



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

JAN - 6 2004

Dr. Georg Schreiber
Director
Federal Office for Consumer Protection and Food Safety
Diedersdorfer Weg 1
D-12277 Berlin
Germany

Dear Dr. Schreiber:

This letter transmits the Food Safety and Inspection Service's final report of a meat inspection system audit conducted in Germany from July 6 through July 26, 2003. Comments from Germany have been included in the final report.

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

Sincerely,

Sally Stratmoen
Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc:

Rich Petges, Counselor, US Embassy, Berlin

Frederich Wacker, Agriculture Counselor, Embassy of Germany

Linda Swacina, Deputy Administrator, FSIS

Agriculture, Fisheries, Food Safety and Consumer Affairs Section, EU Mission to the US

Norval Francis, Minister-Counselor, US Mission to the EU, Brussels

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Amy Winton, State Department

Nancy Goodwin, IES, OIA

Country File (Germany—July 03 Audit)

FINAL

DEC 17 2003

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

JULY 8 THROUGH JULY 25, 2003

Food Safety and Inspection Service
United States Department of Agriculture

TABLE OF CONTENTS

1. INTRODUCTION
2. OBJECTIVE OF THE AUDIT
3. PROTOCOL
4. LEGAL BASIS FOR THE AUDIT
5. SUMMARY OF PREVIOUS AUDITS
6. MAIN FINDINGS
 - 6.1 Legislation
 - 6.2 Government Oversight
 - 6.3 Headquarters Audit
7. ESTABLISHMENT AUDITS
8. LABORATORY AUDITS
9. SANITATION CONTROLS
 - 9.1 SSOP
 - 9.2 EC Directive 64/433
10. ANIMAL DISEASE CONTROLS
11. SLAUGHTER/PROCESSING CONTROLS
 - 11.1 Humane Handling and Slaughter
 - 11.2 HACCP Implementation
 - 11.3 Testing for Generic *Escherichia coli*
 - 11.4 Testing for *Listeria monocytogenes*
 - 11.5 EC Directive 64/433
12. RESIDUE CONTROLS
 - 12.1 FSIS Requirements
 - 12.2 EC Directive 96/22
 - 12.3 EC Directive 96/23
13. ENFORCEMENT CONTROLS
 - 13.1 Daily Inspection
 - 13.2 Testing for *Salmonella*
 - 13.3 Species Verification
 - 13.4 Monthly Reviews
 - 13.5 Inspection System Controls

14. CLOSING MEETING

15. ATTACHMENTS TO THE AUDIT REPORT

ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

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

1. INTRODUCTION

The audit took place in Germany from July 8 through July 25, 2003.

An opening meeting was held on July 8, 2003 in Berlin with the Central Competent Authority (CCA). At this meeting, the auditors confirmed the objective and scope of the audit and discussed the auditors' itineraries.

The auditors were accompanied during the entire audit by representatives from the CCA and/or representatives from the State, District, and Local inspection offices.

2. OBJECTIVES OF THE AUDIT

This was a comprehensive follow-up audit with three objectives. The first objective was to evaluate the performance of the CCA with respect to controls over the processing establishments certified by the CCA as eligible to export meat products to the United States. The second objective was to determine if appropriate corrective actions had been taken by Germany in response to deficiencies noted during the February 2003 audit. The third objective was to determine if the CCA had taken steps to strengthen Federal oversight of certified establishments.

In pursuit of the objectives, the following sites were visited: the headquarters of the CCA in Berlin, two State inspection offices—Lower Saxony and Brandenburg; two district inspection offices within the State of Lower Saxony—Weser Ems and Luneburg, two local inspection offices within the State of Lower Saxony—Ammerland and Winsen/Luhe, one government laboratory performing analytical testing on United States-destined product, one government laboratory performing *Listeria monocytogenes* analysis on United States-destined product, one government laboratory performing species verification testing on United States-destined product, and all five certified meat processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	District	2	
	Local	2	Establishment level
Laboratories		3	
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 visits to three government laboratories: LAVES, a government laboratory located in Oldenburg, was conducting analyses for the presence of *Listeria monocytogenes*; LAVES, a government laboratory located in Hannover, was conducting analyses of field samples for Germany's national residue control program; and LAVES, a government laboratory located in Braunschweig, was conducting species verification testing.

Program effectiveness determinations of Germany's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures, (2) animal disease controls, (3) processing controls, including the implementation and operation of HACCP programs, (4) residue controls, and (5) enforcement controls. Germany's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditors evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditors 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 auditors 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 auditors 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 auditors 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 auditors 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.

Germany does not have any certified slaughter establishments approved for export to the United States, therefore neither the establishments nor the inspection service are required to test for *Salmonella* or generic *Escherichia coli* (*E. coli*)

4. LEGAL BASIS FOR THE AUDIT

The audit was undertaken under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.).
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/HACCP regulations.

In addition, compliance with the following European Community Directives was also assessed:

- Council Directive 64/433/EEC, of June 1964, entitled “Health Problems Affecting Intra-Community Trade in Fresh Meat”
- Council Directive 96/23/EC, of 29 April 1996, entitled “Measures to Monitor Certain Substances and Residues Thereof in Live Animals and Animal Products”
- Council Directive 96/22/EC, of 29 April 1996, entitled “Prohibition on the Use in Stockfarming of Certain Substances Having a Hormonal or Thyrostatic Action and of B-agonists”

5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS’ website at www.fsis.usda.gov/fofo/tsc.

The last two audits of Germany’s inspection system have shown serious problems.

Of the problems identified in May 2002, the following had not been fully corrected by the audit of February 2003:

- SSOP records deficiencies were observed in two establishments.
- SSOP implementation deficiencies were observed in one establishment.
- Sanitary operations were deficient in four establishments.
- Control of condemned product was deficient in two establishments.

During the February 2003 audit, the following new deficiencies were found:

- Control of condemned product was deficient in six establishments.
- Enforcement of US requirements was lacking in six establishments.
- Violations of EC Directive 64/433 were found in six establishments.
- SSOP implementation was deficient in four establishments.
- SSOP corrective actions were deficient in one establishment.
- SSOP records were deficient in three establishments.
- HACCP verification was deficient in one establishment.
- HACCP records were deficient in two establishments.
- Cleaning of equipment and utensils was inadequate in one establishment.
- Sanitary operations were in need of improvement in five establishments.

During this audit, the auditors found that the majority of these audit deficiencies have been corrected.

6. MAIN FINDINGS

6.1 Legislation

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

6.2 Government Oversight

The CCA formerly known as the Federal Institute for Consumer Health Protection and Veterinary Medicine (BvGG) has been reorganized. The Federal Office of Consumer Protection and Food Safety (BVL) has assumed the responsibilities of the former BvGG as well as additional responsibilities for exports of meat products to third countries, including the United States.

Among other things, the CCA is responsible for activities related to coordinating inspections for export activities to the European Union, to the United States and to third countries. The CCA is also responsible for Germany's National Residue Program and the European Union Rapid Alert System for Germany.

6.2.1 CCA Control Systems

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

6.2.2 National Control and Supervision

The BVL has assumed the responsibility for national control and supervision over official inspection activities for all establishments that export meat products to third countries, including the authority to certify and decertify establishments for such export.

6.2.3 Assignment of Competent, Qualified Inspectors

Competent and qualified inspectors are assigned to certified establishments.

6.2.4 Authority and Responsibility to Enforce the Laws

The CCA has the authority and responsibility to enforce the laws. This is evidenced by the recent actions BVL has taken to develop and issue inspection guidelines which contain FSIS requirements. When final, these guidelines will be implemented by all States that have certified establishments within their boundaries.

6.2.5 Adequate Administrative and Technical Support

The CCA has the ability to support a third party audit.

6.3 Headquarters Audit

The auditors did not conduct a review of inspection-related documents at the BVL headquarters.

6.3.1 Audit of State, District and Local Inspection Offices

The auditors interviewed inspection officials at several levels of the inspection program. Inspection officials were interviewed at two State inspection offices—Lower Saxony and Brandenburg; at two District inspection offices within the State of Lower Saxony—Weser Ems and Luneburg, and at two Local inspection offices within the State of Lower Saxony—Ammerland and Winsen/Luhe. The five currently certified establishments are all located within the State of Lower Saxony.

No concerns arose as a result of the interviews.

7. ESTABLISHMENT AUDITS

The FSIS auditors visited a total of five processing establishments. None of these establishments were delisted by Germany. None of these establishments received a notice of intent to delist from Germany.

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 laboratory audits focus on sample handling, sampling frequency, timely analysis data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. If private laboratories are used to test United States samples, the auditors evaluate compliance with the criteria established for the use of private laboratories under the FSIS Pathogen Reduction/HACCP requirements.

The following laboratories were audited:

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

2. LAVES, a government laboratory performing residue analyses on product destined for the United States, located in Hannover.
3. LAVES, a government laboratory performing species verification testing on product destined for the United States, located in Braunschweig.

No deficiencies were noted.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditors focus on five areas of risk to assess an exporting country's meat inspection system. The first of these risk areas that the FSIS auditors review is 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, and except as noted below, 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 SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the United States' domestic inspection program. The SSOP in all five establishments were found to meet the basic FSIS regulatory requirements, with the following deficiencies:

- In one establishment, SSOP implementation was deficient.
- In this same establishment, SSOP records were deficient.

The above deficiencies were scheduled for corrective action by establishment officials.

9.2 EC Directive 64/433

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

- In four establishments, problems were noted with pest control.
- In two establishments, sanitary operations needed improvement.
- In two establishments, dirty, street and work clothes were stored in the same locker as clean working clothes.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditors review is Animal Disease Controls. For processing establishments, these controls include ensuring control over restricted and inedible product and procedures for sanitary handling of returned and reconditioned product.

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 auditors review is 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

At this time, there are no certified slaughter establishments eligible to export meat products to the United States.

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 the five establishments. All five establishments had adequately implemented the HACCP requirements.

11.3 Testing for Generic *E. coli*

Germany does not have any certified slaughter establishment approved for export to the United States. Therefore, neither the establishments nor the inspection service is required to test for generic *E. coli*.

11.4 Testing for *Listeria monocytogenes*

Five of five establishments audited were producing ready-to-eat products for export to the United States. In accordance with FSIS requirements, the HACCP plans in these establishments had been reassessed to include *Listeria monocytogenes* as a hazard reasonably likely to exist.

11.5 EC Directive 64/433

No deficiencies were noted.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditors review is Residue Controls. These controls include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

The LAVES laboratory located in Hannover was audited.

No deficiencies were noted.

12.1 FSIS Requirements

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

12.2 EC Directive 96/22

In the LAVES laboratory in Hannover, a government residue laboratory, the provisions of EC Directive 96/22 were effectively implemented.

12.2 EC Directive 96/23

In the LAVES laboratory in Hannover, a government residue laboratory, the provisions of EC Directive 96/23 were effectively implemented.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditors review is Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella*. The following deficiencies were noted.

- In four of five establishments, the inspection service was not enforcing FSIS or EC requirements for sanitation.

- In one local office, the internal reviewer conducted the audit too quickly, did not adequately review certain sanitary operations, and did not take any action in response to deficiencies noted by the FSIS auditors.
- In another local office, the internal reviewer did not give adequate attention to product-contact equipment and could not answer questions about cleaning and disinfection of product-contact equipment.

13.1 Daily Inspection in Establishments

Inspection was being conducted daily in all processing establishments.

13.2 Testing for *Salmonella*

Germany does not have any slaughter establishment approved for export to the United States. Therefore, neither the establishments nor the inspection service is required to test for *Salmonella*.

13.3 Species Verification

At the time of this audit, Germany was required to test product for species verification. Species verification was being conducted in those establishments in which it was required.

13.4 Monthly Reviews

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

13.5 Inspection System Controls

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

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

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

14. CLOSING MEETING

A closing meeting was held on July 25, 2003 in Berlin with the CCA. At this meeting, the primary findings and conclusions from the audit were presented by the auditors.

The CCA understood and accepted the findings.

Nancy Goodwin
Lead Auditor

15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms
Foreign Country Laboratory Review Reports
Foreign Country Response to Draft Final Audit Report

7-18-05

Niedersächsisches Landesamt für Verbraucherschutz
 und Lebensmittelsicherheit (LAVES)

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY Bundesamt für Verbraucherschutz und Lebensmittelsicherheit	CITY & COUNTRY Hannover, Germany	ADDRESS OF LABORATORY Veterinarinstitut Hannover, Eintrachtweg 17, 30173 Hannover
NAME OF REVIEWER Dr. Oto Urban	NAME OF FOREIGN OFFICIAL Dr. Kruse	

Residue Code/Name			100	111	203	200	400	800						
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE											
	Sample Handling	01	A	A	A	A	A	A						
	Sampling Frequency	02	A	A	A	A	A	A						
	Timely Analyses	03	A	A	A	A	A	A						
	Compositing Procedure	04	O	O	O	O	O	O						
	Interpret Comp Data	05	O	O	O	O	O	O						
	Data Reporting	06	A	A	A	A	A	A						
ANALYTICAL PROCEDURES	Acceptable Method	07	A	A	A	A	A	A						
	Correct Tissue(s)	08	A	A	A	A	A	A						
	Equipment Operation	09	A	A	A	A	A	A						
	Instrument Printouts	10	A	A	A	A	A	A						
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	A	A	A	A	A	A						
	Recovery Frequency	12	A	A	A	A	A	A						
	Percent Recovery	13	A	A	A	A	A	A						
	Check Sample Frequency	14	A	A	A	A	A	A						
	All analyst w/Check Samples	15	A	A	A	A	A	A						
	Corrective Actions	16	A	A	A	A	A	A						
	International Check Samples	17	A	A	A	A	A	A						
REVIEW	Corrected Prior Deficiencies	18	A	A	A	A	A	A						
OTHER REVIEW		19												
		20												

SIGNATURE OF REVIEWER

DATE

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE

NAME OF FOREIGN LABORATORY

(Comment Sheet)

7.18.03

Niedersächsisches Landesamt für Verbraucherschutz und Lebensmittelsicherheit (LAVES)

FOREIGN GOV'T AGENCY

CITY & COUNTRY

ADDRESS OF LABORATORY

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

Hannover, Germany

Veterinärinstitut Hannover, Eintrachtweg 17, 30173 Hannover

NAME OF REVIEWER

NAME OF FOREIGN OFFICIAL

Dr. Oto Urban

Dr. Kruse

RESIDUE

ITEM NO.

COMMENTS

7 9 03

Niedersächsisches Landesamt für Verbraucherschutz
 und Lebensmittelsicherheit (LAVES).

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY Bundesamt für Verbraucherschutz und Lebensmittelsicherheit	CITY & COUNTRY Oldenburg, Germany	ADDRESS OF LABORATORY Veterinarinstitut oldenburg mit Ausenstelle Stade, Damm 46, 26135 Oldenburg
NAME OF REVIEWER Dr. Oto Urban	NAME OF FOREIGN OFFICIAL Dr. Scheleuter	

Residue Code/Name			LIS																	
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE																	
	Sample Handling	01		A																
	Sampling Frequency	02		A																
	Timely Analyses	03		A																
	Compositing Procedure	04		O																
	Interpret Comp Data	05		O																
	Data Reporting	06	A																	
ANALYTICAL PROCEDURES	Acceptable Method	07	A																	
	Correct Tissue(s)	08	A																	
	Equipment Operation	09	A																	
	Instrument Printouts	10	O																	
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	O																	
	Recovery Frequency	12	O																	
	Percent Recovery	13	O																	
	Check Sample Frequency	14	A																	
	All analyst w/Check Samples	15	A																	
	Corrective Actions	16	A																	
	International Check Samples	17	A																	
REVIEW	Corrected Prior Deficiencies	18	A																	
OTHER REVIEW		19																		
		20																		

SIGNATURE OF REVIEWER _____ DATE _____

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE

NAME OF FOREIGN LABORATORY

(Comment Sheet)

7 9 03

Niedersächsisches Landesamt für Verbraucherschutz
und Lebensmittelsicherheit (LAVES).

FOREIGN GOV'T AGENCY

Bundesamt für Verbraucherschutz und
Lebensmittelsicherheit

CITY & COUNTRY

Oldenburg, Germany

ADDRESS OF LABORATORY

Veterinarinstitut oldenburg mit Ausenstelle Stade,
Damm 46, 26135 Oldenburg

NAME OF REVIEWER

Dr. Oto Urban

NAME OF FOREIGN OFFICIAL

Dr. Scheleuter

RESIDUE

ITEM NO.

COMMENTS

7.22.03

Niedersächsisches Landesamt für Verbraucherschutz
 und Lebensmittelsicherheit

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY
 Bundesamt für Verbraucherschutz und
 lebensmittelsicherheit (BVL)

CITY & COUNTRY
 Braunschweig, Germany

ADDRESS OF LABORATORY
 Postfach 4518-38035 Braunschweig

NAME OF REVIEWER
 Dr. Oto Urban

NAME OF FOREIGN OFFICIAL

Residue Code/Name		Item #	Evaluation Code	Spe																
SAMPLING PROCEDURES	REVIEW ITEMS																			
	Sample Handling	01	A																	
	Sampling Frequency	02	A																	
	Timely Analyses	03	A																	
	Compositing Procedure	04	O																	
	Interpret Comp Data	05	O																	
Data Reporting	06	A																		
ANALYTICAL PROCEDURES	Acceptable Method	07	A																	
	Correct Tissue(s)	08	A																	
	Equipment Operation	09	A																	
	Instrument Printouts	10	A																	
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	O																	
	Recovery Frequency	12	O																	
	Percent Recovery	13	O																	
	Check Sample Frequency	14	A																	
	All analyst w/Check Samples	15	A																	
	Corrective Actions	16	A																	
	International Check Samples	17	A																	
REVIEW	Corrected Prior Deficiencies	18	A																	
OTHER REVIEW		19																		
		20																		

SIGNATURE OF REVIEWER

DATE

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Meica Ammerlandische Fleischwarenfabrik Fritz Meinen GmbH & Co EDEWECHT	2. AUDIT DATE 07-16-03	3. ESTABLISHMENT NO. A-IV-10	4. NAME OF COUNTRY Germany
5. NAME OF AUDITOR(S) Dr. Oto Urban		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	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	X
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

GERMANY - Continuation Est.A-IV-10

- 38. There was no screen protection on the ventilator connected to the outside in the processing area bathroom. Spider webs were observed in the same area. Corrective action was scheduled by the establishment officials.

- 46. Standing water was observed on the floor close to the sink in the meat mincing room. This deficiency was not corrected either by the establishment or the inspection official.

- 51. No enforcement performed by the inspection official.

- 56. EC Directive 64/433

61. NAME OF AUDITOR

Dr. Oto Urfhan

62. AUDITOR SIGNATURE AND DATE

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Gebr. Abraham GmbH Seevetal	2. AUDIT DATE 07-17-03	3. ESTABLISHMENT NO. A-IV-23	4. NAME OF COUNTRY Germany
5. NAME OF AUDITOR(S) Dr. Oto Urban		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	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	X	36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.	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.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic <i>E. coli</i> Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	X
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

GERMANY - Continuation Est.22

10. Condensation and blowing pieces of snow were observed from the refrigeration unit in close proximity of the product in the salting room. This deficiency was immediately corrected by the establishment and affected product was reworked.
13. There was no documentation/information on the cleaning and disinfecting of a plastic probe used to fill the inside of each ham in the salting room. Information provided to the auditor prior to the exit conference was not sufficient.
38. A space under the door was observed in the meat receiving room. This deficiency was corrected before the end of the audit by the establishment.
46. A waste receptacle was used for an improper purpose in the cutting room. The employee performing the operation in which the waste receptacle was used did not perform proper sanitation of his hands and gloves immediately but only when instructed by the quality control personnel. Immediate corrective action was performed by the establishment officials with fines issued to the employee and his immediate supervisor.
51. Better enforcement action by the inspection officials is needed in the product contact areas.
56. EC Directive 64/433

61. NAME OF AUDITOR

Dr. Oto Urhan

62. AUDITOR SIGNATURE AND DATE

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Klumper GmbH & Co. Schuttorf	2. AUDIT DATE 07-11-03	3. ESTABLISHMENT NO. A-EV-29	4. NAME OF COUNTRY Germany
5. NAME OF AUDITOR(S) Dr. Oto Urban		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	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	O
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	X
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	X
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	X
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment:

GERMANY - Continuation Est. A-EV-29

38. Several flies were observed in different processing areas of the establishment. Spider webs were observed in the men's dressing room. There is direct contact with outside areas in some processing areas of the establishment after opening the door. This deficiency was scheduled for correction by the establishment.

44. Lockers in the employees' dressing room reserved for clean working clothes were used to store street clothes. This deficiency was corrected by the establishment.

51. Enforcement by the inspection service needs improvement.

56. EC Directive 64/433.

61. NAME OF AUDITOR

Dr. Oto Urhan

62. AUDITOR SIGNATURE AND DATE

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Abraham Ammerlander Shinken GmbhH & Co.KG EDEWECHT	2. AUDIT DATE 07-15-03	3. ESTABLISHMENT NO. A-EV-35	4. NAME OF COUNTRY Germany
5. NAME OF AUDITOR(S) Dr. Oto Urban		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

60. Observation of the Establishment

GERMANY - Continuation Est.A-EV-35

38. The insect management program needs to better prevent the entrance of insects into the establishment. Flies were observed in the establishment. Direct access of flies to the establishment was observed in the box storage room when the door was opened to the storage room and the processing room at the same time. This deficiency was scheduled for correction by the establishment.

44. Street clothes were mixed with clean working clothes in several lockers in the dressing rooms. Immediate corrective action was taken by the establishment officials, including fines for personnel.

51. Inspection enforcement needs improvement.

56. EC Directive 64/433

61. NAME OF AUDITOR

Dr. Oto Urhan

62. AUDITOR SIGNATURE AND DATE

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Abraham Schinken GmbH & Co. KG Barsel - Harkebrugge	2. AUDIT DATE 07 - 10 - 03	3. ESTABLISHMENT NO. A-IV-191	4. NAME OF COUNTRY Germany
5. NAME OF AUDITOR(S) Dr. Oto Urban		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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8. Records documenting implementation.		34. Species Testing	O
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Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
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17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
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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	
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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

GERMANY - Continuation Est. A-IV-191

61. NAME OF AUDITOR

Dr. Oto Urhan

62. AUDITOR SIGNATURE AND DATE



Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

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AKTENZEICHEN 5106-00/205806
(Bitte bei Antwort angeben)

IHRE ZEICHEN/IHRE 15. September 2003
NACHRICHT VOM

DATUM 10. Dezember 2003

Subject: Comments to the draft final report of an audit carried out in Germany covering Germany's meat inspection system July 8 through July 25, 2003, dated August 28, 2003

Dear Ms. Stratmoen,

to the above mentioned report, we have only one comment:

As noted by the competent authority of 'Bezirksregierung Weser-Ems', the report refers several times to Directive 64/433/EEC as the legal base for the audit (page 6, 7, 10 and 12). However, according to the agreement between the US and the EU (Council Decision 98/258/EC, Annex V, No 8, Public Health), the legal base for the present audit is Directive 77/99/EEC.

Hope you had a nice stay in Europe and a safe journey back.

Best regards

Dr. Georg Schreiber
signed

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