



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250



Dr. Klaus Lorenz, Head
Unit 106, Food of Animal Origin and Food Hygiene
Federal Office of Consumer Protection and Food Safety
Mauerstr. 39-42
PO Box 100214
D-10562 Berlin
Germany

Dear Dr. Lorenz:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Germany's meat inspection system June 4 through June 25, 2008. Comments on the draft final report received from the government of Germany have been included as an attachment to the final report. Enclosed is a copy of the final audit report. We apologize for the delay in the submission of this report

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 205-3873, by facsimile at (202) 720-0676, or electronic mail at manzoor.chaudry@fsis.usda.gov.

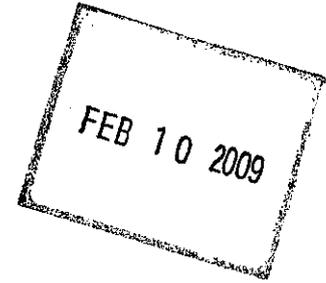
Sincerely,

by Don Carlson, acting Director

for Manzoor Chaudry
Deputy Director
International Audit Staff
Office of International Affairs

Enclosure

U. S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
OFFICE OF INTERNATIONAL AFFAIRS
INTERNATIONAL AUDIT STAFF
WASHINGTON, DC
202-205-3873
FAX 202-720-0676



MEMORANDUM

TO: Bobby Richey, Minister Counselor
US Embassy, Berlin
Clayallee 170
14195 Berlin
Germany

FROM: Manzoor Chaudry
Deputy Director
International Audit Staff, OIA, FSIS, USDA

SUBJECT: FSIS FINAL AUDIT REPORT FOR GERMANY

Dear Mr. Richey,

Please deliver the attached final audit report to Dr. Klaus Lorenz, Head, Unit 106, Food of Animal Origin and Food Hygiene, Federal Office of Consumer Protection and Food Safety. Please contact me via email at manzoor.chaudry@fsis.usda.gov, if you have any further questions.

Best regards,

By Don Carlson, acting Director

For Manzoor Chaudry

cc list:

Bobby Richey, Minister-Counselor, US Embassy, Berlin
Joachim Schaefer, Agricultural Counselor, Embassy of Germany
Debra Henke, Minister Counselor, US Mission to the EU, Brussels
Ghislain Marechal, EC, DG SANCO – Directorate General for Health and Consumers
Wolf Maier, Counselor, Food Safety and Consumer Affairs, EC
Bernard Van Goethem, Director, Directorate E
OSTA/FAS
David Young, FAS Area Director
Ann Ryan, State Department
Lisa Wallenda Picard, Chief of Staff, OA
Alfred Almanza, Administrator, FSIS
Ronald K. Jones, Assistant Administrator, OIA
Philip Derfler, Assistant Administrator, OPPD, FSIS
Daniel Engeljohn, Deputy Assistant Administrator, OPPD, FSIS
Director, IAS, OIA, FSIS
Rick Harries, Acting Director, EPS, OIA
Stephen Hawkins, Acting Director, IES, OIA
Jerry Elliott, Director, IID, OIA
Barbara McNiff, Director, FSIS Codex Programs Staff, OIA
Yolande Mitchell, FCPS, OIA
Francisco Gonzalez, IES, OIA
Germany Country File

FSIS:OIA:IAS:DIRECTOR:202-205-3873:Germany
FINAL AUDIT LETTER February 9, 2009

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

JUNE 4 THROUGH JUNE 25, 2008

**Food Safety and Inspection Service
United States Department of Agriculture**

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

CCA	Central Competent Authority (Bundesamt fuer 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 in the Federal State of Lower Saxony (Landesamt fuer Verbraucherschutz und Lebensmittelsicherheit, Lower Saxony State Office of Consumer Protection and Food Safety)
<i>Lm</i>	<i>Listeria monocytogenes</i>
NOID	Notice of Intent to Delist
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point Systems
RTE	Ready-to-Eat
<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 June 4 through June 25, 2008.

An opening meeting was held on June 4 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. OBJECTIVE 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, one district inspection office in the State of Mecklenburg-Western Pomerania in Ludwigslust, one district inspection office in the State of Lower Saxony in Westerstede, one government laboratory performing *Listeria monocytogenes* (*Lm*) and *Salmonella* species (*Salmonella*) analyses on U.S.-destined product in Oldenburg, and five meat processing establishments in Edewecht, Schuettorf, Barsel-Harkebruegge, and Wittenburg.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	State	1	
	District	2	
Laboratory		1	
Meat Processing Establishments		5	

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 five processing establishments. The fourth part involved a visit to one government laboratory. The Landesamt fuer Verbraucherschutz und Lebensmittelsicherheit, Lower Saxony State Office of Consumer Protection and Food Safety (LAVES) Veterinarinstitut in Oldenburg, was conducting analyses for the presence of *Lm* 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) and Sanitation Performance Standards (SPS); (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 Food Safety and Inspection Service (FSIS) auditor would audit the meat inspection system against European Commission (EC) Directive 64/433/EEC of June 1964; EC Directive 96/22/EC of April 1996; and EC 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 during the production of products eligible for export to the U.S.; the handling and disposal of inedible and condemned materials; and FSIS requirements for HACCP, SSOP, and SPS.

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 U.S. laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.); and
- 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"; and

- 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 the FSIS website at the following address:
http://www.fsis.usda.gov/Regulations_&_Policies/Foreign_Audit_Reports/index.asp

5.1 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 SPS 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; and
- One Notice of Intent to Delist (NOID) was issued during this audit.

5.2 April 2007 Audit

During the April 2007 FSIS audit of Germany's meat inspection system, the following deficiencies were found:

- The CCA, after review and evaluation by the District Office, and the concurrence of the Federal State Ministry, allowed the certification of a new U.S. export establishment that subsequently received a NOID. This certification was permitted for an establishment found to have serious deficiencies in the implementation of HACCP requirements and in the implementation of testing for *Lm* in the ready-to-eat (RTE) product processing environment. In addition, the CCA failed to provide competent, qualified inspectors in this establishment. In the Federal State Ministry and the related District Office, the inspection personnel appeared to lack awareness of many of the U.S. HACCP requirements and the requirements for establishment testing of RTE product contact surfaces for *Lm*;
- In all three establishments audited, the government inspectors were not enforcing some of the U.S. requirements;
- In two of the three establishments audited, the government inspectors were not enforcing some of the EC requirements;
- The Guidance Document supplied by the CCA to inspection personnel did not contain some recent changes in the U.S. requirements, e.g., requirements of the *Listeria* Rule (9 CFR 430);
- In all three establishments, some of the SSOP implementation requirements or records requirements were not met;

- In two of the three establishments audited, the provisions of EC Directive 64/433 were not effectively implemented;
- Two of the three establishments audited did not meet some of the HACCP implementation requirements; and
- One establishment had not evaluated the processing environment regarding post-lethality exposure of meat products to *Lm* and had not developed a plan for testing required by the *Listeria* Rule.

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 the authority to certify and de-certify establishments, the 16 Federal States (Laender) are responsible for the 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 (CCA).

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 de-certify 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.

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' assignments.

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 addenda; 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 and two district inspection offices: one within the State of Mecklenburg-Western Pomerania in Ludwigslust; and the other within the State of Lower Saxony in Westerstede. The interviews focused on the communications between the BVL and the local authorities regarding: U.S. export requirements; periodic 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.

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

7. ESTABLISHMENT AUDITS

The FSIS auditor visited all five processing establishments eligible to export to the U.S. None of these establishments were delisted by Germany. None of these establishments received a NOID.

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 U.S. 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 RTE products for both *Lm* and *Salmonella* as required.

One concern arose as a result of this review:

- The calibration for the balance primarily used to weigh samples was being done at 100 grams and 500 grams, but many of the sample weights are 10 and 25 grams.

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 U.S. domestic inspection program.

In two of the five establishments audited, some of the basic SSOP requirements were not met.

In four of the five establishments audited, some of the SSOP ongoing requirements were not met, primarily in implementation and recordkeeping.

Specific deficiencies are noted in the attached individual establishment reports.

9.2 Sanitation Performance Standards

Four of the five establishments audited had deficiencies in SPS. These included: building construction and maintenance; plumbing; water supply; equipment and utensils; and sanitary operations.

Specific deficiencies are noted in the attached individual establishment reports.

9.3 EC Directive 64/433

There were no significant findings to report concerning this Directive.

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 reported.

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 U.S. are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the U.S. domestic inspection program.

The HACCP programs were reviewed during the on-site audits of all five certified processing establishments.

In three of the five establishments audited, basic HACCP deficiencies were reported.

In two of the five establishments audited, ongoing HACCP deficiencies were reported.

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

11.3 Testing for Generic *Escherichia coli*

No slaughter facilities are currently certified in Germany.

11.4 Testing of Ready-to-Eat (RTE) Products

Four of the five establishments audited were producing RTE products for export to the U.S. In accordance with FSIS requirements, these establishments are required to meet the testing requirements for RTE products.

In all four of these establishments, the government was testing RTE products for both *Lm* and *Salmonella* as required.

11.5 EC Directive 64/433

There were no significant findings to report concerning this Directive.

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 U.S. export. All raw products are obtained from certified slaughter establishments in Denmark and The Netherlands. 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 four of the five establishments audited, the inspection service was not enforcing some of the FSIS requirements for sanitation.

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

13.1 Daily Inspection

Inspection was being conducted daily during all production eligible for export to the U.S. 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 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 U.S. 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 June 25 in Berlin with the CCA. At this meeting, the primary findings from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Rori K. Craver, DVM
Senior Program Auditor

For 

15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Reports
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 Dr. Oetker Tiefkühlprodukte Sudring I Wittenburg, Mecklenburg-Western Pomerania 19243	2. AUDIT DATE 06/09/2008	3. ESTABLISHMENT NO. EV830	4. NAME OF COUNTRY Germany
	5. NAME OF AUDITOR(S) Rori K. Craver, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

Date: 06/09/2008 Est #: EV830 (Dr. Oetker Tiefkühlprodukte [P/CS]) (Wittenburg, Germany)

07/51. The SSOP plan did not differentiate between activities that were pre-operational and those that were operational. The frequencies for the above activities and for monitoring were not clear. [Regulatory reference(s): 9 CFR §416.11-.12, 416.17]

13/51. Pre-operational sanitation monitoring records did not have sufficient detail in the description of the deficiencies or in the corrective actions to allow for verification of these. These same records did not contain preventive measures for deficiencies of product-contact surfaces. [9 CFR §416.16, 416.17]

15/51. The flow diagram and the hazard analysis for the production of pizza did not contain the receipt or storage of meat ingredients, other than meat ingredients, or of packaging materials. The flow diagram included a step for rework, but that step was not addressed in the hazard analysis. [9 CFR §417.2(a), 417.8]

22/51. HACCP monitoring records did not contain the initials of the monitor at the actual time of the event. [9 CFR §417.5, 417.8]

45/51. In several areas of the pizza production line including dough production, electrical lines were not secured in a manner that did not allow potential contact between the line and the product. There was also potential cross-contamination between pizza crusts and a roller bar following the oven and leading to the cooling racks. [9 CFR §416.3]

61. NAME OF AUDITOR
Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

For *Janet A. Chomley* 9/23/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Gebrüder Abraham Ham GmbH & Co KG Königstrasse 3 Barssel/Harkebruegge, Lower Saxony 26676	2. AUDIT DATE 06/19/2008	3. ESTABLISHMENT NO. AIV191	4. NAME OF COUNTRY Germany
5. NAME OF AUDITOR(S) Rori K. Craver, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

60. Observation of the Establishment Date: 06/19/2008 Est #: AIV191 (Gebrueder Abraham Ham GmbH & Co KG [P]) (Barsel/Harkebruegge, Germany)

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

61. NAME OF AUDITOR
Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

For *Natasha A. Choudhry* 9/23/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Meica Meat Packing Plant of Ammerland Postfach 1160 Edeweicht, Lower Saxony D-26188	2. AUDIT DATE 06/12/2005	3. ESTABLISHMENT NO. AIV10	4. NAME OF COUNTRY Germany
	5. NAME OF AUDITOR(S) Rori K. Craver, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

Date: 06/12/2005 Est #: AIV10 (Meica Meat Packing Plant of Ammerland [P]) (Edeweicht, Germany)

10. Direct contact was observed between an employee's boots and the sausages on a rack as he was hanging them after the stuffing machine and prior to the smokehouse. [Regulatory reference(s): 9 CFR §416.13]

42. Several pipes, both in the peeling room and the brine filler area, had leaking connections. These were immediately corrected. [9 CFR §416.2(e) and (f)]

45. Many of the large containers used to transport fresh meat to the cutting machines had unsmooth welds which could allow for the formation of biofilms. Many equipment seals throughout the establishment were broken and deteriorating. The seals were immediately replaced. The establishment has enough transport containers to not use those with welding problems. [9 CFR §416.3]

61. NAME OF AUDITOR

Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

For *James A. Cravens* 9/23/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Gebrueder Abraham GmbH & Company KG Osterschepser Str. 40 Edeweht, Lower Saxony 26188	2. AUDIT DATE 06/16/2008	3. ESTABLISHMENT NO. AEV35	4. NAME OF COUNTRY Germany
5. NAME OF AUDITOR(S) Rori K. Craver, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

60. Observation of the Establishment

Date: 06/16/2008 Est #: AEV35 (Gebrueder Abraham GmbH & Company KG (P)) (Edeweicht, Germany)

10. One of the plastic-link conveyor belts on a dicing machine had a number of breaks all at the same location on the belt. The production was halted on this machine and it was determined that this belt had been intact at the beginning of production. All product from this machine's production was held and re-examined for pieces of plastic. All 414 kilograms of product were destroyed. The cause of the breaks was found by maintenance personnel and corrected. [Regulatory reference(s): 9 CFR §416.13]

15/51. The flow diagram did not include the receipt or storage of non-meat ingredients or of packaging materials. The hazard analysis also did not include and consider those steps. [9 CFR §417.2, 417.8]

22/51. The monitoring records for CCP 3, a metal detector, did not contain a result. [9 CFR §417.5, 417.8]

39/51. Several locations in the establishment did not have a good seal to make structures impervious to water and easily cleanable. These included walls to curbs, curbs to floors, and around the attachment of bumpers to walls. [9 CFR §416.17, 416.2(b)]

45. Some of the red cutting boards in the boning room were deeply scored thereby not allowing for adequate cleaning. They were immediately taken out of service pending repair or replacement. [9 CFR §416.3]

61. NAME OF AUDITOR

Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

For *[Signature]* 9/23/08

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION H. Klumper GmbH & Company KG Ratsherr-Schlikker-Strasse 63 Schutterhof, Lower Saxony D-48465	2. AUDIT DATE 06/18/2008	3. ESTABLISHMENT NO. AEV29	4. NAME OF COUNTRY Germany
5. NAME OF AUDITOR(S) Rori K. Craver, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

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

60. Observation of the Establishment

Date: 06/18/2008 Est #: AEV29 (H. Klumper GmbH & Company KG [P]) (Schuttorf, Germany)

07/51. SSOP written program did not have clearly defined frequencies for activities included in operational sanitation. [Regulatory reference(s): 9 CFR §416.11-.12, 416.17]

13/51. SSOP monitoring records did not include possible involvement and disposition of product in corrective actions for deficiencies recorded. Because of the nature of this operation, product is present in many areas during even pre-operational monitoring. [9 CFR §416.16, 416.17]

15/51. The flow diagram was extremely difficult to follow and included many items not in the direct production steps of the product. This led to confusion in the designation of the CCPs and the resulting HACCP plan. [9 CFR §417.2, 417.8]

43/51. The establishment was not following their own water sampling program and was missing the paperwork from some yearly physical/chemical analysis. Also, the establishment had not done some of the monthly sampling the program requires. [9 CFR §416.17, 416.2(g)]

45/51. Some of the large metal containers used to transport finished hams to the slicing operation had unsmooth welds which could allow for the formation of biofilms. Tape had been used for repairs on a number of locations on the slicing/packaging machines. This shredded and uncleanable surface caused insanitary conditions to exist. All tape will be removed and these surfaces cleaned as well as the necessary repairs will be done. [9 CFR §416.3]

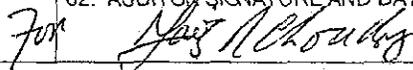
46. One slicing/packaging machine had a hose attached to it that was allowed to lie on the floor. This hose is used for clean-up during breaks in operations and the surface touching the floor could come into contact with food-contact surfaces during clean-up. The veterinary service has previously discussed this problem, but action has not been taken by the establishment to address the deficiency. [9 CFR §416.4]

58/51. This establishment uses Alternative 3, sanitation only, for the *Listeria monocytogenes* program for post-lethality exposed RTE product. There was no identification of the conditions for the implementation of a test and hold program following a positive food-contact surface result. [9 CFR §430.4]

61. NAME OF AUDITOR

Rori K. Craver, DVM

62. AUDITOR SIGNATURE AND DATE

For  9/23/08



Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
Dienstsz Berlin • Postfach 11 02 60 • 10832 Berlin

.) Only by e-mail:
Donald Smart, Director
USDA, FSIS, OIA, IAS
Washington, D. C., 20250

E-mail copy to:

USDA Foreign Agricultural Service
Clayallee 170, 14195 Berlin

Ministerium für Ernährung,
Landwirtschaft und Verbraucherschutz
Rochusstr. 1, 53123 Bonn

Botschaft der Bundesrepublik Deutschland
4645 Reservoir Road, N. W.
Washington, D. C., 20007

Sabine Hausdörfer
Correspondent

PHONE +49 (0)30 18444-10615
FAX +49 (0)30 18444-10699
E-MAIL Sabine.Hausdoerfer@bvl.bund.de
INTERNET www.bvl.bund.de

YOUR REFERENCE
YOUR LETTER OF 23 October 2008

OUR REFERENCE BVL 106 3620-01/287799; 287803
(Please quote with answer)

DATE 19 December 2008

**Draft final report of FSIS 2008 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.

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 were corrected. Corrective measures taken by establishments were controlled by the competent authorities.

Dienstsz Braunschweig
Bundesallee 50, Geb. 247
38116 Braunschweig
Tel: +49 (0)531 21497-0
Fax: +49 (0)531 21497-299

Abt. Pflanzenschutzmittel
Messeweg 11/12
38104 Braunschweig
Tel: +49 (0)531 299-5
Fax: +49 (0)531 299-3002

Dienstsz Berlin
Mauerstraße 39-42
10117 Berlin
Tel: +49 (0)30 18444-000
Fax: +49 (0)30 18444-89999

Referatsgr. Untersuchungen
Diedersdorfer Weg 1
12277 Berlin
Tel: +49 (0)30 18412-0
Fax: +49 (0)30 18412-2955

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

Sincerely yours

(signed)

Dr. Antje Jaensch

Enclosure



**Niedersächsisches Landesamt
für Verbraucherschutz
und Lebensmittelsicherheit**

Nds. Landesamt für Verbraucherschutz und Lebensmittelsicherheit
Postfach 39 49 • 26029 Oldenburg

Nds. Ministerium für Ernährung,
Landwirtschaft und Forsten
Referat 201
Postfach 243

30002 Hannover

per e-mail

Bearbeitet von
Frau Dr. Gerecke
Telefax:
(04 41) 57026 - 179
Email:
jutta.gerecke@laves.niedersachsen.de

Ihr Zeichen, Ihre Nachricht vom Mein Zeichen (Bitte bei Antwort angeben) Durchwahl Oldenburg
Email des BVL vom 05.11.2008 21.2-44112/3-33-1 (04 41) 57026 - 225 24.11.2008

**Export von Fleischerzeugnissen nach den USA; US-Audit vom 04.Juni – 25. Juni 2008
Stellungnahme zum FSIS-Berichtsentwurf vom 23.10.2008**

Aus hiesiger Sicht ist Folgendes anzumerken:

zu Nr. 4 „LEGAL BASIS FOR THE AUDIT“, 2. Satz und Nr. 11.5:

Das Europäische Lebensmittel- und Futtermittelrecht wurde vollständig geändert. Rechtsgrundlage sind mittlerweile die Verordnungen (EG) 852/2004, 853/2004 und 854/2004. Durch die Richtlinie 2004/41EWG wurden die bisher gültigen und im FSIS Bericht zitierten Hygienerichtlinien aufgehoben. Europäische Rechtsgrundlage für den Bereich der Fleischerzeugnisse war die Richtlinie 77/99/EWG (92/05/EWG), nicht die RL 64/433/EWG. Insofern wurde die falsche Rechtsgrundlage zur Bewertung herangezogen. Die RL 77/99/EWG war im Veterinary Equivalence Agreement (VEA) als äquivalent bewertet worden.

zu Nr. 8 „RESIDUE AND MICROBIOLOGY LABORATORY AUDITS“

Die Waage zum Einwiegen der Proben war geeicht bis Ende 2008. Dem Hinweis aus dem Audit wurde Rechnung getragen, indem ein 20g Prüfgewicht beschafft wurde. Die Kalibrierung mit diesem Gewicht ergab keine Mängel der Wägung. Die regelmäßige Prüfung der Waage zusätzlich zum bisherigen Verfahren mit dem 20g-Prüfgewicht wurde in die Arbeitsanweisungen aufgenommen und wird durchgeführt

Anmerkungen zu den aufgelisteten Mängeln der einzelnen Betriebe:

Die Mängel sind zwischenzeitlich beseitigt worden. Im Einzelnen:

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

es wurden keine Mängel festgestellt.

2. Fa. Meica, Edewecht, A-IV-10

zu Nr. 10:

Dienstgebäude
Ecke Sandkruger Straße/
Westernhallsweg
26133 Oldenburg

Besuchszeiten
Mo. - Fr. 9 - 12 Uhr
Mo. - Do. auch 14 - 15.30 Uhr
Besuche bitte möglichst verein-
baren

Telefon
(04 41) 57026 - 0
Telefax
(04 41) 57026 - 179

Paketanschrift
Sandkruger Straße/
Westernhallsweg
26133 Oldenburg

Bankverbindung
Konto-Nr. 0 106 034 788
NordLB (BLZ 250 500 00)
Email
Poststelle@laves.niedersachsen.de
Internet
www.laves.niedersachsen.de

Der Mangel wurde abgestellt. Ein direkter Kontakt zwischen dem Produkt und den Stiefeln der Mitarbeiter findet nicht mehr statt.

zu Nr. 42:

Der Mangel wurde bereits während der Begehung behoben.

zu Nr. 45:

Die Mängel wurden z. T. bereits während der Begehung abgestellt. Kutterwagen mit rauen Schweißnähten sind im Betrieb nicht mehr vorhanden.

3. Fa. Abraham, Edewecht, A-EV-35

zu Nr. 10:

Der Mangel wurde bereits während der Begehung abgestellt

zu Nr. 15/51:

Die Papiere wurden entsprechend angepasst.

zu Nr. 22/51:

In der Dokumentation für CCP 3 (Metalldetektor) werden Ergebnisse aufgeführt.

zu Nr. 39/51:

Die Dichtungen wurden erneuert.

zu Nr. 45:

Der Mangel wurde bereits während der Begehung behoben.

4. Klümper, Schüttdorf, A-EV-29:

zu Nr. 07/51:

Im SSOP wurden mittlerweile Frequenzen festgelegt.

zu Nr. 13/51:

Im SSOP wurde festgelegt, wie mit Produkten zu verfahren ist, die durch eine beim pre-operational monitoring festgestellte Abweichung möglicherweise negativ beeinflusst wurden.

zu Nr. 15/51:

Das HACCP Konzept befindet sich in der Überarbeitung und wird übersichtlicher gestaltet.

zu Nr. 43/51:

Die fehlenden jährlichen chem.-phys. Wasseranalysen wurden nachgepflegt. Die Firma befolgt mittlerweile ihren Plan für die Ziehung von Wasserproben.

zu Nr. 45/51:

Der Mangel wurde abgestellt. Die Klebebänder wurden entfernt, Behälter mit rauen Schweißnähten wurden aussortiert.

zu Nr. 46:

Der Mangel wurde abgestellt, der Schlauch ist mittlerweile ordnungsgemäß aufgehängt.

zu Nr. 58/51:

Die Festlegung der Probenanzahl je Produktionslinie und die Ausarbeitung eines Plans zur weiteren Vorgehensweise inkl. der erforderlichen Probenahme bei positivem Listeria m.-Untersuchungsergebnis ist erfolgt.

Im Auftrage

Dr. Gerecke

(Dieses Schriftstück wird elektronisch übermittelt und ist daher ohne Unterschrift gültig.)

Comments by Lower Saxony (translation provided by BVL 106)

Letter by: Niedersächsisches Landesamt für Verbraucherschutz und
Lebensmittelsicherheit (*Lower Saxony State Office of Consumer Protection
and Food Safety, LAVES*)
To: Nds. Ministerium für Ernährung, Landwirtschaft und Forsten
Dated: November 24, 2008

**Export of meat products to the USA; FSIS audit in Germany from June 04 - 25, 2008
Comments on FSIS draft report of October 23, 2008**

The competent state authority in Lower Saxony has the following comments on the FSIS draft report:

To No. 4 “Legal Basis for the audit”, 2nd sentence and No. 11.5:

The European food and feed law has been profoundly changed. The legal bases are now provided by Regulations (EC) 852/2004, 853/2004, and 854/2004. The hygiene directives cited in the FSIS report were repealed by Directive 2004/41/EEC.

The basis of European legislation concerning meat products is provided by Directive 77/99/EEC. Given that fact, the audit findings should not be evaluated on the basis of Council Directive 64/433/EEC. Directive 77/99/EEC has been evaluated as equivalent in the Veterinary Equivalence Agreement (VEA).

To No. 8 “Residue and Microbiology Audits”

The sample scales in question were reference-calibrated until end of 2008. The audit recommendation was followed as a 20-g reference weight was acquired.

A new calibration using this reference weight did not show any weighing deficiencies.

Periodical additional calibration of the scales using the 20-g reference weight, apart from the usual calibration procedure, has been included in the working instructions and is being done.

Notes on the deficiencies listed with regard to individual establishments:

Noted deficiencies have been corrected. This was in detail:

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

No deficiencies were reported.

2.) Establishment Meica, Edewecht (A-IV-10):

To No. 10:

The deficiency was corrected. There is no contact of the product and the boots of the workers.

To No. 42:

The deficiency was corrected during the inspection tour of the establishment.

To No. 45:

Part of the deficiencies were corrected during the inspection tour.

The establishment has disposed of any transport bins with rough welds.

3.) Establishment Abraham, Edewecht (A-EV-35)

To No. 10:

The deficiency was corrected during the inspection tour.

To No. 15/51:

The documents were amended accordingly.

To No. 22/51:

The documentation of CCP 3 (metal detector) now lists the findings.

To No. 39/51:

The seals were replaced

To No. 45:

The deficiency was corrected during the inspection tour.

4.) Establishment Klümper, Schüttdorf (A-EV-29)

To No. 07/51:

The SSOP has now fixed frequencies of operational sanitation activities.

To No. 13/51:

The SSOP has been change to include procedures for how to deal with product which might have been impaired by deviations found in pre-operational monitoring.

To No. 15/51:

The HACCP plan is being reviewed and re-designed in a manner easier to handle.

To No. 43/51:

The missing results of annual chemical and physical water analyses have been fed into the documentation of the water analysis program. The establishment now adheres to its water sampling plan.

To No. 45/51:

The deficiency was corrected. All tape was removed and containers with rough welds were disposed of.

To No. 46:

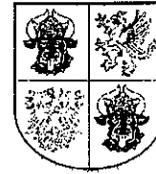
The deficiency was corrected and the hose properly hung up.

To No. 58/51:

The company has fixed the number of samples to be drawn per production line and written down a plan of how to proceed in the case of a positive *Listeria monocytogenes* finding, including testing requirements.

(signed: Dr. Gerecke)

**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 01. 12. 2008

**Entwurf des Abschlussberichtes zur Inspektionsreise des FSIS
vom 4. bis 25. Juni 2008 in Niedersachsen und Mecklenburg-Vorpommern**

Stellungnahme Mecklenburg-Vorpommern

1. Betriebliche Mängel:

Zu 07/51:

Am 2. September 2008 wurde dem Fachdienst Veterinär- und Lebensmittelüberwachung Ludwigslust der überarbeitete SSOP-Plan mit dem Freigabevermerk von Herrn Eiben vom 29.08.2008 übergeben. In den neuen Dokumenten wird zwischen den Tätigkeiten der Mitarbeiter in der Produktion und den betrieblichen Überwachungsmaßnahmen durch die Mitarbeiter der Abteilung Qualitätssicherung unterschieden. Die Mitarbeiter der Reinigungsschicht und der Leiter der Reinigungsschicht haben täglich ein Protokoll zur Durchführung und Abnahme der Maschinenreinigung mit Angabe der Uhrzeit auszufüllen. Die Mitarbeiter an den Produktionslinien haben eine Checkliste Liniensteuerung Produktionsbeginn und -ende zu führen. Die Aufgaben der betrieblichen Überwacher sind extra aufgeführt.

Zu 13/51

Die betrieblichen Hygieneüberwachungsprotokolle, mit denen täglich gearbeitet wird, haben jetzt Platz für die Dokumentation der Reinigung, für die Angabe des Verschmutzungsgrades, für die Dokumentation von Korrekturmaßnahmen sowie für die Dokumentation und Kontrolle der Nachreinigung.

Hausanschrift:
Ministerium für Landwirtschaft, Umwelt und Verbraucherschutz M-V
Paulshöher Weg 1, 19061 Schwerin

Telefon: (0385) 588-0
Telefax: (0385) 588-6024
588-6025

Zu 15/51

Die USA-Ausgabe des HACCP-Konzeptes wurde als von Herrn Eiben am 29.08.2008 freigegeben und ersetzt die HACCP-Version vom 31.01.2008. Im Fließdiagramm sind jetzt die Wareneingänge und die Lagerung von Rohstoffen und Verpackungsmaterial enthalten. Die Zuführung von Rework-Material ist in der neuen Gefahrenanalyse dokumentiert.

Zu 22/51

Die HACCP- Überwachungsprotokolle sind überarbeitet worden und enthalten jetzt eine Spalte, in der der zuständige Kontrollierende an der Verpackungslinie sein Namenskürzel eintragen muss. Es wird die genaue Uhrzeit der Kontrollen am CCP „Metallsucher“ in Stunden und Minuten angegeben.

Zu 45/51

Die elektrischen Leitungen wurden gestrafft, so dass ein potentieller Kontakt mit den Produkten ausgeschlossen werden kann. Kontaminationsmöglichkeiten zwischen Gerätschaften wie Mehlbürsten vor dem Ofen und Stangen nach dem Backprozeß im Ofen wurden beseitigt.

2. Mängel in der Durchsetzung von Rechtsvorschriften durch die Behörden:

Im Rahmen von USA-Produktionen im Dr. Oetker Werk in Wittenburg werden die betrieblichen Dokumente verstärkt kontrolliert, mit Namenskürzel abgezeichnet und die Abstellung von Mängeln angemahnt.

Im Auftrag

Dr. Kühn

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

Letter by: Ministerium für Landwirtschaft, Umwelt und Verbraucherschutz
Mecklenburg-Vorpommern (*Ministry of Agriculture, the Environment, and
Consumer Protection of Mecklenburg-Western Pomerania*)
To: Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Dated: December 01, 2008

**Draft final report of FSIS audit in Lower Saxony and Mecklenburg-Western Pomerania
from June 04 - 25, 2008;
Comments by Mecklenburg-Western Pomerania**

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

1. Deficiencies reported in establishment Dr. Oetker Tiefkühlprodukte

To 07/51:

The establishment's revised SSOP plan signed by Mr. Eiben on August 29, 2008, was submitted to the Ludwigslust Veterinary and Food Control Service on September 02, 2008. The new document makes a clear distinction between activities by workers in production and establishment self-control activities by staff of the quality insurance department. The workers and foreworker of the cleaning shift must fill in a daily protocol including the time of performance and check of the cleaning of machines. Staff working at the production lines have to fill in a line control check list at the beginning and end of production. Activities of the establishment's quality insurance department are listed in extra documents.

To 13/51:

The establishment's daily hygiene monitoring protocols now provide space for documentation of cleaning activities, degree of contamination, corrective measures, and documentation and control of corrective cleaning.

To 15/51:

The US version of the HACCP plan was signed and released by Mr. Eiben on August 29, 2008, and replaces the HACCP plan version dated January 31, 2008. The flow chart now includes receipt and storage of raw materials and packaging material. The new risk analysis addresses the step where rework material is put in.

To 22/51:

HACCP monitoring protocols have been revised to include a column where the person in charge of controls at the packaging line places his/her monogram. The exact time of checks at the metal detector CCP is stated with hour and minutes.

To 45/51:

Electric cables were tightened, so that potential contact with product is precluded. Possible sources of cross contamination between equipment parts, such as flour brushes in front of the oven and bars behind the oven after the baking stage, were eliminated.

2. Deficiencies reported with regard to enforcement of US requirements

The establishment's documents will be more intensively controlled, signed, and realisation of corrective actions will be controlled with regard to any US production in establishment Dr Oetker Tiefkühlprodukte in Wittenburg.

(Signed: Dr. Kühn)