United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

MAR 0 5 2010

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

Dear Dr. Zwiazek:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Poland's meat inspection system September 16 to October 9, 2009. Comments received from the government of Poland have been included as an attachment to the final report. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 205-3969, by facsimile at (202) 720-0676, or electronic mail at james.adams5@fsis.usda.gov.

Sincerely,

for Manzoor H Chaudry
James Adams, DVM
Director
International Audit Staff
Office of International Affairs

Enclosure

cc:

CC: List for Letters

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Country File

FSIS:OIA:IAS:J Adams:202-690-5646:Final Report Letter-Poland [FY2009]:03-01-2010

FINAL REPORT OF AN AUDIT CARRIED OUT IN POLAND COVERING POLAND'S MEAT INSPECTION SYSTEM

SEPTEMBER 16 THROUGH OCTOBER 9, 2009

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority [General Veterinary Inspectorate]
CVO	Chief Veterinary Officer
DCVO	Deputy Chief Veterinary Officer
DVI	District Veterinary Inspectorate
DVO	District Veterinary Officer
E. coli	*Escherichia coli*
FSIS	Food Safety and Inspection Service
GVI	General Veterinary Inspectorate
HFA	Hygiene of Foodstuffs of Animals
MARD	Ministry of Agriculture and Rural Development
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
PVI	Provincial Veterinary Inspectorate
PVO	Provincial Veterinary Officer
SSOPs	Sanitation Standard Operating Procedures
Salmonella	*Salmonella* species
VEA	European Community/United States Veterinary Equivalence Agreement
VI	Veterinary Inspector

1. SUMMARY

1.1 Description/Eligibility

This report summarizes the outcome of the audit conducted in Poland from September 16 through October 09, 2009. This was a routine audit with special emphases on humane handling and slaughter of livestock, microbiological testing programs, and corrective actions taken in response to non-compliances identified during the previous audit. Poland is eligible to export red meat, red meat products to the United States. Between January 1 and August 31, 2009, Poland exported 13,270,669 pounds of meat products to the United States, of which 2,185,208 pounds were re-inspected at US ports of entry (POE). A total of 3,766 pounds were rejected at POE, of which no rejections were for food-safety concerns. The activities of the current audit appear in the table below.

The findings of the previous audit during June/July 2008 resulted in no restrictions of the ability of any establishment in Poland to export meat products to United States.

1.2 Comparison of the Current Audit and the Previous Audit

		09/16-10/09, 2009	06/04-07/03, 2008
Levels of Government Oversight Audited			
	Headquarters	1	1
	Establishment Level	5	9
Laboratories Audited			
	Microbiology	2	1
	Residue	0	1
Establishments Audited			
	Slaughter/processing	4	6
	Processing	1	3
	ID Warehouses	0	0
Enforcement Actions Initiated			
	NOID	0	0
	Delistment	0	0
Risk Area Findings		(5 Ests. audited)	(9 Ests. audited)
	Sanitation Controls (SSOP, SPS)	6	17
	Animal Disease Controls	0	0
	Slaughter/Processing (PR/HACCP)	1	2
	Humane Handling and Slaughter	0	0
	Residue Controls	0	0
	Microbiology Controls	1	1
	Inspection/Enforcement Controls	3	7

1.3 Summary Comments for the Current Audit

The results of this audit raised serious concerns regarding inadequate enforcement of Food Safety Inspection System (FSIS) regulations pertinent to Sanitation Standard Operating Procedures (SSOP) in three of five establishments. In two of five establishments audited

Sanitation Performance Standards (SPS) non-compliances and inadequate enforcements of European Union (EU) requirements were observed.

2. INTRODUCTION

The audit took place in Poland from September 16, through October 9, 2009.

An entrance meeting was held on September 16, 2009, in Warsaw, with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit and the auditor's itinerary, and requested additional information needed to complete the audit of Poland's meat inspection system.

The auditor was accompanied during the entire audit by either representatives from the CCA (the General Veterinary Inspectorate), or representatives from the provincial and/or district inspection offices.

3. OBJECTIVE OF THE AUDIT

This was a routine audit with special emphases on humane handling and slaughter of livestock, microbiological testing programs, and corrective actions taken in response to non-compliances identified during the previous audit. The objective of the audit was to evaluate the performance of the CCA with respect to controls over establishments certified by the CCA as eligible to export meat products to the United States.

In pursuit of the objective, the following sites were visited: The headquarters of the CCA, two provincial inspection offices, two district offices, two laboratories conducting microbiological testing on US-destined product, four slaughter-and-processing establishments, and one meat-processing establishment.

Competent Authority Visits			Comments
Competent Authority	Central	1	GVI in Warsaw
	Provincial Veterinary Offices	2	Kielce Szczecin
	District Veterinary Offices	2	Starachowice Szczecin
Laboratories	National Reference Laboratory	2	Microbiology Laboratory in Puławy
	Provincial Microbiological Laboratory		Provincial Veterinary Hygiene Laboratory at Kielce
Meat Slaughter and Processing Establishments		4	
Meat Processing Establishments		1	

4. PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection headquarters, provincial, and district offices. The third part involved on-site visits to five establishments: Four slaughter/processing establishments and one processing establishments. The fourth part included visits to The National Veterinary Research Institute (NVRI) and the Veterinary Hygiene Laboratory at Kielce. Both laboratories were audited for their functions related to microbiological testing. While NVRI performs numerous functions, those related to FSIS requirements include the analyses of field samples for Poland's national residue control program, some microbiological testing for generic *Escherichia coli (E. coli), Salmonella* species *(Salmonella)* and *Listeria monocytogenes,* and oversight of the other government laboratories conducting similar microbiological testing throughout Poland's sixteen provinces.

Program effectiveness determinations of Poland's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of SSOPs, (2) animal disease controls, (3) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) programs and a testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including a testing program for *Salmonella*. Poland's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditor also assessed how inspection services are carried out by Poland, and determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated, and properly labeled.

At the entrance meeting, the auditor explained to the CCA that their inspection system would be audited in accordance with three areas of focus. First, under provisions of the European Community/United States Veterinary Equivalence Agreement (VEA), the auditor would audit Poland's meat inspection system against European Community (EC) Directive 64/433 of June 1964; EC Directive 96/22 of April 1996; and EC Directive 96/23 of April 1996. These directives have been declared equivalent by FSIS under the VEA.

Second, in areas not covered by these directives, the auditor would audit against FSIS requirements. FSIS requirements include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification, requirements for HACCP programs, SSOPs, testing for generic *E. coli* and *Salmonella*, and government oversight/enforcement.

Third, the auditor would audit against any equivalence determinations that have been made by FSIS for Poland under provisions of the Sanitary and Phytosanitary Agreement. Currently, FSIS has determined that one alternate procedure is equivalent to U.S. requirements:

- The use of *Enterobacteriaceae* and total viable count (TVC) in lieu of generic *E. coli* is acceptable for all European Union exporting countries. However, none of the establishments audited used this equivalence determination; all continued to rely on generic *E. coli* as an indicator of process control.

5. LEGAL BASIS FOR THE AUDIT

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

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP and SSOP regulations.

In addition, compliance with the following European Community Directives was also assessed:

- Council Directive 64/433/EEC of June 1964 entitled Health Problems Affecting Intra-Community Trade in Fresh Meat
- Council Directive 96/23/EC of 29 April 1996 entitled Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products
- Council Directive 96/22/EC of 29 April 1996 entitled Prohibition on the Use in Stockfarming of Certain Substances Having a Hormonal or Thyrostatic Action and of B-agonists

6. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at the following address:
http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp

The following non-compliances were identified during the FSIS audit that was conducted in March 2007:

- In one establishment, unidentified residue was seen on several rods on which sausages were to be hung.
- In one establishment, rail grease was observed on a swine carcass.
- In one establishment, condensation was observed on overhead structures in the product-chilling room.

The following non-compliances were identified during the FSIS audit that was conducted in June/July 2008:

SSOPs & SPS

- In one establishment, residues of fat and meat particles from the previous day's operations were observed on various food contact surfaces in the processing and prime-portion cutting rooms during pre-operational sanitation inspection.

- In one establishment, meat/fat residues from the previous day's operations were observed on multiple ready-to-use metal rods used to hang pork sausages.
- In one establishment meat/fat residues from the previous day's operations were observed on ready-to-use aprons.
- In three establishments, the containers used in the evisceration rooms to collect edible pork fat were placed in such a manner that debris from the operators' stands and boots and drippings from carcasses wash were falling directly onto the product.
- In three establishments, ventilation was inadequate.
- In four establishments, non-compliances regarding sanitary operational practices were reported.
- In one establishment, grounds outside the establishment were not maintained to prevent conditions that could lead to insanitary conditions.
- In one establishment, requirements were not met regarding construction and maintenance to prevent insanitary conditions.

HACCP Implementation

- In one establishment, verification of the critical limit for zero tolerance for the presence of visible feces and ingesta on the carcasses was not possible because the carcasses were mostly intact at this step.
- In one establishment, the edible-offal harvesting step was not indicated in the flow diagram, nor had it been included in the hazard analysis.

Microbiological Testing

- The government laboratories were using methodologies for microbiological testing for *Salmonella* and *Listeria monocytogenes* that differed from those used by FSIS. Poland did not have an equivalence determination in place which would permit the use of these alternative methods.

7. MAIN FINDINGS

7.1. Legislation

No new changes had been implemented in Poland's meat-inspection legislation.

7.2. Government Oversight

The Polish meat inspection system is organized in three levels. The first level is the General Veterinary Inspectorate (GVI) which branches out from the Ministry of Agriculture and Rural Development (MAR). This is the level of government that FSIS holds responsible for ensuring that FSIS requirements are implemented and enforced relative to the exporting of meat products to the United States. The second level is the Provincial Veterinary Inspectorate (PVI) also designated as Regional Veterinary Inspectorate (RVI). There are16 provinces (each province has between 15 to 32 districts). The third level is the District Veterinary Inspectorate (DVI). 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 inspection personnel assigned to the certified establishments are hired

directly by the District Veterinary Officer (DVO); this staff consists of two types of veterinarians (permanent or contracted). The contracted veterinarians are eligible to become permanent under a national legislative authority to perform specific inspection functions as directed by the DVO. Additionally, establishments approved for export to the US market are supervised by veterinarians authorized by the DVO to perform permanent supervision and to issue veterinary health certificates for products exported to this market.

The Provincial Veterinary Officer (PVO) also designated as Regional Veterinary Officer (RVO) and DVO competent for the place of operation of the establishment approved for export to the US market inspect the establishment once a month (with each Veterinary Officer (VO) also designated as Veterinary Inspector (VI) on a different date). The inspections are documented by means FSIS form 5000 - 6. A copy of the above mentioned form prepared by the DVO is submitted to the RVI and to the official Veterinary Officer in charge of supervision of the certified establishment.
The copy of the above-mentioned form prepared by the Regional Veterinary Officer shall be submitted to the General Veterinary Inspectorate and to a competent District Veterinary Officer.

Granting approval of establishments for export to the USA is a process consisting of three stages:

- The DVO competent for the place of operation of a given establishment conducts inspection activities upon the establishment's request and if the establishment meets the requirements of the US law, he/she submits a request to the competent RVO for a verifying inspection.
- If the verifying inspection reveals that specific veterinary standards of the US have been met, the RVO submits a written request to the Chief Veterinary Officer (CVO) for a confirmatory inspection done by the GVI representatives (Controlling Office).
- In case of a positive result of the inspection, the CVO issues a written opinion for the DVO on the possibility of approval of the establishment for export to the US.
- After receiving the approval from the CVO, the DVO issues an administrative decision along and sends a copy of it with a relevant appendix to the instruction of the CVO No. GIWhig-500-3/08 of 20 March 2008 on procedures of Veterinary Inspection bodies, concerning approving, conditional approving, and registration of food sector establishments, suspension and revocation of establishment approvals, to the GVI on through the RVI.

Upon the reception of required documents, the CVO places the establishment on a list of establishments approved for export of its products to the US, and publish on the website of the GVI which is equivalent to receiving export rights for the US market.

With reference to the above, the CVO also informs the US of the fact that a new establishment has been granted export rights to the US market in the specified domain after reaching all stages of approval process and has been placed on the aforementioned list.
In case when the DVO identifies some inaccuracies, he/she ensures that the entity undertakes corrective actions. When deciding what kind of action should be taken, the DVO takes into account the type of inaccuracies and results of previous inspections and the repetitive character of inaccuracies.

The action taken by the DVO consists in issuing administrative decisions which, depending on the gravity of failure, shall include the following measures:

- imposing sanitary procedures or undertaking any other activities considered necessary to ensure food safety or compliance with food legislation, principles of animal health or animal welfare;
- restriction or prohibition of the placing on the market or export of food;
- order to withdraw and/or destroy the food;
- authorization to use the food for purposes other than those to which it was initially intended;
- suspension of activity or company closure or closure of its part for a given period of time;
- suspension or revocation of establishment approval;
- any other measures that a competent authority considers adequate.

The DVO has the authority to suspend the establishment's production operation any time the wholesomeness and safety of the product are jeopardized. Information on revocation of the establishment's export rights to the US market is submitted immediately to the CVO through the RVO.

Upon receipt of the above mentioned information, the CVO removes the establishment from the list of establishments approved for export to the US market and publishes on the website of the General Veterinary Inspectorate which is equivalent to revocation of the establishment's export rights. The CVO communicates the removal of the establishment in questions to his counterpart in FSIS.

Since the last audit, the CCA has conducted official audits of the certified establishments on a monthly basis to verify inspection program, monitor compliance with the FSIS requirements. The inspection plan for a given year is prepared by the officials of the controlling office of GVI and approved by the CVO. It should be emphasized that the inspections that carried out by the central level employees are documented on the Form which is a mirror image of FSIS form 5000-6.

Poland had opted to maintain a monthly frequency for the periodic supervisory reviews; however through its comments on the audit report, the CCA has expressed its desire to change monthly supervisory visits to less than monthly supervisory visits.

7.2.1. CCA Control Systems

The listing and delisting of the establishments approved for United States export is done by the DVI and PVI offices. All veterinarians and inspectors in establishments certified by Poland as eligible to export meat products to the United States were employees of the Local DVI.

7.2.2. Ultimate Control and Supervision

PVI offices have the authority and responsibility to supervise the activities of the DVI offices and the DVI offices have the authority and responsibility to supervise the activities of the veterinarians and inspectors in the certified establishments. FSIS regulatory

requirements are normally distributed via a CCA Intranet to the Provinces; these, in turn, pass the information to the Districts electronically and in hard copy format.

Uniform standard procedures based on FSIS requirements and the FSIS Directive 5000.1, Revision 2, as well as related documents had been translated into Polish. These documents were being used as the basis for the standard procedures used by the government of Poland's meat inspection officials at all levels to verify adherence to FSIS requirements in the certified establishments.

7.2.3. Assignment of Competent, Qualified Inspectors

The DVI has total authority for all human resource activity. All establishments are staffed with competent permanent (full time) and/or part time (contracted) veterinarians and non-veterinary inspectors. However, in case when the DVO is not able to perform statutory tasks defined by the Inspection for financial or organizational reasons (for instance due to low staffing in the District Veterinary Inspectorate), according to Article 16 of the Act on Veterinary Inspection, he/she may appoint, for a given period of time, veterinarians who are not employees of the Veterinary Inspection, for supervision of slaughter of animals, including ante mortem and post mortem examination, assessment of meat and supervision of compliance with the law on animal protection during slaughter and for supervision of cutting, processing and storing meat and issuing health certificates required

7.2.4. Authority and Responsibility to Enforce the Laws

The CCA has the authority and responsibility to enforce applicable laws and regulations. Continuous daily inspection was provided for all certified slaughter and processing establishments.

- Although none of the five establishments audited were delisted or received a Notice of Intent to Delist (NOID), non-compliances involving the enforcement of some FSIS requirements were identified at three of the five establishments audited.

- The government laboratories conducting microbiological testing for *Salmonella* and *Listeria monocytogenes* were using methods which differed from those employed by FSIS. This deficiency was first reported during the FSIS audit in March 2007 and also during the last audit in June/July 2008.

7.2.5. Adequate Administrative and Technical Support

The CCA has the administrative and technical support to implement US requirements such as the translation and dissemination of FSIS requirements to all levels of government inspectors with responsibilities for oversight of certified establishments. During the audit, it was observed that pertinent FSIS requirements had been disseminated to those PVI, DVI, and local inspection offices involved with United States export. Many of the translated versions of FSIS documents were also posted on an internet website. The GVI officials had organized meetings and training sessions on these requirements, and planned to continue conducting more of these meetings to ensure understanding and clarification of issues which may result in inconsistencies between the provinces, districts, and establishments.

The CCA had the ability to support a third-party audit.

7.3. Headquarters Audit

The auditor conducted a review of inspection system documents at headquarters, provincial, and district offices. The records reviews focused primarily on food-safety hazards and included the following:

- Supervisory visits to establishments that were certified to export to the United States
- Training records for inspectors and laboratory personnel
- Polish legislation pertinent to inspection laws and authority to enforce inspection requirements
- Export product inspection and control, including export certificates
- Enforcement records, including examples of withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States
- Consumer complaints and investigation reports maintained at Control Directorate
- Printouts from Poland's Animal Identification Database
- Humane Handling and Slaughter protocol.
- Ante-mortem and post-mortem procedures
- Inedible and condemned material protocol

No concerns arose as a result of the examination of these documents.

7.3.1. Audit of Regional and Local Inspection Sites

Two PVI offices, located in Kielce and Szczecin, and two DVI offices, located in Starahowice and Szczecin were audited. Each PVI office is headed by a PVO, who is an intermediary in the supervisory chain of command between the CCA and the DVI. As noted above, the DVO who is the head of the DVI provides the immediate supervisory oversight to the local inspection staff assigned to the establishments eligible to export to the United States.

8. ESTABLISHMENT AUDITS

The FSIS auditor audited a total of five establishments: Four slaughter/processing establishments and one processing establishments. None of the establishments audited were delisted or issued a NOID.

Specific non-compliances observed during this routine audit are noted in the attached individual establishment checklists.

9. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During the laboratory audit, emphasis was placed on the application of procedures and standards that are equivalent to U.S. requirements.

Residue laboratory audits focus on sample handling, sampling frequency, timely analysis,

data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. If private laboratories are used to test U.S. samples, the auditor evaluates compliance with the criteria established for the use of private laboratories under the Pathogen Reduction (PR)/HACCP requirements.

The National Veterinary Research Institute (NVRI) in Puławy and the provincial laboratory located at Kielce were audited for their functions related to microbiological testing. While NVRI performs numerous functions, those related to FSIS requirements include the analyses of field samples for Poland's national residue control program; some microbiological testing for generic *E. coli, Salmonella,* and *Listeria monocytogenes;* and oversight of the other government laboratories conducting similar microbiological testing throughout Poland's sixteen provinces (regions).

The following concern arose as a result of the laboratory audits.

- The scope of oversight functions exercised by the reference laboratory did not ensure that the appropriate FSIS microbial testing methods were used. The provincial (regional) laboratories were using the ISO 6579; 2003 method to conduct testing for *Salmonella* and the PN-EN ISO 11290-1:1999+ appendix (a) 1:2005 for *Listeria monocytogenes*. These methods differed from those used by FSIS; no equivalence determinations had been made for these alternative methods at the time of audit.

The International Equivalence Staff of the Office of International Affairs is currently reviewing a request from Poland for equivalence determination of its microbiological analytical tests; Poland will be notified of the decision taken by FSIS.

No residue laboratories were included in this audit.

10. SANITATION CONTROLS

As stated previously, the FSIS auditor focuses on five areas of risk to assess an exporting country's meat inspection system. The first of these risk areas that the FSIS auditors reviewed was Sanitation Controls.

Based on the on-site audits of establishments, and except as noted below, Poland's inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene practices, and good product handling and storage practices.

In addition, and except as noted below, Poland's inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of

operations, temperature control, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

The following non-compliances were identified regarding general sanitation performance standards:

- In one establishment, an overhead PVC (Poly Vinyl Chloride) pipe running in close proximity to the hopper of a mixer in the raw-product packaging room had a thick layer of grease buildup and had beaded condensation along its entire length. The non-compliance was observed while conducting pre-operational sanitation verification. A review of the establishment's records pertinent to general plant sanitation and maintenance generated during the previous 90 days contained no mention of this non-compliance. A review of the SSOP/SPS checklists generated by the VI and of the DVO's periodic supervisory reports also revealed no documented non-compliance.
- In one establishment, detached floor tiles, debris from peeling floor material, and littered, hard-to-clean areas were observed in the cooking department; these were creating insanitary operating conditions and the potential for indirect product contamination. This had been cited in the CCA's, the PVO's, and the DVO's reviews, and so appeared to be an ongoing maintenance problem. A review of the establishment's maintenance records indicated that current repairs and future maintenance projects were on schedule.
- In one establishment, containers designated for the handling and storage of edible products were being used to handle and store inedible material. The inspection staff stated that this was an isolated incident and had never occurred in the past.
- In one establishment, numerous flies were observed in the packaging room, despite the presence of a ultra-violet flying-insect-capturing device in the room. No exposed product was observed in the room. Neither the establishment's nor the inspection personnel's verification records indicated flies as an issue in any of the rooms. The pest management records also did not identify flies as a problem.
- In one establishment, feet and heads of swine carcasses were consistently contacting an employee's work station (not a food contact surface). This non-compliance was creating insanitary operational conditions and the potential for cross contamination. Although a review of supervisory reports and the VI's verification record indicated sporadic incidences of non-compliance and subsequent verifications of corrective actions, insanitary operational conditions were not identified as one of the non-compliances.

10.1. SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met. Except for the inadequate implementation in the three establishments audited, the SSOPs in all five establishments audited were found to meet the basic FSIS regulatory requirements.

- In one establishment, fresh hams hung on a metal rod were contacting an employees' work platform (a non food contact surface) as the overhead rail supporting the rods passed the platform. A review of records generated by both establishment and local inspection staff over the course of the previous 90 days revealed no non-compliance relative to the auditor's finding.
- In one establishment, exposed product in one cooler was stored underneath a cooling condenser, underside of which heavy beaded condensate had accumulated, creating the potential for product contamination. The plant and the inspection records for last ninety days indicated sporadic instances of condensation in different areas without product implication.
- In one establishment, a container used to store ham had a dead insect immersed in the meat juices.
- In one establishment, during pre-operational sanitation verification, various food contact surfaces in several departments had fat and meat residues from the previous day's operations. A review of pre-operational SSOP records generated by the establishment over the course of the previous 90 days revealed no similar findings. Pre-operational verification records generated by the inspection staff back to the first of the year contained only one non-compliance regarding inadequate pre-operational sanitation (on January 27, 2009), although the official veterinarian was conducting weekly pre-operational sanitation verification.
- In one establishment, during operational sanitation verification, beaded condensate was observed dripping from aluminum exhaust conduits onto sausages stored below. Also, an overhead steel pipe running across the sausage-washing rooms and the entrance to the sausage room had dripping condensate that created a potential for contamination of the product that was being moved into and out of the room. A review of the operational SSOP records for more than 90 days did not reveal any mention of condensation problems. A review of the inspection personnel's SSOP-verification records revealed that the VI had documented condensation, but in areas other than the sausage room.

10.2. EC Directive 64/433

In two of the five establishments audited, the following provisions of EC Directive 64/433 were not effectively implemented.

- In one establishment, EC directive provisions regarding establishment grounds and pest control were not met. Numerous flies were noted in the packaging room despite the presence of a Ultra-Violet flies capturing device in the room. No exposed product was observed stored in the room.
- In one establishment, EC directive provisions regarding establishment construction/ maintenance were not met. 1) In the raw product packaging room an overhead PVC pipe running in close proximity to the hopper of a mixer had a thick layer of grease build up and had beaded condensation along its entire length. 2) Detached floor plasters, debris of peeling floor material and littered hard to clean areas were observed in the cooking department were all creating insanitary operating conditions and potentials for indirect product contamination.
- In one establishment, EC directive provisions pertinent to ventilation were not met.

1) Beaded condensate was dripping from the aluminum exhaust conduits onto the sausages stored underneath the conduits. The affected product was not intended for U.S export.
2) An overhead steel pipe running across the sausage washing rooms and the entrance to the sausage room had a dripping condensate that created a potential for contamination of the product moving in and out of the room.

- In two establishments, EC directive provisions pertinent to sanitary operations were not met. 1) Porcine feet and head were contacting employee's work station (not a food contact surface) as each time the carcass rail passed by the platform. 2) The designated containers for the use of handling and storage of edible product were utilized to handle and store inedible material.

11. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditors reviewed was Animal Disease Controls. These include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that Poland's inspection system had adequate controls in place.

Animal disease restrictions are in place for Bovine Spongiform Encephalopathy, Foot and Mouth Disease, Classical Swine Fever, and Swine Vesicular Disease. APHIS has assigned Poland a status as free of or at low risk for Classical Swine Fever, Foot and Mouth Disease, and Swine Vesicular Disease. Poland is eligible to export fresh and frozen pork products to the United States.

No deficiency was reported.

12. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditors reviewed was Slaughter/Processing Controls. The controls include the following areas: humane handling and slaughter; ingredients identification; control of restricted ingredients; formulations; processing schedules; equipment and records; and processing controls of cured, dried, and cooked products. The controls also include the implementation of HACCP systems in all establishments and implementation of a testing program for generic *E. coli* in slaughter establishments.

12.1. Humane Handling and Slaughter

No non-compliance was reported.

12.2. HACCP Implementation.

All establishments approved to export meat products to the United States are required to have developed and implemented HACCP programs. Each of these programs was evaluated according to regulatory requirements.

The HACCP programs were reviewed during the on-site audits. The following non-compliance was reported:

- In one establishment, samples for trichinae were being collected and analyzed; however, the significance of the testing could not be determined as the hazard associated with trichinae had not been considered in the HACCP plan. The review of the analytical data for more than 90 days did not reveal any positive results.

12.3. Testing for Generic *E. coli*

Poland has adopted the FSIS regulatory requirements for testing for generic *E. coli.*

Four of the five establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing.

No non-compliance was reported.

12.4. Testing for *Listeria monocytogenes* on Ready-to-Eat Product

Four of the five establishments audited were producing ready-to-eat products (fully cooked hams); only one of the four establishments was required to comply with the regulatory requirements of 9 CFR 430 for testing for *Listeria monocytogenes* on product eligible for export to the United States, due to post-lethality exposure of the product. Of the three establishments that were producing ready-to-eat products and were not required to comply with the regulatory requirements of 9CFR 430, two were producing and exporting canned meat products and the other was producing and exporting ready-to-eat cooked ham-in-bag products to the United States.

The following non-compliance was reported which was also noted during the previous two audits:

- The government laboratories were conducting microbiological testing for *Listeria monocytogenes* employing the ISO PN-EN ISO 11290-1:1999+ appendix (a) 1:2005 method to detect the presence of *Listeria. monocytogenes*. This method differed from the MLG 8.07 method employed by FSIS for isolation and identification of *Listeria monocytogenes* from Ready-to-Eat products.

The International Equivalence Staff of the Office of International Affairs is currently reviewing a request from Poland for equivalence determination of its microbiological analytical tests; Poland will be notified of the decision taken by FSIS.

No residue laboratories were included in this audit.

12.5. Testing for *Salmonella* – Ready-to-Eat Product

Four of the five establishments audited were producing ready-to-eat products (fully cooked hams), but only one of these was required to meet FSIS *Salmonella* testing requirements.

The following non-compliance was reported which was also noted during the previous two audits:

- The government laboratories conducting microbiological testing for *Salmonella* in raw and RTE products were using the ISO 6579;2003 method that differed from the MLG 4.04 method employed by FSIS for isolation and identification of *Salmonella* from meat, poultry and egg products.

The following comments, regarding microbiological analytical testing methods used by regional laboratories which differ from those employed by FSIS, were received from Poland and included in the final 2008 audit report of its meat inspection system:

- The analytical methods employed at the regional laboratories were fully accredited by the Polish accrediting body, and had met international standards.
- The regional laboratories were participating in an inter-laboratory comparison testing which was organized and overseen by the National Reference Laboratory in Pulway.

At the time of submission of this report International Equivalence Staff of the Office of International Affairs was reviewing a request from Poland for equivalence determination of its microbiological analytical tests.

Poland was notified by FSIS in a letter dated January 25, 2010 as follows:

- Analytical method (ISO 6579-2002) employed by Polish laboratories for microbiological testing for *Salmonella* in raw product is equivalent to that employed by FSIS.
- Analytical method (ISO 11290-1) employed for microbiological testing for *Listeria. monocytogenes* in RTE is equivalent to that used by FSIS.

FSIS has requested Poland for additional information on methods employed for *Salmonella* in RTE products and *E. coli* testing employed for process control verification.

12.6. EC Directive 64/433

The provisions of EC Directive 64/433 related to slaughter controls were effectively implemented in the four processing establishments audited.

13. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviewed was Residue Controls. These controls include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

No residue laboratory was included in the scope of this audit.

13.1. EC Directive 96/22

No deficiency was reported concerning the provisions of EC Directive 96/22.

13.2. EC Directive 96/23

No deficiency was reported concerning the provisions of EC Directive 96/23.

14. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditors reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements, ante-mortem and post-mortem inspection procedures and dispositions, and a testing program for *Salmonella*.

14.1. Daily Inspection in Establishments

Inspection was being conducted daily in all slaughter and processing establishments.

No deficiencies were noted.

14.2. Testing for *Salmonella* – Raw Product

Poland had adopted the FSIS regulatory requirements for testing for *Salmonella*.

Four of the five establishments audited were required to meet the basic FSIS regulatory requirements for testing requirements for *Salmonella* on raw product.

14.3. Species Verification

Species verification was being conducted in those establishments in which it was required.

14.4. Periodic Reviews

In all of the five establishments audited, periodic supervisory reviews were being performed and documented as required.

14.5. Inspection System Controls

The CCA had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the United States with product intended for the domestic market.

Poland does not import any livestock or meat from other countries to be used for products eligible for export to the United States.

Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

15. EXIT MEETING

An exit meeting was held on October 9, 2009, in Warsaw with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Alam R Khan, DVM
Senior Program Auditor

16. ATTACHMENTS

Individual Foreign Establishment Audit Forms
Foreign Country Response to Final Audit Report

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 "Animex" S.A. ul. Krancowa 4 Starachowice 27-200	09/25/09	26110201	Poland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alam Khan, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X
11. Maintenance and evaluation of the effectiveness of SSOP's.	X
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	X
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	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 Date: 09/25/09 Est #: 26110201 (Zaklady Miesne "Animex" S.A. [S/P/CS]) (Starachowice, Poland)

10/11/51 (2)

After the plant had performed its pre-operational (pre-op) sanitation and completed its documents for the pre-op sanitation; the documents were reviewed and it was found that no non-compliances were noted.
The official veterinarian incharge (OVI) led the audit and did not find the following non compliances observed by the FSIS auditor:
In the cured product handling room the following non-compliances were observed:
1) A few needles of an injector tenderizer had pieces of meat adhered to them; the veterinary officer rejected the equipment. 2) Meat and fat particles were observed adhered on small detachable parts and on the circular conveyor belt of a meat mixer machine. The belt had torn edges and a hole which prevented thorough cleaning. 3) Meat and fat residues were observed adhered to the vessel of a cured meat dispenser. The OVI rejected the entire room and re-presented the cured room for pre-op verification. No non -compliances were observed during the second pre-op verification.
In the de-boning room the following non-compliances were observed:
1) Meat and fat residues were observed at three locations of a meat conveyor belt. Both edges of the belt were disintegrating in a few places which prevented thorough cleaning. 2) Meat and fat residues were observed in different locations of the three meat slicing machines selected for pre-operational verification. 3) Meat and fat residues were observed on the rollers and other food contact surfaces of three de-skinning machine selected from the several others in the room for pre-operational verification. The entire boning room was rejected by the OVI and re-presented for pre-op verification by the establishment. No non-compliances were observed during the second pre-op verification.
The 90 days SSOP records pertinent to pre-op verification were reviewed and it was noted that there were no findings documented by the plant. The review of more than 90 days pre-operational verification record of the inspection staff indicated that except for the non-compliances regarding pre-op involving multiple equipment documented on January 27, 09 there were no non-compliances of a similar nature were identified. The OVI conducts weekly pre-op verification inspection selecting different areas of the plant's operation. The frequency can vary if warranted. The review of the last six supervisory reports during the audit of the district Kielce on September 23 indicated that the district veterinary officer did not identify any concerns with the pre-operational SSOP. [Regulatory reference: 9CFR 416.13 & 14]

10/41/51 (2)

During the operational SSOP verification the following non-compliance were observed:
1) Beaded condensate was dripping from the aluminum exhaust conduits onto the sausages stored underneath the conduits. The racks of sausages from the affected area were removed by the establishment and retained by the OVI. The non-compliant product was not intended for U.S export.
2) An overhead steel pipe running across the sausage washing rooms and the entrance to the sausage room had a dripping condensate that created a potential for contamination of the product moving in and out of the room. The OVI retained the product that had traversed the entrance and rejected the entrance area.
The review of the operational SSOP record for more than 90 days did not reveal condensation in the establishment to be a problem. The review of the inspection operational SSOP revealed that the establishment was cited less than five times for condensation problems, however, in areas other than the sausage room. [Regulatory reference: 9CFR 416.13 & 14]

15/51 (0)

The establishment did not identify and conducted hazard analysis of the hazard associated with the Trichinae in its HACCP plan. The establishment was collecting and analyzing samples for Trichinae. The inspection record related to HACCP verification did not identify this as an issue. [Regulatory reference: 9CFR 417.2]

39/51 (1)

1) In the raw product packaging room an overhead PolyVinyl Chloride (PVC) pipe running in close proximity to the hopper of a mixer had a thick layer of grease build up and had beaded condensation along its entire length. I reviewed the previous 90 days records pertinent to general plant sanitation and maintenance and noted that there were no findings documented by the plant. The review of the OVI' SSOP/SPS checklists and District Veterinary Officer's (DVO) periodic supervisory reports revealed no documented non-compliance by the inspector or concerns raised in the DVO's monthly supervisory reviews regarding the non-compliance noted above.
2) Detached floor plasters, debris of peeling floor material and littered hard to clean areas were observed in the cooking department were all creating insanitary operating conditions and potentials for indirect product contamination. The problem has been cited in the CCA, Regional Veterinary Officer and DVO's reviews. This appeared to be an ongoing maintenance problem. The review of the plant's maintenance record indicated that current repair and future maintenance projects were on schedule. [Regulatory reference: 9CFR 416.2(b)] [EC Directive 64/433]

46/51 (1)

The designated containers for the use of handling and storage of edible product were utilized to handle and store inedible material. The inspection staff stated that the observation was an isolated incident and had never occurred in the past. The non-compliance was immediately corrected by the establishment management. [Regulatory reference: 9CFR 416.4(d)] [EC Directive 64/433]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alam Khan, DVM	DVM

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
Danish Crown Kolo	09/29/09	30094204	Poland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alam Khan, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Date: 09/29/09 Est #: 30094204 processing (Danish Crown [S]) (Kolo, Poland)

Pre-operational (pre-op) sanitation verification was performed at this establishment. The FSIS auditor observed the designated plant employee conducting the pre-operational sanitation checks of food contact surfaces of tables, conveyors, equipment and utensils. FSIS auditor observed the official veterinarian conducting the pre-op sanitation verification and releasing the establishment after noting no non-compliance. FSIS auditor conducted the pre-op sanitation verification and observed no non-compliance. On review of 90 days records pertinent to the pre-op sanitation of plant and inspection, no trends of any specific non-compliance were detected in either the plant's or inspection's records.

10/51 (2)

During the operational sanitation verification, the FSIS auditor observed the following non-compliance:
The hams hung on a metal rod trees were in contact with the employees' work platform (a non food contact surface) as the overhead rail supporting the rods passed the platform. During my on-site visit of the establishment, one such incident was noted, but the proximity of the platform to the ham receiving line would have allowed the lowly hung hams on the metal rod trees to be in contact with the platform frequently during the operation. The official veterinary incharge retained the product entered in the cooler and rejected the work station. The establishment took immediate corrective action, and the inspector removed the tag and allowed the establishment to resume the operation. The review of the last 90 days record of plant and local inspection staff pertinent to the operational SSOP revealed that neither the plant's nor the establishment's records identified any non-compliance specific to the auditor's findings. During the interview with the official veterinarian incharge regarding enforcement of FSIS requirements, it was indicated that the non compliance noted by the FSIS auditor was an isolated incident and was never noticed in the past. [Regulatory reference: 9CFR 416.13(c) & 416.14]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alam Khan, DVM	DVM

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
Grupa ANIMEX S.A ul. Pomorska 11 5b Oddzial W Szczecine Szczecin 70-812	10/02/09	32620201	Poland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alam Khan, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		**Part F - Inspection Requirements**	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. 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	
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

Date: 10/02/09 Est #: 32620201 (Grupa ANIMEX S.A [S/P/CS]) (Szczecin, Poland)

There were no significant findings to report after consideration of the nature, degree and extent of all observations. All non compliances identified during the last audit were verified to be corrected.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alam Khan, DVM	DVM

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 ul. Przemyalowa 15 Lukow 21-400	10/05/09	06110266	Poland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alam Khan, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	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	X
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.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment Date: 10/05/09 Est #: 06110266 (Zaklady Miesne LMeat Lukow [S/P/CS]) (Lukow, Poland)

10. (2)
In cooler # 74, exposed pork product was stored underneath a cooling condenser which had accumulated heavy beaded condensate at the bottom of the unit creating potential for product contamination. A dead insect was also observed immersed in the meat juices of a ham container. The plant and the inspection records for last ninety days indicated sporadic instances of condensation in different areas without product implication. The official veterinarian retained the product and rejected the area underneath the condenser for product storage. [Regulatory reference(s): 9 CFR §416.13]

38/51. (1)
Numerous flies were noted in the packaging room despite the presence of a Ultra-Violet flies capturing device in the room. No exposed product was observed stored in the room. Neither the establishment's nor the inspection's verification records indicated flies as an issue in any of the rooms. The pest management records did not identify the flies a problem either. The establishment management stated that they had applied ammoniated water in some rooms during the cleaning/washing of floors and had left the door open to allow the fumes to dissipate which may have let flies into the packaging room. The establishment initiated immediate corrective action to control flies problem. [9 CFR §416.2(b)] [EC Directive 64/433]

46/51. (2)
Porcine feet and head were contacting employee's work station (not a food contact surface) as each time the carcass rail passed by the platform. This non-compliance was creating insanitary operational conditions and potential for the cross contamination. Neither the plant employee nor the inspector observed the non-compliance. The review of establishment's record for ninety days pertinent to operational SSOP or SOP did not specifically identify the findings. The record did not identify any trend of non-compliances. Although, the review of supervisory reports and the official veterinarian verification record indicated sporadic incidents of non compliance and subsequent verifications of corrective actions, insanitary operational conditions were not identified as one of the non-compliance. The official veterinarian gave assurance that the employee platform will be moved away from the carcass rail. The product implicated was retained for re-inspection.[9 CFR §416.4(a)] [EC Directive 64/433]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alam Khan, DVM	DVM

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 Sokolowskie Zaklady Miesne AL-550-lecia 1 Sokolow Podlaski 08-300	10/06/09	14290201	Poland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alam Khan, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment Date: 10/06/2009 Est. #: 14290201 ("Sokolow" S.A. Oddzial Sokolowskie Zaklady Miesne [S/P]) (Sokolow Podlaski, Poland)

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

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alam Khan, DVM	DVM

1) Comments and clarifications provided by the Polish party to point 7.2:

➢ The sentence in point 7.2 concerning "the first level of Polish meat inspection system" is imprecise. The above stems from the fact that Veterinary Inspection is managed by the Chief Veterinary Officer who reports to the Minister of Agriculture and Rural Development.

Therefore, to clarify the a/m sentence the Polish party suggests that its wording should be amended in the following manner:

"The first level shall be the General Veterinary Inspectorate. It is the government level....".

➢ According to point 7.2, the staff in charge of inspections in certified establishments is directly employed by District Veterinary Inspectorate.

Since the staff is not employed by the District Veterinary Inspectorate but by the District Veterinary Officer, the above provision is incorrect.

The Polish party therefore proposes to make this provision more precise in the following manner:

"Establishments approved for export to the US market are supervised by veterinarians authorised by the District Veterinary Officer to perform permanent supervision and to issue veterinary health certificates for products exported to this market."

➢ In point 7.2 in the paragraph concerning the so-called contracted veterinarians, the Polish party proposes that the following provision be included:

"In case when the District Veterinary Officer is not able to perform statutory tasks defined by the Inspection for financial or organizational reasons (for instance due to low staffing in the District Veterinary Inspectorate), according to Article 16 of the Act on Veterinary Inspection, he/she may appoint, for a given period of time, veterinarians who are not employees of the Veterinary Inspection, for supervision of slaughter of animals, including pre-mortem and post-mortem examination, assessment of meat and supervision of compliance with the law on animal protection during slaughter and for supervision of cutting, processing and storing meat and issuing health certificates required."

➢ In point 7.2, with reference to monthly audits it needs to be emphasised that these shall be conducted not only by Veterinary Officers of District Veterinary Inspectorates but also by representatives of Regional Veterinary Inspectorates in charge of verification of compliance of activities of the District Veterinary Officer related to the product exported to the USA. The above issue was not discussed in the draft of the report.

However, due to many inconsistencies in the text concerning monthly supervision visits in establishments approved for export to the USA market, the Polish party proposes that for the purpose of clarification the following provision be introduced:

"The Regional Veterinary Officer and District Veterinary Officer competent for the place of operation of the establishment approved for export to the US market shall inspect the establishment once a month (with each Veterinary Officer on a different date). The inspections shall be documented by means of the form FSIS nr 5000 - 6.

A copy of the above-mentioned form prepared by the District Veterinary Officer shall be submitted to the Regional Veterinary Inspectorate and to the official Veterinary Officer in charge of supervision of the certified establishment.

The copy of the above-mentioned form prepared by the Regional Veterinary Officer shall be submitted to the General Veterinary Inspectorate and to a competent District Veterinary Officer.

➢ In point 7.2, with reference to the sentence stating that: „Poland has opted to maintain a monthly frequency for the periodic supervisory reviews", I wish to add that the Polish party submitted a query in the year 2009 to the American party in relation to lowering the frequency of inspections at regional level documented by means of the form FSIS nr 5000-6 in meat processing establishments approved for export to the US market, i.e. the query concerned the possibility of lowering the frequency of the inspections in question from once a month to once every two or three months provided that the frequency of inspections by district veterinary services documented by means of this form is not changed, i.e. they would be performed once a month.

According to the information obtained from Mr. Andreas Keller (the letter of 1 July 2009), the frequency of inspections may be lowered on condition that the Competent Central Authority promises that the decision in this matter will be duly

documented in order to ensure that the Polish system of meat inspection is still equivalent to the meat inspection system in the USA.

In the light of the above, I would like to inform you that the Polish party will in the future work on lowering the frequency of inspections from once a month to once every two or three months at the regional level and will inform the American party of this fact.

➢ Due to numerous inconsistencies present in the document concerning certification or revocation of certification granted to the establishment (7.2) and issues related to placing the establishment on the list of establishments approved for export to the USA or its removal from the list (7.2.1), the Polish party provides the following explanation.

Granting approval for establishments for export to the USA is a process consisting of three stages:

1. The District Veterinary Officer competent for the place of operation of a given establishment shall conduct inspection activities upon the establishment's request and if the establishment meets the requirements of the US law, he/she submits a request to the competent Regional Veterinary Officer for a verifying inspection.

2. If the verifying inspection reveals that specific veterinary standards of the USA have been met, the Regional Veterinary Officer submits a written request to the Chief Veterinary Officer for a confirmatory inspection done by the General Veterinary Inspectorate representatives (Controlling Office).

3. In case of a positive result of the inspection, the Chief Veterinary Officer issues a written opinion for the District Veterinary Officer on the possibility of approval of the establishment for export to the USA.

After receiving the approval from the Chief Veterinary Officer, the District Veterinary Officer issues an administrative decision along and sends a copy of it with a relevant appendix to the instruction of the Chief Veterinary Officer No. GIWhig-500-3/08 of 20 March 2008 *on procedures of Veterinary Inspection bodies, concerning approving, conditional approving, and registration of food sector establishments, suspension and revocation of establishment approvals*, to the General Veterinary Inspectorate on through the Regional Veterinary Inspectorate.

Upon the reception of required documents, the Chief Veterinary Officer places the establishment on a list of establishments approved for export of their products to the USA, published on the website of the General Veterinary Inspectorate, which is equivalent to receiving export rights on the market in question.

With reference to the above, the Chief Veterinary Officer also informs the American party of the fact that a new establishment has been granted export rights to the US market in the specified domain after reaching all stages of approval process and has been placed on the aforementioned list. ,

In case when the District Veterinary Officer identifies some inaccuracies, he/she shall ensure that the entity undertakes corrective actions. When deciding what kind of action should be taken, the District Veterinary Officer takes into account the type of inaccuracies and results of previous inspections - the repetitive character of inaccuracies.

The action taken by the District Veterinary Officer consists in issuing administrative decisions which, depending on the gravity of failure, shall include the following measures:

a) imposing sanitary procedures or undertaking any other activities considered necessary to ensure food safety or compliance with food legislation, principles of animal health or animal welfare;

b) restriction or prohibition of the placing on the market or export of food;

c) order to withdraw and/or destroy the food;

d) authorisation to use the food for purposes other than those to which it was initially intended;

e) suspension of activity or company closure or closure of its part for a given period of time;

f) suspension or revocation of establishment approval;

g) any other measures that a competent authority considers adequate.

In case of serious deficiencies, the District Veterinary Officer shall issue an administrative decision on the basis of which rights to export to the US market shall be immediately suspended or cancelled.

Information on revocation of the establishment's export rights to the US market shall be submitted immediately to the Chief Veterinary Officer through the Regional Veterinary Officer.

Upon the reception of the above-mentioned information, the Chief Veterinary Officer shall remove the establishment from the list of establishments approved for export to the market in question, published on the website of the General Veterinary Inspectorate, which is equivalent to revocation of the establishment's export rights and information concerning this shall be submitted to the competent services of the FSIS.

- In 7.2 there is a sentence according to which the General Veterinary Inspectorate conducts official audits of certified establishments on a monthly basis.

Since this sentence is not adequate, the Polish party has provided the following explanation:

Verifying inspection programme to monitor compliance of establishments with the US standards is defined in an inspection plan for a given year, prepared by employees of the Controlling Office of the General Veterinary Inspectorate and subsequently approved by the Chief Veterinary Officer.

Inspections planned for the year 2009 concerned 6 out of 10 Polish establishments approved for the US market.

By 16 September 2009 (i.e. this was the day in which the visit of the FSIS inspector, Mr Alam Khan started) inspections of 4 out of 6 establishments covered by the inspection plan were carried out.

It should be also emphasised that the inspections carried out by the central level employees have been documented by means of the form FSIS No. 5000-6.

2) With reference to the mentioned in the draft final report issue of absence of equivalence of detection methods for *Salmonella* and *Listeria monocytogenes*, the Polish party would like to submit a clarification.

Referring to the prolonged negotiations between the European Commission and the appropriate US authorities concerning determination of equivalence of testing methods towards *Salmonella* and *Listeria monocytogenes* in pork meat and pork meat products exported to the US market, the Polish party provided the FSIS with

the content of ISO Standards according to which the a/m tests are performed, so that the US services could assess the equivalence of testing methods used in Poland and possibly approve them until agreement with the European Commission is reached.

According to the letter of Mr. Faiz Agarib of 25 January 2010, the FSIS determined that testing methods concerning detection of *Salmonella* in raw meat, in accordance with ISO 6579-2002 and *L. monocytogenes* in ready-to-eat products, in accordance with ISO 11290-1 are equivalent.

However, recently, the US party has requested additional information related to testing of ready-to-eat products (RTE) on Salmonella bacteria and on the application of the Norm ISO 6579 which concerns the sanitary swabs from the surface of pig half-carcases performed by means of the "sponge method".

In the light of the above, the Chief Veterinary Officer has submitted a request to the National Veterinary Research Institute in Puławy (PIW-PIB) for an opinion on the issue in question.