



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

NOV 19 2003

Dr. Gorg Schreiber
Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
(Federal Office of Consumer Protection and Food Safety)
Diedersdorfer Weg 1
12277 Berlin – Marienfield
GERMANY

Dear Dr. Schreiber:

Enclosed is a copy of the final report of the Food Safety and Inspection Service (FSIS) audit of Germany's meat inspection system conducted from February 12, 2003 through March 5, 2003. Comments by Germany on the draft final audit report have been included as Attachment "G" in the final audit report.

If you have any questions or need additional information, please contact me by telephone at 202-720-3781. You may also contact me by fax at 202- 690-4040 or by e-mail at sally.stratmoen@fsis.usda.gov.

Sincerely,

Sally Stratmoen, Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc:

Richard Petges, Minister Counselor, US Embassy, Bonn
Friedrich Wacker, Agricultural Counselor, German Embassy
Agriculture, Fisheries, Food Safety and Consumer Affairs Section, EU Mission to the US
Scott Bleggi, FAS Area Officer
Linda Swacina, Deputy Administrator, FSIS
Karen Stuck, Assistant Administrator, OIA, FSIS
Dave Young, ITP, FAS
Amy Winton, State Department
Donald Smart, Director, Review Staff, PEER, FSIS
Clark Danford, Director, IEPD, OIA
Sally Stratmoen, Director, IES, OIA
Richard F. Brown, IES, OIA
Nancy Goodwin, IES, OIA
Country File (1st Germany Audit FY 2003)

FINAL

OCT 29 2003

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

February 12 through March 5, 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 SSOPs
 - 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
SSOPs	Sanitation Standard Operating Procedures
VEA	European Community/United States Veterinary Equivalence Agreement

1. INTRODUCTION

The audit took place in Germany from February 12 through March 5, 2003.

An opening meeting was held on February 12, 2003 in Berlin with the Central Competent Authority (CCA). At this meeting, the auditor confirmed the objective and scope of the audit, the auditor's itinerary, and requested additional information needed to complete the audit of Germany's meat inspection system.

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 regional and local inspection offices.

2. OBJECTIVE OF THE AUDIT

This was a routine annual audit. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter and 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, two district inspection offices, two local inspection offices, one residue laboratory not performing analytical testing on United States-destined product, one private microbiology laboratory performing *Listeria monocytogenes* analysis on product destined to the U.S., and six meat processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	District	2	
	Local	2	Establishment level
Laboratories		2	
Meat Processing Establishments		6	

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 an audit of a selection of records in the country's inspection District and Local Offices. The third part involved on-site visits to six processing establishments. The fourth part involved visits to one government and one private laboratory. The SGS NATEC private microbiology laboratory was conducting analyses of field samples for the presence of *Listeria monocytogenes* for the establishment certified to export product to the U.S. The Hygiene-Institute in Hamburg, the government

residue laboratory was not conducting analyses of field samples for Germany's national residue control program.

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) slaughter/processing controls, including the implementation and operation of HACCP programs and the testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including the testing program for *Salmonella* species. Germany's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditor also assessed how inspection services are carried out by Germany and also determined if establishment and inspection system controls were in place to ensure the production of meat products that are safe, unadulterated and properly labeled.

During the opening meeting, the auditor explained to the CCA that their inspection system would be audited in accordance with three areas of focus. First, under provisions of the European Community/United States Veterinary Equivalence Agreement (VEA), the FSIS auditor would audit the meat inspection system against European Commission Directive 64/433/EEC of June 1964; European Commission Directive 96/22/EC of April 1996; and European Commission Directive 96/23/EC of April 1996. These directives have been declared equivalent under the VEA.

Second, in areas not covered by these directives, the auditor would audit against FSIS requirements. These include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification testing, and FSIS' requirements for HACCP, SSOP, testing for generic *E. coli* and *Salmonella* species.

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.

Germany doesn't have any certified slaughter establishments approved for export to the U.S. therefore establishments or inspection services are not required to test for *Salmonella* and *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/fo/tsc.

The last two audits of Germany’s inspection system have shown serious problems. Of the problems identified in 2001, the following had been corrected by the audit in 2002:

- Government of Germany (GOG) meat inspection officials were not adequately monitoring/verifying the adequacy and effectiveness of pre-operational and operational sanitation (SSOP) in all establishments.
- Some establishments were not adequately monitoring daily the implementation of the procedures in the Sanitation SOP’s.
- The development and implementation of HACCP requirements was not properly implemented and enforced in all establishments.
- The HACCP plan did not adequately conduct a hazard analysis that included food safety hazards likely to occur in three establishments.
- The HACCP plan did not adequately specify critical limits, monitoring procedures, and the monitoring frequency performed for each CCP in three establishments.
- The HACCP plan did not adequately address the corrective action to be followed in response to a deviation from a critical limit in one establishment.
- The HACCP plan was not validated to determine that it was functioning as intended in three establishments.
- The HACCP plan’s record-keeping system was not documenting the monitoring of CCPs in one establishment.

- The HACCP plan did not adequately state the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequencies with which these procedures will be performed. The on-going verification activities of the HACCP program were not adequately performed by the establishment personnel in four establishments.
- Intralaboratory and/or interlaboratory check samples for their quality assurance program was inadequate for chlorinated hydrocarbons, polychlorinated biphenyls, sulfonamides, organophosphates, trace elements, hormones, chloramphenicol, ivermectin, antibiotics, *Salmonella*, and *Listeria monocytogenes*.
- No corrective action was taken or documented when percent recovery results for check samples of oxytetracycline were unacceptable.
- The control of *Listeria monocytogenes* was not included in the HACCP plan in establishments producing ready-to-eat products.
- Adequate daily inspection coverage for processed products was not provided.
- Second shift operations were not providing inspection coverage in two establishments.

All deficiencies noted during the 2001 audit had been addressed and corrected. During the most recent audit of Germany, conducted by FSIS in May 2002, the following additional deficiencies were identified:

- Sanitation Standard Operating Procedures (SSOP) deficiencies were found in four establishments.
- Deficiencies were observed in categories of Sanitary Operations, Equipment and Utensils, Employee Hygiene, Dressing Rooms/Lavatories, Light, Establishment Construction/Maintenance, Establishment Grounds and Pest Control in all establishments
- Inadequate Slaughter/ Processing Controls were observed in four establishments.
- HACCP program deficiencies were observed in two establishments.

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 formally 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. The reorganization does not impact the responsibilities of the BVL for collaboration with FSIS.

The CCA is responsible for risk management, placing a veterinary food product on the market, formulating administrative rules and their distribution, design monitoring and surveillance plans, coordinating inspections for export activities by the EU, U.S. and third countries, listing of export establishments. They are also responsible for residue control, the National Residue Program and the EU Rapid Alert System.

6.2.1 CCA Control Systems

The CCA has no jurisdiction or direct authority over the 16 State Inspection Programs, but prepares and interprets the laws and coordinates the formal procedures of approved inspection activities. The CCA seeks assurances from state offices that a state inspection program is in place that identifies, evaluates and prevents food safety hazards and verifies the establishment system and process control in Germany. Each State is divided into Districts. The District Office controls, implements, and enforces federal meat hygienic regulations through the Local Office.

6.2.2 Ultimate Control And Supervision

The Local Office has ultimate control and supervision over official activities, including the authority to certify and decertify establishments to export meat products to the United States and of all employees.

6.2.3 Assignment of Competent, Qualified Inspectors

Control and supervision of inspectors in certified establishments was demonstrated at the district and local levels, but there were no written guidelines or documentation for the evaluation of inspection performance at the local level.

6.2.4 Authority and Responsibility to Enforce the Laws

The CCA should strengthen its ability to enforce U.S. requirements by implementing enforcement procedures to identify direct product contamination, take corrective actions, implementation of the 30-day Notice of Intent to Delist policy for SSOP implementation, because five out of six establishments did not adequately implement their SSOP program.

6.2.5 Adequate Administrative and Technical Support

The CCA, through the local and district offices, have the ability to support a third party audit. Based on monthly reports, the CCA did not consistently insure that corrective actions were taken.

6.3 Headquarters Audit

The auditor conducted a review of the inspection system at two District Offices. The District Directors were interviewed in the Districts of Hannover and Luneburg, Germany. No concerns arose as a result of the review.

6.3.1 Audit of Local Inspection Offices

The auditor conducted a review of inspection system documents at the local offices in Hannover and Winsen/Luhe, Germany and in the inspection offices at the audited establishments. The Local Official Veterinarians In Charge of each Local Office and the Official Veterinarians at the audited establishments were interviewed. The records review focused primarily on food safety hazards and included the following:

- Internal review reports
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors and laboratory personnel
- Label approval records such as generic labels, and animal raising claims
- Sampling and laboratory analyses for residues
- Sanitation, and processing inspection procedures and standards
- Export product inspection and control including export certificates

The following concerns arose as a result of the examination of these documents.

- There were no written guidelines or documentation for the evaluation of inspection performance at the Local level.
- The development and implementation of HACCP requirements were not properly implemented and enforced in four establishments.
- Based on monthly reports the CCA did not consistently insure that corrective actions were taken.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of six processing establishments. None of these establishments were delisted by Germany. One establishment received a notice of intent to de-certify the establishment from Germany because of SSOP implementation deficiencies.

This establishment may retain its certification for export to the United States provided that they correct all deficiencies noted during the audit within 30 days of the date the establishment was audited.

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 auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS Pathogen Reduction/HACCP requirements.

The following laboratories were audited:

The Government Institute for Hygiene and Environment of Hamburg Ministry for Environment and Health was performing residue analyses and SGS NATEC private microbiology laboratory was performing *Listeria monocytogenes* analyses for the U.S. certified establishment. The following deficiency was noted:

- The private certified laboratory, SGS NATEC-Institute, was not following the U.S. method for detection of *Listeria monocytogenes*.

Additional findings in these laboratories will be discussed in Section 11.3 (Testing for generic *E. coli*), 12 (RESIDUE CONTROLS), OR 13.2 (Testing for Salmonella species) of this report.

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, and except as noted below, Germany 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 U.S. domestic inspection program. The SSOP in all six establishments were found to meet the basic FSIS regulatory requirements, with the following deficiencies:

- In five of the six establishments audited Sanitation Standard Operation Procedures (SSOP's) were not effectively implemented.
- In one establishment the SSOP's corrective action failed to prevent direct product contamination.
- In three establishments daily records did not adequately document the implementation, monitoring and corrective action of the SSOP's

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

9.2 EC Directive 64/433

In six of six establishments the provisions of EC Directive 64/433 were not effectively implemented.

- In the six establishments with deficiencies, trends were noted, there were two repeat deficiencies, and the inspection officials in two establishments did not take immediate corrective actions.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviews is 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. The following deficiency was noted.

- Inedible product was not denatured/ decharacterized or under secure conditions in all six establishments prior to shipping for rendering.

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 reviews 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 were 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 six establishments. Two establishments had adequately implemented the PR/HACCP requirements. Four establishments had not adequately implemented HACCP, as follows:

- No on-site verification of the monitoring of critical limits of the establishment's HACCP plan was performed.
- HACCP program critical limits for CCP 1 showed three different limits for temperature (4, 7, and 15).
- The establishment's HACCP corrective action was not sufficiently described.

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

11.3 Testing for Generic *E. coli*

Germany does not have any certified slaughter establishment approved for export to the United States. Therefore, no establishment or inspection service is required to test for *E. coli*.

11.4 Testing for *Listeria monocytogenes*

Six of six 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

In six of six establishments, the provisions of EC Directive 64/433 were not effectively implemented and the following deficiencies were noted:

- One establishment was not compliant with requirements for establishment grounds and pest control
- One establishment was not compliant with requirements for equipment and utensils
- Five establishments were not compliant with requirements for sanitary operations.
- Six establishments were not compliant with requirements for condemned product control

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviews 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 Hygiene-Institute Hamburg in Hamburg was a government residue laboratory for the free city of Hamburg primarily involved in the testing of imported goods and not performing any testing for the U.S. certified establishments.

12.1 FSIS Requirements

At the time of this audit, no German slaughter establishments were certified for U.S. export. All raw product was 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 Hygiene-Institute Hamburg, the government residue laboratory, the provisions of EC Directive 96/22 were effectively implemented:

12.2 EC Directive 96/23

In the Hygiene-Institute Hamburg, the 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 auditor reviews is Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella*.

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 certified slaughter establishment approved for export to the U.S. Therefore, no establishment or 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 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 March 5, 2003 in Berlin with the CCA. At this meeting, the primary findings, conclusions, and recommendations from the audit were presented by the auditor.

The CCA understood and accepted the findings.

Dr. Oto Urban
International Audit Staff Officer

for Manzoor H. Chaudry

15. ATTACHMENTS TO THE AUDIT REPORT

Individual Foreign Establishment Audit Forms

Foreign Country Laboratory Review Reports

Foreign Country Response to Draft Final Audit Report

2-27-03

SGS NATEC

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY
 Private micro lab

CITY & COUNTRY
 Hamburg, Germany

ADDRESS OF LABORATORY
 Behrigstrase 154, Hamburg

NAME OF REVIEWER
 Dr. Oto Urban

NAME OF FOREIGN OFFICIAL
 Dr. R. Zschalet, Dr. W. Simmank

Residue Code/Name			▶	List																
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	EVALUATION CODE	C																
	Correct Tissue(s)	08		A																
	Equipment Operation	09		A																
	Instrument Printouts	10		O																
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	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 PROCEDURES			EVAL. CODE																	
Corrected Prior Deficiencies	18	O																		
OTHER REVIEW		19	EVAL. CODE																	
		20																		

SIGNATURE OF REVIEWER

W. Don Parker

DATE

2-27-03

FOREIGN COUNTRY LABORATORY REVIEW <i>(Comment Sheet)</i>		REVIEW DATE 2-27-03	NAME OF FOREIGN LABORATORY SGS NATEC
FOREIGN GOV'T AGENCY Private micro lab		CITY & COUNTRY Hamburg, Germany	ADDRESS OF LABORATORY Behrigstrase 154, Hamburg
NAME OF REVIEWER Dr. Oto Urban		NAME OF FOREIGN OFFICIAL Dr. R. Zschalet, Dr. W. Simmank	

RESIDUE	ITEM	COMMENTS
Listeria	7	Method used for detection of Listeria monocytogenes was not FSIS approved method and findings of Listeria in 25 gr sample was not considered to be a positive sample in the meat product.

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY
 Hamburg Ministry for Environment and Health

CITY & COUNTRY
 Hamburg, Germany

ADDRESS OF LABORATORY
 Marckmannstrasse 129a, Hamburg

NAME OF REVIEWER
 Dr. Oto Urban

NAME OF FOREIGN OFFICIAL
 Drs. P. Horstmann, T. Kuhn, W. Simmank

Residue Code/Name			100	111	300	200	203	400	800	Sp				
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #												
	Sample Handling	01	A	A	A	A	A	A	A	A				
	Sampling Frequency	02	A	A	A	A	A	A	A	A				
	Timely Analyses	03	A	A	A	A	A	A	A	A				
	Compositing Procedure	04	O	O	O	O	O	O	O	O				
	Interpret Comp Data	05	O	O	O	O	O	O	O	O				
	Data Reporting	06	A	A	A	A	A	A	A	A				
ANALYTICAL PROCEDURES	Acceptable Method	07	A	A	A	A	A	A	A	A				
	Correct Tissue(s)	08	A	A	A	A	A	A	A	A				
	Equipment Operation	09	A	A	A	A	A	A	A	O				
	Instrument Printouts	10	A	A	A	A	A	A	A	O				
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	A	A	A	A	A	A	A	O				
	Recovery Frequency	12	A	A	A	A	A	A	A	O				
	Percent Recovery	13	A	A	A	A	A	A	A	O				
	Check Sample Frequency	14	A	A	A	A	A	A	A	A				
	All analyst w/Check Samples	15	A	A	A	A	A	A	A	A				
	Corrective Actions	16	A	A	A	A	A	A	A	A				
	International Check Samples	17	A	A	A	A	A	A	A	A				
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	O	O	O	O	O	O	O	O				
OTHER REVIEW		19												
		20												

SIGNATURE OF REVIEWER

Dr. Oto Urban

DATE

2/26/03

FOREIGN COUNTRY LABORATORY REVIEW

(Comment Sheet)

REVIEW DATE

2-26-03

NAME OF FOREIGN LABORATORY

Institute for Hygiene and Environment

FOREIGN GOV'T AGENCY

Hamburg Ministry for Environment and Health

CITY & COUNTRY

Hamburg, Germany

ADDRESS OF LABORATORY

Marckmannstrasse 129a, Hamburg

NAME OF REVIEWER

Dr. Oto Urban

NAME OF FOREIGN OFFICIAL

Drs. P. Horstmann, T. Kuhn, W. Simmank

RESIDUE

ITEM

COMMENTS

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Meica Ammerlandische Fleischwarenfabrik Fritz Meinen GmbH & Co Edeweicht	2. AUDIT DATE 02 - 20 - 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.	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	
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	X
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	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

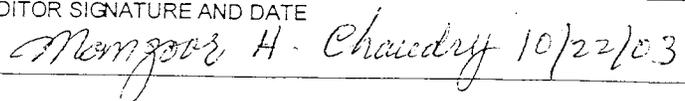
GERMANY - Est. A-IV-10 2-20-03

- 10.a) Water was observed dripping onto product from sausage tree rails in the sausage peeling room. Corrective action was scheduled by the inspection service.
- b) Sausages that were contacting the floor were disposed by inspection personnel and a company representative to inedible and edible product barrel respectively. A plastic container designated for edible purposes was used for inedible product. These deficiencies were scheduled for correction by the establishment.
- 22 Three different critical limits for temperature (4,7,&-15) were record for CCP 1 in the HACCP program. This was scheduled for correction by the establishment.
- 46/56 Flaking paint was observed over the edible product (sausages) in the sausage filling room. This deficiency was scheduled for correction by the establishment management. EC Directive 64/433
- 51 Local official veterinarian did not consistently identified product contact deficiencies and did not document deficiencies during the review process.
- 48/51/56 Inedible product was not denatured/ decharacterized or under secure conditions in this establishment prior to shipping for rendering. EC Directive 64/433

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

Mangoor H. Chaudry 10/22/03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Westfaellische Fleischwarenfabrik Stockmeyer GmbH Sassenberg/Fuechtdorf	2. AUDIT DATE 02 - 28 - 03	3. ESTABLISHMENT NO. A-EV-15	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.	X	47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	X
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 - Est. A-EV-15 2-28-03

- 10 Wheels of washed metal edible product combos were observed to contact clean surfaces of the inside of other metal combos. Pieces of fat were observed in two metal carts used for edible product in the clean equipment storage room. This deficiency was corrected immediately by the establishment management.
- 13 Description of deficiencies was missing in some sanitation records in the establishment SSOP. This deficiency was scheduled for correction by the establishment management.
- 19 The HACCP program did not include on-site verification of monitoring activities. This deficiency was scheduled for correction by the establishment management.
- 38 Several insectocutors were positioning over product areas in the dry storage room and raw storage processing room. The rodent control program did not include inside rodent prevention. The establishment officials scheduled these deficiencies for correction. EC Directive 64/433 was not met.
- 46/56.a) Dusty metal and plastic pallets were used for storage of the edible product. This deficiency was corrected immediately by the company officials. EC Directive 64/433 was not met.
- b) Dirt and water from wheels and underside of a product container were observed to drip toward but not into edible product when lifted by a container-emptying machine in the formulation room. This deficiency was scheduled for correction by the establishment. EC Directive 64/433 was not met.
- c) One establishment employee was observed to pick up meat from the floor and continue working with edible product without washing his hands. This deficiency was corrected immediately by the establishment. EC Directive 64/433 was not met.
- 48/56. The written program for the use of edible and inedible plastic boxes was not clearly defined. Several boxes were used in two areas of the establishment with no clearly defined purpose. This was scheduled for correction by the inspection service. EC Directive 64/433 was not met.
- 48/5. Inedible product was not denatured/ decharacterized or under secure conditions in this establishment prior to shipping for rendering.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

Dr. Manjot H. Chaudry 10/22/03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Gebr. Abraham GmbH Seevetal	2. AUDIT DATE 02 - 21 - 03	3. ESTABLISHMENT NO. A-IV-22	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	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	X
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 - Est. A-IV-22 2-21-03

45/56 Residue of unidentified matter was observed on racks from the smoking room. This was scheduled for correction by the establishment. EC Directive 64/433 was not met.

46/56 Sanitary conditions were not maintained in the water bath used to remove salt from combos of salted hams. Combos of salted hams are placed in a small room. The door to the room is closed and sealed. The room is filled with water and the hams are submerged. The floor is constructed with porous concrete. Employees walk on the surface of this floor and forklifts move combos into this room to begin the washing process. The auditor did not observe this procedure. This observation was discussed with government official. EC Directive 64/433 was not met.

48/51/56. Inedible product was not denatured/ decharacterized or under secure conditions in this establishment prior to shipping for rendering. EC Directive 64/433 was not met.

61. NAME OF AUDITOR

Dr. Oto Urhan

62. AUDITOR SIGNATURE AND DATE

H. Manjoo H. Chaudry 10/22/03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Klumper GmbH & Co. Schuttorf	2. AUDIT DATE 02 - 18 - 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.	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	
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	X
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	X
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	X
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

GERMANY Est. A-EV-29

10.a) Condensation was observed over-product in the ham washing area. This deficiency was corrected immediately by establishment management.

b) Grease particles from rails used to transport hams were observed on hams in the cooler. Unidentified particles were observed on finished product prior to slicing in the slicing room. Proper corrective action was not taken by establishment officials.

22 Corrective action was not sufficiently described in the establishment's HACCP plan. This was scheduled for correction by establishment management.

48/51/56 Inedible product was not denatured/ decharacterized or under secure conditions in this establishment prior to shipping for rendering. This deficiency was discussed with the German inspection officials and corrective action was promised. EC Directive 64/433 was not met.

58. Establishment A-EV 29 was given a Notice of Intent to Dlist (NOID) during last audit on 05/28/02. Because of noncompliance with implementation of SSOPs and HACCP programs with FSIS regulatory requirements and lack of enforcement by GOG inspection officials, the status of this establishment is not equivalent to that required in the U.S. program. Establishment A-EV 29 was delisted by FSIS from the list of establishments eligible to export meat and meat products to the United States, effective 02/18/2003.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

H. Manjoo H. Chaudhry 10/22/03

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Abraham Ammerlander Shinken GmbhH & Co.KG EDEWECHT	2. AUDIT DATE 02 - 19 - 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	

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	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.	X	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.	X	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.		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	X
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.	X
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

GERMANY Est. A-EV-35

10/12 Heavy beaded condensation was observed on air sacks of the cooling system over the product way in the boning room during pre-operational sanitation. Establishment management took insufficient corrective action.

10.a) Washed carts with wheels were contacting other clean contact areas of other clean carts in the equipment wash room during the pre-operational sanitation. Several pieces of meat and fat were observed on clean plastic boxes and carts in the equipment wash room. The establishment management performed corrective action.

b) Pieces of dry meat and fat were observed on a fork and tumblers in the tumbling room during pre-operational sanitation. The establishment management performed corrective action.

c) Several dirty conveyor belts and a meat saw with unidentified particles were observed in the slicing room during pre-operational sanitation. The establishment and inspection officials took immediate corrective action.

13/51 Deficiencies observed during pre-operational sanitation were not recorded in the inspection service records and the establishment records. Corrective action was promised by both; inspection service and the establishment officials.

48/56 Inedible product was not denatured/ decharacterized or under secure conditions in this establishment prior to shipping for rendering. EC Directive 64/433 was not met.

51 Local official veterinarian did not consistently identified product contact deficiencies and did not document deficiencies during the review process.

46/56. One raw ham was observed contacting the floor and several raw hams were in close proximity to the floor in the receiving cooler. Establishment officials immediately condemned the affected ham. EC Directive 64/433 was not met.

58 This establishment was issued a notice of intent to de-certify the establishment from Germany. They can retain their certification if they correct all deficiencies noted during the audit within 30 days of the date the establishment was reviewed..

61. NAME OF AUDITOR

Dr. Oto Urhan

62. AUDITOR SIGNATURE AND DATE

Dr. Manjore H. Chaudhry 10/22/03

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Abraham Schinken GmbH & Co. KG Barsel - Harkebrugge	2. AUDIT DATE 02 - 17 - 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	

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		
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.		X	47. Employee Hygiene		
20. Corrective action written in HACCP plan.			48. Condemned Product Control		X
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.		X
30. Corrective Actions		O	59.		
31. Reassessment		O			
32. Written Assurance		O			

60. Observation of the Establishment

GERMANY - Est. A-IV-191 2-17-03

- 13 SSOP records did not give a clear description of several deficiencies. This deficiency was scheduled for corrective action by establishment management.
- 19 Verification of monitoring critical limits was not included in the written HACCP program. Establishment officials scheduled this deficiency for corrective action.
- 46/56. Plastic containers designated for edible purposes were used for inedible product. This deficiency was corrected immediately by the establishment management. EC Directive 64/433 was not met.
- 48/56. Inedible product was not denatured/ decharacterized or under secure conditions in this establishment prior to shipping for rendering. This deficiency was discussed with the establishment and they promised to correct this deficiency. EC Directive 64/433 was not met.
- 51.a) Monthly supervisory reviews contained several deficiencies, which appeared to be documented incorrectly. The government inspector did not document deficiencies. These deficiencies were discussed with inspection officials and corrective action was promised.
- b) Local official veterinarian did not consistently identified product contact deficiencies and did not document deficiencies during the review process.
58. GOG officials gave a Notice of Intent to Delist if deficiencies identified regarding the implementation requirements for SSOPs and HACCP programs were not corrected within 30 days to establishment officials. GOG is to evaluate the adequacy of corrective actions and provide a full report to FSIS.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

Dr. Manjor H. Chaudry 10/22/03

FEDERAL OFFICE of CONSUMER PROTECTION
and FOOD SAFETY

Reference (please refer to when responding)
5106-00/205806

Tel. 49-1888-412-2134; Fax: 49-1888-412-2177
Email: p.hoppe@bvl.bund.de

Date: July 30, 2003

Federal Office of Consumer Protection and Food Safety
Berlin Office
P. O. Box 480447, 12254 Berlin

United States Department of Agriculture
Food Safety and Inspection Service
Technical Service Center
Ms. Sally Stratmoen

Washington, D.C. 20250 / USA

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

FEBRUARY 12 THROUGH MARCH 5, 2003

Dear Ms. Stratmoen,

I am enclosing comments regarding the above draft of the Audit Report for your information.

Regards,
on behalf of

Dr. Hoppe

encl.

FEDERAL OFFICE of CONSUMER PROTECTION
and FOOD SAFETY

Reference (please refer to when responding)

Tel. 49-1888-412-2114
Fax: 49-1888-412-2177
Email: p.hoppe@bvl.bund.berlin.de

Date: July 30, 2003

5106-00/205806

Federal Office of Consumer Protection and Food Safety
Berlin Office
P. O. Box 480447, 12254 Berlin

United States Department of Agriculture
Food Safety and Inspection Service
Technical Service Center
Ms. Sally Stratmoen

Washington, D.C. 20250 / USA

Comments regarding the Audit Report for Germany, April 14, 2003

Final Draft

Review of the Audit Report resulted in critical comments that address general aspects as well as specific points:

General

The FSIS Draft Report represents, on the one hand, a factual rendering of the conclusions agreed on during the visit. It ends with the sober assertion that "the most important statements, conclusions, and recommendations were presented during the final meeting", but the presentations and conclusions at the final meeting are quite different, as explained in the FSIS letter of April 9, 2003. This is especially noticeable in the case of the company Klümper, whose de-listing is stipulated in the April 9, 2003 letter, a fact that was not even mentioned in the final discussions. This letter, in conjunction with the results of both telephone conferences of March 11 and April 3, 2003, gives the impression that the FSIS questions the requisite competence of the German supervisory agencies. The fact that American inspection officials are critical of

the federate system of the Federal Republic of Germany may not be construed as a failure of the official regulatory system. The fact that deficiencies in the audited companies were identified, shows that this reasoning is not justified. On the contrary, the German supervisory system guarantees European standards that are equal to American standards.

Re: Nr. 3 "protocol", page 6, 4th paragraph:

It must be made clear that the European legal basis in the sphere of meat products is the RL 77/99 EWG (92/05/EWG) and not the RL 64/433/EWG. Insofar, the wrong legal basis was used for the evaluation. The RL 77/99 EWG is contained in the Veterinary Equivalence Agreement (VEA).

Re: Nr. 6.2.2:

The conclusion reached here does not correspond to the facts. The local authorities have by no means the authority to certify resp. de-certify companies. This authority lies with the state agencies in charge of company licensing; e.g. in the states of Lower Saxony and North Rhine Westphalia these are the district administrations. In other states, the highest veterinary agency (ministry level) is responsible. The Federal Ministry, according to §21 of the Meat Hygiene Act, issues the special veterinary control number to companies licensed that way.

Re: Nr. 6.2.3

As repeatedly explained during the Audit, officials in Germany are regularly evaluated in written form. A review of their work in all areas is incorporated into these evaluations; this also includes

their inspection of companies. In the administrative district of Ammerland written procedural instructions for meat inspectors (company employees) are in place. They contain instructions how and how often inspections are to be performed and how they are to be documented. The meat and foodstuffs inspectors are also evaluated at the local level. These evaluations have not, however, been documented up to now. There is furthermore joint monitoring of the meat resp. foodstuffs inspectors with the official veterinary (supervisor) on a regular basis. The schooling and continued training of inspectors is governed by the regulation dealing specifically with foodstuffs inspectors and meat inspectors (Lebensmittelkontrollers- und Fleischkontrollers-Verordnung).

Re: Nr. 6.3.1, 2nd paragraph, and Nr. 11.2:

The monitoring complies with the provisions of the following meat hygiene laws: the Meat Hygiene Act (FIHG = Fleischhygiene-Gesetz), the Meat Hygiene Directive (FIHV = Fleischhygiene-Verordnung), and the General Administrative Directives for the Performance of Official Inspections according to the Meat Hygiene Act and the Poultry Hygiene Act (AW-Fleischhygiene – AW-FIH). What is required of the inspection personnel as well as their schooling and continued training is specified in the respective regulations mentioned above. Therefore, there is actually no need for additional official Internal Guidelines / Operational Instructions. It was nevertheless agreed upon with the FSIS to develop suitable guidelines. These will be forwarded to FSIS when completed.

The contention that the HACCP system has not been adequately implemented, is incorrect. The companies have implemented extensive HACCP plans. The observed deficiencies are rather marginal in our opinion (note also to Nr. 11.2).

Regarding the last point of Nr. 6.3.1, it must again be stated that the BVL is not in charge of ensuring that corrective measures are carried out. The responsibility of ensuring compliance with the regulations lies with the states. It was however agreed that representatives of the BVL must

in future participate in certifying and de-certifying and be involved before a report on the correction of deficiencies is drafted.

Re: Nr. 9.2 and Nr. 10:

As mentioned above, the RL 77/99/EWG is the valid legal basis. Therefore, the stated deficiencies in the implementation of the requirements of RL 63/433/EWG with respect to products not fit for human consumption are only applicable in a limited way. All companies have a functioning waste disposal system according to the Animal Disposal Act resp. according to the requirements of the FIHV, Attachment 2, Chapter 1, Nr. 3.3. Admittedly there were minor deficiencies with respect to closing and locking the containers and weather-proof storage. These deficiencies have already been remedied or are in the process of being remedied. European law does not provide for the denaturing or tinting [coloring?] of non-edible products in meat plants. The handling of products not fit for human consumption (inedible products) is covered in the RL 77/99/EWG (Attachment A, Chapter 1, Nr. 7; Attachment B, Chapter II, Nr. 2), included in the Equivalence Agreement (Attachment V, Nr. 8) and considered to be on par with American regulations (9 CFR 314). Unfit meat (condemned materials) may not be brought into processing plants. It is suggested, for the sake of better understanding, that the terminology (fit, unfit, legally not marketable as foodstuffs, obligation to dispose of) be clarified during the concluding discussion of a future audit.

Re: Nr. 14:

The presentation of the results of the Audit during the final meeting on March 5, 2003 in Berlin was done in a very compressed form. In this short summary it was impossible to

sufficiently point out the relevance of the individually observed deficiencies and especially to weigh the broader decisions based thereon, as should become evident in the case of the Klümper company.

One was left with the impression of a company and an official inspection in a bad state. Looking at the observed (objectively present) deficiencies in a more differentiated way and, at the same time, evaluate them realistically, it can be stated that they are mostly minor and that they were corrected in short order. The correction of these deficiencies required no elaborate structural or systematic changes.

Particulars (deficiencies listed in individual plants)

1. *Plant A – IV – 10, Meica – Edeweicht*

Re: Nr. 10a) on the checklist:

Spraying the sausages before the "peeling" is presently an indispensable technological procedure to which there was previously no objection. Solving this is therefore difficult, because a completely new technological procedure would have to be developed. It should be mentioned that the sausages are still in their casings when this is done. The casings are removed after the spraying in the "peeling room". After the removal of the casings, the sausages are not exposed to dripping water.

Re: Nr. 10b) on the checklist:

Because of a misunderstanding, the sausages were thrown into a scrap waste bucket; a plant employee took the sausages out of that bucket and placed them in the bucket for products unfit for human consumption. Therefore, the sausages that had fallen on the floor were not put into a bucket for edible products.

Re: Nr. 22 on the checklist:

An HACCP plan is developed for a production process which can be used in producing a variety of products. In such a case, the raw material can be different: poultry (+4°C), fresh meat (+7°C), or frozen raw material (-15°C). Because of this, there are different critical limits for the CCP 1. A break-down of the CCP 1 was immediately done.

Re: Nr. 51 on the checklist

This deficiency is incomprehensible because it was not mentioned either during or after the inspection by the auditor.

2. *Plant A – EV 35 – Abraham, Edeweicht:*

Re: Nr. 48 / 56 on the checklist

The waste disposal was not inspected at all.

Re: Nr. 51 on the checklist

It is unclear what is meant by the "review process" – the Audit or the monthly inspection? In any case, inspection records of the local authorities are being prepared.

3. *Plant A – IV 191 – Abraham, Barssel/Harkebrügge*

Re: Nr. 48 / 56 on the checklist

The waste disposal was not inspected at all. There is, however, a lockable container outside the plant.

Re: Nr. 51a) on the checklist

This deficiency is incomprehensible, and perhaps it is the result of a misunderstanding.

Inspection records with deficiency listings are kept by local as well as regional authorities; the local records were also inspected.

Re: Nr. 51b) on the checklist

It is unclear what is meant. It was discussed that, when stacking pallets resp. crates, the lower ones might be contaminated by those stacked above that had previously been on the floor. This potential deficiency has already been corrected.

4. *Plant A – EV – 29 – Klümper GmbH / Co, Schüttorf*

Re: Nr. 22 on the checklist

It was discussed whether rejecting raw material is an adequate corrective action when the critical limits are exceeded (e.g., 8°C core temperature of fresh meat delivery) or whether further measures are to be undertaken. This measure is simple and very effective in ensuring that the product is unobjectionable from a health point of view.

5. *Plant A – IV – 22 – Gebrüder. Abraham GmbH, Seevetal*

Re: Nr. 45 / 56 on the checklist

The inspection of the smoke carts for loose particles has been incorporated into the daily "pre-operational checks". It should be noted that the smoke carts acquire a patina due to the technological process (smoking). The continual removal of the smoke resin with strong cleansers leads to a faster deterioration of the carts. In addition, the firmly adhering patina poses no danger for the product.

Re: Nr. 46 / 56 on the checklist

Hams for the U.S. market are made only of small raw materials. With these small hams, the soaking phase [?] is omitted. [Translator's Note: It is not clear from the context what is actually meant by the term "Wässerungsphase"; I have translated it with "soaking phase" but it could also mean something like watering or rinsing phase] Before the hams are washed, they are tiered and sprayed with drinking water to clean them of adhering seasonings, and thereafter they are washed. Special attention is paid that there are no aerosols are forming.

Re: Nr. 48 / 51 / 56 on the checklist

A locking waste container was built outside. In regular intervals confiscated materials are carried to this waste container by an employee designated for this job. Pick-up is done daily by the carcass disposal facility. Monitoring is done according to the provisions of the meat hygiene laws: the Meat Hygiene Act (FIHG), the Meat Hygiene Directive (FIHV) and the General Administrative Instructions for the Performance of Official Inspections according to the Meat Hygiene Act and the Poultry Hygiene Act (AW-FIH). What is required of the inspection personnel as well as their schooling and continued training is specified in the respective regulations mentioned above. Therefore, there is actually no need for additional official internal Guidelines / Operational Instructions. It was nevertheless agreed upon with the FSIS to develop suitable guidelines. These will be forwarded to FSIS when completed.

The assertion that the HACCP system was not being adequately implemented is incorrect. The plants have installed extensive HACCP plans. The deficiencies observed are, in our opinion, rather marginal (note also to 11.2).

Regarding the last point of Nr. 6.3.1, it must again be stated that the BVL is not in charge of ensuring that corrective measures are carried out. The responsibility of ensuring compliance with the regulations lies with the states. It was however agreed that representatives of the BVL must in future participate in certifying and de-certifying and be involved before a report on the correction of deficiencies is drafted.

Re: Nr. 9.2 and Nr. 10 on the checklist

As explained above, the Guideline 77/99/EWG is the valid legal basis. Therefore, the stated deficiencies in the implementation of the requirements of RL 64/433/EWG with respect to the handling of products not fit for human consumption are only applicable in a limited way. All companies have a functioning waste disposal system according to the Animal Disposal Act resp. according to the requirements of the FIHV, Attachment 2, Chapter 1, Nr. 3.3. Admittedly there were minor deficiencies with respect to closing and locking the containers and weather-proof storage. These deficiencies have already been remedied or are in the process of being done. European law does not provide for the denaturing or tinting [coloring?] of non-edible products in meat plants. The handling of products not fit for human consumption (inedible products) is covered in the RL 77/99/EWG (Attachment A, Chapter 1, Nr. 7; Attachment B, Chapter II, Nr. 2), included in the Equivalence Agreement (Attachment V, Nr. 8) and considered to be on par with American regulations (9 CFR 314). Unfit meat (condemned materials) may not be brought into processing plants. It is suggested, for the sake of better understanding, that the terminology (fit, unfit, legally not marketable as foodstuffs, obligation to dispose of) be clarified during the concluding discussion of a future audit.

Re: Nr. 14 on the checklist

The presentation of the results of the Audit during the final meeting on March 5, 2003 in Berlin was done in a very compressed form. In this short summary it was impossible to sufficiently point out the relevance of the individually observed deficiencies and especially to weigh the broader decisions based thereon, as should become evident in the case of the Klümper company. One was left with the impression of a company and an official inspection in a bad state. Looking at the observed (objectively present) deficiencies in a more differentiated way and, at the same time, evaluate them realistically, it can be stated that they are mostly minor and that they were corrected in short order. The correction of these deficiencies required no elaborate structural or systematic changes.

Confirmation of Receipt

This is to confirm that the following document was received by
Dr. Peter-Paul Hoppe, Chief Veterinary Officer, Federal Office of
Consumer Protection and Food Safety, Bundesamt fuer Verbraucherschutz und
Lebensmittelsicherheit (BVL)



Subject: Reorganization of FSIS functions pertaining to import reinspection

Letter from Karen Stuck, Assistant Deputy Administrator, Office of International Affairs,
Food Safety and Inspection Service (FSIS), United States Department of Agriculture
(USDA), dated July 17, 2003

Signature:

A handwritten signature in black ink, appearing to read "K. Hoppe", written over a horizontal line.

Dr. Hoppe, BVL

Date:

30.07.2003

Please sign this confirmation and fax it to:

Foreign Agricultural Service
Fax: (030) 8431 1935