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

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

OCT 0 5 2007

Dear Dr. Lech:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Poland's meat inspection system March 14 to April 10, 2007. Comments from Poland have been included in the final audit 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 (402) 344-5100, by facsimile at (402) 344-5169, or electronic mail at donald.smart@fsis.usda.gov.

Sincerely,

Donald Smart
Director
International Audit Staff
Office of International Affairs

Enclosure

FINAL

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

MARCH 14 THROUGH APRIL 10, 2007

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

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
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
SSOP	Sanitation Standard Operating Procedures
Salmonella	*Salmonella* species
VEA	European Community/United States Veterinary Equivalence Agreement
VI	Veterinary Inspector

1. INTRODUCTION

The audit took place in Poland from March 14 through April 10, 2007.

An opening meeting was held on March 14, 2007, in Warsaw with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit, 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 representatives from the CCA, the General Veterinary Inspectorate (GVI), and/or representatives from the provincial and district inspection offices.

2. OBJECTIVE OF THE AUDIT

This audit was a routine annual audit. The objective of the audit was to evaluate the performance of the CCA with respect to controls over meat producing 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, three provincial inspection offices, three district offices, one laboratory performing analytical testing on United States-destined product, four slaughter and processing/establishments, and two meat processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	GVI in Warsaw
	Provincial Veterinary Offices	3	
	District Veterinary Offices	3	
Laboratories	National Reference Laboratory	1	Residue and Microbiology in Puławy, Poland
Meat Slaughter and Processing Establishments		4	
Meat Processing Establishments		2	

3. 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, regional, and district offices. The third part involved on-site visits to six establishments; four slaughter/processing establishments, and two processing establishments. The fourth part included a visit to The National Veterinary Research Institute, which is the national reference laboratory. While this laboratory 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,* 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 Sanitation Standard Operating Procedures (SSOP), (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 opening 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 testing, requirements for HACCP, SSOP, 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 EU exporting countries. However, none of the establishments audited utilized this equivalence determination, and continued to rely on generic *E. coli* as an indicator of process control.

4. 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

5. 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 deficiencies were identified during an FSIS enforcement audit of Poland's inspection system in July/August of 2004:

- In one DVI office, the verification documentation was not included in the record for corrective actions taken as a result of observations made during a monthly supervisory visit.
- In regard to *Salmonella* testing for ready-to-eat product the sample size was 25 grams instead of 325 grams as required by FSIS. (FSIS Directive 10, 210.1, Amendment 6.)
- In one establishment, light was not sufficient at the inspection surfaces of the swine head, carcass, and viscera stations.
- In one establishment, the records for the calibration of process-monitoring instruments did not include the time for each entry by the responsible establishment employee.
- In one establishment, the sequence for carcass sponging was not being followed as required. The sequence being used was belly, ham and jowl rather than ham, belly, and jowl as required.

The following deficiencies were identified during the subsequent FSIS audit that was conducted in the May/June 2005:

- In one establishment, the receptacles in the processing room used for storing inedible materials did not bear conspicuous and distinctive markings on their surface so as to identify their purpose.
- In one establishment, several containers used for storing packaged product in the cooler presented a visibly unclean outer surface with a sticky residue originating from the adhesive backing of previously applied labels.
- In one establishment, condensation was seen dripping from an air-cooling unit onto the floor of the ham packaging room.

- In one establishment, the design of the HACCP records associated with the chilling CCP could not accurately demonstrate that the critical limit was met.
- In two establishments, the hazard analysis addressing the production of cooked sausage did not accurately identify all the possible hazards associated with the chilling of product after cooking (e.g. *Clostridium perfringens*).
- In two establishments, noncompliances associated with the CCP for visible feces, ingesta, and milk ("zero tolerance") were identified.
- Two establishments were utilizing the "sponging" method without correct implementation of process control techniques.
- At the National Reference Lab (Puławy), the actual number of the security seal was not indicated on the forms contained within the sample box. This made it impossible to determine whether the seal found on the box is the original seal.

Although the majority of the deficiencies observed during the May/June 2005 audit were corrected, deficiencies involving HACCP requirements were identified during the current audit.

6. MAIN FINDINGS

6.1. Legislation

The auditor was informed that the relevant EC Directives, determined equivalent under the VEA, had been transposed into Poland's legislation.

6.2. Government Oversight

The Polish meat inspection system is organized in three levels. The first level is the Ministry of Agriculture and Rural Development (MARD), which includes the General Veterinary Inspectorate (GVI). 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). 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 certified United States establishment. Copies of the District monthly audit report are provided to the veterinarian in-charge of the certified establishment, District and Provincial offices.

The PVI may approve or disapprove a meat establishment based on the DVI office recommendation. The PVI notifies the CCA regarding approval or disapproval of United States certified establishments. The CCA also retains the authority to delist an establishment and maintains the list of the certified establishments. Since the last audit, the CCA has conducted official audits on a monthly basis of the United States certified establishments (Poland has opted to maintain a monthly frequency for the periodic supervisory reviews). DVI offices have reviewed the United States certified establishments on a monthly basis and have in turn been reviewed by the PVI, which also directly reviewed the certified establishment(s) under their purview. The CCA headquarters received copies of the DVI and PVI monthly review reports and any noncompliance records issued. In addition, the

CCA headquarters office also performed on-site audits in advance of the FSIS enforcement audit of the establishments, and the DVI and PVI offices.

6.2.1. CCA Control Systems

FSIS audited three PVI offices, three DVI offices, and the inspection offices located at six certified establishments. The listing and delisting of the United States approved establishments is being done by the DVI and PVI offices. All inspection veterinarians and inspectors in establishments certified by Poland as eligible to export meat products to the United States were employees of the Public Health Division of MARD.

6.2.2. Ultimate Control and Supervision

PVI offices have the authority to supervise the activities of the DVI offices and the DVI offices have the authority 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 and districts. In addition, copies are e-mailed and delivered in hard copy format as needed.

Uniform standard procedures based on FSIS requirements and the FSIS Directive 5000.1, Revision 1 (at the time of the audit, translated copies of Revision 2 were not yet available), 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 establishment.

6.2.3. Assignment of Competent, Qualified Inspectors

The DVI has total authority for all human resource activity. All establishments were staffed with full time and/or part time veterinarians and non-veterinary inspectors of the Public Health Division of MARD.

6.2.4. 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 six establishments audited were delisted or received a Notice of Intent to Delist (NOID), noncompliances involving the enforcement of FSIS requirements were identified at two of the six establishments visited.

- The government laboratories conducting microbiological testing for *Salmonella* and *Listeria monocytogenes* were utilizing methods which differed from those employed by FSIS. At the time of the audit, Poland did not have an equivalence determination in place which would permit the use of these alternative methods. While the current audit indicated that the CCA relies on the country's reference laboratory to oversee the activities of its regional government labs, this oversight is generally related to

aspects of accreditation and performance, and does not necessarily ensure that specific FSIS methods are utilized.

6.2.5. Adequate Administrative and Technical Support

The CCA has the administrative and technical support to implement United States requirements such as the translation and dissemination of pertinent FSIS requirements to all levels of government inspectors with responsibility for overseeing United States 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 US export. Many of the translated versions of FSIS documents are also posted on an internet website. GVI officials have organized meetings/training sessions on these requirements, and plans to continue conducting more such meetings to ensure a continuing understanding and clarify issues which could result in inconsistencies between the provinces, districts, and/or establishments.

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

6.3. Headquarters Audit

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

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the United States.
- Training records for inspectors and laboratory personnel.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- 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.

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

6.3.1. Audit of Regional and Local Inspection Sites

Three PVI offices located in Kielce, Gdańsk, and Olsztyn were audited. In addition, three DVI offices were audited. These DVI offices were located in Łuków, Człuchów, and Ostróda.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of six establishments: four slaughter/processing establishments, and two processing establishments. None of the establishments audited were delisted or issued a Notice of Intent to Delist (NOID).

Specific deficiencies observed during this enforcement audit are noted in the attached individual establishment review forms.

8. 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 PR/HACCP requirements.

As part of the scope of the current audit, the National Veterinary Research Institute in Puławy was reviewed. While this laboratory 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,* and *Listeria monocytogenes,* and oversight of the other government laboratories conducting similar microbiological testing throughout Poland's sixteen provinces (regions). The following deficiency was observed related to this laboratory's role:

- The scope of oversight functions exercised by the reference laboratory did not ensure that the appropriate FSIS microbial testing methods were utilized, as it was determined during the course of the audit that the provincial (regional) laboratories conducting testing for *Salmonella* and *Listeria monocytogenes* employed methods which differed from those utilized by FSIS.

No deficiencies were observed concerning Poland's residue testing program.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor members focused on five areas of risk to assess Poland'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 deficiencies were identified regarding general sanitation performance standards:

- In one establishment, condensation was identified on the overhead structures of a portion of the product-chilling room. No product was stored under the area where the condensation was identified.

9.1. SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the United States' domestic inspection program. The SSOP in the six establishments audited were found to meet the basic FSIS regulatory requirements. However, observation SSOP implementation revealed the following deficiencies:

- At one establishment, several rods on which sausages were to be hung presented an unidentified residue.
- At one establishment, rail grease was observed on the shoulder of a swine carcass.

9.2. EC Directive 64/433

With the exception of the aforementioned deficiencies, the remaining provisions of EC Directive 64/433 related to sanitation controls were effectively implemented in all six establishments audited.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditors reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditors determined that Poland's inspection system had adequate controls in place. No deficiencies were noted.

Animal disease restrictions are in place for Bovine Spongiform Encephalopathy, Foot and Mouth Disease, Hog Cholera, and Swine Vesicular Disease.

11. 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: ante-mortem inspection procedures; ante-mortem disposition; humane handling and slaughter; post-mortem inspection procedures; post-mortem disposition; 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 generic *E. coli* testing program in slaughter establishments.

11.1. Humane Handling and Slaughter

No deficiencies in humane handling and slaughter were observed.

11.2. HACCP Implementation.

All establishments approved to export meat products to the United States are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program.

The HACCP programs were reviewed during the on-site audits through which the following deficiencies were identified at two of the six establishments visited:

- In one establishment, corrective actions taken in response to a deviation from the critical limit for visible feces, ingesta, and milk (i.e., "zero tolerance") were incomplete. The review of records associated with this CCP indicated that, in many events, corrective actions consisted solely in trimming the affected carcass.
- In one establishment, the frequency at which HACCP verification procedures are performed was not clearly defined in the HACCP plan.

11.3. Testing for Generic *E. coli*

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

Four of the six audited establishments were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing and were evaluated according to the criteria employed in the United States' domestic inspection program.

11.4. Testing for *Listeria monocytogenes* – Ready-to-Eat Product

Four of the six establishments audited were producing ready-to-eat products (cooked hams) for export to the U.S. As these products are prepared in cooking bags where there is no post-lethality exposure to the environment, the requirement to test the finished product for *Listeria monocytogenes* under FSIS Directive 10,240.4 does not apply.

However, these products are subject to non-risk-based testing for *Listeria monocytogenes* and *Salmonella*, as mandated by FSIS Directive 10,210.1 Amendment 6, with regards to which the following deficiency was identified:

- The government laboratories conducting microbiological testing for *Listeria monocytogenes* were utilizing a different method from that employed by FSIS. At the time of the audit, Poland did not have an equivalence determination in place which would permit the use of this alternative method.

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

Four of six establishments were producing ready-to-eat product and were required to meet FSIS *Salmonella* testing requirements. The following deficiency was observed:

- The government laboratories conducting microbiological testing for *Salmonella* were utilizing a different method from that employed by FSIS. At the time of the audit, Poland did not have an equivalence determination in place which would permit the use of this alternative method.

11.6. EC Directive 64/433

Those provisions of EC Directive 64/433 related to slaughter controls were effectively implemented at the six establishments audited.

12. 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.

The National Reference Laboratory in Puławy was audited and no deficiencies were noted.

12.1. EC Directive 96/22

No deficiencies were noted concerning the provisions of EC Directive 96/22.

12.2. EC Directive 96/23

No deficiencies were noted concerning the provisions of EC Directive 96/23.

13. 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 and the testing program for *Salmonella.*

13.1. Daily Inspection in Establishments

Inspection was being conducted daily in all slaughter and processing establishments. However, the following deficiency was noted concerning the execution of inspection activities:

- At one establishment, inspection assignments related to verification of the establishment's HACCP plan routinely involved only the first production shift. As operations associated with production for export to the US currently occur on three shifts, the assignment of verification activities performed by inspection personnel should be distributed accordingly.

13.2. Testing for *Salmonella* – Raw Product

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

Four of the six establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing requirements for raw product. The following deficiency was noted:

- The government laboratories conducting microbiological testing for *Salmonella* were utilizing methods which differed from those employed by FSIS. At the time of the audit, Poland did not have an equivalence determination in place which would permit the use of these alternative methods.

13.3. Species Verification

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

13.4. Periodic Reviews

In all establishments visited, periodic supervisory reviews were being performed and documented as required.

13.5. 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.

In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other counties for further processing.

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

- Deficiencies involving the enforcement of FSIS requirements were identified at two of the six establishments visited. These can be summarized as follows:

    - In one establishment, corrective actions taken in response to a deviation from the critical limit for visible feces, ingesta, and milk (i.e., "zero tolerance") were incomplete.
    - In one establishment, the frequency at which HACCP verification procedures are performed was not clearly defined in the HACCP plan.

14. CLOSING MEETING

A closing meeting was held on April 10, 2007, 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.

Alexander L. Lauro, DVM
Senior Program Auditor

15. ATTACHMENTS

Individual Foreign Establishment Audit Forms
Foreign Country Response to Draft 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 Milesne "AGRYF" S.A. ul. Pomorska 11 5b Szczecin 70-812	3/26/07	32 62 02 01	Poland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alexander L. Lauro, 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.	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	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment Date: 3/26/07 Est #: 32 62 02 01 (Zaklady Milesne "AGRYF" S.A. [S/P/CS]) (Szczecin, Poland)

15/51. The frequency at which HACCP verification procedures are performed was not clearly defined in the HACCP plan. [Regulatory references: 9 CFR 417.2 (c)(7), 417.8)]

51. Inspection assignments related to verification of the establishment's HACCP plan routinely involved only the first production shift. As operations associated with production for export to the US currently occur on three shifts, the assignment of verification activities performed by inspection personnel should be distributed accordingly. [9 CFR 417.8]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alexander L. Lauro, DVM	for 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, Poland 21-400	03/19/07	06 11 02 66	Poland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alexander L. Lauro, 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.

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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 .	
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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	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Date: 03/19/07 Est #: 06 11 02 66 (Zaklady Miesne LMeat Lukow [S/P/CS]) (Lukow, Poland)

10. Rail grease was observed on the shoulder of a swine carcass after the final wash and prior to entry into the cooler. The CCA notified the establishment of the noncompliance, and corrective actions were immediately implemented. [Regulatory reference:9 CFR 416.13(c)] [Council Directive 64/433/EEC, Annex I, Chapter III, section (c)]

61. NAME OF AUDITOR

Alexander L. Lauro, DVM

62. AUDITOR SIGNATURE AND DATE

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
Prime Food Sp. z.o.o. ul. Mlynska 43B Przechlewo 77-320	04/02/07	22 03 02 07	Poland
	5. NAME OF AUDITOR(S) Alexander L. Lauro, DVM		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	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	
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 Date: 04/02/07 Est #: 22 03 02 07 (Prime Food Sp. z.o.o. [S/P/CS]) (Przechlewo, Poland)

10. In the processing area, several rods on which sausages were to be hung presented an unidentified residue. Inspection officials immediately notified establishment personnel who instituted the appropriate corrective actions. [Regulatory reference: 9 CFR 416.3 (c)] [Council Directive 64/433/EEC, Annex I, Chapter III, section (c)]

41. Condensation was identified on the overhead structures of a portion of the product-chilling room. No product was stored under the area where the condensation was identified. [9 CFR 416.2 (d)] [Council Directive 64/433/EEC, Annex I, Chapter II, section (g)]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alexander L. Lauro, DVM	for 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 "Animex" S.A. ul. Krancowa 4 Starachowice 27-200	03/21/07	26 11 02 01	Poland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alexander Lauro, 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	
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9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
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18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	X
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	
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Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
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38. Establishment Grounds and Pest Control	
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45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment Date: 03/21/07 Est #: 26 11 02 01 (Zaklady Miesne "Animex" S.A. [S/P/CS]) (Starachowice, Poland)

20/51: The corrective actions taken in response to a deviation from the critical limit for visible feces, ingesta, and milk (i.e., "zero tolerance") were incomplete. The review of records associated with this CCP indicated that, in many events, corrective actions consisted solely in trimming the affected carcass. [Regulatory reference: 9 CFR 417.3(a), 417.8]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alexander Lauro, 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. 14-100 Ostroda-Morliny Ostroda 14-100	04/05/07	28 15 02 01	Poland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alexander L. Lauro, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
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Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
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12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
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Part D - Continued Economic Sampling	Audit Results
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53. Animal Identification	
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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: 04/05/07 Est #: 28 15 02 01 (Grupa Animex S.A. [S/P/CS]) (Ostroda, Poland)

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

61. NAME OF AUDITOR
Alexander L. Lauro, DVM

62. AUDITOR SIGNATURE AND DATE

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
Wielkopolska Wytworinia Zywnosci " PROFI" ul. Kolejowa 3 Grabow nad Prosna 63-520	3/23/2007	30 18 41 03	Poland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alexander L. Lauro, 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.

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24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
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38. Establishment Grounds and Pest Control	
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47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
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: 3/23/2007 Est #: 30 18 41 03 (Wielkopolska Wytworinia Zywnosci " PROFI" [P/CS]) (Grabow nad Prosna, 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
Alexander L. Lauro, DVM	DVM

Warsaw, 11 September 2007

VETERINARY INSPECTION

CHIEF VETERINARY OFFICER

Mr. Donald Smart
Director
International Audit Staff
Office of International Affairs
Food Safety and Inspection Service
United States Department of Agriculture
Washington D.C.
20250

GIWhig-507-30G/USA/07

Dear Mr. Smart,

Please accept my gratefulness for providing me with the draft final audit report. I would like to kindly inform you that I have no comments to this report. I would like to assure you that all deficiencies identified in this report were corrected and eliminated.

Moreover, I would like to mention that the matter of the laboratory tests equivalence is still unresolved. According to the EU Regulation, all laboratory tests are conducted in accordance with EN-ISO standard. Due to the above, I would like to kindly ask you to consider the regulation of the laboratory tests equivalence in a frame of bilateral agreement. The detailed information required were provided according to FSIS request.

Sincerely yours,

DEPUTY
CHIEF VETERINARY OFFICER
Krzysztof Jażdżewski

General Veterinary Inspectorate, Wspólna Street 30, 00-930 Warsaw
phone: (+ 48 22) 623-20-88, fax: (+ 48 22) 623-14-08, e-mail: wet@wetgiw.gov.pl, www.wetgiw.gov.pl