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United States Department of Agriculture

Food Safety and
Inspection Service

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JAN 15 2020

Dr. Bogdan Konopka
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Dear Dr. Konopka,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an on-site verification audit of Poland's inspection system from July 15 through August 1, 2019. 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.

If you have any questions regarding the audit report, please contact the Office of International Coordination by electronic mail at internationalcoordination@usda.gov.

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN POLAND

JULY 15 THROUGH AUGUST 1, 2019

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

RAW AND PROCESSED MEAT PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

December 20, 2019

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from July 15 through August 1, 2019. 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 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; raw non-intact pork; and not ready-to-eat 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.

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

GOVERNMENT OVERSIGHT(e.g., ORGANIZATION AND ADMINISTRATION)

- Government inspection personnel are not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical testing results prior to signing export certificates.

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 facilities; and failure to inspect the dorsal external surfaces of the carcass at one facility.

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.

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.

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

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Poland's food safety system from July 15 through August 1, 2019. The audit began with an entrance meeting on July 15, 2019, in Warsaw, Poland, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – the General Veterinary Inspectorate (GVI). Representatives from the CCA accompanied the FSIS auditors throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether the food safety system governing raw and processed meat 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	Ground product; other non-intact; and sausage.
Raw – Intact	Raw intact pork	Boneless manufacturing trimmings; carcass (including halves or quarters); cuts (including bone in and boneless meats); edible offal; other intact; and primals and subprimals.
Thermally Processed/Commercially Sterile	Thermally processed, commercially sterile	Corned (species); ham; other; sausage; and soups.
Not Heat Treated – Shelf Stable	RTE acidified/fermented meat (without cooking)	Other – not sliced; other – sliced; sausage/salami – not sliced; and sausage/salami – sliced.
Not Heat Treated – Shelf Stable	RTE dried meat	Ham – not sliced; ham – sliced; jerky; other – not sliced; and other – sliced.
Heat Treated – Shelf Stable	NRTE otherwise processed meat	Bacon; meals/dinners/entrees; other; pies/potpies; rendered fats, oils; sandwiches/filled rolls/wraps; sauces; smoked parts; and soups.

[1] All source meat used to produce products must originate from eligible countries and establishments certified to export to the United States. For processed meat products, meat includes the following species: beef, goat, lamb, mutton, pork, and veal.

Process Category	Product Category	Eligible Products[1]
Heat Treated – Shelf Stable	RTE dried meat	Ham – not sliced; ham – sliced; jerky; other – not sliced; and other – sliced.
Heat Treated - not Fully Cooked – Not Shelf Stable	NRTE otherwise processed meat	Bacon; meals/dinners/entrees; other; pies/potpies; rendered fats, oils; sandwiches/filled rolls/wraps; sauces; sausage products; smoked parts; and soups.
Fully Cooked – Not Shelf Stable	RTE fully-cooked meat	Diced/shredded; ham patties; ham, not sliced; ham, sliced; hot dog products; meat and non-meat component; nuggets; other fully cooked not sliced product; other fully cooked sliced product; parts; patties; salad/spread/pate; and sausage products.
Fully Cooked – Not Shelf Stable	RTE fully-cooked meat without subsequent exposure to the environment	Diced/shredded; ham patties; ham, not sliced; ham, sliced; hot dog products; meat and non-meat component; nuggets; other fully cooked not sliced product; other fully cooked sliced product; parts; patties; salad/spread/pate; and sausage products.

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 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.

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 the CCA through the self-reporting tool (SRT).

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

Administrative functions were reviewed at CCA headquarters, six district offices, and 10 local inspection offices. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended. A sample of 10 establishments was selected from a total of 19 establishments certified to export pork products to the United States. This included nine pork slaughter and processing establishments, and one establishment conducting solely processing activities.

During the establishment visits, the FSIS auditors verified the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. 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.

Additionally, two government laboratories (one conducting both microbiological and chemical residue testing, the other conducting solely chemical residue testing) were audited to verify their ability to provide adequate technical support to the food safety inspection system.

Competent Authority Visits		**#**	**Locations**
Competent Authority	Central	1	• General Veterinary Inspectorate, Warsaw
	District Offices	6	• District Veterinary Inspectorate (DVI), Czluchow • DVI, Elk • DVI, Jaroslaw • DVI, Poznan • DVI, Szczecin • DVI, Starachowice
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		9	• Establishment No. 10 02 38 02, Animex, Kutno • Establishment No. 14 29 02 01, Sokolow, Sokolow Podlaski • Establishment No. 18 04 02 01, Sokolow, Jaroslaw • Establishment No. 22 02 38 01, Skiba, Chojnice • Establishment No. 22 03 02 07, Goodvalley, Czluchow • Establishment No. 26 11 02 01, Animex, Starachowice • Establishment No. 28 05 02 01, Animex, Elk • Establishment No. 30 21 02 25, Sokolow, Poznan • Establishment No. 32 62 02 01, Animex Foods, Szczecin
Swine processing establishments		1	• Establishment No. 10 02 40 02, Animex, Kutno

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

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

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

- Regulation European Commission (EC) No. 178/2002;
- Regulation (EC) No. 852/2004;
- Regulation (EC) No. 853/2004;
- Regulation (EC) No. 854/2004;
- Regulation (EC) No. 882/2004;
- Regulation (EC) No. 1/2005;
- Regulation (EC) No. 2073/2005;
- Regulation (EC) No. 1069/2009;
- Regulation (EC) No. 1099/2009;
- Regulation (EU) No. 142/2011;
- Council Directive No. 93/119/EC;
- Council Directive No. 96/22/EC; and
- Council Directive No. 96/23/EC.

III. BACKGROUND

From April 1, 2016 to March 31, 2019, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 4,098,392 pounds of thermally processed, commercially sterile (TPCS) pork; 13,849,335 pounds of ready-to-eat (RTE) pork fully-cooked without subsequent exposure to the environment; 45,716,375 pounds of RTE fully-cooked pork; 24,146 pounds of RTE dried pork; 193,123 pounds of RTE acidified/fermented pork (without cooking); 354,236,258 pounds of raw intact pork; 30,395 pounds of raw non-intact pork; and 3,399,787 pounds of not ready-to-eat (NRTE) otherwise processed pork exported by Poland to the United States.

FSIS also performed re-inspection on 221,093 pounds of heat treated-not fully-cooked - not shelf stable pork, 30,140 pounds of raw non-intact pork, 27,827,210 pounds of raw intact pork, 19,510 pounds of RTE acidified/fermented pork (without cooking), 12 pounds of RTE dried meat, 5,573,078 pounds of RTE fully-cooked pork, 1,766,503 pounds of RTE fully-cooked pork (without subsequent exposure to the environment), and 248,559 pounds of TPCS pork at POE for

additional types of inspection (TOI). This re-inspection includes testing for chemical residues and microbiological pathogens (*Listeria monocytogenes* [*Lm*] and *Salmonella* in RTE products) for which no products were rejected for issues related to public health.

The previous audit in 2017 identified the following findings:

GOVERNMENT OVERSIGHT(e.g., ORGANIZATION AND ADMINISTRATION)

- The CCA, GVI, has not provided inspection personnel the specialized training on canning and canned products requirements in accordance with the GVI issued *Requirements for Establishments Approved to Export Meat and Poultry and Their Products to the Market of the United States*.
- Poland's use of contracted employees to conduct verification activities during periods when establishments are producing products for the United States without government supervision does not meet FSIS' statutory requirements.

GOVERNMENT SANITATION

- Deficiencies related to the enforcement of sanitation performance standards (SPS) requirements were identified in five of the nine audited establishments and deficiencies related to sanitation standard operating requirements in four of the nine audited establishments. Official inspection personnel had failed to identify, or effectively enforce these findings that posed direct or indirect potential for product contamination if not corrected.

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

- Deficiencies related to the enforcement of HACCP were identified in three of the nine audited establishments.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- The official RTE product sampling methodology and analysis is not consistent with the FSIS equivalence determination for International Organization for Standardization (ISO) 6579.
- Two establishments were using m/M criteria to analyze the generic *E. coli* results from samples collected using the carcass sponge technique. The m/M criteria is designed to be used with excision samples.

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

Prior to the on-site equivalence verification audit, FSIS reviewed and analyzed Poland's SRT responses and supporting documentation. During the audit, the FSIS auditors conducted interviews, reviewed records, and made observations to determine whether Poland's food safety

inspection system governing raw and processed meat products is being implemented as documented in the country's SRT responses and supporting documentation.

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

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

The first of six equivalence components 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 FSIS auditors verified that the CCA for 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 monthly audits at each establishment eligible 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, 318, 319, 416, 417, and 430 in their entirety in order to meet United States requirements for labeling, canning, sanitation, HACCP, and requirements for specific classes of product, respectively.

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 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 verified that each establishment maintained a written recall plan in accordance with these requirements.

During the audit of the GVI headquarters, the FSIS auditors verified the procedures for establishment certification for gaining eligibility to export to the United States. Establishment certification for the United States market requires registration at the DVI. Establishments seeking certification must successfully implement procedures consistent with the United States requirements for three months before they are recommended eligible for certification. The DVO has the authority to accept or reject the application based on the outcome of the on-site inspection verification of establishment compliance with United States requirements. If approved, the DVO submits the application to the RVO, who delegates an RVI official to conduct an inspection and affirm certification. The RVI then sends recommendations for the certification to GVI headquarters. The GVI reviews the documents prior to updating the list of eligible establishments and then submits the list to FSIS. The FSIS auditors reviewed documents associated with the approval process of an establishment recently certified to export to the United States (Establishment No. 22 00 303, Tarczynski S.A.). This review indicated that the GVI implemented the above-referenced procedures for this facility.

Interviews conducted with the GVI indicate that any new establishments applying for the United States market are also evaluated at the central level. The 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 verified that the system ensures only eligible source material are used to produce products intended for export to the United States. The FSIS auditors verified that adequate segregation or separation of products was maintained at all audited establishments.

During the visits to establishments certified to export to the United States, the FSIS auditors verified the key elements associated with the certification of meat products exported 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 officials 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 sampling i.e., "hold and test" prior to certifying product for export to the United States; this was not the case for official chemical residue testing conducted as part of the national residue monitoring program. This resulted in the following finding:

- Government inspection personnel are not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical testing results prior to signing export certificates.

The FSIS auditors verified the corrective actions related to the previous FSIS audit (2017), where it was determined that using contracted employees to conduct verification activities during periods when establishments are producing products for the United States without direct government supervision did not meet FSIS' statutory requirements. These contracted employees, holding the title of Appointed Official Veterinarians (AOV), were responsible for conducting inspection duties such as ante-mortem and post-mortem inspection, sanitation, and HACCP verification activities.

In response to this finding, Poland's CVO created a new position with the title of Supervisory Veterinarian (SV) at establishments eligible to export to the United States. These individuals are full-time government employees of the DVI and are assigned to establishments eligible to export to the United States on a permanent basis, providing continuous inspection coverage on each shift, including both slaughter and processing operations. The SV responsibilities include coordination and direct verification of the activities performed by the AOVs; 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, chemical and biological residues; control of the correct storage of veterinary stamps by the AOVs; checking the validity of the declarations of the AOV's on the absence of conflicts of interest; organizing meetings with AOV's in order to ensure consistent inspection methodology; control over fulfilment of veterinary requirements in the entire facility, including those resulting from the requirements of the United States (e.g., sanitation, HACCP, and humane handling requirements).

The FSIS auditors reviewed records that clearly showed that the 19 establishments currently eligible to export pork products to the United States were staffed with full-time government employees of the DVI. This included a review of the employment contracts of the newly-hired SVs at the audited DVI offices.

Poland follows Regulation (EC) No. 882/2004, which requires the CCA to ensure that all inspection personnel or licensees are paid by the government. This regulation requires the CCA to ensure that adequate financial resources are available to provide the necessary staff and other resources for official 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. Remuneration for SVs and other civil service employees is in accordance with Article 8 of the *Act of 21 November 2008 on Civil Service* and is paid from the state budget. Budget expenditures for wages are financed from Section 4020 of this act. Remuneration for AOVs is conducted in accordance with Articles 12 and 16 of the *Act of 29 January 2004 on the Veterinary Inspection*, which is also paid from the state budget. The FSIS auditors were able to confirm direct payment of the AOVs by reviewing invoices submitted from individual AOVs to the DVI accounting department and subsequent payment.

Regarding the conflict of interest controls, the inspection personnel are required to comply with the provisions of Regulation (EC) No. 882/2004. The Instruction of the *CVO, No. GIWhig-500-4/08 of April 1, 2008*, implements the provisions related to conflicts of interest described in Regulation (EC) No. 882/2004. The persons appointed to perform inspection tasks cannot

perform them in the event of situations described in Article 24 of the *Act of June 14, 1960 – Code of Administrative Procedure*. The FSIS auditors reviewed the AOV employment contracts maintained at the DVI offices which showed that they include signed conflict of interest affidavits for those individuals assigned to establishments eligible to export to the United States.

The FSIS auditors confirmed that all OVs[1] must have a Doctor of Veterinary Medicine or equivalent degree, and the official auxiliaries (OAs) 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. 854/2004, Article 2 and Regulation (EC) No. 882/2004, Articles 4-6, 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 training covering the United States import requirements. The FSIS auditors noted that all newly-assigned SVs had received specific training regarding United States requirements.

The OVs attending 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 personnel working in establishments eligible to export to the United States. 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 official personnel responsible for enforcing regulatory requirements at establishments eligible 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., the RVI, DVI, and local inspection levels). In response to the 2017 FSIS audit finding, the FSIS auditors noted that the GVI had arranged a training session in the latter part of that year entitled "*Training for the Veterinary Inspection on Canning Technology and Critical Points Determining the Quality of Meat and Meat Products"*. Training attendees included 10 members of the GVI, 16 members of the RVI, and 56 members of the DVI.

The GVI maintains a communication system to convey requirements related to United States export throughout its inspection system. The FSIS auditors verified that the 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.

The 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, the GVI created a system of official laboratories, which are accredited to International Organization for Standardization (ISO) standard 17025, *General requirements for the competence of testing and calibration laboratories*. This accreditation is certified 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

[1] The term Official Veterinarian (OV) applies to both Supervisory Veterinarians (SV) and Appointed Official Veterinarians (AOV), as both are directly paid and represent official agents of the Polish government.

has the authority to approve the laboratory for official testing, or alternatively, withdraw approval in the event that the laboratory is unable to meet ISO 17025 requirements.

FSIS determined that the 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. However, the FSIS auditors noted that the inspection personnel are not required to review and confirm acceptable testing results from chemical residue samples of products tested for adulterants as defined by FSIS prior to signing the export certificate.

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

The second of six equivalence components the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of each and every carcass and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

GVI has adopted Regulation (EC) No. 853/2004, Regulation (EC) No. 1/2005, Regulation (EC) No. 1099/2009, and Council Directive No. 93/119/EC 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. Council Directive No. 93/119/EC and Regulation (EC) No. 1099/2009 address 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 Chief Veterinary Officer, No. GIWbż-420-31/13 of March 28, 2013*, states that inspectors are required to ensure swine presented for slaughter are handled and slaughtered humanely. In addition, Poland has developed humane handling verification instructions consistent with FSIS Directive 6900.2 and makes them available on the GVI website.

The FSIS auditors verified that each slaughter establishment includes full-time AOVs dedicated to performing ante-mortem inspection and to verifying compliance with humane handling and slaughter requirements as per the regulations cited above. The FSIS auditors followed the AOVs as they oversaw the unloading of livestock; toured the animal pens, driveways, ramps, and floors; and viewed the procedures of stunning and methods to verify effective stunning. All the slaughtering facilities visited utilized carbon dioxide gas as a means to stun animals.

In accordance with Regulation (EC) No. 854/2004 and other established inspection procedures, animals that show clinical signs of disease may not be slaughtered for human consumption. However, suspect animals may be slaughtered at separate slaughter facilities on official premises that ensure segregation of suspect livestock. The FSIS auditors verified that the GVI developed

adequate procedures to ensure complete segregation of suspect livestock and that any meat products from such animals is precluded from export to the United States.

The *Instruction of the Chief Veterinary Officer, No. GIWbż-500-4/12of November 27, 2012,* provides guidance to the OVs that carry out ante-mortem inspection activities and lays down the rules for the record keeping of such activities. The FSIS auditors confirmed that all livestock presented for slaughter receive ante-mortem inspection, which is performed by government inspection personnel prior to slaughter. The FSIS auditors observed that the AOV conducting the ante-mortem inspection 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 AOV performs ante-mortem inspection at the time of unloading of swine but also evaluates swine in the ante-mortem pens. The FSIS auditors verified that the AOV maintains a log of ante-mortem inspection and also identifies the number of animals passing ante-mortem inspection as well as the time the inspection occurs. The review of records maintained in the offices indicates that all animals arriving at the slaughterhouses receive ante-mortem inspection within 24 hours before slaughter.

The FSIS auditors confirmed that post-mortem inspection is conducted on each and every carcass by an AOV under the direct supervision of an SV. On-line inspection is provided during all hours of slaughter to meet both EC and United States requirements. The FSIS auditors assessed post-mortem examinations through on-site record review, interviews, and observations of inspection activities in all audited slaughter establishments. The FSIS auditors observed and verified the presentation, identification, examination, and disposition of carcasses and parts. This included observation of the performance of the AOVs examining the heads, viscera, and carcasses, for which FSIS auditors identified deficiencies related to post-mortem inspection at four of the nine audited swine slaughter and processing establishments. At four of these establishments, the post-mortem viscera AOVs were not palpating the mesenteric lymph nodes during post-mortem inspection activities as required by Regulation (EC) No 854/2004, Section IV. At one of these establishment, the final carcass AOV was observing only the inside of the carcass and did not rotate the carcass to inspect the dorsal external surfaces.

- 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 facilities, and failure to inspect the dorsal external surfaces of the carcass at one facility.

The control of animal by-products, including condemned materials, is accomplished through the application of Regulation (EC) No. 1069/2009 and the Commission Regulation (EU) No. 142/2011 of February 25, 2011. In addition, the *Instruction of CVO No. GIWpr-02010-11/2014 of December 30, 2014,* provides procedures for the supervision of animal by-products by inspection personnel. During the audit, the FSIS auditors verified that the 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 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. *A letter from the Deputy CVO – Reference No. GIWbż-52-United States-4(1) of January 20, 2010*, describes the basic requirements which have to be met in the case of approving establishments for export to the United States. This document includes requirements for the complete separation of establishments certified to export to the United States from non-certified establishment and states that raw materials used for the preparation 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).

The FSIS auditors noted that the majority of establishments used materials exclusively from their own slaughter production. In the remaining cases, FSIS noted that the SV verified that each shipment of source meat originated only from establishments certified to export to the United States (typically a sister facility within Poland). As indicated previously, SVs are assigned to establishments eligible to export to the United States on a permanent basis, providing continuous inspection coverage on each shift, including both slaughter and processing operations.

The CCA ensures that its meat exports are not subject to animal health restrictions by regularly consulting the relevant sections of the APHIS website in addition to FSIS' product eligibility chart for individual countries, which also considers current APHIS restrictions. Poland is affected by ASF and has adopted the definitions of zones outlined in *Commission Decision 2014/709/EU*. This includes (1) disease-free buffer zones; (2) zones where the disease is present in the wild boar population; and (3) zones where the disease is present in the wild boar and domestic swine population. The FSIS auditors' interviews of GVI officials indicated that all swine used in conjunction with the preparation of product exported to the United States is to originate from "free zones", i.e., areas that do not fall into either of the categories outlined above and are free of any restrictions related to ASF. This was further verified by the FSIS auditors during visits to nine pork slaughter and processing establishments, where it was noted that live pigs are required to be accompanied by documents attesting to their zone of origin.

The monthly supervisory reviews of official establishments are conducted in accordance with the *Requirements for Establishments*. The supervisory reviews include an assessment of the establishment's operations, sanitation 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 named – *Control Report of the Establishment Approved for Export to the United States – Form 5000-6*. Supervisory reviews during on-site visits are conducted by direct observations and complemented with record review activities. Periodic visits at the establishments certified to export to the United States are conducted at a monthly frequency by DVI officials as well as RVI officials at different times each month.

Section 5, Note 3 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 appointed to establishments certified to export to the United States 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 supervisory visit reports conducted by representatives of the DVI and RVI at establishments certified to export to the United States for the last 12 months. The FSIS auditors verified that Poland is performing and documenting supervisory visits to each certified establishment as described. The CCA is ensuring a monthly frequency by both the DVI and RVI officials, and these visits are conducted at separate times each month. All findings are documented on the CCA's Form 5000-6 as described. If findings result in noncompliance, the process ensures documentation on noncompliance records 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 the DVI as intended and documented on the *Control Sheet of the Designated Official Veterinarian (OV).*

The CCA has the legal authority to establish regulatory controls over establishments certified to export meat products to the United States. However, 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 facilities; and failure to inspect the dorsal external surfaces of the carcass at one facility.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components the FSIS auditors reviewed was Government Sanitation. The FSIS auditors verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation standard operating procedures (sanitation SOPs) 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 competent authority 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 (10), 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 on-site 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. GIWbż-500-2/12 (1) of May 25, 2019.* The FSIS auditors further noted that establishments maintained programs through which sanitary dressing

defects are documented and reviewed on a periodic basis in order to identify any significant trends.

The GVI follows Regulation (EC) No. 852/2004 and Regulation (EC) No. 853/2004 to maintain official controls over establishment construction, facilities, and equipment. Regulation (EC) No. 852/2004, Annexes II and III stipulates 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 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.

The 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 GVI issued document, *Requirements for Establishments*. The FSIS auditors verified through direct observation and review of records that each audited establishment has implemented sanitation SOP requirements and has food safety programs to ensure that SPS requirements are addressed. The design of written sanitation SOPs includes operational and pre-operational sanitation procedures and monitoring of these procedures with some defined frequencies.

The FSIS auditors observed the in-plant government inspector conducting pre-operational sanitation verification of slaughter and processing areas. The in-plant government inspector's hands-on verification procedures begin after the establishment personnel completed their pre-operational sanitation inspection and determined that the facility is ready for government pre-operational sanitation verification activities. Additionally, the FSIS auditors followed the offline government inspector and observed inspection verification of operational sanitation procedures at all audited establishments. These verification activities included direct observation of operations and review of the establishments' associated records. The FSIS auditors noted that the results of the government's verification are documented on Form 5000.1-6, *Weekly Verification List in the Establishment.*

The 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 the United States.

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

The fourth of six equivalence components 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 in conjunction with direct observation at ten 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 the CCA's requirements and verification procedures in ensuring that HACCP requirements are effectively and fully implemented in each certified establishment. The FSIS auditors observed the critical control points (CCP), and reviewed the establishment hazard analyses, flow charts, and HACCP plans. The FSIS auditors also reviewed the supporting documents and results of official veterinary verification activities to verify compliance. Each audited establishment had performed a hazard analysis and addressed the expected hazards for appropriate steps of the process. The establishments had developed flow charts that aligned with the process. 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. The GVI requires OVs to follow instructions in the *Requirements for Establishments*, Section 4, 9 CFR 417 – Hazard Analysis and Critical Control Point Systems (HACCP). 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 requirements. Any noncompliance is documented on a noncompliance record. At each audited establishment, the FSIS auditors reviewed a sample of noncompliance records to assess whether inspectors are applying methodology in accordance with instructions provided in the GVI instruction document referenced in the Government Oversight Component in this report.

The FSIS auditors reviewed the zero tolerance (i.e., for visible feces, ingesta, and milk) CCP at nine swine slaughter and processing establishments. The auditors also verified the physical CCP locations by observing inspection personnel conducting HACCP hands-on verification activities. The FSIS auditors noted deficiencies with the procedures used to conduct zero tolerance verification at four of the nine slaughter establishments visited. The GVI has adopted verification procedures which are based on FSIS Directive 6420.2, and the identified deficiencies indicate inconsistent implementation of these procedures in the districts across the nation. These inconsistencies fall into three major classifications (1) independent selection: at one establishment, inspection personnel were conducting daily hands-on government verification on the same set of carcasses identified by the establishment for their routine monitoring; (2) frequency: at three establishments, government inspectors were performing weekly, rather than daily, hands-on verification checks; and (3) sample size*:* at three establishments, the sample size did not meet the values based on slaughter volume outlined in Poland's procedures (which replicate the values outlined in Attachment 1 of FSIS Directive 6420.2).

- The FSIS auditors noted deficiencies related to the manner by which zero tolerance verification was performed 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.

At those establishments producing RTE products, the FSIS auditors reviewed the HACCP programs for these processes 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 outlined in Appendices A and B of the *FSIS Compliance Guidelines for Cooking/Cooling Meat and Poultry Products*.

The audit results show that the CCA verifies that operators of official establishments implement the CCA's requirement to develop, implement, and maintain HACCP programs for each processing category. However, the FSIS auditors identified inconsistencies with implementation of zero tolerance verification procedures in in various districts.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

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

Council Directive 96/23/EC, Articles 5 and 7; Commission Decision 97/747/EC, Articles1-2; Regulation (EC) No. 882/2004, Articles 4, 8, 10, 11, 12, 54-55; and Regulation (EC) No. 178/2002, Articles 12, 14, 18, and 19 mandate that Poland develop and implement 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, the species, the tissues, the 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 farm and slaughterhouses.

The FSIS auditors' verification of this component occurred at all levels of the inspection system which included central, regional, and district offices, local inspection offices at establishments, and at the NVRI. The FSIS auditors reviewed documents including certificates of analysis, interviewed government officials and OVs, and reviewed the residue testing program to confirmed that Poland's NRCP includes the type and size of samples, sampling method, method of analysis, and location of sample collection of the targeted compounds.

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 investigations conducted by a DVO for every violative result. The source farms are subject to more frequent sampling at slaughter; traceable products removed from the market by establishment; and if deemed a significant threat to public health, then the government would also conduct a recall at the consumer level and inform consumers. The FSIS auditors verified the follow-up procedures performed in conjunction with two residue violations for doxycycline (an antibiotic) in swine identified through the NRCP in 2018. The follow-up activities also included on-site investigations of the farms involved in the violations.

Using the GVI's information technology system, e-Klient, the FSIS auditors reviewed the government chemical residue sampling records for the nine audited swine slaughter establishments. This review indicated that the 2019 sampling program was being adhered to as scheduled. 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 *Instructions of the CVO No. GIWpr-02010-8/2019 of April 30, 2019*, 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 observed that an OV verifies that all lots of animals are accompanied by records documenting their veterinary examination and treatment history ("food chain"); and a declaration that attests that owners have adhered to veterinary pharmaceutical withdrawal periods. As indicated under Component 1 of this report, neither the establishment nor government inspection personnel are required to retain the carcass and parts when samples are collected for analyses for chemical residues under the NRCP. However, if samples are collected from an animal suspected of harbouring chemical residues, the carcass and associated parts are held pending acceptable results.

For analyses of samples collected under the NRCP, the GVI relies on the NVRI and six ZHW Laboratories. The NVRI is responsible for the coordination of laboratories, providing technical support, as well as oversight and auditing of the regional laboratories. For the purpose of coordination among regional and central laboratories, the NVRI develops an annual plan to address a variety of topics such as accreditation and new matrices. All laboratories involved in performing analysis for the NRCP are accredited in conformity with the ISO 17025 standard, and due to its enormous capabilities in the scientific and diagnostic fields, the NVRI also serves as a designated reference laboratory in the EC.

The FSIS auditors visited the NVRI and the ZHW-Warsaw laboratories in order to verify their ability to provide adequate technical support to the inspection system. The laboratory audits included interviews with the officials, document reviews, and concluded with a site visit to the

chemical testing portion of the laboratory. These laboratories are accredited to the ISO 17025 standard by the PCA.

The FSIS auditors verified that the laboratory Quality Manual included all expected chapters, including organization, staff qualifications, credentials, and training. The NVRI includes a dedicated quality assurance manager responsible for implementation of the Quality Manual including internal audits and action plans. Newly hired analysts receive three months of general training followed by learning in their assigned laboratory. New hires are assigned proficiency test samples and remain under close supervision. The FSIS audit included a review of proficiency testing for the regional laboratories which was administered by the NVRI. NVRI proficiency testing is scheduled and administered by EC reference laboratories. No concerns arose as a result of the laboratory audit.

There have not been any chemical residue violations at the United States POE since the last FSIS audit occurred in September 2017. The result of the on-site audit activities indicates that the 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 sixth of six equivalence components the FSIS auditors reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that meat products prepared for export to the United States are safe and wholesome.

The FSIS auditors verified that the GVI requires all United States-certified slaughter establishments to implement a written generic *E. coli* plan consistent with FSIS regulatory requirements referenced in 9 CFR 310.25(a). Through review of establishment records, the FSIS auditors verified that the swine slaughter establishments are collecting one sample per 1,000 carcasses and documenting results in process control charts. The FSIS auditors noted that this program was conducted 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. No concerns were identified during the review of these programs.

The GVI has developed a *Salmonella* sampling and testing program for performance standards in swine carcasses which is consistent with 9 CFR 310.25(b). 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 procedures and instructions for inspection personnel regarding the manner and frequency of collecting sample swabs from the surface of pork carcasses with a sponge (sponge technique), rules for randomized selection of carcasses for sampling, sampling techniques, submission of samples to the laboratory, laboratory testing methods, interpretation of test results, and enforcement strategies. All samples are collected by government personnel and analyzed at official laboratories. The

FSIS auditors observed government personnel performing sampling of swine carcass surface for *Salmonella* testing using the sponge techniques. No concerns were identified.

FSIS considers the design of the GVI's official sampling and analysis program for *Salmonella* in swine carcasses equivalent; however, the FSIS auditors identified deficiencies related to the implementation of this program at two establishments eligible to export pork products to the United States. In one establishment, the FSIS auditors noted a request for a *Salmonella* testing series at the ZHW-Warsaw laboratory was initiated at the request of the exporting establishment rather than the DVI. Discussions with representatives from the GVI indicated that this occurred due to the sporadic nature of the establishment's slaughter activities, for which the DVI considered that the familiarity with their own schedule would be helpful for determining when an entire set could most easily be completed. However, the GVI also indicated that this practice is not consistent with the expectations of how the *Salmonella* sets should be scheduled, and that this should originate from the DVI, as the scheduling of the sample sets by the establishment can ultimately introduce biases which would compromise the accuracy of testing results.

In another establishment, inspection personnel were not directly provided with the official *Salmonella* testing results for swine carcasses at one of the audited swine slaughter and processing establishments. The laboratory was in the practice of sending test results solely to the originating establishment, which would then be responsible for providing inspection personnel with a copy. This practice also does not meet the requirements of the GVI, which require all test results to be provided directly to the DVI.

- 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.

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 RTE product 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* by implementing procedures consistent with 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 laboratories were implementing the analytical methodologies approved 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 the CCA 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*.

The 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 United States regulatory requirements in 9 CFR 431, subpart G, in their entirety, and conveys these requirements to both establishments certified to export 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, the GVI conducts government verification testing for *Clostridium botulinum* and *botulinum* toxin. In the event of a processing deviation leading to contamination or adulteration of the product, the GVI implements the provisions in Article 19 of Regulation (EC) No. 178/2002 to include market withdrawal and recall procedures.

The FSIS auditors reviewed the 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' review of these documents showed that they were developed by process authorities, typically constituted by the internal technology staff of the company under the direction of a Chief Technologist, and included critical factors such as fill weight, height space, as well as come-up and venting times. Final incubation procedures were conducted in accordance with the frequencies, times, and temperatures outlined in the *Requirements for Establishments*.

The FSIS auditors visited the ZHW-Warsaw laboratory to review its microbiology program and verified that it 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. The FSIS auditors reviewed records associated with the most recent PCA accreditation issued in March 2017 (valid four years), whereby it was verified that these test methods were included in the laboratory's scope of accreditation. The FSIS auditors also reviewed the results of a recent ISO standard 17025 maintenance audit conducted by the PCA in March 2019 and determined there were no significant findings.

The FSIS auditors interviewed analysts and reviewed their training records. 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 last FSIS audit. FSIS concludes that GVI continues to meet the core equivalence requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on August 1, 2019, in Warsaw, Poland, with the GVI. At this meeting, the preliminary findings from the audit were presented by the FSIS auditors. An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

GOVERNMENT OVERSIGHT(e.g., ORGANIZATION AND ADMINISTRATION)

- Government inspection personnel are not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical testing results prior to signing export certificates.

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 facilities; and failure to inspect the dorsal external surfaces of the carcass at one facility.

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

- The FSIS auditors noted deficiencies related to the manner by which zero tolerance verification was performed 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.

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.

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

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Animex K4 Spółka z ograniczoną odpowiedzialnością Oddział K4 w Kutnie 99-300 Kutno ul. Wschodnia 21	07/17/2019	10 02 38 02	Poland
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

The FSIS auditors identified the following findings related to the implementation of Poland's inspection system:

55. The post-mortem viscera inspector was not following the procedures outlined in Regulation (EC) No 854/2004, Section IV (determined equivalent by FSIS). Palpation of the mesenteric lymph nodes was omitted during post-mortem (swine) inspection activities.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/17/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Animex K1 Kutno	07/16/2019	10 02 40 02	Poland
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

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

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/16/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
SOKOŁÓW" S.A. 08-300 Sokołów Podlaski Al. 550-lecia 1	07/16/2019	14290201	Poland
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
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18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	X
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
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23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

The following non-compliances were not previously identified by Poland's inspection officials:

19. The final carcass inspector was observing only the inside of the carcass and did not rotate the carcass to inspect the dorsal external surfaces. The official veterinarian selects 25 carcasses once per week to verify CCP1 (ZT) on-line which does not meet the frequency listed in FSIS Directive 6420.2. The establishment slaughter approximately 2600 swine per day in one shift.

46. The FSIS auditor observed a swine carcass identified for rail-out by the official carcass inspector (due to a bilateral lung adhesion with large encapsulated abscess) being subject to measurement of fat and vacuuming of the internal surfaces, thereby creating the potential for cross-contamination of the carcasses which followed (vacuum and fat meter were not sterilized after coming into contact with the affected carcass).

55. The post-mortem viscera inspectors were not palpating the mesenteric lymph nodes during post-mortem inspection activities as required by the current equivalence agreement between FSIS and the European Commission (which is based on procedures outlined in Regulation (EC) No 854/2004, Section IV).

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/16/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
SOKOŁÓW" S.A. 37-500 Jarosław ul. Przemysłowa 2	07/19/2019	18040201	Poland
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
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19. Verification and validation of HACCP plan.	X
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25. General Labeling	
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29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

The following non-compliances were not previously identified by Poland's inspection officials:

19. The official veterinarian selects 11 carcasses once per week to conduct ZT check off-line, which does not meet the frequency listed in FSIS Directive 6420.2. The establishment slaughter approximately 1200 swine per day in one shift.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/19/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Zaklady Miesne SKIBA . ul. Droga do Igiel 2 89-600 Chojnice Ubojnia	07/26/2019	22 02 38 01	Poland
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
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Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
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11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
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Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
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18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
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26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
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27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

The following non-compliances were not previously identified by Poland's inspection officials:

13. Records documenting corrective actions taken in response to deficiencies identified during operational monitoring of the establishment's sanitation standard operating procedures (SSOP) were incomplete in that they did not always document the disposition of product. For example, a record documenting the removal of a cracked container from an active production area did not indicate the extent to which product was or was not affected.

22. Records documenting corrective actions taken in response to deviations from the critical limit for the "zero tolerance" (feces, ingesta, milk) critical control point (CCP) were incomplete. Specific omissions included the type of contamination identified; as well as documentation that the CCP was back under control once the corrective action was taken.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/26/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Goodvalley Sp. z o.o. 77-320 Przechlewo ul. Mlynska 43B	07/25/2019	22 03 02 07	Poland
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
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Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
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Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
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29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

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

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/25/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
ANIMEX FOODS 27-200 Starachowice ul. Krańcowa 4	07/23/2019	26110201	Poland
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	
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Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

The following non-compliances were not previously identified by Poland's inspection officials:

10. During verification of pre-operational sanitation in meat cutting department, multiple black stains were observed on the product contact surface of white conveyor belts. In the slaughter room, precipitation of black particles in viscera inspection trays.

19. The official veterinarian selects 10 carcasses once per week to contact ZT check on-line. This does not meet the frequency listed in FSIS Directive 6420.2 as the establishment slaughter approximately 3700 swine per day in one shift.

39. Perforated or broken PVC pipes improperly wrapped with loose duct tape with exposed insulation material in more than one location. Accumulation of dirty grease and rust in multiple locations of overhead carcass rails.

41. Beaded condensation above an entrance door in the cutting room. Dripping condensation from cooling unit and ventilation sleeve in the transition-cooling room past cutting department.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/23/2019

United States Department of Agriculture
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Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
ANIMEX FOODS 19-300 Ełk ul. Suwalska 86	07/26/2019	28050201	Poland
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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30. Corrective Actions	
31. Reassessment	
32. Written Assurance	X

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
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35. Residue	
Part E - Other Requirements	
36. Export	
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38. Establishment Grounds and Pest Control	
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53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57.	
58.	
59.	

60. Observation of the Establishment

The following non-compliances were not previously identified by Poland's inspection officials:

19. Government verification procedure for fecal ZT in swine carcasses is inconsistent with FSIS Directive 6420.2. The contracted veterinarian performs the ZT check only once per day by taking 7 carcasses off-line. The company selects these carcasses and performs its own ZT check then the contracted veterinarian performs his check on the same 7 carcasses. The company slaughters about 5200 hog per day in two shifts (350 hog/hour).

32. Results of the *Salmonella* testing program for swine carcasses are not sent directly from the laboratory to the government inspection personnel or responsible District office; they are reported to the establishment management, which then provides the results to inspection personnel.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/26/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Sokolow SA Oddzial w Robakowie 62-023 Gadki Robakowo ul. Poznanska 14	07/19/2019	30 21 02 25	Poland
	5. AUDIT STAFF OIEA International Audit Branch (IAB)		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

The FSIS auditor identified the following findings related to the implementation of Poland's inspection system:

55. The post-mortem viscera inspector was not following the procedures outlined in Regulation (EC) No 854/2004, Section IV (determined equivalent by FSIS). Palpation of the mesenteric lymph nodes was omitted during post-mortem (swine) inspection activities.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/19/2019

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Animex Foods Szczecin	07/23/2019	32 62 02 01	Poland
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Branch (IAB)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	X
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Thermally Processed / Commercially Sterile Product	X
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

The following non-compliance was not identified by Poland's inspection officials during the establishment review:

57. The FSIS auditor observed improper filling of 300 g containers on the production line for canned luncheon meat. Numerous containers presented chunks of meat mixture along their top edges (flange) as they proceeded to the can closing machine. The presence of meat on the flange can ultimately impact the integrity of the double seam which is created between the body of the can and the lid during the closure process.

In addition, FSIS identified the following findings related to the implementation of Poland's inspection system:

55. The post-mortem viscera inspector was not following the procedures outlined in Regulation (EC) No 854/2004, Section IV (determined equivalent by FSIS). Palpation of the mesenteric lymph nodes was omitted during post-mortem (swine) inspection activities.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Branch (IAB)	07/23/2019

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

Warsaw, 20 December 2019

VETERINARY INSPECTION

CHIEF VETERINARY OFFICER

Dr. Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination
Food Safety and Inspection Service
1400 Independence Avenue, SW
Washington, D.C.
20250
United States of America

Our ref. no.: GIWue.0800-295/2019 (5) US

Ref. no.: – Letter of: 21 October 2019

Dear Dr. Catlin,

Having reference to your letter of 21 October 2019 providing the Polish side with the draft report from the audit that took place in Poland on 15 July – 1 August 2019 and concerned the assessment of the food safety supervision system for pig meat and pig meat products exported to the USA, please find enclosed the Polish side's answer to the draft report, i.e. a summary of actions undertaken in response to audit findings by the establishments and by the local organs of the Veterinary Inspection as well as a description of actions undertaken by the central competent authority.

Please accept the assurances of my highest consideration.

Yours sincerely

DEPUTY
CHIEF VETERINARY OFFICER
Katarzyna Piskorz

Cc (electronic copy only):
Mr. Tomasz Zmiejko, Deputy Director, Department of International Cooperation, MARD
Mr. Jonn Slette, Agricultural Attaché, American Embassy in Warsaw

Główny Inspektorat Weterynarii ul. Wspólna 30, 00-930 Warszawa
tel.: (22) 623-20-88, fax: (22) 623-14-08, e-mail: wet@wetgiw.gov.pl, www.wetgiw.gov.pl

CCA (GVI) CORRECTIVE ACTIONS
WITH REGARD TO THE CONCLUSIONS IN THE DRAFT FINAL REPORT
OF AN AUDIT CONDUCTED IN POLAND
JULY 15 THROUGH 1 AUGUST 2019
EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING
RAW AND PROCESSED MEAT PRODUCTS
EXPORTED TO THE UNITED STATES OF AMERICA

The central competent authority (CCA- GVI) has examined the contents of the draft report and does not wish to raise any comments. The above mentioned draft report has been prepared with great understanding of the meat inspection system in Poland and of the implementation of US laws in the Polish pork sector establishments approved for export to the targeted market.
At the same time, below I present the corrective actions that the General Veterinary Inspectorate (CCA) undertook in relation to non-compliances identified by FSIS auditors during the audit and indicated in the content of the report.

Non-compliances:

1. GOVERNMENT OVERSIGHT(e.g., ORGANIZATION AND ADMINISTRATION)

• Government inspection personnel are not confirming acceptable testing results from livestock carcasses and parts subjected to routine government chemical testing results prior to signing export certificates.

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 facilities; and failure to inspect the dorsal external surfaces of the carcass at one facility.

3. 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.

4. 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.

CORRECTIVE ACTION

First of all, it should be emphasized that on 1 August 2019, at the closing meeting of the audit at the General Veterinary Inspectorate, FSIS inspectors discussed in the form of presentations all non-compliances found during the ongoing audit. In view of the above, the Chief Veterinary Officer before receiving the draft FSIS report, on 9 August 2019 sent a letter to the local organs of the Veterinary Inspection supervising the pig meat establishments authorized to export to the USA, in which he issued relevant recommendations and instructions in connection with the non-compliances found by FSIS auditors (**Annex 1** - letter of 9 August 2019, reference number: GIWbż-52-158 / 2019 (5) US). The letter relates to all non-compliances listed in the draft FSIS report, i.e.:

a. With regard to the non-compliance mentioned in point 1 above, regarding the lack of holding of pig carcasses and parts thereof subject to testing for chemical residues, until receipt and confirmation of acceptable test results before signing export health certificates, in the abovementioned letter on 9 August 2019 the GVI described to the VI field authorities the FSIS "hold and test" requirement and indicated that it was necessary to implement this requirement in Polish establishments authorized to export to the US market. The above issue was also discussed on 23-25 October 2019 at a training in Puławy organized by the Chief Veterinary Officer for employees of the Veterinary Inspection. In addition, on 21 November 2019, the Chief Veterinary Officer sent another letter to Regional Veterinary Officers (see **Annex 2** - letter of November 21, 2019, reference number: GIWbż-52-319/2019(2)US) asking for written guarantees that:

- procedures have been developed and implemented in all pig slaughterhouses authorized for export to the US market which ensure that the carcasses subject to official testing for residues are held and are in a separate place under the supervision of VI until acceptable test results are obtained and that the personnel of the establishment each time verifies whether the staff of the Veterinary Inspection released carcasses subject to the abovementioned tests prior to signing the pre-shipment review records;
- the staff of the Veterinary Inspection daily supervises and controls the carcasses subject to sampling for residues on site, awaiting acceptable test results to ensure that carcasses found to be non-compliant are not approved for use in the manufacture of products intended for export to USA;
- district veterinary officers as part of monthly inspections check whether the staff of the Veterinary Inspection on site at the establishment review and confirm the acceptable results of tests for residues before signing the export health certificate for the shipment of goods intended for the US market.

Regional Veterinary Officers confirmed that the FSIS "hold and test" requirement in establishments authorized to export to the US market has been implemented.

b. With respect to the non-compliance mentioned in point 2, regarding deficiencies in post-mortem inspection (i.e. no palpation of mesenteric lymph nodes and no examination of the external dorsal surface of the carcass), Chief Veterinary Officer in the abovementioned letter of 9 August 2019, reference number: GIWbż-52-158/2019(5) US) (see **Annex 1**) reminded the local authorities of the Veterinary Inspection that in pig slaughterhouses authorized for export to the US market, official veterinarians should perform traditional post-mortem inspection activities consisting of: visual inspection, palpation and incision of carcasses and organs/lymph nodes in relation to each pig carcass. In addition, in the abovementioned letter recommended that district veterinary officers should organize training in the abovementioned scope for designated official veterinarians and full-time employees of the DVI supervising establishments authorized to export to the US market.
Moreover on 23-25 October 2019, the Chief Veterinary Doctor organized the training in Puławy for employees of the Veterinary Inspection on US regulations, in which the principles of ante-mortem and post-mortem inspection of pigs were discussed in the form of presentation (**Annex 3** - training program with a list of its participants). In addition, in a letter dated 21 November 2019, sign: GIWbż-52-319/2019(2)US (see **Annex 2**), the Chief Veterinary Officer asked Regional Veterinary Officers to provide written guarantees that in all pig slaughterhouses eligible for export to the US market, both designated veterinarians and full-time employees of the DVI had been trained, as indicated in the letter: GIWbż-52-158/2019(5)US of 9 August this year. Regional Veterinary Officers confirmed that the above training took place.

c. With regard to the non-compliance mentioned in point 3 regarding deficiencies in the scope of official verification of the FSIS standard of zero tolerance, Chief Veterinary Officer in the abovementioned letter of 9 August 2019, sign: GIWbż-52-158 / 2019 (5) US) (see **Annex 1**) reminded that the abovementioned verification should be performed daily and in accordance with Annex 1 to the FSIS Directive 6420.2, posted on the GIW website under the link:
https://www.wetgiw.gov.pl/handel-eksport-import/stany-zjednoczone
Additionally, on 23-25 October 2019, the Chief Veterinary Officer organized the training in Puławy for employees of the Veterinary Inspection on US regulations, in which the provisions of the FSIS Directive 6420.2 (**Annex 3** - training program along with a list of its participants) were discussed in detail in the form of a presentation. In addition, in the letter of November 21, 2019, sign: GIWbż-52-319 / 2019 (2) US) (see **Annex 2**) the Chief Veterinary Officer asked the Regional Veterinary Officers to provide written guarantees that in all pig slaughterhouses authorized for export to the US market, the official verification of the "zero tolerance" requirement is carried out by the staff of the Veterinary Inspection in accordance with the provisions of FSIS Directive 6420.2 version 1 " Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Livestock Slaughter Operations - Revision 1", with particular regard to the required frequency verification, random selection of carcasses for verification,

the number of carcasses for verification, in accordance with Annex 1 to the abovementioned Directive.
Regional Veterinary Officers, assured that at present the provisions of the abovementioned FSIS directives are implemented correctly.

d. With respect to the non-compliance mentioned in point 4 concerning deficiencies related to the implementation of official sampling and analysis for Salmonella from pig carcasses, the Chief Veterinary Officer in the letter of 9 August 2019, reference: GIWbż-52-158/2019(5)US (see **Annex 1**) issued relevant recommendations in this matter to the local authorities of the Veterinary Inspection.
Moreover, in a letter of 21 November 2019, sign: GIWbż-52-319 /2019(2)US) (see **Annex 2**), the Chief Veterinary Officer asked Regional Veterinary Officers to provide written guarantees that for all slaughterhouses pigs authorized to export to the US market as part of procedures adopted by district veterinary officers regarding the collection of official samples from pig carcasses for Salmonella, the schedule for sampling series for the next 55 slaughter days is developed directly by the District Veterinary Officers and sent to the laboratory (from the DVI email address). It was also underlined that:
- the procedures adopted by DVO have to address the issue of not informing the establishment of the first official sample from a series of 55 samples to be taken;
- issues regarding the accepting of samples by the laboratory, the performance of the test and the way of sending results are agreed between the District Veterinary Officer and the Veterinary Hygiene Institute (without the participation of the establishment). The results of the analyzes are sent from the laboratory directly to the District Veterinary Officer for review.
Regional Veterinary Officers confirmed that the official sampling of pig carcasses for Salmonella (series of samples from the next 55 slaughter days) will be collected in accordance with the abovementioned recommendations of the Chief Veterinary Officer.

INFORMATION ON CORRECTIVE ACTIONS TAKEN BY THE LOCAL VETERINARY INSPECTION BODIES AND ESTABLISHMENTS AGAINST THE NON-COMPLIANCES LISTED IN "ANNEX A" TO THE FSIS AUDIT REPORT (AUDIT CONDUCTED IN POLAND ON 15 JULY -1 AUGUST 2019)

The General Veterinary Inspectorate (CCA) provides below a brief description of the corrective and preventive actions taken by the local organs of Veterinary Inspection and establishments with reference to the non-compliances listed in Annex A to the FSIS report from audit conducted in Poland on 15 July – 1 August 2019. At the same time, Annexes to the description of these activities are included in the folder "Attachment - corrective actions (local Veterinary Inspection and establishments)". This folder is divided into folders with names assigned to individual establishments subjected to the FSIS audit in 2019 in which the abovementioned annexes are included.

1. Animex K4 Spółka z ograniczoną odpowiedzialnością Oddział K4 w Kutnie, 99-300 Kutno, ul. Wschodnia 21 (No 10 02 38 02)

Non-compliances: The post-mortem viscera inspector was not following the procedures outlined in Regulation (EC) No 854/2004, Section IV (determined equivalent by FSIS). Palpation of the mesenteric lymph nodes was omitted during post-mortem (swine) inspection activities.

Corrective actions:
The District Veterinary Officer in Kutno undertook immediate corrective actions – he removed from the performance of official duties the veterinarians performing on the day of the FSIS audit (i.e. 17 July 2019) improper post-mortem inspection. Also on 22 July 2019 there was an additional reminder theoretical training for official veterinarians exercising supervision at the establishment Animex K4 Sp. z o.o. Oddział K4 in Kutno regarding ante-mortem and post-mortem inspection and animal welfare in the light of EU and US requirements (**Annex 1**). On 23 July 2019, a similar practical training was carried out and the correctness of performing ante-mortem and post-mortem inspection of official veterinarians supervising the abovementioned establishment was verified (**Annex 2**). The above verification confirmed the correctness of inspection performed by official veterinarians at individual examination positions. In addition, on 27-29 November 2019, the District Veterinary Officer in Kutno conducted another cascade training for all appointed veterinarians supervising the slaughter of animals (pigs, cattle and poultry) in the field of ante-mortem and post-mortem inspection, meat assessment and compliance monitoring provisions on the protection of animals at the time of slaughter (**Annex 3**).

2. Animex Kutno Spółka z ograniczoną odpowiedzialnością Oddział K1 w Kutnie, 99-300 Kutno, ul. Intermodalna 8 (No 10 02 40 02)

No corrective actions were taken because the Checklist for the abovementioned the establishment states that: „There were no significant findings to report after consideration of the nature, degree, and extent of all observations".

3. „SOKOŁÓW" S.A. Oddział w Sokołowie Podlaskim, 08-300 Sokołów Podlaski, Al. 550-lecia 1 (No 14 29 02 01)

Non-compliances:

a. The final carcass inspector was observing only the inside of the carcass and did not rotate the carcass to inspect the dorsal external surfaces. The official veterinarian selects 25 carcasses once per week to verify CCP1 (ZT) on-line which does not meet the frequency listed in FSIS Directive 6420.2. The establishment slaughter approximately 2600 swine per day in one shift.

b. The FSIS auditor observed a swine carcass identified for rail-out by the official carcass inspector (due to a bilateral lung adhesion with large encapsulated abscess) being subject to measurement of fat and vacuuming of the internal surfaces, thereby creating the potential for cross-contamination of the carcasses which followed (vacuum and fat meter were not sterilized after coming into contact with the affected carcass).

c. The post-mortem viscera inspectors were not palpating the mesenteric lymph nodes during post-mortem inspection activities as required by the current equivalence agreement between FSIS and the European Commission (which is based on procedures outlined in Regulation (EC) No 854/2004, Section IV).

Corrective actions

On 6-7 October 2019, the District Veterinary Officer in Sokołów Podlaski conducted training in the field of ante-mortem and post-mortem inspection of pigs in accordance with US requirements and EU regulations, during which non-compliance mentioned by the FSIS auditor was discussed and the correctness of ante-mortem post-mortem inspection and the method carrying out an assessment of the purity of pig carcasses (**Annex 1**). On October 21 and November 25, 2019, the District Veterinary Officer in Sokołów Podlaski carried out inspections at the plant to meet US requirements, documented with the "Report on the inspection of a plant authorized to export to the USA (Form 5000-6)", during which it found no non-compliance conducted in the abovementioned establishment for post-mortem inspection by official veterinarians. At the same time, from 6 September 2019, a procedure was introduced by the District Veterinary Officer in Sokołów Podlaski for "Verification of procedures for controlling fecal material, ingesta and bile during slaughter of pigs", in which during one slaughter shift 11 pig carcasses are checked for contamination with feces, ingesta and bile (**Annex 2**).

In addition, on 3 September 2019, the establishment updated its own position instruction for pig slaughtering (GMP PR-01.01) (**Annex 3** - page 7 of this instruction), which specifies that in the event of railing out a carcass to the side track for a detailed examination, this carcass is specially marked and not technologically processed by establishment employees. On 27-30 September 2019, a slaughter inspection was carried out documented with the protocol "CHECK LIST SPIWET -00" No. 14290201 / 01US / 2019, during which it was confirmed that the abovementioned procedure is followed by establishment personnel.

4. „SOKOŁÓW" S.A. Oddział w Jarosławiu, 37-500 Jarosław, ul. Przemysłowa 2 (No. 18 04 02 01)

Non-compliances: The official veterinarian selects 11 carcasses once per week to conduct ZT check off-line, which does not meet the frequency listed in FSIS Directive 6420.2. The establishment slaughters approximately 1200 swine per day in one shift.

Corrective actions

On the day of the FSIS audit (i.e. 10 July 2019) the official CCP "zero tolerance" verification was carried out based on the procedure implemented by the District Veterinary Officer in Jarosław titled: "Controlling fecal material and ingesta", which ensures implementation of the provisions of the FSIS Directive 6420.2 version 1 " Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Livestock Slaughter Operations - Revision 1"

According to the provisions of this procedure:
- official CCP "zero tolerance" verification is performed daily,
- 11 carcasses are randomly selected for each slaughter shift (the establishment slaughters approximately 1,200 pigs per day in one shift).

Please find enclosed (**Annex 1**) examples of the 'Daily registration forms' from the official verification of pig carcasses for fecal contamination and ingesta for the period of:
- the week preceding the abovementioned FSIS audit (07 July 2019 – 12 July 2019);
- the week in which the FSIS audit was carried out (15 July 2019 – 19 July 2019, on 17 July 2019 the abovementioned establishment did not perform slaughter);
- the week following the week in which the FSIS audit was carried out (22 July 2019 – 26 July 2019).
- in addition, 'Daily registration forms' for the last period, i.e. 22 October 2019 - 31 October 2019.

The above forms in the following columns indicate: carcass number, time of carrying out verification, carcass assessment, description of contamination (including color, texture and size), signature of the official veterinarian.

5. Zakłady Mięsne SKIBA S. A. Oddział Ubojnia Trzody Chlewnej w Chojnicach, 89-600 Chojnice, ul. Droga do Igieł 2 (No 22 02 38 01)

Non-compliances:

a. Records documenting corrective actions taken in response to deficiencies identified during operational monitoring of the establishment's sanitation standard operating procedures (SSOP) were incomplete in that they did not always document the disposition of product. For example, a record documenting the removal of a cracked container from an active production area did not indicate the extent to which product was or was not affected.

b. Records documenting corrective actions taken in response to deviations from the critical limit for the "zero tolerance" (feces, ingesta, milk) critical control point (CCP) were incomplete. Specific omissions included the type of contamination identified;

as well as documentation that the CCP was back under control once the corrective action was taken.

Corrective actions

A. Activities in the area of official supervision:

- on 29 July 2019 training(**Annex 1)** was provided for official veterinarians supervising slaughter of pigs in the scope of the FSIS Directive 6420.2 version 1 "Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Livestock Slaughter Operations - Revision 1" and official verification of the effectiveness of the establishment's SSOP system;
- on 08 August 2019 training (**Annex 2)** was provided for official veterinarians appointed to perform the inspection of slaughter animals and meat in the abovementioned establishment within the scope of the duties of a veterinarian under the FSIS Directive 6420.2 version 1 " Verification of Procedures for Controlling Fecal Material, Ingesta and Milk in Livestock Slaughter Operations - Revision 1" in relation to individual post-mortem inspection posts;
- on 29 July 2019 a meeting was held with representatives of the management board of the above the establishment at which the basic requirements for establishments approved for export to the US market were reminded, with particular emphasis on corrective and preventive actions taken by the establishment in response to non-compliance found as part of the ownership control in the area of SSOP and HACCP specified in 9 CFR § 310.25, 416 and 417;
- the frequency of checking the records kept by the establishment as part of the owner control was increased;
- on 02 August 2019 the District Veterinary Officer in Chojnice organized a training **(Annex 1**) during which he discussed with the employees of the quality control department a catalog of corrective actions to be taken in the event of a deviation, how to monitor the effectiveness of SSOP and actions to be taken to restore proper sanitation, preventive actions and identification and handling of the adulterated product, as well as correct documentation of the activities carried out.

B. Activities by the establishment

1. The establishment reviewed the CC Monitoring Instruction, as a result of which the provisions for corrective and preventive actions were specified in the following way: "In the event of contamination found at CCP 1, the employee at this position:
- stops the slaughter line and informs the supervisor of the non-compliance found,
- the supervisor (slaughter manager, foreman) immediately identifies the type of contamination (e.g. feces, ingesta, bile, bristles) and determines the reason for its occurrence,
- an employee at the CCP 1 stand removes contamination by cutting with a knife or cutting out the carcass area with changes, dirt (observing the special hygiene and sanitary rules described in the Worker's Instructions in special situations when slaughtering animals and cutting meat I8 / PR6),
- the slaughter manager, foreman or employee of the quality control department takes appropriate corrective actions, i.e.

✓ training of a line worker responsible for contamination (respectively: fecal contamination - rectal encapsulation employee, ingesta contamination -

abdominal opening and evisceration employees, milk contamination - abdominal opening employees, bile contamination - center removal worker);

- ✓ adding a second employee to the position
- ✓ change of employee,
- ✓ release of the slaughter line,
- ✓ increasing the frequency of monitoring (extension of windows by monitoring another 20 carcasses) and,
- ✓ increasing the monitoring frequency by 1 additional window a day for the next 30 days.

2. From 29 July 2019, the establishment introduced the principle of ongoing analysis of documentation in the field of monitoring and verification of CCP 1 by the representative of food safety systems management. The above mentioned representative:

- on 15 August 2019 **(Annex 2)**, conducted training for employees of the quality control and cutting department in the field of: SPS, SSOP - preoperative and intraoperative control method, keeping records and verifying records;
- reviewed the entries for the period from 27 July 2019 to 21 November 2019 during which no non-compliance was found.

The verification of corrective actions of the establishment carried out by the District Veterinary Officer in Chojnice showed as follows:

- review of records on the monitoring and verification of CCP 1 for the period 27 July 2019 – 21 november 2019 - no irregularities,
- review of records regarding SSOP monitoring for the period 27 July 2019 – 21 Nvember 2019 - no irregularities.

6. Goodvalley Sp. z o.o., 77-320 Przechlewo, ul. Młyńska 43 B (No 22 03 02 07)

No corrective actions were taken because in the Checklist for the abovementioned the establishment states that: „There were no significant findings to report after consideration of the nature, degree, and extent of all observations".

7. ANIMEX FOODS Oddział w Starachowicach, 27-200 Starachowice, ul. Krańcowa 4 (No 26 11 02 01)

Non-compliances:

a. During verification of pre-operational sanitation in meat cutting department, multiple black stains were observed on the product contact surface of white conveyor belts. In the slaughter room, precipitation of black particles in viscera inspection trays.

b. The official veterinarian selects 10 carcasses once per week to contact ZT check on-line. This does not meet the frequency listed in FSIS Directive 6420.2 as the establishment slaughter approximately 3700 swine per day in one shift.

c. Perforated or broken PVC pipes improperly wrapped with loose duct tape with exposed insulation material in more than one location. Accumulation of dirty grease and rust in multiple locations of overhead carcass rails.

d. Beaded condensation above an entrance door in the cutting room. Dripping condensation from cooling unit and ventilation sleeve in the transition-cooling room past cutting department.

Corrective actions

During the FSIS audit on 23 July 2019, during the pre-operational control, non-compliance was found in the establishment's operations. Individual departments were detained by safety inspectors until these inconsistencies were removed by the establishment and allowed for production after re-inspection of the abovementioned inspectors. All non-conformities and re-control were included in the SSOP Control Charter - Before Starting Production on 23 July 2019 (**Annex 1**). The FSIS auditor has been informed of the removal of all non-conformities and the release of individual departments for production. The above-mentioned non-compliance, found by food safety inspectors, concerned the following:

- ✓ dirty cutting tapes were found in the pork cutting ward; re-inspection was carried out - the cutting tapes were washed and disinfected (**Annex 2**)
- ✓ condensation was found in the pork cutting department - immediately removed (**Annex 3**)
- ✓ condensation was found on the fan and constructions in the post-cutting warehouse - immediately removed (**Annex 4**)
- ✓ the slaughter ward there were found stains on the trays for intestines, excessive grease on constructions - irregularities removed **(Annex 5**)
- ✓ damaged pipe covers, corroded elements of the slaughter line structure - these incompatibilities have been taken into account in the SPIWET checklist No. 26110201 / No. 7/19, in the form NC and in the administrative decision of the District Veterinary Officer in Starachowice (**Annex 6**). Damaged pipe cover was immediately secured. The establishment submitted a written commitment to completely replace the pipe covers at the slaughterhouse by 31 November 2019 (**Annex 7**).

In addition, from 05 August 2019, the procedure "Verification of CCP 1 control procedures - zero tolerance of contamination for feces, ingesta, milk and bile during slaughtering of pigs" (**Annex 8**) was developed and implemented.

Food safety inspectors in the abovementioned establishment perform CCP1 verification in accordance with the above procedure and the FSIS Directive 6420.2 version 1 "Verification of Procedures for Controlling Fecal Material, Ingesta and Milk in Livestock Slaughter Operations - Revision 1" - i.e. once a shift, i.e. 11 carcasses (22 half-carcasses) (**Annex 9**). In addition, the "Inspection Report of zero tolerance standard for visible fecal material, ingesta and milk and bile on carcasses or parts thereof" was verified (**Annex 10**), which includes in the following columns: CCP, critical limit, hour of verification, controlled element, units selected for inspection (slaughter number of the piece for half-carcasses), result of inspection, place of contamination on the carcass, type of identified contamination, result of repeated inspection, signature of the veterinary inspector.

All non-compliances found during the FSIS audit were consistent with the non-compliances that were observed by food safety inspectors and included in the inspection reports prepared on the day of the audit.

8. ANIMEX FOODS Oddział W EŁKU, 19-300 Ełk, ul. Suwalska 86 (No 28 05 02 01)

Non-compliances:

a. Government verification procedure for fecal ZT in swine carcasses is inconsistent with FSIS Directive 6420.2. The contracted veterinarian performs the ZT check only once per day by taking 7 carcasses off-line. The company selects these carcasses and performs its own ZT check then the contracted veterinarian performs his check on the same 7 carcasses. The company slaughters about 5200 hog per day in two shifts (350 hog/hour).
b. Results of the Salmonella testing program for swine carcasses are not sent directly from the laboratory to the government inspection personnel or responsible District office; they are reported to the establishment management, which then provides the results to inspection personnel.

Corrective actions
As part of the corrective and preventive actions, the procedure specifying the activities performed by the veterinary inspector, consisting of verification, documentation and enforcement of the zero tolerance requirement, i.e. the absence of visible fecal material, ingesta and milk on pig carcasses (**Annex 1**) has been improved and implemented. According to the provisions of the above procedures, the veterinary inspector on the side slaughter line carries out "zero tolerance" verification on pig carcasses once for each slaughter shift. In the above establishment more than 500 pigs are slaughtered in a single shift. The veterinary inspector randomly selects 11 carcasses (22 half-carcasses) during each slaughter shift in such a way that the selection time and slaughter numbers of the selected pieces are previously unknown to the establishment's staff. After randomly selecting the carcasses and directing them to the side slaughter line, the inspector checks all selected carcasses (from two sides - back and front) using the technique used for post-mortem carcasses at the test stand. After checking, the inspector confirms that this verification has been carried out and records its result on Forms 1A or 1B regarding the Verification of procedures for controlling fecal material and ingesta and milk at slaughter (**Annex 2**). The above forms in the following columns include the following: slaughter date, time of verification, slaughter number of the piece, presence of contaminants and their type, corrective actions, if necessary, signature of the veterinary inspector. In addition, the abovementioned the inspector has access to the results of tests carried out by the establishment and to records of all monitoring activities that may affect the analysis of hazards in the establishment and reviews the results of these activities once a week. From the above the reviewer prepares documentation in the form of a note with his own signature and stamp.

At the same time, from January 22 to April 8, 2019, official samples were taken from the surface of pig carcasses with regard to Salmonella. The program has already been completed this year. However, in 2020 the above official samples will be taken by veterinary inspectors, and the client will be the District Veterinary Officer in Ełk. Each time a sample will be attached to the order form for testing in the laboratory of the Institute of Veterinary Hygiene in Bialystok (**Annex 3**). The test results will be forwarded to the client - i.e. the office of the District Veterinary Inspectorate in Ełk.

9. „SOKOŁÓW" S.A. Oddział w Robakowie, 62-023 Gądki, Robakowo, ul. Poznańska 14 (No 30 21 02 25)

Non-compliances:

The post-mortem viscera inspector was not following the procedures outlined in Regulation (EC) No 854/2004, Section IV (determined equivalent by FSIS). Palpation of the mesenteric lymph nodes was omitted during post-mortem (swine) inspection activities.

Corrective actions

In connection with the discrepancy found during the FSIS audit regarding post-mortem inspection of mesenteric lymph nodes, the District Veterinary Officer in Poznań took immediate corrective actions in which:

- on 23 July 2019, he suspended the official duties of an official veterinarian performing improper post-mortem inspection and directed him to a training course ended with checking knowledge in the form of an exam conducted by DVO in Poznań,
- on 30-31 July 2019 organized training for official veterinarians and full-time employees of the Veterinary Inspection exercising supervision in the abovementioned establishment for the post-mortem inspection of slaughter animals and meat in accordance with US and EU regulations, culminating in a practical exam (**Annex 1**).

10. ANIMEX FOODS Oddział w Szczecinie, 70-812 Szczecin, ul. Pomorska 115 b (No 32 62 02 01)

Non-compliances:

a. The FSIS auditor observed improper filling of 300 g containers on the production line for canned luncheon meat. Numerous containers presented chunks of meat mixture along their top edges (flange) as they proceeded to the can closing machine. The presence of meat on the flange can ultimately impact the integrity of the double seam which is created between the body of the can and the lid during the closure process.

b. The post-mortem viscera inspector was not following the procedures outlined in Regulation (EC) No 854/2004, Section IV (determined equivalent by FSIS). Palpation of the mesenteric lymph nodes was omitted during post-mortem (swine) inspection activities.

Corrective actions

After finding incorrect filling of cans during the FSIS audit on 23 July 2019, production on the 4-head closing machine line was stopped by a veterinary inspector. The stopped line was marked, and the non-compliance was described by the abovementioned inspector in form NC. The actions on the part of the establishment concerned contamination of sterilized can edges with stuffing were as follows:

a. Production suspended by the veterinary inspector was re- started only after replacing the ball knives and adjusting the dosing moment in the device;

b. An additional canning closure inspection was carried out for the luncheon 300 g canned food - the closure inspection result was correct. The factual seal percentage was from 54 to 65%; xbar - 60%. Percentage of sidewall hook contact from 77 to 85; xbar - 82%.

c. On 23 July 2019, the establishment conducted training of employees of the Canning Production Department on GHP principles, with particular emphasis on checking the cleanliness of the can edge before closing during production. After the training, from 24 July 2019 an additional person was appointed who is to carry out visual inspection during the can filling process. In addition, from 24 July 2019, production supervision verifies the correctness of controls performed by employees of the Canning Production Department.
d. On 05 October 2019, the establishment's technical staff conducted a technical review of the entire 4-head closing line. This review included disassembly and assembly of new elements such as cutting knives, gear mechanisms, drive shafts, rollers, filters and consumable parts for dosing scales.
e. The establishment conducts daily checks of the 4-head heme dosing machine, with particular emphasis on the sharpening process of the dosing machine's knives. In addition, technical inspections of the abovementioned device are carried out with a frequency of once per quarter. On 26-27 November 2019 the manufacturer of the device carried out another technical review, which concerned all its components.

Whereas the activities of the Veterinary Inspection included the following:
a. The veterinary inspector verified activities and documents carried out by the establishment in the above scope. On 23 July 2019, photos were taken from the line after the production process was resumed. In addition, the establishment's printout of the heat treatment process for the abovementioned product type was verified. No deviations from the process assumptions were found: the assumed parameters +121.1^{0}C, heat treatment time 50 minutes - was implemented (water temperature +121.9^{0}C, heat treatment time 54 minutes). The measurement of free chlorine content in water for cooling sterilized cans was also verified. The required content is 0.5-1.0 ppm - the measurement results were in accordance with the requirements. Incubation tests were completed with a negative result.
b. In accordance with the order of the District Veterinary Officer in Szczecin, veterinary inspectors carried out additional intraoperative inspections with a specified frequency. On 24-29 July 2019, these inspections were carried out by inspectors twice a day. During the inspections, no stuffing was found on the edges of the cans. The results of the control were documented in the protocols of intraoperative control. After the abovementioned control, information about its results was forwarded by the inspectors to the District Veterinary Officer in Szczecin. After conducting a risk analysis, DVO in Szczecin determined that the number of additional inspections in the Canning Production Department will be reduced from twice a day to once a day.
c. From 30 July 2019 – 08 August 2019, additional inspections were carried out by veterinary inspectors once a day. During these inspections, no stuffing was found on the edges of the cans during their filling. After the abovementioned inspections, information on its results was forwarded by the inspectors to the District Veterinary Officer in Szczecin. After conducting a risk analysis, DVO in Szczecin determined that the number of additional inspections in the Canning Production Department will be reduced from once a day to 2 times a week.
d. On 9 September 2019 – 10 October 2019, additional inspections were carried out by veterinary inspectors twice a week. During these inspections, no stuffing was found

on the edges of the cans during their filling. After the abovementioned control, information on its results was on day forwarded by the inspectors to the District Veterinary Officer in Szczecin. After analyzing the results of inspections, DVO in Szczecin decided to end additional inspections.

Annex 1 - Table of inspections for the presence of stuffing on the edges of cans at the 4-head closing line and photos of filled cans - 8 pieces.

At the same time, due to the non-compliance in the scope of post-mortem inspection during the FSIS audit, the District Veterinary Officer in Szczecin on 8-9 October 2019 organized for official veterinarians a training on animal welfare regulations and procedures as well as ante-mortem and post-mortem inspection.

VETERINARY INSPECTION

CHIEF VETERINARY OFFICER

Warsaw, 9 August 2019

- According to distribution list -

Our ref.: GIWbż-52-158/2019(5) US

Re Case No.: Letter of:

Dear Sirs,

Referring to the information provided on 1 August 2019 at the closing meeting of the American audit in Poland, below please find a list of non-compliances identified by the FSIS inspectors together with the recommendations from the central level.

I. Official supervision

Export certification

• "*The official inspection staff, before signing export health certificates for consignments of commodities to be sent to the American market, do not confirm the acceptable results of tests of animal carcasses and parts thereof from which official samples are taken for chemical residues.*"

Recommendations regarding the above-mentioned non-compliances

In accordance with the FSIS requirements for the HACCP verification and export certification, before issuing an official health certificate for products to be sent to the American market, the test results for all samples of products tested for adulteration, as defined by the FSIS, must be reviewed and verified as acceptable (i.e. this means obtaining a negative test result).

The aforementioned requirement applies to the official verification of acceptable test results for all product samples (i.e. ownership tests and official tests) so as to ensure the absence of adulteration defined by the FSIS.

Note: This applies to confirming acceptable test results for the following sampled products:
- raw beef product with a non-intact structure or raw beef product with an intact structure to be used as a product with a non-intact structure which is tested for *STEC;*
- RTE products tested for *Listeria monocytogenes, Salmonella* or *STEC* (with regard to beef products);
- RTE product, which has gone through food contact surfaces which were tested for *Listeria monocytogenes* and *Salmonella*, and;
- animal carcasses and parts thereof selected for routine tests and suspicion tests for chemical residues, i.e. veterinary medicines, pesticides or environmental pollutants.

During the official HACCP verification activities, the FSIS services expect that the inspection staff maintain procedures to verify whether establishments approved for export to the American market receive and confirm acceptable test results for all samples of products tested for adulteration, as defined by the FSIS. This applies to any product to be exported to the USA and should be carried out before completing and signing the pre-shipment review records.

Furthermore, during the export certification activities, the FSIS expects that the inspection staff maintain procedures to ensure that the above-mentioned test results for products to be exported to the USA are reviewed and found acceptable before signing the export health certificate.

The FSIS considers detaining or maintaining control over products tested for adulteration pending obtaining and confirming acceptable test results as an effective method for preventing shipping of an adulterated product to the USA.

Accordingly, establishments must have procedures developed and implemented that require detaining a product from the sampled batch pending the acceptable test results. On the other hand, the inspection staff must adequately demonstrate that they supervise and control a product batch subject to sampling so as to ensure that, in the event of a positive or non-compliant test result, an adulterated product is not placed on the American market.

To this end, the inspection staff must:
- maintain controls clearly demonstrating that a product batch associated with a positive or non-compliant result has been redirected or prevented from being placed on the American market,
- indicate how and at what frequency it is verified whether establishments approved for export to the American market receive and confirm acceptable test results for all samples of products which are tested for adulteration, as defined by the FSIS, and are to be exported to the USA, before signing the pre-shipment review records.

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- indicate how and at what frequency it is verified whether the inspection staff review and confirm acceptable test results from all samples of products which are tested for adulteration, as defined by the FSIS, and are to be exported to the USA, before signing the export health certificate.

In the light of the above-mentioned requirements, the FSIS auditors stressed, during the current audit, that it is necessary to detain pig carcasses from which official samples were taken for chemical residues pending obtaining laboratory test results and confirming that they are acceptable. The above issue also applies to products tested microbiologically.

II. Government statutory body, food safety and other consumer protection rules

1. <u>Post-mortem inspection</u>

"At inspected slaughter and processing establishments, the FSIS auditors found irregularities related to post-mortem inspection:

***a.** Four establishments: as part of post-mortem inspection of the intestines, the inspectors did not carry out palpation of mesenteric lymph nodes, in accordance with the applicable agreement on equivalence concluded between the FSIS and the European Commission (which is based on the procedures laid down in the Regulation (EC) No 854/2004 (i.e. in its previous wording using palpation and incisions)];"*

<u>Recommendations regarding the above-mentioned non-compliances</u>

I would like to remind you that official veterinarians in pig slaughterhouses approved for export to the American market should carry out <u>traditional</u> post-mortem inspection activities consisting in: visual inspection, palpation and incision of carcasses and organs/ lymph nodes with respect to each pig carcass.

According to the above, pig carcasses and their internal organs should be subjected to the following post-mortem inspection procedures:

- visual inspection of the head and throat; incision and examination of the mandibular lymph nodes *(Lnn mandibulares*); visual inspection of the oral cavity, oropharyngeal isthmus and tongue;
- visual inspection of the lungs, trachea and oesophagus; palpation of the lungs; palpation and, if necessary, incision of the tracheobronchial and mediastinal lymph nodes (*Lnn. bifurcationes, eparteriales et mediastinale*). The trachea and the main branches of the bronchi must be opened along their course, while the lungs must be incised in their third posterior lobe, perpendicularly to their main axes; however, these incisions are not necessary where the lungs are excluded from human consumption;

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- visual inspection of the pericardium and heart, whereby the heart is examined after making an oblong incision, so as to open the chambers and cut the interventricular septum;
- inspection of the diaphragm;
- visual inspection of the liver and hepatic and pancreatic lymph nodes *(Lnn portales*); palpation of the liver and its lymph nodes;
- visual inspection of the visceral system, mesenteric lymph centre, gastric and mesenteric lymph nodes (*Lnn. gastrici, mesenterici, craniales et caudales*); palpation and, if necessary, incision of the gastric and mesenteric lymph nodes;
- visual inspection and, if necessary, palpation of the spleen;
- visual inspection of the kidneys; incision, if necessary, of the kidneys and renal lymph nodes (*Lnn. renales*);
- visual inspection of the pleura and peritoneum;
- visual inspection of the genitals (except the penis if it has already been removed);
- visual inspection of the udder and its lymph nodes (*Lnn. supramammaria*); in sows, incision of the supramammary lymph nodes;
- visual inspection and palpation of the periumbilical area and joints of young animals; in case of any doubt, the periumbilical area must be incised and the joints must be opened; the synovial fluid must be examined.

Also, in view of the non-compliances identified by the FSIS inspectors and regarding post-mortem inspection of pigs, it is necessary for district veterinary officers to organise a training course in this regard for designated official veterinarians and full-time DVI staff supervising establishments approved for export to the American market. This training should include:
- a theoretical part in a form of lectures (*Note:* training materials must include photos of specific lesions and lymph nodes, including explaining the purpose of incising the individual lymph nodes) and;
- a practical part carried out along the slaughter line on the individual post-mortem inspection stations.
It is advisable that the trainers during the above-mentioned training course were the VI staff with many years of experience in carrying out post-mortem inspections.
The information confirming that this training course has been carried out (i.e. the course programme and the list of its participants) should be provided to the General Veterinary Inspectorate through the regional level **by 14 October 2019 at the latest,** in a paper and electronic version to the e-mail address: ewa.piotrowska@wetgiw.gov.pl

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In addition, the similar training course on post-mortem inspection (*Note:* not only pigs, but also other species of animals) should be carried out for all designated official veterinarians and full-time DVI staff employed in the district concerned. The collective information confirming that this training course has been carried out in all districts in the region concerned shall be provided to the General Veterinary Inspectorate by **29 November 2019 at the latest,** in a paper and electronic version to the e-mail address: ewa.piotrowska@wetgiw.gov.pl

*„**b.** One establishment: on the final carcass inspection station, the inspector observed only the inside of the carcass and did not turn the carcass to check the external surfaces of the back."*

Recommendations regarding the above-mentioned non-compliances

The final examination of pig carcasses carried out by the official veterinarian must include a visual assessment of the cleanliness of both internal and external surfaces of the carcasses (*Note:* the details are set out in Annex 1 to the FSIS Directive 6420.2, which is placed on the GVI website under the link: https://www.wetgiw.gov.pl/handel-eksport-import/stany-zjednoczone).

Furthermore, on the final carcass inspection station, the official veterinarian should not carry out two activities at a time, i.e. mark meat with a health quality mark and assess the cleanliness of the carcass. If the assessment of the cleanliness of the carcass is to be carried out reliably and in line with the provisions of the above-mentioned FSIS Directive, these two activities should be separated (i.e. the assessment of the cleanliness of the carcass should be carried out separately from marking of meat).

2. Sanitation

Procedures on sanitary post-mortem treatment

• *"At one pig slaughter and processing establishment, the FSIS auditor noticed a carcass identified as requiring detailed veterinary examination which, before being taken to a side track, was subject to additional fat measurement and removal of the internal surfaces using a suction device.*

- the above activity created potential cross-contamination of other carcasses, since the fat meter and suction device were not sterilised by the employee after contact with the suspected carcass.

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- in addition, removal of the internal surfaces from this carcass identified as requiring detailed veterinary examination could finally affect the accuracy of that examination and the further handling of this carcass".

Recommendations regarding the above-mentioned non-compliances

In the case of carcasses which during post-mortem inspection have been marked as "*intended for further detailed veterinary examination"* and shall be sent by the official veterinarian to the side track, before the stage of carrying out this examination they may not be subject to any handling or post-mortem treatment carried out by the employees. Also, the management of the establishment should organise a regular training course for its employees on procedures for carrying out sanitary post-mortem treatment (*inter alia*, sterilisation of equipment after each pig), which should be subject to official verification by observing the employees at work.

Records documenting monitoring of Standard Sanitary Operational Procedures (SSOP)

• *"At one pig slaughter and processing establishment, the records documenting the corrective measures taken in response to the deficiencies identified during operational monitoring of the SSOP at the establishment were incomplete because they did not always describe the handling of the product.*

- for example, the record documenting removal of a cracked container from the active production area did not indicate the extent to which the situation had or did not have any impact on the product."

The specification of the above-mentioned non-compliance: In the establishment documentation related to the corrective measures taken as part of intraoperational SSOP monitoring, there was no description of the handling of the product which was in the cracked container and could be exposed to contamination (i.e. it was only recorded that the container was removed).

Official pre-operational verification for sanitation

• *"The FSIS auditor identified the following irregularities when observing the preoperational verification for sanitation at one pig slaughter and processing establishment:*

- SPS: Excess of grease on transporters; presence of condensate, presence of slack insulation on ducts supplying water to sterilisers.

- SSOP: dark spots on conveyor belts and black spots on the trays for the intestines.

- No direct contamination of the product has been observed."

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Recommendations regarding the above-mentioned non-compliances

I would like to remind that point 3.12 of *"Recommendations to Veterinary Inspection bodies specifying the method of verification and enforcement of the regulations of the Federal Meat Inspection of the U.S. Department of Agriculture 9 CFR and laying down the rules of managing knowledge communicated to Veterinary Inspection employees as part of cascading and continuing training in the field of American requirements of 18 May 2018, version 4"* refers to the provision FSIS 9 CFR § 416.15, which stipulates that corrective measures of the establishment with regard to the SSOP include the following:

- **taking appropriate steps with regard to the product** (i.e. ensuring the adequate handling of any adulterated product);
- restoration of sanitary conditions;
- prevention of the recurrence of non-compliance;
- reassessment/change of the SSOP if necessary or improving the way in which the SSOP procedures are executed, where necessary.

In accordance with the foregoing, it is recommended that district veterinary officers, when assessing official veterinarians using the *"Control sheet for the designated official veterinarian (OV)"*, being *Annex No. 14* to the above-mentioned Recommendations, should regularly check the inspection staff's knowledge regarding the specific American requirements.

Also, I would like to inform that the General Veterinary Inspectorate is planning to organise, in mid-October, a several-day refresher training course for the Veterinary Inspection employees (i.e. GVI, RVI and DVI employees and newly employed full-time DVI inspectors) on the American requirements, of which you will be informed in separate correspondence.

3. HACCP system

Official „Zero Tolerance" verification

• *"At the inspected pig slaughter and processing establishments, the FSIS inspectors identified irregularities concerning the way in which the inspection staff carried out the "zero tolerance" verification (i.e. visible faeces, digesta and milk).*

a. Independent selection of carcasses: At one establishment, the control staff carried out the daily official verification on the same set of carcasses selected by the establishment for routine monitoring.

Note: the FSIS considers this verification measure to be a direct observation of establishment monitoring.

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b. Frequency: at three establishments, the government inspectors carried out direct verification checks once a week, not everyday.

c. Number of carcasses to be examined: At three establishments, the number of carcasses to be examined did not meet the slaughter volume values set out in Annex 1 to the FSIS Directive 6420.2".

Recommendations regarding the above-mentioned non-compliances

Pursuant to Annex 1 to the FSIS Directive 6420.2, placed on the GVI website under the link: https://www.wetgiw.gov.pl/handel-eksport-import/stany-zjednoczone) the official "Zero tolerance" verification of the CCP should be carried out **daily** as follows:

1. Based on the expected daily slaughter rate per shift (number of animals), the inspection staff should determine the number of carcasses or sides of carcasses to be examined according to the table below.

Size of samples of animal carcasses		
Number of animals to be slaughtered per shift	**Number of carcasses to be examined during 1 shift**	**Number of sides of the carcass (back and front) examined during 1 shift**
100 or less	2	4
101-250	4	8
251-500	7	14
More than 500	11	22

2. Select the number of carcasses randomly.

3. Examine the selected carcasses using the same system inspection technique used by the staff on the inspection station pursuant to the FSIS Directive 6100.2.

4. The inspection staff carrying out the "zero tolerance" verification may separately or independently examine the designated number of half-carcasses to check the appropriate number of sides or carcasses.

Verification of keeping the HACCP records

• *At one pig slaughter and processing establishment, the records documenting the corrective measures taken in response to a deviation from the critical limit for the zero tolerance critical control point (CCP) were incomplete.*

- specific omissions included an identified type of contamination as well as the documentation which would indicate that control in the CCP was restored after the corrective measures had been taken.

Recommendations regarding the above-mentioned non-compliances

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I would like to remind that in point 4.3 of the *"Recommendations to Veterinary Inspection bodies specifying the method of verification and enforcement of the regulations of the Federal Meat Inspection of the U.S. Department of Agriculture 9 CFR and laying down the rules of managing knowledge communicated to Veterinary Inspection employees as part of cascading and continuing training in the field of American requirements of 18 May 2018, version 4"* refers to the provision of FSIS 9 CFR § 417.3, which stipulates that the corrective measures of the establishment under the HACCP include the following:

(1) The cause of deviation has been identified and eliminated;

(2) **The CCP will be under control after the corrective measure has been taken**;

(3) The measures have been established to prevent the recurrence of deviations;

(4) No product harmful to health or otherwise adulterated as a result of deviation has been placed on the commercial market.

On the other hand, pursuant to point 4.9 of the above Recommendations, the inspection staff under the official verification should carry out an analysis and determine the correctness of the corrective measures taken by the establishment.

In accordance with the foregoing, it is recommended that district veterinary officers, when assessing official veterinarians using the *"Control sheet for the designated official veterinarian (OV)"*, being *Annex No. 14* to the above-mentioned Recommendations, should regularly check the inspection staff's knowledge regarding the specific American requirements.

5. Official Microbiological Testing Programmes

Reporting official results of tests for *Salmonella*

• *"At one pig slaughter and processing establishment, the inspection staff did not directly receive official test results for Salmonella in pig carcasses (i.e. "Salmonella series").*

- the laboratory used to send official test results only to the establishment, which was then responsible for providing a copy of the results to the inspection staff."

Preparation of a sampling schedule for *Salmonella*

• *"At the official laboratory of microbiological and chemical tests in Warsaw, the FSIS auditors noticed that the request to carry out official tests for Salmonella for pig carcasses (May 2019) had been initiated by the establishment, not by the DVO (i.e. the schedule of official tests for Salmonella from pig carcasses was provided to the RVL in Warsaw by the establishment and not by the DVO).*

- discussions on that matter with the GVI representatives showed that this had taken place due to the occasional nature of slaughters at that establishment, for which the DVO

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considered that the knowledge of the establishment's schedule would be helpful in determining when the whole set of samples could be easily completed.
- however, the GVI also pointed out that this practice was not in line with expectations on the method of developing a sampling schedule for Salmonella and that this schedule should come from the DVO.
- development of a schedule for the sample set by the establishment may ultimately result in an error which would jeopardise the accuracy of the test results.'

Recommendations regarding the above-mentioned non-compliances
1. Official samples taken for microbiological tests, including, *inter alia*, from pig carcasses for *Salmonella,* must be tested **only** at the Regional Veterinary Laboratories or at the National Veterinary Research Institute in Puławy. It is unacceptable to carry out such tests at any other laboratories.
2. The schedule for official tests of pig carcasses for *Salmonella* (i.e. a series of samples from subsequent 55 slaughter days) must be developed directly by the district veterinary officer. It is unacceptable for this schedule to be drawn up by the establishment. This schedule must be sent to the laboratory in a paper and electronic version directly by the district veterinary officer (from the DVI e-mail address). It is unacceptable for the establishment to send the above-mentioned schedule to the laboratory.
3. Issues related to the acceptance of samples by the laboratory, carrying out of the test and the method of sending results must be prearranged directly between the district veterinary officer and the Regional Veterinary Laboratory. *Note:* It is important that the test result be delivered directly to the DVO.
4. The first sample from a series of 55 samples must be taken in an unannounced manner, i.e. the establishment may not know when the DVO is going to start this test.

6. Verification of thermally processed, commercially sterile products (TPCS) [canned]
• At one establishment producing thermally processed, commercially sterile [canned] products, the FSIS auditor noticed the incorrect filling of 300 g containers on the production line for the *"Luncheon Meat"* product range.
- numerous containers showed the presence of pieces of meat stuffing along their upper edges (neck) as they were being passed to the can seamer.
- the presence of meat on the neck can ultimately affect the integrity of the double seam, which is formed between the body and the lid of the can during seaming.

Recommendations regarding the above-mentioned non-compliances

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It is recommended that establishments exporting thermally processed, commercially sterile [canned] products to the American market develop, implement and maintain procedures describing the measures to be taken in the event of overfilling of cans with stuffing. The above must be subject to official verification. *Note:* Excessive filling of cans violates the FSIS rules on the integrity of the container and may be a reason for rejecting the consignment at the port of entry into the American territory.

Stamp and illegible signature:
For Chief Veterinary Officer
Katarzyna Piskorz
Deputy Chief Veterinary Officer

Distribution list:

1. Regional Veterinary Officer in Lublin
2. Regional Veterinary Officer in Poznań
3. Regional Veterinary Officer in Krosno
4. Regional Veterinary Officer in Kielce
5. Regional Veterinary Officer in Szczecin
6. Regional Veterinary Officer in Olsztyn
7. Regional Veterinary Officer in Gdańsk
8. Regional Veterinary Officer in Łódź
9. Regional Veterinary Officer in Siedlce
10. Regional Veterinary Officer in Wrocław
11. District veterinary Officer in Trzebnica
12. District veterinary Officer in Łuków
13. District veterinary Officer in Kutno
14. District veterinary Officer in Sokołów Podlaski
15. District veterinary Officer in Dębica
16. District veterinary Officer in Jarosław
17. District veterinary Officer in Chojnice
18. District veterinary Officer in Człuchów
19. District veterinary Officer in Starachowice
20. District veterinary Officer in Ełk
21. District veterinary Officer in Ostróda
22. District veterinary Officer in Koło
23. District veterinary Officer in Ostrzeszów
24. District veterinary Officer in Poznań
25. District veterinary Officer in Szczecin

CC:

1. Regional Veterinary Officers - all

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VETERINARY INSPECTION
GENERAL VETERINARY INSPECTORATE
Training program on US and Israel regulations
October 23-25, 2019

October 23, 2019, Wednesday

10:00–10:45 Introduction

10:45–11:00 Coffee break

11:00–12:30 FSIS regulations on food safety systems:

- Standard Sanitary Procedures (SPS) - 9 CFR 416
- Standard Sanitary Operating Procedures (SSOP) - 9 CFR 416
- Hazard analysis and critical control points (HACCP) - 9 CFR 417

12:30–13:30 HACCP system validation, FSIS Directive 5000.1, version 5 Official verification of establishment food safety systems

13:30–14:30 Lunch

14:30–15:15 FSIS regulations regarding Listeria monocytogenes

15:15–15:30 Coffee break

15:30–16:15 Pathogen Reduction Program (E.coli, Salmonella)

16:15–17:00 Group exercises

Questions & Answers

October 24, 2019, Thursday

9: 00-10: 45 Tasks of the official veterinarian in the production of fresh pork (pre- and post-mortem inspection of pigs)

10: 45–11: 00 Coffee break

11: 00-11: 45 Tasks of the official veterinarian in the production of fresh pork (pre-and post-mortem inspection of pigs) [*continuation*]

11: 45-13: 00 *FSIS Directive 6420.2 version 1 " Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Livestock Slaughter Operations - Revision 1*

13: 00-14: 00 Lunch

14: 00–15: 30 Practical aspects related to completing the weekly verification list at the establishments authorized to export to the US market and sampling RTE product and environmental samples for Listeria monocytogenes

15:30 - 15:45 Coffee break

15: 45–17: 15 FSIS regulations on canning
Questions & Answers

October 25, 2019, Friday

8:30 - 10:30 Requirements for beef establishments approved for export to the Israel market or applying for such permits.
10: 30-10: 45 Coffee break
10: 45-11: 30 Discussion of the course and results of the audit of FSIS services, which took place in Poland from July 15 - August 2, 2019.
11: 30-12: 15 Discussion of the course and results of the audit of APHIS services that took place in Poland on September 13-20, 2019.
12: 15-13: 00 Discussion on the scope of duties of newly recruited DVI employees as part of the supervision of establishments authorized to export to the US market
13: 00-14: 00 Lunch
Closing the training