



United States Department of Agriculture

Food Safety and
Inspection Service

September 24, 2024

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

Dr. Tatjana Karacic
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Ministry of Agriculture
Planinska ulica 2a, 10000 Zagreb
Croatia

Dear Dr. Karacic,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an onsite verification audit of Croatia's meat inspection system April 8–24, 2024. Enclosed is a copy of the final audit report. The comments received from the Government of Croatia are included as an attachment to the report.

Sincerely,

MARGARET
BURNS RATH

Digitally signed by
MARGARET BURNS RATH
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Margaret Burns Rath, JD, MPH
Acting International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED OF
CROATIA

APRIL 8–24, 2024

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

September 20, 2024

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

Executive Summary

This report describes the outcome of an onsite equivalence verification audit of Croatia conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) April 8–24, 2024. The purpose of the audit was to verify whether Croatia's food safety inspection system governing thermally processed-commercially sterile (TPCS) pork and beef products remains equivalent to that of the United States, with the ability to export processed pork and beef products that are safe, wholesome, unadulterated, and properly labeled and packaged. Croatia currently only exports TPCS 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.

FSIS concluded that Croatia's processed pork products inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The central competent authority (CCA) has required that establishments certified as eligible to export processed pork products to the United States implement sanitation requirements and a HACCP system designed to improve the safety of their exported products. In addition, the CCA has implemented official microbiological and chemical residue testing programs that are organized and administered by the national government to verify its food safety inspection system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

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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 Croatia’s food safety inspection system April 8–24, 2024. The audit began with an entrance meeting held April 8, 2024, in Zagreb, Croatia, to discuss the audit objective, scope, and methodology. The participants included representatives from the Veterinary and Food Safety Directorate (VFSD) — the Central Competent Authority (CCA) and State Inspectorate (SI). The FSIS auditor was accompanied by inspection officials throughout the entire audit. The audit concluded with an exit meeting conducted April 24, 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 processed pork and beef products remains equivalent to that of the United States, with the ability to export processed pork and beef products that are safe, wholesome, unadulterated, and properly labeled and packaged. Croatia is eligible to export the following categories of products to the United States. However, Croatia only exports thermally processed-commercially sterile (TPCS) pork products to the United States at this time.

Process Category	Product Category	Eligible Products ¹
Thermally Processed - Commercially Sterile	Thermally Processed - Commercially Sterile	Beef and Pork - All Products Eligible

Pork imported from Croatia is subject to USDA’s Animal and Plant Health Inspection Service (APHIS) requirements for African swine fever as specified in Title 9 of the United States Code of Federal Regulations (9 CFR) 94.8, classical swine fever requirements specified in 9 CFR 94.31, swine vesicular disease requirements specified in 9 CFR 94.13, and foot-and-mouth disease (FMD) requirements specified in 9 CFR 94.11. Beef imported from Croatia is subject to APHIS requirements for bovine spongiform encephalopathy as specified in 9 CFR 94.18 or 9 CFR 94.19, and FMD requirements specified in 9 CFR 94.11.

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed Croatia’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 Croatia’s food safety inspection system governing 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 capacities of laboratories. The review process included an analysis of data collected by FSIS over a 3-year period, in addition to information obtained directly from VFSD 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 VFSD's headquarters, two branch offices, and three 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 three establishments certified to export to the United States were selected for audit. This included one pork slaughter and processing establishment and two pork processing establishments. These establishments produce and export TPCS pork products to the United States. One of these establishments is also certified to produce and export processed beef products to the United States. However, beef processing was not included in the scope of this audit as the certified beef processing establishment has not yet produced product 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 the VFSD'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 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"> • Veterinary and Food Safety Directorate (VFSD), Zagreb
	Branch Offices	2	<ul style="list-style-type: none"> • Branch Office, Vrbovec • Branch Office, Petrinja

Laboratories	2	<ul style="list-style-type: none"> • Croatian Veterinary Institute Microbiology Laboratory (government), Zagreb • Croatian Veterinary Institute Residue Laboratory (government), Zagreb
Swine slaughter and processing establishment	1	<ul style="list-style-type: none"> • Establishment 10, Pik Vrbovec Meat Industry d.d., Vrbovec
Pork processing establishments	2	<ul style="list-style-type: none"> • Establishment 139, Podravka d.d., Koprivnica • Establishment 399, Gavrilovic d.o.o., Petrinja

FSIS performed the audit to verify that Croatia'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 Croatia's 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 December 1, 2020, to November 30, 2023, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 943,328 pounds of processed TPCS pork products exported by Croatia to the United States. Of this volume, FSIS also performed reinspection on 94,762 pounds at POE for additional types of inspection, including condition of container, product examination, and chemical residue analysis. As a result of these additional types of inspection, 24,138 pounds of processed TPCS pork products were refused entry for issues not related to public health, including missing shipping mark, labeling, or other miscellaneous issues. No product was refused entry for issues related to public health.

The previous FSIS audit in 2022, conducted remotely, did not identify any systemic findings representing an immediate threat to public health.

The FSIS final audit reports for Croatia'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.

The FSIS auditor confirmed that there have been no major changes in VFSD's organizational structure or responsibilities governing processed pork and beef products eligible to export to the United States since the previous FSIS audit conducted remotely in 2022. Croatia's meat inspection system consists of four levels: central, regional, branch, and establishment. VFSD, under the Ministry of Agriculture, is the CCA responsible for development and implementation of policies and programs governing their meat inspection system. Since April 1, 2019, SI is responsible for enforcing European Union (EU) regulations, Croatian national regulations, and third country import regulations, including oversight and enforcement of VFSD's regulatory requirements in certified establishments eligible to export to the United States. At the establishment level, the authorized veterinarians (AV) are responsible for conducting and documenting the results of their daily ante-mortem and post-mortem inspection procedures, sanitation standard operating procedures (Sanitation SOP), sanitation performance standards (SPS), HACCP, and other inspection verification tasks into the Veterinary Inspection (VetIs) application. At the branch level, the senior veterinary inspectors (SVI) are responsible for providing direct supervision over AVs performance and inspection verification activities on the days product is produced for export to the United States. SVIs document the results of their supervision into the e-Inspector application. At the regional level, the regional SVIs conduct performance appraisals of branch SVIs assigned to certified establishments. At the central level, SVIs have access to all inspection generated data including the VetIs and e-Inspector applications to ensure compliance with regulatory requirements.

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

The FSIS auditor verified that each audited establishment has a system in place to identify and segregate pork products destined for export to the United States from those that are destined for other markets, during all stages of production, storage, and shipment. The FSIS auditor verified

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

VFSD have the legal authority and responsibility to ensure that adulterated or misbranded products are not exported to the United States. Regulation (EC) No. 178/2002 provides regulatory definitions for adulterated and misbranded products that are consistent with FSIS requirements. The FSIS auditor verified that government inspection personnel have legal authority to enforce regulatory control actions by applying reject or retain tags on equipment, utensils, rooms, or compartments in accordance with VFSD 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 prior to issuing export health certificates. The FSIS auditor reviewed recently issued export health certificates and confirmed that government inspection personnel follow VFSD requirements.

The FSIS auditor verified that VFSD has provided instructions to government inspection personnel to identify and document any noncompliance findings on a noncompliance record (NR). The FSIS auditor reviewed inspection-generated NRs and verified that government inspection personnel closed NRs 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 2022.

The Croatian Veterinary Institute (CVI) is a national institute within the Ministry of Science and Education that provides technical support for VFSD. The FSIS auditor visited two government laboratories: the CVI Microbiology Laboratory and the CVI Residue Laboratory. The CVI Microbiology Laboratory is the national reference laboratory (NRL) for *Salmonella*. This laboratory conducts analyses for all official samples, including analysis of swine carcass swabs for *Salmonella*. The CVI Residue Laboratory is the NRL that conducts chemical residue testing on official samples originating from slaughter establishments. These government laboratories are accredited by Croatian Accreditation Agency in accordance with International Organization for Standardization/International Electrotechnical Commission 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. The FSIS auditor did not identify any concerns during these reviews.

FSIS onsite audit verification activities indicate that Croatia's food safety inspection system governing 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 AVs are required to conduct daily humane handling and slaughter verification procedures in accordance with VFSD requirements that are consistent with the procedures described in FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock. In addition, SVIs provide daily supervision of AVs humane handling and slaughter verification activities. 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, Croatia has one swine slaughter establishment certified as eligible to produce source material for products that are intended for export the United States. The FSIS auditor confirmed that humane handling and slaughter of livestock are conducted in accordance with VFSD's requirements.

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 AVs conduct ante-mortem inspection procedures prior to slaughter and document their examination results in accordance with VFSD requirements. Ante-mortem inspection procedures include observations of live animals, 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 AVs to conduct post-mortem inspection procedures. This includes AVs 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 VFSD requirements that are consistent with the procedures described in FSIS Directive 6100.2, Post-mortem Livestock Inspection. The FSIS auditor confirmed that SVIs provide onsite supervision over AVs ante-mortem and post-mortem inspection procedures to evaluate AVs performance during all operational shifts and on the days that animals are slaughtered for product

destined for export to the United States. The FSIS auditor confirmed that humane handling and slaughter, ante-mortem, and post-mortem inspection procedures are conducted in accordance with VFSD requirements.

The FSIS auditor verified that VFSD 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 AVs conduct daily inspection verification activities to verify proper collection, segregation, storage, and disposal of condemned and inedible pork products in accordance with VFSD requirements.

The FSIS auditor confirmed that AVs verify that certified pork processing establishments source their raw products from the only swine certified slaughter establishment in Croatia or other certified swine slaughter establishments in eligible countries that have equivalent raw products inspection system. The FSIS auditor also verified that certified processing establishments maintain separation and identity of source material utilized in processed pork products destined for export to the United States.

The FSIS auditor verified that SVIs conduct daily supervisory visits at certified slaughter or processing establishments when these establishments are producing products intended for export to the United States. The supervisory visits include assessment and verification of ante-mortem, humane handling and slaughter, post-mortem inspection, Sanitation SOPs, SPS, HACCP, labeling, establishment's monitoring and inspection's verification sampling programs, separation and identification of eligible source material, establishment's maintenance, controls over condemned and inedible material, and export certification process.

FSIS onsite audit verification activities indicate that VFSD continues to maintain the legal authority, a regulatory framework, and adequate verification procedures to ensure sufficient official regulatory control using statutory authority consistent with criteria established for this component.

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 VFSD requires 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 VFSD requirements. These verification activities consist of a combination of document review, observation, and hands-on inspection verification.

The FSIS auditor confirmed that AVs conduct daily pre-operational sanitation verification prior to production of product intended for export to the United States. The FSIS auditor observed an AV conducting pre-operational sanitation verification in one of the audited establishments. The AV's hands-on verification procedures began after the establishment personnel completed their pre-operational sanitation inspection and determined that the establishment was ready for government inspection personnel pre-operational sanitation verification activities. The FSIS auditor assessed the ability of government inspection personnel to identify insanitary conditions and exercise regulatory enforcement controls to ensure proper implementation of sanitary requirements during pre-operation inspection and did not identify any concerns.

The FSIS auditor observed that AVs 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 reviews 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.

VFSD requires certified establishments to develop, implement, and maintain written sanitary procedures to prevent contamination of carcasses, organs, and other parts throughout the slaughter and dressing process. 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 VFSD's food safety inspection system governing 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 VFSD requires 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 three certified establishments to verify whether Croatia continues to maintain HACCP system 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 establishment records for monitoring, verification, corrective actions, and validation. The FSIS auditor assessed the implementation of government inspection personnel daily verification procedures in ensuring that HACCP requirements are effectively implemented in each certified establishment.

The FSIS auditor verified that government inspection personnel conduct daily HACCP verification activities for all production shifts when products are produced 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 VFSD requires 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 VFSD is responsible for annual planning, coordination, and monitoring of the implementation of the National Residue Control Plan (NRCP). The NRCP is issued each year, in collaboration with NRL, based on the number of animals slaughtered and an evaluation of sampling results from the previous year. The NRCP contains sampling protocol, the number of samples to be taken per year/month/county, the species, the tissues, the target compounds, testing methods, action level (i.e., maximum residue level (MRL)), and enforcement strategy. The sample collection locations include both swine farms and swine slaughter establishments.

The FSIS auditor verified that trained government inspection personnel collect, prepare, seal and ship required samples to NRL in accordance with VFSD 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 related documentation that discloses the origin of every lot of animals and includes the owner's signed declaration attesting that they have adhered to veterinary pharmaceutical withdrawal periods prior to shipping animals for slaughter. In addition to the NRCP monitoring plan sampling, government inspection personnel may perform additional targeted sampling of any animal identified as suspect during ante-mortem or post-mortem inspection procedures.

The acceptability of test results is based on EU requirements and FSIS identified banned substances with zero tolerance levels and substances with established maximum residue levels permitted in pork products. If a U.S. MRL or EU MRL is exceeded or a prohibited substance detected, VFSD initiates an investigation into the cause. VFSD then requires that each certified establishment evaluate the results to determine if product meets all FSIS import requirements prior to requesting export certification.

VFSD has adopted a hold and test policy within its NRCP. The FSIS auditor verified that sampled carcasses and parts are properly identified, segregated, and based on VFSD's requirements are excluded from production of product intended for export to the United States.

FSIS onsite audit verification activities indicate that VFSD has overall authority of a chemical residue testing program designed and implemented to prevent and control the presence of veterinary drugs 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 2022. FSIS concludes that VFSD 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 VFSD requires slaughter establishments follow Commission Regulation (EC) No. 2073/2005 regarding process hygiene criteria testing and analysis for carcasses, per RU-8.2-0-4-SU-32 and the Procedure for Planning. VFSD also requires certified establishments eligible to export to the United States to perform swine carcass sampling at pre-visceration and at post-chill, consistent with FSIS requirements in 9 CFR 310.18, in addition to sampling required by Commission Regulation (EC) No. 2073/2005. The FSIS auditor reviewed the establishment's written program, sample collection frequency of one sample per every 1,000 swine, and the use of statistical process control to evaluate results. The FSIS auditor confirmed that government inspection personnel conduct daily verification activities that include assessment of establishment compliance with VFSD requirements.

The FSIS auditor verified that swine slaughter establishments are required to test swine carcasses for *Salmonella* in accordance with the requirements in Commission Regulation (EC) No. 2073/2005. VFSD has an FSIS equivalence determination allowing for the analysis of swine carcass swabs collected by the establishment employees under the direct supervision of government inspection personnel and analyzed by establishments laboratories. The FSIS auditor noted that VFSD provides its oversight of establishments laboratories by conducting annual audits. In addition, government inspection personnel conduct periodic reviews of establishments laboratory methodology and testing records to verify their compliance with VFSD requirements. The FSIS auditor observed *Salmonella* sample collection methodology in the audited slaughter establishment, which was performed in accordance with VFSD requirements. The FSIS auditor also reviewed the current year's *Salmonella* sampling results. The FSIS auditor did not identify any concerns.

VFSD requires establishments producing TPCS products to address potential hazards using HACCP principles. In addition, VFSD requires certified establishments eligible to export to the United States to meet requirements consistent with 9 CFR 431. The Implementation Procedure of Official Controls and Supervision Onsite, by Location by USDA FSIS Provisions in Facilities Permitted for Import into the United States, describes procedures in accordance with Codex Alimentarius' Guide for Hygienic Practices for Canned Foods with Low Acidity and Sour and Canned Foods with Low Acidity (CAC/RCP 23- 1979). The FSIS auditor interviewed government inspection personnel regarding verification activities and reviewed related documentation addressing process schedules for products eligible 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.

FSIS onsite audit verification activities indicate that VFSD conducts microbiological sampling and testing programs to ensure that pork products are safe and wholesome. There have not been any POE violations related to this component since the previous FSIS audit in 2022. FSIS concludes that VFSD continues to meet the core requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held April 24, 2024, with VFSD and SI officials. FSIS concluded that Croatia's processed pork products inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. VFSD has required that establishments certified as eligible to export processed pork products to the United States implement sanitation requirements and a HACCP system designed to improve the safety of their products. In addition, VFSD has implemented official microbiological and chemical residue testing programs that are organized and administered by the national government to verify its food safety system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

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 Pik Vrbovec Meat Industry d.d., Vrbovec	2. AUDIT DATE April 10, 2024	3. ESTABLISHMENT NO. 10	4. NAME OF COUNTRY Croatia
5. NAME OF AUDITOR(S) 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	
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	X
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	X
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 and Processing
Prepared Products:	Thermally Processed – Commercially Sterile

60. Observation of the Establishment

- 39-Presence of loose silicone type materials and several holes in the ceiling in production areas where exposed product was present. No direct product adulteration observed.
- 40-Lighting of good quality and sufficient intensity was not provided after the post-mortem rail inspection station where in-plant inspectors perform a livestock zero tolerance verification inspection task.
- 55-Several swine kidneys were not either presented for post-mortem inspection or popped out of their capsules; therefore, the viscera in-plant inspector was not able to perform a proper post-mortem examination.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Podravka d.d., Koprivnica	2. AUDIT DATE April 11, 2024	3. ESTABLISHMENT NO. 139	4. NAME OF COUNTRY Croatia
5. NAME OF AUDITOR(S) 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	
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	X
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:	Prok Processing
Prepared Products:	Thermally Processed – Commercially Sterile

60. Observation of the Establishment

- 22-The establishment’s HACCP monitoring records did not include the times of the monitoring activities.
- 22-The establishment’s HACCP ongoing verification records did not include the dates or results of the verification activities.
- 39-Gaps between the ceiling and protruding pipes in the ceiling above exposed products and food contact surfaces in the production areas. No direct product adulteration observed.
- 45-Presence of rusted areas on the ice contact surfaces of an ice making machine. No direct product adulteration observed.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Gavrilovic d.o.o., Petrinja	2. AUDIT DATE April 15, 2024	3. ESTABLISHMENT NO. 399	4. NAME OF COUNTRY Croatia
5. NAME OF AUDITOR(S) 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	
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.	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:	Thermally Processed – Commercially Sterile

60. Observation of the Establishment

22-The establishment’s HACCP system did not include its return product procedures in its flowchart or resulting hazard analysis

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

39-Presence of numerous holes in the ceiling above exposed products and food contact surfaces in the production areas. No direct product adulteration observed.

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



REPUBLIKA HRVATSKA
DRŽAVNI INSPEKTORAT
Područni ured Zagreb
Služba veterinarske inspekcije

KLASA: UP/I-322-07/24-06/97
URBROJ: 443-02-05-04-24-1
Vrbovec, 22. travnja 2024. godine

Viši veterinarski inspektor - samostalni izvršitelj Državnog inspektorata, OIB: 33706439962, Područnog ureda Zagreb, Službe veterinarske inspekcije, temeljem članka 66. i članka 70. stavka 1. Zakona o državnim inspektoratu („Narodne novine“, br. 115/18, 117/21, 67/23), članka 96. stavka 1. Zakona o općem upravnom postupku („Narodne novine“, br. 47/09, 110/21), članka 137.b. stavka 1. i članka 152. Zakona o veterinarskom postupku („Narodne novine“, br. 82/13, 148/13, 115/18, 52/21, 83/22, 152/22), članka 36. stavka 2. Zakona o hrani („Narodne novine“, br. 18/23), članka 19. stavka 2. Zakona o higijeni hrane i mikrobiološkim kriterijima za hranu („Narodne novine“, br. 83/22) i članka 22. stavka 1. Zakona o službenim kontrolama i drugim službenim aktivnostima koje se provode sukladno propisima o hrani, hrani za životinje, o zdravlju i dobrobiti životinja, zdravlju bilja i sredstvima za zaštitu bilja („Narodne novine“, br. 52/21), u postupku pokrenutom po službenoj dužnosti, u predmetu inspeksijskog nadzora u objektu odobrenom za klanje papkara, rasijecanje mesa papkara i divljači, preradu mesa papkara, peradi i divljači, proizvodnju mljevenog mesa, mesnih pripravaka i strojno otkošenog mesa, topljene životinjske masti i čvaraka, preradu želudaca, mjehura i crijeva, uskladištenje hrane životinjskog podrijetla u uvjetima kontrolirane temperature i prepakiravanje, s odobrenjem izvoza u SAD, Kanadu, Japan i ostale treće zemlje, odobrenog broja 10, koji se nalazi na lokaciji Vrbovec, Zagrebačka 148, subjekta u poslovanju s hranom PIK VRBOVEC plus d.o.o., OIB 41976933718, sa sjedištem Zagrebačka 148, 10340 Vrbovec, zastupanom po odgovornim osobama Slaven Ružić, OIB 06403187786, Petrovaradinska 3A, Zagreb, predsjednik uprave i Irena Jendriš, OIB 66737181554, Ive Lole Ribara 11, Vrbovec, član uprave, koje zajedno zastupaju društvo, d o n o s i

RJEŠENJE

Naređuje se subjektu u poslovanju s hranom PIK VRBOVEC plus d.o.o., OIB 41976933718, sa sjedištem Zagrebačka 148, 10340 Vrbovec, a vezano na objekt odobren za klanje papkara, rasijecanje mesa papkara i divljači, preradu mesa papkara, peradi i divljači, proizvodnju mljevenog mesa, mesnih pripravaka i strojno otkošenog mesa, topljene životinjske masti i čvaraka, preradu želudaca, mjehura i crijeva, uskladištenje hrane životinjskog podrijetla u uvjetima kontrolirane temperature i prepakiravanje, s odobrenjem izvoza u SAD, Kanadu, Japan i ostale treće zemlje, odobrenog broja 10, koji se nalazi na lokaciji Vrbovec, Zagrebačka 148:

- 1) osiguranje odgovarajućeg osvjetljenja na mjestu nadzora kritične kontrolne točke „Kontrola završne obrade polovica (CCP3B)“ u klaonici svinja;
- 2) sanacija oštećenja stropa i stropnih konstrukcija u svinjskoj rasjekavaonici te uklanjanje kondenzata i sprečavanje njegovog nastanka u skladištu svježeg visećeg svinjskog mesa (H1);
- 3) otvaranje kapsule bubrega u svrhu post mortem pregleda;
- 4) preciznije definirati pojam nečistoće pod kritičnom kontrolnom točkom „Kontrola preevisceracijskog pranja (CCP1B)“ u klaonici svinja;
- 5) provođenje nadzora fekalne kontaminacije prije pranja trupova, a vezano na kritičnu kontrolnu točku „Kontrola završne obrade polovica (CCP3B)“ u klaonici svinja.

Rok za izvršenje mjera pod točkama 1), 2) i 4) je 15 dana, a mjera pod točkama 3) i 5) je odmah.

Žalba na ovo rješenje ne odgađa njegovo izvršenje.

O b r a z l o ž e n j e

Dana 10.04.2024 izvršen je inspeksijski nadzor u objektu odobrenom za klanje papkara, rasijecanje mesa papkara i divljači, preradu mesa papkara, peradi i divljači, proizvodnju mljevenog mesa, mesnih pripravaka i strojno otkošenog mesa, topljene životinjske masti i čvaraka, preradu želudaca, mjechura i crijeva, uskladištenje hrane životinjskog podrijetla u uvjetima kontrolirane temperature i prepakiranje, s odobrenjem izvoza u SAD, Kanadu, Japan i ostale treće zemlje, odobrenog broja 10, koji se nalazi na lokaciji Vrbovec, Zagrebačka 148, objekta u poslovanju s hranom PIK VRBOVEC plus d.o.o., OIB 41976933718, sa sjedištem Zagrebačka 148, 10340 Vrbovec, a o utvrđenom je sastavljen zapisnik KLASA: 322-07/24-06/640, URBROJ: 443-02-05-04-24-

Inspeksijski nadzor je izvršen u sklopu audita FSIS/USDA inspektora Dr. Nadera Memariana. Inspeksijskim nadzorom su utvrđene sljedeće nesukladnosti:

- Neodgovarajuće osvjetljenje (cca 220 luxa) na mjestu kontrole CCP3B (Kontrola završne obrade polovica) u klaonici svinja,
- Rupe u stropu, neodgovarajući spojevi stropnog panela (odvajanje silikona), trakasti predmet na ventilaciji u svinjskoj rasjekavaonici, kondenzacija u skladištu B1,
- Nije otvorena bubrežna kapsula u svrhu post mortem pregleda,
- U kritičnim granicama pod CCP1B (Kontrola preevisceracijskog pranja) upisane vidljive nečistoće nisu preciznije definirane (klaonica svinja),
- Kontrola fekalne kontaminacije pod CCP3B (Kontrola završne obrade polovica) se provodi nakon pranja, a ne prije (klaonica svinja).

Na temelju utvrđenog činjeničnog stanja donijeto je rješenje kao u izreci ovog rješenja temeljem članka 152. točke 6. Zakona o veterinarstvu („Narodne novine“, br. 82/13, 148/13, 115/18, 52/21, 83/22, 152/22) i članka 19. stavka 1. alineje 2. Zakona o higijeni hrane i mikrobiološkim kriterijima za hranu („Narodne novine“, br. 83/22), kao i odredaba članka 5. i Priloga II. Poglavlja I. 7. i Poglavlja II. 1. c) Uredbe (EZ) br. 852/2004, članka 12. stavak 1. Uredbe (EZ) br. 178/2002 i odredaba 9 CFR 307.2 i 310.19.

Žalba protiv ovog rješenja ne odgađa njegovo izvršenje u skladu s člankom 19. stavkom 3. Zakona o higijeni hrane i mikrobiološkim kriterijima za hranu („Narodne novine“, br. 83/22).

Temeljem članka 9. stavka 2. točke 60. Zakona o upravnim pristojbama („Narodne novine“, br. 115/16, 114/22) ovo rješenje oslobođeno je naplate upravne pristojbe.

Putnik o pravnom lijeku:

Protiv ovog rješenja može se izjaviti žalba Državnom inspektoratu, Sektoru za drugostupanjski upravni postupak, Zagreb, Šubićeva 29, u roku od 15 dana od dana dostave ovog rješenja. Žalba se može predati tijelu koje je donijelo prvostupanjsko rješenje u pisanom obliku neposredno, poslati poštom, dostaviti elektroničkim putem ili usmeno izjaviti na zapisnik.

Stavlja se može odreći prava na žalbu u pisanom obliku ili usmeno na zapisnik, od dana primitka prvostupanjskog rješenja do dana isteka roka za izjavljivanje žalbe.

U skladu s napomenom uz Tbr. 3. Tarife upravnih pristojbi Uredbe o tarifi upravnih pristojbi („Narodne novine“, br. 156/22) i Zakonom o upravnim pristojbama („Narodne novine“, br. 115/16, 114/22) na žalbu protiv rješenja tijela državne uprave ne plaća se upravna pristojba iz Tbr. 3. Tarife upravnih pristojbi.



Dostaviti:

1. PIK VRBOVEC plus d.o.o., Zagrebačka 148, 10340 Vrbovec
2. Veterinarska stanica Vrbovec d.o.o., Kolodvorska 68, 10340 Vrbovec - na znanje
3. Arhiva, ovdje



REPUBLIKA HRVATSKA
DRŽAVNI INSPEKTORAT
Područni ured Varaždin
Ispostava u Koprivnici

P/22886825

KLASA: UP/I-322-07/24-06/90
URBROJ: 443-02-04-15-24-1
Koprivnica, 15. travnja 2024. godine

Viši veterinarski inspektor Državnog inspektorata OIB: 33706439962, Služba veterinarske inspekcije, Područnog ureda Varaždin, Ispostave Koprivnica, na temelju članka 69. stavak 1., članka 70. Zakona o državnom inspektoratu (NN 115/18, 67/23), članka 22. stavak 1. Zakona o službenim kontrolama i drugim službenim aktivnostima koje se provode sukladno propisima o hrani, hrani za životinje, o zdravlju i dobrobiti životinja, zdravlju bilja i sredstvima za zaštitu bilja (Narodne novine, broj 52/21), članka 19. Zakon o hrani i mikrobiološkim kriterijima (NN 83/22), članka 137 a i 137 b. Zakona o veterinarstvu (NN 83/2022, 152/22), a u skladu s člankom 96. stavak 1. i člankom 97. stavak 3. Zakona o općem upravnom postupku (NN 47/09, 110/21) u predmetu inspeksijskog nadzora u PODRAVKA d.d. Tvornica Danica, Đelekovečka cesta 21, OIB 18928526252, po službenoj dužnosti d o n o s i

RJEŠENJE

NAREĐUJE SE subjektu u poslovanju s hranom PODRAVKA d.d., Ante Starčevića 32, 48000 Koprivnica, da u odobrenom objektu za rasijecanje mesa papkara, preradu mesa papkara i peradi, proizvodnju mesnih pripravaka, topljene životinjske masti i čvaraka, preradu proizvoda ribarstva, uskladištenje hrane životinjskog podrijetla u uvjetima kontrolirane temperature i veleprodaju s odobrenjem izvoza u SAD, Kanadu, Australiju i ostale treće zemlje, PODRAVKA d.d. Tvornica Danica, odobrenog broja 139, na lokaciji Đelekovečka cesta 21, Koprivnica

I

- 1) Da površine stropova i stropne konstrukcije održava na način da spriječi kontaminaciju hrane**
- 2) Da prozore iznad prostora za blanširanje mesa izvede na prihvatljiv način**
- 3) Da pribor i oprema za uzimanje uzoraka za mikrobiološku analizu budu održavani na prihvatljiv način**
- 4) Da osposobi ledomat za opskrbu ledom**
- 5) Da provodi učinkovit postupak sustavnog praćenja kritične kontrolne točke-CCP 1B-prihvat mesne sirovine**
- 6) Da izvrši reviziju HACCP plana.**

II Rok za izvršenje je: po točkama 3., 5 i 6. odmah, po točkama 1. i 2. je 15 dana po primitku rješenja, a rok za izvršenje točke 4. je 60 dana.

III Žalba na ovo rješenje ne odgađa njegovo izvršenje.

O b r a z l o ž e n j e

Dana 11.04.2024. izvršen je inspeksijski nadzor temeljem članka 7. Zakona o državnom inspektoratu (NN 115/18, 117/21), članka 137. Stavak 1. Zakona o veterinarstvu (NN 82/13; 148/13; 115/18), članka 32. Zakona o hrani (81/13; 14/14), članka 6. stavka 2. i članka 7. stavka 1b) Zakona o službenim kontrolama koje se provode sukladno propisima o hrani, hrani za životinje, o zdravlju i dobrobiti životinja, zdravlju bilja i sredstvima za zaštitu bilja (NN 52/2021), a vezano

za članak 12. stavak 1. Uredbe (EZ) br. 178/2002., te relevantnih odredbi FSIS Direktive 5000.1, Rev. 7, Provjera sustava sigurnosti hrane u ustanovama, na subjektu PODRAVKA d.d., Koprivnica Tvornica Danica Ante Starčevića 32, 48000 Koprivnica, a o utvrđenom je sastavljen zapisnik 322-07/24-06/641

Inspekcijskim nadzorom utvrđeno je:

Prostorije u kojima se posluje s hranom nisu čiste, održavane i u dobrom stanju.

Površine stropova se ne održavaju u dobrom stanju, što je protivno odredbama Uredbe (EZ) br. 852/2004 Europskog parlamenta i vijeća, o higijeni hrane, Prilog II, Poglavlje II, točka 1(c). Uočena su oštećenja stropa (rupe u stropu) u proizvodnom pogonu, koja u trenutku nadzora nisu predstavljali mogućnost kontaminacije sirovine i gotovog proizvoda-odredba CFR 416.2 do 416.4, vezano za članak 12. stavak 1. Uredbe (EZ) br. 178/2002.

Prozori se ne održavaju u dobrom stanju. Prozori iznad prostora proizvodnje goveđeg mesa za gulaš su prljavi-prozori iznad blanšera.

Pribor i oprema za uzimanje uzoraka nije odgovarajuća.

Opskrba ledom i korištenje leda je odgovarajuće. Oštećenja na ledomatu, pojava hrđe, naslage kamenca. Tijekom inspekcijskog nadzora ledomat je stavljen izvan funkcije, te je stavljena oznaka „ZABRANJENA UPOTREBA“-Ovlašteni veterinar, 11.04.2024.

Ne provodi se revizija HACCP plana.

Nisu utvrđeni učinkoviti postupci sustavnog praćenja kritičnih kontrolnih točaka. U evidencijama prihvata mesne sirovine CCP 1B, nije uvijek potvrđeno, zabilježeno vrijeme prijema sirovine, CFR 417.5.-promjeniti obrazac.

Temeljem utvrđenog činjeničnog stanja donijeto je rješenje kao u izreci ovog rješenja temeljem članka 70., stavak 1. Zakona o državnom inspektoratu (NN 115/18), članka 33. Zakona o hrani (81/13; 14/14), stavka 2.

Žalba protiv ovog rješenja ne zadržava izvršenje temeljem članka 112. stavak 2. Zakona o zdravlju životinja (Narodne novine, br. 152/22 i 154/22).

Ovo rješenje donijeto je po službenoj dužnosti te je oslobođeno plaćanja upravne pristojbe temeljem članka 8. stavka 1., članka 9. stavka 1., stavka 2., točke 60., Zakona o upravnim pristojbama (Narodne novine, br. 115/16).

Pouka o pravnom lijeku:

Protiv ovog rješenja može se izjaviti žalba Državnom inspektoratu RH, Sektoru za drugostupanjski upravni postupak, Zagreb, Šubićeva 29, u roku od 15 dana od dana dostave ovog rješenja. Žalba se može predati tijelu koje je donijelo prvostupanjsko rješenje u pisanom obliku neposredno, poslati poštom, dostaviti elektroničkim putem ili usmeno izjaviti na zapisnik.

Stranka se može odreći prava na žalbu u pisanom obliku ili usmeno na zapisnik, od dana primitka prvostupanjskog rješenja do dana isteka roka za izjavljivanje žalbe.

U skladu s napomenom uz Tbr. 3. Tarife upravnih pristojbi Uredbe o tarifi upravnih pristojbi („Narodne novine“ br. 156/22) i Zakonom o upravnim pristojbama („Narodne novine“, br. 115/16) na žalbu protiv rješenja tijela državne uprave ne plaća se upravna pristojba iz Tbr. 3. Tarife upravnih pristojbi.

**Viši veterinarski inspektor
Branimir Komljenović dr.vet.med.**

Dostaviti:

1. PODRAVKA d.d. Tvornica Danica, Đelekovečka cesta 21 Koprivnica
2. Delegirano tijelo VETKON Veterinarska stanica Koprivnica d.o.o.
- ③ 3. Arhiva, ovdje





REPUBLIKA HRVATSKA
DRŽAVNI INSPEKTORAT
Područni ured Zagreb
Služba veterinarske inspekcije

KLASA: UP/I-322-07/24-06/89
URBROJ: 443-02-05-04-24-2
Petrinja, 15. travnja 2024. godine

Viši veterinarski inspektor - samostalni izvršitelj Državnog inspektorata Republike Hrvatske, OIB: 33706439962, Područnog ureda Zagreb, Službe veterinarske inspekcije, Samostalni izvršitelj u Petrinji, temeljem članka 66. i 70. stavaka 1. i 2. Zakona o državnom inspektoratu (NN 115/2018, 117/21, 67/23), a vezano za članak 12. Uredbe (EZ) br. 178/2002 i primjenjivom Direktivom FSIS 5001. Rev. 7., relevantnih odredbi 416.1 do 417.8, 9 CFR, članka 22. stavka 1. Zakona o službenim kontrolama i drugim službenim aktivnostima koje se provode sukladno propisima o hrani, hrani za životinje, o zdravlju i dobrobiti životinja, zdravlju bilja i sredstvima za zaštitu bilja (NN 52/2021), članka 35. i 36. Zakona o hrani (NN 18/23), članka 18. i 19. Zakona o higijeni hrane i mikrobiološkim kriterijima za hranu (NN 83/22) i članka 96. Zakona o općem upravnom postupku (NN 47/09, 110/21) u postupku službene kontrole udovoljavanja propisima o hrani subjekta u poslovanju s hranom GAVRILOVIĆ d.o.o., Gavrilovićev trg 1, 44250 Petrinja, odobrenog broja HR 399 EU, na istoj adresi, OIB: 83570236060 po službenoj dužnosti d o n o s i

RJEŠENJE

Naređuje se GAVRILOVIĆ d.o.o., Gavrilovićev trg 1, 44250 Petrinja, objekt odobrenog broja HR 399 EU, na istoj adresi:

1. U prostoriji za proizvodnju leda broj 19 na ledomatu, tačnu ispod valjaka ledomata potrebno je izvesti na tehnički ispravan i prihvatljiv način kako se neće moći nakupljati višak vode sa valjaka ledomata prilikom proizvodnje leda.
2. U prostoriji 34 – punilište konzervi, iznad elevatora linije MD 150, sanirati rupe u stropu uz nosače elevatora stroja.
3. U prostoriji u kojoj se vrši stavljanje praznih limenki proizvoda MD 150 na liniju/stol, građevinski sanirati oštećenja prozora u uglu prostorije i oštećenja zida.
4. U okviru HACCP plana u dijelu stabla odluke i dijagrama tijekom implementirati proceduru rikola proizvoda sa tržišta sa opisanom mogućom analizom opasnosti.
5. Plan samokontrole u dijelu koji se odnosi na proceduru verifikacije kritičnih kontrolnih točaka potrebno je uskladiti sa zapisom o verifikaciji.

Rok za izvršenje točaka 1), 2) i 3) je sedam (7) dana a za točke 4) i 5) određuje se rok od četrnaest (14) dana.

Žalba na ovo rješenje ne odgađa njegovo izvršenje.

O b r a z l o ž e n j e

Dana 15.4.2024. izvršen je inspekcijski nadzor na subjektu GAVRILOVIĆ d.o.o., Gavrilovićev trg 1, 44250 Petrinja, a o utvrđenom je sastavljen zapisnik KLASA: UP/I-322-07/24-06/89, URBROJ: 443-02-05-04-24-1.

Inspekcijskim nadzorom utvrđeno je:

Obilaskom pogona i proizvodnje tijekom rada utvrđene su slijedeće nesukladnosti vezano za odvijanje proizvodnog procesa:

1. U prostoriji za proizvodnju leda broj 19 u prostoru ispod valjaka ledomata uočena je nečistoća u obliku zaostale vode u tacni ispod valjaka ledomata kao i PVC čaša u istoj tacni. Zaostala voda je nastala kao višak vode prilikom tuširanja valjaka i nastajanja leda te je navedeni prostor tacne ispod valjaka potrebno izvesti na tehnički ispravan i prihvatljiv način kako se neće moći nakupljati višak vode sa valjaka ledomata prilikom proizvodnje leda – rizik od *L. monocytogenes*.
2. U prostoriji 34 – punilište konzervi, iznad elevatora linije MD 150, uočene su rupe u stropu uz nosače elevatora.
3. U prostoriji u kojoj se vrši stavljanje praznih limenki proizvoda MD 150 na liniju/stol uočena su oštećenja prozora u uglu prostorije i oštećenja zida.
4. U okviru HACCP plana u dijelu stabla odluke i dijagrama tijeka nedostaje procedura rikola proizvoda sa tržišta sa opisanom mogućom analizom opasnosti.
5. Plan samokontrole u dijelu koji se odnosi na proceduru verifikacije kritičnih kontrolnih točaka nije usklađen sa zapisom o verifikaciji.

Propusti čije se otklanjanje nalaže u suprotnosti su sa općim odredbama Uredbe (EZ) 852/2004 o higijeni hrane, PRILOG II, Poglavlja I, V, VII, te članak 3., članak 4. stavak 2, i članak 5. točka 2g iste Uredbe i odredbama Pravilnika o pravilima uspostave sustava i postupaka temeljenih na načelima HACCP sustava (NN 68/2015).

Sukladno navedenom potrebno je izvršiti sve mjere navedene ovim rješenjem, izvršiti reviziju plana samokontrole temeljenog na načelima HACCP-a na način da se izvrši revizija plana samokontrole u preduvjetima koji su nastali upotrebom opreme kako bi plan samokontrole bio provediv i učinkovit u svim fazama proizvodnje i kako bi se hrana u svim fazama proizvodnje zaštitila od izravne i neizravne mogućnosti zagađenja.

Temeljem utvrđenog činjeničnog stanja donijeto je rješenje kao u izreci ovog rješenja, temeljem članka 35. Zakona o hrani (NN 18/23) i odredbama USDA/FSIS Direktive 5001. Rev.7 i relevantnih kriterija SPS, SSOP, HACCP - 416.1 – 417.8 9 CFR.

Temeljem utvrđenog činjeničnog stanja donijeto je rješenje temeljem članka 70. stavka 1. i članka 93. stavka 1. Zakona o državnom inspektoratu (NN 115/18, 32/19), članka 33, 34, 35 i 36. Zakona o hrani (NN 18/23) te članka 18. i 19. Zakona o higijeni hrane i mikrobiološkim kriterijima za hranu (NN 83/22) valjalo je riješiti kao u izreci ovog rješenja.

Žalba protiv ovog rješenja ne zadržava izvršenje temeljem članka 19. stavka 3. Zakona o higijeni hrane i mikrobiološkim kriterijima za hranu (NN 83/22). i članka 23. stavka 2. Zakona o službenim kontrolama i drugim službenim aktivnostima koje se provode sukladno propisima o hrani, hrani za životinje, o zdravlju i dobrobiti životinja, zdravlju bilja i sredstvima za zaštitu bilja (NN 52/2021).

Temeljem članka 9. stavka 2. podstavka 60. Zakona o upravnim pristojbama (Narodne novine 115/16) ovo rješenje oslobođeno je naplate upravne pristojbe.

Ovo rješenje donijeto je po službenoj dužnosti te je oslobođeno plaćanja upravne pristojbe temeljem članka 8. stavka 1., članka 9. stavka 1., stavka 2., točke 60., Zakona o upravnim pristojbama (Narodne novine, br. 115/16).

Pouka o pravnom lijeku:

Protiv ovog rješenja može se izjaviti žalba Državnom inspektoratu, Sektoru za drugostupanjski upravni postupak, Zagreb, Šubićeva 29, u roku od 15 dana od dana dostave ovog rješenja. Žalba se može predati tijelu koje je donijelo prvostupanjsko rješenje u pisanom obliku neposredno, poslati poštom, dostaviti elektroničkim putem ili usmeno izjaviti na zapisnik.

Stranka se može odreći prava na žalbu u pisanom obliku ili usmeno na zapisnik, od dana primitka prvostupanjskog rješenja do dana isteka roka za izjavljivanje žalbe.

U skladu s napomenom uz Tbr. 3. Tarife upravnih pristojbi Uredbe o tarifi upravnih pristojbi („Narodne novine“, br. 92/21) i Zakonom o upravnim pristojbama („Narodne novine“, br. 115/16) na žalbu protiv rješenja tijela državne uprave ne plaća se upravna pristojba iz Tbr. 3. Tarife upravnih pristojbi.

Viši veterinarski inspektor - samostalni izvršitelj
ZVONIMIR DUMBOVIĆ dr.vet.med.



Dostaviti:

1. GAVRILOVIĆ d.o.o., Gavrilovićev trg 1, 44250 Petrinja
2. Arhiva, ovdje

