases.

Thus, IHVPH reviewed the working sheets for *Salmonella* and *Listeria monocytogenes*, documents attached in copy, clearly mentioning the date and time of introducing the samples into the thermostat (date and time of seeding), as well as the date and time of thermostating completion, thus ensuring traceability, in conformity with the provisions of the SR EN ISO 17025:2018 standard.





**AUTORITATEA NAȚIONALĂ SANITARĂ VETERINARĂ
ȘI PENTRU SIGURANȚA ALIMENTELOR**

b) The National Sanitary Veterinary and Food Safety Authority (NSVFSA), as the Central Competent Authority, by the Directorate for the Coordination of Laboratories and Veterinary Medicinal Products will monitor and verify during the controls carried out in sanitary-veterinary and food safety laboratories, the records that ensure the traceability of the samples.

II. Regarding the deficiencies observed during the mission, registered in the Individual Foreign Establishment Audit Checklists, we resume the measures which were taken, for each audited establishments:

a) S.C. Comtim Romania S.R.L.

22-The establishment's HACCP ongoing verification records did not include the times of the verification activities.

Documents were revised by including the times of the verification activities

41-Presence of beaded condensate on the overhead structures above exposed products in the swine carcass coolers.

The deficiency was fixed by proper applying of Hygiene Operational Control Procedure, respectively of the corrective measures for removing condensation, cleaning the area, retraining the personnel, re-check and taking the responsibility for verifications by signature

b) S.C. Salbac S.A.

22-The establishment's HACCP records for calibration of monitoring instruments did not include the times of the verification activities

Documents were revised by including the times of the verification activities

c) S.C. Aldis S.R.L.

12-The establishment's written Sanitation SOPs did not include all three parts of corrective actions when either the establishment or inspection personnel determines that the establishment's Sanitation SOPs may have failed to prevent direct contamination or adulteration of products.

Documents were revised by including all three parts of corrective actions, retraining the personnel was performed.

15-The establishment's hazard analysis did not address physical, chemical, or biological hazards in some steps of its production process.

Documents were revised by including all hazards for the steps where is missing, retraining the personnel was performed.

20-The establishment's written HACCP plan did not include all four parts of corrective actions to be followed in response to a deviation from a critical limit.





**AUTORITATEA NAȚIONALĂ SANITARĂ VETERINARĂ
ȘI PENTRU SIGURANȚA ALIMENTELOR**

Documents were revised by including all four parts of corrective actions, retraining the personnel was performed.

22-The establishment's HACCP verification records for calibration of monitoring instruments did not include the signature or initial of the person responsible for performing the verification activity

Documents were revised by including the signature of the person responsible for performing the verification activity of the verification activities and retraining the personnel was performed.

38-Presence of deteriorated seals above an exterior shipping door could not provide a tight seal when the door was closed. This could create insanitary condition and facilitate the entrance of vermin to the production areas.

The deficiency was immediately fixed, by replacing de deteriorated seals of the exterior shipping door, and in order to prevent re-emergence of this deficiency, the maintenance and surveillance team was retrained.

d) S.C. Scandia Food S.R.L.

39-Presence of numerous holes in the ceiling above exposed products and food contact surfaces in the production areas.

The deficiency was immediately fixed, by sealing the holes from the production area, and in order to prevent re-emergence of this deficiency, the maintenance and surveillance team was retrained.

Please, contact us if additional information is needed.

Waiting forward to your answer, we wish you all the best.

With the highest consideration,

PRESIDENT • SECRETARY OF STATE

Dr. Alexandru Nicolae BOCIU

