United States Department of Agriculture

Food Safety and
Inspection Service

1400 Independence
Avenue, SW.
Washington, D.C.
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APR 12

Dr. Paweł Niemczuk
Chief Veterinary Officer
General Veterinary Inspectorate
Ul. Wspolna 30
00-930 Warszawa
Poland

Dear Dr. Niemczuk,

The Food Safety and Inspection Service (FSIS) conducted an on-site ongoing equivalence verification audit of Poland's meat inspection system from September 11 through September 27, 2017. Enclosed is a copy of the final audit report, which will be published on the FSIS website. The comments received from the Government of Poland are included as an attachment to the report.

FSIS acknowledges that the General Veterinary Inspectorate (GVI) has provided documentation to address the findings noted during the on-site audit. We are seeking further clarification on your intended implementation plan to provide direct supervision of the appointed official veterinarians by GVI government inspectors throughout slaughter operations and at least daily, once per shift, during processing. FSIS suggests a teleconference with our respective experts would be most effective way to resolve this issue. Please let us know a convenient date to organize the call. Once we receive this information, we will complete our review of your submitted corrective actions and supporting documentation, and determine whether your raw and processed pork products inspection system remains equivalent to that of the United States.

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

Sincerely,

Todd Furey
Acting International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

POLAND

SEPTEMBER 11- 27, 2017

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT

EXPORTED TO THE UNITED STATES OF AMERICA

April 12, 2018

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from September 11-27, 2017. The purpose of the audit was to determine whether Poland's food safety system governing meat 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 the following categories of products to the United States: raw–intact; raw–non-intact; fully cooked–not shelf stable; heat treated but not fully cooked–not shelf stable; and thermally processed–commercially sterile pork products.

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

Government Oversight

- The Central Competent Authority (CCA), the General Veterinary Inspectorate (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 of 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 enforcement of sanitation performance standards (SPS) requirements were identified in five of the nine establishments and sanitation standard operating procedures (SSOPs) 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 Points (HACCP) System

- Deficiencies related to 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.

An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. During the audit exit meeting, the GVI committed to begin addressing the preliminary findings as presented. FSIS will evaluate the adequacy of the GVI's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an onsite audit of Poland's food safety system from September 11-27, 2017. The audit began on September 11, 2017, with an entrance meeting held in Warsaw, Poland, during which FSIS discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) - the General Veterinary Inspectorate (GVI). In Poland the inspectorate is known as *Główny Inspektorat Weterynarii.*

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to verify whether the food safety system governing meat maintains equivalence 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 raw–intact; raw–non-intact; fully cooked–not shelf stable; heat treated but not fully cooked–not shelf stable; and thermally processed–commercially sterile pork products to the United States.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from the CCA through a self-reporting process.

FSIS conducted the last audit of Poland in 2015. In that audit, operational deficiencies related to sanitation and HACCP were identified. The current audit verified and confirmed the establishments had corrected the findings, which was verified by GVI.

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

The FSIS auditors reviewed administrative functions at CCA headquarters, two provincial offices, six district offices, and nine local inspection offices. During the review, the FSIS auditors evaluated the implementation of control systems in place that ensure that the national system of inspection, verification, and enforcement is being implemented as intended. A sample of nine establishments was selected from a total of 18 establishments certified to export to the United States, six slaughter and processing establishments and three processing only establishments.

During the audit at each of the establishments, the FSIS auditor paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threaten food safety. The FSIS auditor examined the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems. These requirements are outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) §327.2.

FSIS audited two government laboratories to verify their ability to provide adequate technical support to the inspection system. Poland's Regional laboratory located in Szczecin was audited for its microbiology program, and the National Veterinary Research Institute located in Pulawy was audited for its chemical residue testing program.

Competent Authority Visits		**#**	**Locations**
Competent Authority	Central	1	• GVI, Warsaw
	Provincial Offices	2	• PVI, Gdansk • PVI, Lublin
	District Offices	6	• DVI, Czluchow • DVI, Gdansk • DVI, Jaroslaw • DVI, Ostroda • DVI, Poznan • DVI, Starachowice
Laboratories		2	• National Veterinary Research Institute, Pulawy (selected for residue program) • Provincial Laboratory, Szczecin (selected for microbiology program)
Meat slaughter and processing establishments		6	• Establishment 06 11 02 66, Lublin • Establishment 18 04 02 01, Jaroslaw • Establishment 22 03 02 07, Czluchow • Establishment 26 11 02 01, Starachowice • Establishment 30 21 02 25, Poznan • Establishment 32 62 02 01, Szczecin
Meat processing establishments		3	• Establishment 10 02 40 02, Kutno • Establishment 28 15 40 03, Ostroda • Establishment 30 09 02 01, Poznan

The audit was performed to verify whether the country's food safety system met requirements equivalent to those 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 FSIS Regulations for Imported Meat (9 CFR Part 327).

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

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

III. BACKGROUND

Poland currently exports raw–intact; raw–non-intact; fully cooked–not shelf stable; heat treated but not fully cooked–not shelf stable; and thermally processed–commercially sterile pork products to the United States. From January 1, 2014, to May 1, 2016, FSIS import inspectors performed 100 percent POE re-inspection for labeling and certification on 274,619,828 pounds of pork products exported by Poland to the United States. Of that amount, additional types of inspection (TOIs) were performed on 32,513,495 pounds, of which inspection (TOI), of which no product was rejected due to any food safety related reasons. 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 Web site at: *http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports.*

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

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

component included a review and analysis of the information provided by the CCA in the updated self-reporting tool (SRT) and observations during the onsite audit.

The FSIS 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 (MARD). 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 Provincial Veterinary Inspectorate (PVI), headed by the Provincial Veterinary Officer (PVO). There are 16 provinces in Poland, and each province 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 United States-certified establishments, 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.* In the document, GVI has mandated compliance with certain provisions consistent with those in 9 CFR Parts 317, 318, and 319, and in Parts 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.

During the audit of 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 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 onsite inspection verification of establishment compliance with United States requirements. If approved, the DVO submits the application to the PVO, who delegates a PVI official to conduct an inspection and affirm certification. PVI then sends recommendations for the certification to GVI headquarters. GVI reviews the documents prior to updating the list of eligible establishments and then submits the list to FSIS.

Interviews conducted with the GVI indicate that any new establishments applying for the United States market are also evaluated at the central level. Examples were shared with the FSIS auditors where GVI had rejected an establishment's request for certification due to a lack of experience with United States requirements. Additionally, GVI maintains a register on its web portal that includes the list of all United States-certified establishments. The FSIS auditors verified that the system ensures only eligible products are used to produce products intended for export to the United States. While some certified establishments do import source meat from other countries or establishments, the certification process ensures that imported product comes from establishments certified as eligible to export product from countries that are eligible to

export the applicable product to the United States. The FSIS auditors verified that adequate segregation or separation of products was maintained or that all establishment operations meet United States requirements at all times.

The FSIS auditors verified uniformity in government inspection activities throughout the system. Consistent implementation is ensured through the application of uniform requirements, policies and instructions. Additionally, GVI structure from headquarters through PVIs and DVIs to the establishment level provides for systematic communication, management, and supervisory oversight**.** The FSIS auditors verified that GVI has procedures to analyze needs and provide staffing at certified establishments, which reflects GVI's ability to provide government inspection during all slaughter operations and at least once per shift during processing operations. The staffing for post-mortem inspection was consistent with Annex No. 2 of the *Instruction of the Chief Veterinary Officer, No. GIWbż-500-1/13, pigs*. The FSIS auditors verified adequate government inspection during the observed slaughter process to perform ante-mortem and post-mortem inspections as well as offline verification activities.

The FSIS auditors verified that all inspection personnel assigned to certified establishments are recruited and appointed by the DVO, usually under annual contract to the DVI. These contracted inspectors also known as appointed inspectors are required to perform inspection duties such as ante-mortem and post-mortem inspection, sanitation, and HACCP verification activities under DVI- assigned government inspectors. United States-certified establishments are always supervised by permanent, government employees at the DVI level, however they are located in headquarters. In Poland, industry is assessed fees for meat inspection and directly pays the Polish government. All funds for disbursement of salaries to the inspection personnel assigned to the United States-certified establishments come from the Ministry of Finance. The FSIS auditors identified the following finding:

- Poland's use of contracted employees to conduct inspection (e.g., ante-mortem inspection, final carcass dispositions during post-mortem inspection, and sanitation and HACCP verification activities) during the production of product for export to the United States does not meet FSIS' statutory requirements that inspection be conducted by a government inspector. These verification activities extend to both the slaughter of source materials, as well as the production of processed products (e.g., TPCS product) intended for export to the United States.

The FSIS auditors confirmed that official veterinarians (OVs) 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 states that 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.

OVs who attend sessions organized by GVI are certified as trainer(s) of cascade training 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 auxiliaries. 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., PVI, DVI, and local inspection levels). While verifying the implementation of canning regulation requirements at establishments producing thermally processed-commercially sterile (TPCS) products, the FSIS auditors concluded:

- GVI has not provided DVOs or OVs assigned to canning establishments with specialized training for 9 CFR 318.300, subpart G, Canning and Canned Products, requirements adopted by Poland. In addition, GVI does not have available thermal processing expertise for technical questions associated with thermally processed, commercially sterile products.

Instruction of the Chief Veterinary Officer, No. GIwbz500-4/12 provides instruction to OVs who conduct ante-mortem and post-mortem inspections in slaughter establishments on how to document and keep ante-mortem and post-mortem inspection records for meat. *Instruction of the Chief Veterinary Officer No. GIWhig500-4/08,* provides instructions for performing and documenting official controls, and verification of the official actions performed accordingly by regional and district veterinary officers. One objective of the *Guidelines Issued by the Chief Veterinary Officer* is to provide a uniform way of determining the frequency of verification of sample collection to evaluate the process of hygiene and safety of products and enforcement of requirements. The GVI maintains a communication system to convey requirements related to United States export throughout its inspection system. The FSIS auditors verified that GVI disseminates information related to regulatory and administrative affairs to all levels of the inspection system by mail and e-mail, and by posting it on its Web site.

GVI also maintains administrative and technical support to operate its laboratory system through issuance of the Act on Veterinary Inspection. To ensure a uniform laboratory tests for the purpose of official controls GVI created a system of official laboratories, including accredited laboratories. The CVO has, by way of administrative decision, the authority to approve the laboratory for official testing, or alternatively, withdraw approval in the event that the laboratory is unable to meet International Organization for Standardization (ISO) standard 17025, *General requirements for the competence of testing and calibration laboratories.*

While the CCA maintains many of the administrative and technical elements to operate its inspection system, the use of contracted employees to conduct ante-mortem inspection, final carcass dispositions during post-mortem inspection, and sanitation and HACCP verification activities during periods when establishments are producing products for the United States does not meet FSIS' statutory requirements that these activities be conducted by a government inspector. Furthermore, FSIS does not consider the current level of oversight provided is sufficient, as it is expected that these contracted employees be under the supervision of a government veterinarian that is physically present in the establishment whenever slaughter of livestock for use in processed product intended for export to the United States occurs.

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

The second of six equivalence components that the FSIS 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 carcasses and parts; daily inspection; at least once per shift for processing and during all slaughter operations and periodic supervisory visits to official establishments. The evaluation of this component included a review and analysis of the information provided by the CCA in the updated SRT and observations during the onsite audit.

GVI has adopted Regulation (EC) No. 853/2004, Regulation (EC) No. 1/2005, Regulation (EC) No. 1099/2009, and Council Directive 93/119/EC to meet the requirement of humane handling and slaughter of animals. Regulation (EC) No. 1/2005 addresses protection of animals during transport and related operations. Council Directive 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 FSIS auditors verified that each slaughter establishment includes full-time OVs dedicated to performing ante-mortem inspection and to verify compliance with humane handling and slaughter requirements as per regulations cited above. GVI has issued an instruction document *Instruction of the Chief Veterinary Officer, No. GIWz.420-31/13*, which states that inspectors are required to ensure pigs presented for slaughter are handled and slaughtered humanely. The FSIS auditors followed the OVs 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 adequate procedures ensure complete segregation of suspect livestock and any meat products from such animals is precluded from export to the United States.

The FSIS auditors confirmed that livestock presented for slaughter receive ante-mortem inspection, which is performed by government inspection personnel prior to slaughter. The FSIS auditors observed that the OV conducting the ante-mortem inspection verified the accompanying health certificate of the lot issued by another official veterinarian at the farm, and traceability documents identifying all the required information for the livestock. The OV 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 OV 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 every carcass by an OV under the direct supervision of the DVO. Post-mortem inspection includes incision of mandibular lymph nodes, palpation, and observation of viscera, and inspection of carcasses for the purpose of determining whether they are eligible for the mark of inspection. Correlation of viscera and associated carcasses was ensured during the slaughter process, typically through marking the carcass number on the lungs of each pluck. OVs perform inspection of each carcass requiring a veterinary disposition. Observation of the disposition of carcasses confirmed that the OVs made supportable dispositions and ensured aggressive trimming of all affected tissue before allowing the mark of inspection to be applied.

A final carcass inspection occurs after establishment trimming, but before the final wash or exit from the slaughter floor. The OV instructs OAs to either mark or refuse to mark each carcass as inspected and passed. The FSIS auditors verified that post-mortem inspection procedures meet the United States requirements for swine. On-line inspection is provided during all hours of slaughter to meet both EC and United States requirements. GVI also ensures that OVs provide inspection at least once per shift for processing operations of establishments during production of product intended to export to the United States.

GVI's document *Instruction of the Chief Veterinary Officer, No. GIWhig 500-4/08,* concerning official control methodology provides procedures and methods for the PVI and DVI officials on how to conduct effective periodic supervisory visits. When visiting the United States-certified establishments, the supervisor uses Form 5000-6, *Control Report of the Establishment Approved for Export to the USA,* which is a checklist designed to encompass all aspects of the food safety system including HACCP, SSOP, and SPS, sampling and labeling. Direct observations during the onsite visit are complemented with record review activities. Periodic visits at the United States-certified establishments are conducted at a monthly frequency by the DVO and additionally by the PVO at a different time during each month. Lastly, GVI also conducts audits of certified establishments.

In 2017, the CCA selected six DVOs and six certified establishments for audit. To date the GVI has performed four of those audits. They use the same Annex 2 form as the supervisory visits conducted by DVOs and PVOs. The FSIS auditors reviewed a report for an audit that the GVI conducted in one of the United States-certified processing establishments on August 9-11, 2017. The audit findings were correlated with the DVO and PVO. The OV issued a noncompliance record (NR) to the establishment. The DVO and the PVO reviews corrective actions and communicates them to GVI.

The FSIS auditors reviewed supervisory visit reports conducted by the DVO and PVO at certified establishments 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 DVO and PVO, and these visits are conducted

at separate times each month. All findings are documented on Poland's Form 5000-6 as described. If findings result in noncompliance, the process ensures documentation on NRs and issuance of an administrative decision instructing the establishment to correct the finding(s). Only when the DVO has verified resolution of the noncompliance is the administrative decision repealed, indicating closure of the issue.

The CCA has legal authority to establish regulatory controls over certified establishments that export meat products to the United States. The FSIS auditors verified that the CCA has adequate verification procedures to ensure United States requirements are met.

VI. COMPONENT THREE: GOVERNMENT SANITATION

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

GVI has adopted provisions consistent with 9 CFR 416 to meet requirements pertaining to sanitation in the United States-certified establishments, which are documented in Sections 3.1 to 3.7 and Sections 3.8 to 3.14 of the GVI issued document, *Requirements for establishments approved for export of meat and poultry and their products to the market of the United States of America*. The FSIS auditors verified through direct observation and review of records that each audited establishment has implemented SSOP requirements and has food safety programs to ensure SPS requirements are addressed. The design of written SSOP includes operational and pre-operational sanitation procedures and monitoring of these procedures with some defined frequencies.

To verify implementation of SSOP requirements, the FSIS auditors observed OV verification activities at two of the nine audited establishments. The OVs perform daily activities including direct observation and review of records to verify that SPS and SSOP requirements are met. The results of OA's verification are documented on Form 5000.1-6, *Weekly Verification List in the Establishment.*

- The FSIS auditors identified:
    - Deficiencies related to enforcement of SPS requirements in five of nine audited establishments including deficiencies affecting ventilation, plumbing, equipment, and establishments' maintenance; and
    - Concerns with inadequate enforcement of SSOP requirements in four of nine audited establishments, such as failure to take enforcement actions for findings of dripping condensation over edible product and failure to prevent direct product contamination during the slaughter process.

The GVI requires certified establishments 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 POINTS (HACCP) SYSTEM

The fourth of six equivalence components that the FSIS auditors reviewed was Government HACCP System. The inspection system is to require that each official establishment develop, implement, and maintain a HACCP system. The evaluation of this component included a review and analysis of the information provided by the CCA in the updated SRT and observations during the onsite audit.

The FSIS auditors conducted interviews and reviewed documents in conjunction with direct observation at nine establishments certified to export to 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 HACCP requirements are effectively fully implemented in each certified establishment. The FSIS auditors utilized direct observation of critical control points (CCPs), review and assessment of establishment hazard analyses, flow charts, and HACCP plans in conjunction with review of supporting and implementing documents and results of official veterinary verification activities. Each audited establishment had performed a hazard analysis and addressed the expected hazards for appropriate steps of the process. Slaughter establishments had implemented CCPs to address zero tolerance contamination with fecal material, ingesta, and milk. The establishments had developed flow charts that aligned with the process.

The FSIS auditors verified that OVs routinely review the establishments' implementation of their HACCP systems. GVI requires OVs to follow instructions in the document *Requirements for establishments approved for export of meat and poultry and their products to the market of the United States of America*, Section 4, 9 CFR part 417 – Hazard Analysis and Critical Control Point Systems (HACCP). Section 4.9 addresses verification methodology to ensure that the design and execution of HACCP systems in the United States-certified establishments meets requirements. Any noncompliance is documented on a NR. At each audited establishment, the FSIS auditors reviewed a sample of NRs to assess whether inspectors are applying methodology in accordance with instructions provided in the GVI instruction document referenced in the government oversight component in the report; the FSIS auditors determined that inspectors adhere to instructions provided in Section 4 of the CCAs requirements.

The FSIS auditors verified that establishments implemented the corrective actions proffered by GVI in response to HACCP findings identified during the FSIS audit conducted in 2015. Although corrective actions to all findings were fully implemented, the FSIS auditors identified the following findings:

- One establishment's HACCP plan did not define a procedure or frequency for calibration of process monitoring instruments;
- Two establishments failed to conduct some of the ongoing verification activities at the frequencies identified in their HACCP plans;
- One establishment documented corrective actions in response to a deviation from a critical limit that failed to address all the elements of Poland's requirements (consistent with 9 CFR 417.3(a)); and

- One establishment failed to support the critical limits for RTE lethality due to failure to include the duration at which the critical temperature must be maintained.

During the exit meeting, GVI committed to address these findings and provide supporting documentation that all of these corrective actions were implemented by the establishments and verified by the inspection personnel.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

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

Prior to the onsite visit, FSIS' residue experts reviewed Poland's 2017 National Residue Control Program (NRCP), associated methods of analysis, and additional SRT responses outlining the structure of Poland's chemical residue testing program. There have not been any POE violations related to this component since the last FSIS audit.

In order to execute the NRCP consistent with the EC regulatory framework, GVI has issued a document *Instruction of the Chief Veterinary Officer, No. GIWpr02010-5/2017.* The document describes in detail the various features of Poland's NRCP as well as instructions for all levels of inspection systems as to their respective roles in achieving objectives and goals of the plan to prevent contamination of food products with chemical residues.

The FSIS auditors' verification of this component occurred at all audit sectors of the inspection system which included central, provincial, and district offices, local inspection offices at establishments, and at the National Reference Laboratory (NRL). The FSIS auditors reviewed documents including certificates of analysis, interviewed government officials and OVs, and reviewed the residue testing program at the NRL. The FSIS auditors confirmed that Poland's NRCP includes the type and size of samples, sampling method, method of analysis, and location of sample collection (farms or slaughterhouses) of the targeted compounds. Regarding chemicals that need to be targeted, the plan included prohibited substances, veterinary drugs, pesticides, and environmental contaminants. Depending on the targeted compounds, the type of matrices may differ and include muscle, liver, kidney, fat, urine, or blood.

The FSIS auditors further confirmed that Poland's enforcement programs include: 1) procedures to document 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 (RASFF) 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 recall at the consumer level and inform consumers.

Neither the establishment nor government inspection retains the carcass and parts when samples are collected for analyses for chemical residues under the NRCP pending acceptable results. 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, GVI relies on the National Veterinary Research Institute (NVRI) and six Regional Veterinary Hygiene Institution (ZHW) Laboratories. However, NVRI is encumbered with major responsibilities in terms of coordination among laboratories, technical support, oversight and auditing of regional laboratories. For the purpose of coordination among regional and central laboratories, NVRI develops an annual plan to discuss a variety of topics like accreditation and new matrices. ZHW laboratories submit all screen positive samples to NVRI where two confirmatory tests are conducted in tandem to ensure the accuracy of the result. All laboratories involved in performing analysis for the NRCP are accredited in conformity with ISO 17025 standard, and due to its enormous capabilities in the scientific and diagnostic fields, NVRI also serves as a designated reference laboratory in the EC.

The FSIS auditors reviewed NVRI for its chemical residue testing program. The laboratory audit included interviews with the officials, document reviews, and concluded with a site visit to the chemical testing portion of the laboratory. This laboratory is ISO 17025 standard accredited by the Polish Center for Accreditation (PCA) and has a flexible scope of accreditation. The FSIS auditors reviewed the most recent accreditation audit of the laboratory that took place May 9-10, 2017. There were no findings that would require corrective actions.

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

The GVI continues to demonstrate the ability to meet the equivalence requirements for this component to present a chemical residue testing program, organized and administered by the national government.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components that the FSIS auditors reviewed was Government Microbiological Testing Programs. The system is to implement certain testing programs to

ensure that raw and cooked or thermally processed pork products produced to export to the United States are safe and wholesome.

The evaluation of this component included an analysis of information provided by the CCA in the SRT and accompanying documents, as well as interviews and observations made during the onsite equivalence verification audit. There have not been any POE violations related to this component since the last FSIS audit conducted in 2015.

According to Regulation (EC) No. 882/2004, GVI is required to apply approved methods of analysis that have been scientifically validated and adopted by an international organization. Poland's laboratory quality control and assurance program is ISO standard 17025 accredited which outlines the control requirements for laboratory system including: equipment; test method validation; test and calibration methods; control of records; reporting the results; sampling handling (sampling integrity and chain of custody); personnel qualifications and training (laboratory analysts); corrective and preventive action; internal audits; and management reviews.

The FSIS auditors verified that GVI requires all United States-certified slaughter establishment must implement a written generic *E. coli* plans 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. However, in two establishments the FSIS auditors identified the following finding:

- The establishments are using m/M criteria to assess generic *E. coli* results. The m/M criteria is designed to be used with excision samples. As the establishments are using carcass sponges, results should be evaluated using statistical process control and establishment defined upper control limits.

GVI implements official sampling and analysis for *Salmonella* sampling and testing program for performance standards 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 and analyzed at official laboratories. Through document reviews and interviews conducted at the local inspection offices, DVI, and PVI, the FSIS auditors determined that the *Salmonella* testing program was being carried out as intended in all swine slaughter establishments.

Section 7.4 of the document, Requirements for establishments approved to export of meat and poultry and their products to the market of the United States of America*,* 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, certified establishments producing post-lethality exposed RTE product must comply with the requirements by employing one of the three alternatives to address *Listeria monocytogenes (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 in 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.

The FSIS auditors verified that the laboratories are utilizing 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 employs 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 FSIS auditors identified a finding related to sampling and analysis of RTE product for *Salmonella*:

- The official RTE product sampling and analysis is not consistent with the methodology determined equivalent by FSIS. For an official RTE sample of product produced at one establishment, the OV collected a minimum 65-gram sample from each of five RTE hams. The official laboratory combined the five analytical portions for one 325-gram analytical result for the five hams. The FSIS approved methodology for ISO standard 6579 specified that analysis of five 65-gram samples should be conducted for each sampled product to achieve equivalence with the FSIS methodology for analysis of 325-grams per sample.

GVI maintains a regulatory definition for TPCS product as product subjected to heat treatment under specified time/temperature parameters and placed on the market in hermetically sealed containers. Poland has adopted the United States regulatory requirements in 9 CFR 318.300, subpart G, in their entirety, and conveys these requirements to both certified establishments and inspection personnel in an instruction document referenced in the government oversight component of the report. The GVI inspection personnel verify implementation of these requirements by following instruction provided consistent with FSIS Directive 7530.2, *Verification Activities in Canning Operations that Choose to Follow the Canning Regulations.* Furthermore, GVI conducts government verification testing for *Clostridium botulinum* and *botulinum* toxin. In the event of a processing deviation leading to contamination or adulteration of the product, GVI implements the provisions in Article 19 of Regulation (EC) No. 178/2002 to include market withdrawal and recall procedures. Interviews conducted with government officials at the district and provincial veterinary inspectorates and the inspectors at the local offices indicate that there is not currently any staff expertise in the area of thermal processing. The FSIS auditors identified the following at one TPCS establishment:

- The establishment lacked supporting documentation from a processing authority recommending the process schedules and there was no evidence a processing authority had performed the appropriate tests to develop process schedules (e.g., heat penetration tests among others);
- The process schedules used by the establishment included fill weight of each can. During operations (not for United States export), an establishment employee was observed to randomly check fill weight from three cans but weight measurement was not recorded;

- The establishment could not provide supporting documentation that the employee conducting teardown examinations was directly supervised by a person who has successfully completed a school of instruction generally recognized as adequate for training supervisors of canning operations; and
- Records and procedures for the teardown examination of container integrity did not include examination of the canner's end. Records documenting teardown examinations did not include the time of closing machine operations or the time of the teardown examination.

The FSIS auditors visited a Regional Laboratory located in Szczecin, 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 on products destined for export to the United States.

The FSIS auditors reviewed the recent ISO standard 17025 accreditation report issued by PCA conducted in June 2017. Accreditation audits are conducted every four years; the FSIS auditors reviewed the recent report and determined there were no significant findings. Reports are not posted on the internet; however, the accreditation certificates can be found on the PCA's Web site.

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 audits report were in accordance with ISO standards. No concerns were identified.

FSIS concludes that GVI continues to meet the core equivalence requirements for this component, but needs to address issues identified with *Salmonella* sample size and the lack of training government inspectors need for verification of canning regulatory requirements at the TPCS establishments.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on September 27, 2017, in Warsaw, Poland with GVI. The FSIS auditors presented the preliminary findings from the audit.

This audit did not identify any concerns that represented an immediate threat to public health. However, the FSIS auditors identified the following findings.

Government Oversight

- The 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 of 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 enforcement of SPS requirements were identified in five of the nine establishments and SSOP 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 Points (HACCP) System

- Deficiencies related to 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 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.

An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. During the audit exit meeting, the GVI committed to begin addressing the preliminary findings as presented. FSIS will evaluate the adequacy of the GVI's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Zaklady Miesne LMeat Lukow S.A. 21-400 Lukow ul. Przemyslowa 15	09/20/2017	06 11 02 66	Poland
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	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.	X	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	X
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. Enforcement	X
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	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58. Thermally Processed, Commercially Sterile (9 CFR 318.300)	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

10/46/51 The FSIS auditor identified the foreshanks from multiple hog carcasses dragging across the boots and faceplate of the trim stand the employees were standing on, thereby contaminating the product. The boots and faceplate are not cleaned and sanitized between carcasses. The establishment's SSOP failed to prevent direct product contamination. The Official Veterinarian (OV) immediately instructed the establishment to implement corrective measures.

58/51 Poland has adopted 9 Code of Federal Regulations (CFR), Part 318, Subpart G—Canning and Canned Products in its entirety for thermally processed, commercially sterile products. The FSIS auditor identified the following:

- The establishment lacked supporting documentation from a processing authority recommending the process schedules
- The process schedules used by the establishment included fill weight of each can. During operations (not for US export), an establishment employee was observed to randomly check fill weight from 3 cans but no record of the weight measurement was recorded.
- Records and procedures for the teardown examination of container integrity did not include examination of the canner's end. Records documenting teardown examinations did not include the time of closing machine operations nor the time of the teardown examination.
- The establishment could not provide supporting documentation that the employee conducting teardown examinations was directly supervised by a person who has successfully completed a school of instruction generally recognized as adequate for training supervisors of canning operations (§ 318.310).

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

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Pini Polska Sp. zo.o ul Intermodalna 8 99-300 Kutno	09/22/2017	10 02 40 02	Poland
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
16. Records documenting implementation and monitoring of the HACCP plan.	X
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.	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.	
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	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

15/51 The establishment's HACCP Plan for CCP 3, cooking, did not define a procedure or frequency for calibration of process monitoring instruments.

16/51 The establishment's control point for RTE product chilling lacks a defined time parameter and therefore does not establish the time/temperature limits to be achieved. The records documenting the chilling control point include internal product temperature records but do not include the time the products were monitored. The establishment has failed to support a decision in the hazard analysis that hazards associated with product chilling (e.g., Clostridium species toxin formation) is not reasonably likely to occur based on the design of the control point.

19/51 The establishment is not conducting ongoing verification procedures for direct observation of monitoring and review of records at the frequency specified in the HACCP plan for CCP 3, Cooking.

At the time of the audit, no product intended for the U.S. was being produced. The government inspection immediate actions included intent to notify the establishment and suspend issuance of export certificates until such time as the corrective actions were analyzed and determined adequate.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/22/2017

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Sokolow S.A. Oddzial w Jaroslawiu 37-500 Jaroslaw ul. Przemyslowa 2	09/14/2017	18 04 02 01	Poland
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP	X	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.	X	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	X
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	X
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. Enforcement	X
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	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis	X	56. European Community Directives	X
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

7/51 The establishment lacks a sufficiently detailed written sanitation program and facilities to ensure that sanitary procedures are used to recondition (dropped) product. The establishment has a written program that states product will be trimmed with a knife and no additional details. The establishment has a table and knives dedicated to trimming dropped product. There were two yellow-handled knives and two blue-handled knives. The yellow handles are used before lunch break and blue after. However, there is no means of sanitizing knives during the reconditioning process, no nearby sink or other means for employees to wash and sanitize hands.

10/41/51 The FSIS auditor identified extensive beaded condensation involving ventilation units in multiple locations in a carcass cooler with carcasses on rails directly beneath the condensation. The Official Veterinarian (OV) informed the plant of the finding. At that time, an establishment employee proceeded to wipe condensation with a squeegee resulting in the beaded condensation falling and directly contaminating carcasses underneath. Subsequently, the OV proceeded to ensure the carcasses were identified and retained pending corrective actions and moved from beneath the ventilation units with condensation. The FSIS auditor also identified beaded and dripping condensation in the slaughter floor, directly over the viscera rail but no direct product contamination was observed. The establishment's written sanitation procedures failed to protect product contamination. Condensation is a repeat finding from the previous audit indicating that previous corrective actions were ineffective in preventing recurrence.

28/51 The establishment is using m/M criteria to assess generic *E. coli* results. The m/M criteria in 9 CFR 310.25, adopted by GVI, are designed to be used with excision samples. As the establishment is using carcass sponges, results should be evaluated using statistical process control and defined upper control limits.

42/51 The FSIS auditor identified water dripping from the drain line of a ventilation unit in the ready-to-eat (RTE) cooling room where post-lethality exposed (PLE) RTE products are stored on racks prior to packaging. The establishment had an employee in the location with a squeegee to wipe condensation but neither the OV nor establishment had identified the dripping pipe with about two drips per minute and a wet area of flooring beneath. This location was directly in line with the doorway for which racks are wheeled into the packaging room and creating the potential for direct product contamination. In response, immediate corrective actions including the establishment rejecting the area to preclude use pending repair. No direct product contamination was noted.

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
Prime Food Sp. z.o.o. 77-320 Przechlewo ul. Mlynska 43B	09/15/2017	22 03 02 07	Poland
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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	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	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

.

41/51 Dripping condensation was observed in multiple carcass chilling rooms. At the time of observation only one of the chillers was in use for carcass chilling, and the other rooms were ready to receive carcasses for chilling during the production. The inspector rejected all the chilling rooms with condensation problem and required immediate corrective actions. In the chiller that had carcasses stored, product no direct product contamination was observed.

28/51 The establishment did not use correct criteria for the evaluation of its generic *E. coli* test results. The establishment was using swabbing method to sample swine carcass, however, to evaluate results it utilized m/M criteria instead of employing statistical process control techniques required with sponging sampling method. The m/M criteria are used if the sampling is utilized excision method.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/15/2017

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Animex Foods 19-300 Elk Oddzial w Starachowicach ul. Krancowa 4	09/18/2017	26 11 02 01	Poland
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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	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.	X	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.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
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	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58. Official RTE Sampling Methodology	X
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

19/51 The establishment's HACCP Plans for CCP 4 and CCP5 included a specific frequency for the ongoing verification activities for direct observation of monitoring and review of records. However, the establishment is not conducting the verification activities at the frequency identified in the plan.

22/51 Documented corrective actions in response to a deviation from a critical limit for CCP 5, cooling, failed to address all the elements of 9 CFR 417.3(a) including elimination of the cause of the deviation, bringing the CCP under control, and measures to prevent recurrence. The establishment did address and document assessment of product safety and product disposition.

58/51 The official ready-to-eat (RTE) product sampling methodology and analysis is not consistent with the methodology determined equivalent by FSIS. For an official RTE sample of product produced at this establishment, the official veterinarian (OV) collected a minimum 65-gram sample from each of five RTE hams. The official laboratory combined the five analytical portions for one 325-gram analytical result for the five hams. The FSIS approved methodology for ISO 6579 specified analysis of five (5) 65-gram samples should be conducted for each sampled product to achieve equivalence with the FSIS methodology for analysis of 325-grams per sample.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/18/2017

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Animex Foods 14-100 Ostroda Morliny 15	09/13/2017	28 15 40 03	Poland
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	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	X
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. Enforcement	X
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	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

45/51 In the raw material receiving room and other production areas several of the plastic totes used to store raw meat were cracked at different places with jagged and rough surfaces. Some of these totes which were stacked in layers appeared uncleaned and unwashed as they had collected dirt or debris on their outer and hard to clean surfaces. The product stored in totes were potentially exposed to contamination, especially, when plastic liners sheathing the product are ripped due to handling or other activities requiring movement of totes.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/13/2017

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Sokolow S.A. Oddzial Kole 62-600 Kolo ul. Torunska 262	09/25/2017	30 09 02 01	Poland
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
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	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	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

41/51 In the sausage drying room the overhead pipes over the passage used for product movement had collected beaded condensation, which could potentially contaminate product during product movement. The inspector retained the room and required an immediate corrective action from the establishment.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/25/2017

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Sokolow SA Oddzial w Robakowie 62-023 Gadki Robakowo ul. Poznanska 14	09/20/2017	30 21 02 25	Poland
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	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	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
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. Enforcement	
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	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

45/51 Multiple cracked and broken plastic containers used to store raw material was observed in the processing room. Establishment management removed cracked and broken containers.

46/51 In the offal harvesting room containers to store edible offal were placed directly underneath the metal grid platform for employee to collect edible product. Non-edible trims and liquid waste was observed dripping into these containers. The product was rejected by the inspection personnel. Similar offal harvesting practice were also observed in the in the evisceration room. The inspector rejected the product and requested immediate action from the establishment.

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

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Animex Foods 70-812 Szczecin ul. Pomorska 115b	09/19/2017	32 62 02 01	Poland
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X
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	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	X
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

15/51 In the HACCP plan for the cooked ham; the establishment controls its microbiological hazards to eliminate pathogens through a CCP by heating product to a finite temperature. However, the critical limits in the HACCP plan did not include the duration at which the critical temperature must be maintained. The CCP monitoring records reviewed revealed that establishment does document both time and temperature.

39/51 Rust, flaking paint and heavy buildup of grease was observed on carcass rail in the boning room. Although no carcass contamination was observed, there was imminent potential for product contamination from grease falling on the carcasses.

46/51 In the evisceration room containers to collect edible offal and fat were placed directly under the evisceration line and non-edible trim waste and fluid was observed dripping into these containers, resulting in direct contamination of edible product. The inspection personnel rejected the product

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	09/19/2017

Appendix B: Foreign Country Response to Draft Final Audit Report

Warsaw, 19 March 2018

VETERINARY INSPECTION

CHIEF VETERINARY OFFICER

Dr. Mary Stanley
Acting International Coordination
Executive
Office of International Coordination
Food Safety and Inspection Service
U.S. Department of Agriculture
1400 Independence Ave., S.W.
Washington, DC 20250-3700
Mary.Stanley@fsis.usda.gov

Our ref. no: GIWue.0800-130/2018

Issue ref. no: – Letter of: 17 January 2018

Dear Dr. Stanley,

In reference to your letter of 17 January 2018, regarding the draft final report of an audit conducted in Poland on 11-27 September 2017 evaluating the food safety systems governing meat exported to the United States of America, I would like to provide you with the corrective actions undertaken by the General Veterinary Inspectorate in relation to non-compliances identified by FSIS auditors during the audit and presented in the draft final report.

Additionally, I would like to inform you that documents confirming undertaking corrective actions in response to Appendix A: *"Individual Foreign Establishment Audit Checklist"* are still being translated by the General Veterinary Inspectorate. Therefore, they will be provided by 27 March 2018.

We apologize for inconvenience.

Please accept my highest consideration.

Yours sincerely,

CHIEF VETERINARY OFFICER

Paweł Niemczuk

Attachments:

Corrective actions undertaken by the General Veterinary Inspectorate in relation to non-compliances identified by FSIS auditors during the audit conducted in Poland 11-27 September 2017

Corrective actions of Central Competent Authority in relations to non-compliances included in the draft final report of an audit conducted in Poland on 11-27 September 2017 evaluating the food safety systems governing meat exported to the United States of America

The central competent authority (CCA) 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 please find presented the corrective actions that the General Veterinary Inspectorate (CCA) undertook in relation to non-compliances identified by FSIS auditors during the audit and shown in the content of the above-mentioned project report.

1. Non-compliance: *The Central Competent Authority (CCA), the General Veterinary Inspectorate (GVI), has not provided inspection personnel with the specialized training on canning and canned products requirements in accordance with the GVI issued "Requirements for establishments approved to export of meat and poultry and their products to the market of the United States".*

In order to solve the above problem, the General Veterinary Inspectorate (GVI) on 7 December 2017, organized a training for local Veterinary Inspection bodies in canning technology, which was carried out by an expert from the University of Life Sciences (SGGW) in Warsaw, dr. Lech Adamczak, employed at the Faculty of Food Sciences, Department of Food Technology in the Department of Meat Technology. Please find attached a presentation of the above training along with a list of participants (**Annex 1** - Polish and English version).

In addition, on 20-21 February 2018 at the headquarters of the General Veterinary Inspectorate a meeting with Regional Food Safety Inspectors was held, at which a presentation on FSIS regulation of canning was presented, prepared by an employee of the General Veterinary Inspectorate, Ms. Ewa Piotrowska, Chief Specialist in the Food Safety Office of Animal Origin. Attached please find a presentation of the above trainings along with a list of participants (**Annex 2** - Polish and English version).

At the same time with reference to the above mentioned non-compliance, the

General Veterinary Inspectorate (GVI) is planning to organize further specialized training for Veterinary Inspection staff on the FSIS requirements in 2018 with the participation of trainers from an American company conducting such trainings. In the programme of such course, the General Veterinary Inspectorate will include the issues related to the production of canned food, in order to further develop knowledge in this area.

2. <u>Non-compliance:</u> *The official RTE product sampling methodology and analysis are not consistent with the FSIS equivalence determination for International Organization for Standardization (ISO) 6579.*

The official RTE product sampling and analysis are not consistent with the methodology determined equivalent by FSIS. For an official RTE sample of product produced at one establishment, the official veterinarian collected a minimum 65-gram sample from each of five RTE hams. The official laboratory combined the five analytical portions for one 325-gram analytical result for the five hams. The FSIS approved methodology for ISO standard 6579 specified that analysis of five 65-gram samples should be conducted for each sampled product to achieve equivalence with the FSIS methodology for analysis of 325-grams per sample.

In order to eliminate the above irregularities, Chief Veterinary Officer issued and distributed to local authorities of the Veterinary Inspection the letter no. GIWlab 800 - 1/2018 (2) of March 2, 2018 (attached – **Annex 3** - in the Polish and English language versions), in which he recommended that the official sampling of Ready-to-eat (RTE) products towards Salmonella for the US market were as follows:

• The total sample weight from one RTE product (e.g. one ham) should be 325g, which consists of 5 samples of 65g. In accordance with good laboratory practice, it will be appropriate to take a total sample of not less than 400g, consisting of 5 samples of 80g from one RTE product, so that the analytical sample tested in the laboratory had the required 325g;

• If the total weight of one RTE product (e.g. sausage, kabanos) is less than 325g, then a sample should be taken from more than one RTE product, but coming from the same production batch (one boiler) so that the total sample weight it was not less than 400g (e.g. from 3 sausages with 150 g).

3. <u>Non-compliance:</u> *Two establishments are 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.*

In order to eliminate the above irregularities Chief Veterinary Officer issued and distributed to local authorities of the Veterinary Inspection the letter no. GIWbż-52-295/2017(17) US of 6 March 2018 with two attachments (attached – **Annex 4** - in the Polish and English language versions).

4. <u>Non-compliance:</u> *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. While the CCA maintains many of the administrative and technical elements to operate its inspection system, the use of contracted employees to conduct ante-mortem inspection, final carcass dispositions during post-mortem inspection, and sanitation and HACCP verification activities during periods when establishments are producing products for the United States does not meet FSIS' statutory requirements that these activities be conducted by a government inspector. Furthermore, FSIS does not consider the current level of oversight provided is sufficient, as it is expected that these contracted employees be under the supervision of a government veterinarian that is physically present in the establishment whenever slaughter of livestock for use in processed product intended for export to the United States occurs.*

Due to the fact that it is not possible to replace all appointed official veterinarians with inspectors employed by the DVI, the Polish side would like to ask FSIS to accept a solution whereby appointed official veterinarians (who are not employees of the DVI) will perform their duties under the supervision of full-time working inspectors from the DVI.

At the same time, bearing in mind that in accordance with the requirements of the USA, verification activities (e.g. as part of sanitation and HACCP procedures) must be conducted daily (the so-called "daily inspection"), regardless of whether the establishments carry out production of meat or products in a given period intended for shipment to the US or not, such a district inspector will perform his activities on a continuous (daily) basis at the plant during each production shift.

Simultaneously, at present the General Veterinary Inspectorate is taking actions in order to eliminate this irregularity (i.e. by increasing the number of posts in the DVI

to supervise the establishments exporting to the USA), but these are long-term actions.

In connection with the above, until the above-mentioned systemic problem is solved, Chief Veterinary Officer provided the local Veterinary Inspection authorities with the letter no: GIWbż-52-295 / 2017 (20) US of 15 March 2018, along with the attachment (attached - **Appendix 5** - in the Polish and English language versions), in which he recommended that in establishments approved for export to the USA market district veterinary officers, while carrying out monthly inspections documented by means of the FSIS 5000.6 form, carried out additional verifications regarding the correctness of performing official activities by selected designated persons. Verification of the performance of official activities by designated veterinarians should be carried out once a month by the district veterinary officer or an authorized person, employed in the DVI and must relate to their compliance with the US legislation, taking into account the scope of activities for a designated person. At the same time, during the calendar year verification should cover all official veterinarians appointed to carry out permanent supervision in a given establishment with export authorization to the US market (Note: the above verification cannot be carried out on one day and cover all persons designated in the establishment, but must be evenly planned with separation for individuals throughout the year).

However, at the time of increasing the number of posts in the DVI for supervision over plants exporting to the US, the above verification of official activities performed by designated veterinarians will be performed daily by district inspectors posted by the District Veterinary Officer permanently to the plant, about which FSIS will be informed in a separate correspondence.

At the same time, as regards the remaining non-compliances identified by FSIS auditors during the audit and shown in the content of the above-mentioned draft report and in the "Appendix A: Individual Foreign Establishment Audit Checklist", the Chief Veterinary Officer in accordance with the information obtained from FSIS at the closing meeting of the audit on 27 September 2017, provided the local authorities of the Veterinary Inspection with the letter no. GIWbż-52 -295/2017 (14) dated 13 December 2017 (attached - **Annex 6** - in the Polish and English language versions).

According to the above letter and the draft FSIS report received in 2018, local authorities of the Veterinary Inspection have implemented a number of corrective actions to date regarding the irregularities detected in the field of food safety systems. Due to the fact that the documentation of the actions taken is still completed at the central level and needs to be supplemented, and some of it, is being translated into English, the Polish side is forced to submit the concerned documents to FSIS at a later date, i.e. until **March 27, 2018** in a separate correspondence.

We apologize in advance for the inconvenience.

Warsaw, 18 March 2018

VETERINARY INSPECTION

CHIEF VETERINARY OFFICER

Dr. Mary Stanley
Acting International Coordination
Executive
Office of International Coordination
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Our ref. no: GIWue.0800-130/2018 (2) US

Issue ref. no: GIWue.0800-130/2018 Letter of: 19 March 2018

Dear Dr. Stanley,

Having regard to me previous letter concerning the corrective actions undertaken by local veterinary inspection bodies and establishments in relation to non-compliances identified by FSIS auditors during the audit and presented in the draft final report, I would like to hereby provide you with documents confirming undertaking corrective actions in response to Appendix A: *"Individual Foreign Establishment Audit Checklist"*.

Please accept my highest consideration.

Yours sincerely,

CHIEF VETERINARY OFFICER
Paweł Niemczuk

Attachment:
Information on corrective action taken by the local veterinary inspection bodies and establishments against the non-compliances listed in "annex a" to the FSIS audit report conducted in Poland on 11-27 September 2017

INFORMATION ON CORRECTIVE ACTION TAKEN BY THE LOCAL VETERINARY INSPECTION BODIES AND ESTABLISHMENTS AGAINST THE NON-COMPLIANCES LISTED IN "ANNEX A" TO THE FSIS AUDIT REPORT CONDUCTED IN POLAND ON 11-27 SEPTEMBER 2017

The General Veterinary Inspectorate (CCA) provides a brief description of the corrective and preventive actions taken by the local Veterinary Inspectorate and establishments against the non-compliances listed in Annex A to the FSIS audit report conducted in Poland on 11-27 September 2017. More detailed information on the above activities are included in an annex to this document called "**Attachment - corrective actions (local Veterinary Inspection and establishments)".** This appendix contains the folders assigned names for individual establishments subjected to the FSIS audit in 2017. The documentation contained in individual folders, for example letters from the regional and district level, is available in the English version, as well as the vast majority of documentation constituting attachments to these letters. The above is intended to help FSIS analyze the corrective actions taken by the Polish side.

1. ANIMEX FOODS Oddział w Morlinach, 14-100 Ostróda, Morliny 15 (No. 28 15 40 03)

Non-compliances: In the raw material receiving room and other production areas several of the plastic totes used to store raw meat were cracked at different places with jagged and rough surfaces. Some of these totes which were stacked in layers appeared uncleaned and unwashed as they had collected dirt or debris on their outer and hard to clean surfaces. The product stored in totes were potentially exposed to contamination, especially, when plastic liners sheathing the product are ripped due to handling or other activities requiring movement of totes.

Corrective action

On 13/09/2017, due to non-compliances found during the FSIS audit, the Regional Inspector for Food Safety prepared the inspection report no. 8/2017. District Veterinary Officer in Ostróda on 13/09/2017 based on the above protocol issued a record of non-compliance NR 14/2017. On 19.09.2017, the DVO in Ostróda

checked the corrective actions taken by the establishment, which was documented by the inspection protocol No. 09/2017.

As a result of the inspection, it was determined that all activities undertaken by the establishment were carried out and damaged containers or damage to the foil protecting the meat raw material were not found in the premises for receiving meat raw materials nor in the production premises.

At the same time, due to non-compliances found during the audit, the DVO in Ostróda took special care of the raw meat receiving zone. The official veterinarian controls equipment and devices once a week in the meat reception area with special regard to the technical and sanitary condition as well as the security of containers arriving at the establishment with meat and the results are documented in form 5000.1-6 - Weekly verification list in the establishment.

In the period from 01/10/2017 - 30/01/2018 no damaged meat containers were found in the raw material receiving room and production areas, which was confirmed during the inspection:

a. of DVO in Ostróda carried out on 30/11/2017, 20/12/2017, 25/01/2018 and 20/02/2018, documented by inspection protocols No. 11/2017, 12/2017, 1/2018 and 2/2018,

b. of Regional Inspector for Food Safety on 30/01/2018 and 27/02/2018 during which it was found that the establishment, among others, controls all consignments in terms of technical and sanitary quality of containers and that damaged containers are marked and withdrawn from use, and unsuccessfully washed directed to repeated washing.

By letter of 12 March 2018, the sign: WIW-BZ.923.64.2018 Warmińsko-Mazurski Regional Veterinary Officer informed that the assessment of the effects of corrective actions taken by the plant and official activities implemented by the DVO confirmed that the threat was overcome and the veterinary conditions were restored defined by the requirements of food law and American law.

Note: A detailed description of the above corrective actions taken in this area has been included in the folder named "**Animex Ostróda**": **Annex 1** - control protocols (in Polish and English language version), **Annex 2** - Letter of DVO 26/02/2018, **Annex 3** - Letter of the establishment, **Letter of RVO 12.03.2018,** signature: WIW-BŻ.923.6.4.2018.

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

Non-compliances:

1.Dripping condensation was observed in multiple carcass chilling rooms. At the time of observation only one of the chillers was in use for carcass chilling, and the other rooms were ready to receive carcasses for chilling during the production. The inspector rejected all the chilling rooms with condensation problem and required immediate corrective actions. In the chiller that had carcasses stored, product no direct product contamination was observed.

2.The establishment did not use correct criteria for the evaluation of its generic E. coli test results. The establishment was using swabbing method to sample swine carcass, however, to evaluate results it utilized m/M criteria instead of employing statistical process control techniques required with sponging sampling method. The m/M criteria are used if the sampling is utilized excision method.

Corrective action

By letter of 22/03/2018, the sign: WIWbż-920-5/ 2017 (7) Pomorski Regional Veterinary Officer (the above letter is attached in the folder named: "PRIME FOOD") informed that the effects of corrective actions taken by the DVO in Człuchów and by the establishment in relation to the non-compliance described in item 1 above indicate that the threat has been properly controlled and the veterinary conditions defined by the EU and US requirements have been restored. The evaporator was repaired and the cold room was drained and the employees responsible for the refrigeration system were instructed so that the defrost would be carried out after emptying the cold store. In addition, the checks were intensified in the cold stores by the employees of the quality control department.

However, in relation to non-compliance described in point 2 above, the current procedure and the current plant records from monitoring results confirm the correct interpretation of the assessment criteria.

The corrective actions taken from the PLW in Człuchów and the plant are described in detail in English in the letter mark: PIW 03.9111.40.2018 of 21/03/2018 with the attachments - see the folder named "PRIME FOOD".

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

Non-compliances:

1. In the HACCP plan for the cooked ham; the establishment controls its microbiological hazards to eliminate pathogens through a CCP by heating product to

a finite temperature. However, the critical limits in the HACCP plan did not include the duration at which the critical temperature must be maintained. The CCP monitoring records reviewed revealed that establishment does document both time and temperature.
2. Rust, flaking paint and heavy buildup of grease was observed on carcass rail in the boning room. Although no carcass contamination was observed, there was imminent potential for product contamination from grease falling on the carcasses.
3. In the evisceration room containers to collect edible offal and fat were placed directly under the evisceration line and non-edible trim waste and fluid was observed dripping into these containers, resulting in direct contamination of edible product. The inspection personnel rejected the product.

Corrective action

RVO and DVO in Szczecin by letters: WIW.HŻ.923.2.3 (2) 2018 of 22/03/2018 and the sign: PIW.HŻ.911.08.2018 of 20/03/2018 (see attachment in the folder named: "Animex Szczecin") reported as follows:
1. Until 20/02/2018, the establishment has verified the critical limit set in the CCP4 monitoring and verification procedure "Pasteurisation of preserves". The new version of the monitoring and verification procedure of CCP 4 "Pasteurisation of preserves" takes into account the temperature and time in which the product must be kept at critical temperature The new procedure is valid from 05/03/2018.

2. The document was issued, the record of non-compliance No. 6 / 2017. Immediately after finding nonconformities on 19.09.2017, the excess of grease, peeling paint and rust on the slides over the conveyor belt were removed. Washing was carried out and disinfection of the conveyor belt. On 19/09/2017, the plant trained employees of the Maintenance Department in the field of "Cleaning instructions and maintenance of "KS / PR2 / IN3" pipe and transport chains. On 19.09.2017, on the third shift, the process of cleaning and maintenance of the slides in the Pork cutting department supervised by the Master of Maintenance was carried out. The actions taken by the establishment have been verified by the Official Veterinary Surgeons supervising the establishment. No irregularities were found in this regard.

3. A document stating the non-compliance was issued No. 7 / 2017. Immediately after finding non-compliance, the container with fat in the amount

of 165 kg and with the diaphragm in the amount of 30 kg were withdrawn from production. The meat raw material in quantities as above was transferred to the animal by-products Warehouse as a category III material. On 19.09.2017 the plant trained employees managing the pork slaughter area in the scope of: GMP and GHP rules in force during production with particular regard to the proper treatment of the raw material, rules for setting production containers while maintaining a safe distance from the landings to minimize the risk of contamination of the produced raw material. On 20.09.2017, fenders were mounted at the platforms protecting the containers against their incorrect positioning. The actions taken by the establishment have been verified by the Official Veterinarians supervising the establishment. No irregularities were found in this regard.

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

Non-compliances:

1. Multiple cracked and broken plastic containers used to store raw material was observed in the processing room. Establishment management removed cracked and broken containers.
2. In the offal harvesting room containers to store edible offal were placed directly underneath the metal grid platform for employee to collect edible product. Non-edible trims and liquid waste was observed dripping into these containers. The product was rejected by the inspection personnel. Similar offal harvesting practice were also observed in the in the evisceration room. The inspector rejected the product and requested immediate action from the establishment.

Corrective action

According to the letter from the Wielkopolski Regional Veterinary Officer from 22/03/2018, mark: BŻ.923.318.2017 US. (see attached in the folder named: "**Sokołów Robakowo**"):

1. The plant took corrective action, namely all damaged containers were removed from the production rooms, the palbox zone was isolated by means of a metal screen and marked with a yellow sign saying: for withdrawal/rendering. Intervention training was conducted for the staff responsible for visual inspection of the containers and their further transfer for disposal.

The above-mentioned non-compliances were identified and recorded by the official veterinarian supervising compliance with US requirements in the plant

on 20 September 2017. In the report drawn up by the the official veterinarian there are also records of the corrective actions taken by the plant's operator.
2. The plant has taken corrective action as regards the raw material (disposal). Raw material storing containers that were placed too close to the slaughter line have been withdrawn and sent for cleaning. The employee was trained on the applicable GHP rules and the containers were placed in a designated place.
The above-mentioned non-compliances were recorded by the official veterinarian supervising compliance with US requirements in the plant on 20 September 2017. In the report drawn up by the the official veterinarian there are also records of the corrective actions taken by the plant's operator.
The inspection by the official veterinarian on 21 September 2017 showed no inconsistencies in this respect. The weekly check at the plant (weekly checklist at the plant - form 5000.1-6) also included a check of the technical condition of the plant and its equipment.
During the next inspection in the plant carried out by the District Veterinary Officer in Poznań on 17 October 2017, no non-compliances were found in the areas indicated in the FSIS audit report. At each subsequent monthly check for the plant's compliance with the requirements for export to the US market, the following criteria are verified: technical condition of the plant, technical condition of equipment (including containers and their presence in designated places).
In addition, a retraining of official veterinary officers was carried out on 26 February 2018 on the following subject: The regulations, procedures and operation of the SSOP system and their enforcement in red meat processing plants in accordance with US requirements. Establishment of the NR Protocol.
The actions above were also checked by inspectors of the Regional Veterinary Inspectorate in Poznań during monthly inspections which are documented in the report no 5000.6. The checks confirmed that the risk has been contained and that the veterinary conditions laid down by the requirements of both EU and US legislation have been restored.

Note: Detailed information about the activities of the District Veterinary Officer in Poznań are included in the folder named: "**Sokołów Robakowo**": see the letter from the District Veterinary Officer in Poznań of March 21, 2018, mark: BŻ.501.16.2018 with attachments.

5. „SOKOŁÓW" S.A. Oddział w Kole, 62-600 Koło, ul. Toruńska 262 (No. 30 09 02 01)

Non-compliances:

In the sausage drying room the overhead pipes over the passage used for product movement had collected beaded condensation, which could potentially contaminate product during product movement. The inspector retained the room and required an immediate corrective action from the establishment.

Corrective action

According to the letter by the Wielkopolski Regional Veterinary Officer of 22/03/2018, mark: BŻ.923.318.2017 US. (see attached in the folder named: "**Sokołów Koło**"), during the audit at the plant, the auditor carried out observations of the activities taken by the official veterinarian who carried out an intraoperative control of the establishment's compliance with specific US requirements.

On 21 September 2017, having found the irregularities above, the official veterinarian took immediate action to remove non-conformities, secure the goods and assure compliance with veterinary requirements. The veterinarian issued instructions to employees of the plant to immediately isolate 2 trolleys with cold meats in the vicinity and mark them as a non-compliant product, which was done by the staff, and informed the plant's director about the irregularities.

On 22 September 2017 the official veterinarian carried out a control to check whether non-conformities found the previous day were addressed. He confirmed that actions had been taken by the establishment to immediately mark the non-compliant goods and remove them from the room, to report the problem to the company responsible for repairing technical failures at the plant, to impound the product by the Quality Assurance Department and to transfer it to undergo additional thermal treatment. Staff responsible for the technical condition of production equipment were properly instructed and the employees' attention was drawn to the technical condition of production halls. It was also recommended that aggregates in the maturing chambers be checked.

On 26 September 2017 the official veterinarian carried out a re-verification of the rectification of non-compliance found on 21 September 2017 and concluded that the plant has inspected the aggregates in the maturing chambers and that no condensate was present in the drying and maturing chamber No 14.

The actions above were also checked by inspectors of the Regional Veterinary Inspectorate in Poznań during monthly inspections which are documented in the report no 5000.6. The checks confirmed that the risk has been contained

and that the veterinary conditions laid down by the requirements of both EU and US legislation have been restored.

Note: Detailed information about the activities of the District Veterinary Officer in Koło are included in the folder named: "**Sokołów Koło**": see the letter from the District Veterinary Officer in Koło of March 21, 2018, mark: BŻ.511.6.4.2018 with attachments.

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

Non-compliances:

1. The establishment lacks a sufficiently detailed written sanitation program and facilities to ensure that sanitary procedures are used to recondition (dropped) product. The establishment has a written program that states product will be trimmed with a knife and no additional details. The establishment has a table and knives dedicated to trimming dropped product. There were two yellow-handled knives and two blue-handled knives. The yellow handles are used before lunch break and blue after. However, there is no means of sanitizing knives during the reconditioning process, no nearby sink or other means for employees to wash and sanitize hands.
2. The FSIS auditor identified extensive beaded condensation involving ventilation units in multiple locations in a carcass cooler with carcasses on rails directly beneath the condensation. The Official Veterinarian (OV) informed the plant of the finding. At that time, an establishment employee proceeded to wipe condensation with a squeegee resulting in the beaded condensation falling and directly contaminating carcasses underneath. Subsequently, the OV proceeded to ensure the carcasses were identified and retained pending corrective actions and moved from beneath the ventilation units with condensation. The FSIS auditor also identified beaded and dripping condensation in the slaughter floor, directly over the viscera rail but no direct product contamination was observed. The establishment's written sanitation procedures failed to protect product contamination. Condensation is a repeat finding from the previous audit indicating that previous corrective actions were ineffective in preventing recurrence.
3. The establishment is using m/M criteria to assess generic E. coli results. The m/M criteria in 9 CFR 310.25, adopted by GVI, are designed to be used with excision

samples. As the establishment is using carcass sponges, results should be evaluated using statistical process control and defined upper control limits.

4. The FSIS auditor identified water dripping from the drain line of a ventilation unit in the ready-to-eat (RTE) cooling room where post-lethality exposed (PLE) RTE products are stored on racks prior to packaging. The establishment had an employee in the location with a squeegee to wipe condensation but neither the OV nor establishment had identified the dripping pipe with about two drips per minute and a wet area of flooring beneath. This location was directly in line with the doorway for which racks are wheeled into the packaging room and creating the potential for direct product contamination. In response, immediate corrective actions including the establishment rejecting the area to preclude use pending repair. No direct product contamination was noted.

Corrective action

By the letter of 23/03/2018 signature: WIWhig 923.2.13.2018, the Podkarpacki Regional Veterinary Officer informed that The inspection performed on the 9th of March 2018 by the Inspector at Provincial level proved the removal of all above mentioned incompatibilities. The evaluation of the effects of the corrective actions undertaken by the company and operational tasks implemented by the Regional Veterinary Officer in Jarosław has confirmed that in the establishment ,,SOKOŁÓW" S.A in Jarosław were reintroduced veterinarian conditions defined by the requirements of Food and American laws. With respect to such incompatibilities as improper collection of official samples of ready-to-eat products (RTE) for Salmonelle, according ISO 6579 Standard and as inappropriate evaluation of the carcass results for E.coli due to using M/m criteria, currently are implemented GIW recommendations included in the documents: GIWlab 800 - 1/2018 (2) on the 2nd March 2018 and GIWbż-52-295/2017(17) US on the 6th March 2018.

All attachments in Polish and English are included in the folder named "**Sokołów Jarosław": RVO letter of 23/03/2018**, signature: WIWhig 923.2.13.2018, **Annex 1 -** RVI form 5000-6 dated 9 March 2018 and **Annex 2**- documentation of the District Veterinary Officer in Jarosław - see the DVO letter about the reference number PIW.hig.4031 / II / 35-1 / 2018 of 22/03/2018 describing the administrative actions taken by the DVO and the corrective actions of the plant in **Annex 9**, which specifies that the establishment has verified the procedure for procedure regarding handling meat dropped on the floor, in the case of condensate, installed additional system of drying in a pork half-carcasses cooler and in order to verify

the control processes E. coli applied the recommendations of the General Veterinary Inspectorate.

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

Non-compliances:

1. The establishment's HACCP Plans for CCP 4 and CCP5 included a specific frequency for the ongoing verification activities for direct observation of monitoring and review of records. However, the establishment is not conducting the verification activities at the frequency identified in the plan.
2. Documented corrective actions in response to a deviation from a critical limit for CCP 5, cooling, failed to address all the elements of 9 CFR 417.3(a) including elimination of the cause of the deviation, bringing the CCP under control, and measures to prevent recurrence. The establishment did address and document assessment of product safety and product disposition.
3. The official ready-to-eat (RTE) product sampling methodology and analysis is not consistent with the methodology determined equivalent by FSIS. For an official RTE sample of product produced at this establishment, the official veterinarian (OV) collected a minimum 65-gram sample from each of five RTE hams. The official laboratory combined the five analytical portions for one 325-gram analytical result for the five hams. The FSIS approved methodology for ISO 6579 specified analysis of five (5) 65-gram samples should be conducted for each sampled product to achieve equivalence with the FSIS methodology for analysis of 325-grams per sample.

Corrective action

According to the letter from the Świętokrzyski Regional Veterinary Officer of 22/03/2018, sign: IS.1610.2.2017 (see attached in the folder named "Animex Starachowice"), the leader of the food safety team at the Regional Veterinary Inspectorate in Kielce (RVI) participated in the audit activities in the establishment in Starachowice. After conducting by the District Veterinary Officer in Starachowice of the administrative proceedings towards the establishment, the Regional Veterinary Inspectorate analyzed it, giving a positive opinion concerning the obligations imposed on the establishment.

After that, the analysis was performed of the documentation submitted by the District Veterinary Officer, concerning the corrective actions taken by the establishment

and the documentation of the proceedings of the District Veterinary Officer in supervision. In the opinion of the Regional Veterinary Inspection, the proceedings conducted in the establishment, included in the submitted documentation, was consistent with effective procedures and led to the consistency with FSIS veterinary requirements. This above opinion was confirmed by the documentation of the supervisory activities performed by the District Veterinary Officer.

On 26 February 2018, from the level of the Regional Veterinary Inspectorate, an audit was performed in establishment Animex Foods Starachowice which was documented with an audit report following the form FSIS 500-6. The audit results confirmed the implementation of the changes previously presented in documents and the consistency of the functioning of the plant with veterinary requirements, both EU and FSIS ones. On the basis of the activities listed above, the corrective actions taken by the plant's owner and the supervisory actions taken by the District Veterinary Officer were assessed positively.

At the same time, according to the letter of the DVO in Starachowice of 22 March 2018, the mark: PIW.cz.5200.a.22.2018 with reference to the above non-compliances:

1. The plant performed a review and introduced changes to the HACCP plan for CCP 4 and CCP 5 and in the monitoring procedures of CCP 4 and CCP 5, making them conforming.

2. The plant performed a verification of the Procedure of corrective actions in CCP 5 – cooling pork export hams in the scope of taking corrective actions of irregularities are found.

3. The District Veterinary Officer in Starachowice taking next official samples, will take into account the recommendations of the Chief Veterinary Officer and the manner of sample-taking of RTE products for Salmonella will be changed.

The District Veterinary Officer in Starachowice documented all non-conformities found during the audit on 18.09.2017, preparing control documentation on the forms FSIS 5000-6 and FSIS NR. By the administrative decision No 8A/2017/C of 19 September 2017, it imposed on the plant the obligation to eliminate the non-conformities found. After receipt of the communication from the plant on implementing the corrective actions, he verified them during the inspection on 22.09.2017, documented with the inspection report on the form FSIS 5000-6.

After performing the analysis of the documentation provided by the plant and the results of the inspection, he determined that they are consistent with EU and FSIS veterinary requirements. In particular, the implementation in the plant

of the changed HACCP procedures was found to be effective and correct. In addition, during the inspection on 12.03.2018, the review of documentation was performed from the point of view of execution of verification procedures in all CCP – no irregularities were found.
All attachments have been included in the folder named "**Animex Starachowice**": Letter from RVO dated 22/03/2018, mark: IS.1610.2.2017, a copy of the inspection protocol carried out by RVI - FSIS form 5000-6 dated 26.02. 2018, the cover letter of the DVO in Starachowice, mark PIW.cz.5000.A.22.2018 with attachments and a letter from Zakład Animex Foods in Starachowice with attachments.

8. Zakłady Mięsne „Łmeat-Łuków" S.A., 21-400 Łuków, ul. Przemysłowa 15 (No. 06 11 02 66)

Non-compliances:

1. The FSIS auditor identified the foreshanks from multiple hog carcasses dragging across the boots and faceplate of the trim stand the employees were standing on, thereby contaminating the product. The boots and faceplate are not cleaned and sanitized between carcasses. The establishment's SSOP failed to prevent direct product contamination. The Official Veterinarian (OV) immediately instructed the establishment to implement corrective measures.
2. Poland has adopted 9 Code of Federal Regulations (CFR), Part 318, Subpart G—Canning and Canned Products in its entirety for thermally processed, commercially sterile products. The FSIS auditor identified the following:

• The establishment lacked supporting documentation from a processing authority recommending the process schedules
• The process schedules used by the establishment included fill weight of each can. During operations (not for US export), an establishment employee was observed to randomly check fill weight from 3 cans but no record of the weight measurement was recorded.
• Records and procedures for the teardown examination of container integrity did not include examination of the canner's end. Records documenting teardown examinations did not include the time of closing machine operations nor the time of the teardown examination.
• The establishment could not provide supporting documentation that the employee conducting teardown examinations was directly supervised by a person who has

successfully completed a school of instruction generally recognized as adequate for training supervisors of canning operations (§ 318.310).

Corrective action

Details of corrective actions are described in the English version of the letters: Regional Veterinary Officer in Lublin, mark: BŻ.923.9.7.2018 of 23/03/2018 and DVO in Łuków, mark: PIW.BŻ.4300.2.3.2.2018 of 8/03/2018 (Note: placed in the folder named: "**ZM Łuków**").

The Regional Veterinary Officer in Lublin, confirmed that on the basis of documentation provided by the DVO in Łuków and the inspection carried out on 13/03/2017 by RVI inspectors, corrective actions restored veterinary conditions defined by EU legislation and US requirements. The corrective actions were carried out in the following way (but not only):

1. The training of all employees of the Slaughter Department in the scope of handling carcasses at appropriate positions was carried out in order to prevent contact between carcasses and landings and workers' clothing.
2. On 21/09/2017, the expert team for the production and sterilization of canning was established in the plant, which developed and approved the documentation for each product exported to the USA. In addition, an external training was conducted by a recognized specialist in the field of canning dr. eng. Jerzy Wadzik.
3. In the process harmonograms the control of the weight of the feed was taken into account by controlling the weight of cans with stuffing every 10 containers before closing.
4. In the process harmonograms, the operation time of the closing machine is taken into account by monitoring the closing time of the first can from the boiler to the autoclave stopping max 2 h which is recorded in factory evaluation sheets of the finished product.
5. The employees responsible for the leak testing have been trained in the field of canning requirements in accordance with 9 CFR 318.310.

Note: More detailed information on the corrective actions carried out is contained in the following documents: Provincial Veterinary Officer in Lublin sign: BŻ.923.9.7.2018 of 23/03/2018 and PLW in Łuków sign: PIW.BŻ.4300.2.3.2.2018 dated 8.03 .2018 (Note: placed in the folder named "ZM Łuków").

9. „PINI POLSKA" Sp. z o.o., 99-300 Kutno, ul. Intermodalna 8 (No. 10 02 40 02)

Non-compliances:

1. The establishment's HACCP Plan for CCP 3, cooking, did not define a procedure or frequency for calibration of proces monitoring instruments.
2. The establishment's control point for RTE product chilling lacks a defined time parameter and therefore does not establish the time/temperature limits to be achieved. The records documenting the chilling control point include internal product temperature records but do not include the time the products were monitored. The establishment has failed to support a decision in the hazard analysis that hazards associated with product chilling (e.g., Clostridium species toxin formation) is not reasonably likely to occur based on the design of the control point.
3. The establishment is not conducting ongoing verification procedures for direct observation of monitoring and review of records at the frequency specified in the HACCP plan for CCP 3, Cooking.

   At the time of the audit, no product intended for the U.S. was being produced. The government inspection immediate actions included intent to notify the establishment and suspend issuance of export certificates until such time as the corrective actions were analyzed and determined adequate.

Corrective action

Regional Veterinary Officer in Łódź by the letter letter mark: WIW-BŻ.923.40.6.2017 (4) dated 27 March 2018 (see attached in the folder named "**Pini Polska**") provided inspection reports (Forms 5000-6) carried out in March 2018 from the level of the DVO in Kutno as well as from the level of the RVO in Łódź. These controls were carried out to verify the implementation of remedial actions in relation to the non-compliances identified during the audit of the relevant FSIS services carried out in Poland on 11-28 September 2017.

The audited establishment was Animex Foods K 1 Sp. z o.o., 99-300 Kutno ul. Intermodalna 8, WNI 10024002, which at that time operated under the name Pini Polska Sp. z o.o. Following the non-compliances found, the establishment took immediate corrective action by introducing changes to the CCP monitoring procedure marked as P / HACCP / 01 on 26 September 2017, consisting in:

– establishing a CCP-5 critical control point (cooling) to monitor the time and cooling temperature parameters after the thermal treatment process and the way the verification is carried out,

- developing a calibration procedure for process monitoring instruments.

In connection with the change of the owner of the establishment and change of name on November 27, 2017, the above-mentioned CCP monitoring procedure, marked ANX-K1-P / HACCP / 01 (**Annex 1**) was updated.

The establishment implements verification procedures on a current basis based on direct observation, review of records from monitoring and review of records from calibration of control and measurement equipment.

In connection with the undertaking immediate remedial actions aimed at eliminating non-compliances found during the inspection of appropriate FSIS services, the DVO in Kutno was analyzing the situation on an ongoing basis and in his opinion there was no need to suspend issuing export certificates.

Based on the analysis of updated documentation and current records, it was found that Animex Foods K 1 took corrective action to remedy the non-compliances found during the FSIS service audit as confirmed by the records in the system documentation and monitoring and verification sheets CCP 3 and CCP 5 (**Annex 2**).

The undertaking of corrective actions was confirmed during the inspection carried out from the level of the DVO in Kutno documented on Forms 5000-6. (**Annex 3**- DVO Form 5000-6 of March 13, 2018). The implementation of corrective actions of non-compliances found during the audit of the relevant FSIS services was additionally confirmed on March 14, 2018 during the inspection at the level of the RVO in Łódź (**Annex 4** - Form 5000-6 of 14 March 2018).