USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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OCT 0 3 2019

Dr. Karacic Tatjana
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Croatia

Dear Dr. Tatjana,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Croatia's meat inspection system from May 6 through May 17, 2019. Enclosed is a copy of the final audit report.

If you have any questions, please contact the Office of International Coordination by email at InternationalCoordination@usda.gov.

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

CROATIA

MAY 6 THROUGH 17, 2019

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

PROCESSED PORK PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

October 3, 2019

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from May 6 through 17, 2019. The purpose of the audit was to determine whether Croatia's food safety inspection system governing slaughter and processing of pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Croatia currently exports thermally processed pork commercially sterile 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.

The FSIS auditor found that Croatia's food safety inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. Croatia has implemented sanitary operating procedures and a HACCP system to ensure controls of hazards in processed pork products. In additional, Croatia has implemented a microbiological and chemical residue testing programs that are organized and administered by the nation to verify establishments meet necessary requirements. An analysis of each component did not identify any findings that represented an immediate threat to public health.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Croatia's food safety inspection system from May 6 through May 17, 2019. The audit began with an entrance meeting held on May 6, 2019 in Zagreb, Croatia, at which time the FSIS auditor discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – the Ministry of Agriculture. Representatives from the CCA accompanied the FSIS auditor throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether the food safety inspection system governing slaughter and processing of pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Croatia is currently eligible to export the following category of products to the United States. However, Croatia only ships thermally processed, commercially sterile pork products at this time.

Process Category	Product Category	Eligible Products[1]
Thermally Processed, Commercially Sterile	Thermally processed, commercially sterile	Beef, Veal, Goat, Lamb, Mutton and Pork – All Products Eligible

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Croatia as free of African swine fever, free of foot-and-mouth disease (with restrictions), free of swine vesicular disease (with restrictions), and low risk for classical swine fever (with restrictions).

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product type and volumes, frequency of prior audit-related site visits, point-of-entry (POE) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from the CCA through the self-reporting tool (SRT).

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.

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

Administrative functions were reviewed at CCA headquarters, two regional offices, and three local inspection offices. 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 intended.

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 thermally processed, commercially sterile (TPCS) pork products to the United States.

During the establishment visits, the FSIS auditor paid 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 CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §327.2.

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

Competent Authority Visits		**#**	**Locations**
Competent Authority	Central	1	• Ministry of Agriculture, Zagreb
	Regional offices	2	• Branch Office, Vrbovec • Branch Office, Petrinja
Laboratories		2	• Croatian Veterinary Institute Microbiology Laboratory (government) Zagreb • Croatian Veterinary Institute Residue Laboratory (government) Zagreb
Pork slaughter and processing establishment		1	• Establishment 10, Pik Vribovec Meat Industry d.d., Vrbovec
Pork processing establishments		2	• Establishment 139, Podravka d.d., Koprivnica • Establishment 399, Gavrilovic d.o.o., Petrinja

FSIS performed the audit to verify the food safety inspection system met requirements equivalent to those under the specific provisions of United States' laws and regulations, in particular:

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] 601 *et seq.*);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901-1906); and
- The Meat Inspection Regulations (9 CFR Parts 301 to the end).

The audit standards applied during the review of Croatia's inspection system for slaughter and processed pork products included: (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence

determinations that have been made by FSIS under provisions of the World Trade Organization's *Agreement on the Application of Sanitary and Phytosanitary Measures*; and includes the following regulations and directives for the European Union (EU):

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

III. BACKGROUND

From February 1, 2016 through January 31, 2019, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 825,364 pounds of TPCS pork products from Croatia. FSIS also performed reinspection on 107,305 pounds at POE for additional types of inspection, including condition of container, product examination, and testing for chemical residues, for which no products were rejected for issues related to public health.

The previous audit in 2017 identified the following findings:

GOVERNMENT OVERSIGHT (E.G., ORGANIZATION AND ADMINISTRATION)

- Croatia's use of contract employees to conduct verification activities during periods when establishments are producing products for the United States does not meet FSIS' statutory requirements.

GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (E.G., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

- At one of the two audited canning facilities, the initial temperature of the coldest container to be processed was not being recorded by the establishment at the start of each processing cycle.

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

- At two of the three audited establishments, the corrective actions outlined in the HACCP plan in response to a deviation from the critical limit did not specify the measures needed to prevent recurrence of the deviation.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- The government microbiological laboratory was currently using the International Organization for Standardization (ISO) 6579, Microbiology of the food chain -- Horizontal method for the detection, enumeration, and serotyping of *Salmonella* -- Part 1: Detection of *Salmonella*, method for the testing of swine carcasses for *Salmonella* in conjunction with export to the United States. The government of Croatia has not submitted an equivalence request to recognize the use of an alternative method.

The FSIS auditor verified that the corrective actions taken for the previously reported findings were implemented and effective in resolving the findings.

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

The FSIS final audit reports for Croatia's food safety inspection system are available on the FSIS website at:

http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (E.G., ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components that the FSIS 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 inspection personnel at establishments where products are prepared for export to the United States.

The national government of Croatia organizes and manages the meat inspection system. The CCA is the Ministry of Agriculture with overall responsibility for policy, legislation, and implementation of official controls in relation to food safety as established in the *Food Act* (Official Gazette (OG) 81/13 and 14/14). The Veterinary and Food Safety Directorate (VFSD) is an organizational unit of the Ministry of Agriculture responsible for animal health, food safety, veterinary medical products, animal by-products, animal welfare, and the European Commission's Rapid Alert System for Food and Feed (RASFF). The VFSD is comprised of

three organizational sectors: the Animal Health Protection Sector, the Food Safety Sector, and, the Inspection Supervision Sector (ISS).

The Animal Health Protection Sector is responsible for policy in the fields of animal health and welfare, animal identification and registration, and organization of the veterinary field network. This sector is also responsible for control and eradication of animal diseases, contingency planning and crisis management, animal welfare, delegation of official tasks to veterinary organizations, and veterinary information systems. The Food Safety Sector is responsible for policy related to food safety, veterinary medical products and residues, and animal by-products.

The ISS includes the Veterinary Inspection Service, the Border Veterinary Inspection Service, and the International Trade Service. The ISS is responsible for communicating and coordinating food safety official controls and is comprised of Department Veterinary Offices in different geographic regions responsible for inspection, planning, and coordinating official controls. Branch Office Senior Veterinary Inspectors (VIs) are responsible for performing inspection and verification procedures as well as oversight of Authorized Veterinarians (AVs). Currently, three Branch Offices are responsible for oversight of the establishments certified to export to the United States.

The VFSD is also responsible for delegating official tasks to authorized veterinary organizations, referred to as control bodies, according to Article 115 of the *Veterinary Act* (OG 82/13 and 148/13). Control bodies must fulfill requirements including adherence to ISO 17020:2012 standards, *Conformity assessment – Requirements for the operation of various types of bodies performing inspection,* and are subject to official contract with the VFSD for a period of five years. *Regulation (EC) No. 882/2004*, Article 5, requires that the CCA have proof that the control body is impartial and free from any conflict of interest related to assigned tasks. The control bodies employ AVs who perform specific tasks according to the contract, including the performance of ante-mortem and post-mortem inspection, verification of humane handling and slaughter, and verification of sanitation, HACCP, and all other requirements at establishments certified to export to the United States.

The CCA has the authority and responsibility to enforce laws and regulations governing meat and has the authority to certify establishments eligible to export to the United States in accordance with Croatian statutes. The *Food Act*, *Veterinary Act*, *Act on Official Controls Performed in Accordance with the Requirements of Food and Feed Law, Animal Health and Animal Welfare Rules* (OG 81/13, 14/14, and 56/15), and the *Act on Food Hygiene and Microbiological Criteria for Food* (OG 81/13) all implement EC regulations and provide the legal basis for the VFSD to perform official controls, act when noncompliance is identified, and initiate enforcement actions.

The *Veterinary Act,* Article 152, describes the authority for enforcement measures including the expectation that VIs implement measures in response to an establishment's failure to comply with requirements or in the event the safety of any food is questionable. The FSIS auditor verified that, in cases where the Senior VI identified noncompliance, the Senior VI prepared a written noncompliance record, and conducted the appropriate follow-up to ensure the issues were

resolved prior to closing out the record. The CCA has not implemented any enforcement actions since the last FSIS audit in 2017.

The *Food Act*, Article 10, defines adulterated food and states that it is prohibited to possess, sell, use, and administer adulterated foods and references expected actions in accordance with *Regulation (EC) No. 178/2002* and *882/2004*. Additionally, the *Ordinance on Health Marks and Identification Marks of Foods of Animal Origin* (OG 69/15) specifies the criteria for determining meat unfit for human consumption in slaughterhouses.

Article 8 of the *Ordinance on the Rules for the Establishment of the System and Procedures Based on HACCP Principles* (OG 68/15) includes a requirement for the establishment to include a prerequisite program detailing procedures for withdrawal and recall of food from the market. It also entails the process of informing the competent authorities that they have recalled or withdrawn product from commerce, consistent with *Regulation (EC) No. 178/2002*. There have been no pork product recalls for any market since the last FSIS audit in 2017.

The CCA ensures that source meat products used in processing operations originate from eligible countries and establishments certified to export to the United States as described in the VFSD's *Implementation Procedure of Official Controls in Accordance with USDA/FSIS Provisions* (21.03.2018). The FSIS auditor verified that at receiving of raw meat, the AV monitors unloading, verifies controls including the temperature chart recording of the transport truck, sanitary condition of the transport truck, valid health marks and labels, reviews delivery documents, performs a visual and organoleptic examination of selected product, and observes establishment sampling for microbiological analysis.

The FSIS auditor noted that the AV verifies that each shipment of source meat used to produce TPCS pork originates only from establishments certified to export to the United States by utilizing the FSIS website listing eligible establishments by country, as described in the document above. In addition, the FSIS auditor reviewed records documenting source meat and demonstrating traceability through the export certification process. The FSIS auditor verified that the AVs and Senior VIs maintain the pertinent documents for each production lot intended for export to the United States. At the time of the audit, the certified processing establishments in Croatia were sourcing raw pork meat from Croatia, Spain, Poland, Hungary, and Denmark, all from establishments listed on the FSIS website as eligible to export to the United States.

The AVs are responsible for export certification of products to the United States. All export certification items, including blank certificates and stamps, are stored in the secure control body office at each establishment. The CCA provides the official export certificate with unique serial numbers to the control body. The AV observes the staged lot to verify the weight declaration, shipping marks, and labels. In addition, the AV conducts a pre-shipment review that includes all associated traceability documents, including verification of the raw meat source used to produce products, and food safety records for each lot prior to applying the official stamp and signature on the export certificate. The AV review includes ensuring that all products have tested negative for microbial pathogens and residues whether through establishment or official sampling programs prior to signing an export certificate.

The CCA maintains a single set of laws, regulations, and procedures applicable to the establishments certified to export to the United States. As described above, there are national acts that implement measures of the EC regulations. In addition, the VFSD annually develops implementation procedures of official controls consistent with FSIS requirements. Each Senior VI in the Branch Office is responsible for developing an annual plan of verification activities in accordance with the annual official controls procedure. The head of the Department Veterinary Office is responsible for reviewing and approving the Senior VI's annual plan. In addition, each control body is responsible for developing an annual plan of controls for the AVs. The result of the annual plans are verification checklists, including a food processing checklist that includes verification of sanitation, HACCP, and all other requirements for establishments certified to export to the United States.

The AVs utilize the Veterinary Inspection (VETI) database to record results of ante-mortem and post-mortem inspection in the VETI1 component of the database and to document time spent on official controls in the VETI2 component. Additional results are documented in daily reports (*Zapisnik*) with specific details of the verification activities and outcomes. The Branch Office Senior VIs utilize the e-Inspector database to generate a daily checklist of verification activities and document the results of all verification and oversight activities. From the database, a detailed written daily report of activities and results is generated.

VFSD headquarters personnel are responsible for distributing all significant information including revisions to policy and requirements, to the establishments, inspection personnel, and the Croatian Veterinary Chamber via registered letters. For significant changes, the VFSD arranges lecturing through the University of Zagreb Veterinary Medical faculty. VFSD headquarters personnel are notified of FSIS regulatory and policy matter and receive FSIS correspondence through emails. When official letters are received from FSIS, they are translated and entered into an official database for distribution.

All VFSD personnel are employed by the government of Croatia. Under the authority of the *Veterinary Act,* the CCA is responsible for collecting fees from establishments to finance the costs of performing official controls. The *Ordinance on the Amount of Fees and Fees for Official Controls* (OG 84/15, 100/15, and 14/16) specifies the fees charged to establishments for the costs of inspection. The additional costs associated with meeting the additional requirements of the United States are also authorized under the ordinance. Payment of fees is made directly to the state (national) budget of Croatia. Payment of VFSD personnel is through direct deposit from the state budget. The control body AVs are paid by the control body who receives the funds directly from the Ministry of Agriculture. The FSIS auditor verified that official inspection personnel assigned to certified establishments exporting processed pork products to the United States are government employees paid by the Croatian government.

The 2017 FSIS audit identified a systemic finding due to the use of contracted AVs to conduct inspection and verification activities rather than government employees. In response, the Minister of Agriculture issued a decision on October 23, 2017, under Croatian law specifying the required oversight of establishments approved to export to the United States. The decision specifies the Senior VIs assigned to each establishment are responsible for providing direct

government authority over all inspection activities when establishments are producing product for export to the United States.

A renewed decision was issued on April 1, 2019, designating the Senior VIs and the continued responsibilities as noted above. The FSIS auditor verified through review of daily reports that the CCA fully implemented the actions in response to the prior audit finding and ensures the presence of government VIs throughout slaughter and once per shift in processing operations.

The VFSD assigns inspection personnel to official establishments that export products to the United States, and ensures that they have appropriate educational credentials, training, and experience to carry out their inspection tasks in accordance with the *Veterinary Act*. VIs may be appointed if they have completed an undergraduate and graduate program in veterinary medicine, pass the national qualifying examination for VIs, and have at least four years of experience in carrying out the relevant tasks. Senior VIs must have at least eight years of experience in carrying out the relevant tasks. AVs are required to have degrees in veterinary medicine, pass the national qualifying examination for AVs, have a professional license, and two years of experience.

The FSIS auditor verified that the VFSD developed and implemented training covering FSIS import regulations and Croatian and EC regulations in cooperation with the Croatian Veterinary Chamber. The CCA and Croatian Veterinary Chamber are responsible for training AVs in ante-mortem and post-mortem inspection. The Quality Manager of each control body is responsible for additional training of the AVs; however, the CCA typically invites Quality Managers to attend training organized by the VFSD. The FSIS auditor verified ongoing training since the 2017 FSIS audit, including training in United States requirements. The Croatian Veterinary Chamber conducts annual training for three days covering a wide variety of veterinary topics including food safety, animal health, and animal welfare. Additional training includes the annual EC Better Training for Safer Food course. Lastly, Senior VIs have received training on African swine fever and animal health.

The Croatian Veterinary Institute (CVI) is a national institute within the Ministry of Science and Education that provides technical support for the CCA, including diagnostics of animal infectious and parasitic diseases, food and animal feed analysis, control of veterinary medical products, and research activities. The CVI in Zagreb consists of five departments and 16 individual laboratories. In addition, the CVI has five branches, including the Poultry Centre Zagreb, Veterinary Department Križevci, Veterinary Department Rijeka, Veterinary Department Split, and Veterinary Department Vinkovci.

Within the CVI Zagreb, the Department of Veterinary Public Health includes the Laboratory for Food Microbiology, the National Reference Laboratory (NRL) for *Salmonella* along with other bacterial pathogens. The laboratory conducts analyses for all official samples, including analysis of carcass swabs for *Salmonella* collected in accordance with *Regulation (EC) No. 2073/2005*. Also, within the Department of Veterinary Public Health are the Laboratory for Determination of Residues and the Laboratory for Analysis of Veterinary Medical Products, both are the NRLs responsible for analysis of chemical residues in livestock.

The CCA has a FSIS equivalence determination allowing for analysis of carcass swabs collected for the purpose of meeting FSIS *Salmonella* performance standards to be collected by the establishment employees and analyzed by private establishment laboratories. The private laboratories are not required to be accredited. Oversight of the establishment laboratory consists of a system of audits. First, the control body AVs conduct audits of the establishment laboratory four times each year to evaluate the quality control system and laboratory records. Senior VIs from the Branch Office conduct audits twice a year to assess the establishment laboratory methods and good laboratory practices including sampling, storage of samples, sample analysis, reporting of results, employee training, and equipment calibration. Lastly, at least once per year VFSD headquarters VIs audit the establishment laboratory.

At least twice each month, carcass sponge "split samples" collected at the establishment are analyzed for *Salmonella* by the establishment laboratory and CVI for the purpose of ensuring integrity. However, the FSIS auditor determined through interviews with the CVI that the samples were not truly "split", but rather different sponge samples collected from the leading and trailing halves of the same carcass. Therefore, this procedure does not provide a direct correlation for assessing the proficiency of the establishment laboratory.

The Croatian *(Hrvatski)* Accreditation Agency (HAA) is an independent public institution that acts as the national accreditation service. The HAA is responsible for conducting accreditation audits according to the ISO 17025:2017 standards, *General requirements for the competence of testing and calibration laboratories*. In addition, because the CCA is responsible for designating official laboratories, the VFSD conducts annual audits of the CVI laboratories for the purpose of verifying valid accreditation according to ISO 17025 standards and accreditation of methods to ensure that the designation requirements are achieved.

The FSIS auditor reviewed the most recent HAA accreditation certificate, issued May 14, 2018, and valid for five years. The scope includes a total of 16 microbiological methods, including the ISO 6579-1:2017, *Microbiology of the food chain -- Horizontal method for the detection, enumeration and serotyping of Salmonella -- Part 1: Detection of Salmonella* method. For residue analyses the HAA issues a flexible scope of accreditation. At the time of the FSIS audit the laboratories had fixed accreditation for nine methods and an additional 25 methods accredited under the flexible scope.

HAA performs accreditation audits every five years, as well as annual audits of the CVI, but not every laboratory within the CVI is audited annually. In addition, the CVI performs annual internal audits according to their Quality Manual using qualified assessors from one of the branch laboratories to maximize independence. Like HAA, not every method is assessed during every annual internal audit. Lastly, the VFSD Veterinary Inspection Sector conducts annual audits of the CVI to ensure the institute meets all requirements for official laboratories designated by the Ministry of Agriculture. The FSIS auditor evaluated the most recent HAA, internal, and VFSD audit reports, none of which documented any major findings requiring an action plan.

The CVI participates in annual proficiency testing organized by European Union Reference Laboratories. The most recent Laboratory for Food Microbiology proficiency testing results for

detection of *Salmonella* demonstrated 100 percent accuracy. The residue laboratories participate in ongoing European Union Reference Laboratory proficiency tests throughout the year for different analytes and matrices. The FSIS auditor reviewed proficiency testing results and confirmed that all results were satisfactory for swine samples.

The FSIS auditor confirmed that the CCA ensures the CVI official laboratories comply with ISO 17025 criteria through review of the HAA accreditation certificates and audit reports, review of the annual VFSD report, and review of internal audits conducted in accordance with ISO 17025 as well as on-site visits to the laboratories. However, the FSIS auditor identified one observation at the microbiological laboratory. The official government microbiology laboratory failed to ensure all media used in the analytical procedure for detection of *Salmonella* were labeled with contents, batch, and date.

The FSIS auditor verified that the CCA's food safety inspection system has the organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements for this component. However, the CCA should ensure that the observation associated with the CVI laboratory is corrected.

V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (E.G., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

The second of six equivalence components that the FSIS 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 each and every carcass and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; periodic supervisory visits to official establishments; and requirements for TPCS products.

The *Act on the Implementation of the European Union Animal Protection Act* (OG 125/13, 14/14, and 92/14) establishes the competent authority, supervision, conditions for staff training, and penalty provisions for the implementation of *Regulation (EC) No. 1099/2009* on the protection of animals at the time of slaughter. The *Ordinance on Conditions to be Met by Slaughterhouses* (OG 57/15) sets the design, construction, and equipment slaughterhouse conditions to be met in accordance with the EC regulation. The CCA has also issued a *Guide for Handling Ungulates (Bovine, Sheep, Goats, Pigs, Horses) and Ostriches During Slaughterhouse Procedures* to provide direction to slaughterhouses on how to comply with animal welfare requirements.

The VFSD's *Implementation Procedure of Official Controls in Accordance with USDA/FSIS Provisions* (21.03.2018) states that verification of animal welfare control is carried out in accordance with the country's regulations and procedures consistent with *FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock*. Currently Croatia has one swine slaughter establishment certified eligible to export to the United States. The AVs are responsible for daily

verification of humane handling and slaughter requirements. In addition, Senior VIs provide daily oversight of AVs and perform verification activities for humane handling and slaughter. The FSIS auditor verified that the CCA has implemented requirements and procedures to ensure humane handling and slaughter of swine.

The FSIS auditor verified that the CCA has developed procedures to ensure ante-mortem inspection tasks in slaughter establishments. In accordance with *Regulation (EC) No. 854/2004*, the CCA has established procedures for conducting ante-mortem inspection to ensure that all livestock presented for slaughter are eligible for human food. The assigned AVs carry out an ante-mortem inspection of all livestock before slaughter. Ante-mortem procedures include checks on documentation and health certificates that accompany the livestock, examination of animal identification, assessment of animal cleanliness, and examination of the livestock to determine whether they are fit for slaughter for human food, including observation of swine in motion from each side and at rest.

Records of ante-mortem inspection, including the date, time, and responsible AV are promptly entered into VETI1, at which time the database locks the record, so no additional changes may be made. In addition, documents confirming the outcome of ante-mortem inspection accompany each lot of swine into slaughter. The AVs and Senior VIs always have access to the VETI1 data and the documentation accompanying the lot is available for verification by the online AVs performing post-mortem inspection. The FSIS auditor observed AVs performing ante-mortem inspection as well as verification of required documentation and corresponding VETI1 data and confirmed that the CCA's procedures are implemented as described.

The AVs perform post-mortem inspection of swine consistent with the procedures detailed in *FSIS Directive 6100.2*, *Post-mortem Livestock Inspection*, on days that swine are slaughtered for products intended for export to the United States. The FSIS auditor observed that post-mortem inspection procedures included head inspection with mandibular lymph node incision, viscera inspection, and carcass inspection for each and every carcass. If pathology is identified that might impact the fitness of a carcass for human food, the carcass and viscera are subject to a thorough inspection by an offline AV. The FSIS auditor assessed post-mortem inspection through on-site observations, record reviews, and interviews in the audited slaughter establishment and verified that the CCA's procedures are implemented as described.

The FSIS auditor verified that staffing at the slaughter establishment was adequate to ensure that ante-mortem and post-mortem inspection requirements are achieved. Staffing of AVs at the slaughter establishment is the responsibility of the control body described in Component One. At the audited slaughter establishment, the FSIS auditor determined that there is a total of three shifts each day that swine are received for ante-mortem inspection, each shift staffed with two AVs dedicated to performing ante-mortem inspection. Post-mortem inspection was also performed by AVs. The FSIS auditor also verified that Senior VIs in the Branch Office arrange their activities to ensure their presence throughout slaughter days when products are intended for export to the United States.

Supervisory visits by Senior VIs occur daily, at least once each shift, when establishments are slaughtering or otherwise producing products intended for export to the United States according

to the *Implementation Procedure of Official Controls in Accordance with USDA/FSIS Provisions* (21.03.2018). The Quality Manager of the control body is directly responsible for supervision and performance assessment of assigned AVs. In addition, twice each year a Senior VI evaluates all requirements, including performance of AVs, during single on-site visits.

The HAA conducts accrediting audits of each control body every five years. At least twice per year a Senior VI utilizes an established checklist of elements in the e-Inspector database to audit the control body. The objective is to assess accreditation status, adherence to a valid contract with the CCA, whether the control body is completing all data in the VETIS database for traceability, whether the control body is fulfilling animal health requirements, and other measures.

In addition, a central audit from the VFSD occurs at least once per year for the purpose of assessing effectiveness of the Senior VIs from the Branch Office as well as the control body in ensuring United States requirements are met and all official inspection activities are being conducted as expected. The outcome includes a written report for the Chief of the responsible Department Veterinary Office with conclusions and recommendations, if any.

The supervisory reviews include assessment of ante-mortem and post-mortem inspection, humane handling, sanitation standard operating procedures (sanitation SOPs), sanitation performance standards (SPS), HACCP, economic adulteration and labeling, sampling programs, export certification, complete separation of establishments, and official controls over condemned material as well as all other requirements. The FSIS auditor reviewed supervisory visit and oversight reports at multiple regional and establishment offices. The FSIS auditor confirmed that supervisory visits occurred at the described frequency and were documented using e-Inspector results and report forms. In addition, the FSIS auditor verified documentation in response to identified noncompliance, including follow-up reports detailing corrective actions and resolution of findings.

The FSIS auditor verified that the CCA requires establishments to maintain identity of products, and to control and segregate product destined for the United States from other products as applicable. Each audited establishment had distinct storage coolers and finished product storage areas designated for meat products intended for export to the United States. The storage areas were secured by locks and accessible to AVs and Senior VIs. In addition, production of products intended for export to the United States occurs on separate days or during the first shift only.

The CCA requires that all scales used for weighing products be calibrated by the State Office for Metrology. AVs at certified TPCS establishments perform net weight verification of finished containers. In addition, labeled ingredient statements are verified accurate according to the formulation used for each product. Label verification is based on the FSIS label approvals on file at each establishment and final verification occurs during each pre-shipment verification procedure.

The CCA ensures that its meat exports are not subject to animal health restrictions by regularly consulting the relevant sections of the APHIS website in addition to FSIS' product eligibility chart for individual countries, which also considers current APHIS restrictions. Lastly, the

export certificates issued by the CCA include APHIS requirements. Only those products that have been previously identified by the CCA as meeting both FSIS and APHIS requirements can be certified for export to the United States.

The CCA follows *Regulation (EC) No. 1069/2009* and *Regulation (EU) No. 142/2011* to ensure official controls over inedible materials until they are destroyed or removed, and that products that are inedible or not for human consumption are segregated from edible product. In addition, the *Food Act* specifies requirements including required containers, labeling, sanitation, handling and disposal. Any livestock condemned during ante-mortem inspection are disposed of by denaturing and disposal as Category 1 materials, unfit for food or feed. During the audit, FSIS verified that inedible materials were properly identified, segregated, and disposed.

The CCA has legal authority to establish regulatory controls over certified meat establishments that export their products to the United States.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components that the FSIS auditor reviewed was Government Sanitation. The FSIS auditor verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation SOPs to prevent direct product contamination or insanitary conditions.

The CCA requires establishments certified to export to the United States to develop and adhere to written programs that prevent direct product contamination and operate in a manner that prevents the creation of insanitary conditions by complying with the requirements consistent with 9 CFR Part 416. Each certified establishment must develop procedures to address sanitary requirements, including cleaning, facility construction and maintenance, equipment maintenance, and pest control. The AVs and Senior VIs verify compliance with sanitation requirements daily by direct observation and review of records as described in the *Implementation Procedure of Official Controls in Accordance with USDA/FSIS Provisions* (21.03.2018).

The FSIS auditor verified the adequacy of official verification and inspection activities related to sanitation programs at establishments certified to export to the United States by observing AVs as they assessed the implementation of the establishments' sanitation procedures. The FSIS auditor assessed the adequacy of pre-operational sanitation by observing an AV conduct pre-operational verification of the establishment's sanitation program at an audited establishment. The FSIS auditor reviewed inspection records and assessed the overall sanitary conditions of production areas and storage rooms and observed the production processes in slaughter and processing establishments. The FSIS auditor also reviewed written establishment sanitation SOPs and records at the audited establishments.

The FSIS auditor evaluated verification of sanitary dressing procedures in slaughter establishments. The AVs routinely verify establishment sanitary dressing and perform daily verification of zero tolerance for fecal material, ingesta, and milk on swine carcasses after final carcass inspection as described in the *Implementation Procedure of Official Controls in Accordance with USDA/FSIS Provisions* (21.03.2018). Overall, the CCA has written

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

If the AV identifies insanitary conditions or practices, they have the authority to take immediate action to prevent product contamination or adulteration. However, the AV must notify a Senior VI of identified noncompliance or concerns, as only the Senior VI can document noncompliance and initiate formal enforcement actions when required. The CCA requires Senior VIs to document identified noncompliance and requires the establishment to implement adequate corrective actions. The FSIS auditor reviewed noncompliance reports and supervisory visit reports, and verified records demonstrating establishment corrective actions and verification by the Senior VIs that establishment corrective actions were implemented and effective.

For the most part, the FSIS auditor noted that the AVs, Senior VIs, and establishment records mirrored the actual sanitary conditions of the establishment, although the FSIS auditor identified isolated noncompliance at one of the three audited establishments. These isolated findings are documented on the individual establishment checklist attached to this report (Appendix A). The CCA's food safety inspection system continues to maintain sanitary regulatory requirements that meet the core requirements for this component.

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

The fourth of six equivalence components that the FSIS 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 the CCA requires establishments to design, implement, and maintain HACCP systems consistent with EC and United States requirements. Croatia's *Ordinance on the Rules for the Establishment of the System and Procedures Based on HACCP Principles* (OG 68/2015) stipulates the detailed rules for the establishment, implementation, and maintenance of the system and procedures based on HACCP principles for the purpose of implementing *Regulation (EC) No. 852/2004* and the *Act on Food Hygiene and Microbiological Criteria for Foodstuffs* (OG 81/13). In addition, the CCA requires that requirements consistent with 9 CFR Part 417 are met by each establishment certified eligible to export to the United States.

The CCA's *Implementation Procedure of Official Controls in Accordance with USDA/FSIS Provisions* (21.03.2018) provides an overview of official inspection verification activities. The AVs and Senior VIs conduct daily verification activities for HACCP requirements through direct observation and hands-on activities as well as review of records. The Senior VIs are responsible for verification of the flow chart, hazard analysis, HACCP plan, and all other HACCP requirements. The FSIS auditor verified through review of inspection records that official inspection personnel conduct daily HACCP verification activities.

The FSIS auditor reviewed programs and records maintained by inspection personnel and the audited establishments and observed the implementation of the HACCP systems. Each audited

establishment has developed a flow chart and conducted hazard analyses for expected hazards. For specific hazards that are reasonably likely to occur, the establishments have instituted critical control points (CCPs) described in HACCP plans. At the slaughter establishment, the FSIS auditor verified that AVs also perform daily verification for zero tolerance of fecal material, ingesta, and milk in the swine slaughter establishment to ensure establishment compliance with sanitary dressing and the establishment's CCP for zero tolerance.

Lastly, the FSIS auditor verified that the 2017 FSIS audit findings associated with HACCP corrective actions at two establishments were resolved. The FSIS auditor verified that the CCA requires establishments certified to export to the United States to develop and implement HACCP systems.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components that the FSIS 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, and muscle of carcasses for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants. For product intended for export to the United States, Croatia requires the carcass and parts be held pending the receipt of acceptable results.

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

Croatia's *Ordinance on The Monitoring of Certain Substances and Residues thereof in live Animals and Animal products* (OG 79/08, 51/13) transposes *Council Directive No. 96/23/EC*. In accordance with *Regulation (EC) No. 882/2004* and the above ordinance, the CCA publishes and implements an annual NRCP. The number of the samples to be taken, substances to be tested, and sampling procedures are determined in accordance with the above ordinance as well as the *Ordinance on Detailed Rules of Official Sampling for the Monitoring of Certain Substances and Residues Thereof in Live Animals and Animal Products* (OG 138/08, 142/12). Additional Croatian legislation implements chemical residue-related EC legislation.

In the VFSD, the Food Safety Sector includes the Veterinary Medical Products and Residue Monitoring Division that is responsible for drafting legislation and the annual NRCP, issuing requests for sampling, coordinating sampling, monitoring the implementation of the NRCP, collecting and analyzing data, and reporting on results. The NRCP is based on production data from the previous year and collaboration with the CVI Residue NRL in Zagreb.

The ISS includes a coordinator in each Department's Veterinary Office that is responsible for distributing detailed instructions to the Branch Offices for sampling according to the NRCP. The Branch Office coordinator is responsible for tracking all assigned samples to ensure the

scheduled samples are collected and analyzed. Samples are collected by AVs and the Senior VI performs specific oversight and drafts a report documenting sample collection at slaughter establishments. Samples are delivered to the assigned laboratory either via driver or post with next day delivery to the laboratory. The CCA's *Sampling Guidelines for the NRCP and Treatment of Non-conforming Findings* describes sampling and the corrective measures that must be taken in the case of noncompliant results.

During the evaluation of ante-mortem inspection at one slaughter establishment, the FSIS auditor observed that AVs verify documentation that discloses the origin of every lot of swine and includes the owner's signed declaration attesting they have adhered to veterinary pharmaceutical withdrawal periods. In addition to the NRCP, the AVs may implement sampling of any swine that are identified during ante-mortem or post-mortem inspection as suspects for possible residues.

In addition to accreditation audits, the CCA also conducts an annual audit of the CVI laboratories. The CCA audits include review of the quality manual, organization of activities, work of employees, sampling handling, equipment, subcontract activities, results analysis and reporting, and quality control of results. Each audit is documented in a written report and a review of the most recent audit indicates there were no findings identified.

The audit of the CVI Residue NRL in Zagreb included interviews with the laboratory management, document reviews, and observations of the laboratory. The FSIS auditor verified that the audited laboratory ensured traceability throughout sample receipt, analysis, and reporting.

The CCA's meat inspection system has regulatory requirements for a chemical residue testing program that is organized and administered by the national government. No concerns arose during the audit with the chemical residue laboratory.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components that 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.

The CCA has adopted requirements consistent with the FSIS generic *E. coli* requirements in 9 CFR Part 310.25(a) as referenced in the *Implementation Procedure of Official Controls in Accordance with USDA/FSIS Provisions* (21.03.2018). The FSIS auditor verified 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. There have been no samples exceeding the established upper control limit. The AVs conduct verification activities that include assessment of establishment compliance with the generic *E. coli* requirements.

The CCA also requires slaughter establishments to meet the *Salmonella* performance standards consistent with those in 9 CFR Part 310.25(b). Based on prior FSIS equivalence determinations, the establishment collects samples under the direct supervision of the AV and results are analyzed by the establishment laboratory. The FSIS auditor verified that sample collection methods are consistent with *FSIS Directive 10,250.1*, *Attachment 7*, *How to Sponge a Swine Carcass*. Sample results are reported to the control body and AV and discussed during the weekly meeting with the establishment. The FSIS auditor verified sample results for the current year and determined all were negative for *Salmonella* species.

In addition, for purposes of meeting EC requirements, additional sampling for *Salmonella* occurs on an ongoing basis. These official samples are submitted to a CVI microbiology laboratory for analysis. Results from the CVI microbiology NRL are distributed via email and hard copy via post to the Senior VIs at the Branch Office. The FSIS auditor reviewed establishment and official inspection records at the audited slaughter establishment and concluded that the generic *E. coli* and *Salmonella* process control sampling programs are implemented as described.

Within Croatia, establishments producing TPCS products are required to address the hazards using HACCP principles. In addition, according to the *Implementation Procedure of Official Controls in Accordance with USDA/FSIS Provisions* (21.03.2018), establishments are required to meet requirements consistent with 9 CFR Part 431, Thermally Processed, Commercially Sterile Products. The FSIS audit included two processing establishments producing TPCS products. The AVs and Senior VIs perform daily, per shift, verification activities at processing establishments to verify food safety requirements are met. Verification activities include the entire process as well as verification of container incubation, closure examinations, and verification of the thermal process CCP.

The 2017 FSIS audit documented an audit finding due to the failure of one establishment to document the initial temperature of the coldest container to be processed at the start of the thermal process. The FSIS auditor confirmed the CCA's response that this finding was resolved by observing that both TPCS establishments had minimum initial temperatures established and were measuring and recording the initial temperature of the coldest container for each retort load. In addition, the AVs and Senior VIs verify that this requirement is met.

The CCA organizes and administers microbiological testing programs to verify that meat products destined for export to the United States are unadulterated, safe, and wholesome in accordance with United States requirements. The CCA's meat inspection system continues to meet the core requirements for this component. There have not been any POE violations related to this component since the last FSIS audit.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on May 17, 2019 in Zagreb, Croatia, with the Ministry of Agriculture. The FSIS auditor concluded that Croatia's food safety inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The CCA has implemented sanitary operating procedures and a HACCP system to ensure controls of hazards in processed pork products. In addition, the CCA has implemented a microbiological and

chemical residue testing programs that are organized and administered by the nation to verify establishments meet necessary requirements. An analysis of each component did not identify any findings that represented 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	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Pik Vrbovec Meat Industry d.d. Zagrebacka 148 Vrbovec Hrvatska	05/08/2019	10	Croatia
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	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	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		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

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

10. The Associate Veterinarian failed to identify insanitary food contact surfaces when verifying the effectiveness of the establishment's pre-operational sanitation procedures in the slaughter floor. The insanitary conditions included observation of meat and fat particles from prior production on the following food contact surfaces: multiple viscera pans, gambrel hooks, and a stainless steel gondola for meat products.

39. The overhead carcass rails, hangers, and structures throughout the slaughter area had extensive dark brown grease buildup, globules of grease, chipped paint, and rust creating insanitary conditions with the potential for direct product contamination. The establishment's maintenance of overhead rails and weekly cleaning procedure for overhead rails was inadequate in ensuring sanitary conditions.

41. Beaded condensation was observed below the ventilation unit and overhead structures in two locations in the carcass cooler in the processing area, directly above carcasses. No direct contamination was noted but the potential for imminent contamination was present. The establishment implemented immediate corrective actions.

46. Swine carcasses diverted onto the side rail for additional trimming due to contamination or pathology were in direct contact with each other prior to trimming and final inspection. The establishment implemented immediate corrective actions.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	05/08/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Tvornica Danica Delekovecka 21 Koprivnica Hrvatska	05/09/2019	139	Croatia
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

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

60. Observation of the Establishment

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	05/09/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Gavrilovic d.o.o. Gavrilovicev trg 1 Petrinja Hrvatska	05/14/2019	399	Croatia
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	X
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Thermally Processed Commercially Sterile	X
58.	
59.	

60. Observation of the Establishment

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

16. Each entry of CCP 2, retort process schedule, monitoring records do not include the time the observation was made. Verification records do not include the date, time and result of the record review.

46. Upon entering tempering cooler 42a/ATA 1 a foul and overpowering odor was immediately noticeable throughout the cooler. At the time unwrapped meat was present in the cooler though not destined for production to the United States. Immediate actions were taken including preventing use of the cooler until the noncompliance is resolved.

57. The can codes on thermally processed commercially sterile products do not include the day and year of production.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	05/14/2019