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

Dr. Klaus Lorenz
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Unit 106, Food of Animal Origin and Food Hygiene
Federal Office of Consumer Protection and Food Safety
Mauerstr. 39 – 42
PO Box 100214
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GERMANY

SEP 18 2007

Dear Dr. Lorenz:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Germany's meat inspection system April 16 to May 2, 2007. Comments from Germany have been included in the final audit report. Enclosed is a copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (402) 344-5100, by facsimile at (402) 344-5169, or electronic mail at donald.smart@fsis.usda.gov.

Sincerely,

Donald Smart
Director
International Audit Staff
Office of International Affairs

Enclosure

FINAL

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

APRIL 16, THROUGH MAY 2, 2007

Food Safety and Inspection Service
United States Department of Agriculture

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14. CLOSING MEETING

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority (Bundesamt fur Verbraucherschutz und Lebensmittelsichereit, BVL-Federal Office of Consumer Protection and Food Safety)
E. coli	*Escherichia coli*
FSIS	Food Safety and Inspection Service
LAVES	Exporting Establishment Certifying Authority in the Federal State of Lower Saxony (Landesamt fur Verbraucherschutz und Lebensmittelsicherheit, Lower Saxony State Office of Consumer Protection and Food Safety)
Lm	*Listeria monocytogenes*
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
Salmonella	*Salmonella* 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 16, through May 2, 2007.

An opening meeting was held on April 16, 2007, 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. The 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.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA in Berlin, one Federal State inspection office in the State of Mecklenburg-Western Pomerania in Schwerin, the offices of LAVES in Oldenburg, one district inspection office in the State of Mecklenburg-Western Pomerania in Ludwigslust, one government laboratory performing *Listeria monocytogenes* and *Salmonella* analysis on United States-destined product in Oldenburg, and meat processing establishments in Schuttorf, Bassel-Harkebrugge, and Wittenburg.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	State	1	
	LAVES	1	
	District	1	
Laboratories		1	
Meat Processing Establishments		3	

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 three processing establishments. The fourth part involved a visit to one government laboratory. The LAVES Veterinarinstitut in Oldenburg, was conducting analyses for the presence of *Listeria monocytogenes* and *Salmonella* in product destined for 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 (SSOP), (2) animal disease controls, (3) processing controls, including the implementation and operation of Hazard Analysis Critical Control Point (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 Beta-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

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 product from eligible establishments was not being tested for both *Listeria monocytogenes* and *Salmonella* as required.

November 2005 Audit

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

- In one of five establishments, the SSOP implementation requirements and record keeping requirements were not met.
- In four of five establishments, the provisions of the Sanitation Performance Standards and the provisions of EC Directive 64/433 were not effectively implemented.
- In two of the five establishments, the HACCP plan did not meet the U.S. regulatory requirements for implementation and/or documentation.
- One Notice of Intent to Delist (NOID) was issued during this audit.

6. MAIN FINDINGS

6.1 Legislation

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

6.2 Government Oversight

The CCA for Germany is the Federal Office of Consumer Protection and Food Safety (BVL). This office is the contact point for export inspections and 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 activities. This office is also responsible for verifying that appropriate corrective actions are taken and communicating that information to third parties when deficiencies are noted during audits.

6.2.1 CCA Control Systems

Although the CCA has authority to certify and de-certify establishments the 16 Federal States (Lander) are responsible for administration, coordination, and supervision of inspection activities in their respective State. Each of the 16 Federal States is divided into one or more Districts. The District Office controls, implements, and enforces Federal meat inspection regulations through the individual local offices. The Federal States communicate with the German Federal Government and other Federal States on matters of food and feed laws through working groups or committees that are a responsibility of a Departmental Unit (Department 1, Unit 103) of the BVL.

6.2.2 Ultimate Control and Supervision

The Federal Office of Consumer Protection and Food Safety is the responsible authority for matters concerning exports, including the authority to certify and decertify establishments for such export, and communication with entities outside Germany. Control and supervision over official inspection activities for all establishments that export meat products rests with the Federal State Ministry in the respective Federal State. Federal law in Germany does not currently allow the Federal Office to audit functions of the Federal State Ministry. Regarding the separation of authorities the following is noted:

- The CCA failed to control and supervise the review and certification process, for establishments exporting to the U.S., conducted by the Mecklenburg-Western Pomerania Ministry of Agriculture and the Ludwigslust District Office of Veterinary Affairs.
- The CCA, with the concurrence of these authorities in the Federal State of Mecklenburg-Western Pomerania, permitted the certification of an establishment, which was found to have serious deficiencies in the implementation of HACCP requirements and in the implementation of requirements for *Listeria monocytogenes* testing.

6.2.3 Assignment of Competent, Qualified Inspectors

Responsibility for the assignment of competent, qualified inspectors lies with the District Veterinary Office where the establishment is located. Training is provided in accordance with EC Directives, Federal State laws, and the requirements of the inspectors' assignment. Regarding assignment of competent, qualified inspection personnel the following is noted:

- The State Ministry in Mecklenburg-Western Pomerania and the District Office in Ludwigslust appeared to be unaware of many of the HACCP requirements and the requirements for testing of ready-to-eat product and product contact surfaces for *Listeria monocytogenes.* This resulted in an establishment newly certified to export product to the U.S. receiving a Notice of Intent to Delist.

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 action 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. These documents included the organizational structure of the Federal Office of Consumer Protection and Food Safety, communications and translations of correspondences from FSIS, reports of investigations into violations of food safety regulations, employment contract addendums, and tables of laboratories providing testing for certified establishments.

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 Federal State Ministry office in the State of Mecklenburg-Western Pomerania in Schwerin, at the LAVES office in Oldenburg (responsible for export establishment certification activities in Lower Saxony), and one district inspection office within the State of Mecklenburg-Western Pomerania in Ludwigslust. The interviews focused on the communications between the BVL and the local authorities regarding U.S. export requirements, periodic supervisory reviews in the

certified establishments, procedures and documentation for daily inspection in U.S. export establishments, the training of inspection personnel regarding U.S. requirements, and the procedures for distribution and assessment of laboratory reports. Documents reviewed included copies of the Guidance Document for U.S. export establishments distributed by the BVL, daily inspection and periodic review documents from the establishments exporting to the U.S., e-mail files of communications concerning U.S. requirements, and laboratory analysis reports. As a result of these interviews the following was noted:

- The Guidance Document for inspection in U.S. export establishments, which is heavily utilized by the inspection personnel, has not been updated since 2005 and does not contain references to the *Listeria* Rule requirements.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited three of five processing establishments eligible to export to the U.S. None of these establishments were delisted by Germany. One of these establishments received a Notice of Intent to Delist (NOID). This establishment may retain its certification for export to the United States provided that they correct all deficiencies noted during the audit within 30 days of the date the establishment was reviewed.

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.

No residue laboratory was reviewed during this audit.

The following microbiology laboratory was reviewed:

The LAVES Veterinarinstitut, a government laboratory, in Oldenburg, Lower Saxony.

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 this review.

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 all three of the establishments audited, some of the SSOP implementation requirements or records requirements were not met.

Specific deficiencies are noted in the attached individual establishment reports.

9.2 Sanitation Performance Standards

There were no significant findings to note concerning SPS.

9.3 EC Directive 64/433

In two of the three 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 three certified processing establishments.

In two of three 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

All three of the 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 testing ready-to-eat products for both *Listeria monocytogenes* and *Salmonella* as required.

One of the three establishments had not evaluated the processing environment for post lethality exposure of Ready-to-Eat product to *Listeria monocytogenes* according to U.S. regulatory requirements.

11.5 EC Directive 64/433

In two of the three 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 laboratory was 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 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

No residue laboratory was reviewed during this audit.

12.3 EC Directive 96/23

No residue laboratory was 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 all three establishments audited, the inspection service was not enforcing some of the 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

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

13.4 Periodic Reviews

During this audit, it was found that in all establishments visited, periodic supervisory reviews were being performed and documented as required.

13.5 Inspection System Controls

The CCA had controls in place for prevention of commingling of product intended for export to the United States with product intended for the domestic market.

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

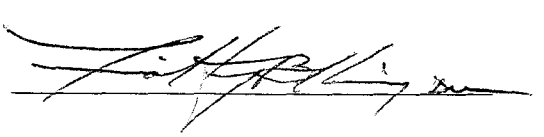
Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on May 2, 2007, in Berlin with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Dr. Timothy B. King
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	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Klumper GmbH & Company KG Ratsherr-Schlikker-Strabe 63 Schuttorf D-48465	19 Apr 2007	AEV29	Germany
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Timothy B. King, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment | Date: 19 Apr 2007 Est #: AEV29 (Klumper GmbH & Company KG [P]) (Schuttorf, Germany)

10/56 A) During the pre-operational sanitation inspection blood, fat, and product residue from a previous production period was observed on product contact surfaces in areas approved to start production. Immediate corrective action was taken by establishment personnel. [Regulatory references: 9CFR416.13(a) and EC Directive 64/433(V)(18)(c)]

B) During operational sanitation inspection, product residue from a previous production period was observed on clean racks used to hold product in the smoking chambers. Immediate corrective action was taken by establishment personnel. [9CFR416.13(c) and EC Directive 64/433(V)(18)(c)]

19/51 The HACCP plan did not identify the calibration of process monitoring instruments in the ongoing verification activities for one of the Critical Control Points (CCPs) which utilized a process monitoring instrument. [9CFR417.4(a)(2) and 9CFR417.8]

22/51 A) There was insufficient supporting documentation for the frequency chosen for conducting the ongoing verification activities associated with one of the CCPs. The frequency stated for ongoing verification activities was "randomly." [9CFR417.5(a)(2) and 9CFR417.8]

B) There was insufficient supporting documentation for the selection and maintenance of one Critical Control Point in the HACCP plan. This CCP also utilized the government's microbiological sampling as the ongoing verification of the monitoring. [9CFR417.5(a)(2) and 9CFR417.8]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Timothy B. King, DVM	DVM 19 Apr 2007

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Abraham Ham GmbH & Co Konigstrasse Barssel-Harkebrugge 26676	20 Apr., 2007	AIV191	Germany
	5. NAME OF AUDITOR(S) Timothy B. King, DVM		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Date: 04/20/07 Est #: AIV191 (Abraham Ham GmbH & Co [P]) (Barssel-Harkebrugge, Germany)

10/51/56 During operational sanitation inspection, establishment employees were observed placing cryovac packages of product on the processing tables, opening the packages, and placing the exposed product back on the tables without sanitizing the table surface or their hands. [Regulatory references: 9CFR416.13(c), 9CFR416.17, and EC Directive 64/433(V)(18)(c)]

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Timothy B. King, DVM	20 APRIL 2007

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Dr. Oetker Tiefkuhlprodukte Sudring 1 Wittenburg 19243	26 Apr., 2007	EV830	Germany
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Timothy B. King, DVM		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

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

60. Observation of the Establishment

Date: 04/26/07 Est #: EV830 (Dr. Oetker Tiefkuhlprodukte [P/CS]) (Wittenburg, Germany)

13/51 The daily records of the establishment did not sufficiently document the monitoring of the sanitation SOP's and any corrective actions taken. The monitoring records only contained a circle that was either checked or not checked and no explanation of the significance of the check mark was evident. The form used for this monitoring had no provision for documentation of corrective actions made in response to sanitation failures. [Regulatory references: 9CFR416.16(a) and 9CFR416.17]

18/51 A) The monitoring description of the HACCP plan Critical Control Point 1 (CCP 1) was missing a frequency for testing the metal detector with seeded samples which was the activity being performed. [9CFR417.2(c)(4) and 9CFR417.8]

B) The HACCP plan CCP 1 did not have an objective measure for documenting the product passed through the metal detector. [9CFR417.2(c)(6) and 9CFR417.8]

19/51 The Critical Control Point 1 (metal detection) did not describe the ongoing verification activities of the monitoring or the frequency at which they would be conducted. [9CFR417.4(a)(2) and 9CFR417.8]

58/51 The establishment had not evaluated its processing environment regarding post lethality exposure of product to *Listeria monocytogenes* and had not developed a plan for the testing of product contact surfaces or finished product for the presence of *Listeria monocytogenes*, Listeria *spp.*, or Listeria like organisms according to the requirements of the Listeria rule. [9CFR430.4]

59 After review of the findings and consultation with FSIS supervisors a Notice of Intent to Delist was issued effective May 1, 2007.

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Timothy B. King, DVM	26 APR 2007

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
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YOUR REFERENCE
YOUR LETTER OF

OUR REFERENCE BVL 106 3620-01/259780
(Please quote with answer)

DATE 06 September 2007

Draft final report of FSIS 2007 audit of German meat inspection system; Comments

Dear Dr. Smart

Please find enclosed with this letter the comments by the competent authorities of the states of Lower Saxony and Mecklenburg-Western Pomerania on the draft final report of this year's FSIS audit of the German meat inspection system for establishments eligible to export meat or meat products to the United States.

With regard to certification and de-certification of establishments for export activities (f. e. Point 2, 6.2, 6.2.1, 6.2.2 of the draft report) BVL wishes to clarify again that the competence for approval of establishments is within the responsibility of the federal states. Please refer to the Country Profile of Germany which has been sent to you. The Country Profile provides an

overview of legal bases and arrangement of responsibilities at federal and federal state level. In that framework, BVL advises the competent authorities at federal state level about FSIS requirements concerning the export of meat and meat products to the United States, and notifies approved establishments to FSIS.

The competent authorities report that the deficiencies noted during the audit both with regard to government oversight and implementation of some SSOP and HACCP requirements by the establishments have been eliminated. The pizza-producing establishment Dr. Oetker Tiefkühlkost (EV 830) in Wittenburg, Mecklenburg-Western Pomerania, in particular has revised its SSOP procedures as well as the HACCP plan and was thereby able to retain eligibility to export to the US.

For easy reference, I have added an English translation of the comments delivered by the Lower Saxony Ministry of Rural Areas, Food, Agriculture and Consumer Protection and by the Ministry of Agriculture, the Environment, and Consumer Protection of Mecklenburg-Western Pomerania. Please let me know if any further information is wanted.

Sincerely yours

(signed)

Dr. Antje Jaensch

Enclosure

Niedersächsisches Ministerium für den ländlichen Raum, Ernährung,
Landwirtschaft und Verbraucherschutz, Postfach 2 43, 30002 Hannover

**Niedersächsisches Ministerium
für den ländlichen Raum, Ernährung,
Landwirtschaft und Verbraucherschutz**

Bundesamt für Verbraucherschutz und
Lebensmittelsicherheit

Bearbeitet von
Dr. Angelika Coenen

E-Mail
angelika.coenen@ml.niedersachsen.de

Ihr Zeichen, Ihre Nachricht vom	Mein Zeichen (Bei Antwort angeben)	Durchwahl (05 11) 1 20-	Hannover
	201-42471-74	21 31	09.08.2007

Inspektionsreise des FSIS vom 16.04. – 02.05.2007 in Niedersachsen und Mecklenburg-Vorpommern

Zu den aufgelisteten Mängeln der einzelnen Betriebe in Niedersachsen werden folgende Anmerkungen gemacht:

1. Fa. Abraham, Harkebrügge, A-IV-191:

um zu verhindern, dass die Schinken nach dem Auspacken aus der Folie die Arbeitsflächen berühren, die vorher mit der Folie in Kontakt gekommen sind, sind in der Zwischenzeit mehrere Mitarbeiter dahingehend geschult worden, die Folienumhüllung in den Rollwagen bereits zu öffnen. Die Schinken werden dann aus der Folie heraus auf die Tische oder in andere Rollwagen gekippt, so dass die Kontamination verhindert wird.

2. Fa. Klümper, Schüttorf, A-EV-29:

zu Nr. 19/51:

Die Kalibrierung ist im HACCP-Plan nunmehr unter Verifikation aufgeführt.

Zu Nr. 22/51:

A) Die Frequenz wurde festgelegt (alle drei Monate laut Angabe des Herstellers des Messgerätes).

B) Der CCP (Listeria-Untersuchung) wurde gestrichen

Im Auftrage

Coenen

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Comments by Lower Saxony (translation provided by BVL 106)

Letter by:	Niedersächsisches Ministerium für den ländlichen Raum, Ernährung, Landwirtschaft und Verbraucherschutz
To:	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
Dated:	August 09, 2007

FSIS audit in Lower Saxony and Mecklenburg-Western Pomerania from April 16 – May 02, 2007

The competent state authority in Lower Saxony has the following comments on the deficiencies listed with regard to establishments in Lower Saxony:

1.) Establishment Abraham, Harkebrügge (A-IV-191):

To avoid potential contamination of hams while they are unpacked on a work table which had contact with the plastic wrap before, the workers concerned have meanwhile been trained so that the plastic wrap is opened while the hams are still in the transport tubs, and hams are than dumped out of the wrapping on the clean table, or might be dumped into another tub which had no contact with the plastic wrapping. This way, there is no contamination.

2.) Establishment Klümper, Schüttorf (A-EV-29):

To No. 19/51:
Calibration is now listed under verification in the HACCP plan.

To No. 22/51:

A) The frequency was fixed at once every three months (in accordance with the manufacturer's instructions).
B) The Critical Control Point 'Listeria analysis' has been deleted.

(signed: Coenen)

Ministerium für Landwirtschaft, Umwelt und Verbraucherschutz Mecklenburg-Vorpommern

Ministerium für Landwirtschaft, Umwelt und Verbraucherschutz
Mecklenburg-Vorpommern, 19048 Schwerin

Bundesamt für Verbraucherschutz
und Lebensmittelsicherheit (BVL)
Ref. 106

nur per E-mail

bearbeitet von: Dr. Kühn

Telefon: 0385/588 6550
Telefax: 0385/588 6028
E-Mail : Kristian.Kuehn@lu.mv-regierung.de

Aktenzeichen: VI 550/7252.42 EV 830
(bitte bei Schriftverkehr angeben)

Schwerin, den 19.08.2007

Entwurf des Abschlussberichtes zur Inspektionsreise des FSIS vom 16. April bis 2. Mai 2007 in Niedersachsen und Mecklenburg-Vorpommern

Stellungnahme Mecklenburg-Vorpommern

Zum o. g. Entwurf wird folgende Stellungnahme abgegeben:

Zu Nr. 6.2.3
Die Anforderungen hinsichtlich der Untersuchungen von Kontaktflächen auf *Listeria monocytogenes* sind bekannt. Es besteht ein betrieblicher Plan zur Entnahme von 14 Hygienetupferproben an festgelegten Stellen der Linie 12 im Werk Dr. Oetker Wittenburg. Diese Untersuchung wird viermal jährlich durchgeführt. Das aktuelle HACCP-Konzept des Herstellungsbetriebes ist bekannt und liegt in Schriftform vor. Weiterhin ist festgelegt worden, dass jährlich 9 amtliche Produktproben nach FSIS-Methode im LAVES Oldenburg untersucht werden.

Zu Nr. 9.1
Die am Kontrolltag 26. April 2007 erstellte Mängelliste wurde abgearbeitet. Die aufgeführten Mängel wurden abgestellt.

Zu Nr. 11.2
Der festgestellte Mangel im HACCP-System (CCP „Metalldetektion") wurde abgestellt. Maßnahmen zur Verifizierung wurden festgelegt. Checklisten für die Dokumentation der Verifizierungsmaßnahmen sind vorhanden.

Zu Nr. 13
Es wird eine Schulung zur Durchführung der FSIS-Anforderungen hinsichtlich Hygiene und HACCP implementiert. Als Multiplikator konnte Herr Dr. Graf vom LAVES Oldenburg gewonnen werden.

Stellungnahme zur Audit Checkliste vom 26. April 2007, Fa. Dr. Oetker Tiefkühlprodukte in Wittenburg

Zu Nr. 13
Zur Überwachung des SSOP-Planes sind innerhalb von 30 Tagen nach der Inspektion im Betrieb neue Kontrolllisten eingeführt worden, in denen grundsätzlich die Reinigungskontrolle vor Arbeitsbeginn und Korrekturmaßnahmen bei Beanstandungen sowie das Ergebnis nach erfolgter Korrektur vermerkt werden. Korrekturmaßnahmen bei einer möglichen Kontamination von Produkten sind innerhalb von 30 Tagen nach Inspektion in einer Arbeitsanweisung zur Durchführung von Abstrichuntersuchungen bei USA Produktion festgelegt worden (Sperrung von Chargen, Nachuntersuchung, Vernichtung).

Zu Nr. 18 und 19
Der betriebliche HACCP-Plan ist innerhalb von 30 Tagen nach der Inspektion überarbeitet worden. Maßnahmen zur Verifizierung des CCP „Metalldetektion" sind festgelegt worden. Erfahrungen über einen langjährigen Zeitraum beweisen, dass die gewählte Größe der Loma-Prüfstäbchen als Prüfmittel geeignet ist.

Zu Nr. 51
Zur Durchsetzung der FSIS-Vorschriften werden Schulungen der amtlichen Supervisor und des betrieblichen Personals mit Herrn Dr. Graf vom LAVES Oldenburg in der Zeit vom 9. bis 11 Oktober 2007 durchgeführt.

Zu Nr. 58
Nach einer betrieblichen Arbeitsanweisung zur Listerien-Überwachung der Produktionslinie 12 (mindestens viermal 14 Hygienetupfer jährlich) wird gearbeitet. Die Untersuchungen finden im Gissel-Institut Hannover statt. Bisher sind zweimal 14 Hygienetupfer negativ auf Listerien getestet worden. Produktuntersuchungen zum Nachweis von pathogenen Keimen u. a. auf Listerien werden im LAVES Oldenburg durchgeführt. Jährlich ist die Untersuchung von 9 Proben vorgesehen. Die erste Probennahme erfolgt im August 2007.

Zu Nr. 59
Das NOID-Verfahren wurde eingestellt.

Im Auftrag

Dr. Kühn

Comments by Mecklenburg-Western Pomerania (translation provided by BVL 106)

Letter by:	Ministerium für Landwirtschaft, Umwelt und Verbraucherschutz Mecklenburg-Vorpommern
To:	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Dated:	August 19, 2007

Draft final report of FSIS audit in Lower Saxony and Mecklenburg-Western Pomerania from April 16 – May 02, 2007

Mecklenburg-Western Pomerania has the following comments on the draft final report:

To No. 6.2.3
Requirements with regard to analyses of product and product contact surfaces for *Listeria monocytogenes* are understood.
The establishment has drafted a plan for taking 14 hygiene swab tests in defined places along production line 12 at the plant in Wittenburg. This analysis is performed four times a year.
The establishment has also produced an updated HACCP plan.
It has been decided that nine official product samples per year will be analysed according to FSIS methods by the LAVES official laboratory in Lower Saxony.

To No. 9.1
The list of deficiencies drafted as a result of the audit in the Wittenburg plant of Dr. Oetker (EV 830) on April 26, 2007, was worked up and deficiencies were eliminated.

To No. 11.2
The deficiencies about the metal detection CCP in the HACCP system of establishment Dr. Oetker Wittenburg have been corrected. Verification measures have been laid down and check lists for documentation of verification measures have been produced.

To No. 13
Officers will be trained about enforcement of FSIS hygiene and HACCP requirements. Dr. Graf of the Lower Saxony State Office of Consumer Protection and Food Safety (LAVES) has agreed to make that training.

Comments on the attached establishment audit checklist concerning *Dr. Oetker Tiefkühlprodukte Wittenburg (EV 830)*:

To No. 13
To monitor the SSOP's, the establishment has implemented, within 30 days after the inspection, new check lists which provide for notes on the following: sanitation check before the start of production, corrective measures in case of deficiencies, and the result of the check after correction of the deficiency.

Corrective actions in case of possible contamination of product were defined within 30 days after the audit in written working instructions on performance of swab tests in US production and cover blocking of production lots, follow-up sampling and elimination of product.

To Nos. 18 and 19
The establishment revised its HACCP plan within 30 days of the audit and defined procedures to monitor and verify the CCP "metal detection". By assessing empirical data of a period of multiple years, it was validated that the size of the LOMA test rods chosen for testing the metal detector is an appropriate choice.

To No. 51
To ensure enforcement of FSIS requirements, official supervisors and the establishment's supervisory personnel will be trained by Dr. Graf of the Lower Saxony State Office of Consumer Protection and Food Safety (LAVES) in Oldenburg in the period from October 9 to 11, 2007.

To No. 58
The establishment is implementing its operation procedure for *Listeria* controls at production line 12 (at least 14 hygienic swabs, four times a year). Swabs are analysed at the accredited private laboratory of Gissel Institute in Hannover. Two test series of 14 swabs each have been performed to date, with negative result. Product analyses for pathogenic germs, including *Listeria*, are performed by the official laboratory of LAVES Veterinary Institute in Oldenburg. Nine samples per year will be analysed. The first sampling date was in August 2007.

To No. 59
The procedure following the NOID was completed. The company was not delisted.

Signed: Dr. Kühn