



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

Don

Dr. Antje Jaensch
Director
Federal Office of Consumer Protection and Food Safety
Diedersdorfer Weg 1
12277 Berlin – Marienfield
Germany

AUG 31 2005

Dear Dr. Jaensch:

This letter transmits the Food Safety and Inspection Service final report of a meat inspection system audit conducted in Germany from April 13 through May 4, 2005. Comments from Germany have been included as an attachment to the final report. Enclosed is a copy of the final report.

If you have any questions about this audit or need additional information, please contact me at 202-720-3781, facsimile 202-690-4040, or email at sally.white@fsis.usda.gov.

Sincerely,

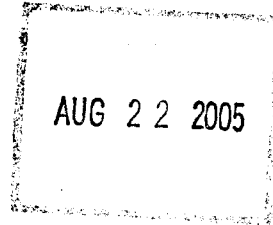
Sally White
Director
International Equivalence Staff
Office of International Affairs

Enclosure

Cc:

Rich Petges, Counselor, US Embassy, Berlin
Frederich Wacker, Agriculture Counselor, Embassy of Germany
Canice Nolan, EU Mission to the US, Washington, DC
Norval Francis, Minister-Counselor, US Mission to the EU, Brussels
Barbara Masters, Administrator, FSIS
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Country File (Germany—Apr05 Audit)

FINAL



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

APRIL 13 THROUGH MAY 4, 2005

Food Safety and Inspection Service
United States Department of Agriculture

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15. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, BVL-Federal Office of Consumer Protection and Food Safety)
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
<i>Salmonella</i>	<i>Salmonella</i> species
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures
VEA	European Community/United States Veterinary Equivalence Agreement

1. INTRODUCTION

The audit took place in Germany from April 13 through May 4, 2005.

An opening meeting was held on April 13, 2005, in Berlin with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit and discussed the auditor's itinerary.

The auditor was accompanied during the entire audit by representatives from the CCA, the Federal Office of Consumer Protection and Food Safety and/or representatives from the state, district, and local inspection offices.

2. OBJECTIVES OF THE AUDIT

This was a routine audit with two objectives. The first objective was to evaluate the performance of the CCA with respect to controls over the processing establishments certified by the CCA as eligible to export meat products to the United States. The second objective was to audit the pork slaughter establishment proposed for future certification by the CCA.

In pursuit of the objectives, the following sites were visited: the headquarters of the CCA in Berlin, one state inspection office in the State of Thuringia in Erfurt, one Regional inspection office within the State of Thuringia in Weimar, one local inspection office within the State of Thuringia in Altenburg, one government laboratory performing *Listeria monocytogenes* and *Salmonella* analysis on United States-destined product, all four certified meat processing establishments, and one pork slaughter establishment proposed for future certification. This pork slaughter establishment was presented as fully meeting FSIS inspection requirements.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	State	1	
	District	1	
	Local	1	
Laboratories		1	
Meat Processing Establishments		4	
Pork Slaughter Establishment		1	This establishment was proposed for future certification

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 audits of selected state, district and local inspection offices responsible for oversight of establishments certified for export to the United States. The third part involved on-site visits to four processing establishments and one pork slaughter

establishment proposed for future certification. The fourth part involved visits to one government laboratory. LAVES, located in Oldenburg, was conducting analyses for the presence of *Listeria monocytogenes*.

Program effectiveness determinations of Germany's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures, (2) animal disease controls, (3) processing controls, including the implementation and operation of HACCP programs, (4) residue controls, and (5) enforcement controls. Germany'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 Germany and also determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated and properly labeled.

During 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 FSIS auditor would audit the meat inspection system against European Commission Directive 64/433/EEC of June 1964; European Commission Directive 96/22/EC of April 1996; and European Commission Directive 96/23/EC of April 1996. These directives have been declared equivalent under the VEA.

Second, in areas not covered by these directives, the auditor would audit against FSIS requirements. These include daily inspection in all certified establishments, the handling and disposal of inedible and condemned materials, and FSIS' requirements for HACCP and SSOP.

Third, the auditor would audit against any equivalence determinations that have been made by FSIS for Germany under provisions of the Sanitary/Phytosanitary Agreement. There are no equivalence determinations pertaining to Germany at this time.

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 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

July 2003 Audit

During the July 2003 FSIS audit of Germany’s meat inspection system, the following deficiencies were found:

- SSOP implementation was deficient in one establishment.
- SSOP records were deficient in this same establishment.
- Problems were noted with pest control in four establishments.
- Sanitary operations needed improvements in two establishments.
- Dirty street and work clothes were stored in the same locker as clean working clothes in two establishments.
- Enforcement of FSIS or EC sanitation requirements was lacking in four of five establishments.

During the May 2004 FSIS audit, the auditor found that all the above deficiencies had been corrected.

May 2004 Audit

During the May 2004 FSIS audit of Germany’s meat inspection system, no deficiencies were reported.

6. MAIN FINDINGS

6.1 Legislation

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

6.2 Government Oversight

The CCA for Germany is the Federal Office of Consumer Protection and Food Safety. Among other things, this office is responsible for all activities related to the export of meat products to other countries, including the certification and de-certification of

establishments for export. This office is also responsible for verifying that appropriate corrective actions are taken when deficiencies are noted in establishments.

6.2.1 CCA Control Systems

Although the CCA has no jurisdiction or direct authority over the 16 State Inspection Programs, the CCA is responsible for certifying and decertifying establishments for export and for verifying that necessary corrective actions have been carried out by establishments and inspection personnel. Each of the 16 States is divided into one or more Districts. The District Office controls, implements, and enforces Federal meat inspection regulations through the individual local offices.

6.2.2 Ultimate Control and Supervision

The Federal Office of Consumer Protection and Food Safety is responsible for national control and supervision over official inspection activities for all establishments that export meat products, including the authority to certify and decertify establishments for such export.

In one establishment, the government inspection records for SSOP, HACCP and others, are kept electronically in the local government office. These records cannot be accessed electronically from the government inspection office which is located in this establishment. The local government office is located approximately 20 miles away from this establishment.

6.2.3 Assignment of Competent, Qualified Inspectors

Competent and qualified inspectors are assigned to certified establishments. In the slaughter establishment proposed for future certification, further HACCP training is needed for assigned government inspectors.

6.2.4 Authority and Responsibility to Enforce the Laws

The CCA has the authority and responsibility to enforce the laws. This is evidenced by the actions the Federal Office of Consumer Protection and Food Safety has taken to develop and issue inspection guidelines which contain FSIS requirements. These guidelines have been implemented by all States that have certified establishments within their boundaries.

6.2.5 Adequate Administrative and Technical Support

The CCA has adequate administrative and technical support to operate its inspection system.

6.3 Headquarters Audit

The auditor conducted a review of inspection-related documents at the Federal Office of Consumer Protection and Food Safety headquarters.

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

6.3.1 Audit of State, Regional and Local Inspection Offices

The auditor interviewed inspection officials at several levels of the inspection program. Inspection officials were interviewed at one State inspection office in the State of Thuringia in Erfurt, one Regional inspection office within the State of Thuringia in Weimar, and one local inspection office within the State of Thuringia in Altenburg. The pork slaughter establishment proposed for future certification is located within the State of Thuringia.

No concerns arose as a result of these interviews.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of four processing establishments. None of these establishments were delisted by Germany. None of these establishments received a Notice of Intent to Delist from Germany.

In addition, one pork slaughter establishment proposed for future certification was presented for this audit as fully meeting the FSIS inspection requirements. The establishment would have been delisted if it had been a certified establishment.

Specific deficiencies are noted on the attached individual establishment reports.

8. RESIDUE AND MICROBIOLOGY LABORATORY AUDITS

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

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples.

The following microbiology laboratory was reviewed:

LAVES, a government laboratory located in Oldenburg, was performing microbiological analyses on product destined for the United States.

This laboratory was not performing analyses of ready-to-eat products for both *Listeria monocytogenes* and *Salmonella*, as required. The laboratory was only testing for *Listeria monocytogenes*.

No residue laboratories were reviewed during this audit.

9. SANITATION CONTROLS

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

Based on the on-site audits of establishments, and except as noted below, Germany'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, Germany's inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, welfare facilities, and outside premises.

9.1 Sanitation Standard Operating Procedures

Each establishment was evaluated to determine if the FSIS regulatory requirements for SSOP were met, according to the criteria employed in the United States' domestic inspection program.

In four of the five establishments audited, SSOP deficiencies were noted.

Specific deficiencies are noted in the attached individual establishment reports.

9.2 Sanitation Performance Standards

In four of the five establishments audited, deficiencies regarding sanitation performance standards were noted.

Specific deficiencies are noted in the attached individual establishment reports.

9.3 EC Directive 64/433

In four of the five establishments audited, certain provisions of EC Directive 64/433 were not implemented.

Specific deficiencies are noted in the attached individual establishment reports.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor 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 auditor determined that Germany's inspection system had adequate controls in place.

No deficiencies were noted.

There had been no outbreaks of animal diseases with public health significance since the last FSIS audit.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures, ante-mortem disposition, humane handling and humane 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.

11.1 Humane Handling and Humane Slaughter

One pork slaughter establishment proposed for future certification was audited.

No deficiencies were noted regarding humane handling or humane slaughter.

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 of all the five establishments.

- In the pork slaughter establishment proposed for future certification, there was no critical control point for zero tolerance of fecal material, ingesta and milk. In addition, the establishment selected ante-mortem and post-mortem inspection as critical control points. These are government responsibilities not establishment responsibilities.

The specific deficiencies are noted in the attached individual establishment reports.

11.3 Testing for Generic *E. coli*

One pork slaughter establishment proposed for future certification was audited.

The government inspection officials take generic *E. coli* samples from the pork carcasses and these samples are analyzed in the government laboratory. In the absence of an equivalence determination, these samples should be collected by an establishment employee and analyzed in private laboratories.

11.4 Testing of Ready-to-Eat Products

Three of the five establishments audited were producing ready-to-eat products for export to the United States. In accordance with FSIS requirements, these establishments are required to meet the testing requirements for ready-to-eat products.

In all three establishments, the government was not testing ready-to-eat products for both *Listeria monocytogenes* and *Salmonella* as required.

11.4 EC Directive 64/433

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

The specific deficiencies are noted in the attached individual establishment reports.

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.

No residue laboratories were reviewed during this audit.

12.1 FSIS Requirements

At the time of this audit, no German slaughter establishments were certified for United States export. All raw product is obtained from certified slaughter establishments in Denmark and therefore residue controls are enforced at the Denmark slaughter establishments.

12.2 EC Directive 96/22

No residue laboratories were reviewed during this audit.

12.3 EC Directive 96/23

No residue laboratories were reviewed during this audit.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella*.

In four of five establishments audited, the inspection service was not enforcing FSIS or European Community (EC) requirements for sanitation.

The specific deficiencies are noted in the attached individual establishment review forms.

13.1 Daily Inspection

Inspection was being conducted daily in all establishments audited.

13.2 Testing for *Salmonella* in Raw Product

In the pork slaughter establishment proposed for future certification, *Salmonella* testing was conducted by the government.

No deficiencies were observed.

13.3 Species Verification

Germany is required to test product for species verification. Species verification was being conducted in those establishments in which it was required.

13.4 Monthly Reviews

During this audit, it was found that 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 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 countries 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.

14. CLOSING MEETING

A closing meeting was held on May 4, 2005, in Berlin with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

Dr. Farooq Ahmad
Senior Program Auditor



15. ATTACHMENTS TO THE AUDIT REPORT

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 Meica Meat Packing Plant of Ammerland Edeweicht	2. AUDIT DATE April 21, 2005	3. ESTABLISHMENT NO. A-IV-10	4. NAME OF COUNTRY Germany
	5. NAME OF AUDITOR(S) Dr. Farooq Ahmad		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

	Audit Results		Audit Results
Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements		Part D - Continued Economic Sampling	
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

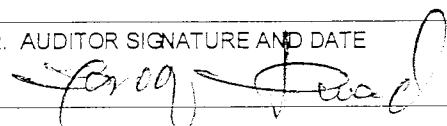
Country: Germany Est. No: A-IV-10 (Processing only) Date of audit: April 21, 2005

- 51 The government inspection records for SSOP, HACCP and others, are kept electronically in the government local office which is located approximately 20 miles away from this establishment. These records cannot be accessed electronically from this establishment's government inspection office.

61. NAME OF AUDITOR

Dr. Farooq Ahmad

62. AUDITOR SIGNATURE AND DATE

 5/16/05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Klumper GmbH & Company KG Schuttorf	2. AUDIT DATE April 26, 2005	3. ESTABLISHMENT NO. A-EV-29	4. NAME OF COUNTRY Germany
5. NAME OF AUDITOR(S) Dr. Farooq Ahmad		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	X
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X	38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	X
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment:	O		
32. Written Assurance	O		

60. Observation of the Establishment

Country: Germany Est. # A-EV-29 (Processing only) Date of Audit: 04/26/2005

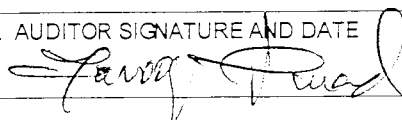
- 12/51 The preventative measures after the corrective action was taken were not included in the SSOP program. This deficiency was observed in the establishment's and Government's records.
9 CFR 416.15
- 33/51 The RTE product samples taken for *Listeria monocytogenes* analysis were not analyzed for *Salmonella*.
- 38/51 The cob webs were observed in the corner of dry packaging storage room. The packaging material was stored against the wall, which preclude thorough inspection by Government program employees.
9 CFR 416.2 (a)
EC Directive 64/433, Annex 1, Chapter 111, 3
- 45/51 In the processing room where hams were stored, during the opening of a metal door vertically, the water dripping was observed from the bottom of this swinging door, which was a source of potential contamination of the product.
9 CFR 416.3

NOTE: The first line supervisor (veterinarian) has no certificate of HACCP training.

61. NAME OF AUDITOR

Dr. Farooq Ahmad

62. AUDITOR SIGNATURE AND DATE

 5/16/05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Abraham Ammerlaender Ham GmbH & Company KG Edewecht	2. AUDIT DATE April 27, 2005	3. ESTABLISHMENT NO. A-EV-35	4. NAME OF COUNTRY
5. NAME OF AUDITOR(S) Dr. Farooq Ahmad		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	X
8. Records documenting implementation.		34. Speces Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.	X	37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	X
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

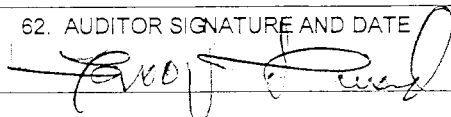
Country: Germany Est. # A-EV-35 (Processing only) Date of audit: 04/27/2005

- 10 The pieces of meat and fat were observed in a stainless steel ham bin in the cleaned equipment storage room. Also the curing spices were observed on the edge of the plastic ham bins.
9 CFR 416.13 (c)
EC Directive 64/433, Annex 1, Chapter 111, 3 (c)
- 11 The procedures to clean the complex equipment such as dicers, etc; did not describe the dismantling of such equipment during the pre-operational cleaning in their SSOP program.
9 CFR 416.14
- 33/51 The RTE product samples taken for *Listeria monocytogenes* analysis were not analyzed for *Salmonella*.
- 45/51 It was observed in the hams dicing room that 5 ham slicing equipments has rough and torn edges of the metal plates, where hams were placed for slicing, these rough and torn edges were caused by the cutting blade.
9 CFR 416.3 (a)
EC Directive 64/433, Annex 1, Chapter 111, 3 (c)

61. NAME OF AUDITOR

Dr. Farooq Ahmad

62. AUDITOR SIGNATURE AND DATE

 5/16/05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Abraham Ham GmbH and Company KG Barsel-Harkebruegge	2. AUDIT DATE April 28, 2005	3. ESTABLISHMENT NO. A-IV-191	4. NAME OF COUNTRY Germany
5. NAME OF AUDITOR(S) Dr. Farooq Ahmad		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	X
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.	X	37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	X
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

Country: Germany

EST. # A-IV-191 (Processing only)

Date of Audit= 04/28/2005

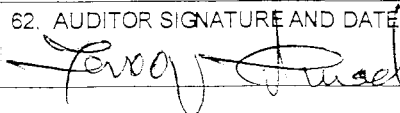
- 11 The procedures to clean the complex equipment such as slicers, etc; did not describe the dismantling of such equipment during the pre-operational cleaning in their SSOP program.
9 CFR 416.14
- 33/51 The RTE product samples taken for *Listeria monocytogenes* analysis were not analyzed for *Salmonella*.
- 38/51 The cob webs, trash and dust were observed in the dry packaging storage room. The packaging material was stored against the wall, which precluded thorough inspection by Government program employees.
9 CFR 416.2 (a)
EC Directive 64/433, Annex 1, Chapter 111, 3
- 46/51 The accumulation of trash and dust was observed, where labels for sliced product were stored in the sliced product packaging room.
9CFR 416.4 (b)
EC Directive 64/433, Annex 1, Chapter 111, 3

NOTE: The first line supervisor (veterinarian) has no certificate of HACCP training.

61. NAME OF AUDITOR

Dr. Farooq Ahmad

62. AUDITOR SIGNATURE AND DATE

 5/16/05

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Sudost-Fleisch GmbH Am Poschwitzer Park 07 04600 Altenburg	2. AUDIT DATE April 18, 2005	3. ESTABLISHMENT NO. A/ES 1061	4. NAME OF COUNTRY Germany
5. NAME OF AUDITOR(S) Dr. Farooq Ahmad		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	O
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	X	38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	X	42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	
27. Written Procedures		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	X
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Country: Germany

Est. No: D/ES/EZ 1061 (slaughter & processing)

Date of audit: April 18, 2005

Note: This establishment is proposed to be certified by Germany officials in the future.

- 12/51 (1) Establishment's corrective action records did not include preventative measures in their SSOP program.
9 CFR 416.15 (b)
- (2) Inspection records for corrective action did not include preventative measures.
9 CFR 416.17
- 15/51 (1) Establishment's HACCP plan did not include a CCP for zero tolerance of fecal material, injesta and milk.
9 CFR 310.17 (a); 310.18 (a); 318.4 (b) & 417.2
- (2) Establishment have included ante-mortem inspection as a CCP-1 & post-mortem inspection as a CCP-2 in their HACCP plan.
9 CFR 417.2
- 45/51 The metal frames of approximately 19 deboning tables, which hold the containers (tubs) for edible pork meat has rough patches of welding.
9 CFR 416.3 (b)
EC Directive 64/433, Annex 1, Chapter 111, 3 (c)
- 46/51 (1) In the entire deboning room the pork meat pieces were scattered on the floor.
9 CFR 416.4 (b))
- (2) In the pork carcass cooler room the condensation was observed on the overhead pipes and under the cooling unit.
9 CFR 416.4 (b) & (d)
- (3) The overhead condensation was observed in a door between two cooler rooms.
9 CFR 416.4 (b) & (d)
- (4) In the main hallway the condensation was dripping on the floor from the overhead pipes.
9 CFR 416.4 (b) & (d)
- (5) A build-up of Calcium carbonate (lime stone) was observed on the overhead metal structure, in the deboning room and two cooler rooms.
9 CFR 416.4 (b) & (d)

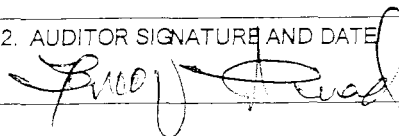
Note: (1) This establishment would have been delisted if it was a certified establishment, due to above findings.

- (2) The government inspection officials take generic *E. coli* samples from the pork carcasses, and these samples are analyzed in the government laboratory.

61. NAME OF AUDITOR

Dr. Farooq Ahmad

62. AUDITOR SIGNATURE AND DATE



5/16/05



Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
- Dienststelle Berlin – Postfach 480447, 12254 Berlin

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Ms. Sally White, Director
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Office of International Affairs
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REFERENCE 5106-00/224411
(please quote in response)

e-mail copy to:

Foreign Agricultural Service (FAS)
Embassy of the United States of America
Clayallee 170
14195 Berlin

YOUR REFERENCE/
YOUR NOTE FROM Letter of June 10, 2005

DATE August 08, 2005

German Embassy Washington
4645 Reservoir Rd.
Washington, D.C. 20007

Comments on FSIS draft final report of the meat inspection system audit conducted in Germany from April 13 through May 4, 2005

Dear Ms. White,

Please find enclosed with this letter the comments of the federal states of Lower Saxony and Thuringia on the draft final report of this year's FSIS meat inspection system audit in Germany. I have also enclosed an English translation of the comments by the Thuringia Ministry of Social Affairs, Family, and Health, and the Lower Saxony State Office of Consumer Protection and Food Safety.

The Thuringia ministry reports on the state of affairs concerning the elimination of deficiencies noted in the Altenburg slaughterhouse (establishment no. A/EZ 1061). The competent authority notes that most of the deficiencies listed in the draft report are already eliminated. At present they continue on the revision of the HACCP plan. As soon as this is finalised I will contact you again.

Yours sincerely,

signed

Dr. Antje Jaensch

Annex

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**Export of meat products to the US; US Audit from 13 April to 04 May 2005
Comments on the FSIS Draft Report of 26 May 2005**

From our point of view the following comments need to be made:

Ad point 4 “Legal Basis for the Audit”, sentence 2, and point 11.5:

In Europe the legal basis for meat products is Council Directive 77/99/EEC (92/05/EEC), and not Council Directive 64/433/EEC. Thus the wrong legal basis was used for the assessment. Council Directive 77/99/EEC is covered by the Veterinary Equivalence Agreement (VEA).

Ad point 6.2.2, paragraph 2:

There was a misunderstanding: When the American auditor asked for the official documentation in the district “office”, the German officials thought that this referred to the electronically saved data in the *Veterinär- und Lebensmittelüberwachungsamt* (Veterinary and Food Inspection Agency) in Westerstede. In fact the District of Ammerland keeps its written documents, which go back in time approx. one year, in the veterinary room on the sites of the companies Meica and Abraham.

Ad point 8, last paragraph, and point 11.4:

As far as we know, the requirement to test ready-to-eat products for *Salmonella* was communicated for the first time at the presentation „Testing Programs for Ready-to-Eat (RTE) Products, April 2005“. This presentation was introduced and discussed in detail during a telephone conference on 7 April 2005. Further details regarding the analysis for *Salmonella* were clarified during the visit of Dr. Schleuter and Dr. Moss of the *Veterinärinstitut Oldenburg* (Veterinary Institute of Oldenburg) to the FSIS laboratory in Athens.

During the audit, these circumstances were explained and it was promised that the analysis for *Salmonella* would be taken up in May 2005 after preparing the method and training the technical staff. This promise was kept and the analyses were started in due time. Furthermore, a meeting dealing with detailed questions was held at the LAVES headquarters on 6 June 05 between the LAVES headquarters - *Dezernat 21* (department 21), the LAVES - *Veterinärinstitut Oldenburg* and the districts of Ammerland, Cloppenburg and Grafschaft-Bentheim.

Comments on the listed deficiencies in the individual establishments:

1. Abraham, Edeweicht, A-EV-35:

Ad point 10:

The deficiencies have been eliminated. The staff of the department was trained. The control of the cleaning was further intensified. In addition the disinfection is checked microbiologically.

Ad point 11:

There was a misunderstanding: The machines are dismantled by the technical personnel of the company before cleaning and disinfection and are afterwards reassembled.

Ad point 33/51:

See above comment ad point 8.

Ad point 45/51:

The worktables of the saws were exchanged. They are checked regularly and are exchanged in case of damage.

2. Abraham, Harkebrügge, A-IV-191:

Ad point 11:

There was a misunderstanding: The machines are dismantled by the technical personnel of the company before cleaning and disinfection and are afterwards reassembled.

Ad point 33/51:

See above comment ad point 8.

Ad point 38/51:

The deficiency has been eliminated. The area was cleaned and tidied. Now enough room is left to allow a proper control behind the stored material.

Ad point 46/51:

The deficiency has been eliminated. The area was cleaned and tidied.

3. Klümper, Schüttorf, A-EV-29:

Ad point 12/51:

A column for the documentation of the preventive measures taken was added on the company's forms for the documentation of corrective measures. For documentation of official preventive measures, a special draft has been prepared and is still to be agreed on a federal level.

Ad point 33/51:

See above comment ad point 8.

Ad point 38/51:

The deficiency has been eliminated. The area was cleaned. A space was left free between each shelf (coloured marks on the floor), so that now the entire area near the wall can be controlled.

Ad point 45/51:

This deficiency cannot occur anymore, as the hams are no longer watered. They are washed in a ham washing machine.

4. Meica, Edewecht, A-IV-10:

Ad point 51:

See comments on point 6.2.2, paragraph 2.

for the director

Dr. Graf

(This document is submitted electronically and is therefore valid without signature.)

Draft report on FSIS inspection visit to Lower Saxony and Thuringia from 13 April to 04 May 2005

BVL letter of transmission dated 23 June 2005

With regard to the draft report sent to us with the above letter I would like to comment as follows:

The deficiencies listed in the report concerning the pork slaughter establishment in Altenburg have been described correctly and correspond to the established facts.

The *Veterinär- und Lebensmittelüberwachungsamt* (Veterinary and Food Inspection Agency) of the district of Altenburger Land, which is responsible for the control of the establishment Südost-Fleisch GmbH, reported the following state of affairs regarding the progress made on the individual points on the Establishment Audit Checklist:

Point 12/51

1. The checklists contained in the SSOP were changed by adding a column for preventive measures. The modified lists are already being used.
2. The lists used by the inspection agency were also completed by adding records of preventive measures.

Point 15/51

1. The modification of the establishment's HACCP concept to add a CCP for the surveillance of the contamination of the carcasses with faeces, intestinal contents and milk is under process.
2. In the revised HACCP concept the ante-mortem and post-mortem inspections as CCP will be deleted.

The process of changing the HACCP concept and of introducing the changes into practice has not yet been finalised.

Point 45/51

The metal frames of the deboning tables were reworked or exchanged step by step. The welding seams were ground smooth and gaps were closed, so that now the surface is smooth and easy to clean and to disinfect. In the meantime the cleaning and disinfection and the control thereof were intensified.

The works to fix the metal frames have been finalised, the deficiency has thus been eliminated. It can be confirmed that the requirements of Council Directive 64/433 are met.

Point 46/51

1. The staff have been lectured on the thorough intermediate cleaning of the floor during breaks and a corresponding cleaning at the end of shift. The controls were intensified. The deficiency has been eliminated. Ongoing controls are effected.
2. The formation of condensation at the cooling units and overhead pipes is prevented permanently by renewing the insulation and installing fans. The deficiency has been eliminated.
3. The formation of condensation at the cool room doors is avoided by modifying the routing of the air flow. Moreover the staff were given a working instruction on keeping the cool room doors shut. The deficiency has been eliminated. Ongoing controls have been fixed.
4. The cooling regime was changed; it is checked permanently and is implemented successfully.
5. The cleaning of the overhead metal structures was intensified by placing an order with an external service company. Moreover a chemical analysis of the deposits was commissioned in order to receive hints on how to permanently avoid the formation of these deposits. The deposits consist of zinc oxide. The deficiency has been eliminated for the time being. Permanent correction is under process.

To sum things up it can be stated that the establishment, in collaboration with the responsible inspection agency, undertakes all efforts to permanently eliminate the established deficiencies as soon as possible. The aim to seek certification for the US is upheld. The elimination of the deficiencies has not yet been checked by the Thuringia State Office of Food Safety and Consumer Protection as the authorising body, because substantial works have not yet been finalised.

The training of the staff of the responsible inspection agency on the HACCP concept has been included into this calendar year's training programme. One veterinarian has acquired up-to-date knowledge on this topic through her further training as a specialist veterinarian. By 31 July 2005 a document of approx. 10 pages will become available for the on-spot training of the meat inspectors.

We will inform you as soon as the authorising body is satisfied that all detected deficiencies have been eliminated.

for the director

Dr. Karin Schindler