USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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NOV 05 2015

Dr. Marek Pirsztuk
Chief Veterinary Officer
Veterinary Inspection
General Veterinary Inspectorate
Republic of Poland
30 Wspolna Street
00-930 Warsaw, Poland

Dear Dr. Pirsztuk,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Poland's meat inspection system from April 21 through May 8, 2015. 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.

For technical questions regarding the FSIS audit report, please contact Dr. Shaukat H. Syed, Director of the International Audit Staff with the Office of Investigation, Enforcement and Audit (OIEA) at telephone number (202) 720-8609, by facsimile at (202) 720-0676, or by electronic mail at international.audit@fsis.usda.gov.

If you have any other questions, please feel free to contact me directly.

Sincerely,

for Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

POLAND

APRIL 21 TO MAY 8, 2015

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

November 5, 2015

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 Food Safety and Inspection Service (FSIS) from April 21 to May 8, 2015. The audit was conducted to determine whether Poland's food safety system governing pork products continues to be 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 pork products: Raw – intact; raw product – non-intact; fully cooked – not shelf stable; heat treated but not fully cooked - not shelf stable; and thermally processed – commercially sterile.

The audit was designed to determine the equivalence of Poland's meat inspection system and focused on six main system components: (1) Government Oversight (Organization & Administration), (2) Statutory Authority and Food-Safety Regulations (Inspection System Operation and Product Standards), (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Government Chemical Residue Control Programs, and (6) Government Microbiological Testing Programs. The previous FSIS audit of Poland's meat inspection occurred from May 10 to June 1, 2011. During the course of the 2011 audit, FSIS identified several findings within the equivalence components for Sanitation and Hazard Analysis and Critical Control Points (HACCP). The FSIS FY2015 audit verified the implementation of corrective actions proffered to FSIS by Poland to remedy the 2011 findings.

The 2015 FSIS audit results confirm that Poland's meat inspection system continues to maintain equivalence. FSIS identified some operational (or procedural) weaknesses related to sanitation and HACCP. However, none of these weaknesses was significant enough as to raise a question about Poland's on-going equivalence.

An exit meeting was held on May 8, 2015 in Warsaw with the General Veterinary Inspectorate (GVI, Polish name: *Główny Inspektorat Weterynarii*). The preliminary audit findings were presented by FSIS. FSIS will evaluate any information provided by Poland including the submittal of the Central Competent Authority (CCA) proposed corrective actions in response to the audit findings to assess the effectiveness of the corrective actions.

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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 April 21 to May 8, 2015. The audit began with an entrance meeting held on April 21, in Warsaw with the participation of representatives from the Central Competent Authority (CCA) – General Veterinary Inspectorate (GVI, Polish name: *Główny Inspektorat Weterynarii*) and auditors from the FSIS.

II. OBJECTIVES, SCOPE, AND METHODOLOGY

This was a routine on-going equivalence verification audit. The audit objective was to ensure the food safety system governing pork products maintains equivalence to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged.

In pursuit of this objective, FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, previous audit reports, port-of-entry (POE) testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process included an analysis of data collected by FSIS over a three-year timeframe, in addition to information obtained directly from the GVI through a self-reporting process.

The FSIS auditors were accompanied throughout the entire audit by representatives from the GVI or representatives from the Provincial Veterinary Inspectorate (PVI, Polish name: *Wojewódzkie Inspektoraty Weterynarii*), the District Veterinary Inspectorate (DVI, Polish name: *Powiatowe Inspektoraty Weterynarii*), and staff from inspection offices located within the audited establishments. Determinations concerning program effectiveness focused on performance within the following six equivalence components upon which system equivalence is based: : (1) Government Oversight (Organization & Administration), (2) Statutory Authority and Food-Safety Regulations (Inspection System Operation and Product Standards), (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems (5) Government Chemical Residue Control Programs, and (6) Government Microbiological Testing Programs.

The auditors reviewed the administrative functions at the GVI headquarters in Warsaw; two provincial offices; two district offices; and local inspection offices at eight establishments. During the review, the FSIS auditors evaluated implementation of the management control systems put in place to ensure that the national system of inspection, verification, and enforcement are implemented as intended. The auditors conducted reviews of the administrative functions of local inspection offices as part of the establishment review. The FSIS auditors assessed the administrative functions of sampling and testing through a review of records at the GVI's headquarters office and provincial and district offices. The auditors further assessed sampling and testing methodology through document review and observations at the central laboratory and eight local inspection offices.

A sample of eight establishments was selected from 15 establishments certified to export to the United States. During the establishment visits, particular attention was paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the GVI's ability to provide oversight through supervisory reviews conducted in accordance with 9 CFR 327.2.

The National Veterinary Research Institute (NVRI), which also serves as the National Reference Laboratory was audited to verify its ability to provide adequate technical support to the inspection system.

Audit Scope Summary

Competent Authority Visits		**#**	**Locations**
Competent Authority	**Central**	1	GVI/Warsaw
	Provincial Offices	2	Provincial Veterinary Inspectorate offices in • Krosno • Szczecin
	District Offices	2	District Veterinary Inspectorate offices in • Jaroslaw • Szczecin
	Local Offices	8	local inspection offices in: Kutno, Jarosław, Starachowice, Sokołów Podlaski, Łuków, Szczecin, Chojnice, and Ostróda
Government Laboratories (*microbiological and residue testing*)		1	• National Veterinary Research Institute (NVRI)/National Reference Laboratory (Pulawy)
Establishments			
Pork slaughter/processing		7	• Est. 10023802, Kutno • Est. 18040201, Jarosław • Est. 26110201, Starachowice • Est. 14290201, Sokołów Podlaski • Est. 06110266, Łuków • Est. 32620201, Szczecin • Est. 22023801, Chojnice
Pork processing		1	• Est. 28154003, Ostróda

The audit was undertaken under the specific provisions of United States' laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.),
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. Title 7), and
- The Food Safety and Inspection Service Regulations for Imported Meat (9 CFR Part 327).

The audit standards applied during the review of Poland's inspection system for pork products included: (1) All applicable legislation originally determined by FSIS as equivalent as part of the

initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the WTOSPS Agreement.

Currently, Poland has equivalence determinations in place for the following:

- The use of ISO 11290-1 microbiology testing method for *Listeria monocytogenes* (*Lm*) in ready-to-eat (RTE) products,
- The use of ISO 11290-2 microbiology testing method for *Lm* in RTE products as confirmatory method only when use in conjunction with ISO 11290-1, and
- The use of ISO 6579:2002 microbiology testing for *Salmonella* in
    - Raw pork products,
    - Swine carcasses sponge, and
    - RTE products (325 g).

III. BACKGROUND

Poland is eligible to export raw and processed pork products to the United States. Between October 1, 2013, and September 30, 2014, FSIS' import inspectors performed 100% re-inspection for labeling and certification on 49,374,443 pounds of pork products exported by Poland to the United States. FSIS also performed re-inspection on 8,072,295 pounds at Point-of Entry (POE) using additional Types of Inspection (TOI), of which a total of 7,363 pounds were refused entry for issues not involving food safety concerns (e.g. missing shipping marks, container shipping damage). Poland is eligible to export the following categories of pork products: Raw – intact; raw – non-intact; fully cooked – not shelf stable; heat treated but not fully cooked – not shelf stable; and thermally processed – commercially sterile.

The FSIS final audit reports for Poland's food safety system are available on the FSIS' website at:
http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports

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

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

The Chief Veterinary Officer (CVO), who is appointed by the Prime Minister based on recommendation of the Minister of Agriculture and Rural Development, is the head of the GVI. The GVI is the highest level of the inspection system and has direct authority over the subsequent two inspection levels. The GVI receives copies of the monthly reviews conducted by

DVI and PVI and summary reports of noncompliance records and administrative actions issued to official establishments. The PVI is the second inspection level and is headed by the Provincial Veterinary Officer (PVO). Each of Poland's 16 PVIs oversees the inspection activities carried out by 12 to 42 DVIs. The DVI is the third level of the inspection system and is headed by the District Veterinary Officer (DVO). The DVI oversees all inspection activities in the establishments that export pork products to the US. The DVI evaluates the performance of in-plant personnel. FSIS auditors verified that the GVI operations are funded by the government budget and supplemented by fees assessed by the GVI on inspected products.

FSIS auditor verified that inspection program personnel assigned to establishments are full-time employees of the national government and perform activities under administration of the DVI and the PVI. The FSIS auditors also verified that the DVO has the authority and responsibility to hire and assign competent, qualified inspectors to official establishments that export products to the United States. The GVI employs an ongoing plan to analyze, and meet staffing requirements at establishments that export products to the United States. Every inspector receives a monthly salary payment directly from government funds. Furthermore, every establishment that produces product for export to the United States receives government inspection at least daily, each shift while producing product for the United States.

FSIS' review of activities carried out at all three levels of the inspection system demonstrated that the GVI has a single set of rules, legal authority, and responsibility to enforce inspection laws and to ensure that adulterated or misbranded products are not exported to the United States. Because Poland is a member of the EU, the EC regulations, the primary overarching laws for regulating meat inspection, are implemented throughout the country. These are supplemented with national legislation to address the implementation of inspection activities. Vested by Poland's legislation, the GVI issues guidelines and instructions that address performance of official inspection tasks, supervisory reviews, establishes registration procedures comparable to a FSIS grant of inspection (i.e., approval, conditional approval, suspension, and withdrawal of approval of regulated establishments), oversees microbiological sampling and testing; and defines the scope and method of carrying out the National Residue Control Plan. 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 the GVI website.

The GVI also organizes training sessions for Veterinary Inspection (VI) employees on the regulations, procedures, and functioning of the requirements of Standard Sanitation Operating Procedures and their enforcement in establishments approved to export to the United States. Veterinary Inspection employees who attend sessions organized by the GVI are certified as "*Trainer(s) of cascade training*" and are then made responsible for delivering "*cascade training*" and "*continuous training*" to personnel working in establishments eligible to export to the United States. The "*cascade training*" consists of imparting the knowledge gained in the training sessions organized by the GVI, whereas "*continuous training*" is a process of constant renewal and expansion of the practical and theoretical knowledge, raising awareness, and improving skills of official personnel in verifying and enforcing regulatory requirements at United States eligible establishments.

The GVI has enforcement procedures based on Regulation (EC) 882/2004, and the instructions of the CVO are issued and based on the Veterinary Inspection Act. These enforcement procedures are comparable to those outlined in 9 CFR 500, Rules of Practice. Inspection personnel follow these enforcement procedures by issuing administrative decisions in response to noncompliance (Code of Administration Procedure- Art 104, the Instruction of the Chief Veterinary Officer No GIWhig-500-2/13) and verify the effectiveness of the establishment's corrective actions. The administrative decision includes a deadline for rectifying the identified deficiency, and monetary fines may be imposed when the establishment fails to meet the specified deadline.

FSIS's audit of Poland's meat inspection system confirmed that the GVI has adequate administrative and technical support for its inspection system. The GVI uses an official laboratory system that consists of the NVRI and 16 Regional Diagnostic Laboratories (RDLs) that conduct chemical and microbiological testing of product destined for the United States. The NVRI serves as the National Reference Laboratory (NRL) responsible for setting the standards and harmonizing activities among the RVLs. The RVLs are technically under the supervision of the NRL and administratively under the PVI. The GVI's Laboratories Unit coordinates activities among the GVI and regional laboratories and collaborates with the NRL, the RVLs and other bureaus in the GVI.. Laboratories used by the GVI are accredited under the International Organization for Standardization (ISO) - ISO/IEC 17025:2005 General Requirements for the Competence of Calibration and Testing Laboratories.

FSIS observations of inspection program activities, interviews with official personnel, and reviews of official inspection records during the audit helped confirm that the GVI has administrative controls to support its inspection system, and that the GVI was consistently enforcing applicable regulations.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS (INSPECTION SYSTEM OPERATION AND PRODUCT STANDARDS)

The second equivalence component that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; daily inspection; periodic supervisory visits to official establishments; and requirements for thermally processed/commercially sterile products.

FSIS has determined that the European Commission's (EC) 2004 food hygiene legislation is equivalent as overarching legislation, given that CCAs of the EU Member States address the implementation of the legislation and the United States requirements (special conditions) through their national laws, regulations, and policies. Poland supplemented the EC 2004 food hygiene legislation through a series of statutory instruments that organize the national framework of control programs related to inspection of pork products, including both slaughter and processing. The framework of the inspection and control programs includes: the Products of Animal Origin Act; the Veterinary Inspection Act, as amended; the Instructions of the Chief Veterinary Officer

No GIWbż-500-2/2013 on the conduct of the Veterinary Inspection bodies, as amended; the Code of Administrative Procedure; the Instruction of the Chief Veterinary Officer No GIWbż-500-2/11 on using risk analysis to determine the frequency of controls in food sector operators; the ordinance of the Ministry of Agriculture and Rural Development (MARD) on the scope of activities and qualifications of personnel; and the GVI document titled "*Requirements for establishments approved for export of meat and poultry and their products to the market of the United States of America"*, GVI Version 2, 7/18/14. These Statutory Instruments form the basis of regulatory oversight of Poland's inspection system for meat and pork products. There were no regulatory changes in the United States since the last audit that would have required changes by the CCA associated with the exported pork products.

FSIS's evaluation of this component included a review and analysis of documents submitted by the GVI in the Self Reporting Tool (SRT)), interviews of inspection officials, and observations made during the on-site audit. By reviewing manuals and procedures at the GVI, PVI, and DVI, FSIS auditors verified that official inspection activities, including ante-mortem, humane handling slaughter, and post-mortem inspection, found that establishments have the necessary construction, facilities, and equipment and control over inedible and condemned materials, in accordance with the responses provided in the SRT and supporting documentation. The GVI continues to maintain equivalent legislative controls for this component at United States-eligible establishments as outlined in the official instructions from the GVI.

FSIS auditor verified that the GVI takes measures to ensure that pork and pork products are safe to consume by carrying out daily inspection of slaughter establishments while slaughter is going on, and by conducting direct inspections in processing establishments, at least once per day per shift, when the establishments are producing product for export to the United States. The auditor further verified that official veterinarians conduct ante-mortem inspection on the day of slaughter by examining individual animals. They also review the incoming registration and food chain information, including identification documents, which make it possible to trace the animals to their source. In accordance with the regulatory requirements and other established inspection procedures (Regulation (EC) No 854/2004), animals that show clinical signs of disease may not be slaughtered for human consumption. However, suspect animals may be slaughtered at the end of the normal slaughter process, and precautions must be taken to avoid the risk of spreading pathogenic organisms.

The FSIS auditor verified that inspection program personnel documented ante-mortem inspection activities in all slaughter establishments audited. During ante-mortem inspection activities, official veterinarians verified and documented that the establishments follow the requirements of humane handling and slaughter of livestock prescribed in FSIS Directive 6900.2, which Poland has adopted in its entirety and makes available on the GVI website.

FSIS auditor verified through record reviews, interviews, and observations that official veterinarians perform post-mortem inspection activities by observing carcasses, palpating viscera, and incising mandibular lymph nodes of every swine carcass. Additionally, the auditors were able to verify that post-mortem inspection of carcasses and viscera were synchronized, ensuring that the association of viscera and carcasses is complete until post-mortem inspection.

The design of the postmortem inspection stations included sufficient lighting and, based on Polish staffing guidelines, the appropriate number of inspection program personnel.

FSIS auditor verified that the GVI ensures complete separation of establishments that intend to export product to the United States from those which are not certified for export to the United States. The GVI uses traceability to ensure that processing establishments that intend to export product to the United States only use products originating from an approved source.

The FSIS auditor assessed the GVI's ability to exercise effective coordination among the GVI, the PVI, the DVI, and staff from inspection offices located within the audited establishments and to provide oversight through supervisory reviews in accordance with the requirements described in 9 CFR 327.2. Poland's inspection system provides for periodic supervisory visits by a representative of the inspection system to each establishment that export products to the United States.

During the FSIS audit, the CCA provided evidence of monthly supervisory reviews conducted by the PVIs and DVIs at United States-eligible establishments. Monthly supervisory reviews of official establishments are conducted in accordance with the GVI document titled, "*Requirements for establishments approved for export of meat and poultry and their products to the market of the United States of America*," last published by the GVI on July 18, 2014. The supervisory reviews included assessment of the establishment's operation and its compliance with the regulatory requirements. During the course of their monthly review, supervisors tour the establishment, review the establishment's operations, review the sanitation and HACCP records generated and maintained by the establishment, and examine official inspection records. The monthly supervisory reviews are conducted using a uniform detailed checklist titled "*Control report of the establishment approved for export to the USA*," Form 5000-6. Official veterinarians working at the establishments also complete Form 5000.1-6 titled "WEEKLY VERIFICATION LIST AT ESTABLISHMENT NO." The form is completed to document the daily verification activities performed by official personnel at an establishment that exports products to the United States.

FSIS auditors interviewed supervisors, reviewed supervisory records, and concluded that periodic supervisory reviews are being conducted monthly according to the specified frequency. FSIS auditors verified that supervisory reviews also placed emphasis on the competency of inspection program personnel, and that if training needs were identified, these were documented. The supervisory review results were found to be consistent with the knowledge of inspection personnel.

Poland's meat inspection system continues to have both legal authority and a regulatory framework to implement requirements equivalent to those governing the United States' system of meat inspection. The analysis and on-site verification activities indicate that the GVI continues to maintain equivalence.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. To be considered equivalent to FSIS' program, the CCA is to provide general requirements for sanitation, sanitary handling of products, and development and implementation of sanitation standard operating procedures (SSOP).

The FSIS auditor's review of regulations, official instructions, and guidelines demonstrates that Poland's pork products inspection system adopted sanitation requirements equivalent to FSIS's requirements. The GVI requires that each establishment that exports pork products to the U.S. develop, implement, and maintain written SSOPs to prevent direct product contamination or the creation of insanitary conditions. The GVI's regulatory oversight of establishment compliance is conducted in accordance with Regulation (EC) No 852/2004; Regulation (EC) No 853/2004; Regulation (EC) No 882/2004; and the *Requirements for establishments approved for export of meat and poultry and their products to the market of the United States of America*, GVI, Version 2, 7/18/14.

During the 2011 audit, FSIS found that the GVI had erroneously dropped a legislative article (Food Safety and Nutrition Act) that authorizes the GVI to require establishments that intend to export to the United States to develop and maintain SSOPs. In response to the previous audit finding, the GVI reinstated the amended articles, and issued the Instructions of the Chief Veterinary Officer No GIWhig-500-2/2013, as amended , that reestablish the regulatory requirement and describe verification and enforcement methodology of the regulations.

FSIS auditors verified that the GVI has communicated these regulatory requirements to all inspection program personnel. Official inspection program personnel perform daily inspection and verification of the establishments' Sanitation Performance Standards (SPS) programs and SSOPs and document the outcome of their verification activities using Form 5000.1-6.

FSIS auditors assessed the GVI's ability to verify and enforce the regulatory requirements for sanitation at the establishment level. The assessment included a review of the official inspection records, establishments' sanitation monitoring records, documented corrective actions, and assessment of the actual sanitary conditions in production areas. FSIS auditors verified that each establishment maintained a written SSOP to prevent direct product contamination or adulteration. The programs include processes for maintenance and improvement of sanitary conditions through routine assessments by establishments of their hygienic practices and of the condition of their premises. FSIS auditors confirmed that inspection program personnel conduct daily verification of the establishments' sanitation programs. The official verification activities consist of a combination of document review and organoleptic inspection. These verification activities are described in the *Requirements for establishments approved for export of meat and poultry and their products to the market of the United States of America*, GVI, Version 2, 7/18/14.

Although FSIS auditors verified that sanitation verifications activities were performed in accordance with regulatory requirements, the following SPS deficiencies were identified in two slaughter and processing establishments eligible to export to the United States.

- In one establishment, beaded condensation was observed in an area of the main cooler above areas where exposed product was or would be stored. No direct product contamination was observed at the time.
- In two establishments, shipping doors were not properly sealed to prevent the entrance of vermin.

In response to the two deficiencies noted above, the GVI officially notified the establishments by issuing administrative actions to implement immediate corrective actions, including measures to restore the sanitary conditions and proper disposition of any affected products.

FSIS auditors verified that the GVI had implemented corrective action plans related to previous audit findings and the two SPS deficiencies identified during this audit for this component. The GVI has taken measures to ensure that certified establishments implement effective Sanitation SOPs and other sanitary measures that prevent direct contamination and adulteration of products destined for the United States. The measures, employed by the GVI were found to be equivalent to those governing the United States inspection system.

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

The fourth of six equivalence components that the FSIS auditors reviewed was HACCP. The inspection system requires that each official establishment develop, implement, and maintain a HACCP plan.

The FSIS auditor's review of the regulations, official instructions, and guidelines demonstrates that Poland's inspection system has HACCP requirements equivalent to FSIS's. The GVI requires that every United States eligible establishment develop and implement an effective HACCP plan. The GVI continuously evaluates the effectiveness of its regulatory oversight and performs daily as well as monthly verification activities to ensure that establishments comply with the regulatory requirements described in: Regulation (EC) No 852/2004; Regulation (EC) No 853/2004; Regulation (EC) No 882/2004. Poland has requirements consistent with FSIS HACCP requirements (9 CFR Part 417) through the *Requirements for establishments approved for export of meat and poultry and their products to the market of the United States of America*, GVI, Version 2, 7/18/14.

During the 2011 audit, FSIS determined that the GVI had erroneously dropped a legislative article (Food Safety and Nutrition Act) that authorizes the GVI to require establishments that intend to export product to the United States to develop, implement, and maintain HACCP systems as one of the conditions for meeting the certification requirements. In response to the previous audit finding, the GVI reinstated the amended articles and issued the Instructions of the Chief Veterinary Officer No GIWhig-500-2/2013, as amended, that re-establish the regulatory requirement and describe verification methodology of the homologous regulations for HACCP

(9 CFR Part 417). FSIS auditors verified that the GVI has communicated these regulatory requirements to inspection program personnel, took effective measures to ensure continuous compliance with the regulatory requirements, and instituted measures to ensure that the veterinary supervisors added this requirement to the checklist of verification activities for establishments that export products to the United States. Furthermore, FSIS verified that the inspection system has established official procedures to verify that each establishment has an effective HACCP system that meets regulatory requirements. Official inspectors follow verification methods described in the *Requirements for establishments approved for export of meat and poultry and their products to the market of the United States of America.* Official veterinarians perform daily supervision over HACCP procedures at the establishment level. Official veterinarians at the DVI level and RVI level perform monthly supervisory reviews at United States eligible establishments.

To determine whether equivalence was maintained for this component, FSIS auditors assessed the design and verified the implementation of HACCP programs in establishments that export to the United States. The assessment included review of the establishments' HACCP plans; establishments' records, including establishment pre-shipment review records; and the official records maintained by official inspection personnel. Additionally, FSIS auditors observed the establishments' operations and assessed their ability to produce safe product. FSIS auditors verified that establishments had developed, implemented, and maintained HACCP system for products intended for United States export. The establishments' HACCP systems are subject to audits performed by GVI auditors.

During this audit, the FSIS auditor verified that the in-plant inspection personnel stationed in slaughter and processing establishments conducted and documented official daily verification activities related to HACCP in accordance with regulatory requirements. Additionally, the inspection personnel verification procedure encompasses the evaluation of written HACCP programs and verification of HACCP prerequisites and plan monitoring, corrective actions, and recordkeeping in accordance with Regulations (EC) No 852/2004 and Regulations (EC) No 882/2004. Furthermore, supervisory reviews (supervisory veterinary inspector and lead auditor) of HACCP verification activities by inspection personnel were conducted and well documented.

The FSIS auditor verified that in-plant inspection personnel executed HACCP verification activities in accordance with Poland's regulatory requirements. The auditor found the following deficiencies while performing this task:

- In one establishment, the establishment's HACCP monitoring records did not document the time monitoring activities were conducted by the establishment's personnel for each entry.
- In three establishments, the establishment's HACCP verification records did not document the time of the verification activities conducted by the establishment's personnel for each entry.
- In one establishment, the Hazard Analysis and flow chart listed two sequential process and product flow steps in the wrong order.

The above recordkeeping findings were corrected by establishments by modifying the format of their HACCP records. During the exit meeting, the CCA provided supporting documentation

that all of these corrective actions were implemented by the establishments and verified by the inspection personnel.

The FSIS auditor's review and observations during this audit support that Poland's meat inspection system had effectively implemented corrective actions in response to all previous audit findings. FSIS auditors verified that the GVI requires operators of official establishments to develop, implement, and maintain HACCP programs for each processing category, as set forth in United States regulatory requirements and relevant GVI requirements. The measures employed by the GVI appear to be equivalent to those governing the United States inspection system.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of the six equivalence components that the FSIS auditor reviewed was Chemical Residue Control Programs. To be equivalent to FSIS's inspection system, the inspection system must have a chemical residue control program designed and administered by the national government that functions to prevent chemical residue contamination of food products. In addition, to be considered equivalent to the FSIS program, the program must include random sampling of internal organs, muscle, and fat of carcasses for chemical residues identified by the exporting countries and FSIS as potential contaminants. The CCA must provide a description of its residue sampling and testing plan and the process used to design the plan. The CCA must maintain oversight of laboratories to ensure the validity and reliability of test data.

Poland's National Residue Plan is designed and conducted as coordinated efforts of the GVI and NRL. The residue plan includes a description of the various sampling schemes, lists the selected matrices for each compound, and includes a rationale and process for adding and removing chemical compounds. The GVI provides direction, coordination, and oversight of the residue control program in accordance with Council Directive 96/23/EC and Commission Decision 97/747/EC. The Instruction of the Chief Veterinary Officer No GIWlab 830-9/13 describes the scope and method of implementation of the national residue control plan for detecting unauthorized chemical, biological, and medicinal residues in animals, products of animal origin, water intended for animals, and animal nutrition products. FSIS auditors verified that the residue plan has measures in place that ensure that there is segregation of domestic product from product that would be destined for export to the United States when domestic residue tolerances are higher. The separation ensures that a product that does not meet United States standards is not commingled with a product destined for export to the United States.

The GVI determines the number of random and targeted samples to be distributed among regions. RVI ensures distribution of samples among DVIs and ensures execution of a random and targeted testing program for chemical residues is conducted by district officers. The testing programs and operational processes include sample collection, shipping to laboratories, management, and analysis of data and initiation of trace-back activities as well as initiation of enforcement procedures in case of detecting the presence of forbidden chemical substances or exceeding of the maximum limit of chemical, biological and medicinal residues.. The FSIS auditor reviewed, in government laboratories, records related to the sample handling, sample

arrival temperature, sampling frequency, timely analysis, date reporting, analytical methodologies and matrices, equipment operation and detection levels, intra-laboratories check samples, and quality assurance programs. The auditor's review found that the laboratory conditions, records generated, and results of past audits met EN ISO/IEC 17025:2005 standards. The FSIS auditor did not identify any deficiencies or areas of concern during the audit of the official laboratories. The staff and management of visited laboratories are knowledgeable about and apprised of Poland's testing requirements for products destined for the United States. The FSIS auditor received copies of the scopes of accreditation for chemical testing for the NRL by the Polish Center for Accreditation (PCA). The FSIS auditor concluded that laboratory personnel are qualified, adequately trained, and capable of conducting analytical methods, and that the residue laboratories demonstrated the ability to produce timely and accurate data.

Poland uses the EU's Rapid Alert System for Food and Feed (RASFF) as a tool to exchange information about measures taken responding to serious risks detected in food or feed. The enforcement actions taken by the GVI in response to recurring violative residue findings are based on the guidelines set out in article 16, 22-28 of Council Directive 96/23/EC and the Instruction of the Chief Veterinary Officer No GIW lab 830-5/11. Enforcement actions include investigations at the farm of origin. The enforcement actions may result in restriction of animal movement, intensified sampling at the farm and the slaughter establishment for 6-12 months, discontinuation of slaughter of animals from a suspect source for the entire withdrawal period of subject drug, and, in the case of repeated violations, the GVI may permanently withdraw the slaughter establishment from the official establishment list.

FSIS determined that the Government Chemical Residue Testing Programs component includes a national program managed by the GVI. The GVI has access to and supervises the activities of analytical laboratories that have testing capabilities to ensure the validity and reliability of test data. Poland's meat inspection system has regulatory requirements for a chemical residue testing program that is organized and administered by the national government. The program includes random sampling of internal organs, muscle, and fat of carcasses for chemical residues. The program is adjusted on a yearly basis to address emerging concerns. Testing conducted by FSIS at United States POE has not detected violative chemical residues in pork products produced by Polish certified establishments.

FSIS analysis and audit verification activities of Poland's chemical residue testing program found that the GVI continues to demonstrate the ability to meet the equivalence requirements for this component.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component that the FSIS auditor reviewed was government Microbiological Testing Programs. An equivalent system is required to implement certain sampling and testing programs to ensure that pork products produced for export to the United States are safe and wholesome. This component pertains to the microbiological testing programs organized and administered by the GVI to verify that products destined for export to the United States are safe, wholesome, unadulterated, and meet all relevant equivalence criteria.

The evaluation of this component included an analysis of the information provided by the GVI through the SRT, review of establishments' and official inspection records, interviews with inspection and laboratory personnel, as well as observations during the on-site audit.

Poland's inspection system requires that slaughter establishments seeking certification to export of pork and pork products to the United States conduct sampling and testing for generic *E. coli* in raw carcasses as a means to assess the effectiveness of sanitation and process control in slaughter facilities. Inspection program personnel are to review the establishment records to verify that they accurately document the generic *E. coli* results (CFU/cm2), and that results are recorded on a process control chart or table that shows at least the most recent 13 test results. The DVI verification activities (once a month) are documented using Form 5000.1-3-Checklist of Meeting the Basic Requirements of *E. coli* Testing Program. Furthermore, the FSIS auditor found that some establishments were conducting additional testing (e.g., Enterobacteriaceae; Aerobic Plate Count). The purpose of these testing programs is to verify the effectiveness of sanitation and process control processes used as an indicator for fecal contamination in slaughter establishments. Ongoing testing for indicator organisms by slaughter establishments helps them to determine whether the slaughter process is under control, and whether carcasses are being contaminated with feces. The auditor reviewed the establishments' written programs, and the official inspection records did not present any concerns.

Poland, as an EU Member State, participates in the EC's *Salmonella* reduction program in slaughter and processing establishments. The GVI conducts *Salmonella* testing of market hog carcasses at regulated establishments. If the *Salmonella* testing finds a positive result, the operator has to immediately start doing daily sampling until satisfactory results are obtained and to institute sanitation and hygienic procedures deemed acceptable by the GVI to prevent recurrence. In response to recurring unsatisfactory results, an establishment must reassess its HACCP plan, take appropriate corrective action, and start sampling for the third time. Failure by the plant to meet the established standard for the third consecutive time is deemed by the GVI as a failure to maintain the minimum standard for slaughter hygiene and sanitation and consequently would bring into question the adequacy of the establishment's HACCP plan. Accordingly, the GVI would impose regulatory sanctions consistent with the statutory framework of Poland's inspection system and exclude the establishment from the export program.

FSIS auditors verified that GVI follows the Instructions of the Chief Veterinary Officer, designed to verify that official establishments follow the regulations for export certification of RTE products. The inspection verifications are conducted according to the CVO instructions directing the verification of sections of 9 CFR Part 430 that relate to the control of *Lm* in post-lethality exposed RTE products. The testing programs for RTE products include specific provisions for government sampling of product, government verification of establishment sampling, and the verification of control measures in every establishment that intends to export product to the United States. The establishments are required to take corrective action in response to positive *Lm* findings in official or companion samples taken by the establishment. The CVO instructions clearly articulate that there is no tolerance for any detectable level of *Lm*

in finished product regardless of whether the product supports growth of *Lm*, and that the level of detection for *Lm* is equivalent to that of FSIS.

FSIS auditors verified that visited establishments have annual sampling programs that include sampling of product and product contact surfaces, as well as environmental sampling of the post-lethality areas where RTE products are handled or stored. In addition, the FSIS auditors verified that visited establishments are aware of and implement procedures to ensure that there is no detectable *Lm* in RTE products regardless of whether the products support growth of *Lm*. Furthermore, the DVO conducts verification sampling and testing for *Lm*, *Listeria spp*., or *Listeria*-like organisms in post-lethality exposed RTE products and on product contact and environmental surfaces and for *Salmonella* in the RTE products. This sampling is conducted at a frequency that ensures that the establishments' control measures for these pathogens of concern are effective. In accordance with the Instructions of the Chief Veterinary Officer No GIWhig-500-2/2013, as amended, the GVI requires that canning establishments notify inspection personnel when they find abnormal containers as defined in provisions homologous to FSIS standards described in 9 CFR 318.300(a).

There are no requirements for routine microbiological testing for thermally processed commercially sterile (canned) products. However, the inspection system demonstrated its capability to maintain a microbiological program that would ensure that canned pork products produced for export to the United States are safe, wholesome, and not contaminated with *Clostridium botulinum* spores or toxins. The establishments are required to assess the nature and cause of abnormal containers according to their HACCP plan and are to provide acceptable final disposition of the affected production. The inspection system ensures that only safe and stable product is exported to the United States. The FSIS auditor verified that the GVI oversees the performance of establishment verification activities, ensuring that when problems are identified, corrective and preventive measures are implemented.

The FSIS auditor verified that Poland's microbiological testing laboratories are ISO 17025 accredited and equipped to provide adequate technical support to the meat inspection system. The management and staff of the laboratories are familiar with requirements for exporting to the United States as applicable to microbiological testing. The FSIS auditor verified that Poland collects test portions for *Lm* and *Salmonella* of 25 g and 325 g, respectively, that are analyzed by methods that have been determined to be equivalent by FSIS.

FSIS auditors verified that the NRL participated regularly in proficiency tests organized by the EU Reference Laboratories with satisfactory results. The NRL executes its supervisory role over the RVLs through periodic supervisory visits and administration of proficiency tests. These proficiency tests are regularly organized to cover different microbiological criteria including *Salmonella* and *Listeria* and uses different matrices.

The findings of the current equivalence audit show that Poland's meat inspection system has a microbiological testing program, organized, and administered by the national government, and that the GVI requires generic *E. coli* testing and conducts *Salmonella* sampling and testing programs to verify the effectiveness of its system. FSIS concludes that, based on the results of

the overall microbiological component assessment, the GVI continues to meet the equivalence requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on May 8, 2015 in Warsaw with GVI, PVI, and DVI representatives. At this meeting, the preliminary audit findings were presented by the FSIS auditors. The GVI understood and accepted the findings. The 2015 FSIS audit results confirm that Poland's meat inspection system continues to maintain equivalence. FSIS identified some operational (or procedural) weaknesses related to sanitation and HACCP. However, none of these weaknesses was significant enough as to raise a question about Poland's on-going equivalence.

FSIS will evaluate any information provided by Poland, including the submittal of the Central Competent Authority (CCA) proposed corrective actions in response to the audit findings to assess the effectiveness of the corrective actions.

APPENDICES

APPENDIX A: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
PINI POLONIA Sp. z o.o. 99-300 Kutno Ul. Wschodnia 21	04/24/15	10 02 38 02	Poland
	5. NAME OF AUDITOR(S) Juan Rodriguez, DVM/Nader Memariam, DVM		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.	X
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. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

22/51: The establishment's HACCP verification records for calibration of monitoring instruments did not document the time of the calibration activities conducted by the establishment's personnel for each entry [9 CFR part 417.5 and 417.8].

Species slaughtered and processed: porcine.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE	
Juan Rodriguez, DVM | Nader Memarian, DVM		4/24/15

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 70-812 Szczecin ul. Pomorska 115b	4/28/15	32 62 02 01	Poland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, DVM		[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.	
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. Enforcement	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

April 28, 2015 | Est# 32 62 02 01 | ANIMEX Foods, Szczecin | (S/P) | Poland

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

Species slaughtered and processed: porcine.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	Nader 4-28-15

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. Oddział w Jarosław 37-500 Jarosław ul. Przemysłowa 2	4/28/15	18 04 02 01	Poland
	5. NAME OF AUDITOR(S) Juan F. Rodriguez, DVM		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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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	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	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

41/51. Beaded condensation was observed in a section of the carcass cooler immediately above product [9 CFR 416.2]. No direct contamination of product was observed at the time. Product stored beneath the area was immediately moved to another section of the cooler.

Species slaughtered and processed: porcine.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Juan F. Rodriguez. DVM	4/28/15

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	4/29/15	26 11 02 01	Poland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Juan F. Rodriguez, DVM		[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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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	X
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

38/39/51. Seal around shipping door did not provide a tight seal when door was closed, which would allow for the entrance of pests into this area [9 CFR 416.2]. Facility was notified of need to correct this situation immediately by official inspection personnel.

Species slaughtered and processed: porcine.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Juan F. Rodriguez. DVM	DVM 4/29/15

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
Zakłady Mięsne SKIBA 89-600 Chojnice ul. Droga do Igiel 2	4/30/15	22 02 38 01	Poland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, DVM		[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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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	
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37. Import	
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39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

22/51: The establishment's HACCP verification records for calibration of monitoring instruments did not document the time or the result of the calibration activities conducted by the establishment's personnel for each entry [9 CFR part 417.5 and 417.8].

Species slaughtered and processed: porcine.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	4-30-15

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	4/30/15	14 29 02 01	Poland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Juan F. Rodriguez, DVM		[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.	
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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. Enforcement	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

April 30, 2015 | Est# 14 29 02 01 | SOKOŁÓW S.A., Sokołów Podlaski | (S/P) | Poland

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

Species slaughtered and processed: porcine.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Juan F. Rodriguez. DVM	4/30/15

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 14-100 Ostróda Morliny 15	5/4/15	28 15 40 03	Poland
	5. NAME OF AUDITOR(S) Nader Memarian, DVM		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.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

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

60. Observation of the Establishment

22/51: A) The establishment's HACCP monitoring records did not document the time of monitoring activities conducted by the establishment's personnel for each entry [9 CFR part 417.5 and 417.8].
B) The establishment's HACCP verification records did not document the time of the verification activities conducted by the establishment's personnel for each entry [9 CFR part 417.5 and 417.8].

Species processed: porcine.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	5-4-15

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
Łmeat-Łuków S.A. 21-400 Łuków ul. Przemysłowa 15	5/4/15	06 11 02 66	Poland
	5. NAME OF AUDITOR(S) Juan F. Rodriguez, DVM		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.	X
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)	
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Salmonella Performance Standards - Basic Requirements	
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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	X
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

22/51. The establishment's Hazard Analysis and flow chart identified all the process and product flow steps, however, two of the steps were listed in the wrong order [9 CFR 417.2]. Representatives from the CCA (Provincial Veterinary Office, District Veterinary Office, Veterinary Inspection personnel assigned to work in the facility) accompanying the FSIS auditor immediately notified the establishment of this observation.

38/39/51. Seal around shipping doors did not provide a tight seal when doors were closed, which would allow for the entrance of pests into this area [9 CFR 416.2]. Facility was notified of need to correct this situation immediately by official inspection personnel.

Species slaughtered and processed: porcine.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Juan F. Rodriguez. DVM	5/4/15

APPENDIX B: Poland's Response to Draft Final Audit Report

Polish side's revised comments to the draft audit report regarding food safety in the pork meat sector 21 April – 8 May 2015

The central competent authority (CCA) has examined the contents of the draft report and does not wish to raise any major substantive 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.

However, Poland requests to make a few minor editorial corrections to the contents of the said draft report. The corrections are as follows:

1. Regarding: "Poland exports the following categories of products..."

Page I, Executive Summary, **paragraph 1**

Proposed correction:

Poland is eligible to export the following categories of pork products: raw – intact; raw product – non-intact; fully cooked – not shelf stable; heat treated but not fully cooked - not shelf stable; and thermally processed – commercially sterile.

Attention: The same applies to **page 3** Part III BACKGROUND.

2. Regarding:

Page 5, paragraph 2: "The GVI's Laboratories Policy Office coordinates activities among the GVI, the NRL and regional laboratories".

Proposed correction:

The GVI's Laboratories Unit coordinates activities among the GVI and regional laboratories and collaborates with the NRL, the RVLs and other bureaus in the GVI.

3. Regarding:

Page 5, paragraph 5: "the Instructions Chief Veterinary Officer No. GIWbż-500-2/2013...".

Proposed correction:

add phrase "**as amended**".

Attention: The same applies to **page 8**, **paragraph 3** and **page 9**, **paragraph 6**, and **page 14**, **paragraph 1**.

4. Regarding:

Page 10, **paragraph 1**: the sentence: "....official veterinarians perform daily and periodic supervision over HACCP procedures carried out at the establishment and document it using Form 5000.1-6 (daily)".

Proposed correction:

Official inspectors follow verification methods described in the *Requirements for establishments approved for export of meat and poultry and their products to the market of the United States of America.* Official veterinarians perform daily supervision over HACCP procedures at the establishment level. Official veterinarians at the DVI level and RVI level perform monthly supervisory reviews at United States eligible establishments.

5. Regarding:

Page 11, **paragraph 4**, "The GVI manages random and targeted testing programs for chemical residues. The testing programs and operational processes include sample collection, shipping to laboratories, management, and analysis of data and initiation of trace-back activities and are managed by the GVI."

Proposed correction:

The GVI determines the number of random and targeted samples to be distributed among regions. RVI ensures distribution of samples among DVIs and ensures that execution of a random and targeted testing program for chemical residues is conducted by district officers. The testing programs and operational processes include sample collection, shipping to laboratories, management, and analysis of data and initiation of trace-back activities as well as initiation of enforcement procedures in case of detecting the presence of forbidden chemical substances or exceeding of the maximum limit of chemical, biological and medicinal residues.

Simultaneously, in relation to non-compliance found by FSIS auditors during the audit and reported on the content of the above mentioned draft report on page 9 (Sanitation) and page 10 (HACCP), the Polish side would like to make a few additional comments. As described in the draft report, Poland has referred to all FSIS's comments provided during the audit and has undertaken all the necessary corrective measures in relation to the irregularities identified during the said audit.

Corrective and preventive actions are as follows:

1. Regarding:

- In one establishment, beaded condensation was observed in an area of the main cooler above areas where exposed product was or would be stored. No direct product contamination was observed at the time.

Non-compliance with 9 CFR 416.2. (d). The establishment has immediately taken corrective and preventive actions which involved, among others,: separation of carcasses located within the immediate threat of pollution condensate (5 carcasses), drying the location of the condensate, examination of the said 5 carcasses and a recommendation to increase the frequency of inspection of the site of inconsistencies in the form of condensation forms. In addition, the plant has implemented a procedure: "Supervision of condensate".

2. Regarding:

- In two establishments, shipping doors were not properly sealed to prevent the entrance of vermin.

Non-compliance with 9 CFR 416.2. (a). The establishments have immediately taken corrective and preventive action, which involved, among others: improvement of sealing doors in the loading docks and installation of additional movable doors.

3. Regarding:

- In one establishment, the establishment's HACCP monitoring records did not document the time monitoring activities were conducted by the establishment's personnel for each entry.

Non-compliance with 9 CFR 417.5 and 417.8. The establishment has immediately taken corrective and preventive actions. In the monitoring sheet CCP7 and CCP7r, column 6: the time of measuring the temperature of pasteurization is defined as the time of the product when the process is finished. Amendments were introduced in the instructions I/HACCP/02 and in the monitoring sheet CCP7 and CCP7r by adding a new column 11 entitled: "The time of finishing thermal treatment process, which means obtaining the desired temperature in the product core", and by training of operatives who are responsible for monitoring the CCP7 and the CCP7r.

4. Regarding:

- In three establishments, the establishment's HACCP verification records did not document the time of the verification activities conducted by the establishment's personnel for each entry.

Non-compliance with 9 CFR 417.5 and 417.8. The establishments have immediately taken corrective and preventive action, which consisted of, among others: taking into account the hour, not only the date, when verifying registers monitoring the HACCP system as well as records of the calibration process monitoring.

5. Regarding:

- In one establishment, the Hazard Analysis and flow chart listed two sequential process and product flow steps in the wrong order.

Non-compliance with 9 CFR 417.2. (a). The mistake was immediately corrected by the establishment during the inspection. On 4th May 2015 annex E was issued for the plan HACCP PJH-7.5-02-01, "Pig slaughter line" for pages 10/11 of the graphical part and as well as for pages 30/31 of the threat analysis.

Additionally, in order to harmonize practices of local veterinary authorities' supervision in establishments approved for export to the US market or seeking to obtain such permission, the Chief Veterinary Officer issued a letter (attached), which recommended to the authorities of the Veterinary Inspection that during the conducting of verification duties in the above establishments, official veterinarians should pay special attention to the aspects resulting from the provisions of 9 CFR 416.2. (a) and (d); 9 CFR 417.5 and 417.8. and 9 CFR 417.2. (a).