



United States Department of Agriculture

Food Safety and
Inspection Service

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

FEB 28 2022

Dr. Alexandru Nicolae Bociu
Sanitary-Veterinary and Food Safety Authority (ANSVSA)
President – Secretary of State
1 Piata Presei Libere D 1, Sector 1
013701 Bucharest ROMANIA

Dear Dr. Bociu,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an onsite equivalence verification audit of Romania's inspection system August 31–September 29, 2021. 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,

A handwritten signature in blue ink, appearing to read "Michelle Catlin".

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN ROMANIA

AUGUST 31, 2021–SEPTEMBER 29, 2021

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

RAW AND PROCESSED PORK PRODUCTS

TO BE EXPORTED TO THE UNITED STATES OF AMERICA

February 28, 2022

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a reinstatement of equivalence verification audit of Romania conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from August 31, 2021–September 29, 2021. Due to the global COVID-19 pandemic, the audit was conducted following an audit process which included both remote and onsite audit activities. The purpose of the audit was to determine whether Romania's food safety inspection system governing raw and processed pork products is equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Romania had previously been eligible to export meat to the United States. In 2008, the Romanian government voluntarily ceased exporting meat product 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.

The FSIS auditors concluded that Romania's raw and processed pork products inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The National Sanitary Veterinary and Food Safety Authority (NSVFSA), as the Central Competent Authority (CCA), has required that establishments that will be eligible to export products to the United States implement sanitary operating procedures and a HACCP system designed to improve the safety of their products. In addition, NSVFSA has implemented microbiological and chemical residue testing programs to verify its food safety inspection system. An analysis of each component did not identify any systemic findings that would represent an immediate threat to public health.

TABLE OF CONTENTS

I.	INTRODUCTION.....	1
II.	AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY.....	1
III.	BACKGROUND.....	3
IV.	COMPONENT ONE: GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION).....	3
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)	7
VI.	COMPONENT THREE: GOVERNMENT SANITATION.....	9
VII.	COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM	10
VIII.	COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS	11
	1	
IX.	COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS.....	12
X.	CONCLUSIONS AND NEXT STEPS	14
	APPENDICES	16
	Appendix A: Individual Foreign Establishment Audit Checklists	17
	Appendix B: Foreign Country Response to the Draft Final Audit Report	18

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an audit of Romania's food safety system from August 31 to September 29, 2021. The audit began with an entrance meeting held via videoconference on August 31, 2021, with the Central Competent Authority (CCA)— NSVFSA which is located in Bucharest. During the entrance meeting, the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the CCA. Representatives from NSVFSA accompanied the FSIS auditors during the onsite portion of the audit which included laboratories and establishments.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a reinstatement of equivalence verification audit. The audit objective was to determine whether the food safety inspection system governing raw and processed pork products is being implemented as documented in the Self-Reporting Tool (SRT) and is functioning in a manner equivalent to that of the United States, producing products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Romania is seeking reinstatement of equivalence for fully cooked – not shelf stable and thermally processed – commercially sterile pork products.

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Romania as free of swine vesicular disease (SVD) with no special restrictions but is affected with African swine fever (ASF), classical swine fever (CSF), and foot-and-mouth disease (FMD). Romania will need to meet all APHIS import requirements in order to export products to the United States. Therefore, if FSIS determines that the Romanian inspection system for raw and processed pork products is equivalent to FSIS, but certain products are restricted by APHIS, Romania will not be eligible to export the restricted products to the United States until APHIS removes the restrictions.

Prior to the reinstatement equivalence verification audit, FSIS reviewed and analyzed Romania's SRT responses and supporting documentation. During the audit, the FSIS auditors conducted interviews, reviewed records, and observed operations to determine 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.

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 audit process was accomplished by having remote meetings via videoconferences with government personnel and laboratory staff, and by conducting onsite visits to laboratories and

establishments. FSIS scheduled three remote meetings each week for the first two weeks of the audit. After the remote portion of the audit, onsite visits were conducted at two laboratories and five establishments over a two-week period. 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 documented in the SRT and supporting documentation.

All five establishments Romania identified as intending to export to the United States were audited remotely and onsite. This included four further processing establishments and one slaughter establishment intending to supply raw materials for further processing. The products these establishments intend to export to the United States include fully cooked – not shelf stable and thermally processed – commercially sterile pork products.

The FSIS auditor reviewed records related to administrative functions from NSVFSA headquarters, regional offices, laboratories, and local government inspection offices within establishments. Additionally, onsite visits were conducted at all four processing establishments and one slaughter establishment intending to supply raw materials for further processing at establishments intending to export products to the United States. 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.

During the audit, the FSIS auditors assessed NSVFSA’s ability to provide oversight through supervisory reviews. The FSIS auditors paid particular attention to the extent to which industry and the government interacted to control hazards and prevent noncompliance that would threaten food safety. During the audit, the FSIS auditors assessed Romania’s raw and processed pork products inspection system 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 audited one government microbiological laboratory and one chemical residue laboratory to verify that these laboratories are capable of providing adequate technical support to the food safety inspection system.

Audit Scope		#	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> • NSVFSA, Bucharest
Laboratories		2	<ul style="list-style-type: none"> • Institute of Hygiene and Veterinarian Public Health, Government Chemical Residue Laboratory, Bucharest • Sanitary Veterinary and Food Safety Laboratory, Government Microbiological Laboratory, Prahova
Pork slaughter establishment		1	<ul style="list-style-type: none"> • Establishment No. 6 S.C. Smithfield Prod S.R.L., Timisoara
Pork processing establishments		4	<ul style="list-style-type: none"> • Establishment No. 400 S.C. Scandia Food S.R.L., Sibiu • Establishment No. 731 S.C. Recunostinta Prodcom Impex S.R.L., Prahova

	<ul style="list-style-type: none"> • Establishment No. 46 S.C. Salbac S.A., Bacua • Establishment No. 43 S.C. Vascar S.A., Vaslui
--	---

FSIS performed the audit to verify that the 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.] 601, et seq.)
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901, et seq.)
- The Meat Inspection Regulations (9 CFR 301 to the end)

The audit standards applied during the review of Romania’s inspection system for raw and processed pork included all applicable legislation originally determined by FSIS as equivalent as part of the review process.

III. BACKGROUND

Romania had previously been eligible to export meat to the United States. In 2008, the Romanian government voluntarily ceased exporting products to the United States. On March 7, 2011, FSIS received a letter from Romania requesting reinstatement of the raw and processed pork inspection system. From July 16 to August 3, 2012, FSIS conducted an onsite audit of Romania’s processed pork inspection system to verify Romania’s eligibility to export processed pork products to the United States. This onsite audit included a review of Romania’s pork slaughter and processing establishments which resulted in FSIS not reinstating eligibility.

Romania resubmitted its equivalence request in 2015 for reinstatement of its eligibility to export to the United States processed pork under the fully cooked, not shelf stable and thermally processed/commercially sterile (TPCS) hazard analysis and critical control point (HACCP) process categories. Romania is ineligible to export any raw pork products to the United States because of animal health restrictions imposed by USDA’s APHIS. However, Romania is requesting an equivalence determination for their slaughter and raw pork inspection system because Romania intends to use domestically slaughtered pork as source materials for processed pork intended for export to the United States.

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. The 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.

NSVFSA is Romania's CCA and is organized and administered by the national government of Romania. NSVFSA was established in 2004 by Government Ordinance No. 42/2004 and is structured to have a General Secretary. Under the General Secretary are the Economic Directorate, Judicial Directorate, and Human Resources Directorate. Additionally, within NSVFSA are three General Directorates: General Directorate of Animal Health and Animal Welfare, General Directorate of Food Safety, and General Directorate of Official Control and Laboratory Coordination and Veterinary Medicines. These General Directorates are under the presidents and vice presidents of NSVFSA. Oversight of the inspection system is maintained at three at three levels by NSVFSA: central, regional (district), and local.

Under NSVFSA, there are 42 Sanitary Veterinary and Food Safety Directorates (SVFSD) that provide supervision over establishment offices for the control of products of animal origin. There is one SVFSD for each county and one for the municipality of Bucharest. The official veterinarians from the establishment report to the local sanitary veterinary and food safety units. Each of the 42 SVFSDs is managed by an Executive Director and a Deputy Director. In addition to the Deputy Director, the offices of Economic Services, Legal and Human Resources, Internal Public Audit, and Laboratories report to the Executive Director. The Deputy Director organizes, coordinates, and controls the activities of the following offices: Official Animal Health and Welfare Control Office, Official Food Safety Control Office, and Data Inventory, Authorization, Registration and Computerized Evidence Office.

NSVFSA derives its authority and responsibility as the competent authority from the European Union (EU) regulations and is authorized to enforce the laws and regulations governing raw and processed pork inspection, to require corrective actions in establishments, and to take additional enforcement measures as appropriate. NSVFSA Order No. 68/2005, NSVFSA Order No. 10/2008, NSVFSA Order No. 57/2010, and Government Decision No. 984/2005 enable the EU regulations. Additionally, NSVFSA Order No. 35/2016 (and subsequent amendments) establishes the standard methodologies for surveillance and official controls regarding food safety and hygiene applicable to all establishments including those intending to export to the United States.

NSVFSA Order No. 57/2010 is the Romanian procedure in place for certifying and de-certifying establishments as eligible to export to the United States; this order establishes provisions on the process for authorizing establishments to operate in accordance with the EU regulations. The order outlines the procedures to suspend, delist, or relist an establishment approved for export. The certification of establishments is based on the evaluation and audit of the establishments to verify whether these establishments meet FSIS import requirements. The FSIS auditor conducted interviews, reviewed records, and reviewed the certification process without identifying any findings.

The procedures pertaining to the issuance of veterinary certificates denote that verification checks and inspections are performed by the competent veterinary authority in accordance with the provisions of the sanitary veterinary legislation in force. NSVFSA Service Note No. 29469/2016 specifies that source materials must originate from establishments eligible for export to the United States. Establishments are required to implement procedures for selecting suppliers

of raw pork to ensure compliance with this requirement, and this is verified by government inspection personnel during routine verification and prior to issuance of the health certificate. NSVFSA Service Note No. 29469/2016, further supported by NSVFSA Service Notes No. 26217/2017 and 26775/2019, requires the official veterinarian to ensure that raw and processed pork products subject to chemical residue and microbiological analyses are held until the procurement of analysis records that must certify their compliance. The FSIS auditor conducted interviews, reviewed records, and directly observed the export certification process without identifying any findings.

Romania maintains penalties and sanctions for noncompliance of Romanian sanitary, veterinary, and food safety legislation in Government Decision No. 984/2005. NSVFSA Order No. 57/2010 provides measures for how NSVFSA takes effective enforcement actions. Enforcement actions include suspension and withdrawal of inspection for those establishments that fail to prevent product contamination or take corrective actions. The FSIS auditor conducted interviews and reviewed records without identifying any findings.

Romania's recall authority is found in Government Decision No. 984/2005 that requires establishments to withdraw food that does not comply with food safety requirements. NSVFSA's inspection personnel verify that the establishments include procedures for product recall and traceability. In the event adulterated product is shipped to the United States, NSVFSA will notify FSIS through the Rapid Alert System for Food and Feed (RASFF) and the European Commission. RASFF procedures are described in NSVFSA Order No. 68/2005. The FSIS auditor conducted interviews and reviewed records without identifying any findings.

NSVFSA ensures that a single standard of laws and regulations is applicable to all establishments intending to export to the United States in accordance with EU legislation. The NSVFSA Order No. 35/2016 establishes the standard of laws and regulations applicable to all establishments including those intending to export to the United States. Additionally, NSVFSA has issued numerous Service Notes containing instructions for verification activities to government inspection personnel on the specific requirements for establishments intending to export to the United States. The Technical Audit Service organized within NSVFSA carries out verification that government inspection duties are performed as required at establishments intending to export to the United States. Establishment audits are carried out by NSVFSA's central and regional directorates for food safety. The FSIS auditor conducted interviews, reviewed records, and directly observed government inspection activities without identifying any findings in this area.

Service Note No. Intranet 6080/2016 stipulates that government inspection personnel in establishments intending to export pork products to the United States are veterinary doctors who are public servants not hired based on a contract. NSVFSA requires enough qualified government veterinarian inspectors to provide government inspection coverage at each of the establishments continuously during slaughter operations, and at least once per production shift during processing operations when producing pork products intended for export to the United States, including during planned or unplanned government inspector absences. The FSIS auditor conducted interviews, reviewed records, and directly observed government inspection staffing without identifying any findings.

NSVFSA complies with EU regulations regarding educational and training requirements for all staff performing official controls. The EU regulations require competent authorities to establish specific minimum requirements for official veterinarians, official auxiliaries, and other staff. Only those veterinarians that have undergone training and passed an examination are eligible for employment. In Romania, potential government inspection personnel must pass a test according to Government Decision No. 611/2008. Prior to assignment in an establishment eligible to export to the United States, government inspection personnel must pass a theoretical and practical test (including requirements specific to the United States) in accordance with Commission Delegated Regulation (EU) 2019/624. Government inspection personnel must undertake annual continuing education activities/training and must pass the test. The FSIS auditor reviewed hiring records, training records, and conducted interviews verifying NSVFSA conducts continuous training and hires government inspection personnel with the appropriate education.

The national reference laboratory in Romania is the Institute for Hygiene and Veterinary Public Health (IHVPH). NSVFSA ensures adequate oversight of government laboratories that perform analyses for official government sampling and testing programs for pork products intended to be exported to the United States, including oversight to ensure that laboratories conducting official government analyses implement general quality assurance and control criteria consistent with International Organization for Standardization (ISO)/International Electrotechnical Commission Guide (IEC) 17025 standards.

Each SVFSD oversees a Sanitary Veterinarian and Food Safety Laboratories that will conduct microbiological analysis for products intended to be exported to the United States. Specifically, these laboratories will conduct official government analysis for *Listeria monocytogenes* (*Lm*) and *Salmonella* in ready-to-eat (RTE) products produced by establishments intending to export to the United States. All official government chemical residue samples originating from slaughter establishments intending to export to the United States will be analyzed at the IHVPH laboratory. NSVFSA derives its legal authority and responsibility to approve and disapprove laboratories conducting testing of official government samples of product intended for export to the United States, per Government Ordinance No. 42/2004.

The Laboratory Division of Technical Coordination in NSVFSA authorizes public and private laboratories that perform testing of self-control samples for the establishment. The list of approved laboratories is maintained by the SVFSD. NSVFSA has the authority to order regulatory sanctions, prohibit the laboratory's activities, or suspend the laboratory's activities until corrective actions are taken per NSVFSA Order No. 114/2013. NSVFSA ensures official government laboratories are accredited by a recognized independent scientific accreditation body. The Romanian Accreditation Association (RENAR) is the national accreditation body responsible for granting accreditation of the laboratories.

NSVFSA Order No. 205/2007 requires that the National Reference Laboratories in the field of food safety to organize annual proficiency tests with all SVFSD laboratories that have been authorized for performing official food control. Additionally, Romania does not allow the retesting of samples for products intended for export to the United States.

The FSIS auditor conducted interviews, reviewed records, and audited laboratories that will be utilized for analysis for official government sampling of products intending to be exported to the United States. The FSIS auditor did not identify findings with these laboratories or the NSVFSA's oversight of these laboratories.

The FSIS auditor determined that Romania's government organizes and administers the country's food safety inspection system to provide ultimate control, supervision, and enforcement of regulatory requirements. NSVFSA officials enforce laws and regulations governing production and export of processed pork at establishments intending to export to the United States.

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 part; 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.

Romania's inspection system implements humane handling requirements in accordance with EU Regulation European Commission (EC) No. 1099/2009 and Council Directive 93/119/EC on the protection of animals at the time of slaughter. NSVFSA requires slaughter establishments to establish a procedure regarding humane handling from the receiving of animals at the establishment to stunning. NSVFSA Order No. 180/2006 specifically implements the EU requirements, which include minimizing stress, access to water, and proper stunning. Additionally, Government Decision No. 984/2005 provides instruction for enforcement actions in response to humane slaughter noncompliance. The FSIS auditor conducted interviews, reviewed records, and directly observed government veterinarians conducting humane handling verification activities without identifying any findings.

Regulation (EU) No. 2017/625 states that ante-mortem inspection of animals that are not poultry or lagomorphs must be conducted by the official veterinarian. Commission Implementing Regulation (EU) 2019/627 requires ante-mortem inspection of all animals be conducted within 24 hours of the animals' arrival and less than 24 hours before slaughter. NSVFSA Service Note No. 7318/2009 contains instructions to government inspection personnel regarding the performance of ante-mortem inspection in accordance with EU regulations. The FSIS auditor conducted interviews, reviewed records, and directly observed government veterinarians conducting ante-mortem inspection activities without identifying any findings.

NSVFSA ensures that government inspection personnel perform post-mortem inspection of every livestock carcass, head, and viscera during and after the slaughter of livestock. Commission Implementing Regulation (EU) 2019/627 stipulates the speed of the slaughter line and the number of government inspection staff present are to be such as to allow for proper

inspection to meet requirements for exporting to the United States. Maximum line speeds appeared consistent with FSIS line speed requirements during the audit. NSVFSA Service Note No. 26775/2019 requires swine carcasses and organs intended for export to the United States be subject to both visual inspection and incision and palpation of lymph nodes. The FSIS auditor conducted interviews, reviewed records, and directly observed government veterinarians conducting post-mortem inspection activities without identifying any findings.

NSVFSA Order No. 57/2010 requires NSVFSA to perform audits of food establishments approved for intra-EU trade and for export to third countries, including the United States. Additionally, NSVFSA requires periodic supervisory visits to establishments in accordance with NSVFSA Order No. 57/2010 and the National Surveillance Program. The Technical Audit Service, organized within NSVFSA, carries out the audits of the official control system (including the inspection duties) to verify the compliance of inspection activities performed by inspection personnel at establishments intending to export to the United States. Government Decision No. 611/2008 provides the general requirements for evaluating the civil servant's performance. The FSIS auditor conducted interviews, reviewed audits, and directly observed supervisors auditing personnel without identifying any findings.

NSVFSA Service Note No. 29469/2016 provides requirements and measures that establishments must take to segregate domestic (including EU market) products from products intended to be exported to the United States. Additionally, this document includes instructions for government inspection personnel to verify the requirements. The separation of pork products destined for export to the United States from pork products destined for other markets is further reinforced by NSVFSA Service Note No. 26775/2019. The establishments intending to produce pork products intended for export to the United States must develop and implement procedures that address separation of time and space. The FSIS auditor conducted interviews, reviewed records, and directly observed implementation of separation procedures in establishments without identifying any findings.

NSVFSA Order No. 10/2008 provides NSVFSA regulatory authority to ensure products intended for United States export are properly labeled and packaged. The FSIS auditor reviewed NSVFSA's process to ensure the accurate labeling of products intended for export to the United States without identifying any findings.

Per APHIS, Romania is free of SVD with no special restrictions but is affected with ASF, CSF, and FMD. Romania will need to meet all APHIS import requirements in order to export products to the United States. When notification is made by APHIS of any disease restriction, NSVFSA emails the information to every SVFSD and to government offices in establishments. The FSIS auditor verified NSVFSA has a system in place for notification of APHIS requirements and procedures for verification of requirements.

NSVFSA implements the Regulation (EC) No. 1069/2009 and Regulation (EU) No. 142/2011 regarding the identifying, handling, and controlling of animal by-products and derived products not intended for human consumption. The EU classifies animal by-products not intended for human consumption into three categories—categories 1 and 2 are considered condemned materials and category 3 is considered inedible. NSVFSA has procedures for government

verification of the control of condemned products including supervisory verifications. The FSIS auditor conducted interviews, reviewed records, and directly observed how establishments implement procedures without identifying any findings.

The FSIS auditor concluded that NSVFSA maintains the legal authority, a regulatory framework, and adequate verification procedures to ensure sufficient official regulatory control over raw and processed pork establishments intending to export products to the United States.

VI. COMPONENT THREE: GOVERNMENT SANITATION

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

Romania adheres to sanitation requirements of the EU Regulation (EC) No. 852/2004, Regulation (EC) No. 853/2004, Regulation (EU) 2017/625, and Regulation (EC) No. 2073/2005 that require the central competent authority to mandate that each official establishment operates in a manner to prevent insanitary conditions. NSVFSA Service Note No. 1618/2006 provides checklists for government inspection personnel to use on how to verify that establishments meet the sanitation requirements of the EU regulations, including the general sanitary conditions (e.g., water potability, drainage, construction) within the establishment and general sanitary practices including employee hygiene.

NSVFSA Service Note No. 25241/2017 requires establishments to develop sanitation SOPs that prevent contaminating the surfaces in contact with food and include procedures on monitoring, recordkeeping, assessing efficiency, and establishing corrective measures. NSVFSA requires government inspection personnel to verify the operational implementation of sanitation once per day and to verify the preoperational implementation of sanitation at least twice per week, once by direct observation and once by reviewing records. Government inspectors may conduct ad hoc verification in the event of noncompliant findings. NSVFSA requires government inspection verification of all corrective actions for deviations found with sanitation SOPs.

NSVFSA Service Note No. 1618/2006 provides instructions to government inspection personnel on how to evaluate that all Romanian establishments regardless of export status meet the sanitation and good hygiene practice requirements of the appropriate EU regulations. NSVFSA Service Note No. 25450/2012 contains instructions to the government inspection personnel consistent with FSIS Directive 5000.1, Verifying an Establishment's Food Safety System, and provides the weblink to the FSIS website containing the directive. The FSIS auditor conducted interviews, reviewed records, and directly observed implementation of sanitation requirements and verification activities conducted by the government veterinarians without observing any systemic findings. However, observations regarding sanitary noncompliance requiring corrective actions were made at three establishments, as detailed on the establishment checklists in Appendix A.

NSVFSA Service Note No. 29945/2016 outlines how to implement EU requirements concerning slaughter hygiene (e.g., sanitary dressing procedures). NSVFSA Service Note No. 29945/2016 requires the establishment to have trained employees conduct the bleeding, pre skinning/skinning, tying/pushing back the esophagus and tying the bung, and the dressing operations. The establishment must also assign an employee to make regular checks (at least once for each slaughter consignment) at each workstation on the slaughter line, to identify any noncompliance that might lead to the contamination of carcasses intended for human consumption and ensure compliance with hygienic good practices. Additionally, the establishment must have trained individuals ensuring dirty animals do not enter the slaughter process.

NSVFSA requires slaughter establishments to have zero tolerance for feces, milk, stomach content, urine, insects, and other contaminants. The location for verification activities must be located immediately after the final rail prior to entering the chiller. The one slaughter establishment audited had a critical control point for zero tolerance and the government veterinarians performed zero-tolerance verification activities daily at a frequency based on the number of carcasses processed.

NSVFSA requires checklists for government inspection personnel to verify the implementation of sanitary dressing procedures throughout the slaughter process in compliance with EU regulations. The official veterinarian must monitor for dirty animals during ante-mortem and post-mortem inspection. The FSIS auditor conducted interviews, reviewed records, and observed implementation of sanitary dressing requirements, zero tolerance procedures, and verification activities conducted by the government veterinarians without identifying any findings.

The FSIS auditor determined that NSVFSA requires establishments to develop, implement, and maintain sanitation programs, and includes requirements for SPS and sanitary dressing. FSIS concludes that NSVFSA meets the core requirements for this component.

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.

NSVFSA requires all establishments to implement their food safety systems in accordance with EU requirements. NSVFSA Service Note No. 1949/2007 contains instructions to government inspection personnel on how to evaluate HACCP requirements to comply with the EU regulations. Additionally, this Service Note provides a checklist to government inspection personnel on how to evaluate the compliance of establishment HACCP programs and sanitation in accordance with the Regulation (EC) No. 852/2004 and Regulation (EU) 2017/625.

NSVFSA requires all establishments, regardless of export status, to implement HACCP. NSVFSA Service Note No. 20080/2011 includes the HACCP requirements consistent with 9

CFR 417, by which all slaughter and processing establishments intending to export to the United States must comply. NSVFSA Service Note No. 25241/2017 contains procedures and instructions for government inspection personnel on how to perform HACCP inspection tasks and document noncompliance or take enforcement action if needed. The FSIS auditor conducted interviews and reviewed records confirming establishments are required to develop and implement a HACCP system without identifying any findings.

NSVFSA Service Note No. 25450/2012 states that government inspection personnel will verify that establishments comply with FSIS requirements. NSVFSA developed an evaluation form for official veterinarians consistent with FSIS Directive 5000.1. NSVFSA Service Note No. 25241/2017 contains procedures and instructions for government inspection personnel on how to perform HACCP inspection tasks and document noncompliance or take enforcement action if needed. Romania maintains penalties and sanctions for noncompliance of Romanian sanitary, veterinary, and food safety legislation in Government Decision No. 984/2005.

The official veterinarians conduct HACCP record keeping requirement verification procedures at all establishments. The official veterinarians also verify the implementation of HACCP requirements at establishments. The FSIS auditor conducted interviews, reviewed records, and observed government inspection personnel conducting HACCP verification procedures without observing any systemic findings. However, observations regarding noncompliance with HACCP requirements were made at two establishments as detailed on the establishment checklists in Appendix A.

The FSIS auditor determined that NSVFSA requires establishments to develop, implement, and maintain a HACCP system for each processing category.

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 inspection authorities or by FSIS as potential contaminants.

Romania has the legal authority to implement and enforce a National Residue Control Program (NRCP) based on EU regulations per NSVFSA Order No. 35/2016. The relevant authority for this NRCP is based on: Regulation (EU) 2017/625, Council Directive 96/23/EC, Council Directive 96/22/EC, Commission Decisions 97/747/EC, 98/179/EC, and (EC) Regulations No. 854/2004, 1871/2019, 37/2010, 1881/2006, 37/2010, and 396/2005 (and amending regulations).

The annual NRCP is issued according to the Council Directive 96/23/EC that sets forth measures to monitor certain substances and residues thereof in live animals and animal products. Romania implements EU requirements for the NRCP through NSVFSA Order No. 95/2007, which explains that the annual plan shall consider the specific situation in Romania, including legislation related to the chemical compounds, on their prohibition or authorization, distribution

in the market, and rules governing their administration. Consideration is also given to laboratory capacity and analytical capability. NSVFSA Order No. 95/2007 prescribes measures to be taken in the event of a violation. The Romanian NRCP includes the appropriate compounds and compound classes.

NSVFSA Service Note No. 22873/2010 specifies that in-plant government inspection personnel have the authority within the establishment to collect samples of suspect animals and test for illegal residues. NSVFSA Order No. 95/2007 defines the sampling levels and frequencies for animal classes based on species, location (farm or slaughterhouse), random selection, or at the discretion of Romania. Government Decision No. 984/2005 establishes sanctions and provisions to penalize chemical residue violators. The FSIS auditors conducted interviews and reviewed records without identifying any findings.

The FSIS auditors verified that the NSVFSA implements a system for sample analysis that ensures that each sample is tested for the appropriate analytes and that the criteria used to evaluate the samples 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.

The FSIS auditors verified that Romania's pork inspection system has in place a chemical residue testing program organized and administered by the national government. NSVFSA maintains the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in pork products intended for export 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 pork products.

NSVFSA Service Note No. 26146/2020 describes sampling requirements for indicator organism testing by establishments eligible for United States export during swine slaughter operations. The requirements are based on the changes to FSIS regulation 9 CFR 310.18 as indicated in 84 FR 52300 (New Swine Slaughter Inspection System, effective December 2, 2019). The samples are collected by either excision (destructive method) or by sponge-sampling (non-destructive method) from the following areas of pig carcasses: ham, belly, and jowl. Sampling frequency is one pre-evisceration sample and one post-chill sample for every 1,000 carcasses or one pair of samples at least weekly. Samples are to be tested for Enterobacteriaceae. In addition, NSVFSA implements prechill hog carcass testing in accordance with Regulation (EC) No. 2073/2005. All establishments conduct this sampling and testing in accordance with the European Union requirements regardless of third country export status. The FSIS auditors conducted interviews, reviewed records, and directly observed implementation of sampling without identifying any findings.

Romania requires establishments intending to export to the United States to adopt certain FSIS requirements for RTE food products, which is accomplished primarily via NSVFSA Service Note No. 29469/2016 and Service Note No. 25241/2017. Additionally, NSVFSA Service Note No. 26217/2017 and the addendum to Service Note No. 29469/2016 contain instructions regarding official verification procedures to assess compliance with United States specific requirements for raw and processed pork of establishments intending to export to the United States. The Romanian Service Notes require establishments to address pathogens of concern in RTE food products that will be exported to the United States, including requirements for lethality and stabilization to address foodborne pathogens. Further, NSVFSA requires establishments to adhere to requirements consistent with 9 CFR 430 for post-lethality exposed RTE product.

The government inspection personnel verify establishment control measures through sampling and testing of RTE products, product food contact surfaces, and the environment. In addition, NSVFSA requires that establishments sample RTE products, food contact surfaces, and environmental surfaces. According to the Regulation (EC) No. 2073/2005 and NSVFSA Order No. 35/2016, NSVFSA considers RTE products that test positive for *Lm* and RTE products that are in direct contact with food contact surfaces that have tested positive for *Lm* (from either an establishment test or an official government test) to be adulterated. Additionally, through NSVFSA Service Note No. 25346/2013, NSVFSA has established zero tolerance (absence of *Lm*) for all categories of RTE foods intended for export to the United States. NSVFSA requires official government RTE samples to be tested in accordance with ISO 11290-1 analytical method for a 25-gram test portion. For official *Salmonella* sample collection, Service Note 26217/2017 and Presidential Order 35/2016 outline that veterinarians are to collect official samples of RTE pork products intended for export to the United States for *Salmonella* testing. Laboratories testing these samples must use FSIS Microbiology Laboratory Guidebook methods 4 and 4C for analysis, testing 325 g of product. Additionally, the Service Note 26217/2017 stipulates if laboratory analyses return positive for the presence of *Salmonella* and/or *Lm* in RTE processed pork samples or *Lm* on a direct food contact surface, the affected batches are declared unfit for human consumption and shall not be exported to the United States. The FSIS auditors conducted interviews with official government personnel responsible for conducting sampling activities and did not identify any concerns with their knowledge of these activities.

Service Note No. 26217/2017 requires pork processing establishments intending to export to the United States to sample and test each batch of RTE pork product for *Salmonella* and *Lm*. Additionally, this Service Note requires pork processing establishments intending to export RTE pork to the United States to sample and test for *Lm* (or its indicator) on food surfaces and in the environment of post-lethality exposed RTE pork products. Per Service Note No. 26217/2017, the official veterinarians must assess the control programs at the establishments intending to export RTE pork products to the United States by implementing procedures consistent with the FSIS Directive 10,240.4, Verification Activities for the *Lm* Regulation and the Ready-to-Eat (RTE) Sampling Program.

During the audit, the FSIS auditors conducted verification activities for laboratory testing of RTE products that will be required for Romanian establishments intending to export RTE products to the United States. These verification activities included review of testing programs and

implementation of the ISO 11290-1 analytical method (for samples not intended for export to the United States) without identifying any findings. However, as the laboratories were not conducting *Salmonella* testing for U.S. product during the audit, the FSIS auditors were unable to verify whether analytical testing procedures were conducted as documented in the SRT and supporting documentation.

NSVFSA requires establishments producing TPCS pork products 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). Notably, Regulation (EC) No. 852/2004 includes specific provisions for canned products. NSVFSA requires all establishments producing TPCS products to develop a HACCP program that addresses the food safety hazards associated with the production of TPCS pork products.

NSVFSA Service Note No. 1618/2006 and Service Note No. 25450/2012 provide Romanian government inspection procedures for TPCS products to include verification of the process and closure of retorts. NSVFSA Service Note No. 25047/2017 contains government verification procedures in accordance with FSIS regulations consistent with 9 CFR 431. Government personnel verify the processing schedule applied by the establishment is adequate to ensure the safety of TPCS products, and NSVFSA does not permit establishments to utilize third-party processing authorities. NSVFSA Order No. 35/2016 requires official veterinarians to conduct sampling of canned products in establishments intending to export to the United States to verify efficacy of sterilization.

NSVFSA Service Note No. 25047/2017 contains establishment requirements and government verification procedures that are specific to the establishments intending to export to the United States and are consistent with FSIS regulations and directives for TPCS pork products. In establishments that will be eligible to export TPCS pork to the United States, the Official Veterinarian must evaluate TPCS compliance with each verification of the HACCP system. The FSIS auditors conducted interviews, reviewed records, and directly observed government verification of TPCS establishments without identifying any findings.

The FSIS auditors determined that NSVFSA maintains the legal authority to implement its microbiological sampling and testing programs to ensure that pork products destined for export to the United States are unadulterated, safe, and wholesome. FSIS intends to review pending updated documentation from NSVFSA to verify that equivalence criteria are met.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held with NSVFSA on September 29, 2021 by videoconference. At this meeting, the FSIS auditors presented the preliminary observations 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 did not identify any systemic or significant findings.

The FSIS auditors concluded that Romania's raw and processed pork inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. NSVFSA will require that establishments intending to export products to the United States implement sanitary operating procedures and a HACCP system designed to improve the safety of their products. In addition, NSVFSA has implemented microbiological and chemical residue testing programs to verify its food safety inspection system. An analysis of each component did not identify any findings that would represent an immediate threat to public health.

During the audit exit meeting, NSVFSA committed to address the preliminary isolated observations as presented. FSIS will assess the adequacy of NSVFSA's corrective actions and determine whether those proposed corrective actions satisfy FSIS' equivalence requirements.

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. SMIT HFIELD PROD S.R.L Timasoara, Romania	2. AUDIT DATE 9/15, 9/16	3. ESTABLISHMENT NO. 006	4. NAME OF COUNTRY Romania
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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	O
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards	O	51. Periodic Supervisory Reviews	
24. Labeling - Net Weights	O	52. Humane Handling	
25. General Labeling	O	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
Products Prepared:	Raw meat for further processing

60. Observation of the Establishment

46:

After the hook wash designated area and prior to entering the cutting room, the rails and area above them had some rusting as well as grease buildup and dirt.

15:

Establishment did not list verification activities in the written HACCP plans, the government inspection team did not ensure the establishment was meeting all HACCP requirements.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION SC VASCARSA Vaslui, str Podul Inalt nr. 4,jud. Vaslui	2. AUDIT DATE 9/24/2021	3. ESTABLISHMENT NO. 043	4. NAME OF COUNTRY Romania
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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	O
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
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.	X	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	O	51. Periodic Supervisory Reviews	
24. Labeling - Net Weights	O	52. Humane Handling	O
25. General Labeling	O	53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	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:	Thermal Processing Commercially Sterile
Products Prepared:	Canned Pork

60. Observation of the Establishment

16

The records review and direct observation verification records did not include the date and time of the event.

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, Str. Abatorului, nr 5, Jud. Bacau	2. AUDIT DATE 9/23/2021	3. ESTABLISHMENT NO. 46	4. NAME OF COUNTRY Romania
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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	O
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
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	O	51. Periodic Supervisory Reviews	
24. Labeling - Net Weights	O	52. Humane Handling	O
25. General Labeling	O	53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	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:	Not Heat Treated Shelf Stable RTE
Products Prepared:	Dry Cured Salami Pork

60. Observation of the Establishment

39

A gap was observed at the bottom right corner of the door in a receiving area. the gap was approximately two inches long and 1/2 inch wide. This could facilitate the entrance of vermin to production areas and create insanitary conditions.

61. OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

09/23/2021

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, Romania	2. AUDIT DATE 9/17/2021	3. ESTABLISHMENT NO. 400	4. NAME OF COUNTRY Romania
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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	O
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
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	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	O	51. Periodic Supervisory Reviews	
24. Labeling - Net Weights	O	52. Humane Handling	O
25. General Labeling	O	53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	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:	Thermal Processing Commercially Sterile
Products Prepared:	Canned Pork

60. Observation of the Establishment

41 and 46:

In the area where product is emulsified, and mixed condensate was observed dripping from the underside of the refrigeration unit and droplets were observed on the refrigeration unit itself. No product was affected. The establishment has a written program for condensation control that was not being implemented effectively.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION S.C. RECUNOS TJNT A PRODCOM IMP EX S.R.L. Maguren i, sat Lunca Prahovei nr. 94N, jud. Prahova.	2. AUDIT DATE 9/21/2021	3. ESTABLISHMENT NO. 731	4. NAME OF COUNTRY Romania
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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	O
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
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	O	51. Periodic Supervisory Reviews	
24. Labeling - Net Weights	O	52. Humane Handling	O
25. General Labeling	O	53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	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:	Not Heat Treated Shelf Stable RTE
Products Prepared:	Dry Cured Salami

60. Observation of the Establishment

61. OIEA International Audit Staff (IAS)

62. DATE OF ESTABLISHMENT AUDIT

09/21/2021

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



AUTORITATEA NAȚIONALĂ SANITARĂ VETERINARĂ
ȘI PENTRU SIGURANȚA ALIMENTELOR
CABINET PREȘEDINTE - SECRETAR DE STAT



To: Mrs. Michelle Catlin, PhD

International Coordination Executive

USDA, FSIS, Office of International Coordination

InternationalCoordination@usda.gov

Subject: The National Sanitary Veterinary and Food Safety Authority (NSVFSA) answer to the Food Safety and Inspection Service (FSIS) Draft final report, which was sent by your letter dated 22nd of December 2021.

Dear Mrs. Michelle Catlin,

Thank you for the Draft final audit report, which was sent by your letter dated 22nd of December 2021, regarding the FSIS audit mission conducted in Romania between 31 August - 29 September 2021, remote and onsite, in order to reinstate the equivalency of the Romanian meat inspection system with the one of the United States of America.

According to your request, we send the NSVFSA comments regarding the information in the audit report, as well as the corrective actions taken to address the deficiencies observed during the mission, registered in the Individual Foreign Establishment Audit Checklists.

Taking into consideration the actual context of the COVID pandemics, for the official veterinary services, was organized on 20.01.2022, by representatives of Food Safety General Directorate and Official Control General Directorate, a **videoconference regarding the FSIS audit mission conducted in Romania between 31 August - 29 September 2021**, in order to reinstate the equivalency of the Romanian meat inspection system with the one of the United States of America. In the videoconference frame, was presented to those five involved County Sanitary Veterinary and Food Safety Directorates (CSVFSD) (Bacău, Prahova, Sibiu, Timiș and Vaslui), the draft audit report, and clarifications on USDA - FSIS requirements for pork meat and meat products intended for export to US, sampling from the carcasses for *Enterobacteriaceae*, and deficiencies in implementing the procedures based on HACCP principles (please, find attached the Power point presentations). The draft order for modifying the NSVFSA president order no. 35/2016 - national strategical programme - before publishing into the Romanian Official Gazette - must be posted on NSVFSA web-site, to Decisional Transparency, for comments.

At the same time, we would like to thank you for FSIS letter dated 04th of January 2022, by which you confirmed receiving NSVFSA request for approval of export from Romania of dried cured salami (NHT-SS), and of the additional information and supporting documents that are under evaluation, letter by which you have also sent clarifications regarding this type of product.





**AUTORITATEA NAȚIONALĂ SANITARĂ VETERINARĂ
ȘI PENTRU SIGURANȚA ALIMENTELOR
CABINET PREȘEDINTE - SECRETAR DE STAT**

As regards the **draft audit report**, we would like to communicate you the following **comments**:

In the Executive Summary of the draft audit report it is written that "In 2008, the Romanian government voluntarily ceased exporting meat product to the United States." Actually, between 25th of August to 10th of September 2008, the last FSIS audit in Romania was performed, before delisting, on their own initiative, in the year 2009, because of the financial crisis, of the establishments which were listed for export red meat and meat products to USA. The same sentence is repeated in the body of the report in page 3, point III. Background. Another remark is that following the FSIS audit from 2012, NSVFSA did not receive the mission report, although several requests were undertaken. On the FSIS web-site, the last FSIS reports for Romania are those from 2005 and 2008.

In the body of the report, on page 4, Government Oversight (e.g. Organization and Administration) of NSVFSA for the NSVFSA management, before the General Secretary, must be inlaid the President and three Vice-presidents.

The sentence " The Technical Audit Service organized within NSVFSA carries out the audit of these establishments which includes verification that government inspection duties are performed as required at establishments intending to export to the United States" should be replaced by the following: With regard to the audit of the food industry establishments intending to export to the United States, we would like to emphasize that the NSVFSA structure which is responsible for food safety performs the food industry audit.

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 establishment:

- SC SMITHFIELD ROMANIA SRL, Timiș

(15). Establishment did not list verification activities in the written HACCP plans, the government inspection team did not ensure the establishment was meeting all HACCP requirements - documents were revised by including verification activities, and modifying the procedures associated with.

(46). After the hook wash designated area and prior to entering the cutting room, the rails and area above them had some rusting as well as grease buildup and dirt - immediately the measures for proper cleaning of the respective area were applied.

- SC SCANDIA FOOD SRL, Sibiu

(41) and (46). In the area where product is emulsified and mixed, condensate was observed dripping from the underside of the refrigeration unit and droplets were observed on the refrigeration unit itself. No product was affected. The establishment has a written program for condensation control that was not being implemented effectively - the deficiency was fixed by proper applying of the Hygiene Operational Control Procedure, respectively of the corrective measures for removing condensation, cleaning the area, retraining the personnel, re-check and taking responsibility for verifications by signature.





**AUTORITATEA NAȚIONALĂ SANITARĂ VETERINARĂ
ȘI PENTRU SIGURANȚA ALIMENTELOR
CABINET PREȘEDINTE - SECRETAR DE STAT**

- SC SALBAC SA, Bacău

(39). A gap was observed at the bottom right corner of the door in a receiving area. The gap was approximately two inches long and ½ inch wide. This could facilitate the entrance of vermin to production areas and create insanitary conditions - the deficiency was immediately fixed, by replacing the defect fitting, and in order to prevent re-emergence of this deficiency, the maintenance and surveillance team training was performed.

- SC VASCAR SA, Vaslui

(16). The records review and direct observation verification records did not include the date and time of the event - the unconformity was fixed by revising the procedure for verification of the registered parameters, introducing the date and time of the verification. A training of all the chiefs of sections from SC VASCAR SA was performed, for a proper register of the information, as well as with the top management and the HACCP team representatives, in order to issue correctly the periodic observational verification, including the date and time of the verification.

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

