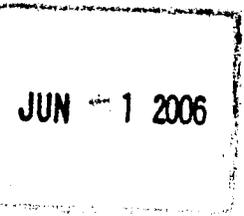




United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250



Dr. Antje Jaensch  
Deputy Head of Unit  
Unit 106  
Federal Office of Consumer Protection and Food Safety  
Diedersdorfer Weg 1  
12277 Berlin – Mariendorf  
Germany

Dear Dr. Jaensch:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of the German meat inspection system from November 24 through December 20, 2005. Enclosed is a copy of the final audit report. Comments from Germany to the draft final audit report were received in a letter dated April 19, 2006, which is included as an addendum to the final report.

If you have any questions regarding the FSIS audit, please contact me at telephone (202) 720-3781. You may also reach me at my facsimile number (202) 690-4040 or e-mail address (sally.white@fsis.usda.gov).

Sincerely,

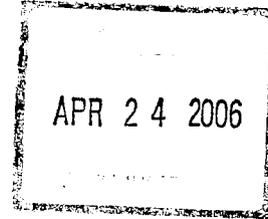
Sally White  
Director  
International Equivalence Staff  
Office of International Affairs

Enclosure

cc:

William Westman, Minister Counselor, US Embassy, Bonn  
Friedrich Wacker, Agricultural Counselor, Embassy of Germany  
Norval Francis, Minister Counselor, US Mission to the EU, Brussels  
Canice Nolan, EU Mission to the US, Washington, DC  
Scott Bleggi, FAS Area Officer  
Barbara Masters, Administrator, FSIS  
Linda Swacina, Executive Director, FSIA, OIA  
Karen Stuck, Assistant Administrator, OIA  
William James, Deputy Asst. Administrator, OIA  
Donald Smart, Director, Review Staff, OPEER  
Clark Danford, Director, IEPS, OIA  
Sally White, Director, IES, OIA  
Mary Stanley, Director, IID, OIA  
Barbara McNiff, Director, FSIS Codex Programs Staff  
Gerald Zirnstein, IES, OIA  
Amy Winton, State Department  
Country File (Germany FY 2006 Annual Audit)

**FINAL**



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

NOVEMBER 24 THROUGH DECEMBER 20, 2005

Food Safety and Inspection Service  
United States Department of Agriculture

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  - 13.4 Monthly Reviews
  - 13.5 Inspection System Controls

14. CLOSING MEETING

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  |
| LAVES             | Exporting Establishment Certifying Authority (Landesamt für Verbraucherschutz und Lebensmittelsicherheit, Lower Saxony State Office of Consumer Protection and Food Safety) |
| <i>Lm</i>         | <i>Listeria monocytogenes</i>   |
| 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 November 24 through December 20, 2005.

An opening meeting was held on November 24, 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 a cold storage 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, two federal state inspection offices (one in the State of Bavaria in Munich and one in the state of Lower Saxony in Hannover), one Regional inspection office within the State of Bavaria in Ansbach, the offices of LAVES in Oldenburg, two district inspection offices (one in the State of Bavaria in Ansbach and one in the State of Lower Saxony in Westerstede), one government laboratory performing *Listeria monocytogenes* and *Salmonella* analysis on U.S.-destined product, one government laboratory performing residue analysis on U.S.-destined product, all five certified meat processing establishments, and one cold storage establishment proposed for future certification.

| Competent Authority Visits     |          |   | Comments   |
|--------------------------------|----------|---|--|
| Competent Authority            | Central  | 1 |  |
|                                | State    | 2 |  |
|                                | Regional | 1 |  |
|                                | LAVES    | 1 |  |
|                                | District | 2 |  |
| Laboratories                   |          | 2 |  |
| Meat Processing Establishments |          | 5 |  |
| Cold Storage 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, regional, 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 five processing establishments and one cold storage establishment proposed for future certification. The fourth part involved visits to two government laboratory. The Bavarian State Laboratory for Health and Food Safety (LGL), located in Erlangen, was conducting analyses for the presence of *Listeria monocytogenes* and *Salmonella*. The LAVES laboratory, located in Hannover, was conducting residue analysis on domestic product and export product destined for export to the United States.

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 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](http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp)

### May 2004 Audit

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

### April 2005 Audit

During the April 2005 FSIS audit of Germany’s meat inspection system, the following deficiencies were found:

- In one establishment, government inspection records were unavailable at the time of the audit.
- Further HACCP training was needed for government inspectors assigned to the pork slaughter establishment, proposed for certification.
- The pork slaughter establishment audited, if it were certified, would have been delisted.
- In four of five establishments audited SSOP deficiencies were found.
- In four of five establishments audited deficiencies were found in the implementation of SPS or EC Directive 64/433 requirements.
- The pork slaughter facility, proposed for certification, had deficiencies in selection of Critical Control Points in its HACCP plan.
- No equivalence determination had been made for the collection and testing of generic *E. coli* samples by government officials in the pork slaughter facility, proposed for certification.
- Ready-to-eat products from eligible establishments were not being tested for both *Lm* and *Salmonella* as required.

## 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.

#### 6.2.3 Assignment of Competent, Qualified Inspectors

Competent and qualified inspectors are assigned to the certified establishments.

#### 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 that 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 two State inspection offices, one in the State of Bavaria in Munich and one in the State of Lower Saxony in Hannover, one Regional inspection office within the State of Bavaria in Ansbach, and two district inspection offices one within the State of Bavaria in Ansbach and one within the State of Lower Saxony in Westerstede.

No concerns arose as a result of these interviews.

## 7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of five processing establishments. None of these establishments were delisted by Germany. One of these establishments received a Notice of Intent to Delist (NOID) from the German inspection officials.

In addition, one cold storage establishment proposed for future certification was presented during this audit. This establishment would have met requirements for cold stores eligible to handle export products for the United States.

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.

Residue and 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 residue laboratory was reviewed:

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

The following microbiology laboratory was reviewed:

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

This laboratory was performing analyses of ready-to-eat products for both *Listeria monocytogenes* and *Salmonella*, as required.

No concerns arose as a result of these reviews.

## 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 one 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

No slaughter facilities are currently certified in Germany.

### 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 five certified processing establishments.

In two of five establishments audited, HACCP deficiencies were noted.

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

### 11.3 Testing for Generic *E. coli*

No slaughter facilities are currently certified in Germany.

#### 11.4 Testing of Ready-to-Eat Products

Four 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 four establishments, the government was 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.

The following residue laboratory was reviewed:

LAVES, a government laboratory in Hannover, performs residue analyses on product destined for the EC and the United States.

No concerns arose as a result of this review.

#### 12.1 FSIS Requirements

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

#### 12.2 EC Directive 96/22

The following residue laboratory was reviewed:

LAVES, a government laboratory in Hannover, performs residue analyses on product destined for the EC and the United States.

No concerns arose as a result of this review.

### 12.3 EC Directive 96/23

The following residue laboratory was reviewed:

LAVES, a government laboratory in Hannover, performs residue analyses on product destined for the EC and the United States.

No concerns arose as a result of this review.

## 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

No slaughter facilities are currently certified in Germany.

### 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 December 20, 2005, in Berlin with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

Dr. Timothy B. King  
Senior Program Auditor

A handwritten signature in black ink, appearing to read "Timothy B. King", written over a horizontal line.

15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms

Foreign Country Response to Draft Final Audit Report

### Foreign Establishment Audit Checklist

|   |                             |   |                               |
|---|-----------------------------|---|-------------------------------|
| 1. ESTABLISHMENT NAME AND LOCATION<br>Meica Meat Packing Plant of Ammerland<br>Postfach 1160<br>Edeweicht Niedersachsen<br>DE | 2. AUDIT DATE<br>12/09/2005 | 3. ESTABLISHMENT NO.<br>A-IV-10   | 4. NAME OF COUNTRY<br>Germany |
| 5. NAME OF AUDITOR(S)<br>Timothy B. King, DVM   |                             | 6. TYPE OF AUDIT<br><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                                     | O             |
| 9. Signed and dated SSOP, by on-site or overall authority.   |               | 35. Residue   | O             |
| <b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>  |               | <b>Part E - Other Requirements</b>                      |               |
| 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              | X             |
| <b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>  |               | 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                           |               |
| <b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>   |               | 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.   |               | <b>Part F - Inspection Requirements</b>                 |               |
| 22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. |               | 49. Government Staffing                                 |               |
| <b>Part C - Economic / Wholesomeness</b>   |               | 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             |
| <b>Part D - Sampling Generic E. coli Testing</b>   |               | 55. Post Mortem Inspection                              | O             |
| 27. Written Procedures   | O             | <b>Part G - Other Regulatory Oversight Requirements</b> |               |
| 28. Sample Collection/Analysis   | O             | 56. European Community Directives                       | X             |
| 29. Records  | O             | 57. Monthly Review                                      |               |
| <b>Salmonella Performance Standards - Basic Requirements</b>   |               | 58.   |               |
| 30. Corrective Actions   | O             | 59.   |               |
| 31. Reassessment   | O             |   |               |
| 32. Written Assurance  | O             |   |               |

60. Observation of the Establishment

Est.#: A-IV-10  
City and Country: Edeweicht, Germany  
Date: 12/09/2005

39- 51/56 In the casing filling area there was a build up of black grease on an overhead rail and drops of the same material on the floor below the rail in front of the sausage cooking units. 9CFR416.4(b), EC 64/433Annex I(V)(18)(3)

61. NAME OF AUDITOR

Timothy B. King, DVM

62. AUDITOR SIGNATURE AND DATE

*Timothy B. King, DVM* 12/22/05

### Foreign Establishment Audit Checklist

|   |   |                                 |   |
|---|---|---------------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION<br>Klumper GmbH & Co KG<br>Ratsherr-schlikker-strasse 40<br>Schutterof Niedersachsen<br>48465 DE | 2. AUDIT DATE<br>12/07/2005                   | 3. ESTABLISHMENT NO.<br>A-EV-29 | 4. NAME OF COUNTRY<br>Germany   |
|   | 5. NAME OF AUDITOR(S)<br>Timothy B. King, DVM |                                 | 6. TYPE OF AUDIT<br><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                                     | O             |
| 9. Signed and dated SSOP, by on-site or overall authority.   |               | 35. Residue   | O             |
| <b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>  |               | <b>Part E - Other Requirements</b>                      |               |
| 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              | X             |
| <b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>  |               | 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                           |               |
| <b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>   |               | 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.   |               | <b>Part F - Inspection Requirements</b>                 |               |
| 22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. | X             | 49. Government Staffing                                 |               |
| <b>Part C - Economic / Wholesomeness</b>   |               | 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             |
| <b>Part D - Sampling Generic E. coli Testing</b>   |               | 55. Post Mortem Inspection                              | O             |
| 27. Written Procedures   | O             | <b>Part G - Other Regulatory Oversight Requirements</b> |               |
| 28. Sample Collection/Analysis   | O             | 56. European Community Directives                       | X             |
| 29. Records  | O             | 57. Monthly Review                                      |               |
| <b>Salmonella Performance Standards - Basic Requirements</b>   |               | 58.   |               |
| 30. Corrective Actions   | O             | 59.   |               |
| 31. Reassessment   | O             |   |               |
| 32. Written Assurance  | O             |   |               |

## 60. Observation of the Establishment

Est.#: A-EV-29

City and Country: Schutterf, Germany

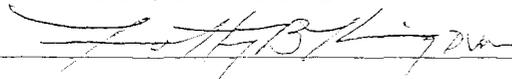
Date: 12/07/2005

- 22- 51 The establishment HACCP records documenting ongoing verification of the monitoring of the CCPs did not include either direct observation of the monitoring activity or calibration of process monitoring instruments. 9CFR417.4(a)(2), 9CFR417.8
- 39- 51/56 Rust was observed on switches and bolts of the overhead rails in the product receiving cooler and on a hanger holding a tray over a product cutting table. 9CFR416.2(b)(1), 9CFR416.4(b), EC 64/433(V)(18)(c)
- 46- 51/56 In the "salting" and "burning" rooms large bins, containing exposed product, were stacked on top of one another after they had contacted the wet processing room floor. 9CFR416.4(d), EC 64/433(V)(20)

61. NAME OF AUDITOR

Timothy B. King, DVM

62. AUDITOR SIGNATURE AND DATE

 12/22/05

### Foreign Establishment Audit Checklist

|  |                             |   |                               |
|--|-----------------------------|---|-------------------------------|
| 1. ESTABLISHMENT NAME AND LOCATION<br>Abraham Ammerlander Ham GmbH & Co KG<br>Osterschepser Strasse 40<br>26188 Edeweicht Niedersachsen DE | 2. AUDIT DATE<br>12/08/2005 | 3. ESTABLISHMENT NO.<br>A-EV-35   | 4. NAME OF COUNTRY<br>Germany |
| 5. NAME OF AUDITOR(S)<br>Timothy B. King, DVM  |                             | 6. TYPE OF AUDIT<br><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)<br>Basic Requirements   | Audit Results | Part D - Continued Economic Sampling                    | Audit Results |
|--|---------------|---|---------------|
| 7. Written SSOP  |               | 33. Scheduled Sample                                    |               |
| 8. Records documenting implementation.   |               | 34. Species Testing                                     | O             |
| 9. Signed and dated SSOP, by on-site or overall authority.   |               | 35. Residue   | O             |
| <b>Sanitation Standard Operating Procedures (SSOP)<br/>Ongoing Requirements</b>  |               | <b>Part E - Other Requirements</b>                      |               |
| 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 SSOPs 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              |               |
| <b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>  |               | 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                           |               |
| <b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>   |               | 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.   |               | <b>Part F - Inspection Requirements</b>                 |               |
| 22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. |               | 49. Government Staffing                                 |               |
| <b>Part C - Economic / Wholesomeness</b>   |               | 50. Daily inspection Coverage                           |               |
| 23. Labeling - Product Standards   |               | 51. Enforcement   |               |
| 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             |
| <b>Part D - Sampling<br/>Generic E. coli Testing</b>   |               | 55. Post Mortem Inspection                              | O             |
| 27. Written Procedures   | O             | <b>Part G - Other Regulatory Oversight Requirements</b> |               |
| 28. Sample Collection/Analysis   | O             | 56. European Community Directives                       |               |
| 29. Records  | O             | 57. Monthly Review                                      |               |
| <b>Salmonella Performance Standards - Basic Requirements</b>   |               | 58.   |               |
| 30. Corrective Actions   | O             | 59.   |               |
| 31. Reassessment   | O             |   |               |
| 32. Written Assurance  | O             |   |               |

60. Observation of the Establishment

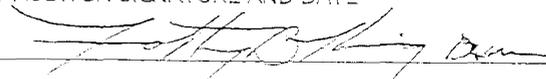
Est.#: A-EV-35  
City and Country: Edeweicht, Germany  
Date: 12/08/2005

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

61. NAME OF AUDITOR

Timothy B. King, DVM

62. AUDITOR SIGNATURE AND DATE

 12/22/05

### Foreign Establishment Audit Checklist

|   |   |                                  |   |
|---|---|----------------------------------|---|
| 1. ESTABLISHMENT NAME AND LOCATION<br>Abraham Ham GmbH & Co.<br>Königstrasse [4-4]<br>Barsel-Harkebruegge Niedersachsen<br>26676 DE | 2. AUDIT DATE<br>12/13/2005                   | 3. ESTABLISHMENT NO.<br>A-IV-191 | 4. NAME OF COUNTRY<br>Germany   |
|   | 5. NAME OF AUDITOR(S)<br>Timothy B. King, DVM |                                  | 6. TYPE OF AUDIT<br><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)<br>Basic Requirements   | Audit Results | Part D - Continued Economic Sampling                    | Audit Results |
|--|---------------|---|---------------|
| 7. Written SSOP  |               | 33. Scheduled Sample                                    |               |
| 8. Records documenting implementation.   |               | 34. Species Testing                                     | O             |
| 9. Signed and dated SSOP, by on-site or overall authority.   |               | 35. Residue   | O             |
| <b>Sanitation Standard Operating Procedures (SSOP)<br/>Ongoing Requirements</b>  |               | <b>Part E - Other Requirements</b>                      |               |
| 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              | X             |
| <b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>  |               | 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                           |               |
| <b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>   |               | 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.   |               | <b>Part F - Inspection Requirements</b>                 |               |
| 22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. |               | 49. Government Staffing                                 |               |
| <b>Part C - Economic / Wholesomeness</b>   |               | 50. Daily Inspection Coverage                           |               |
| 23. Labeling - Product Standards   |               | 51. Enforcement   |               |
| 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             |
| <b>Part D - Sampling<br/>Generic E. coli Testing</b>   |               | 55. Post Mortem Inspection                              | O             |
| 27. Written Procedures   | O             | <b>Part G - Other Regulatory Oversight Requirements</b> |               |
| 28. Sample Collection/Analysis   | O             | 56. European Community Directives                       | X             |
| 29. Records  | O             | 57. Monthly Review                                      |               |
| <b>Salmonella Performance Standards - Basic Requirements</b>   |               | 58.   |               |
| 30. Corrective Actions   | O             | 59.   |               |
| 31. Reassessment   | O             |   |               |
| 32. Written Assurance  | O             |   |               |

60. Observation of the Establishment

Est.#: A-IV-191  
City and Country: Barssel-Harkebruegge, Germany  
Date: 12/13/2005

39- 56 Water was observed dripping from the drain pipe of an air evaporation unit above an area where employees worked. 9CFR416.2(e)(3), EC 64/433(I)(5)

Immediate corrective action was implemented by the establishment.

61. NAME OF AUDITOR

Timothy E. King, DVM

62. AUDITOR SIGNATURE AND DATE

*Timothy E. King DVM* 12/22/05

### Foreign Establishment Audit Checklist

|  |   |   |                               |
|--|---|---|-------------------------------|
| 1. ESTABLISHMENT NAME AND LOCATION<br>Hans Kupfer & Sohn GmbH & Co. KG<br>Mausendorfer Weg 11<br>Heilsbronn<br>91560 | 2. AUDIT DATE<br>11/29/2005                   | 3. ESTABLISHMENT NO.<br>A-EV-218  | 4. NAME OF COUNTRY<br>Germany |
|  | 5. NAME OF AUDITOR(S)<br>Timothy B. King, DVM | 6. TYPE OF AUDIT<br><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                                     | O             |
| 9. Signed and dated SSOP, by on-site or overall authority.   |               | 35. Residue   | O             |
| <b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>  |               | <b>Part E - Other Requirements</b>                      |               |
| 10. Implementation of SSOP's, including monitoring of implementation.  | X             | 36. Export  |               |
| 11. Maintenance and evaluation of the effectiveness of SSOP's.   |               | 37. Import  |               |
| 12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.                                 |               | 38. Establishment Grounds and Pest Control              |               |
| 13. Daily records document item 10, 11 and 12 above.   | X             | 39. Establishment Construction/Maintenance              |               |
| <b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>  |               | 40. Light   |               |
| 14. Developed and implemented a written HACCP plan.  |               | 41. Ventilation   | X             |
| 15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.          |               | 42. Plumbing and Sewage                                 |               |
| 16. Records documenting implementation and monitoring of the HACCP plan.   | X             | 43. Water Supply  |               |
| 17. The HACCP plan is signed and dated by the responsible establishment individual.  |               | 44. Dressing Rooms/Lavatories                           |               |
| <b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>   |               | 45. Equipment and Utensils                              | X             |
| 18. Monitoring of HACCP plan.  |               | 46. Sanitary Operations                                 | X             |
| 19. Verification and validation of HACCP plan.   | X             | 47. Employee Hygiene                                    |               |
| 20. Corrective action written in HACCP plan.   | X             | 48. Condemned Product Control                           |               |
| 21. Reassessed adequacy of the HACCP plan.   |               | <b>Part F - Inspection Requirements</b>                 |               |
| 22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. | X             | 49. Government Staffing                                 |               |
| <b>Part C - Economic / Wholesomeness</b>   |               | 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             |
| <b>Part D - Sampling Generic E. coli Testing</b>   |               | 55. Post Mortem Inspection                              | O             |
| 27. Written Procedures   | O             | <b>Part G - Other Regulatory Oversight Requirements</b> |               |
| 28. Sample Collection/Analysis   | O             | 56. European Community Directives                       | X             |
| 29. Records  | O             | 57. Monthly Review                                      |               |
| <b>Salmonella Performance Standards - Basic Requirements</b>   |               | 58. <b>NOID ISSUED</b>                                  | X             |
| 30. Corrective Actions   | O             | 59.   |               |
| 31. Reassessment   | O             |   |               |
| 32. Written Assurance  | O             |   |               |

## 80. Observation of the Establishment:

Est.#: A-EV-218

City and Country: Heilsbronn, Germany

Date: 11/29/2005

- 10- 51 The written Sanitation Standard Operating Procedures (SSOP) did not clearly state the daily operational sanitation activities that the establishment would monitor or the frequency of that monitoring. 9CFR416.13(b), 9CFR416.17
- 13- 51 The SSOP records did not indicate that the responsible person had monitored pre-operational sanitation activities and procedures on a daily basis, and documentation of corrective actions failed to address measures to prevent recurrence. 9CFR416.16(a), 9CFR416.17
- 16-51 The establishment Hazard Analysis Critical Control Point (HACCP) plan did not specify or include records that would be used for monitoring Critical Control Points (CCP) or for verification of monitoring activities and the HACCP plan did not specify the critical limit that would be used at the CCP for detection of metal in products. 9CFR417.2(c), 9CFR417.8
- 19-51 The HACCP plan did not identify the frequency of monitoring at the CCPs or address the frequency and person responsible for conducting verification of monitoring activities. 9CFR417.2(c), 9CFR417.8
- 20- 51 The HACCP plan did not describe the corrective actions to be taken in response to a deviation from a critical limit. 9CFR417.3(a), 9CFR417.8
- 22- 51 Identifiable documentation of HACCP monitoring and ongoing verification had not been produced by the establishment. 9CFR417.5(a)(3), 9CFR417.8
- 41- 56 Water was observed dripping from the ceiling of the raw product receiving room in an area where exposed product was held. 9CFR416.2(d), EC64/433Annex I(I)(e)
- 41- 51/56 Beaded condensation was observed on ceilings and doorframes in several areas of the plant. No product contamination was observed as a result of the dripping water or condensation. 9CFR416.2(d), EC64/433 Annex I(I)(e)
- 45- 51/56 Three stainless steel, wheeled trucks which had been cleaned and were ready for use had pieces of fat and product residue (up to .5 cm wide and 3 cm long) present on areas that could contact product. 9CFR416.3(a), EC64/433Annex I(V)(18)(c)
- 46- 51/56 A bottle labeled for equipment sanitation and an unlabeled pump, spray tank used for pre-op cleaning were observed next to a product slicing machine during production operations. 9CFR416.4(c), EC64/433 Annex I(V)(23)

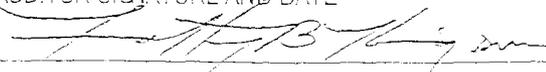
The establishment instituted immediate corrective actions regarding items 41, 45, 46

- 58 A Notice of Intent to Delist was issued on 11/29/2005 by the German inspection officials as a result of these finding.

81. NAME OF AUDITOR

Timothy B. King, DVM

82. AUDITOR SIGNATURE AND DATE


 12/22/05

### Foreign Establishment Audit Checklist

|  |                             |   |                               |
|--|-----------------------------|---|-------------------------------|
| 1. ESTABLISHMENT NAME AND LOCATION<br>Franz Haake Cold Storage<br>Kranstrasse 1<br>26160 Bad Zwischenahn, DE | 2. AUDIT DATE<br>12/14/2005 | 3. ESTABLISHMENT NO.<br>EK-711  | 4. NAME OF COUNTRY<br>Germany |
| 5. NAME OF AUDITOR(S)<br>Timothy B. King, DVM  |                             | 6. TYPE OF AUDIT<br><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  | O             | 33. Scheduled Sample                                    | O             |
| 8. Records documenting implementation.   | O             | 34. Species Testing                                     | O             |
| 9. Signed and dated SSOP, by on-site or overall authority.   | O             | 35. Residue   | O             |
| <b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>  |               | <b>Part E - Other Requirements</b>                      |               |
| 10. Implementation of SSOP's, including monitoring of implementation.  | O             | 36. Export  |               |
| 11. Maintenance and evaluation of the effectiveness of SSOP's.   | O             | 37. Import  |               |
| 12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.                                 | O             | 38. Establishment Grounds and Pest Control              |               |
| 13. Daily records document item 10, 11 and 12 above.   | O             | 39. Establishment Construction/Maintenance              |               |
| <b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>  |               | 40. Light   |               |
| 14. Developed and implemented a written HACCP plan.  | O             | 41. Ventilation   |               |
| 15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.          | O             | 42. Plumbing and Sewage                                 |               |
| 16. Records documenting implementation and monitoring of the HACCP plan.   | O             | 43. Water Supply  |               |
| 17. The HACCP plan is signed and dated by the responsible establishment individual.  | O             | 44. Dressing Rooms/Lavatories                           |               |
| <b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>   |               | 45. Equipment and Utensils                              |               |
| 18. Monitoring of HACCP plan.  | O             | 46. Sanitary Operations                                 |               |
| 19. Verification and validation of HACCP plan.   | O             | 47. Employee Hygiene                                    |               |
| 20. Corrective action written in HACCP plan.   | O             | 48. Condemned Product Control                           |               |
| 21. Reassessed adequacy of the HACCP plan.   | O             | <b>Part F - Inspection Requirements</b>                 |               |
| 22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. | O             | 49. Government Staffing                                 |               |
| <b>Part C - Economic / Wholesomeness</b>   |               | 50. Daily Inspection Coverage                           | O             |
| 23. Labeling - Product Standards   | O             | 51. Enforcement   |               |
| 24. Labeling - Net Weights   | O             | 52. Humane Handling                                     | O             |
| 25. General Labeling   | O             | 53. Animal Identification                               | O             |
| 26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins/Moisture)  | O             | 54. Ante Mortem Inspection                              | O             |
| <b>Part D - Sampling Generic E. coli Testing</b>   |               | 55. Post Mortem Inspection                              | O             |
| 27. Written Procedures   | O             | <b>Part G - Other Regulatory Oversight Requirements</b> |               |
| 28. Sample Collection/Analysis   | O             | 56. European Community Directives                       |               |
| 29. Records  | O             | 57. Monthly Review                                      |               |
| <b>Salmonella Performance Standards - Basic Requirements</b>   |               | 58.   |               |
| 30. Corrective Actions   | O             | 59.   |               |
| 31. Reassessment   | O             |   |               |
| 32. Written Assurance  | O             |   |               |

60. Observation of the Establishment

Est.#: EK-711, cold stores  
City and Country: Bad Zwischenahn, Germany  
Date: 12/14/2005

This is a non-certified establishment that the government of Germany requested to be visited and reviewed.

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

*F. H. Blum* 12/22/05



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

**Per e-mail and fax:**

USDA FSIS  
Ms. Sally White, Director  
International Equivalence Staff  
Office of International Affairs  
Room 2137 South Building  
1400 Independence Avenue, SW  
Washington, D. C., 20250  
U. S. A.

**E-mail copy to**

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

Embassy of the Federal Republic  
of Germany  
4645 Reservoir Rd.  
Washington, D. C., 20007, U. S. A

**Dr. Antje Jaensch**

Scientific Officer

Unit 106

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ments and complaints  
INTERNET http://www.bvl.bund.de

REFERENCE 3620-01/236433  
(please quote in response)

YOUR REFERENCE/ YOUR NOTE FROM Your letter of 14 February 2006

DATE 19 April 2006

**Draft final report on FSIS audit in Germany from November 24 to December 20, 2005;  
Comments by Germany**

Dear Mrs. White,

Please find enclosed with this letter the comments of the federal states of Bavaria and Lower Saxony on the draft final report of last year's second FSIS meat inspection system audit in Germany. For easy reference, there is also an English translation of the comments of the Bavarian regional Government of Central Franconia and the Lower Saxony Ministry of Rural Areas, Food, Agriculture and Consumer Protection.

The federal states of Lower Saxony and Bavaria report that the deficiencies noted during the audit have been eliminated. With regard to establishment A-EV 218 in particular, the competent authority notes that necessary corrective action was taken and the relevant official report sent to FSIS within the 30-day deadline set by the NOID issued on 29 November 2005. The company was therefore maintained on the list of establishments eligible to export meat products to the US.

Yours sincerely,

*(signed)*

Dr. Antje Jaensch

**Annex**

From: Government of Central Franconia  
To: Federal Office of Consumer Protection and Food Safety (BVL)  
Dated: 03 March 2006

--- Translation provided by BVL ---

**Comments by the Government of Central Franconia on the draft report on FSIS mission to Germany from 24 November to 20 December 2005**

Dear madams/sirs,

The Government of Central Franconia has the following comments upon the draft report on the FSIS mission to Germany from 24 November to 20 December 2005:

**Item no. 3 „Protocol“**  
**Item no. 4 „Legal Basis for the Audit“**  
**item no. 9.3 „EC Directive 64/433“ :**

The draft report cites Council Directive 64/633/EEC on health problems affecting intra-Community trade in fresh meat. That directive settles the conditions of authorisation of slaughtering and cutting plants only (German abbreviations: ES and EZ plants), but not the conditions for processing plants.

The EU authorisation of meat processing plants (EV plants) is based on the relevant requirements fixed in Council Directive 77/99/EEC on health problems affecting the production and marketing of meat products.

**Individual Establishment Reports:**  
**Audit Checklist - Establishment No. EV 218 , Firma Hans Kupfer & Sohn,**  
**City and Country: Heilsbronn, Germany**  
**Date: 11/29/2005**

To point 10-51:

The written SSOP plan has been re-designed.

It is arranged in groups of measures carried out as pre-operational, operational, daily, general, and training measures.

The plan spells out in detail which hygiene activities are performed and at what frequency, who is responsible for them, and how they are to be monitored and documented.

To point 13-51:

As a preoperational measure, the cleaning personnel keep daily documentation that they finished cleaning according to cleaning instructions.

Also before beginning of production, the shift leader/foreman checks the hygienic condition of the production room and production surfaces and confirms performance of the cleaning protocol with his signature.

During operation, the shift leader checks the hygienic condition of the room and equipment

and signs a hygiene protocol if hygiene is perfect.

Any deficiencies, corrective and preventive measures must be described in the cleaning and in the hygiene protocol.

Successful performance of corrective measures is checked by the next superior, and verified and signed by the company's supervisor.

To points 16-51, 19-51, 20-51, 22-51 - HACCP:

The HACCP plan has been completely revised.

A hazard analysis of all steps of the production process identifies the CCPs in the course of production.

Critical limits, the required frequency of monitoring, verification and validation are described for all CCPs, including the metal detector.

The responsibilities for monitoring at the CCPs and verification of monitoring activities are defined in writing.

The plan fixes corrective and preventive measures in the case of deviation from the critical limit.

Performance of controls of the CCPs is documented in the form sheets for the respective CCPs.

The documentation of CCP monitoring is checked by official supervisors (frontline supervisor, first-line supervisor).

To point 41-56, 41-51/56:

Basic hygiene deficiencies were all eliminated immediately.

Product which might have been contaminated by condense water was immediately removed from potential dripping zone and subjected to a new heating process.

Workers were once again made aware of the risk of condense water formation.

To prevent condense water, the company's technicians measured indoor humidity in the critical rooms. Some constructional changes and technical alterations of ventilation control systems were made, including a sealing of free spaces between the ceiling and condenser, and modification of indoor humidity by warming up the air in the rooms and changing condenser-directed air streams.

An instruction for immediate measures in the case of dripping water has been written down and is valid for all staff members of the plant.

To point 45-51/56:

Wheeled tubs with production residues of fat and meat were immediately removed from the production rooms.

All production surfaces with food contact (such as tubs, conveyor belts, cutting boards, etc.) are included in the operational hygiene protocol.

To point 46-51/56:

The alcohol spray bottle used for surface disinfection was immediately removed.

There is a special rack to leave detergents and disinfectants.

To point 58 - NOID:

The NOID issued to establishment A-EV 218 on 29 November 2005 caused the company, the official control body (local government with veterinary office of Ansbach), and the establishment authorisation body (regional *Government of Central Franconia*) to introduce the following measures:

Establishment A-EV 218 appointed a new internal supervisor.

The frontline supervisor wrote an official protocol of deficiencies noted during the inspection on 29 November 2005 and tabled it at the company on 30 November 2005.

The company completed a supplement to the protocol, in which the measures which were ordered to eliminate the deficiencies were filled in, the company's supervisor checked elimination of the deficiencies and signed, and preventive measures were documented.

By letter of 05 December 2005 (ref. no. 621-2625.204), the regional Government of Central Franconia as the authorisation body notified the company about warned delistment unless the deficiencies noted by the frontline supervisor would be eliminated within 30 days at the latest.

Apart from regular controls of the company by the frontline and first-line supervisors, there was a meeting among the Government of Central Franconia, the local veterinary office, and establishment A-EV 218 in the Ansbach local government office on 15 December 2005 to verify that documentation deficiencies had been eliminated. At this meeting, the government parties examined the company's revised SSOP and HACCP plans.

The protocol of deficiencies including the list of corrective measures performed was tabled at the veterinary office on 19 December 2005.

The Government of Central Franconia, as the authorisation body, and Ansbach Veterinary Office as the local official control body finally verified during an on-site inspection of establishment A-EV 218 on 27 December 2005 that deficiencies had been efficiently and completely eliminated.

With deficiencies eliminated and relevant preventive measures taken within the 30-day deadline given, the Government of Central Franconia as the authorisation body judged that the establishment did not need to be delisted.

Performance of corrective and preventive measures in establishment A-EV 218 was confirmed in an official letter sent by the Government of Central Franconia to

Director Mrs. Sally White  
United States Department of Agriculture,  
Washington DC 202-720-6400

via Germany's Federal Office of Consumer Protection and Food (BVL) on 27 December 2005 (reference number 621-2625.204).

With kind regards  
(signed:)  
Dr. Kathrin Leip  
Veterinary Director

II Copy by e-mail to:

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