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

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JAN 25 2006

Dr. Krzystof Jażdżewski
Acting Chief Veterinary Officer
Veterinary Inspection
General Veterinary Inspectorate
Republic of Poland
30 Wspolna Street
00-930 Warsaw, Poland

Dear Dr. Jażdżewski:

The Food Safety and Inspection Service conducted an on-site audit of the Poland meat inspection system May 25 through June 30, 2005. The comments from Poland have been included in the final report. Enclosed is a copy of the final report.

If you have any questions regarding the audit or need additional information, please contact me by telephone at 202-720-3781, by fax at 202-690-4040, or by e-mail at sally.white@fsis.usda.gov.

Sincerely,

Steven McDermott
for

Sally White, Director
International Equivalence Staff
Office of International Affairs

Enclosure

Cc:
Ed Porter, Agriculture Counselor, US Embassy, Warsaw
Andrzej Gdula, Economic Counselor, Embassy of Poland
Alejandro Checchi-Lang, Director, Directorate E, European Commission, Brussels
Tony Van der haegen, EU Mission to the US, Washington, DC
Norval Francis, Minister-Counselor, US Mission to the EU, Brussels
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Country File

FINAL

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

MAY 25 THROUGH JUNE 30, 2005

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
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 May 25 through June 30, 2005.

An opening meeting was held on May 25, 2005, 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, six provincial inspection offices, seven district offices, one laboratory performing analytical testing on United States-destined product, five slaughter and processing establishments, three meat processing establishments, and one slaughter establishment.

Competent Authority Visits			Comments
Competent Authority	Central	1	GVI in Warsaw, Poland
	Provincial Veterinary Offices	6	
	District Veterinary Offices	7	
Laboratories	National Reference Laboratory	1	Residue and Microbiology in Puławay, Poland
Establishments	Meat Slaughter and Processing Establishments	5	
	Meat Processing Establishments	3	
	Meat Slaughter Establishments	1	

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 nine establishments: five slaughter and processing establishments, three processing establishments, and one slaughter establishment. The fourth part included a visit to The National Veterinary Research Institute, Pulawy, which is the national reference laboratory, was conducting analyses of field samples for Poland's national residue control program, as well as some microbiological sampling for generic *Escherichia coli (E. coli), Salmonella,* and *Listeria monocytogenes*.

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. No equivalence determinations have been made for Poland.

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 United States import requirements listed in 9 CFR 327 and 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 the FSIS audit of Poland's inspection system conducted in November/December 2003:

- In five of ten establishments, SSOP were not effectively implemented and maintained.
- SSOP in five establishments also did not include all the required corrective action elements.
- Inadequate implementation of HACCP.
- Inadequate supervision from the CCA over provincial and district offices, as well as in certified establishments.
- In five establishments, product residues from the previous day's operation were observed on the food contact surfaces.
- In five establishments, swine carcasses were in direct contact with other contaminated/suspect carcasses on the retain rail and/or with non-food contact surfaces.
- In two establishments, overhead supports had rust, flaking paint, and build up of black discoloration over exposed product.
- In two establishments, dripping condensate from overhead structures and ceilings was falling onto exposed products/food contact surfaces in the boning and processing rooms.
- In one establishment, hogs were not stunned effectively prior to being shackled, hoisted, thrown, or cut.

- In all ten establishments audited, HACCP plans did not contain all required regulatory requirements.
- In eight of ten establishments audited, procedures for monitoring critical control points and/or frequency of monitoring were not performed as written in the HACCP plan.
- In all ten establishments audited, verification procedures, frequency, and on-going verification activities did not comply with FSIS requirements.
- In nine of ten establishments audited, corrective actions to be followed in response to a deviation from a critical limit did not address all four parts of the corrective actions in the HACCP plan.
- In eight of the ten establishments audited, the establishment failed to take appropriate corrective actions in response to deviations from critical limits.
- In all ten establishments audited, records for documentation of the monitoring, corrective actions, and verification of the HACCP plan were not properly completed.
- In two of ten establishments audited, pre-shipment review records were not completed correctly.

The subsequent FSIS audit was an enforcement audit conducted in July/August of 2004, during which the following deficiencies were identified:

- 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.

Although the majority of the deficiencies observed during the July/August 2004 enforcement audit were corrected, deficiencies involving HACCP recordkeeping 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. 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 six PVI offices, seven DVI offices, and the inspection offices located at nine 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. All key FSIS regulatory requirements had been translated into the Polish language and copies were available to staff at the headquarters office, as well as all provincial, district and establishment level offices.

Uniform standard procedures based on FSIS requirements and the FSIS Directive 5000.1, Revision 1, 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. Supervisory monthly checklists varied slightly in each district

office in format, the design of each checklist adequately addressed PR/HACCP requirements.

- Although no objections were raised concerning the design of the supervisory and communication channels supporting Poland's inspection system, noncompliances involving the enforcement of FSIS requirements were identified at seven of the nine establishments visited. As such, it is expected that the CCA reevaluate the effectiveness of these channels of supervision and communication, and modify them accordingly.

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.

- The enforcement audit conducted in 2004 determined that meat inspection personnel had a much more thorough understanding of PR/HACCP regulations and other FSIS requirements than was found during the November/December 2003 audit. However, as the majority of the findings contained within this report are associated with basic elements of HACCP and generic *E. coli* testing, the GVI needs to continue its efforts to ensure proper training of inspection personnel.

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

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 FSIS rules and directives to all levels of government inspectors with responsibility for overseeing United States certified establishments. FSIS Directives, Notices, Guidelines and other documents had been translated into Polish, disseminated to all PVI, DVI, and United States certified establishment level inspection offices in all the regions that have or have had United States certified establishments. Documents were transmitted in hard copy format and via e-mail. The FSIS requirements and documents are also posted on an internal Intranet website available to all GVI personnel. GVI officials have conducted meetings/training sessions on these requirements and new documents, and plans to conduct more such meetings in the future to ensure on-going understanding of the documents and clarify issues that 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

Six PVI offices located in Poznan, Kielce, Szczecin, Krakow, Siedlce, and Lublin were audited. In addition, seven DVI offices were audited. These DVI offices were located in Sokolow Podlaski, Lukow, Starachowice, Krotoszyn, Ostrzeszow, Jaroslaw, and Tarnow.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of nine establishments: five slaughter/processing establishments, three processing establishments, and one slaughter establishment. None of the establishments audited were delisted or issued a NOID.

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

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

During laboratory audits, emphasis was placed on the application of procedures and standards that are equivalent to United States 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.

The laboratory audit conducted National Veterinary Research Institute in Pulawy focused on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples.

The National Veterinary Research Institute in Pulawy was serves as the national reference laboratory and conducts both residue and microbiological analysis.

The FSIS requirements were being followed as required, except for the following deficiency concerning sample security:

- Security seals are being utilized on sample boxes. However, the actual number of the security seal was not indicated on the forms contained within the sample box, thereby making it impossible to determine whether the seal found on the box is the original seal.

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 sanitation performance standards (SPS):

- 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.
- At one establishment, condensation was seen dripping from an air-cooling unit onto the floor in the ham packaging room.

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 nine establishments audited were found to meet the basic FSIS regulatory requirements. However, observation SSOP implementation revealed the following deficiencies:

- At three establishments, torn conveyor belts used for transporting edible product were identified in the processing rooms. These belts were damaged to an extent which would inhibit their thorough cleaning, and could result in product adulteration during operations.
- At one establishment, condensation was seen dripping from a rail of the slaughter line onto viscera pans containing edible product.

9.2. EC Directive 64/433

With the exception of the aforementioned deficiencies, the remaining provisions of EC Directive 64/433 were effectively implemented in all nine 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 seven of the nine establishments visited:

- In one establishment, the design of the HACCP records associated with the chilling CCP could not accurately demonstrate that the critical limit was met. This establishment determined the need for a CCP to address product chilling after cooking, and utilizes "Appendix B" (guideline #3: product with nitrites) as supporting documentation for the critical limit. However, the design of the HACCP records addressed only the total chilling time is documented (15 hours), not the individual phases of chilling (130° to 80° F in 5 hours, and from 80° to 45° F in 10 hours).
- 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. This document did not address the possible germination and subsequent toxin production of spore forming organisms such as *Clostridium perfringens* during this production phase, nor did it reference any further documentation supporting this omission. As both establishments were blast-freezing product during this step, it is unlikely that conditions would allow for toxins from these organisms to be produced. However, failure to address all possible hazards at this step does not meet the regulatory requirements of 9 CFR 417.2(a)(1).
- At two establishments, noncompliances associated with the CCP for visible feces, ingesta, and milk ("zero tolerance") were identified:
    - At one of these establishments, the records associated with the monitoring of this critical control point did not include the time at which each entry occurred.
    - At the other establishment, ongoing verification procedures did not include the element of records review.
- At three establishments, noncompliances associated with the CCP for carcass chilling were identified:
    - In two of these establishments, the critical limit associated with the critical control point for carcass chilling addresses only surface temperature without a reference to time. Review of the establishment's hazard analysis indicated that this CCP was necessary to control the growth of microbial pathogens. From a scientific standpoint, the parameters of both time and temperature should be utilized to describe the growth-curve of microorganisms, for which the current design of this CCP cannot assure that pathogen growth is controlled. No further documentation was provided by these establishments to support the omission of the time parameter from this CCP.
    - One establishment determined the critical limit (CL) associated with carcass chilling to be 6° C within 24 hours, yet the records associated with the monitoring of this CCP did not include the time element.

11.3. Testing for Generic *E. coli*

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

Six of the nine 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. During the course of this evaluation, the following deficiencies were identified:

- Two establishments were utilizing the "sponging" method for generic *E. coli* testing, which requires that sample results be analyzed using statistical process control techniques. The values which delimitated the establishments' upper and lower control limits (10,000 and five CFU/cm^2 respectively) were blanket values provided by the National Reference Lab in Puławay. The correct implementation of process control techniques should include data which is specific for a particular establishment, so that a true assessment can be attained.

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

Four of the nine establishments audited were producing ready-to-eat products for export to the United States, and were required to meet FSIS *Listeria monocytogenes* testing requirements. In accordance with United States requirements, the HACCP plans in these four establishments have been reassessed for *Listeria monocytogenes*, and the appropriate testing was being conducted.

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

Four of nine establishments were producing ready-to-eat product and were required to meet FSIS Salmonella testing requirements. No deficiencies were noted concerning these requirements.

11.6. EC Directive 64/433

The provisions of EC Directive 64/433 were effectively implemented in the nine establishments implemented.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditors 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 Pulawy was reviewed, and no deficiencies were noted.

12.1. EC Directive 96/22

The provisions of EC Directive 96/22 were effectively implemented at the National reference Laboratory in Pulawy.

12.2. EC Directive 96/23

No deficiencies were noted at the National Reference Laboratory 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.

13.2. Testing for *Salmonella* – Raw Product

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

Six of the nine establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing requirements for raw product. No deficiencies were identified concerning these requirements.

13.3. Species Verification

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

13.4. Monthly Reviews

In all establishments visited, monthly 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.

- The CCA should continue to improve its ability to enforce U.S. requirements, as the current system of inspection was unsuccessful in previously identifying noncompliances found at seven of the nine establishments visited. These noncompliances can be summarized as follows:

- At three establishments, torn conveyor belts used for transporting edible product were identified in the processing rooms.
- 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, 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*).
- At two establishments, noncompliances associated with the CCP for visible feces, ingesta, and milk were identified.
- At three establishments, noncompliances associated with CCP for carcass chilling were identified.
- Two establishments were utilizing the "sponging method" for generic *E. coli* sampling without the correct implementation of process control techniques.

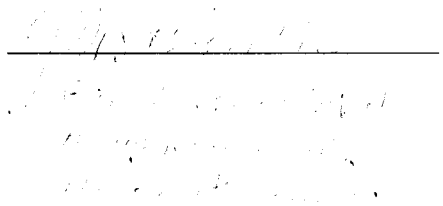
More detailed descriptions of these findings can be found in the preceding sections.

14. CLOSING MEETING

A closing meeting was held on June 30, 2005, in Warsaw with the CCA, and by teleconference with a member of the European Community in Brussels, Belgium and an International Equivalence staff officer in Washington, D.C. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Dr. Alexander L. Lauro
Program Auditor



15. ATTACHMENTS

Individual Foreign Establishment Audit Forms
Foreign Country's 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
"ŁMeat-Łukow" ul. Przemyslowa 15 21-400 Łukow	May 31, 2005	06 11 02 66	Poland
	5. NAME OF AUDITOR(S)	6. TYPE OF AUDIT	
	Alexander L. Lauro	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 SSOPs 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	X
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	X
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

Est. #: 06 11 02 66
City and Country: Łukow, Poland
Date: May 31, 2005

15/51: The critical limit (CL) associated with the critical control point (CCP) for carcass chilling addresses only surface temperature (7 ^{0} C) without a reference to time. Review of the establishment's hazard analysis indicated that this CCP was necessary to control the growth of microbial pathogens. From a scientific standpoint, the parameters of both time and temperature should be utilized to describe the growth-curve of microorganisms, for which the current design of this CCP cannot assure that pathogen growth is controlled. No further documentation was provided by the establishment to support the omission of the time parameter from this CL [9 CFR 417.2(c)(3)].

28/51: The establishment is utilizing the "sponging" method for generic *E. coli* testing, which requires that sample results be analyzed using statistical process control techniques. The values which delimitate the establishment's upper and lower control limits (10,000 and five CFU/cm^2 respectively) are blanket values provided by the National Reference Lab in Puławay. The correct implementation of process control techniques should include data which is specific for a particular establishment, so that a true assessment can be attained [9 CFR 310.25(a)(5)(ii)].

45/51: 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. Although the metal stands supporting these receptacles were labeled appropriately, loss of identity would occur once the containers were removed from the stands [9 CFR 416.3(c)].

61. NAME OF AUDITOR
Dr. Alexander L. Lauro

62. AUDITOR SIGNATURE AND DATE
Alexander L. Lauro 9/9/2005

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
"Sokołów" S.A. Oddział Zakłady Mięsne "Jarosław" Filia w Tarnówie ul.. Klikowska 101, 33-102 Tarnów	June 6, 2005	12 63 02 15	Poland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Alexander L. Lauro		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.	X
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

Est. #: 12 63 02 15
City and Country: Tarnów, Poland
Date: June 6, 2005

10/56: Condensation was seen dripping from a rail of the slaughter line onto viscera pans containing edible product. This problem was immediately corrected by establishment personnel, and all affected product (day's production) was condemned. [9 CFR 416.2(d), 416.13] [Council Directive 64/433/EEC, Annex I, Chapter I, section (n)]

19/51: The ongoing verification procedures contained within the HACCP plan controlling the presence of visible feces, ingesta, and milk on product (i.e. "zero tolerance") did not include the element of records review. [9 CFR 417.4(a)(2)(iii)]

61. NAME OF AUDITOR
Dr. Alexander L. Lauro

62. AUDITOR SIGNATURE AND DATE
Alexander L. Lauro 6/6/2005

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
"Sokołów" S.A. Oddział Zakłady Mięsne Al. 550-lecia 1 08-300 Sokołów Podlaski	June 21, 2005	14 29 02 01	Poland
	5. NAME OF AUDITOR(S)	6. TYPE OF AUDIT	
	Dr. Alexander L. Lauro	[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 SSOPs 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

Est. #: 14 29 02 01
City and Country: Sokołów Podlaski, Poland
Date: June 21, 2005

15/51: 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. This document did not address the possible germination and subsequent toxin production of spore forming organisms such as *Clostridium perfringens* during this production phase, nor did it reference any further documentation supporting this omission. As the product is subjected to blast-freezing during this step, it is unlikely that conditions would allow for toxins from these organisms to be produced. However, failure to address all possible hazards at this step does not meet the regulatory requirements of 9 CFR 417.2(a)(1).

61. NAME OF AUDITOR
Dr. Alexander L. Lauro

62. AUDITOR SIGNATURE AND DATE
9/9/2005

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
"Sokołów" S.A. Oddział Zakłady Mięsne "Jarosław" ul. Przemyslowa 2 37-500 Jarosław	June 8, 2005	18 04 02 01	Poland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Alexander L. Lauro		[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.	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	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Est. #: 18 04 02 01
City and Country: Jarasłow, Poland
Date: June 8, 2005

41/56: Condensation was seen dripping from an air-cooling unit onto the floor in the ham packaging room. No product was directly affected, although product was being packaged in this room at the time. [9 CFR 416.2(d)] [Council Directive 64/433/EEC, Annex I, Chapter II, section (g)]

10/51/56: A torn conveyor belt used for transporting edible product was identified in one of the processing rooms. This belt was damaged to an extent which would inhibit its thorough cleaning, and could result in product adulteration during operations. The establishment took corrective actions immediately to repair the belt, and to ensure appropriate disposition of product. [9 CFR 416.3(a), 416.13] [Council Directive 64/433/EEC, Annex I, Chapter III, section (c)]

15/51: 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. This document did not address the possible germination and subsequent toxin production of spore-forming organisms such as *Clostridium perfringens* during the production phase, nor did it reference any further documentation supporting this omission. As the product is subjected to blast-freezing during this step, it is unlikely that conditions would allow for toxins from these organisms to be produced. However, failure to address all possible hazards at this step does not meet the regulatory requirements of 9 CFR 417.2(a)(1).

61. NAME OF AUDITOR
Dr. Alexander L. Lauro

62. AUDITOR SIGNATURE AND DATE
Alexander L. Lauro 9/9/2005

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
"Constar" S.A. Ul. Krańcowa 4 27-200 Starachowice	June 2, 2005	26 11 02 01	Poland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Alexander L. Lauro		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

Est. #: 26 11 02 01
City and Country: Starachowice, Poland
Date: June 2, 2005

15/51: The critical limit (CL) associated with the critical control point (CCP) for carcass chilling addresses only surface temperature (7 ^{o} Celsius) without a reference to time. Review of the establishment's hazard analysis indicated that this CCP was necessary to control the growth of microbial pathogens. From a scientific standpoint, the parameters of both time and temperature should be utilized to describe the growth-curve of microorganisms, for which the current design of this CCP cannot assure that pathogen growth is controlled. No further documentation was provided by the establishment to support the omission of the time parameter from this CL [9 CFR 417.2(c)(3)].

16/51: The establishment has determined that a CCP is necessary to address product chilling after cooking, and is utilizing "Appendix B" (guideline #3: product with nitrites) as supporting documentation for the critical limit. However, the design of the HACCP records cannot accurately demonstrate that the critical limit has been met, as only the total chilling time is documented (15 hours), not the individual phases of chilling (130° to 80° F in 5 hours, and from 80° to 45° F in 10 hours) [(9 CFR 417.2(c)(6)].

28/51: The establishment is utilizing the "sponging" method for generic *E. coli* testing, which requires that sample results be analyzed using statistical process control techniques. The values which delimitate the establishment's upper and lower control limits (10,000 and five CFU/cm^2 respectively) are blanket values provided by the National Reference Lab in Puławay. The correct implementation of process control techniques should include data which is specific for a particular establishment, so that a true assessment can be attained [9 CFR 310.25(a)(5)(ii)].

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Alexander L. Lauro, D.V.M.	Alexander L. Lauro 7/7/2005

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
"Sokołów" S.A. Oddział Zakłady Mięsne w Koło ul. Toruńska 262 62-600 Koło	June 17, 2005	30 09 02 01	Poland

5. NAME OF AUDITOR(S)	6. TYPE OF AUDIT
Dr. Alexander L. Lauro	[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.	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	X
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

Est. #: 30 09 02 01
City and Country: Koło, Poland
Date: June 17, 2005

15/51: The establishment determined the critical limit (CL) associated with carcass chilling to be 6° C within 24 hours, yet the records associated with the monitoring of this CCP did not include the time element. Without an indication of time on the records, it is impossible to determine whether the CCP was met. [9 CFR 417.5(a)(3)]

10/51/56: A torn conveyor belt used for transporting edible product was identified in one of the processing rooms. This belt was damaged to an extent which would inhibit its thorough cleaning, and could result in product adulteration during operations. The establishment took corrective actions immediately to repair the belt, and to ensure appropriate disposition of product. [9 CFR 416.3(a), 416.13] [Council Directive 64/433/EEC, Annex I, Chapter II section (n), Chapter III section (c)]

45/51/56: 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. Equipment used for handling edible product must be of such material to facilitate thorough cleaning, and must be maintained in a sanitary condition. [9 CFR 416.3(a)] [Council Directive 64/433/EEC, Annex I, Chapter II, section (n)]

61. NAME OF AUDITOR
Dr. Alexander L. Lauro

62. AUDITOR SIGNATURE AND DATE
Alexander L. Lauro 9/9/2005

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Zakłady Mięsne "Krotoszyn" Ul. Kynobylinska 1 63-700 Krotoszyn	June 15, 2005	30 12 03 01	Poland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Alexander L. Lauro		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

Est.#: 30 12 03 01
City and Country: Krotoszyn, Poland
Date: June 15, 2005

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
Dr. Alexander L. Lauro	Alexander L. Lauro 9/9/2005

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 Wytwórnia Żywności "Profi" Ul. Kolejowa 3 63-520 Grabów n/Prosną	June 16, 2005	30 18 41 03	Poland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Alexander L. Lauro		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

Est.#: 30 18 41 03
City and Country: Grabów n/Prosną, Poland
Date: June 16, 2005

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

61. NAME OF AUDITOR
Dr. Alexander L. Lauro

62. AUDITOR SIGNATURE AND DATE
Alexander L. Lauro 9/9/2005

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Zakłady Mięsne "AGRYF" S.A. u.l Pomorska 115b 70-812 Szczecin	June 24, 2005	32 62 02 01	Poland
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Dr. Alexander L. Lauro		[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 SSOPs 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.	X
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

60. Observation of the Establishment

Est. #: 32 62 02 01
City and Country: Szczecin, Poland
Date: June 24, 2005

19/51: The records associated with the monitoring of the critical control point for visible feces, ingesta, and milk (CCP #1: "zero tolerance") did not include the time at which each entry occurred. [9 CFR 417.5(b)]

10/51/56: Two torn conveyor belts used for transporting edible product were identified in one of the processing rooms. These belts were damaged to an extent which would inhibit their thorough cleaning, and could result in product adulteration during operations. The establishment took corrective actions immediately to repair the belts, and to ensure appropriate disposition of product. [9 CFR 416.3(a), 416.13] [Council Directive 64/433/EEC, Annex I, Chapter II, section (n), Chapter III section (c)]

61. NAME OF AUDITOR
Dr. Alexander L. Lauro

62. AUDITOR SIGNATURE AND DATE
9/9/2005

Translation of the letter:

Warsaw, November 21, 2005

Mr. Ed Porter,
Agricultural Counselor
US Embassy, Warsaw

I would like to inform you that the Chief Veterinary Officer has no comments to the Draft Audit Report of the audit carried out in Poland on Polish Meat Inspection from May 25 to June 30, 2005.

I would like to assure you that the register of all corrective actions undertaken by plants in which there were reported deficiences was sent for translation. As soon as we receive the English translation of this document we will send it to you.

Thank you for your cooperation.

Dr. Cezary Bogusz
Deputy CVO