USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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Washington, D.C.
20250

APR 12 2018

Dr. Gordan Jerbic
Acting Assistant Minister for Veterinary Issues
Ministry of Agriculture
Planinska ulica 2a, 10000 Zagreb
Croatia

Dear Dr. Jerbic,

The Food Safety and Inspection Service (FSIS) conducted an on-site ongoing equivalence verification audit of Croatia's processed pork products inspection system from September 18 through September 29, 2017. Enclosed is a copy of the final audit report, which will be published on the FSIS website. The comments received from the Government of Croatia are included as an attachment to the report.

In addition, FSIS acknowledges that the Veterinary and Food Safety Directorate (VFSD) has provided documentation to address the findings noted during the on-site audit. During the March 20, 2018 teleconference, VFSD committed to providing further information on its thermally processed/commercially sterile (TP/CS) food safety inspection system. VFSD needs to provide documentation describing the procedures and frequencies used by inspection personnel to verify that certified establishments measure and record the initial temperature of the contents of the coldest container at the start of each processing cycle when producing TP/CS meat products for export to the United States. We expect to receive this information by April 20, 2018. Once the requested information is received, we will complete our review of Croatia's submitted corrective actions and supporting documentation, and determine whether Croatia's pork products inspection system remains equivalent to that of the United States.

If you have any questions, please feel free to contact the Office of International Coordination at (202) 708-9543, or by electronic mail at internationalcoordination@fsis.usda.gov.

Sincerely,

Todd M. Furey
Acting International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN CROATIA

SEPTEMBER 18 - 29, 2017

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

April 12, 2018

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from September 18 to 29, 2017. The purpose of the audit was to determine whether Croatia's food safety system governing processed pork 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, commercially sterile pork products to the United States.

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

The FSIS auditor identified the following findings:

Government Oversight

- Croatia's use of contracted 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

- At one of 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 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 spp.,* 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.

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

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of Croatia's food safety system from September 18 to 29, 2017. The audit began on September 18, 2017, with an entrance meeting held in Zagreb, Croatia, during which the FSIS auditor discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA), the Ministry of Agriculture, Veterinary and Food Safety Directorate.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to verify whether the food safety system governing raw and processed pork maintains equivalence 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 thermally processed, commercially sterile (TPCS) pork products to the United States.

As of October 23, 2015, the USDA's Animal and Plant Health Inspection Service (APHIS) identified Croatia as free of foot-and-mouth disease, rinderpest, swine vesicular disease, and low risk for classical swine fever.

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) 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 a self-reporting process.

Representatives from the CCA accompanied the FSIS auditor throughout the entire audit. 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 Points (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

Administrative functions were reviewed at CCA headquarters, one branch office, 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 audited. During the audit at each of the establishments, the FSIS auditor paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that impact food safety. The FSIS auditor examined the CCA's ability to provide oversight through

supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems. These requirements are outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §327.2.

Additionally, FSIS audited the microbiological and chemical testing departments of a government laboratory to verify their ability to provide adequate technical support to the inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• Ministry of Agriculture, Veterinary and Food Safety Directorate, Zagreb
	Branch Office	1	• Veterinary and Food Safety Directorate Branch Office, Vrbovec
Laboratory		1	• The Croatian Veterinary Institute, Zagreb (Government laboratory) o Microbiology Department o Residue Department
Pork slaughter establishment		1	• Establishment 10, Pik Vrbovec Meat Industry d.d, Vrbovec
Pork processing establishments		2	• Establishment 139, Tvornica Danica, Koprivnica • Establishment 399, Gavrilovic d.o.o., Petrinja

The audit was undertaken to verify whether the country's food safety system was equivalent to FSIS's system in regards to specific provisions of United States' laws and regulations, in particular:

- The Federal Meat Inspection Act (FMIA) (21 United States Code [U.S.C.] 601, *et seq*.);
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. 1901, *et seq*.); and
- The Federal Meat Inspection Regulations for Imported Products (9 CFR Part 327).

The audit standards applied during the review of Croatia's inspection system for meat 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 Sanitary/Phytosanitary Agreement, and included the following:

- Regulation European Commission (EC) No. 142/2011;
- Regulation (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. 1069/2009;
- Regulation (EC) No. 1099/2009;
- Regulation (EC) No. 2073/2005;
- EC Directive No. 96/22/EC; and
- EC Directive No. 96/23/EC.

III. BACKGROUND

Croatia currently exports TPCS pork products to the United States. From June 2014 to May 2017, FSIS import inspectors performed 100 percent POE re-inspection for labeling and certification on 912,108 pounds of meat exported by Croatia to the United States. Of that amount, additional types of inspection (TOIs) were performed on 288,657 pounds, of which no product was rejected.

The previous FSIS audit (2014) identified systemic findings related to HACCP recordkeeping at all three audited establishments. This audit also identified isolated findings related to sanitation at two establishments (presence of condensation on overhead structures). Because the current audit included visits to many of the same facilities, the FSIS auditor was able to verify that proffered corrective actions to all previous findings had been adequately implemented and resolved.

The FSIS final audit reports for Croatia's food safety system are available on the FSIS Web site 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 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 evaluation of this component included a review and analysis of the information provided by the CCA in the updated self-reporting tool (SRT) and observations during the onsite audit.

The FSIS auditor verified that the Ministry of Agriculture (MA) has the overall responsibility for policy, legislation, and implementation of official controls in relation to food safety. In accordance with the current organization of the MA, the CCA is the Veterinary and Food Safety Directorate (VFSD). VFSD has the responsibility for carrying out Croatia's inspection program, including oversight and enforcement of regulatory requirements in meat producing establishments certified as eligible to export to the United States. The VFSD also has oversight of the residue and microbiology laboratories in which United States-eligible product is analyzed. VFSD has three organizational sectors: the Animal Health Protection Sector (AHPS), the Food Safety Sector (FSS), and the Inspection Supervision Sector (ISS). The current organizational structure represents a change from that observed during the previous FSIS audit, for which the previously independent sectors of International Trade and Veterinary Inspection are now incorporated under ISS.

AHPS responsibilities include developing policies and managing activities related to animal health surveillance and monitoring; control and eradication of animal diseases; contingency planning and crisis management; animal welfare; financing of measures on early detection and eradication of animal diseases; and identification of animals and registration of their movements.

FSS responsibilities include drafting legislation on hygiene requirements for food of animal origin and procedures on implementing legislation for food of animal origin, and keeping and updating registrations of establishments dealing with food of animal origin.

ISS is responsible for implementing and enforcing official controls on food safety issues and drafting the annual official control plan. ISS consists of 12 Regional Veterinary Inspection Departments (RVIDs) and 65 branch offices throughout the country. Heads of RVIDs supervise the regional senior veterinary inspectors (SVIs). The regional SVIs supervise and verify the performance of in-plant authorized veterinarians (AVs). The MA authorizes the implementation of specific food safety tasks to authorized veterinary organizations on a contract basis for a period of five years.

Within Croatia, the *Veterinary Act* (Official Governance [OG] 82/13, 148/13) outlines the specific conditions for the delegation of specific tasks to a contracted control body. While onsite, the FSIS auditor noted that specific tasks of the AVs assigned to establishments certified as eligible to export to the United States include ante-mortem and post-mortem inspection at slaughter establishments, as well as the authority to pass or condemn carcasses and parts; verification of the humane handling and slaughter of livestock; and verification of establishment's HACCP, sanitation, and other prerequisite programs at slaughter and processing establishments. The AVs are hired by the contracted control body and are not government employees. The *Ordinance on Fees and Charges Related to Official Controls of Food of Animal Origin and Foodstuffs* (OG 79/09) requires establishments to pay fees for official controls directly to the State budget. Remuneration for carrying out controls is then paid directly to the contracted control body from the State budget.

The CCA's regulatory oversight of its meat inspection system occurs on four organizational levels: central, regional, branch, and establishment. At the establishment level, the AVs enter the results of the daily inspection verification into the veterinary inspection application, VETI. The SVIs are responsible for remotely reviewing the contents of VETI with a minimum frequency of one review per month, and for conducting an onsite performance appraisal of the AVs with a minimum frequency of four reviews per year. The results of these SVI reviews are entered into the government's "e-inspector" application. In addition, SVIs are responsible for conducting periodic supervisory reviews in United States-certified establishments. At the regional level, the supervisory personnel review the function and performance of branch SVIs on an annual basis. At the central level, a senior veterinarian at the CCA's headquarters has access to all inspection data including the contents of VETI and "e-inspector*"* applications. The FSIS auditor identified the following finding:

- Croatia's use of contracted employees to conduct inspection (e.g., ante-mortem inspection, final carcass dispositions during post-mortem inspection, and sanitation and HACCP verification activities) during the production of product for export to the United States does not meet FSIS' statutory requirements that inspection be conducted by a government

inspector. These verification activities extend to both the slaughter of swine to produce source materials, as well as the production of processed products from source materials (e.g., TPCS product) intended for export to the United States.

The FSIS auditor noted that AVs were provided with CCA-approved written procedures, developed by the local contracted control body, to ensure that raw materials originate only from establishments certified to export to the United States. This was verifiable onsite by cross-referencing the export certificates with the bills of lading and additional certifications (e.g., health certificates, transfer certificates) that accompany each shipment of source materials.

The CCA ensures that its meat exports are not subject to animal health restrictions by regularly consulting the relevant sections of the APHIS Web site in addition to FSIS' product eligibility chart for individual countries, which also considers current APHIS restrictions. Lastly, the pre-printed export certificates issued by the CCA for a given country are species and commodity specific. 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.

Under the *Act on Official Controls Performed in Accordance with Food, Feed, Animal Health, and Animal Welfare Rules* (OG 81/13, 14/14), the MA is responsible for ensuring effective cooperation and coordination between the CCA and authorities on regional or local levels. The FSIS auditor noted that VFSD ensures regular communication of United States import requirements to its relevant stakeholders, which includes both SVIs and contracted control bodies.

Regulation (EC) No. 882/2004, Article 4, requires the CCA to have an inspection system that is organized and staffed so as to ensure uniform enforcement of the laws and regulations governing meat inspection in all certified establishments and an ongoing plan to continuously analyze and implement staffing requirements. Article 78 of the *Food Act* ensures funds are secured in the State budget to provide for the necessary number of staff performing official controls and to cover all the costs for the implementation of such controls. While onsite, the FSIS auditor observed that the contracted control body overseeing the activities of the certified swine slaughter establishment developed a CCA-approved written staffing protocol for conducting post-mortem inspection *(Postupakza Dostatnost Osoblja Kontrolnog Tijela)* based on the number of hogs and weight of the animals, and included a provision for the rotation of inspection personnel. The FSIS auditor also noted that the current line speed at this facility (approximately 120 carcasses/hour) complied with the established protocol, as well as the regulatory requirements for a two-inspector configuration outlined in 9 CFR 310.1.

The FSIS auditor verified the CCA's adherence to Annex I, Chapter 3, of Regulation (EC) No. 854/2004, whereby VFSD is required to ensure that SVIs (i.e., government officials) receive the appropriate training to undertake their duties competently and to carry out official controls in a consistent manner. In accordance with Croatia's *Veterinary Act,* Article 125, a veterinary inspector must meet both the requirements stipulated for civil servants and the following additional conditions: a university degree in veterinary medicine; passed the state examination for the occupation of veterinary inspector (i.e., official veterinarian); and at least five years of service in the profession.

The FSIS auditor reviewed the procedures of appointment of a sample of inspection personnel assigned to branch inspection offices and determined that the CCA followed the applicable national and European Union (EU) regulations in the recruitment procedure. The FSIS auditor also noted that the CCA provided the following training to its SVIs and contracted control body AVs since the last FSIS audit: ante-mortem and post-mortem inspection of cattle and pigs, 2016, and ante-mortem and post-mortem inspection of cattle and pigs, 2017.

The FSIS auditor noted that each audited certified establishment maintained comprehensive recall procedures and maintained records sufficient to conduct trace-back activities if adulterated product were exported to the United States. No such recalls have occurred in recent history regarding product from Croatia.

The CCA provides oversight for the government and private laboratory systems. All authorized official and reference laboratories are accredited according to International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025:2007, *General requirements for the competence of testing and calibration laboratories*, in accordance with Article 12 of Regulation (EC) No. 882/2004. Official samples are tested exclusively in laboratories that comply with Article 12 of Regulation (EC) No. 882/2004. Within Croatia, 38 laboratories are authorized for the purposes of official controls and there are 5 reference laboratories.

The approval process for the analytical methods is completed through regular assessment of the management system (audits of internal and external assessors) in accordance with ISO/IEC 17025:2007, required validation and verification procedures, and regular participation in proficiency testing for each method and/or substance. Laboratories are required to submit relevant documentation to MA (including methods they use for testing) proscribed by the legislation.

All the official laboratories have valid accreditation according to the ISO/IEC 17025:2007, issued by the Croatian *(Hrvatski)* Accreditation Agency (HAA), which is an independent public institution that acts as the national accreditation service. Every year HAA conducts regular supervision of accredited methods, and every five years the CCA conducts re-accreditation of the laboratory. According to the annual audit plan of the Veterinary Inspection Service, control of official and reference laboratories is scheduled once per year. There is an approval process for the analytical methods through regular assessment of the management system (audits of internal and external assessors) in accordance with ISO/IEC 17025:2007, required validation and verification procedures, and regular participation in proficiency testing for each method and/or substance. The FSIS auditor confirmed that both the HAA and CCA audits were conducted at the intended frequency and any identified non-conformities were appropriately addressed.

While the CCA maintains many of the administrative and technical elements to operate its inspection system, the use of contracted employees to conduct ante-mortem inspection, final carcass dispositions during post-mortem inspection, and sanitation and HACCP verification activities during periods when establishments are producing products for the United States does not meet FSIS' statutory requirements that these activities be conducted by a government

inspector. Furthermore, FSIS does not consider the current level of oversight provided by the SVIs to the contracted control body AVs conducting post-mortem inspection sufficient, as it is expected that these non-government individuals be under the supervision of a government veterinarian that is physically present in the establishment whenever slaughter of livestock for use in processed product intended for export to the United States occurs.

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 carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; daily inspection; at least once per shift for processing operations; periodic supervisory visits to official establishments; and requirements for TPCS products.

The *Veterinary Act* requires that only veterinarians conduct ante-mortem inspection. During the onsite audit of a porcine slaughter and processing establishment, the FSIS auditor verified that AVs conducted ante-mortem inspection on the day of slaughter by reviewing the incoming registrations and identification documents. AVs observed all animals from both sides at rest and in motion in designated holding pens prior to slaughter in order to determine whether they were fit for slaughter and for human food purposes. A designated holding pen for suspect animals was present in the audited establishment for further examination of these animals, as needed. The FSIS auditor verified that implementation of the ante-mortem inspection and the humane handling of animals is meeting Regulation (EC) No. 854/2004; Regulation (EC) No. 1099/2009, *Protection of Animals at the Time of Killing*; and the CCA's *Law on Veterinary Activities, Animal Welfare, and Protection Act* .

The *Veterinary Act* also requires that only veterinarians conduct post-mortem inspection. The FSIS auditor assessed post-mortem inspection examinations through onsite record reviews, interviews, and observations of veterinarians performing continuous post-mortem examinations in the audited porcine slaughter establishment. The FSIS auditor observed the performance of the AVs as they examined the heads, viscera, and carcasses to ensure that the proper incision, observation, and palpation of required organs and lymph nodes is conducted in accordance with Regulation (EC) No. 854/2004 requirements.

The FSIS auditor also reviewed the AVs' documentation supporting daily presence at least once per shift at processing establishments and daily on the line at slaughter establishments. Documented verification procedures included direct observation and review of establishment records of establishment activities, including HACCP, Sanitation Standard Operating Procedures (SSOP), Sanitation Performance Standards (SPS), and microbiological sampling programs. Inspection records are standardized through the "e-inspector*"* application and implemented in all United States-certified establishments intending to export to the United States. This intranet

application is available for review and verification by the inspection officials at the CCA, regional, and branch levels.

During the onsite audit of three United States-certified establishments, the FSIS auditor observed the SVIs responsible for conducting the periodic (quarterly) supervisory reviews. During these reviews, the inspection personnel verified the requirements for ante-mortem inspection; humane handling and slaughter requirements; post-mortem inspection; *Salmonella* and generic *Escherichia coli (E. coli)* sample collection; verification of pre-operational and operational sanitation monitoring procedures; and HACCP verification activities, including the zero tolerance critical control point (CCP) verification in the slaughter establishment. These reviews were recorded on a standard form that includes a follow-up section regarding the previous supervisory review findings. While the FSIS auditor's evaluation of previous reports indicated that these reviews were performed as intended, it is important to note that the deficiency identified under this component (below), as well as the deficiency outlined under the Government HACCP System component, should have been identified during prior supervisory reviews.

The control of condemned materials is accomplished through application of Regulation (EC) Nos. 1069/2009 and 142/2011. During the audit, FSIS verified that the relevant portions of this regulation were applied, including: (1) appropriate identification in accordance with the categories described therein; (2) segregation in specially-marked or otherwise secure containers; and (3) final documented disposal of these materials at nearby rendering facilities.

The FSIS audit included two establishments producing TPCS products. Within Croatia, establishments producing TPCS products are required to address the hazards using HACCP principles according to Regulation (EC) No. 852/2004, Article 5. In addition, Regulation (EC) No. 852/2004, Annex 2, Chapter XI, outlines requirements applying to food placed on the market in hermetically sealed containers by stating that the heat treatment process used to process an unprocessed product or to process further a processed product is: (1) to raise every part of the product treated to a given temperature for a given period of time; and (2) to prevent the product from becoming contaminated during the process. Furthermore, the FSIS auditor noted that the contracted control body for these establishments had developed CCA-approved written verification procedures based on 9 CFR 318.300, Subpart G, Canning and Canned Products.

Specific onsite verification activities conducted by the FSIS auditor related to Croatia's adherence to Regulation (EC) No. 852/2004, Annex 2, Chapter XI and the CCA verification requirements included the review of process schedules for products exported 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. The onsite audit identified the following finding:

- At one of two processing facilities, the initial temperature of the contents of the coldest container to be processed was not being recorded by the establishment at the start of each processing cycle. Rather, the establishment was recording initial temperatures on a monthly basis as part of process verification procedures. While the FSIS auditor's review of the monthly monitoring indicated that the establishment's production process typically achieved

the initial temperatures specified in the process schedule, failure to record initial temperatures for each processing cycle does not meet the regulatory requirements of 9 CFR 318.304 (c).

While the CCA maintains the statutory authority to implement the core requirements for this component, the FSIS auditor identified an inadequate verification of requirements for TPCS product at one of two audited canning facilities.

VI. COMPONENT THREE: GOVERNMENT SANITATION

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

The FSIS auditor verified that within Croatia's inspection system, the principal documents outlining the sanitation requirements for establishments certified to export to the United States include:

- Regulation (EC) No. 852/2004, Annexes II and III: stipulate that food premises are to be kept clean and maintained in good repair and condition. The layout, design, and construction of the establishment facilities must permit adequate maintenance to prevent conditions that can lead to insanitary conditions. Equipment and utensils must be maintained in a sanitary manner.
- Regulation (EC) No. 853/2004 Chapter II, Section I, Annex III: outlines specific requirements for food business operators to ensure that the construction, layout, and equipment of slaughterhouses prevent the contamination or adulteration of meat.
- Croatia's *Ordinance on the Hygiene of Foodstuffs, Annex II, General Hygiene Requirements for all Food Business Operators,* contains provisions that are consistent with the above EC regulations, as well as, SPS of 9 CFR 416.1-416.6, to ensure that each certified establishment develops, implements, and maintains daily pre-operational and operational sanitation procedures sufficient to prevent the direct contamination or adulteration of meat products.

In accordance with these requirements, the CCA has provided the contracted control body with a checklist of controls to verify (and document) that certified establishments are complying with sanitation requirements.

The FSIS auditor observed in-plant inspection verification of operational sanitation procedures at all audited establishments. Pre-operational verification activities were also observed at one location. Additional audit evidence was gathered through direct observation of establishment operations and a review of the establishments' associated records. The establishment employees responsible for the implementation and monitoring of the SSOP properly authenticated these records with initials or signatures and the date. The audited establishments maintained sanitation records sufficient to document the implementation and monitoring of the SPS and SSOP and any corrective actions taken. For the most part, the FSIS auditor noted that the AV and establishment records mirrored the actual sanitary conditions of the establishment, although the FSIS auditor identified isolated non-compliances at two of the three audited establishments. These isolated

non-compliances are noted on the individual establishment checklists attached to this report (Appendix A).

The FSIS auditor concluded that the CCA requires certified establishments to develop, implement, and maintain sanitation programs consistent with 9 CFR Part 416 to ensure that the establishment's construction, facilities, and equipment prevent the contamination or adulteration of meat products destined for United States export.

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

The fourth of six equivalence components that the FSIS auditor reviewed was Government HACCP System. The inspection system is to require that each official establishment develop, implement, and maintain a HACCP system.

Without prejudice to the relevant EC regulations for HACCP, the CCA has instructed establishments certified to export to the United States to comply with the requirements outlined in 9 CFR Part 417. Croatia's Ordinance on the Hygiene of Foodstuffs, Chapter 1, Article 1, and Chapter 2, Article 5 set forth requirements for Hazard Analysis Critical Control Point System (HACCP). National Ordinance on rules for implementing HACCP system (Official Gazette No. 68/2015), Articles 1, 3-6, 11, 15-17, and 19, 20-27. This ordinance stipulates the detailed rules for the establishment implementation and maintenance of the system and procedures based on HACCP principles. In order to provide support to its supervisory inspection personnel and AVs, Croatia has developed and implemented checklist official controls to verify whether certified establishments are complying with SSOP and HACCP requirements of 9 CFR 417.

The FSIS auditor visited one swine slaughter establishment and two establishments producing TPCS products to determine whether the CCA maintains adequate government oversight for the implementation of HACCP requirements. The FSIS auditor also assessed the adequacy of HACCP program verification activities conducted by the AVs and establishment management at all three audited establishments.

The FSIS auditor verified through record reviews and observations that the AVs at United States-certified establishments properly conduct daily verification of HACCP plans in accordance with Croatia's requirements, which include the evaluation of written HACCP programs, monitoring, verification, corrective actions, recordkeeping, and hands-on verification inspection. The in-plant daily verification also includes CCP verification with results entered into the VETI system. As indicated previously, the systemic finding related to HACCP recordkeeping (e.g., initialing of records) identified during the previous FSIS audit (2014) had been adequately addressed.

The FSIS auditor verified that the TPCS establishments had implemented a HACCP system including a CCP for a validated thermal process to meet applicable food safety and commercial sterility requirements. This included critical limits for time and temperature, in addition to applicable supporting documentation demonstrating that the minimum F_3 level of sterilization was applied for food safety purposes (i.e., destruction of *Clostridium botulinum* spores), as required by Croatia's Ordinance on Meat Products, OG 131/2012. The FSIS auditor noted that

the establishment management maintains sufficient documentation to demonstrate that commercial sterility was achieved through its implemented cooking schedules and product storage conditions.

The FSIS auditor conducted an onsite observation and review of the zero tolerance (feces, ingesta, and milk) control records generated over the past 12 months in the audited porcine slaughter establishment. The FSIS auditor reviewed the AV's associated zero tolerance verification records, for which no deviations from the critical limits were identified. The FSIS auditor also verified the physical CCP location by observing the AV conducting HACCP hands-on verification activities. The onsite audit identified the following finding concerning enforcement of HACCP requirements:

- 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. This does not meet the regulatory requirements of 9 CFR 417.2 (c) (5).

During the exit meeting, the CCA presented evidence that it had taken immediate measures to resolve the noncompliance identified at the above-referenced locations, including issuance of noncompliance reports and verification that the local control body had modified their HACCP programs accordingly. The audit results show that the CCA verifies that operators of official establishments implement the CCA's requirement to develop, implement, and maintain HACCP programs for each processing category.

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 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.

Prior to the onsite visit, FSIS' residue experts thoroughly reviewed Croatia's National Residue Monitoring Plan (NRMP) for 2017 (and 2015-2016 results), 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 since the FSIS audit in 2014.

The NRMP covers animal species slaughtered for the production of meat for domestic and international markets. In accordance with EC Directive 96/23, *Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products,* the design of the sampling protocols has taken the following into consideration: the registered use of a chemical compound of interest; the likelihood of a residue occurring in animal tissues; the extent and pattern of use of the compound; incentives for misuse; known persistence of the compound in the environment; past monitoring results; and requirements of importing countries.

FSIS' review of non-compliant results for 2015-2016 identified the following instances where maximum residue levels (MRLs) were exceeded in swine slaughtered in Croatia.

Residue Group	Farm		Slaughterhouse	
	Total samples	Non-compliant	Total samples	Non-compliant
Resorcyclic acid lactones (A4)	1	0	42	0
Beta Zearalanol (Taleranol)	0	0	42	1
Zearalanone	0	0	42	4
Other substances and environmental contaminants (B3)	0	0	73	0
Mycotoxins (B3d)	0	0	42	0
Zearalenol-alpha	0	0	42	12
Zearalenol-beta	0	0	42	9
Zearalenone (Mycotoxin F)(ZON)	0	0	42	9

While onsite, the FSIS auditor was able to verify that the appropriate follow-up procedures were conducted in all instances. This included an assessment of the CCA's ability to differentiate between the use of Zeranol (ZER), a veterinary drug, and zearalenone (ZON), a mycotoxin originating from different species of *Fusarium* molds. The CCA's investigation indicated that, in all cases, the non-compliant results were linked to contamination of feed (ZON), rather than abuse of ZER. Furthermore, the FSIS auditor noted that no product originating from these swine was exported to the United States.

A review of the sampling records maintained at the local inspection office of the audited slaughter establishment indicated that the 2017 sampling program was being adhered to as scheduled. Monitoring residue samples are collected by the AVs and are shipped under inspection seal. During the evaluation of ante-mortem inspection at the porcine slaughter facility, the FSIS auditor observed that the AVs verify that all lots of animals are accompanied by documentation that discloses their origin and includes a signed declaration that attests that owners have adhered to veterinary pharmaceutical withdrawal periods.

The FSIS auditor conducted an onsite audit of the Veterinary Institute (Zagreb), the national reference laboratory for microbiological and residue testing in Croatia. This laboratory is accredited to the ISO/IEC 17025:2007 standard by HAA. The FSIS auditor verified the review of the HAA Accreditation Certificate and Scope of Accreditation issued to the laboratory in September 2016. The FSIS auditor's review of the internal standard operating procedures and onsite observations verified that sampling procedures, quality assurance procedures, calibration and temperature recording, and intra-laboratory check samples for this laboratory are being properly implemented and recorded. Analytical procedures used by the laboratory were consistent with those reported in the NRMP. This laboratory was also conducting species verification testing with a frequency of one test per each shipment to the United States in accordance with the CCA's requirements.

The result of the onsite audit activities indicate that Croatia continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in meat products destined for human consumption.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components that the FSIS auditor reviewed was Government Microbiological Testing Programs. The system is to implement certain sampling and testing programs to ensure that meat products produced for export to the United States are safe and wholesome.

The evaluation of this component included an analysis of information provided by the CCA in the SRT and accompanying documents, as well as interviews and observations made during the onsite equivalence verification audit. There have not been any POE violations related to this component since the last FSIS audit (2014). The CCA has microbiological testing programs for generic *E. coli* and *Salmonella* in raw products.

The CCA has established process control criteria that are consistent with those listed in 9 CFR Part 310.25(a) in order to verify process control for generic *E. coli* in raw products. The FSIS auditor verified the microbiological sampling and testing program through document reviews at the branch office and in one audited slaughter establishment. The FSIS auditor reviewed the establishment's written program and confirmed that the AVs and official veterinarians (during supervisory reviews) verify that the audited United States-certified slaughter establishment complies with the CCA's regulatory requirements about generic *E. coli* criteria including sampling frequency, technique, and methodology; maintaining records of analytical results; and sampling requirements. The FSIS auditor's review of the establishment program and inspection personnel records identified no concerns.

The FSIS auditor reviewed the CCA's *Salmonella* sampling and testing program, which is consistent with 9 CFR Part 310.25(b). The FSIS auditor verified that the implementation of the program in the audited slaughter establishment is meeting the CCA's requirements. Establishment employees collect the carcass samples for *Salmonella* testing in the presence of the AV, and samples are sent under official seal to government laboratories. The FSIS auditor noted that test results were consistently entered into an electronic database, and available for analysis by the CCA and the local control body. There have not been any *Salmonella* set failures since the last FSIS audit (2014).

During the audit of Croatia's Veterinary Institute, FSIS reviewed official reports of laboratory audits conducted by the CCA and HAA, documentation of analysts' proficiency evaluations, and records of evaluations of corrective actions taken in response to audit findings. The FSIS auditor also verified that the laboratory maintained appropriate discard criteria to ensure the integrity of the sample and testing results. This included written standard operating procedures to ensure that samples arrive under government seal within specified timeframes and required

temperatures, as well as outlining specific follow-up activities to be undertaken when these requirements are not met. The onsite audit identified the following finding:

- The FSIS auditor noted that this laboratory was currently using the ISO 6579, Microbiology of the food chain -- Horizontal method for the detection, enumeration and serotyping of Salmonella -- Part 1: Detection of Salmonella spp., method for the testing of swine carcasses for Salmonella intended for export to the United States. FSIS currently uses the Microbiology Laboratory Guidebook (MLG) 4.09 method and does not have an individual sanitary measure (ISM) on file permitting the use of an alternative method for Salmonella analysis by Croatia. Consequently, FSIS requires that VFSD employ the MLG method for microbiological analysis until the alternative method (ISO 6579) has been submitted for equivalence review and approved.

The products presently exported to the United States are TPCS products, not exposed to the environment after heat treatment. Therefore, FSIS does not require testing for *Listeria monocytogenes* or *Salmonella* for this type of product.

FSIS concludes that Croatia's inspection system continues to meet the core requirements for this component. However, it is important that CCA ensure that all alternative microbiological methods are submitted to FSIS for equivalence review.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on September 29, 2017, in Zagreb, Croatia, with VFSD. At this meeting, the FSIS auditor presented preliminary findings from the audit.

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

Government Oversight

- Croatia's use of contracted 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

- At one of 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 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 spp., 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.

During the audit exit meeting, the CCA committed to addressing the preliminary findings as presented and provided additional evidence that the isolated findings related to sanitation described on the individual establishment checklists (Appendix A) had been addressed. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklist

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	09/21/2017	10	Croatia
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
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.	X
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	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

The following non-compliances were neither identified by veterinarians authorized to conduct inspection activities at this facility, nor during periodic supervisory reviews conducted by Croatian inspection officials:

20/51. The corrective actions outlined in the establishment's HACCP plan did not specify that *measures to prevent recurrence* needed to be established for each instance that a deviation from a critical limit occurred.

46/51. Blocked floor drains in the carcass de-hairing area resulted in the pooling of blood and water and the creation of insanitary conditions for employees and equipment transiting this zone. The blockage resulted from a build-up of fat, hair, and other debris which was not removed at sufficient frequency to permit drainage of blood and water from this area.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/21/2017

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	09/20/2017	139	Croatia
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
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.	X
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. Enforcement	X
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. Monthly Review	
58.	
59.	

60. Observation of the Establishment

The following non-compliance was neither identified by veterinarians authorized to conduct inspection activities at this facility, nor during periodic supervisory reviews conducted by Croatian inspection officials:

20/51. The corrective actions outlined in the establishment's HACCP plan did not specify that *measures to prevent recurrence* needed to be established for each instance that a deviation from a critical limit occurred.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/20/2017

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	09/26/2017	399	Croatia
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The following non-compliances were neither identified by veterinarians authorized to conduct inspection activities at this facility, nor during periodic supervisory reviews conducted by Croatian inspection officials:

10/51. The FSIS auditor identified meat residue from the previous day's operation in the stainless steel tubes of a meat extruder used in the production canned product during a review of hands-on preoperational sanitation verification procedures.

46/51. The FSIS auditor identified the following non-compliances related to enforcement of sanitary performance standards (SPS):

- A white trash barrel located near a hand-wash sink did not bear conspicuous and distinctive marking sufficient to distinguish it from other similar containers used to store product ingredients (spices) in this area (pork chopping and mixing room).
- The drain of a production area sink was broken and water was draining directly on the floor.
- The wall panels of a production cooler presented numerous areas with a yellowish, sticky residue (attributed to protective tape used during the installation process) which would render them difficult to clean.

58/51. The initial temperature of the contents of the coldest container was not being recorded by the establishment at the time each processing cycle begins to assure that the temperature of the contents of every container to be processed is not lower than the minimum initial temperature specified in the process schedule. Rather, the establishment was recording initial temperatures on a monthly basis. While the FSIS auditor's review of the monthly initial temperature monitoring indicated that the establishment's production process typically achieved the initial temperatures outlined in the process schedule, failure to record initial temperatures for each processing cycle does not meet the regulatory requirements of 9 CFR 318.304 (c).

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/26/2017

Appendix B: Foreign Country Response to Draft Final Audit Report

REPUBLIC OF CROATIA
MINISTRY OF AGRICULTURE

10000 Zagreb, Ul. grada Vukovara 78, P.P. 1034
Phone: (+385 1) 61 06 111, Fax: (+385 1) 61 09 201

P / 7274320

CLASS: 322-07/17-01/2853
RegNo: 525-10/0600-18-7
Zagreb, March 22, 2018

Mary H. Stanley
Acting International Coordination Executive
Office of International Coordination
Food Safety and Inspection Service
1400 Independence Ave., SW
Washington, D.C. 20250

Subject: Reply to the Draft final report of the FSIS audit conducted in Croatia, September 18 - 29, 2017

Dear Dr. Stanley,

Thank you very much for the opportunity to respond to the Draft final audit report from January 24, 2018. Veterinary and Food Safety Directorate (VFSD) would like to present our response within this letter. FSIS draft final audit report from January 24, 2018 is related to the on-site equivalence verification audit of Croatia's inspection system governing raw and thermally processed/commercially sterile (TP/CS) pork products carried out by the USDA/FSIS in the Republic of Croatia from September 18 - 29, 2017. The audit was performed by Dr. Alexander Lauro, Senior International Program Auditor who officially verified Croatia's veterinary meat inspection system.

1. Regarding identified findings in component one: Government oversight (e.g., organization and administration) - "Croatia's use of contracted employees to conduct verification activities during periods when establishments are producing products for the United States does not meet FSIS' statutory requirements"

Our comments are as follows:

Competent Authority, Veterinary and Food Safety Directorate following the on-site equivalence verification audit received by mail a 30 day letter on October 3, 2017., and replied on document CLASS: 322-07/17-01/4122, File No: 525-10/0600-17-3 from October 31, 2017., and Minister's Decision, CLASS: 322-07/17-01/4122, FileNo: 525-10/0600-17-2 from October 23, 2017.

Veterinary and Food Safety Directorate designated veterinary inspectors who are employees of the Ministry of the Agriculture and eligible to perform inspection tasks to perform on-site supervision of authorized veterinarians during the slaughter of source materials for use in processed products (e.g., thermally processed product) as well as during the production of processed products (e.g., thermally processed product) intended for export to the United States. Thus, authorized veterinarians (AVs), conducting ante and post-mortem inspection, as well as official controls during production are now under direct and on-site supervision by the government veterinary inspectors.

Please find the documents enclosed:

- Senior veterinary inspector designation,
- Minister's Decision (signed and unofficial translation)

2. Regarding identified deficiencies in component two: Government Statutory Authority and Food Safety and Other Consumer Protection Regulations: "At one of 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".

Our comments are as follows:

Senior veterinary inspector made a record on September 26, 2017 listing all related noncompliance. Regarding these findings a decision was issued to the FBO on the same date to rectify non-compliances listed in the decision with the deadlines for correction. Follow up record was made on November 10, 2017 with a finding that the non-compliances are corrected. HACCP plans was revised, detailed corrective measures were taken in case of discrepancies at critical control points and measurement and evaluation of initial temperature of the coldest container is performed prior to thermal treatment.

Please find the documents enclosed:

- A record on September 26, 2017,
- A decision on September 26, 2017,
- Follow up record on November 10, 2017,
- HACCP Plan rev. 17,
- Corrective actions RU RPPR-01,
- Initial temperature RU RPPR-06,
- Records of initial temperature,
- Education record.

3. Regarding identified deficiencies in component three: Government 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"

Our comments are as follows:

In the slaughterhouse, Senior veterinary inspector made a record on September 21, 2017 and noted all related non-compliances. Regarding these findings a decision was issued to the FBO on September 27, 2017 to rectify non-compliances listed in the decision with the deadlines for correction. Follow up record was made on October 23, 2017 with the findings that the non-compliances are corrected. The HACCP plan was revised by introducing the provisions of the FSIS Directive, CFR 417.3 in the section related to implementing corrective measures.

Please find the documents enclosed:

- A record on September 21, 2017,
- A decision on September 27, 2017,
- Follow up record on October 23, 2017,
- Corrective measures rev. 7 on 11.10.2017.

Based on the findings in the establishment for thermally processed/commercially sterile meat products, Senior veterinary inspector issued a decision to the FBO on 22 September 2017 to rectify non-

compliances with the deadlines for correction. These were related to the revision of the HACCP Plan and implementation of corrective measures for prevention of repetition of the same non-compliance - relevant provisions of the FSIS Directive, CFR 417.3. Following the decision, the establishment carried out the revision of the HACCP plan and more detailed corrective measures were planned for possible occurrence of deviation at the critical control points (CCP).

Please find the documents enclosed:

- A decision on September 22, 2017,
- Follow up record on October 23, 2017,
- Revised corrective measures and procedure in case of deviation to CCP and CP, HACCP Study Pâté, HACCP Study Meat Loaf, Work instructions: Corrective measures and handling in case of deviation from CCP and CP points, Form: Corrective measures on CCP and CP points.

4. Regarding identified deficiencies in component four: 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 spp., 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".

Our comments are as follows:

Concerning the USDA / FSIS Approach MLG 4.09 Compliant with the Reference Method ISO 6579-1: 2017 of Commission Regulation (EC) No. 2073/2005, intended to prove the genus *Salmonella*, VFSD would like to clarify that both methods are based on the same principles. For the purpose of showing equivalence or differences, please find below a tables showing the excerpt from the standard with the list of microbiological bases specified in the methods and a conclusion with references that are in favor of our position.

In addition to the statement above, VFSD has so far taken into account the Conference call with Croatian Officials from March 18, 1999 and Draft final report from the Audit taken in Croatia from 15 to 19 November 1999., in which, as we understand, Croatia´s microbiological testing for Salmonella is rated satisfactory. We hope that this document can be found in the USDA/FSIS archive.

Please find the document enclosed:

- The letter from Croatian Veterinary Institute.

VFSD would like to thank FSIS for all comments provided, as well as for an open professional cooperation extended by Dr. Lauro during the audit.

Sincerely yours,

State Secretary

Željko Kraljičak, PhD

Cc:
1. United States Embassy,
Agricultural Specialist: Ms. Andreja Misir
Thomas Jefferson st. 2, 10 010 Zagreb, Croatia

REPUBLIC OF CROATIA
MINISTRY OF AGRICULTURE

10000 Zagreb, Ul. grada Vukovara 78, P.P. 1034
Phone: (+385 1) 61 06 111, Fax: (+385 1) 61 09 201

P / 7 1 4 8 7 6 1

Class: 322-07/17-01/4122
File No: 525-10/0600-17-3
Zagreb, October 31, 2017.

Mary H. Stanley
Acting International Coordination Executive
Office of International Coordination
Food Safety and Inspection Service
1400 Independence Avenue, SW.
Washington, D.C. 20250

Subject: Reply by the competent authority of the Republic of Croatia to the 30 day letter received by mail on October 3, 2017.

Dear Mrs. Stanley,

Referring to your letter of 3 October, 2017, whereas you request that Croatia submits documentation to FSIS which demonstrates that its meat inspection system meets FSIS's statutory requirements, namely that inspection of meat be conducted by government inspectors during the production of product for export to the United States, I would like to inform you on the activities taken to rectify this issue:

Veterinary and Food Safety Directorate (VFSD) has, by Minister's Decision, CLASS: 322-07/17-01/4122, FileNo: 525-10/0600-17-2 since October 23, 2017 designated veterinary inspectors who are employees of the Ministry of the Agriculture and eligible to perform inspection tasks **to perform on-site supervision** of authorized veterinarians during the slaughter of source materials for use in processed product (e.g., thermally processed product) as well as during the production of processed products (e.g., thermally processed product) intended for export to the United States as follows:

1. PIK VRBOVEC MI d.d. Zagrebačka 148, 10340 Vrbovec, est. N° HR 10 EU: Senior veterinary inspector Ivica Mikec, DVM and Senior veterinary inspector Ivan Geceg, DVM,
2. Danica d.o.o., Đelekovečka cesta 21, 48000 Koprivnica, est. N° HR 139 EU: Senior veterinary inspector Branimir Komljenović, DVM and Senior veterinary inspector MSc Josip Bunta, DVM,
3. GAVRILOVIĆ d.o.o. Gavrilovićev trg 1, 44250 Petrinja est. N° HR 399 EU: Senior veterinary inspector MSc. Zvonimir Dumbović, DVM and Senior veterinary inspector Vesna Rukavina, DVM.

Government inspectors are obligated to perform on-site supervisory veterinarian (livestock) making final carcass dispositions at Croatian slaughter establishment, as well as all the routine verification inspection

activities, such as verification on ante-mortem inspection, post-mortem inspection and sanitation and Hazard Analysis and Critical Control Point (HACCP) verification activities at certified Croatian establishments.

In your letter dated October 3, 2017 you gave to the Republic of Croatia 30 days to appoint government inspectors referring to FMIA (21 U.S.C. 603 (a)), which requires that inspection of meat be conducted by government inspectors and FMIA (21 U.S.C. 608), which requires that sanitary inspection be conducted by government inspectors. Thus, Republic of Croatia, by this appointment of government inspectors, fulfilled the requirements that requires inspection activities to be performed by government inspectors during the slaughter of source materials for use in processed product (e.g., thermally processed product) as well as during the production of processed products (e.g., thermally processed product) intended for export to the United States.

By implementing above listed measures, the Republic of Croatia holds that our inspection system operators would fall under this category and therefore be deemed equivalent to a government inspector.

If you have any additional questions or would like to further discuss our reply, please feel free to contact me by e-mail at damir.agicic@mps.hr or directly by telephone at +38516443540.

Sincerely,

Damir Agičić, DVM
Assistant to the Minister, CVO

P/7147514

KLASA: 322-07/17-01/4122
URBROJ: 525-10/0600-17-2
Zagreb, 23. listopada 2017.

Based on Article 39. of the State Administration System Act (Official Gazette, No. 150/11), Article 44, paragraph 4 of the Collective Agreement for Civil Servants and Employees (Official Gazette No. 104/13) and Article 9. paragraph 3. of the Ordinance on the internal order of the Ministry of Agriculture (CLASS: 011-01 / 17-01 / 23, FILENO: 525-05 / 1569-17-6 from July 11, 2017), the Minister of Agriculture issues

DECISION

on oversight of facilities approved for export to the United States

I

For the purpose of carrying out inspections in accordance with the requirements of the importing country regulations in facilities approved for export to the United States, the following Officials are defined:

1. For the establishment PIK VRBOVEC MI d.d. Vrbovec, Zagrebačka 148, 10340 Vrbovec, est. No HR 10 EU: Senior Veterinary Inspector Ivica Mikec DVM, and Senior Veterinary Inspector Ivan Geceg DVM.

2. For the establishment Danica d.o.o., Đelekovečka cesta 21, 48000 Koprivnica, est. No HR 139 EU: Senior Veterinary Inspector Branimir Komljenović DVM, and Senior Veterinary Inspector Josip Bunta Ms DVM. i

3. For the establishment GAVRILOVIĆ Prva tvornica salame, sušena mesa i masti Mate Gavrilovića Gavrilovićev trg 1, 44250 Petrinja est. No HR 399 EU: Senior Veterinary Inspector Zvonimir Dumbović Ms DVM, and Senior Veterinary Inspector Vesna Rukavina DVM.

II

Officials referred to the point I of this Decision are obliged to carry out on-site inspections of ante mortem and post mortem inspection in the slaughter process, sanitation, hazard analysis and critical control points (HACCP) as well as during the production of processed products in facilities approved for export to the United States. Officials referred to the point I of this Decision are competent and authorized to make the final decision on the conformity of raw materials and processed products intended for export to the United States.

III

Personal Veterinary inspector's control plan for the Facilities Approved for Export to the United States in accordance with the requirements in force in the importing country, Officials from point I shall make up for each subsequent year. The records about time conducted on on-site inspection in facilities approved for export to the United States shall be issued by the Officials referred to in paragraph 1 of this Decision run independently on its own and they are approved by the Assistant Minister for Veterinary and Food Safety Directorate.

IV

Officials referred to item I of this Decision, the Ministry of Agriculture shall pay the overtime allowance paid during the on-the-spot inspection in facilities approved for export to the United States in accordance with the provisions of the Collective Agreement for Civil Servants and Employees (Official Gazette, No. 104 / 13, 123/2016).

V

This Decision shall enter into force on the date of issuing.

MINISTAR POLJOPRIVREDE

Tomislav Tolušić, dipl. iur.

Deliver to:

1. Designated Officials,
2. Heads of Local Department - Veterinary Offices,
3. PIK VRBOVEC MI d.d. Vrbovec, Zagrebačka 148, 10340 Vrbovec, est. No HR 10 EU,
4. Danica d.o.o., Đelekovačka cesta 21, 48000 Koprivnica, est. No HR 139 EU,
5. GAVRILOVIĆ Prva tvornica salame, sušena mesa i masti Mate Gavrilovića Gavrilovićev trg 1, 44250 Petrinja, est. No HR 399 EU,
6. Control body V. S. Petrinja d.o.o., Gajeva 40a, 44250 Petrinja,
7. V. S. Vrbovec d.o.o., Kolodvorska 68, 10340 Vrbovec,
8. V. S. Koprivnica, M. P. Miškine 66, 48000 Koprivnica,
9. Archive.

HRVATSKI VETERINARSKI INSTITUT
10000 ZAGREB, Savska cesta 143, P.P. 883
Telefon 01/6123-666, Telefax 01/6190-841
www.veinst.hr

Odjel za veterinarsko javno zdravstvo

Laboratorij za mikrobiologiju hrane

Poštovani

Frane Rupčić, dr. med. vet.
Viši veterinarski inspektor
Ministarstvo poljoprivrede
Uprava za veterinarstvo i sigurnost hrane
Sektor inspekcijskog nadzora
Služba veterinarske inspekcije
Voditelj Odjela za inspekciju, planiranje i koordinaciju službenih kontrola

U Zagrebu, 27. veljače 2018.

Predmet: Podudarnost USDA/FSIS referentne metode s referentnom metodom HRN EN ISO 6579-1:2017– mišljenje, daje se

Poštovani,

Vezano uz upit o podudarnosti USDA/FSIS metode MLG 4.09 s referentnom metodom ISO 6579-1:2017 iz Uredbe Komisije (EZ) br. 2073/2005, namijenjenih dokazivanju bakterija roda *Salmonella*, želim pojasniti kako su obje temeljene na istima načelima. U svrhu prikazivanja podudarnosti odnosno razlika, u nastavku dostavljam tablicu, izvadak iz norme s listom mikrobioloških podloga specificiranih u metodama te zaključak s referencama koje govore u prilog našem mišljenju.

S poštovanjem,

Doc.dr.sc. Andrea Humski

1.) Comparison of MLG-4 method with the EN ISO 6579-1:2017

The differences between MLG-4and EN ISO 6579-1:2017 are summarized in the following table.
The third column shows additional information with the tests carried out in the laboratory (in accordance with the current ISO standard):

Step/parameter	MLG-4	EN ISO 6579-1:2017	Lab for Food Microbiology HVI Zagreb
Pre-enrichment in non-selective liquid medium	- BPW (+mTSB - selective enrichment for *Escherichia coli* O157) - Incubation at 35 ± 2°C for 20-24 h	- BPW - Incubation at 36 ± 2°C for 18 h ± 2 h	-carried out according to ISO
Selective enrichment	- TT broth (Hajna) - mRV broth - Incubation at 42 ± 0.5°C for 22-24 h	- RVS broth and/or MSRV agar - Incubation at41,5 °C for 24 h ± 3 h. - MKTTn broth - incubation at 37 °C for 24 h ± 3 h.	For carcass samples: - MSRV selective semi-solid agar; Incubation at41,5 °C for 24 h ± 3 h, and additional 24 h if negative - MKTTn broth; incubation at 37 °C for 24 h ± 3 h
Plating out	- BGS - either DMLIA or XLT4 - Incubation at 35 ± 2°C for 18-24 h	- XLD agar - the second selective plating-out medium (chosen by the laboratory*) - incubation at 37 °C for 24 h ± 3 h	- XLD agar - Rambach agar -SMID2 (optional)
Selection of colonies for confirmation	- at least one typical isolated colony; if this is negative pick at least three total typical colonies	- at least one typical or suspect colony; if this is negative, select up to four more	-carried out according to ISO
Biochemical ID	TSI and LIA Commercially available biochemical test kits, i.e. VITEK® 2 Compact System	TSI agar Urea agar LDC agar *β* –galactosidase (optional) indole reaction(optional)	- TSI agar - Urea agar - LDC agar - VITEK 2
Serological testing	molecular serotyping or slide agglutination	slide agglutination (detailed in the ISO 6579-3	slide agglutination according to ISO 6579-3

2.) Annex E - Examples of selective plating-out media

Table E.2 — Indicator systems used in some plating media for isolation of *Salmonella* spp. Indicated are reactions as shown by the majority of the *Salmonella* strains. Between brackets the concentration of the relevant agent is given in g/l

Medium[a]	α-galactosidase positive	β-galactosidase negative	β-glucosidase negative	Esterase positive	Cellobiose neg.	H_2S pos.	Lactose negative	Lysine decarboxylase positive[b]	Mannitol positive	Propylene glycol positive	Salicin negative	Sucrose negative	Trehalose pos.	Xylose positive
ABC[c]	X	X												
BGA							X (10)					X (10)		
BS						X								
BSA™ (OSCM II)[d]			X	X										
CHROMagar™ Salmonella[i]		x	x	x										
CHROMagar™ Salmonella Plus[i]			x	x										
CSE				X			X (14,6)							
DCLS							X (5,0)					X (5,0)		
DCA						X	X (10,0)							
HE						X	X (12,0)				X (2,0)	X (12,0)		
MLCB						X		X (5,0)	X (3,0)					
MM		X			X (5,0)	X	X (10,0)		X (1,2)				X (1,33)	
Önöz[e]						X	X (11,5)					X (13,0)		
Rambach™ Agar[i]		X								X (10,5)				
chromID® *Salmonella* (SMID2)[f]		X	X	X			X (6,0)							
SS						X	X (10,0)							
XLD						X	X (7,5)	X (5,0)				X (7,5)		X (3,75)
XLT4						X	X (7,5)	X (5,0)				X (7,5)		X (3,75)
ASAP®[f]			X	X										
IBISA®[f]			X	X										

3. Statement

It is our opinion that shown differences are minor and have no impact on the final result of analysis, in support of which we mention some references:

1) K.A. Mooijman Culture media for the isolation of *Salmonella*. In: Handbook of Culture Media for Food and Water Microbiology, 3rd Edition, RSC Publishing, Edited by Janet E L Corry,Gordon D W Curtis, R M Baird (2012)
2) Kyung-Min Lee a, Mick Runyon a , Timothy J. Herrman, Robert Phillips, John Hsieh (2015): Review of *Salmonella* detection and identification methods: Aspects of rapid emergency response and food safety; Food Control 47 (2015); 264-276
3) Feldsine P. Recovery of Salmonella in Selected Foods by the ISO 6579 *Salmonella* Culture Procedure and the AOAC International Official Method of Analysis: Collaborative Study. J. AOAC Int. 2001
4) AFSSA, 2001. Evaluation of microbiological methods for detection and for enumeration of microbiological contaminants in food. Final report Contract SMT4/CT96 2098. Coordination by Agence Française de Sécurité Sanitaire des Aliments. AFSSA, France, February 2001.