USDA

United States Department of Agriculture

DEC 0 2 2021

Food Safety and
Inspection Service

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Paweł Niemczuk, DVM
Chief Veterinary Officer
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Ul. Wspolna 30
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Dear Dr. Niemczuk,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted a remote ongoing verification audit of Poland's pork products inspection system May 25 through July 8, 2021. Enclosed is a copy of the final audit report. The comments received from the Government of Poland are included as an attachment to the report.

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF A REMOTE AUDIT CONDUCTED OF

POLAND

MAY 25–JULY 8, 2021

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

RAW AND PROCESSED PORK PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

December 1, 2021

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a remote equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from May 25–July 8, 2021. Due to the global COVID-19 pandemic, the audit was conducted remotely using video conferences to conduct interviews and records reviews. The purpose of the audit was to determine whether Poland's food safety inspection system governing raw and 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. Poland currently exports thermally processed, commercially sterile (TPCS) pork; ready-to-eat (RTE) pork fully-cooked without subsequent exposure to the environment; RTE fully-cooked pork; RTE dried pork; RTE acidified/fermented pork (without cooking); raw intact pork; and not ready-to-eat (NRTE) otherwise processed pork to the United States.

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

The FSIS auditors concluded that Poland's inspection system for raw and processed pork products is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The Central Competent Authority (CCA) has required that establishments certified as eligible to export products to the United States implement sanitary operating procedures and a HACCP system designed to improve the safety of their products. In addition, the CCA has implemented microbiological and chemical residue testing programs 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 United States Department of Agriculture (USDA) conducted a remote audit of Poland's food safety inspection system from May 25–July 8, 2021. The audit began with an entrance meeting held via videoconference on May 25, 2021, with representatives from the Central Competent Authority (CCA)–the General Veterinary Inspectorate (GVI). Representatives from GVI 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 Poland's food safety inspection system governing raw and 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. Poland is eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products[1]
Raw – Non-Intact	Raw Ground, Comminuted, or Otherwise Non-intact Pork	Pork - All Products Eligible except Mechanically Separated and Advanced Meat Recovery Product (AMR)
Raw - Intact	Raw Intact Pork	Pork - All Products Eligible
Thermally Processed - Commercially Sterile (TPCS)	TPCS	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	Ready-to-Eat (RTE) Acidified/Fermented Meat (without cooking)	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	RTE Dried Meat	Pork - All Products Eligible
Heat Treated - Shelf Stable	RTE Dried Meat	Pork - All Products Eligible
Heat Treated - Shelf Stable	RTE Salt-Cured Meat	Pork - All Products Eligible
Heat Treated but Not Fully Cooked - Not Shelf Stable	Not Ready-to-Eat (NRTE) Otherwise Processed Meat	Pork - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE Fully-Cooked Meat	Pork - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE Meat Fully-Cooked Without Subsequent Exposure to the Environment	Pork - All Products Eligible

The USDA's Animal and Plant Health Inspection Service (APHIS) subjects the pork imported from Poland to African swine fever (ASF) requirements specified in Title 9 of the United States Code of Federal Regulations (9 CFR) 94.8, classical swine fever requirements specified in 9

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

CFR 94.31, swine vesicular disease requirements specified in 9 CFR 94.13, and foot-and-mouth disease requirements specified in 9 CFR 94.11.

Prior to the remote equivalence verification audit, FSIS reviewed and analyzed GVI's Self-Reporting Tool (SRT) responses and supporting documentation. During the audit, the FSIS auditors conducted interviews and reviewed records to determine whether Poland's food safety inspection system governing pork meat 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 collected by FSIS over a three-year period, in addition to information obtained directly from GVI 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 auditors reviewed records related to administrative functions at GVI headquarters and three district offices, in addition to government verification records from three local inspection offices. The remote audit involved meetings with government personnel and laboratory staff. FSIS scheduled up to two meetings each week over an eight-week period. FSIS did not conduct virtual establishment visits as part of these remote audits. Through records reviews, the FSIS auditors evaluated the implementation of control systems that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

A sample of 3 establishments was selected from a total of 18 establishments certified to export to the United States. This included two pork slaughter and processing establishments and one pork processing establishment. The products these establishments are certified to export to the United States include raw intact pork; ready-to-eat (RTE) acidified/fermented pork (without cooking); RTE dried pork; not ready-to-eat (NRTE) otherwise processed pork; RTE fully-cooked pork; and thermally processed, commercially sterile (TPCS) pork.

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 establishments' conditions or records. The FSIS auditors assessed the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in 9 CFR 327.2.

The FSIS auditors also remotely audited two government laboratories (one conducting both microbiological and chemical residue testing, the other conducting solely chemical residue testing) to verify that that these laboratories provide adequate technical support to the food safety inspection system.

Remote Audit Scope		#	Locations
Competent Authority	Central	1	• General Veterinary Inspectorate, Warsaw
	District Offices	3	• District Veterinary Inspectorate (DVI), Debica • DVI, Kutno • DVI, Szczecin
Government Laboratories		2	• National Veterinary Research Institute (NVRI), Pulawy (chemical residue testing) • Regional Veterinary Hygiene Institution (ZHW), Warsaw (microbiological and chemical residue testing)
Swine slaughter and processing establishments		2	• Establishment No. 10 02 38 02, Animex Foods Sp. zo.o. Oddzial K4 w Kutnie, Kutno • Establishment No. 32 62 02 01, Animex Foods Sp. zo.o. ul. T. Chalubinskiego 8, 00-613 Warszawa, Oddzial w Szczecinie, ul. Pomorska 115 B, 70-812 Szczecin
Swine processing establishment		1	• Establishment No. 18 03 40 01, Sokolow Spolka Akcyjna Oddzial w Debicy, Debica

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

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

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

III. BACKGROUND

From December 1, 2017 to February 8, 2021, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 359,794,555 pounds of pork meat products from Poland. This includes:

- 4,018,365 pounds of TPCS pork;

- 12,855,745 pounds of RTE pork fully-cooked without subsequent exposure to the environment;
- 47,620,386 pounds of RTE fully-cooked pork;
- 372,143 pounds of RTE dried pork;
- 339,439 pounds of RTE acidified/fermented pork (without cooking);
- 293,485,511 pounds of raw intact pork; and
- 1,102,966 pounds of NRTE otherwise processed pork exported by Poland to the United States.

Of these amounts, additional types of inspection were performed on 37,251,989 pounds of meat, including:

- 301,772 pounds of TPCS pork;
- 1,634,862 pounds of RTE pork fully-cooked without subsequent exposure to the environment;
- 5,838,741 pounds of RTE fully-cooked pork;
- 51,174 pounds of RTE dried pork;
- 32,671 pounds of RTE acidified/fermented pork (without cooking);
- 29,308,982 pounds of raw intact pork; and
- 83,787 pounds of NRTE otherwise processed pork.

These additional types of inspection included physical examination, condition of container examination for TPCS products, chemical residue analysis, and testing for microbiological pathogens (*Listeria monocytogenes* (*Lm*) and *Salmonella* in RTE products).

Since the previous FSIS audit of Poland in 2019, there have been seven public health critical violations identified at POE which resulted in the rejection of 390,221 pounds of pork products. The principal cause of these rejections was the presence of ingesta. In addition, there were five other consumer protection/non-critical violations related predominately to foreign materials (193,806 pounds). All identified POE violations were limited to two establishments, both of which were selected for in-depth review during the remote audit reflected in this report.

The last FSIS audit in 2019 identified the following findings:

Summary of Findings from the 2019 FSIS Audit of Poland
Component 1: Government Oversight (e.g., Organization and Administration)
• Government inspection personnel were not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical testing results prior to signing export certificates.
Component 2: Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling)
• Deficiencies related to post-mortem inspection were identified at four of the nine audited swine slaughter and processing establishments, including failure to palpate the mesenteric lymph nodes at four establishments; and failure to inspect the dorsal external surfaces of the carcass at one establishment.

Component 4: Government Hazard Analysis and Critical Control Point (HACCP) System
• The FSIS auditors noted deficiencies related to performance of zero tolerance verification by inspection personnel in four of the nine audited swine slaughter and processing establishments. Examples of deficiencies included: lack of independent sampling, whereby government verification was conducted on the same carcass set selected by the establishment during routine monitoring; a less-than-daily verification frequency; and insufficient sample size.
Component 6: Government Microbiological Testing Programs
• The FSIS auditors identified deficiencies related to the implementation of the official sampling and analysis program for *Salmonella* in swine carcasses at two audited establishments. At one location, the scheduling of the sample set was initiated by the establishment rather than by the District Veterinary Inspectorate personnel; at another location, test results were sent directly to establishment management rather than the District Veterinary Inspectorate personnel.

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

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

The European Commission (EC) Regulations Nos. 178/2002 and 2017/625 provide GVI with the legal and enforcement authority and responsibility to ensure that adulterated product is not eligible for United States export. Article 3 of the Act of January 29, 2004 on Veterinary Inspection describes the requirements for the implementation of inspection tasks to ensure the protection of public health and the Methodology of Official Controls and Verification of the Performance of Official Activities No. GIWpr02010-14/2019, provides instructions for implementing and documenting the official controls at the supervised establishments.

Poland's meat inspection system is organized into three levels. At the first level is GVI, which is headed by the Chief Veterinary Officer (CVO). The CVO is appointed by the Prime Minister following recommendation by the Minster of Agriculture and Rural Development. The CVO has direct authority over all levels, including inspection personnel at the establishments certified to export to the United States.

The second level includes the Regional Veterinary Inspectorate (RVI), headed by the Regional Veterinary Officer (RVO). There are 16 regions in Poland, and each region has between 15 and 32 districts. The third level is the District Veterinary Inspectorate (DVI), headed by the District Veterinary Officer (DVO). The district is responsible for all veterinary related activities, including meat inspection and periodic supervisory reviews at each establishment certified to export to the United States.

The EC regulations are the primary overarching laws for regulating meat inspection in Poland. To standardize the uniform application of requirements, inspection and supervision in establishments certified to export to the United States, GVI has published the document Requirements for Establishments Approved to Export of Meat and Poultry and Their Products to the Market of the United States of America (hereafter referred to as Requirements for Establishments). In the document, GVI has mandated compliance with certain provisions consistent with those in 9 CFR 317, 319, 416, 417, 430, and 431 in their entirety in order to meet FSIS import requirements.

Poland maintains definitions of adulteration (Article 14 of Regulation (EC) No. 178/2002) and misbranding (Article 8 of Regulation (EC) No. 178/2002) in accordance with European Union (EU) regulations. Additionally, under Sections 7.3.1 and 7.3.2 of the Requirements for Establishments, Poland adopts requirements consistent with the FSIS definition that provides that products are "misbranded" when their labels are false or misleading (9 CFR 317.8). Article 18 of Regulation (EC) No. 178/2002 describes the general requirements for traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed at all stages of production, processing, and distribution. Article 19 of Regulation (EC) No. 178/2002 requires establishments to immediately initiate procedures to recall food products if they have reason to believe that they are not in compliance with food safety requirements. The FSIS auditors confirmed through interviews with inspection personnel that each establishment maintained a written recall plan in accordance with these requirements.

During the audit, the FSIS auditors reviewed the procedures for certification of establishments for eligibility to export to the United States. No additional establishments have been certified to export to the United States since the previous FSIS audit in 2019. Establishment certification for the United States market requires registration at DVI. Establishments must successfully implement procedures consistent with the United States requirements for three months before they are recommended for certification. The DVO has the authority to accept or reject the application based on the outcome of the onsite inspection verification of establishment compliance with United States requirements. If approved at this level, the DVO submits the application to the RVO, who delegates an RVI official to conduct an additional inspection and affirm certification. RVI then sends recommendations for the certification to GVI headquarters. GVI reviews the documents prior to updating the list of eligible establishments and then submits the list to FSIS.

GVI maintains a register on its web portal that includes the list of all establishments certified to export to the United States. The FSIS auditors confirmed that the system ensures only eligible source materials are used to produce products intended for export to the United States.

The FSIS auditors verified that inspection officials maintained export certificates and an accountable item inventory of all issued certificates in a secure environment. A review of export certificates and accompanying documents associated with lots of product previously exported to the United States demonstrated that establishments routinely provide certifying inspection personnel with their HACCP pre-shipment reviews, as well as the results of any product testing conducted as part of their HACCP verification procedures. The FSIS auditors' review of records indicated that inspection personnel routinely confirm acceptable test results of official microbiological and chemical residue sampling, i.e., "hold and test" prior to certifying product for export to the United States.

The FSIS auditors verified that Supervisory Veterinarians (SV) at establishments certified to export to the United States are full-time government employees of DVI. These individuals are assigned to certified establishments on a permanent basis, providing continuous inspection coverage on each shift, including both slaughter and processing operations. The SVs' responsibilities include coordination and direct verification of the inspection activities performed by the Appointed Official Veterinarians (AOV), which are contracted employees; informing the DVO of identified noncompliance, suspension of production, and reporting suspect infectious animal diseases; conducting administrative proceedings and enforcement proceedings in the event of noncompliance; control of the implementation of the national control program for prohibited substances, including chemical and biological residues; control of the proper storage of veterinary stamps by the AOVs; checking the validity of the declarations of the AOVs on the absence of conflicts of interest; organizing meetings with AOVs in order to ensure consistent inspection methodology; and control over fulfilment of inspection requirements in the entire facility, including those resulting from FSIS requirements (e.g., sanitation, HACCP, and humane handling requirements).

Poland follows Regulation (EC) No. 625/2017, which requires GVI to ensure that all inspection personnel or contracted employees are paid by the government. This regulation requires GVI to ensure that adequate financial resources are available to provide the necessary staff and other resources for official inspection controls by whatever means considered appropriate, including through general taxation or establishing fees or charges. Industry is assessed fees for meat inspection and directly pays the Polish government. Salaries for SVs and other civil service employees are in accordance with the Regulation of the Minister of Agriculture and Rural Development of 15 January 2018 and paid from the state budget as described in Article 8 of the Act of 21 November 2008 on Civil Service. Budget expenditures for wages are financed from Section 4020 of this act. Payment of AOVs is conducted in accordance with Articles 12 and 16 of the Act of 29 January 2004 on Veterinary Inspection, and is also paid from the state budget. The FSIS auditors were able to confirm direct payment of the inspection personnel by reviewing invoices maintained by each DVI's accounting department.

The FSIS auditors confirmed that all Official Veterinarians (OV), i.e., both SVs and AOVs, must have a Doctor of Veterinary Medicine or equivalent degree, and the official auxiliaries (OA) must have specialized experience or education that allows them to perform their assigned duties. Through Article 18 of the Veterinary Inspection Act, On Products of Animal Origin, GVI implements the provisions of Regulation (EC) No. 625/2017, Articles 17-18, which state the inspection staff performing official control must receive appropriate training. Only those

inspectors that have undergone training and passed an examination are eligible for employment. In addition, GVI provides ongoing training covering the United States import requirements. The FSIS auditors verified that all newly assigned OVs had received specific training regarding requirements for export to the United States.

The OVs attending training sessions organized by GVI are certified as trainers of cascade training (i.e., train the trainer) and are then made responsible for delivering cascade training to inspection personnel working in certified establishments. GVI customizes cascade training sessions for veterinary upper-level staff, who in turn disseminate the information amongst the OAs. Continuous training focuses on refreshing and adding to the knowledge and skills of inspection personnel responsible for enforcing regulatory requirements at establishments certified to export to the United States. The FSIS auditors verified documentation of the training and written examination results at multiple levels of the inspection system (e.g., RVI, DVI, and local inspection levels) and did not identify any concerns.

GVI maintains a communication system to convey requirements related to United States export throughout its inspection system. The FSIS auditors verified that GVI disseminates information related to regulatory and administrative affairs to all levels of the inspection system by mail and e-mail, and by posting it on its website.

GVI also maintains administrative and technical support to operate its laboratory system through issuance of the Act on Veterinary Inspection. To ensure uniform performance of laboratory tests for the purpose of official controls, GVI created a system of official laboratories, which are accredited according to International Organization for Standardization (ISO) 17025 standards, General requirements for the competence of testing and calibration laboratories. This accreditation is performed by the Polish Centre for Accreditation (PCA) in Warsaw and is valid for four years. Participation in the quality system involves regular maintenance audits by the PCA that monitor the activities of the accredited laboratories to ensure that they consistently meet the criteria required for the award of such accreditation. The CVO has the authority to approve the laboratory for official testing, or alternatively, withdraw approval in the event the laboratory is unable to maintain standards consistent with ISO 17025.

During the review of the two government laboratories, the FSIS auditors verified the CCA's ability to coordinate evaluations of laboratory performance, including the maintenance of valid PCA accreditation certificates and proficiency testing schemes for analysts and evaluations of the quality controls maintained by laboratory managers. FSIS also verified that laboratory managers possess relevant academic credentials and experience as analysts in their specialty areas.

FSIS determined that GVI organizes and administers the country's food safety inspection system and that government inspection personnel enforce laws and regulations governing production and export of raw and processed meat at establishments certified to export to the United States.

V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (e.g.,

INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

The second equivalence component the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. FSIS requires that the foreign country's inspection system provides for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of every carcass and part; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

GVI has adopted Regulation (EC) Nos. 853/2004, 1/2005 and 1099/2009 to meet the requirement of humane handling and slaughter of animals. Regulation (EC) No. 1/2005 addresses the protection of animals during transport and related operations. Regulation (EC) No. 1099/2009 addresses the protection of animals at the time of slaughter. Regulation (EC) No. 853/2004, Annex III, Section 1, Chapter 2, addresses necessary facility requirements for humane handling of animals at the slaughterhouses. The Instruction of the CVO No. GIWpr.0200.1.19.2020 of 8 July 2020 states that government inspection personnel are required to ensure livestock presented for slaughter are handled and slaughtered humanely. In addition, Poland has developed humane handling verification instructions consistent with FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock - Revision 3 and made them available on the GVI website. The FSIS auditors, through records reviews and interviews of government inspection personnel, confirmed that humane handling and slaughter of livestock are conducted in accordance with the requirements.

The FSIS auditors confirmed that all livestock presented for slaughter receive ante-mortem examination in accordance with Regulation (EC) No. 625/2017, Articles 17-18; and Regulation (EC) No. 627/2019, Article 11. The Instruction of the CVO No. BP.0200.1.9.2021 of May 18, 2021 provides guidance to the OVs that carry out ante-mortem inspection activities and lays down the rules for the record-keeping of such activities. Records review indicated that at least one government veterinarian conducts ante-mortem examination of all swine prior to slaughter. GVI provided inspection documentation to show that the AOV conducting the ante-mortem examination verified the accompanying health certificate of the lot issued by another OV at the farm, and traceability documents identifying all the required information for the livestock. The FSIS auditors confirmed that the AOV performs ante-mortem examination at the time of unloading of swine and documents inspection observations in accordance with the GVI requirements.

GVI provided inspection documentation to show that each slaughter establishment is staffed with a sufficient number of government inspectors to conduct post-mortem inspection activities in accordance with Regulation (EC) No. 854/2004. The FSIS auditors confirmed that post-mortem inspection is conducted on every carcass by online AOVs during all hours of slaughter to meet both EC and FSIS requirements. This included reviews of supervisory records to verify the implementation of inspection requirements regarding proper presentation and identification; examination of heads, viscera, and carcasses; and disposition of affected carcasses and parts.

The control of animal by-products, including condemned materials, is accomplished through the application of Regulation (EC) No. 1069/2009 and Commission Regulation (EU) No. 142/2011. In addition, the Instruction of CVO No. GIWpr.0200.1.12.2020 of May 26, 2020 provides procedures for the supervision of animal by-products by inspection personnel. GVI provided inspection documentation to demonstrate that relevant portions of this regulation were applied, including: (a) appropriate identification in accordance with the categories described therein, (b) segregation in specially marked or otherwise secure containers, and (c) documented final disposal of these materials at nearby rendering facilities. Receipts documenting the cost of final disposal were maintained by each establishment and routinely reviewed by inspection personnel, as indicated by the presence of an official stamp.

Section 5, Note 7 of the Requirements for Establishments indicates that the DVO or the person(s) authorized by him or her are responsible for verifying on an ongoing basis that certified meat and meat products at any stage of their production and/or storage are separated from non-certified products. The GVI document Recommendations for the Veterinary Inspection Authorities Setting Out the Method for the Verification and Enforcement of the Provisions of the Federal Meat Inspection of the United States Department of Agriculture 9 CFR and Specifying the Rules for Managing the Knowledge Imparted to the Veterinary Inspection Employees Within the Framework of Cascade Training and Continuous Training on the United States Requirements dated July 15, 2020, describes the mandatory inspection requirements for establishments approved for export to the United States. This document includes requirements for the complete separation of establishments certified to export to the United States from noncertified establishments and states that raw materials used for the preparation of products intended for export to the United States should come from approved sources (i.e., eligible countries and establishments certified to export to the United States).

GVI stated that the majority of establishments used materials exclusively from their own slaughter production. In the remaining cases, the SV verifies that each shipment of source meat originated only from establishments certified to export to the United States. As indicated previously, SVs are assigned to establishments certified to export to the United States on a permanent basis, providing continuous inspection coverage on each shift, including both slaughter and processing operations.

GVI ensures that meat exports are not subject to animal health restrictions by regularly consulting the relevant sections of the APHIS website in addition to FSIS' foreign establishment eligibility table for individual countries, which also outlines current APHIS restrictions in place for these establishments. Poland is affected by ASF and has adopted the definitions of zones outlined in Commission Implementing Regulation (EU) 2021/605.

The periodic supervisory reviews of official establishments are conducted monthly in accordance with GVI requirements. The supervisory reviews include an assessment of the establishment's sanitary operations and HACCP records generated and maintained by the establishment, and examination of the official inspection records. The reviews are documented using a uniform detailed checklist entitled Control Report of the Establishment Approved for Export to the United States – Form 5000-6. Supervisory reviews are conducted by direct observations and complemented with records review activities by DVIs and RVIs. Periodic visits at the

establishments certified to export to the United States are conducted monthly by DVI officials, and quarterly by RVI officials.

Section 5, Note 2 of the Requirements for Establishments indicates that during the monthly supervisory visit, the DVI officials also evaluate the performance of the government inspection personnel at the establishments certified to export to the United States. This evaluation is conducted and documented using the Control Sheet of the Designated Official Veterinarian (OV). The objective of this supervisory procedure is to evaluate all the OVs assigned to establishments that export products to the United States during a calendar year. Some of the topics that are verified during the supervisory visits are inspection staffing, work rotations, work schedules, previous training on FSIS requirements, findings of previous audits, official documentation, and knowledge of FSIS requirements.

The FSIS auditors reviewed periodic supervisory reports conducted by representatives of DVI and RVI for selected establishments for this remote audit. All findings are documented on GVI's Form 5000-6 as described. If findings result in noncompliance, the process ensures documentation on noncompliance records (NR) and issuance of an administrative decision instructing the establishment to correct the finding(s). Only when the DVI officials have verified resolution of the noncompliance is the administrative decision repealed, indicating closure of the issue. The FSIS auditors also verified that the annual evaluations of inspection personnel were conducted by representatives of DVI as intended and documented on the Control Sheet of the Designated Official Veterinarian (OV). The FSIS auditors confirmed that these reviews were performed and documented in accordance with GVI requirements.

The FSIS auditors concluded that GVI continues to maintain the legal authority, a regulatory framework, and adequate verification procedures to ensure sufficient official regulatory control using statutory authority consistent with criteria established for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that GVI requires each official establishment to develop, implement, and maintain written sanitation standard operating procedures (sanitation SOP) to prevent direct product contamination or insanitary conditions.

The EC legislation outlines the criteria and standards for good hygiene practices. The legislation also requires the CCA in each EU Member State to be responsible for enforcing the EC food regulations by maintaining a system of official controls and other verification activities appropriate to each situation. Chapter IV of Regulation (EC) No. 853/2004 describes the requirements for sanitary dressing (slaughter hygiene) of livestock throughout the slaughter operations. Regulation (EC) No. 853/2004, Section I, Chapter IV, states that the carcass must not contain visible fecal contamination and that any visible contamination must be removed immediately by trimming or alternative means. Through remote interviews, the FSIS auditors confirmed that inspection personnel routinely verify that the establishment implements sanitary dressing procedures throughout the slaughter process in accordance with the instructions

provided in Guidelines for Official Veterinarians on Checks in Slaughterhouses in Good Hygiene Practices (GHP) and Animal Welfare, No. GIWbz-500-2/12 (1) of May 25, 2019.

GVI follows Regulation (EC) Nos. 852/2004 and 853/2004 to maintain official controls over establishment construction, facilities, and equipment. Annexes II and III of Regulation (EC) No. 852/2004 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 stipulates specific requirements for food business operators to ensure that the construction, layout, and equipment of slaughterhouses prevent the contamination or adulteration of meat.

GVI has adopted provisions consistent with 9 CFR 416 to meet requirements pertaining to sanitation in the establishments certified to export to the United States, which are documented in Section 3 of the Requirements for Establishments. The FSIS auditors confirmed through the review of inspection records that the official inspection personnel are verifying pre-operational and operational sanitation SOP requirements in accordance with GVI's requirements. The FSIS auditors also reviewed a sample of NRs generated by government in-plant inspection personnel to verify that in-plant inspection personnel had identified deficiencies during pre-operational and operational verification activities. The in-plant inspection personnel closed the NRs after verifying the adequacy and effectiveness of the establishment's corrective actions and preventive measures. The FSIS auditors' review of this documentation determined that government inspection personnel adequately described noncompliance and verified the effectiveness of the establishment's corrective actions.

GVI requires establishments certified to export to the United States to develop, implement, and maintain sanitation programs to ensure that the establishment's construction, facilities, and equipment prevent the contamination or adulteration of meat products destined for export to the United States.

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

The fourth equivalence component the FSIS auditors 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 auditors conducted interviews and reviewed documents at three establishments certified to export to the United States to verify whether Poland continues to maintain equivalence with respect to the HACCP system requirements. The FSIS auditors assessed the implementation and effectiveness of GVI's requirements and verification procedures in ensuring that HACCP requirements are effectively and fully implemented in each certified establishment. The FSIS auditors reviewed the critical control points (CCP), and results of official veterinary verification activities to verify compliance. All slaughter establishments had implemented CCPs to address zero tolerance contamination with fecal material, ingesta, and milk, as well as

additional controls to ensure that carcasses were chilled in a manner sufficient to prevent the outgrowth of microbial pathogens.

The FSIS auditors verified that OVs routinely review the establishments' implementation of their HACCP systems. GVI requires OVs to follow HACCP instructions in the Requirements for Establishments, Section 4. This section addresses verification methodology to ensure that the design and implementation of HACCP systems in the establishments certified to export to the United States meet GVI requirements. Any noncompliance is documented on an NR. The FSIS auditors reviewed a sample of NRs in three audited establishments to assess whether inspection personnel are applying proper verification methodology in accordance with the GVI instruction document referenced in the Government Oversight component in this report.

For the two establishments producing RTE products, the FSIS auditors reviewed the government HACCP verification records with a special emphasis on lethality for *Salmonella* and other relevant pathogens. Establishments producing cooked pork products elected to follow the lethality and stabilization performance standards consistent with Appendices A and B of the FSIS Compliance Guidelines for Cooking/Cooling Meat and Poultry Products. GVI also provided evidence demonstrating that the establishment producing dry-cured pork products maintained a validated HACCP program to support a 5-log reduction for *Salmonella* in these products.

The audit results show that GVI verifies that operators of official establishments comply with GVI's requirement to develop, implement, and maintain HACCP programs for each processing category.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

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

Council Directive 96/23/EC, Articles 5 and 7; Commission Decision 97/747/EC, Articles 1-2; Regulation (EU) No. 625/2017, Articles 4, 5, 6, 12, 34, 35, 37, 105, and 138-139; and Regulation (EC) No. 178/2002, Articles 12, 14, 18, and 19 mandate the development and implementation of a chemical residue control program, which includes random sampling of internal organs and fat of carcasses for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants. These EU legislations require Poland to design and submit an acceptable residue plan that follows EU guidelines.

According to the EU legislations, Poland's National Residue Control Plan (NRCP) provides instructions to its inspection system on method of sampling (strategy and criteria of sampling choice), type and quantity of samples, directions for performed examinations, course of action in case of detection of prohibited substances or excess of maximum permitted residue limits of

chemical residues, biological residues and medicinal products, and method of documentation of the action taken. Poland's NRCP specifies type and size of samples, sampling strategy, location, species, tissues, target compounds, and maximum residue limit. Depending on the target compounds, the type of samples consists of muscles, liver, kidney, fat, urine, and blood. The sample location includes farms and slaughterhouses.

The FSIS auditors' verification of this component, while conducted remotely, occurred at all levels of the inspection system which included interviews with central, regional, and district offices, local inspection offices at establishments, and at the National Veterinary Research Institute (NVRI). The FSIS auditors reviewed documents including certificates of analysis, interviewed government officials and OVs, and reviewed the residue testing program to confirm that the type and size of samples, sampling method, method of analysis, and location of sample collection of the targeted compounds were consistent with the information included in the CCA's SRT submission.

The FSIS auditors further confirmed that Poland's enforcement programs include: (1) procedures to document the disposition of contaminated product, (2) enforcement action against violators, and (3) measures to prevent recurrence of the same or similar violations. In the event a sample collected under the NRCP exceeds defined tolerance limits, it becomes a violative result upon confirmatory testing. The following actions are taken for violative results in accordance with Article 19 of Regulation (EC) No. 178/2002, which initiates a Rapid Alert System for Food and Feed notification and an on-farm investigation conducted by a DVO for every violative result. The source farms are subject to more frequent sampling at slaughter; traceable products are removed from the market by the establishment; and if deemed a significant threat to public health, the government would conduct a recall and inform consumers. The FSIS auditors verified the follow-up procedures performed in conjunction with two residue violations for anabolic steroids in swine identified through the NRCP in 2019. The follow-up activities also included onsite investigations of the farms involved in the violations.

Using GVI's information technology system, e-Klient, the FSIS auditors reviewed the government chemical residue sampling records for the two audited swine slaughter establishments. This review indicated that the 2021 sampling program was being adhered to as scheduled. The FSIS auditors confirmed that residue samples are collected by government personnel and are shipped under inspection seal. Samples are shipped to the laboratory in accordance with protocols outlined in Chief Veterinary Officer Instruction No. BP.0200.1.11.2021, which includes requirements and controls for sample collection, including procedures used to ensure sample integrity and chain of custody, packaging, storage, and transportation to the laboratory.

During review of ante-mortem inspection procedures at these establishments, the FSIS auditors confirmed that an OV verifies that all lots of animals are accompanied by records documenting their veterinary health examination, including proper withdrawal periods for medications used prior to slaughter. In response to the previous FSIS audit finding in 2019, the FSIS auditors verified that government inspection personnel maintain official custody over carcasses and parts when samples are collected for chemical residue analyses under the NRCP.

For analyses of samples collected under the NRCP, GVI relies on NVRI and 10 Regional Veterinary Hygiene Institution (ZHW) laboratories. NVRI is responsible for the coordination of laboratories, providing technical support, as well as oversight and auditing of the regional laboratories. For coordination among regional and central laboratories, NVRI develops an annual plan to address a variety of topics such as accreditation and new matrices. NVRI also serves as a designated reference laboratory in the EC.

The FSIS auditors interviewed government personnel from NVRI and the ZHW-Warsaw laboratories to verify their ability to provide adequate technical support to the inspection system. These interviews included a review of records documenting sample receipt, application of equivalent testing methods, adherence to maximum residue limits, and reporting of results. The FSIS auditors also reviewed proficiency testing for the regional laboratories which was administered by NVRI. No concerns arose from interviews held with laboratory personnel.

There have not been any chemical residue violations at the United States POE since the last FSIS audit in July of 2019. The result of the remote audit activities indicates that GVI 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 chemical contaminants in pork products destined for human consumption.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component the FSIS auditors reviewed was Government Microbiological Testing Programs. The food safety inspection system is to include certain sampling and testing programs to ensure that meat prepared for export to the United States are safe and wholesome. This component also addresses requirements for TPCS meat products.

The FSIS auditors verified that GVI requires all slaughter establishments certified to export product to the United States to collect and analyze carcass samples for indicator organisms in a manner consistent with the FSIS regulatory requirements referenced in 9 CFR 310.18(c). Through interviews with government officials, the FSIS auditors confirmed that the two selected slaughter establishments for this audit conducted sampling for generic *E. coli* at both pre-evisceration and post-chill points at a frequency of one sample for every 1,000 swine carcasses. Control charts shared by GVI with the FSIS auditors indicated that results were properly recorded. The FSIS auditors also reviewed a case of loss of process control at one establishment (identified through pre-evisceration sampling) for which it was determined that in-plant inspection personnel had verified that the establishment had implemented the necessary corrective actions. The FSIS auditors determined that the program for generic *E. coli* was implemented in parallel with the microbiological control testing program for *Enterobacteriaceae* established within the EU to verify process control in slaughter establishments, as per Regulation (EC) No. 2073/2005.

GVI continues to implement a *Salmonella* sampling and testing program for performance standards in swine carcasses which is consistent with the requirements previously outlined in 9 CFR 310.25(b) (now rescinded). Poland's *Salmonella* testing program is further detailed in the

document Rules of Salmonella Testing in the Process of Verification Control at Pig Slaughterhouses According to USDA-FSIS, which describes sampling procedures and instructions for inspection personnel regarding sampling frequency, collection sites on pork carcasses, randomized selection, sampling techniques, submission of samples to the designated laboratory, laboratory testing methods, interpretation of test results, and enforcement strategies. All samples are collected by inspection personnel and analyzed at official laboratories. The FSIS auditors reviewed government sampling results from two slaughter establishments and concluded that GVI is implementing their *Salmonella* carcass testing program as intended.

Section 7.4 of the Requirements for Establishments contains provisions that are consistent with 9 CFR 430 as well as verification activities conducted by OVs and official sampling programs. According to these provisions, establishments certified to export post-lethality exposed (PLE) RTE pork products to the United States must comply with the requirements by employing one of the three alternatives to address *Lm.* This document provides detailed procedures and instructions to inspection personnel on how to collect RTE product and environmental samples (product contact and non-product contact). In addition, Poland has adopted sampling and testing programs for *Lm* and *Salmonella* in non-PLE RTE products by implementing procedures consistent with FSIS Directive 5000.1, Verifying an Establishment's Food Safety System and FSIS Directive 10,240.4, Microbial Sampling of Ready-To-Eat (RTE) Products for the FSIS Verification Testing Program. The FSIS auditors confirmed that all official sampling is organized, scheduled, and collected by OVs, and all analyses are conducted at official laboratories. Product intended for export to the United States is maintained under official control pending acceptable laboratory results.

The FSIS auditors verified that the audited laboratories were implementing the analytical methodologies found equivalent by FSIS including ISO standard 6579, Microbiology of the food chain — Horizontal method for the detection, enumeration and serotyping of *Salmonella* — Part 1: Detection of *Salmonella* spp. The FSIS auditors further confirmed that GVI implements method ISO standard 11290-1, Microbiology of the food chain - Horizontal method for the detection and enumeration of *Listeria monocytogenes* and of *Listeria* spp. -- Part 1: Detection method.

GVI maintains a regulatory definition for TPCS product as product subjected to heat treatment under specified time and temperature parameters and placed on the market in hermetically sealed containers. Poland has adopted the FSIS regulatory requirements consistent with 9 CFR 431, subpart G, in their entirety, and conveys these requirements to all establishments certified to export TPCS product to the United States and inspection personnel in an instruction document previously referenced as Requirements for Establishments in the Government Oversight component of this report.

The GVI inspection personnel verify implementation of these requirements by following instructions provided that are consistent with FSIS Directive 7530.2, Verification Activities in Canning Operations that Choose to Follow the Canning Regulations. Furthermore, GVI conducts government verification testing for *Clostridium botulinum* and *botulinum* toxin. In the event of a processing deviation leading to contamination or adulteration of product, GVI

implements the provisions in Article 19 of Regulation (EC) No. 178/2002 to include market withdrawal and recall procedures.

The FSIS auditors interviewed GVI officials regarding verification activities and reviewed related documentation addressing 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 FSIS auditors interviewed personnel at the ZHW-Warsaw laboratory, which conducts analytical testing, including *Salmonella* and *Lm* in RTE products and environmental samples for official verification of products destined for export to the United States. These interviews included review of records for each phase of the analytical process, including sample receipt, application of equivalent testing methods, and reporting for these pathogens. No concerns were identified.

The FSIS auditors reviewed laboratory staff training records for those individuals conducting microbiological testing in conjunction with exports to the United States. The review determined that all analysts received required training to conduct analytical testing. Additionally, the FSIS auditors reviewed the test results including *Salmonella* and *Lm* and did not identify any issues. The recent proficiency test, quality manual, and the internal audit reports were in accordance with ISO standards. No concerns were identified.

There have not been any POE violations related to this component since the previous FSIS audit in 2019. FSIS concludes that GVI continues to meet the core equivalence requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held July 8, 2021, by videoconference with GVI. The FSIS auditors concluded that Poland's inspection system for raw and processed pork products is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The CCA has required that establishments certified as eligible to export products to the United States implement sanitary operating procedures and a HACCP system designed to improve the safety of their products. In addition, the CCA has implemented 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 POLAND
VETERINARY INSPECTION
DEPUTY
CHIEF VETERINARY OFFICER
Katarzyna Piskorz

Warsaw, 24 November 2021

WORKING TRANSLATION

TO:
Ms Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination
Food Safety and Inspection Service
1400 Independence Avenue, SW.
Washington, D. C.
20250 USA

OUR REFERENCE: BUEiWZ.0903.2.2021

SUBJECT: Pork audit

Dear Madam,

I kindly inform you that the Central Competent Authority (GVI) has read the submitted report describing the result of the USDA Food Safety and Food Safety Service (FSIS) Remote Equivalence Verification Audit from May 25 - July 8, 2021 and has not commented on it . The project of the above-mentioned report was prepared with a great understanding of the operation of the meat inspection system in Poland and the implementation of US regulations in Polish establishments of the pork sector approved for export to the indicated market.

The following issues require correction in the content of the report, i.e .:
1. In part II of the above-mentioned report, titled "Purpose, scope and methodology of the audit", in Table 2 showing the scope of the remote audit and locations, there was a mistake in the number of one establishment, ie the correct veterinary identification number of the Animex Foods Sp. z o. o., ul. T. Chałubińskiego 8, 00-613 Warsaw, Szczecin Branch, ul. Pomorska 115 B, 70-812 Szczecin is: 32620201, and not as indicated in the report 32020202;
2. In part IV of the above-mentioned report, titled "Component one: government supervision (eg organization and administration)", the CVO Instruction No. GIWhig-500-4 / 08 of April 1, 2008 *on the methodology of official controls* was indicated. The number of this Instructionl in connection with its update at the moment is:
GIWpr02010-14 / 2019 of December 31, 2019 *on the methodology of official controls and verification of the performance of official activities.*

At the same time, with reference to the content of the report in Component 5 on chemical residues:

1. Regarding the sentence: "Samples are shipped to the laboratory in accordance with protocols outlined in Instructions of the CVO No. GIWpr-02010-8 / 2019 of April 30, 2019 "I would like to explain that the new monitoring instruction is valid, ie the Chief Veterinary Officer Instruction No. BP.0200.1.11.2021 of May 26, 2021. on the scope and manner of implementation of the national program for the control of prohibited substances, chemical and biological residues, medicinal products in animals, in animal products and in water intended for animal water and fodder.

2. Regarding the sentence: "GVI relies on NVRI and six Regional Veterinary Hygiene Institution (ZHW) laboratories", I would like to explain that the residue control tests are carried out in the Department of Pharmacology and Toxicology and in the Department of Hygiene of Food of Animal Origin of NVRI (PIWet-PIB in Puławy) (National Reference Laboratories) and in the laboratories of 10 Regional Veterinary Laboratories (ZHW - Białystok, Bydgoszcz, Gdańsk, Katowice, Kielce, Łódź, Olsztyn, Poznań, Warsaw and Wrocław).

Kind regards,

Katarzyna Piskorz
(signed electronically)