



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

FEB 11 2003

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2/14/03

Dr. Peter-Paul Hoppe, Chief Veterinary Officer
Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (EVL)
(Federal Office of Consumer Protection and Food Safety)
Diedersdorfer Weg 1
12277 Berlin - Marienfeld
GERMANY

Dear Dr. Hoppe:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Germany's meat inspection system from May 22, 2002 through June 6, 2002. Enclosed is a copy of the final audit report. Comments by Germany on the draft final audit report have been included as an attachment to the enclosed final audit report.

FSIS was very pleased with your comments of November 15, 2002 and have noted the organizational and name changes for our records. We were particularly pleased to learn that you will continue to be our contact until further notice. FSIS has also reviewed your comments regarding the audit report and made the necessary changes. Some of the discrepancies appeared to be translation problems and we have tried to adjust the report accordingly.

Finally, the information received from your office regarding the actions taken by the inspection service and by the three establishments receiving a 30-day notice of intent-to-delist was sufficient to address our concerns. FSIS is grateful that you have made the necessary adjustments to the German meat inspection system in response to the aforementioned audit and taken the indicated corrective and preventive actions.

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

Sincerely,

Sally Stratmoen JD

Sally Stratmoen, Acting Director
Equivalence Staff
Office of International Affairs

Enclosure

Dr. Peter-Paul Hoppe

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cc:

Friedrich Wacker, Agricultural Counselor, German Embassy

Richard Petges, Minister Counselor, American Embassy, Bonn

Joerg Niederberger, Agric./Consumer Affairs, EU Mission to the US, Wash., DC

Norval Francis, Minister/Counselor for Agricultural Affairs, US/EU/Brussels

John Wilson, FAS Area Officer

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Sally Stratmoen, Acting Director, ES, OIA

Richard F. Brown, ES, OIA

Country File (Germany - FY 2003 Audit)



AUDIT REPORT FOR GERMANY MAY 22 THROUGH JUNE 6, 2002

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Germany's meat inspection system from May 22 through June 6, 2002. The six establishments certified to export meat to the United States were audited. All establishments were conducting processing operations.

The last audit of the German meat inspection system was conducted in July/August 2001. Five establishments were audited. The auditor found serious deficiencies in one establishment, which was evaluated as acceptable/re-review. The following major concerns were reported at that time:

Sanitation Controls

- 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.
- The sanitizer in the receiving room in Establishment A-EV-36 was not maintained at the required temperature during hog carcass trimming operations.
- A few racks for exposed product in the receiving room in Establishment A-EV-36 were found with old fat residues and black discolorations.
- One employee was observed cleaning the floor with a broom and, without washing her hands, handling edible product in the processing room in Establishment A-EV-36.

Animal Disease Controls

- Inedible product was not denatured/decharacterized or under secure conditions before shipping for rendering in Establishment A-EV-36.

Slaughter/Processing Controls

- The HACCP plans in Establishments A-EV-36, AIV-191, and A-IV-22 did not contain hazard analyses that included all food safety hazards likely to occur.

- The HACCP plans in Establishments A-IV-10, A-EV-36, and A-EV-139 did not adequately specify critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
- The HACCP plan in Establishment A-IV-22 did not adequately address the corrective actions to be followed in response to deviations from critical limits.
- The HACCP plans in Establishments A-EV-36, A-EV-139, and A-IV-10 were not validated to determine that they were functioning as intended.
- The HACCP plans in Establishments A-IV-10, A-EV-36, A-EV-139, and A-IV-191 did not adequately state the procedures that the establishments will use to verify that the plans are being effectively implemented and the frequencies with which these procedures will be performed. The on-going verification activities of the HACCP programs were not adequately performed by the establishment personnel.
- The monitoring of CCPs was not documented in Establishment A-IV-10.
- Intralaboratory and/or interlaboratory check samples for chlorinated hydrocarbons, polychlorinated biphenyls, sulfonamides, organophosphates, trace elements, hormones, chloramphenicol, ivermectin, and antibiotics were inadequate.
- No corrective action was taken when percent recovery results for check samples of oxytetracycline were unacceptable (below 80%).

Enforcement Controls

- The control of *Listeria monocytogenes* was not included in the HACCP plan in establishments producing ready-to-eat products.
- Inspection coverage for establishments producing processed products was not provided daily.
- Inspection coverage for second shift-operations was not adequate in Establishments A-IV-10 and A-IV-191.
- The inspection and establishment system documents were maintained in the city, district, or regional offices, but were not sent to the BgVV national headquarters in Berlin.
- Lines of authority and supervision of subordinates and inspection activities through the National, State, Regional, District, and City levels, including the certification of U.S. export establishments, were disjointed.

Germany exports only cured and processed pork to the United States. Restrictions are placed on fresh pork and beef due to presence of Hog Cholera and Bovine Spongiform Encephalopathy (BSE). All fresh pork is imported from eligible establishments in Denmark.

From January 1 to April 30, 2002, German establishments exported 248,480 pounds of pork sausage and cured port to the U.S. Of this amount, 45,340 pounds were reinspected at ports of entry. A total of 17 pounds were rejected for transportation damage.

PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with German national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second was conducted by on-site visits to establishments. The third was a visit to two laboratories, both performing analytical testing of field samples for the national residue testing program, and culturing field samples for the presence of microbiological contamination with *Salmonella* and *Listeria monocytogenes*.

Germany's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems, and (5) enforcement controls, including the testing program for *Salmonella* species.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Six establishments (A-IV-10, A-EV-15, A-IV-22, A-EV-29, A-EV-35, and A-IV-191) were audited; three of these (A-EV-15, A-EV-29, and A-IV-191) were issued a 30- day reassessment letter. Details of audit findings, including compliance with HACCP and SSOP requirements, are discussed later in this report.

At the time of this audit, no slaughter establishments were certified for U.S. export, therefore carcass testing for generic *E. coli* and *Salmonella* species was not required. The ready-to-eat products were routinely tested for *Listeria monocytogenes* (with one exception) and *Salmonella*.

As stated above, several major concerns had been identified during the last audit of the Germany meat inspection system conducted in July/August 2001. During this new audit, the auditor determined that those concerns had been addressed and corrected.

Entrance Meeting

On May 22, 2002, an entrance meeting was held in the Berlin offices of the Federal Institute for Health Protection of Consumer and Veterinary Medicine (BgVV), and was attended by Dr. Ekkerhard Weise, Director and Professor, Food Safety and Hygiene (FSH), BgVV; Dr. Peter Paul Hoppe, Deputy Director, Food Safety and Hygiene; Dr. W. Peter Voigt, Import/Export, BgVV; Mr. Richard Petges, Minister-Counselor for Agricultural Affairs, Foreign Agricultural Service (FAS), the United States Embassy in Berlin; Ms. Kerstin Kruger, Agricultural Assistant, Foreign Agricultural Service (FAS), the United States Embassy in Berlin; and Dr. Oto Urban, International Audit Staff Officer, FSIS.

Topics of discussion included the following:

1. A welcome by Dr. Ekkehard Weise, Director, FSH, BgVV and a presentation of familiarization with the German inspection system.
2. The audit itinerary and travel arrangements,
3. Discussion of previous audit findings and corrective actions, and
4. A presentation of the national residue testing program, enforcement, the species verification program, and the current disease status of Germany.

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of Germany's inspection system in July/August, 2001. To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The auditor conducted reviews of inspection system documents pertaining to the establishments certified for U.S. export. These reviews were conducted in the inspection service offices in the audited establishments. The records reviews focused primarily on food safety hazards and included the following:

- Internal review reports,
- Supervisory visits,
- Label approval records such as generic labels, and animal raising claims,

- Sampling and laboratory analyses for residues,
- Food safety initiatives such as SSOPs, and HACCP programs,
- Sanitation and processing inspection procedures and standards, and
- Export product inspection and control, including export certificates.
-

The following concern arose as a result of the examination of these documents:

- The pre-operational and operational sanitation activities were not clearly defined in the written SSOPs in Ests. A-EV-29 and A-EV-35. These deficiencies were scheduled for correction by the establishment officials.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Germany as eligible to export meat products to the United States were full-time state government employees, receiving no remuneration from either industry or establishment personnel. The relationship between the Federal Institute for Consumer Health Protection and Veterinary Medicine (BgVV) and the State Inspection System was explained by the Deputy Director, Food Safety and Hygiene.

The BgVV responsibilities are:

- Release of information on companies licensed to supply foodstuffs of animal origin
 - a) Release of border control information.
 - b) Release of other information required by the European Union guidelines.
- Monitoring of export firms in third countries by veterinarians (in areas not covered by common regulations).
- Recognition and listing of export companies in third countries (in areas not covered by common regulations).
- Responding to complaints regarding shipments of foodstuffs of animal origin
 - a) From EU member states.
 - b) From third countries, and
 - c) From Germany, if the complaints originate in other EU or third countries.
- Statistics concerning foodstuffs of animal origin.
- Approval and listing of border control points.
- Approval and listing of tariffs and storage facilities.

- Mentoring and oversight of EU experts and evaluation of EU inspections in Germany by the Food and Veterinary Office of the European Commission (FVO).

The federal government (BgVV) has no jurisdiction or direct authority over the 16 State Inspection Programs, but prepares and interprets the laws and coordinates the formal procedures of approval inspection activities.

Through the periodic conferences and meetings with the state authorities, the federal government (BgVV) seeks assurances from states 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.

Establishment Audits

Six establishments (A-IV-10, A-EV-15, A-IV-22, A-EV-29, A-EV-35, and A-IV-191) were certified to export meat and meat products to the United States at the time this audit was conducted. All six were visited for on-site audits. Three of these (A-EV-15, A-EV-29, and A-IV-191) were issued a 30-day reassessment letters because of deficiencies regarding sanitation and the condition of facilities.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected about the risk areas of government oversight of accredited, approved, and private laboratories and intra-laboratory quality assurance procedures, including sample handling and methodology.

The Veterinary Institute laboratory in Oldenburg, which was performing residue and microbiology testing, was audited on May 23, 2002. Except as noted below, effective controls were in place for 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 methods used for the analyses were acceptable. No compositing of samples was done (this was not a deficiency).

- The check sample program did not meet FSIS requirements. No intralaboratory, interlaboratory or international check sampling was performed for chloramphenicol in this laboratory.

The government Veterinary Institute laboratory in Hannover was performing both the residue and microbiological testing for *Salmonella* and *Listeria monocytogenes*. The methodologies employed for testing for *Salmonella* species and *Listeria monocytogenes* were appropriate.

- No intralaboratory, interlaboratory or international check sampling was performed for chloramphenicol or arsenic in this laboratory.

Establishment Operations by Establishment Number

The following operations were being conducted in the six establishments:

Pork processing - all six establishments (A-IV-10, A-EV-15, A-IV-22, A-EV-29, A-EV-35, and A-IV-191).

SANITATION CONTROLS

Based on the on-site audits of the establishments, Germany's inspection system had controls in place for ventilation, plumbing and sewage, and water supply.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements, with the following exceptions:

- In Est. A-IV-10, product hangers in the sausage-filling area were found with pieces of meat on them during pre-operational sanitation inspection. This deficiency was overlooked by the responsible establishment employee. It was corrected immediately and production resumed after approximately 1 hour.
- Dripping over-product condensation was observed in Est. A-EV-15. Corrective actions were taken by the in-plant inspection service but not by the responsible establishment employee. This deficiency was not documented in the pre-operational or operational SSOP records.
- The pre-operational and operational sanitation activities were not clearly defined in the written SSOPs in Ests. A-EV-29 and A-EV-35. These deficiencies were scheduled for correction by the establishment officials.

Sanitary Operations

- Three hams were contacting the wall in the receiving cooler and black spots were observed on the product in the slicing room in the Est. A-EV-29. These deficiencies were corrected immediately by the establishment management.
- Water was dripping from a door into combo bins of meat in the receiving room in Est. A-IV-191. This deficiency was corrected immediately and the door was scheduled for replacement by the establishment.

- In Est. A-EV-35, standing water was present in two coolers, presenting a potential to contaminate product. The BgVV officials ordered correction.
- In Est. A-EV-35, grease from rails was observed on the product (hams). The BgVV officials ordered correction.
- Edges of clean metal containers were contacting the floor in Est. A-EV-15. Correction was ordered by the inspection service.

Equipment and Utensils

- There was no knife sanitizer in the preparation and slicing room in Est. A-EV-15. The meat inspection officials ordered prompt correction.
- Washing of dirty combos and barrels was not adequate (product residues were present in some) in Est. A-IV-191. This was corrected immediately by the establishment official.

Employee Hygiene

- Metal protective shirts were contacting the floor in the changing room in Est. A-IV-22. This deficiency was corrected immediately by the establishment management.

Dressing Rooms/Lavatories

- Clean work coveralls were stored in contact with street clothes in two dressing room lockers in Est. A-EV-15. This deficiency was scheduled for correction by the establishment management.

Lighting

- No light source was installed over the inspection table in the inspection room in Est. A-IV-22. This deficiency was scheduled for correction by the establishment management.

Establishment Construction/Maintenance

- A broken wall with holes was observed in the freezer in Est. A-IV-191. This deficiency was scheduled for correction by the establishment management.
- Flaking paint and a rusty doorframe were observed in the meat receiving room and a rusty pipe was observed above exposed product in the salting room in Est. A-IV-22. These deficiencies were scheduled for correction by the establishment.
- Flaking paint was observed over an edible product traffic area in the inspection room. This deficiency was scheduled for corrective action by the establishment.

Establishment Grounds and Pest Control

- There were gaps between doors and floors in the receiving rooms in Ests. A-EV-29 and A-EV-35. Corrections were scheduled by the establishments.
- There was a gap between the door and the floor in the export area in Est. A-IV-10, providing a potential entrance point for rodents. The deficiency was scheduled for correction.
- A bait station containing a toxic rodenticide was used inside the spice room in Est. A-IV-10. This was corrected immediately by the establishment management.

ANIMAL DISEASE CONTROLS

No slaughter establishments were certified as eligible for U.S.-export at the time of this audit.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit. APHIS has restrictions on importation of beef from Germany due to the presence of BSE, and of pork due to hog cholera.

RESIDUE CONTROLS

Germany's National Residue Testing Plan for 2002 was being followed, and was on schedule. The German inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals. Residue testing is also being performed at the slaughter establishments in Denmark. If violation is found this is immediately reported to the German Inspection Service.

SLAUGHTER/PROCESSING CONTROLS

At the time of this audit, no slaughter establishments were certified for U.S. export. Except as otherwise noted below, the German meat inspection system had adequate controls in place for condemned and restricted products and procedures for sanitary handling of returned and rework product. Additionally, establishments had adequate controls in place to prevent meat products intended for German domestic consumption from being commingled with products eligible for export to the U.S.

The following deficiencies were identified:

- A barrel designated for edible product was used for inedible materials in each of two establishments, Est. A-EV-29 and A-IV-191. These deficiencies were corrected immediately by the establishment officials.

- The U.S. Standards and Labeling Division approval of one of the "hot dog" labels in Est. A-IV-10 still included beef. The actual product label did not include beef. The establishment will correct this deficiency.
- There was still a temporary U.S. approval for one of the "sliced hams" in Est. A-IV-22. The establishment will obtain the final approval.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were found to meet the basic FSIS regulatory requirements. Two deficiencies regarding other HACCP requirements were found:

- On-site verification was not performed in Est. A-EV-29. This was scheduled for correction by the establishment.
- The calibration requirement was not included in the verification portion of the HACCP program in Est. A-EV-35. This deficiency was scheduled for correction.

Testing for Generic *E. coli*

At the time of this audit, no slaughter establishments were certified for U.S. export, so testing for generic *E. coli* was not required. Germany receives raw pork for processing into U.S.-eligible products from eligible establishments in Denmark.

ENFORCEMENT CONTROLS

Inspection System Controls

The German inspection system controls were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. These included control of restricted product and inspection samples; boneless meat reinspection; shipment security, including shipment between establishments; prevention of commingling of product intended for export to the United States with domestic product; monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans); inspection supervision and documentation; and the importation of only eligible meat products from other countries (i.e., only from eligible countries and certified establishments within those countries). In addition, adequate controls were found to be in place for security items, shipment security, and other products entering the establishments from outside sources.

Testing for *Salmonella* Species

At the time of this audit, no slaughter establishments were certified for U.S. export, so testing for *Salmonella* species was not required. Germany receives raw pork for processing into U.S.-eligible products from eligible establishments in Denmark.

Species Verification

At the time of this audit, Germany was not exempt from the species verification requirement. The auditor verified that species verification was being conducted in accordance with FSIS requirements.

One deficiency was identified:

- No testing for *Listeria* was performed in Est. A-EV-29.

Monthly Reviews

These reviews were being performed by the German County/Local District/Regional officials, approximately equivalent to Circuit Supervisors/District Managers. All were veterinarians.

The internal review program was applied equally to both export and non-export establishments. Internal reviews were not announced in advance, and were conducted, at times by individuals and at others by more than one reviewer, at least once per month. The records of audited establishments were kept in the county/local district inspection offices, and were routinely maintained on file for a minimum of two years.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again qualify for eligibility to be reinstated, the County, District or Regional supervisor is empowered to conduct an-in-depth review, and only recommendation for certification is reported to BgVV in Berlin through the State Inspection system.

Enforcement Activities

The domestic and exporting country requirements are enforced by the State Inspection system officials. They are empowered by law to take corrective measures, penalize violators, and suspend or withdraw their licenses to operate. Other federal and state law enforcement agencies are involved in investigations and control.

The meat inspection system is administered independently by each of the 16 states. Each State controls, implements, and enforces federal meat hygiene regulations. The inspection and establishment system documents are maintained in the county, district or regional offices. The inspectors are also responsible for inspection and compliance enforcement of the inspection laws for various products, in addition to periodic meat inspection. Controls were in place to ensure adequate export product identification, inspector verification, export certifications, and products entering the establishments from outside sources. In general, in-plant inspection personnel did not sufficiently enforce sanitary requirements. Regional inspection service officials were performing their supervisory reviews effectively.

The following deficiencies were identified:

- In half the establishments, in-plant inspection personnel did not sufficiently enforce sanitation requirements.
- Daily inspection coverage was not provided during the second shift in Est. A-EV-29 and was not always provided during the second shift in Est. A-EV-15.

Exit Meetings

An exit meeting was conducted on June 6, 2002, in the Berlin offices of the Federal Ministry of Health, and was attended by Dr. Peter Paul Hoppe, Deputy Director, Food Safety and Hygiene; Dr. W. Peter Voigt, Import/Export, BgVV; Ms. Kerstin Kruger, Agricultural Assistant, Foreign Agricultural Service (FAS), the United States Embassy in Berlin, Dr. Sally Stratmoen, Acting Director of the International Policy Division (by telephone), and Dr. Oto Urban, International Audit Staff Officer, FSIS. Additionally, three representatives of the European Commission (EC) participated from Brussels by teleconference.

The following topics were discussed:

- The individual findings from the audits of the six establishments and the two laboratories, as itemized in the body of this report.
- The concerns that arose from the audits of inspection system documentation.

CONCLUSION

Six establishments were audited. Three of these establishments were issued letters of reassessment. The deficiencies encountered during the on-site establishment audits were either adequately addressed to the auditor's satisfaction or scheduled for timely correction. The German federal government has no direct authority to monitor periodically the on-site implementation of meat inspection programs run by the individual states; however, all previously identified deficiencies had been adequately addressed and corrected by the state inspection services.

Dr. Oto Urban
International Audit Staff Officer

ATTACHMENTS

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs
- C. Data collection instrument for *E. coli* testing (*not applicable*)
- D. Data collection instrument for *Salmonella* testing (*not applicable*)
- E. Laboratory Audit Forms
- F. Individual Foreign Establishment Audit Forms
- G. Written Foreign Country's Response to the Draft Final Audit Report

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1. Written program addressed	2. Pre-op sanitation addressed	3. Oper. Sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible indiv. Identified	7. Documentation done daily	8. Dated and signed
A-IV-10	√	No	√	√	√	√	√	√
A-EV-15	√	√	No	√	√	√	No	√
A-IV-22	√	√	√	√	√	√	√	√
A-EV-29	√	√	√	√	√	√	No	√
A-EV-35	√	√	√	√	√	√	No	√
A-IV-191	√	√	√	√	√	√	√	√

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing routine pre-shipment document reviews.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. Use & users included	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corr. actions are described	8. Plan validated	9. Adequate verific. procedures	10. Adequate documentation	11. Dated and signed	12. Pre-shipment doc. review
A-IV-10	√	√	√	√	√	√	√	√	√	√	√	√
A-EV-15	√	√	√	√	√	√	√	√	√	√	√	√
A-IV-22	√	√	√	√	√	√	√	√	√	√	√	√
A-EV-29	√	√	√	√	√	√	√	√	No	√	√	√
A-EV-35	√	√	√	√	√	√	√	√	No	√	√	√
A-IV-191	√	√	√	√	√	√	√	√	√	√	√	√

REVIEW DATE
 5-23-02

NAME OF FOREIGN LABORATORY
 Veterinary Institute Laboratory

Att. E-1a

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY
 Federal Lander Lower Saxony

CITY & COUNTRY
 Oldenburg, Germany

ADDRESS OF LABORATORY

NAME OF REVIEWER
 Dr. Oto Urban

NAME OF FOREIGN OFFICIAL
 Dr. W. Peter Voigt

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

SIGNATURE OF REVIEWER

DATE

FOREIGN COUNTRY LABORATORY REVIEW

(Comment Sheet)

REVIEW DATE

5-23-02

NAME OF FOREIGN LABORATORY

Veterinary Institute Laboratory

E-16

FOREIGN GOV'T AGENCY
Federal Lander Lower Saxony

CITY & COUNTRY
Oldenburg, Germany

ADDRESS OF LABORATORY

NAME OF REVIEWER

Dr. Oto Urban

NAME OF FOREIGN OFFICIAL

Dr. W. Peter Voigt

RESIDUE	ITEM	COMMENTS
203	14,15, 16,17	Intralaboratory, interlaboratory and international check samples for quality assurance were not performed for chloraphenicol.

FOREIGN COUNTRY LABORATORY REVIEW

5-24-02

Veterina y Institute Laboratory *E-2a*

FOREIGN GOV'T AGENCY
 Federal Lander Lower Saxony

CITY & COUNTRY
 Hannover, Germany

ADDRESS OF LABORATORY

NAME OF REVIEWER
 Dr. Oto Urban

NAME OF FOREIGN OFFICIAL
 Dr. W. Peter Voigt

Residue Code/Name		100	111	200	203	300	410	500	800	Sal	List		
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE										
	Sample Handling	01	A	A	A	A	A	A	A	A	A		
	Sampling Frequency	02	A	A	A	A	A	A	A	A	A		
	Timely Analyses	03	A	A	A	A	A	A	A	A	A		
	Compositing Procedure	04	O	O	O	O	O	O	O	O	O		
	Interpret Comp Data	05	O	O	O	O	O	O	O	O	O		
Data Reporting	06	A	A	A	A	A	A	A	A	A			
ANALYTICAL PROCEDURES	Acceptable Method	07	A	A	A	A	A	A	A	A	A		
	Correct Tissue(s)	08	A	A	A	A	A	A	A	A	A		
	Equipment Operation	09	A	A	A	A	A	A	A	A	A		
	Instrument Printouts	10	A	A	A	A	A	A	A	O	O		
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	A	A	A	A	A	A	A	O	O		
	Recovery Frequency	12	A	A	A	A	A	A	A	O	O		
	Percent Recovery	13	A	A	A	A	A	A	A	O	O		
	Check Sample Frequency	14	A	A	A	C	A	C	A	A	A		
	All analyst w/Check Samples	15	A	A	A	C	A	C	A	A	A		
	Corrective Actions	16	A	A	A	C	A	C	A	A	A		
International Check Samples	17	A	A	A	C	A	C	A	A	A			
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	A	A	A	A	A	A	A	A	A		
OTHER REVIEW		19											
		20											

SIGNATURE OF REVIEWER

DATE

FOREIGN COUNTRY LABORATORY REVIEW

(Comment Sheet)

REVIEW DATE

5-24-02

NAME OF FOREIGN LABORATORY

Veterinary Institute Laboratory

E-26

FOREIGN GOV'T AGENCY
Federal Lander Lower Saxony

CITY & COUNTRY
Hannover, Germany

ADDRESS OF LABORATORY

NAME OF REVIEWER
Dr. Oto Urban

NAME OF FOREIGN OFFICIAL
Dr. W. Peter Voigt

RESIDUE	ITEM	COMMENTS
203	14, 15, 16, 17	Intralaboratory, interlaboratory and international check samples were not performed for chloramphenicol and arsenic.

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Meica Ammerlandische Fleischwarenfabrik Edeweicht, Lower Saxony	2. AUDIT DATE 5-30-02	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	
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.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling	X	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

F-16

A-IV-10

- 10. Product hangers in the sausage-filling area were found with pieces of meat on them during pre-operational sanitation inspection. This deficiency was overlooked by the responsible establishment employee. It was corrected immediately and production resumed after approximately 1 hour.
- 25. The U.S. Standards and Labeling Division approval of one of the "hot dog" labels still included beef. The actual product label did not include beef. The establishment will correct this deficiency.
- 38. There was a gap between the door and the floor in the export area, providing a potential entrance point for rodents. The deficiency was scheduled for correction.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Westfälische Fleischwarenfabrik Stockmeyer GmbH & Co. Sassenberg/Fuchtorf	2. AUDIT DATE 6-4-02	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	
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.	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	X
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	X
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

F-26

.Est. A-EV-15

12/13 Dripping over-product condensation was observed. Corrective actions were taken by the in-plant inspection service but not by the responsible establishment employee. This deficiency was not documented in the pre-operational or operational SSOP records.

44. Clean work coveralls were stored in contact with street clothes in two dressing room lockers in Est. A-EV-15. This deficiency was scheduled for correction by the establishment management.

45. There was no knife sanitizer in the preparation and slicing room in Est. A-EV-15. The meat inspection officials ordered prompt correction.

46. Clean metal containers were contacting the floor with the product contact edge in. This deficiency was scheduled for correction by the inspection service.

50. Daily inspection coverage was not always provided during the second shift.

61. NAME OF AUDITOR Dr. Oto Urban	62. AUDITOR SIGNATURE AND DATE
--------------------------------------	--------------------------------

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Gebr. Abraham GmbH Seevetal, Lower Saxony	2. AUDIT DATE 5-31-02	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	
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	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	X
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	X
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling	X	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

F-36

A-IV-22

- 25. There was still a temporary U.S. approval for one of the "sliced hams." The establishment will obtain the final approval.
- 39. Flaking paint and a rusty doorframe were observed in the meat receiving room and a rusty pipe was observed above exposed product in the salting room in Est. A-IV-22. These deficiencies were scheduled for correction by the establishment.
- 39. Flaking paint was observed over an edible product traffic area in the inspection room. This deficiency was scheduled for corrective action by the establishment.
- 40. No light source was installed over the inspection table in the inspection room in Est. A-IV-22. This deficiency was scheduled for correction by the establishment management.
- 47. Metal protective shirts were contacting the floor in the changing room in Est. A-IV-22. This deficiency was corrected immediately by the establishment management.

61. NAME OF AUDITOR
Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Heinrich Kluemper GmbH Schuettorf, Lower Saxony	2. AUDIT DATE 5-28-02	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	X
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.	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	X
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

F-46

Est. A-EV-29

- 13. The pre-operational and operational sanitation activities were not clearly defined in the written SSOPs.
- 19. On-site verification was not performed. This was scheduled for correction by the establishment.
- 33. No testing for *Listeria* was performed in this establishment. This was scheduled for correction by the establishment.
- 38. There was a gap between the door and the floor in the receiving room. This was scheduled for correction by the establishment.
- 46. Three hams were contacting the wall in the receiving cooler and black spots were observed on the product in the slicing room in the Est. A-EV-29. These deficiencies were corrected immediately by the establishment management.
- 48. A barrel designated for edible product was used for inedible materials. This was corrected immediately by the establishment officials.
- 50. Daily inspection coverage was not provided during the second shift.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Abraham Ammerlander Schinken Edewecht, Lower Saxony	2. AUDIT DATE	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	
8. Records documenting implementation.		34. Species Testing	O
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	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	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	O
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

60. Observation of the Establishment

F-56

A-EV-35

- 13. The pre-operational and operational sanitation activities were not clearly defined in the written SSOPs. This was scheduled for correction by the establishment officials.
- 19. The calibration requirement was not included in the verification portion of the HACCP program. This deficiency was scheduled for correction.
- 38. There was a gap between the door and the floor in the receiving rooms. Correction was scheduled by the establishments.
- 46. Standing water was present in two coolers, presenting a potential to contaminate product. The BgVV officials ordered correction.

61. NAME OF AUDITOR
Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Abraham Schinken GmbH Barsel-Harkebrugge	2. AUDIT DATE 5-27-02	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	
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	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan.		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		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	
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

F-66

A-IV-191

- 39. A broken wall with holes was observed in the freezer in Est. A-IV-191. This deficiency was scheduled for correction by the establishment management.
- 45. Washing of dirty combos and barrels was inadequate. This was corrected immediately by the establishment official.
- 46. Water was dripping from a door into combo bins of meat in the receiving room. This deficiency was corrected immediately and the door was scheduled for replacement by the establishment.
- 48. A barrel designated for edible product was used for inedible materials. This was corrected immediately by the establishment officials.

61. NAME OF AUDITOR
Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

FEDERAL OFFICE of CONSUMER PROTECTION
and FOOD SAFETY

Reference (please refer to when responding)
5106-00/197415

Tel. 01888 412 – 2114
Fax 01888 412 – 217
E-mail: imex@bvgv.de

Date:
November 14, 2002

Federal Office of Consumer Protection and Food Safety
Berlin Office
P.O. Box [illegible], [illegible]

Ms. Sally Stratmoen, Chief,
Equivalence Section
International Policy Staff
Office of Policy, Program Development and Evaluation
United States Department of Agriculture
Food Safety and Inspection Service
Washington, D. C. 20250

Draft Final Audit Report for Germany, May 22 – June 6, 2002

Dear Ms. Stratmoen,

The enclosed letter (Attachment 1 [Anlage 1]) from the Federal Ministry of Consumer Protection, Food and Agriculture dated June 11, 2002 informs you of the new organization of consumer health protection and food safety in Germany. The Federal Institute for Consumer Health Protection and Veterinary Medicine (BvGG) no longer exists as of October 31, 2002. The Federal Office of Consumer Protection and Food Safety (BVL) has assumed the responsibility for broad areas of the tasks of the dissolved Federal Institute.

With respect to the responsibility for collaboration with the FSI 3, there has been no change for the time being, except for the official name change. Communications data (fax, telephone numbers, e-mail addresses, etc.) remain the same until further notice. As soon as any changes are made here, I will inform you immediately. I am enclosing the data valid at the present time on a separate sheet (Attachment 2 [Anlage 2]).

The German comment on the above mentioned Audit Report for Germany – Draft Final – is enclosed with this letter (Attachment 3 [Anlage 3]).

Regards,
on behalf of
[signed]
Dr. Hoppe



Bundesministerium für
Verbraucherschutz, Ernährung
und Landwirtschaft

POST

Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft
Postfach 14 02 70, 53107 Bonn

Anlage 1

Bernhard Kühnle
Head of the Directorate-General for Food Safety and
Veterinary Affairs

HAUSANSCHRIFT Rochusstraße 1, 53123 Bonn

TEL +49 (0)1888 529 - 4646

FAX +49 (0)1888 529 - 4262

E-MAIL poststelle@bmvel.bund.de

INTERNET www.verbraucherministerium.de

Z 315-0220-1/0000

DATE 06.11.2002

Translation

Reorganization of consumer health protection and food safety in Germany

Dear Madam/Sir,

The Act concerning the reorganization of consumer health protection and food safety (Federal Law Gazette I, p. 3081), that took effect on 1 November 2002, institutionally separated the fields of risk assessment and risk management from each other. The cooperation with the European Union in the exercise of legislative, control and supervisory functions between the Federal Government and the Länder (federal states) is also subject to improvement.

Based on the legally enacted separation between the fields of risk assessment, on the one hand, and risk management, on the other hand, two new institutions are being set up at federal level:

- a Federal Institute for Risk Assessment (Federal Institute) charged with risk assessment,
- a Federal Office of Consumer Protection and Food Safety (Federal Office) charged with risk management.

Federal Office of Consumer Protection and Food Safety (BVL)

The Federal Office of Consumer Protection and Food Safety has been established as an independent higher federal authority and also meets sovereign tasks of risk management. The Federal Office will, inter alia, exercise authorization function as regards substances and products that harbor potential health risks and that are directly or indirectly related to food safety. So the BVL will be the **competent authority in Germany** (see directive 2001/82/EC) **for placing a veterinary medicinal product on the market**. It will be involved in formulating general administrative rules to implement acts in the fields of consumer health protection and food safety as well as in the preparation and monitoring of surveillance schemes and plans by the Länder. In addition, the Federal Office is to act as coordinator in the run-up to inspections carried out by the Food and Veterinary Office (FVO) in Grange and will accompany these inspections. It acts as a contact point for FVO in this context. Furthermore, it is responsible for implementing the European rapid alert system in the fields of consumer health protection and food safety in Germany (Art. 50 of Regulation No. 178/2002/EC)¹ and acts as a national contact point as defined in Art. 6 of Directive 93/99². The national reference laboratory for the detection of residues in accordance with Decision 98/536/EC³ and the Community reference laboratory for the detection of residues in accordance with Directive 96/23/EC⁴ form part of the Federal Office.

The address of the new institution is as follows:

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
(Federal Office of Consumer Protection and Food Safety)
Rochusstraße 65
53123 Bonn
Tel.: +49 – 228 – 6198-0
Fax: +49 – 228 – 6198-120
E-mail: poststelle@bvl.bund.de
Homepage: www.bvl.bund.de

¹ Regulation of the European Parliament and of the Council No. 178/2002/EC dated 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ EC No. L31, p. 1).

² Council Directive 93/99/EEC dated 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs (OJ EC Nr. L290, p. 14).

³ Commission Decision 98/536/EC of 3 September 1998 establishing the list of national reference laboratories for the detection of residues (OJ EC No. L251, p. 39).

The following e-mail address has been established with respect to the processing of notifications of Community-wide approval of businesses in third countries (proposal; information), deletion of businesses as well as rejections of consignments of goods:

E-mail: Imex@bvl.bund.de

An additional transmission by fax, as has been standard practice in the past, is thus no longer necessary.

So far, the Federal Institute for Health Protection of Consumers and Veterinary Medicine (BgVV) has been responsible for risk assessment and risk management at federal level in the field of consumer health protection. This higher federal authority will be dissolved.

I would be grateful if you could inform your services accordingly.

Federal Institute for Risk Assessment

The Federal Institute meets the following tasks: providing scientific advice as well as scientific support for the law-making activities and policies of the Federal Government in all fields with a direct or indirect impact on food safety and consumer health protection, except for animal diseases. It will provide impartial information on all matters in these fields and call attention to risks in good time. The activities of the Federal Institute focus on the implementation of risk assessments, aiming at the drafting of risk assessment reports, opinions or dossiers in the fields of consumer health protection and food safety. In addition, it will take a pro-active approach to the dialogue with consumers and inform about potential health hazards as well as acquired insights and work results at an early stage. Hence, it is also responsible for risk communication to a major extent. The Federal Institute acts as the contact point for the planned European Food Safety Authority.

The Federal Institute is the national veterinary reference laboratory pursuant to

- Directive 92/46/EEC concerning analyses and tests of milk and milk products⁵,
- Directive 92/117/EEC concerning salmonella, trichinellosis, escherichia coli, epidemiology of zoonoses and diseases transmitted by ticks⁶,
- Decision 93/383/EEC for the monitoring of marine biotoxins⁷ and
- Decision 1999/313/EC for bacteriological and viral contamination of bivalve molluscs⁸.

⁵ Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products (OJ EC No. L 268, p. 1).

⁶ Council Directive 92/117/EEC dated 17 December 1992 concerning measures of protection against specified zoonoses and specified zoonotic agents in animals and products of animal origin to prevent outbreaks of food-borne infections and intoxications (OJ EC No. L 62, p. 38).

⁷ Council Decision 93/383/EEC of 14 June 1993 on reference laboratories for the monitoring of marine biotoxins (OJ EC No. L 166, p. 31).

The key and new criterion in the structural organization of the Federal Institute, as provided for in the Reorganization Act, is that it can act autonomously in public information about potential health hazards, other acquired insights and work results and in the fields of scientific advice and research. It is not subject to a supervisory authority with respect to applied scientific methods, assessments and research. This rules out possible political interference in the scientific assessment of the Federal Institute.

The address of the new institution is as follows:

Bundesinstitut für Risikobewertung
(Federal Institute for Risk Assessment)
Thielallee 88 – 92
14195 Berlin
Tel.: +49 – 1888 – 412-0
Fax: +49 – 1888 – 412-4741
E-mail: poststelle@bfr.bund.de
Homepage: www.bfr.bund.de

Yours sincerely,
signed: B. Kühnle

*Att. G-1a*FEDERAL OFFICE of CONSUMER PROTECTION
and FOOD SAFETYReference (please refer to when responding)
5106-00/197415Tel. 01888 412 - 2114
Fax 01888 412 - 2177
E-mail: imcx@bgvv.deDate:
November 14, 2002Federal Office of Consumer Protection and Food Safety
Berlin Office
P.O. Box [illegible], [illegible] BerlinUnited States Department of Agriculture
[handwritten]
Food Safety and Inspection Service
- Technical Service Center -
Washington, D.C. 20250**Attachment 3****Comments on the Audit Report for Germany, May 21 - June 6, 2002
Draft Final**

The Audit Report is acceptable on the whole, particularly with respect to its balanced approach. For this reason, only a few critical comments are necessary. Specifically, the comments concern:

Hygiene Controls: SSOP - Company A (V - 10 -:

To 1.)

It was not meat pieces hanging on the gambrelling table but rather dried roasting residue, which could possibly point to a translation error. Besides, the responsible official veterinary pointed out this deficiency to the auditor and an immediate correction was undertaken by ordering stoppage of the production line until cleaning had been completed.

Concluding discussions of the next to last point:

In Company A IV - 10, controls did not indicate an inadequate coverage during the second shift. It contradicts the remarks made in the last sentence under "Procedural Measures" (the companies A-EV-29 and A-EV-15 are named here).

The remark about Company A-EV-15 "There is continuous inspection in the meat processing companies with the exception of the second shift in the newly certified companies" does not apply. In Company A-EV-15 the first as well as the second shift was then and still is today continually inspected.

G-16

The remark "Generally the company inspection personnel did not take care that hygiene rules were satisfactorily implemented" is not justified based on the documented results of the audit.

Finally, as a matter of form, attention is called to the choice of words in one point. In the section "RESULTS AND DISCUSSION" under the title "Audit of the Central Office", the following reference is made in the title to the last two paragraphs: "The inspection of these documents leads to the establishment of the following wor isome facts....". In both of the following descriptions of deficiencies, it is a matter of omission of record keeping; on the one hand, insufficient record keeping before and during business operations; on the other hand, insufficient written definitions of the hygiene measures. Both deficiencies, however, can be corrected easily, quickly and without further ado, but they should in no way result in the judgmental term "worrisome". Terms of this sort should be used only for hygiene deficiencies which could actually affect negatively the health of the consumer.

FEDERAL OFFICE of CONSUMER PROTECTION
and FOOD SAFETY

Reference (please refer to when responding)

Attachment 2

Official address to be used for communications between FSIS and BVL :

Federal Office of Consumer Protection and Food Safety
(BVL)
Diedersdorfer Weg 1
12277 Berlin - Marienfeld / Germany

Dr. Hoppe: 0049 – 1888 – 412-2114
Ms. Hackel: 0049 – 1888 – 412-2117
H. Sommer: 0049 – 1888 – 412-2133
Fax: 0049 – 1888 – 412-2177
E-mail: imex@bgvv.de
p.hoppe@bgvv.de

Upcoming changes in communications data will be immediately made known.

FEDERAL OFFICE of CONSUMER PROTECTION
and FOOD SAFETY

Reference (please refer to when responding)
5106-00/197415

Tel. 01888 412 – 2114
Fax 01888 412 – 217
E-mail: imex@bvgv.de

Date:
November 14, 2002

Federal Office of Consumer Protection and Food Safety
Berlin Office
P.O. Box [illegible], [illegible] Berlin

United States Department of Agriculture
[handwritten]
Food Safety and Inspection Service
- Technical Service Center -
Washington, D.C. 20250

Attachment 3

**Comments on the Audit Report for Germany, May 12 – June 6, 2002
Draft Final**

The Audit Report is acceptable on the whole, particularly with respect to its balanced approach. For this reason, only a few critical comments are necessary. Specifically, the comments concern:

Hygiene Controls: SSOP - Company A (V – 10 -:

To 1.)

It was not meat pieces hanging on the gambrelling table but rather dried roasting residue, which could possibly point to a translation error. Besides, the responsible official veterinary pointed out this deficiency to the auditor and an immediate correction was undertaken by ordering stoppage of the production line until cleaning had been completed.

Concluding discussions of the next to last point:

In Company A IV – 10, controls did not indicate an inadequate coverage during the second shift. It contradicts the remarks made in the last sentence under “Procedural Measures” (the companies A-EV-29 and A-EV-15 are named here).

The remark about Company A-EV-15 “There is continuous inspection in the meat processing companies with the exception of the second shift in the newly certified companies” does not apply. In Company A-EV-15 the first as well as the second shift was then and still is today continually inspected.

The remark "Generally the company inspection personnel did not take care that hygiene rules were satisfactorily implemented" is not justified based on the documented results of the audit.

Finally, as a matter of form, attention is called to the choice of words in one point. In the section "RESULTS AND DISCUSSION" under the title "Audit of the Central Office", the following reference is made in the title to the last two paragraphs: "The inspection of these documents leads to the establishment of the following worrisome facts.....". In both of the following descriptions of deficiencies, it is a matter of omission of record keeping: on the one hand, insufficient record keeping before and during business operations; on the other hand, insufficient written definitions of the hygiene measures. Both deficiencies, however, can be corrected easily, quickly and without further ado, but they should in no way result in the judgmental term "worrisome". Terms of this sort should be used only for hygiene deficiencies which could actually affect negatively the health of the consumer.