FINAL REPORT OF A REMOTE AUDIT CONDUCTED OF

CROATIA

AUGUST 29-SEPTEMBER 30, 2022

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING

PROCESSED PORK PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

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Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a remote ongoing equivalence verification audit of Croatia conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) August 29-September 30, 2022. Due to the global COVID-19 pandemic, the audit was conducted remotely using video conferences to conduct interviews and records review. The purpose of the audit was to verify whether Croatia's food safety inspection system governing thermally processed, commercially sterile pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly 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 Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

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

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) conducted a remote audit of Croatia's food safety system August 29-September 30, 2022. The audit began with an entrance meeting held via videoconference August 29, with the Central Competent Authority (CCA) the Veterinary and Food Safety Directorate (VFSD). Representatives from VFSD participated throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit that was conducted remotely. The audit objective was to determine whether the food safety inspection system governing processed 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 eligible to export the following categories of products to the United States:[1]

Process Category	Product Category	Eligible Products[2]
Thermally Processed - Commercially Sterile (TPCS)	Thermally Processed, Commercially Sterile	Beef and Pork - All Products Eligible

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

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

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data

[1] Croatia is eligible to export to the United States thermally processed - commercially sterile (TPCS) beef products produced from raw beef materials sourced from eligible establishment(s) in eligible countries. However, verification of Croatia's inspection system for TPCS beef products was not included in the scope of this remote audit because at the time there were no certified establishments producing TPCS beef products for export to the United States.
[2] All source meat used to produce products must originate from eligible countries and establishments certified to export to the United States.

collected by FSIS over a 3-year period, in addition to information obtained directly from VFSD through the SRT.

Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditor reviewed records related to administrative functions and oversight at VFSD and State Inspectorate (SI) headquarters, as well as government verification records from two branch offices, and three local inspection offices within the establishments. The remote audit involved meetings with government personnel and laboratory staff. Over the course of five weeks, FSIS scheduled up to three meetings each week. Through records review, the FSIS auditor evaluated the implementation of control systems that ensure the national system of inspection, verification, and enforcement is being implemented as documented in the country's SRT responses and supporting documentation.

All three establishments certified to export to the United States were selected for the remote audit. This included one pork slaughter and processing establishment, and two pork processing establishments. The products these establishments produce and export to the United States include TPCS pork. Beef processing was not included in the audit as there were no beef processing establishments currently certified for export to the United States.

This remote audit focused on a review of records associated with official government verification activities conducted at the selected establishments. It did not include review of onsite establishments' conditions or records. The FSIS auditor assessed the VFSD's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in 9 CFR 327.2.

The FSIS auditor also remotely audited one official microbiological laboratory and one official chemical residue laboratory to verify that the laboratory system is capable of providing adequate technical support to the food safety inspection system.

Remote Audit Scope		#	Locations
Competent Authority	Central	1	• Veterinary and Food Safety Directorate (VFSD), Zagreb
	Branch 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 that Croatia's food safety inspection system meets requirements equivalent to those under the specific provisions of United States laws and regulations, in particular:

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

The audit standards applied during the review of Croatia's inspection system for pork products included: (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures.

III. BACKGROUND

From July 1, 2019, to June 30, 2022, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 853,810 pounds of processed TPCS pork products exported by Croatia to the United States.

Of this volume, FSIS also performed reinspection on 55,556 pounds at POE for additional types of inspection, including condition of container, product examination, and chemical residue analysis. As a result of these additional types of inspection, one lot of 8,153 pounds of processed TPCS pork products was rejected due to container damage.

The previous FSIS audit in 2019 did not identify any systemic findings representing an immediate threat to public health.

The FSIS final audit reports for Croatia's food safety inspection system are available on the FSIS website at: www.fsis.usda.gov/foreign-audit-reports.

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

The first equivalence component the FSIS auditor reviewed was Government Oversight. FSIS import regulations require the foreign food safety inspection system to be organized by the national government in such a manner as to provide ultimate control and supervision over all official inspection activities; ensure the uniform enforcement of requisite laws; provide sufficient administrative technical support; and assign competent qualified government inspection personnel at establishments where products are prepared for export to the United States.

The VFSD is the CCA of Croatia's meat inspection system and is organized and administered by the national government's Minister of Agriculture. VFSD represents the first level of legal authority of the inspection system and provides overall regulatory oversight to the establishments that are certified to export products to the United States. VFSD is also responsible for development and implementation of policies and programs, including Croatia's inspection program. The oversight and enforcement of VFSD's regulatory requirements in establishments certified to export to the United States is under the responsibility of the State Inspectorate (SI), established on April 1, 2019. The SI is responsible for the European Commission's (EC) Rapid Alert System for Food and Feed. The VFSD is comprised of three organizational sectors: the Animal Health Sector, the Veterinary Public Health and Food Safety Sector (VPHFSS), and, the Sector for Veterinary Services Network, Legal and Financial Support.

Since April 1, 2019, the SI is the governmental institution responsible for inspection in Croatia and it is organized and administered as part of the national government. The SI enforces European Union (EU) regulations, Croatian national regulations, and non-EU country regulations to protect the health and welfare of consumers. Part of the SI is Veterinary Inspection (SI-VI), which implements Croatia's inspection program, including oversight and enforcement of VFSD's regulatory requirements in establishments certified to export to the United States. SI-VI implements official controls and inspection on the veterinary tasks, animal health, animal welfare, and production of food and feed. SI-VI ensures that domestic and imported food and feed are safe, wholesome, and correctly labeled and packaged. The SI-VI head of the central office is aide of the chief inspector. SI-VI is comprised of four inspection offices: Veterinary Inspection, Sanitary Inspection, Phytosanitary Inspection, and Agricultural Inspection. VFSD and SI-VI's regulatory oversight of its meat inspection system control consists of four levels: central, regional, branch, and establishment.

The FSIS auditor verified through review of programs and records that VFSD has procedures in place to ensure an effective level of oversight is maintained and official government inspectors are present to conduct inspection of every carcass and parts and processing inspection activities at least once per shift. The senior veterinary inspectors (SVI) 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. The FSIS auditor verified through review of daily reports that the SI ensures the presence of government inspection personnel during all slaughter operations and once per shift in processing operations.

The FSIS auditor verified through interviews and record reviews that VFSD receives and reacts as needed to laboratory testing results and has procedures in place to notify FSIS of the shipment of adulterated products. VFSD has the ability to take enforcement actions if a certified establishment does not meet the requirements of VFSD.

The authorized veterinarians (AV) are responsible for export certification of products to the United States. The AV ensures the inspection and certification of product for export in accordance with FSIS requirements. All export certification items, including blank certificates and stamps, are stored in the secure control body office at each establishment. The SI provides the official export certificate with serial numbers unique to the delegated body. The AV inspects product integrity of packages, labeling of packages, temperature of product, and quantity to be

certified. During the export certification process, the AV can verify product was produced for United States export and is eligible based on the product information provided by the establishment (i.e., daily production records). 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 FSIS auditor verified through interviews and record reviews with VFSD that before issuing an export health certificate, pre-shipment reviews, including a review of laboratory test results, were conducted. These reviews included the microbiological sampling results for products and the verification of the proper labeling of the products and that the certification of product for export does not occur until microbiological test results of the establishment or official VFSD microbiological testing results are received as acceptable. Under VFSD's routine residue monitoring program, and when an AV suspects or chooses to sample an animal for any chemical residues under the targeted testing program based on observations during ante-mortem or post-mortem inspections, that carcass and parts are held pending acceptable test results.

The VFSD 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 SI annually develops implementation procedures of official controls consistent with FSIS requirements. Each SVI 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 SVI's annual plan. In addition, each control body is responsible for developing an annual plan of controls for the AVs. The annual plans include verification checklists and a food processing checklist to document 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 SVIs 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.

The FSIS auditor verified through interviews and record reviews with VFSD that all government inspection personnel are employed by the government of Croatia. Under the authority of the Act on official controls and amended Veterinary Act, the SI 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 and SI personnel is through direct deposit from the state budget. The control body AVs are paid by the control body, which receives the funds directly from the SI. The FSIS auditor verified that government inspection personnel assigned to certified establishments exporting processed pork products to the United States are government employees paid by the Croatian government. The government inspection personnel consists of AVs and SVIs. The AVs perform the following inspection activities: ante-mortem and post-mortem inspection at slaughterhouses, including condemnation of carcasses and offal, verification of animal welfare at slaughter, and audits on HACCP and good manufacturing practices at establishments. AVs work under the authority, supervision, and responsibility of an SVI.

The FSIS auditor verified through interviews and record reviews that the AVs and SVIs have met pre-employment requirements of VFSD including appropriate educational credentials, training, and experience to carry out their inspection tasks in accordance with the Veterinary Act. The VFSD also indicated in interviews that ongoing training sessions for government inspection personnel overseeing certified establishments eligible to export to the United States were held on a routine basis and included specialized training pertaining to FSIS import requirements and Croatian and EC regulations in cooperation with the Croatian Veterinary Chamber. The VFSD 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. The FSIS auditor verified records of ongoing training since the 2019 FSIS audit, including training in FSIS import requirements. VFSD also indicated that any changes in FSIS requirements are made available through its intranet website and are also communicated by SI directly to official inspection offices and establishments through e-mail and training events.

The Croatian Veterinary Institute (CVI) is a national institute within the Ministry of Science and Education that provides technical support for the VSFD, including food analysis. The CVI in Zagreb consists of 5 departments and 16 individual laboratories. Within the CVI Zagreb, the Department of Veterinary Public Health includes the Laboratory for Food Microbiology, the national reference laboratory (NRL) for *Salmonella* and other bacterial pathogens. The laboratory conducts analyses for all official samples, including analysis of carcass swabs for *Salmonella* collected in accordance with Commission 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.

VFSD provides direct oversight of government operated laboratories, which are responsible for the analysis of all official chemical residue and microbiological samples, and privately operated laboratories. VFSD requires laboratory accreditation by the accrediting body, Croatian Accreditation Agency (Hrvatska akreditacijska agencija (HAA)) in accordance with International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 standards. HAA is an independent public institution that is the national accrediting body in Croatia. HAA performs accreditation audits every five years, and annual audits of select laboratories within CVI. In addition, VFSD conducts annual audits of CVI laboratories. VFSD 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. The FSIS auditor reviewed the most recent HAA accreditation certificate, issued May 14, 2018, and valid for five years, and the most recent HAA and VFSD audit reports. The FSIS auditor did not identify any concerns during review of the most recent audit reports from HAA and VFSD.

VFSD has an FSIS equivalence determination allowing for the 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. The control body AVs conduct audits of the establishment laboratory four times each year to evaluate the quality control system and laboratory records. SVIs 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. At least once per year, VFSD headquarters SVIs audit the establishment laboratory.

CVI participates in annual proficiency testing organized by EU 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 EU 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.

The FSIS auditor verified through interviews and record reviews with SI-VI that sample schedules are received from the branch offices providing the specific details for every sample to be submitted. Sample tissues are then collected according to test instructions and packaged by the AVs. Information on the requested sample is entered on the form by the AV and included with the sampled tissues, which are packed, sealed, and shipped to the laboratory.

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

The FSIS auditor verified that Croatia's slaughter and processed pork inspection system is organized and administered by the national government, and that VFSD inspection officials are assigned to enforce the laws and regulations governing pork products.

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

The second equivalence component the FSIS auditor reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of every carcass and its parts; controls over condemned materials; controls over

establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

The Ordinance on Conditions to be Met by Slaughterhouses (OG 57/15) sets the design, construction, and equipment conditions slaughterhouses must meet in accordance with the EC regulation. The VFSD 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 FSIS auditor verified through interviews and record reviews that in-plant veterinary inspectors are required to conduct humane handling and slaughter procedures in accordance with SI's Implementation Procedure of Official Controls in Accordance with USDA/FSIS Provisions that 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 as eligible to produce source material for products that will be exported to the United States. VFSD requirements for AVs include inspection verification of proper repair and maintenance of holding pens and alleyways, verification of proper handling of livestock prior to slaughter including transport, and evaluation of the stunning effectiveness and sticking procedures. The AVs are responsible for daily verification of humane handling and slaughter requirements. The AVs conduct verification activities by using a Checklist of Official Controls generated from the e-Inspector/VETI computer application to ensure that certified establishments are complying with VFSD requirements. In addition, SVIs provide daily oversight of AVs and perform verification activities for humane handling activities for livestock during each shift that animals are slaughtered and record the results. The FSIS auditor's remote audit activities confirmed that humane handling and slaughter of livestock are conducted in accordance with VFSD requirements.

For movement of animals within Croatia, an animal health certificate signed and stamped by an AV is required for animals to be received at a slaughter establishment. Shipments of live animals are also accompanied by an attestation and record of animal health provided by the farm operator indicating if any treatment was administered to the animals in the shipment and that the required withdrawal periods associated with all such treatments have been met. The signed and stamped health certificate allows the in-plant AV to confirm all requirements for animal health and that the origin of the animals complies with the disease statuses outlined by APHIS.

The FSIS auditor verified that the VFSD has developed procedures to ensure ante-mortem inspection tasks in slaughter establishments. In accordance with Regulation (EU) 2017/625, the VFSD 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 reviewing the incoming registrations and identification documents. The Ordinance on the Content, Form and Manner of Submitting Reports on the Performance of Veterinary Activities and on the Manner of Keeping and the Content of the Official Records and Reports in the Slaughterhouse (OG 84/2011) outline the requirements that official records contain for incoming animals for slaughter.

The FSIS auditor verified through interviews and record reviews that official veterinarians perform ante-mortem inspection on every shipment of animals prior to slaughter at a certified establishment in accordance with Regulation (EU) 2017/625. Ante-mortem inspection must take place within 24 hours of an animal's arrival at a slaughterhouse, and less than 24 hours prior to slaughter. Additionally, any swine that arrive dead are condemned as ineligible for human consumption. Records of ante-mortem inspection, including the date, time, and responsible AV are entered into VETI1, at which time the database locks the record, so no additional changes may be made. Documents confirming the outcome of ante-mortem inspection accompany each lot of swine into slaughter. The AVs and SVIs 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. No concerns arose regarding VFSD's ante-mortem inspection procedures.

Implementation Procedure of Official Controls and Supervision on Site, by Location by USDA/FSIS Provisions in Facilities Permitted for Import into the United States describes that SI-VI must ensure that products intended for export to the United States originate from regions not currently restricted by APHIS. This is verified by the SVI monitoring the APHIS website and verifying restrictions under 9 CFR 94 prior to signing an export certificate every time a certificate is requested. SI, through AVs and SVI onsite supervision, verifies during ante-mortem inspection that animals presented for slaughter do not display symptoms of animal disease and reportable conditions. Only those pork products that have been previously identified by SI as meeting both FSIS and APHIS requirements can be certified for export to the United States.

The FSIS auditor verified through interviews and record reviews that the audited establishment is staffed with a sufficient number of government inspection personnel to conduct post-mortem inspection activities. This includes in-plant inspection verification of proper presentation and identification of all carcasses and parts; examination of heads, viscera, and carcasses; and disposition of affected carcasses and parts in accordance with the Ordinance on Official Controls of Products of Animal Origin. 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. If pathology is identified that might impact the fitness of a carcass for human food, the carcass and viscera are railed out and subject to a thorough inspection by an offline AV. The FSIS auditor also verified that SVIs in the branch office arrange their activities to ensure their presence throughout slaughter days when products are intended for export to the United States. SVIs perform onsite supervision on the day of slaughter during each shift that animals are slaughtered to verify the AV's performance and the certified establishment's operations. After completing post-mortem livestock inspection, AVs record their findings with daily slaughter data in VETI's application. The FSIS auditor confirmed that post-mortem inspection is conducted continuously during slaughter operations in accordance with VFSD requirements.

The VFSD follows Regulation (EC) No. 1069/2009 and Commission 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.

The FSIS auditor verified through interviews and record reviews that the AVs verify certified establishments meet the requirements concerning animal by-products of animal origin not intended for human consumption. Certified establishments are responsible for the handling, marking, and storage of inedible materials with controls to ensure that inedible carcasses and parts are clearly identified. AVs verify establishment controls of condemned material handling as part of their routine inspection verification procedures. The AVs continuously verify compliance with the establishment's collection, transport, storage, handling, processing, and use or disposal of animal by-products for which the establishment is responsible. AVs complete a Checklist of Official Controls to verify whether certified establishments are complying with the requirements, which includes a section for the verification of disposition of contaminated product.

The FSIS auditor verified through records review and interviews that the following supervisory reviews occur at the specified frequency: supervisory visits by SVIs 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. The quality manager of the control body is directly responsible for supervision and performance assessment of assigned AVs. In addition, twice each year, an SVI evaluates all requirements, including the performance of AVs, during single onsite visits.

The HAA conducts accrediting audits of each control body every five years. At least twice per year, an SVI 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 SI, whether the delegated body is properly documenting information necessary for traceability, whether the control body is fulfilling animal health requirements, and other measures. In addition, a central audit from the SI occurs at least once per year for the purpose of assessing effectiveness of the SVIs from the branch office as well as the delegated body in ensuring FSIS import 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 SOP), 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. Any observations of noncompliance during reviews are also documented, requiring the certified establishment to document corrective actions, which are subject to verification. 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 these VFSD procedures during the audit through interviews and review of records.

The FSIS auditor verified through interviews and record reviews that certified establishments are required to properly label products according to the VFSD document, Ordinance on Health Marking Labels and Identification Labels of Food of Animal Origin (OG 69/15). The AV verifies that products certified to export to the United States are produced and stored separately by time or space from products destined for export to other markets. The FSIS auditor was informed that in-plant government inspection personnel conduct label verification of products destined for export to the United States based on the FSIS label approvals on file at each establishment and final verification occurs during each pre-shipment verification procedure.

The VFSD 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.

The FSIS analysis and remote verification activities indicate that VFSD maintains the legal authority and a regulatory framework that is consistent with the criteria for this component and therefore continues to meet the core requirements.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component 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, and to maintain requirements for SPS and sanitary dressing.

The FSIS auditor verified through interviews and record reviews that VFSD requires certified establishments to comply with the document, Regulation on the Rules and Procedures Based on the Principles of the HACCP System. In addition, the certified establishments must comply with requirements consistent with 9 CFR 416. Certified establishments are required to develop, implement, and maintain Sanitation SOPs, or other prerequisite programs in accordance with national laws consistent with FSIS regulations to ensure operations occur under sanitary conditions and prevent the contamination of products. The document requires certified establishments to have written programs and include procedures conducted before and during production and to identify the frequency at which procedures are conducted. VFSD also requires certified establishments to take corrective actions, including disposal of contaminated product, restoration of sanitary conditions, and measures to prevent recurrence of product contamination; these last measures include evaluation and modification of the written Sanitation SOP programs. Certified establishments must also maintain daily Sanitation SOP records of implementation, monitoring, and corrective actions.

The AVs verify that SPS and Sanitation SOP requirements are met by each certified establishment according to the Implementation Procedure of Official Controls in Accordance with USDA/FSIS Provisions. The document provides instructions to government inspectors to

verify specific facility requirements consistent with 9 CFR 416.1 to 416.5. These requirements include general sanitary conditions, adequate ventilation, adequate lighting, water potability, proper conveyance of sewage, pest control, and adequate condition of walls, floors, and ceilings.

SI has developed and implemented a Checklist of Official Controls report to verify whether certified establishments comply with those requirements and to verify implementation of Sanitation SOP programs at least once per shift. The Checklist of Official Controls includes questions regarding sanitation requirements, deficiencies identified, and resolution of the deficiencies. During inspections, the frequency of cleaning and sanitation of all food contact surfaces and non-food contact surfaces of facilities, equipment, and utensils must be verified through the Checklist of Official Controls to prevent product adulteration. Pre-operational sanitation verification inspection is performed by the AV on establishment equipment prior to operations. The AV conducts pre-operational sanitation verification on a daily basis prior to production of product designated for export to the United States in accordance with VFSD's established procedures. The FSIS auditor verified these VFSD procedures during the audit through interviews and review of records.

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 an SVI of identified noncompliance or concerns, as only the SVI can document noncompliance and initiate formal enforcement actions when required. The VFSD requires SVIs 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 SVIs that establishment corrective actions were implemented and effective.

Regulation on the Rules and Procedures Based on the Principles of the HACCP System requires certified establishments to develop, implement, and maintain written procedures to prevent contamination of carcasses, organs, and other parts throughout the slaughter and dressing process. Certified establishments must maintain daily records sufficient to document implementation and monitoring of procedures that must be incorporated in their HACCP plan. The FSIS auditor verified through interviews and review of records that the AVs perform a sanitary dressing verification activity every slaughter day to verify that establishments implement effective sanitary dressing and process control procedures to prevent contamination of carcasses. The Checklist of Official Controls includes a section for the sanitary dressing verification. AVs verify that establishments properly assess any microbial testing results, including results for indicators of process control at any point during slaughter and at subsequent trimming, cutting, fabrication, and grinding operations.

The FSIS auditor verified through interviews and review of records that VFSD requires the AVs and SVIs to verify certified establishments follow zero tolerance requirements for fecal material, ingesta, and milk as described in the Implementation Procedure of Official Controls in Accordance with USDA/FSIS Provisions. The AVs perform zero tolerance checks and document results during each shift.

The FSIS analysis and remote verification activities indicate that VFSD requires operators of certified establishments to develop, implement, and maintain sanitation programs, including requirements for SPS, Sanitation SOPs and sanitary dressing procedures. FSIS concluded that VFSD continues to meet the core requirements for this component.

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

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

The FSIS auditor verified through interviews and record reviews that VFSD requires certified establishments to develop and implement a HACCP system in accordance with Croatia's law National Ordinance on Rules for Implementing HACCP System that is consistent with the requirements in 9 CFR 417. Croatia's Ordinance on the Rules for the Establishment of the System and Procedures Based on HACCP Principles 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. In addition, VFSD requires that requirements consistent with 9 CFR 417 are met by each establishment certified as eligible to export to the United States.

The VFSD's Implementation Procedure of Official Controls and Supervision Onsite, by Location by USDA/FSIS Provisions in Facilities Permitted for Import into the United States provides an overview of official inspection verification activities. VFSD has implemented the Checklist of Official Controls to verify if certified establishments are complying with the HACCP requirements. The Checklist of Official Controls includes pre-requisite programs and HACCP requirements. The AVs and SVIs conduct daily verification activities for HACCP requirements through direct observation and hands-on activities as well as review of records. The Implementation Procedure of Official Controls and Supervision Onsite, by Location by USDA/FSIS Provisions in Facilities Permitted for Import into the United States document also provides further instructions on how SVIs are to verify the product flow chart, hazard analysis, HACCP plan, monitoring, verification, corrective actions, recordkeeping, and pre-shipment reviews.

The FSIS auditor verified through review of inspection records that government inspection personnel conduct daily HACCP verification activities for all shifts. 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 critical control point (CCP) for zero tolerance. Documents reviewed included Checklist of Official Controls, performance of daily zero tolerance checks, SVI reviews of establishment pre-shipment reviews and laboratory results, and verification of certified establishment CCPs by either review of records, observation, or by direct observation of establishment monitoring of the CCP. The FSIS auditor verified that if a non-compliance was observed, the certified establishment is provided

notification, the findings are documented, and the certified establishment must take corrective actions which are then verified by the SVI.

The FSIS analysis and remote verification activities indicate that VFSD requires operators of certified establishments to develop, implement, and maintain a HACCP system. FSIS concludes that VFSD continues to meet the core requirements for this component.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth equivalence component the FSIS auditor reviewed was Government Chemical Residue Testing Programs. The food safety inspection system is to present a chemical residue testing program, organized and administered by the national government, which includes random sampling of internal organs, fat, or muscle of carcasses for chemical residues identified by the exporting country's meat products inspection authorities or by FSIS as potential contaminants.

Prior to the audit, and as part of the annual SRT review for ongoing equivalence determination, FSIS reviewed Croatia's 2022 National Residue Control Plan (NRCP), associated methods of analysis, reported results of the testing program, and additional SRT responses outlining the structure of Croatia's official chemical residue testing program. The NRCP specifies the analytes included in the testing program, the method of analysis to be used, the matrix to be collected, and the total number of samples to be collected and tested.

The FSIS auditor verified that the NRCP is developed and administered by VFSD to plan and manage the testing of carcasses and parts for chemical residues and contaminants in pork products. The NRL for chemicals in Zagreb, in coordination with VFSD, is responsible for planning, implementation, and coordination of the NRCP on a yearly basis in accordance with OG 51/2013 and 79/2008 (transposed Commision Directive 96/23/EC). The yearly sampling plan is developed based on the number of animals slaughtered and results of sampling during the previous year with a distribution of analyses performed for several categories including substances having an anabolic effect, unauthorized substances, veterinary drugs, and environmental contaminants. NRCP contains sampling location, the number of samples to be taken per year/month/county, the species, the tissues, the target compounds, screen method, and action level (i.e., maximum residue level), respectively. The sample collection locations include farms and establishments.

The SI, VPHFSS, is responsible for disseminating the requests, taking samples for the NRCP, and taking enforcement actions in cases where violations are detected. The residue samples are collected by AVs and the SVI performs specific oversight and drafts a report documenting sample collection at slaughter establishments. In addition to the NRCP, the AVs may implement sampling of any swine that are identified during ante-mortem or post-mortem inspection as suspect for possible residue violations. All samples are sent to CVI, which is the NRL for residue monitoring. Samples are delivered either via driver or post with next day delivery to the laboratory. SVIs are responsible for monitoring the proper implementation of the residue plan in their assigned regions. CVI is responsible for checking if the samples were taken in accordance

with the request (requested matrix and animal), delivered in time (four days), and at the appropriate temperature.

The SVIs indicated during interviews that any carcass sampled for chemical residue testing is identified and segregated to ensure that the specific carcass and its parts are held pending acceptable test results and that these carcasses and parts are excluded from export to the United States. VFSD hold and test requirements state that animal carcasses sampled for residual toxicology may not be included in the production of product intended for export to the United States. The acceptability of test results is based on EU requirements and FSIS identified banned substances with zero tolerance levels and substances with maximum residue levels permitted in foodstuffs. If a maximum U.S. MRLs and EU MRLs residue level is exceeded or a prohibited substance is detected, VFSD initiates an investigation into the cause. VFSD then requires that each certified establishment evaluate test results to determine if product meets all FSIS import requirements prior to requesting export certification. The FSIS auditor verified through interviews that based on these VFSD requirements, all establishments currently certified to export to the United States have procedures in place to separate and exclude all carcasses and parts tested for residues and to ensure the tested product is not exported to the United States.

The FSIS auditor verified that when a violative result is found, the VFSD NRL chemical laboratory immediately notifies VFSD headquarters and the VPHFSS. The Coordinator for Residue Monitoring in the VPHFSS disseminates requests for NRCP sampling, gives detailed instructions to the veterinary inspectors in branch offices on sampling (from which farm/slaughter-house samples have to be taken), monitors sampling, and gives detailed instructions to the veterinary inspectors in branch offices that have to take action in case of noncompliant finding(s) within the territory of its regional veterinary office.

VFSD's Sampling Guidelines for the NRCP and Treatment of Nonconforming Findings describes sampling and the corrective measures that must be taken in the case of noncompliant results. Upon receiving information on the noncompliant sample, the coordinator for residue monitoring informs the SVI in the branch office where the sample was taken. Only the SVI is authorized to take actions in response to a violative result. VPHFSS keeps records of sent requests, samples taken, noncompliant results, and actions taken when violative results are received from the respective coordinator.

The FSIS analysis and remote verification activities indicate that VFSD has overall authority of a chemical residue testing program which is designed and implemented to prevent and control the presence of chemical residues in pork products destined for export to the United States. There have not been any POE violations related to this component since the previous FSIS audit in 2019. FSIS concludes that VFSD continues to meet the core requirements for this component.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth equivalence component the FSIS auditor reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that meat products prepared for export to the United States are safe

and wholesome. This component also addresses requirements for thermally processed, commercially sterile meat products.

Prior to the audit, FSIS reviewed Croatia's national microbiological sampling and testing programs, laboratory methods of analysis, and SRT responses outlining the structure of VFSD's microbiological verification sampling and testing programs. The FSIS auditor confirmed there have not been any major changes to VFSD's official microbiological verification testing programs or requirements regarding pork products exported to the United States since the previous FSIS audit conducted in 2019.

VFSD ensures that a slaughter establishment's microbiological sampling and testing program for pork verifies process control using microbiological analyses for indicators of intestinal and fecal contamination. The FSIS auditor verified through interviews and record reviews that VFSD requires certified establishments follow Commission Regulation (EC) No. 2073/2005 regarding process hygiene criteria testing and analysis for carcasses. Per RU-8.2-0-4-SU-32 and the Procedure for Planning, VFSD also requires and verifies that establishments perform sampling of swine carcasses at pre-evisceration and at post-chill sampling, consistent with FSIS requirements in 9 CFR 310.18, in addition to sampling required by Commission Regulation (EC) No. 2073/2005. Certified establishments must take actions based on test results and immediately notify the SVI of any single test result or a trend of test results requiring action.

SVIs perform a review of the certified establishment's indicator organism sampling program. The VFSD Procedure for Planning and Implementing Official Controls According to American Regulations and Guide to Microbiological Criteria for Foodstuffs contains activities the inspector verifies, including review of the sample plan, sampling frequency, sampling procedures, test methodology, results, analysis of results, decision making based on results, and records of the testing program. The FSIS auditor verified through interviews with SVIs that the AVs conduct verification activities that include assessment of establishment compliance with the Procedure for Planning, that the establishments have elected to require *Enterobacteriaceae* testing of samples collected at a frequency of one sample per every 1,000 swine, and that statistical process control is used to evaluate results. The FSIS auditor reviewed official inspection records at the audited slaughter establishment and concluded that the indicator organism process control sampling programs are implemented as required by VFSD.

Although no longer required by FSIS for equivalence, VFSD also requires slaughter establishments to meet *Salmonella* performance standards in accordance with requirements in Commission Regulation (EC) No. 2073/2005. The FSIS auditor verified that VFSD implements a government verification sampling program for *Salmonella* to verify process controls in swine slaughter operations for chilled carcasses. The establishment collects samples under the direct supervision of the AV and results are analyzed by the establishment laboratory. Samples are taken under the direct supervision of the government veterinary inspector. The laboratories are under the supervision of VFSD.

Confirmation testing by official government laboratories is undertaken twice each month. These official samples are submitted to a CVI microbiology laboratory for analysis. Results from the CVI microbiology NRL are distributed via email to the SVIs at the branch office and AV and

discussed during the weekly meeting with the establishment. The FSIS auditor verified through interviews and records review of sample results for the current year that were negative for *Salmonella* species.

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 and Supervision Onsite, by Location by USDA/FSIS Provisions in Facilities Permitted for Import into the United States, establishments are required to meet requirements consistent with 9 CFR 431. The Implementation Procedure of Official Controls and Supervision Onsite, by Location by USDA FSIS Provisions in Facilities Permitted for Import into the United States, also describes procedures in accordance with Codex Alimentarius' Guide for Hygienic Practices for Canned Foods with Low Acidity and Sour and Canned Foods with Low Acidity (CAC/RCP 23-1979).

The Implementation Procedure of Official Controls and Supervision Onsite, by Location by USDA FSIS Provisions in Facilities Permitted for Import into the United States indicates that the SVIs perform inspection tasks every production day for products intended for export to the United States. The document describes sanitation performance standards, Sanitation SOPs, and HACCP procedures for SVIs. The document also states what verification activities the SVIs must verify for facilities certified as eligible for TPCS products.

The FSIS audit included two processing establishments producing TPCS products. The AVs and SVIs 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 sterilization of the entire production batch is considered suspect if visible changes appear on the samples during incubation, such as deformations, swelling and content leakage. The document states that if the CCP for heat treatment is not met or if there is any deviation from the process schedule, the product cannot be exported to the United States.

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

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held September 30, 2022, by videoconference with VFSD. The FSIS auditor concluded that Croatia's processed pork products inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. VFSD has required that establishments certified as eligible to export products to the United States implement sanitation requirements and a HACCP system designed to improve the safety of their products. In addition, VFSD has implemented official microbiological and chemical residue testing programs that are organized and administered by the national government to verify its

system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

Appendix: Foreign Country Response to the Draft Final Audit Report

REPUBLIC OF CROATIA
MINISTRY OF AGRICULTURE
VETERINARY AND FOOD SAFETY
DIRECTORATE

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CLASS: 322-01/22-01/27
REGNO: 525-09/569-23-8
Zagreb, 13 February, 2023

Ms. Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination
Food Safety and Inspection Service
U.S. Department of Agriculture

Subject: Draft audit report of Croatia's meat inspection system

Dear Dr. Catlin,

Thank you for the draft final audit report on FSIS remote verification audit of Croatia's meat inspection system conducted from August 29 through September 30, 2022.

The report is well written and reflects the meat inspection system in Croatia at the time of audit. Nevertheless, for the sake of clarity, we have few minor suggestions regarding some information in the report, mostly related to new division of responsibilities between the two competent authorities (Veterinary and Food Safety Directorate and State Inspectorate of the Republic of Croatia), which came into force with new *Act on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products (OG 55/2021).*

I. INTRODUCTION

1. Page 1
   Representatives from the State Inspectorate (SI) central office participated in the entrance meeting as well, so we suggest to add State Inspectorate (SI) as underlined in the text below:

   "The audit began with an entrance meeting held via videoconference August 29, with the Central Competent Authorities (CCA) - Veterinary and Food Safety Directorate (VFSD) ***<u>and State Inspectorate (SI)</u>****. Representatives from VFSD* ***<u>and SI</u>*** *participated throughout the entire audit".*

2. Page 2, table

   Under the Locations column, we suggest to add State Inspectorate (SI) Central Office, Zagreb under the No.1., as other CCA.

II.AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

Page 2, third paragraph
Representatives of the SI headquarters were included as well, so we suggest amendment as underlined below:

„The FSIS auditor reviewed records related to administrative functions and oversight at VFSD ***and SI*** *headquarters, as well as government verification records from two branch offices, and three local inspection offices within the establishments. "*

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)

3. Page 4, first paragraph
   According to the Article 6 of the above mentioned Act on official controls, SI is responsible for the European Commission's (EC) Rapid Alert System for Food and Feed so we suggest slight amendment as underlined below:

   "VFSD is also responsible for development and implementation of policies and programs, including Croatia's inspection program and ***SI is responsible*** *for the European Commission's (EC) Rapid Alert System for Food and Feed".*

   Third paragraph

   According to the Article 6 of the above mentioned Act on official controls, SI is responsible for the organization of official controls so we suggest correction accordingly, as underlined below:

   The FSIS auditor verified through review of daily reports that the ~~VFSD~~ ***SI*** *ensures the presence of government inspection personnel during all slaughter operations and once per shift in processing operations*

   Fifth paragraph

   According to the Article 6 of the above mentioned Act on official controls SI is responsible for the organization of official certification which includes the distribution of the official export certificate with serial numbers unique to the control body.

   In line with the Regulation (EU) 2017/625 on official controls and other official activities, certain changed terminology has been adopted in the Act on official controls as well, which includes change of "control body" into "delegated body".

   "The ~~VFSD~~ ***SI*** *provides the official export certificate with serial numbers unique to the ~~control~~* ***delegated*** *body."*

4. Page 5, third paragraph
According to the Article 6 of the above mentioned Act on official controls, SI is responsible for the organization of official controls, which includes development of implementation procedures of official controls so we suggest correction accordingly, as underlined below

*In addition, the ~~VFSD~~ **SI** annually develops implementation procedures of official controls consistent with FSIS requirements*

Fifth paragraph
In accordance with the Article 62 of the above mentioned Act on official controls and amended Veterinary Act, SI is responsible for collecting fees from establishments to finance the costs of performing official controls, therefore, we suggest the correction in the sentence below accordingly:

*"Under the authority of the **Act on official controls and amended** Veterinary Act, the **SI** ~~VFSD~~ is responsible for collecting fees from establishments to finance the costs of performing official controls."*

5. Page 6, First paragraph
SI veterinary inspectors are governments employees and their payment is also through direct deposit from the state budget, so we suggest to mention it along with VFSD personnel.
In accordance with the Article 62 of the above mentioned Act on official controls and amended Veterinary Act, SI is collecting fees and paying to delegated bodies for the official controls and other official activities performed.

*"Payment of VFSD **and SI** personnel is through direct deposit from the state budget. The control body AVs are paid by the control body, which receives the funds directly from the **SI** ~~Ministry of Agriculture~~.*

Second paragraph
SI is responsible for distributing guidelines and changes in legislation, which includes FSIS requirements to veterinary inspectors and delegated bodies and whenever doing it, FBO's are included in recipients list when relevant, so we suggest slight amendment as underlined below:

*VFSD also indicated that any changes in FSIS requirements are made available through its intranet website and are also communicated **by SI** directly to official inspection offices and establishments through e-mail and training events.*

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)

6. Page 8, third paragraph

SI is the CA that developed Implementation Procedure of Official Controls in Accordance with USDA/FSIS Provisions, so we suggest to correct it as underlined below and in all places where it is mentioned as VFSD Implementation Procedure.

*"The FSIS auditor verified through interviews and record reviews that in-plant veterinary inspectors are required to conduct humane handling and slaughter procedures in accordance with ~~VFSD~~ **SI**'s Implementation Procedure of Official Controls in Accordance with USDA/FSIS Provisions that states that verification…"*

7. Page 9, second paragraph
   As written above, the SI is responsible for the organization of official controls, so we suggest correction as underlined below:

   *"~~VFSD~~ **SI**, through AVs and SVI onsite supervision, verifies during ante-mortem inspection that animals presented for slaughter do not display symptoms of animal disease and reportable conditions. Only those pork products that have been previously identified by **SI** ~~VFSD~~ as meeting both FSIS and APHIS requirements can be certified for export to the United States."*

8. Page 10, fourth paragraph
   With the new Act on official controls coming into force SI became the competent authority for the organization of official controls, which includes delegation of specific tasks of official controls to delegated bodies.

   *"The objective is to assess accreditation status, adherence to a valid contract with the **SI** ~~VFSD~~, whether the **delegated** ~~control~~ body is…"*
   *"In addition, a central audit from the **SI** ~~VFSD~~ occurs at least once per year for the purpose of assessing effectiveness of the SVIs from the branch office as well as the **delegated** ~~control~~ body…"*

VI. COMPONENT THREE: GOVERNMENT SANITATION

9. Page 12, second paragraph

   *"**SI** ~~VFSD~~ has developed and implemented a Checklist of Official Controls report to verify whether certified establishments comply with those requirements and to verify implementation of Sanitation SOP programs at least once per shift."*

We remain at your disposal for any further clarification you might need.

Sincerely,

DIRECTOR GENERAL, CVO

Tatjana Karačić, MSc, DVM

REPUBLIKA HRVATSKA MINISTARSTVO POLJOPRIVREDE ZAGREB 128

cc. United States Embassy in Zagreb, Agricultural Specialist: Ms. Andreja Misir