United States Department of Agriculture
Food Safety And Inspection Service
Technical Service Center
Suite 300, Landmark Center
1299 Farnam Street
Omaha, NE 68102

AUDIT REPORT FOR GERMANY

October 31 through November 21, 2000

May 24, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Germany's meat inspection system from October 31 through November 21, 2000. Six of the eleven 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 December 1999. Eight establishments were audited and all were acceptable.

The major concerns from the previous audit were the following.

- Each of the 16 states self-governs its inspection program and implements federally mandated meat inspection requirements. Federal Institute for Health Protection of Consumers and Veterinary Medicine (BGVV) has no legal or system control authority over their activities. BGVV headquarters staff periodically coordinates with states to seek uniform application of federally mandated meat inspection regulations.

  No change from last audit.

- Periodic supervisory visits were not performed monthly. Only one to three internal reviews were conducted per year by local or regional officials.

  No change from last audit.

- Inspection coverage is not provided during second shift and/or third shift operations in Establishments AE-IV-21, A-EV-139, and A-EV-874.

  No change from last audit.

- GOG meat inspection officials were not providing continuous inspection coverage to processed products establishments. Inspectors were visiting establishments at variable frequencies such as once a week, twice a week, or once a month and between one to two hours each visit

  No change from last audit.

- Inspection control records are maintained in the establishment. No information is available in the States or BGVV headquarter.

  No change from last audit.

- Establishments maintain documents and are not sent to State or Federal government officials.

  No change from last audit.

- All establishments failed to have a pre-shipment verification system.

  Only one (Est. A-IV-10) of the three establishments that were active exporters to the United States had fulfilled the requirement for developing and implementing a pre-shipment document review.

As of end of September 2000, German establishments exported 463,498 pounds of canned products containing processed pork, cured pork, and sausages to the U.S. Port-of-entry rejections were for violative net weight (1.15) %, missing shipping marks (2.63) %, and transportation damage (2.63 %). Three establishments (Ests. A-IV-10, A-EV-36, and A-IV-22) were active exporters to the United States.

Germany exports only pork processed products to the United States. Restrictions are placed on German fresh pork and beef due to presence of hog cholera and Bovine Spongiform Encephalopathy (BSE).

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with German national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat inspection headquarters facilities preceding the on-site visits. The establishments for documents audit were selected randomly, and the establishments for on-site audit were selected based on establishment's performance, and the port of entry re-inspection results for public health hazards. The third was conducted by on-site visits to establishments. The fourth was a visit to three laboratories, one performing analytical testing of field samples for the national residue testing program, and the other two culturing field samples for the presence of microbiological contamination with *Salmonella*.

Program effectiveness determinations focused on 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. German'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, 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-21, A-EV-36, A-EV-139, and A-Ev-218) were audited; two establishments (Ests. A-EV-15 and A-EV-218) were judged Acceptable Subject to Re-review on the next audit. The deficiencies of audit findings, including compliance with HACCP, and SSOPs, programs are discussed later in this report under the appropriate headings.

At the time of audit no slaughter establishment was U.S. certified, therefore carcass testing for *E.coli*. and *Salmonella* species testing did not apply. The ready-to-eat products are routinely tested for *Listeria monocytogenes* and *Salmonella.*

As stated above, no system failure but major concerns had been identified during the last audit of the German meat inspection system, conducted in December 1999. During this new audit, the auditor determined that the major concerns had been not addressed and not corrected.

No HACCP-implementation deficiencies had been observed in all of the eight establishments visited during the last FSIS audit.

During this new audit, implementation of the required HACCP programs was now found to be deficient in all six establishments visited on-site and in the documentation from the other five establishments not visited. Details are provided in the Slaughter/ Processing Controls section later in this report.

No SSOPs-implementation deficiencies had been observed in all of the eight establishments visited during the last FSIS audit.

During this new audit, implementation of the required SSOPs programs was now found to be deficient in all six establishments visited on-site and in the documentation from the other four of the five establishments not visited. Details are provided in the Sanitation Controls section later in this report.

Entrance Meeting

On October 31 an entrance meeting was held at the Berlin offices of the Federal Institute for Health Protection of Consumer and Veterinary Medicine (BGVV), and was attended by Dr. Ekkehard Weise, Director and Professor, Food Safety and Hygiene (FSH), BGVV; Dr. Peter Paul Hoppe, Deputy Director, Food Safety and Hygiene; MS. Kerstin Kruger, Agricultural Assistant, Foreign Agricultural Service (FAS), American Embassy in Berlin and Dr. Faiz R. Choudry, International audit Staff Officer, FSIS.

Topics of discussion included the following:

1. Welcome by Dr. Ekkehard Weise, Director, FSH, BGVV and explanation of the German meat inspection system.

2. Overview of the National Residue Program.

3. Discussion of the previous audit report.

4. The auditor provided copies of the data-collection instruments and a copy of the current Quarterly Regulatory and Enforcement Report. He inquired whether German also makes similar information available to the public; the German officials replied in the negative.

5. The audit itinerary and travel arrangements.

6. Discussion regarding what BGVV can and cannot do in relation to the States, especially in the area of the listing and delistment of establishments.

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 December 1999

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 a review of inspection system documents pertaining to the establishments listed for records review. This records review was conducted at individual establishments. No arrangement was made to conduct records review at the BGVV Berlin office or at a district or regional office. 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.
- Label approval records such as generic labels.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs.
- Sanitation, processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding,

suspending, with drawing inspection services from or delisting an establishment that is certified to export product to the United States.

The following concerns arose as a result of examination of the HACCP, and SSOPs, records review.

- The HACCP plan did not specify critical limits, for each CCP and the frequency with which these procedures will be performed adequately in Establishments A-EV-874, A-EV-1277, A-IV-23, A-IV-26, and A-IV-22.

- The HACCP plan did not address adequately, the corrective action to be followed in response to a deviation from a critical limit in Establishments A-EV-1277, A-IV-26, A-IV-23, and A-IV-22.

- The HACCP plan was not validated to determine that it is functioning as intended in Establishments A-EV-1277, A-IV-26, A-IV-23, and A-IV-22.

- The HACCP plan did not state adequately 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 in Establishments A-EV-874, A-EV-1277, A-IV-26, A-IV-23, and A-IV-22. The ongoing verification activities of the HACCP program were not performed adequately either by the establishment personnel or by the GOG meat inspection officials.

- The HACCP plan's record-keeping system was not documenting the monitoring of CCPs in Establishments A-EV-1277, A-IV-23, and A-IV-22.

- The HACCP plan was not dated and signed by a responsible establishment official in Establishment A-IV-26.

- One establishment (Est. A-IV-22) that was active exporter to the United States, was not performing and documenting pre-shipment document review as required.

- The written SSOP program did not address the procedure for pre-operational sanitation in Establishments A-EV-874, A-EV-1277.

- The written SSOP procedure did not address operational sanitation in Establishments A-EV-874, A-EV-1277, A-EV-26, and A-IV-22.

- The records for SSOP operational sanitation and any corrective action taken were not being maintained in Establishments A-EV-874, A-EV-1277, A-IV-22, and A-IV-26.

- Government of Germany (GOG) meat inspection officials were not monitoring/verifying the adequacy and effectiveness of the pre-operational sanitation SSOP in Establishments A-EV-874, A-EV-1277, A-IV-23, A-IV-26, and A-IV-22.

- GOG meat inspection officials were not providing continuous inspection coverage to

processed products establishments. Inspectors were visiting establishments at variable frequencies such as once a week, twice a week, or once a month and between one to two hours each visit in Establishments A-EV-874, A-EV-1277, A-IV-23, A-IV-26, and A-IV-22.

- GOG meat inspection officials were not providing inspection coverage for second and/or third shift operations in Establishments A-EV-874, A-IV-23, and A-IV-26.

- Periodic supervisory visits were not performed monthly in Establishments A-IV-22 that was active exporter to the United States? No internal reviews were conducted by the local or regional officials.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by German as eligible to export meat products to the United States were full-time State employees, receiving no remuneration from either industry or establishment personnel.

Dr. Peter P. Hoppe explained the relationship among BGVV- the National Government, and the State Inspection Systems. The tasks and responsibilities listed below which were previously assigned to the former Division 4 of the Federal Ministry of Health (in Berlin) have been transferred to the Federal Institute for Consumer Health Protection and Veterinary Medicine (BGVV) Division 3.

Responsibilities;

- Release of information regarding companies licensed to supply foodstuffs of animal origin. a) Release of border control information. b) Release of other information required by 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. 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).

Federal government (BGVV) has no jurisdiction or direct authority over the 16 State Inspection Programs, but prepares and interprets the laws, 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

Eleven establishments were certified to export meat products to the United States at the time this audit was conducted. Six establishments (A-IV-10, A-EV-15, A-IV-21, A-EV-36, A-EV139, and A-EV-218) were visited for on-site audits. In four of these establishments (A-IV-10, A-IV-21, A-EV-36, and A-EV-139) visited, with the exception noted below, both German inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products. These four establishments were found acceptable. Two establishments (A-EV-15 and A-EV-218) were rated acceptable subject to re-review on the next audit because of several deficiencies regarding sanitation and the condition of facilities, which are mentioned later in this report.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information about the following risk areas was also collected:

1. Government oversight of accredited, approved laboratories.
2. Intra-laboratory quality assurance procedures, including sample handling.
3. Methodology.

The EU (CRL) National Reference Laboratory (NRL) for Residues of Veterinary Drugs in Berlin was audited on November 17, 2000. 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.

A State Veterinary Drug Residues Laboratory in Oldenberg (Lower Saxony) was audited on November 7, and another laboratory Chemisches Landes-und Staatliches Veterinarunter-suchungsamt in Munster (Northrhine-Westphalia) was audited on November 13, 2000. In both laboratories microbiological testing for *Salmonella* was being performed.

Establishment Operations by Establishment Number

The following operations were being conducted in the six establishments:

Pork and beef cooked /smoked sausages in jars, and canned and smoked sausages - four establishments (Ests. A-IV-10, A-IV-21, A-EV-36, A-IV-139)

Pork and beef smoked sausages – two establishments (Ests. A-EV-218, A-EV-15)

SANITATION CONTROLS

Based on the on-site audits of establishments, Germany's inspection system had controls in place for water potability records; back-siphonage prevention; hand washing facilities; separation of operations; sanitizers; temperature control; lighting; operations work space; ventilation; dry storage areas; welfare facilities; outside premises; and personal dress and habits.

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).

On-site records of SSOPs programs were audited and the following noncompliance with FSIS regulatory requirements were found:

1. The written SSOP procedure did not address pre-operational sanitation in Establishment A-EV-218, and A-EV-15.

2. The written SSOP procedure did not address operational sanitation in Establishments A-IV-10, A-EV-15, A-IV-21, A-EV-36, A-EV-139, and A-EV-218.

3. The written SSOP procedure did not indicate the frequency of the tasks to be conducted in Establishment A-EV-218.

4. The written SSOP procedure did not identify the individuals responsible for implementing and maintaining the activities in Establishments A-EV-15, and A-EV-218.

5. The records for SSOP operational sanitation and any corrective action taken were not being maintained in Establishments A-IV-10, A-EV-15, and A-EV-218.

6. GOG meat inspection officials were not monitoring pre-operational sanitation to verify the adequacy and effectiveness of the sanitation SSOP in Establishments A-IV-10, A-EV-15, A-IV-21, A-EV-36, A-EV-139, and A-EV-218.

Basic Establishment Facilities

1. Gaps at the bottoms of doors in the brine room were not sealed properly to prevent the entry of rodents and other vermin in Establishment A-IV-21. Establishment officials ordered correction.

2. The waste receptacle at the hand washing facility was hand operated and employees were observed after washing their hands opening the lid with hands and, handling edible product in all processing rooms. Establishment officials proposed modification of waste receptacles to meat inspection officials.

Condition of Facilities and Equipment

1. Overhead ducts, pipes in the sausages filling room were observed with accumulations of dust and dirt in Establishment A-IV-10. Establishment officials ordered correction immediately.

2. Overhead pipes and ducts in the raw product processing room were observed with accumulations of dried fat, old pieces of meat, and dirt. Plastic flappers over rail were found with grease and dirt at the doors of carcass coolers in Establishment A-EV-15. Inspection officials agreed with the corrective/preventive actions to be implemented by the establishment.

3. Numerous plastic bins for edible product ready for use in the processing room were broken and cracked in Establishment A-IV-10. Establishment officials ordered correction immediately.

4. Numerous containers of edible product and a few conveyor belts for edible product ready for use in the product receiving and boning rooms were found with fat and grease. A plastic cutting board ready for use, located adjacent to the ham circular saw in the boning room, was deeply scored and deteriorated in Establishment A-EV-15. Neither establishment nor GOG meat inspection officials took corrective action.

5. In the processing room, numerous racks for processed product and a few working tables were found with fat, grease, dirt; containers of edible product were found with dried pieces of meat and with open seams; cover over minced meat chute to prevent contamination from overhead catwalk, was found with accumulations of fat and dirt in Establishment A-Ev-139. In each Establishment officials took corrective action promptly.

6. A few working tables ready for use in the raw product processing room were found with dried fat, black discoloration, and dirt in Establishment A-EV-218. Inspection officials agreed with the corrective/preventive actions to be implemented by the establishment.

Cross-Contamination

1. Dripping condensate, from ceilings that were not cleaned/sanitized daily, was falling onto exposed edible product in the ham pumping and raw product processing rooms in Establishment A-EV-218. Neither establishment nor meat inspection officials took corrective action.

2. Dripping condensate, from overhead air sock that was not cleaned/sanitized daily, was falling onto exposed edible product in the sausages filling room in Establishment A-IV-21. Establishment officials took corrective action immediately and proposed a modification of cooling system to prevent recurrence to GOG meat inspection officials.

3. Dripping condensate, from overhead refrigeration units, that was not cleaned/sanitized daily, was falling onto exposed edible product in one cooler and another cooler there was no product stored underneath at the time of audit in Establishment A-IV-10. Establishment officials took corrective action immediately and proposed preventive measures to prevent recurrence to GOG meat inspection officials.

4. Dripping condensate, from overhead pipe, that was not cleaned/sanitized daily, was falling onto edible product in the sausages filling room in Establishment A-IV-10. Establishment officials proposed corrective/preventive measures to GOG meat inspection officials.

5. Several doors between product receiving and ham pickling rooms and between raw product and meat grinding rooms opened upwards. Puddles of water below the doors resulted in dripping dirty water drops that was observed to fall onto employees' clothes and exposed edible product during passing through these doors in Establishment A-EV-218. Establishment officials proposed modification of doors to prevent recurrence to GOG meat inspection officials.

6. Several doors between equipment washing and processing rooms and between edible product receiving and product grinding rooms opened upwards. Puddles of water below the doors resulted in dripping dirty water drops that was observed to fall onto exposed edible product, employees' clothes, and containers for edible product ready for use during passing through these doors in Establishment A-IV-21. Establishment officials proposed modification of doors to prevent recurrence to GOG meat inspection officials.

7. Doors between sausages filling and cooler rooms opened upward. Puddles of water below the door resulted in dripping dirty water drops that was observed to fall onto exposed edible product and employees' clothes during passing through this door in Establishment A-IV-10. Establishment officials proposed modification of doors to prevent recurrence to GOG meat inspection officials.

8. A container of minced meat in the sausages filling room was too close to hand washing facility potential for cross contamination from splash water in Establishment A-EV-139. Establishment officials corrected immediately.

9. Several containers for edible product ready for use and one container with exposed edible product were stored under the catwalk potential for contamination from employees' walking on the overhead open grating in Establishment A-EV-218. Establishment officials ordered correction.

<u>Personnel Hygiene and Practices</u>

Several employees were not observing good hygienic work habits to prevent product contamination:

1. A few employees' were observed contacting dirty legs of containers of edible product during transportation and, without washing their hands, handling edible product in the receiving room in Establishment A-EV-15. Neither establishment nor GOG meat inspection officials took corrective action.

2. One employee was observed picking up sausages that contacted the floor and, without washing her hands, handling edible product in the sausages filling room and another employee was observed picking up pieces of meat from the floor and, without washing his hands, handling edible product in the processing room in Establishment A-IV-10.

Establishment officials took corrective action immediately and proposed preventive measures to meat inspection officials.

3. A third employee was observed picking up dirty meat hook from the floor and, without washing his hands or washing/sanitizing meat hook, handling edible product in the processing room in Establishment A-EV-15. Neither establishment nor GOG meat inspection officials took corrective action.

4. A fourth employee was observed picking up pieces of meat from the floor and, without washing his hands, handling edible product in the processing room in Establishment A-EV-15. Establishment officials took corrective action.

5. A fifth employee was observed picking up used wrapping material from the floor and dirty pallets and, without washing his hands, handling edible product in the processing room in Establishment A-EV-15. Neither establishment nor GOG meat inspection officials took corrective action.

6. A sixth employee was observed keeping an ax for edible product when not in use, on the floor of an employee's work platform and, without washing his hands or washing/sanitizing an ax, handling edible product in the processing room in Establishment A-EV-15. Establishment officials took corrective action.

7. A seventh employee was observed picking up pieces of meat from the floor and saving them in a container of edible product and, without washing his hands, handling edible product in the product receiving room in Establishment A-IV-21. Establishment officials took corrective action immediately.

8. An eighth employee was observed cleaning floor with a broom and, without washing his hands, handling edible product in the processing room in Establishment A-EV-36. Establishment officials took corrective action immediately.

9. A ninth employee was observed picking up pieces of meat from the floor and saving them in a container of edible product and, without washing hands, handling edible product in the meat grinding room in Establishment A-EV-139. Establishment officials took corrective action immediately.

10. A tenth employee was observed using a dirty water hose and, without washing his hands, handling edible product in the ham pickling room in Establishment A-EV-218. Establishment officials took corrective action immediately.

<u>Product Handling and Storage</u>

1. Exposed edible product was contacting dirty bottom of containers of edible product during stacking on each other in the processing room in Establishments A-EV-15 and A-IV-21. Neither establishment nor GOG meat inspection officials took corrective action.

2. Exposed edible frozen meat was contacting dirty pallets in the meat grinding room in Establishments A-IV-21, A-EV-139, and A-EV-218. Establishment officials took corrective

action immediately and proposed modification of facility to prevent recurrence to GOG meat inspection officials.

ANIMAL DISEASE CONTROLS

With the exceptions listed below Germany's inspection system had no slaughter establishment U.S. certified. Therefore the risk factors were not evaluated.

1. Containers for edible and inedible product were not identified in four Establishments (Ests. A-EV-218, A-EV-139, A-EV-15, and A-IV-10). Inspection officials agreed with the corrective/preventive actions to be implemented by the establishment.

2. Three containers of pet food were not identified in the product receiving area in Establishment A-EV-139. Establishment officials took corrective action immediately.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit. No positive case for Bovine Spongiform Encephalopathy (BSE) was reported in Germany. APHIS has restrictions on importation of meat and other animal products from Germany due to hog cholera and BSE.

On-farm Activities

Animal Identification**.** The German identification and registration system for farm animals is the responsibility each Lander. Mr. Gerd Wemkens' farm (Landwirtschaftlicher Betrieb besichtigt) located in village 26215 Wiefelstede was visited on November 15, 2000. It was a small dairy farm with about 300 dairy cows and a few hundreds hogs and calves. Each farm (producer) is required to register and is responsible for identifying animals in accordance with requirements for the species. In the case of bovine, each individual animal is identified within a week of birth and is issued a passport (VIT) "includes date of birth, ear tag number, farm assigned number etc", which must accompany the animal during transport. Swine are identified as a group using tattoos and transportation documents that identify the origin and destination of the group.

This registration is entered into the state (Lander) computer database. The database maintains a complete history of producer activities relating to animal production, and provides a means to track the movement of animals between farms, out of the country or to slaughter. If necessary, trace back to the farm of origin is possible.

RESIDUE CONTROLS

Germany's National Residue Testing Plan for 2000 was being followed, and was on schedule. German inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.
Please see laboratory report.

SLAUGHTER/PROCESSING CONTROLS

Except as noted below, the German inspection system had controls in place to ensure adequate boneless meat re-inspection; condemned product control; restricted product control; ingredients identification; control of restricted ingredients; formulations; packaging materials; label approvals; inspector monitoring; processing equipment, processing records; empty can inspection; filling procedures; container closure examination; and post-processing handling.

Currently there are no slaughter establishments certified to export to the U.S.

The incubation temperature was maintained at minimum 37°C with no maximum limit for 7 days and at minimum 35°C with no maximum limit for 10 days as compared to 95°F ± 5°F (35C± 2.8°C) in the U. S. in Establishment A-EV-21 and A-EV-139.

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 audited and the following noncompliance with basic FSIS regulatory requirements were found:

1. The HACCP plan did not specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP adequately in Establishments A-IV-10, A-EV-15, A-IV-21, and A-EV-139.

2. The HACCP plan did not address adequately, the corrective action to be followed in response to a deviation from a critical limit in Establishments A-IV-10, A-EV-15, A-IV-21, A-EV-36, A-EV-139, and A-EV-218.

3. The HACCP plan was not validated to determine that it is functioning as intended in Establishments A-EV-15, A-IV-21, A-EV-36, A-EV-139, and A-EV-218.

4. The HACCP plan did not state adequately 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 ongoing verification activities of the HACCP program were not performed adequately either by the establishment personnel or by the GOG meat inspection officials in Establishments A-IV-10, A-IV-21, A-EV-36, A-EV-139, and A-EV-218.

5. The HACCP plan's record-keeping system was not documenting the monitoring of CCPs in Establishments A-EV-15 and A-IV-21.

6. The HACCP plan was not dated and signed by a responsible establishment official in Establishments A-EV-36 and A-EV-218.

7. The establishment A-EV-36, that was active exporter to the United States, was not performing and documenting pre-shipment document review as required.

Testing for Generic *E. coli*

E.coli testing is not required in Germany establishments that are certified to export meat products to the U.S. because APHIS regulations prohibit the import of meat from hogs and cattle slaughtered in Germany. Germany obtains meat for U.S. export from hogs and cattle slaughtered in a country eligible to export slaughtered hogs and cattle to the U.S.

ENFORCEMENT CONTROLS

Inspection System Controls

The German inspection system controls boneless meat re-inspection, 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, the importation of only eligible meat products from other counties for further processing (i.e.; only from eligible countries and certified establishments within those countries) were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* Species

Germany has adopted the FSIS regulatory requirements for HACCP, *Salmonella* testing is nor required in Germany's establishments that are certified to export meat products to the United States because APHIS regulations prohibit the import of meat from hogs and cattle slaughtered in Germany. Germany obtains meat for U.S. export products from hogs and cattle slaughtered in the third country that is eligible to export meat to the United States.

Species Verification Testing

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

Listeria monocytogenes

1. The control of *Listeria monocytogenes* is not included in the HACCP plan in those establishments producing ready-to-eat products.

2. Establishment officials have a surveillance program for *Listeria monocytogenes* testing between one to five samples per month in most establishments producing ready-to-eat products.

Monthly Reviews

These reviews were being performed by the German County/ Local District/Regional officials equivalent of Circuit Supervisors/District Manager and they were all veterinarians.

The internal review program was applied equally to both export and non-export establishments. Internal review visits were not announced in advance, and were conducted, at times by individuals, in most establishments only one or two reviews per year, and a few establishments were reviewed monthly. The records of audited establishments were kept in the county/local district inspection offices, and were routinely maintained on file for a minimum of 2 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 or 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.

Periodic supervisory visits were not performed monthly in Establishments A-EV-15, A-IV-21, A-EV-139, and A-EV-1277. Only one or two internal reviews were conducted per year by the county or regional officials. No internal review was conducted this year in Establishment A-IV-22.

Enforcement Activities

The domestic and exporting country requirements are enforced by the State Inspection system (Lander) officials. They are empowered by law to take corrective measures, penalize them 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 mandatory Fleischhgiene-Verordnung (FIH)-federal meat hygiene regulations. The inspectors visit these establishments at variable frequencies: once a week, up to two times a week, once a month and between one to two hours each visit. . Continuous inspection coverage to processed products establishments is not provided. Second or third shift operations are not covered in Establishments A-EV-874, A-EV-15, A-EV-21, A-IV-10, and A-IV-26. The inspection and establishment system documents are maintained in the county or district or regional office. Information is not sent to BGVV national headquarters in Berlin.

The inspectors, in addition to periodic meat inspection, are also responsible for inspection and compliance enforcement of the inspection laws for all kinds of food products including vegetables, cereals, bakeries, honey, fish, egg, milk, and poultry products.

Controls were in place to ensure adequate export product identification, inspector verification, export certifications, a single standard of control throughout the establishment, and adequate controls for security items, shipment security, and product entering the establishments from outside sources.

Exit Meetings

An exit meeting was conducted in Berlin on November 21, 2000. The German participants were Dr. Ekkehard Weise, Director and Professor, Food Safety and Hygiene (FSH), BGVV; Dr. Peter Paul Hoppe, Deputy Director, Food Safety and Hygiene; MS. Joani Dong, Agricultural Attache, Foreign Agricultural Service (FAS), American Embassy in Berlin; MS. Kerstin Kruger, Agricultural Assistant, (FAS), American Embassy in Berlin and Dr. Faiz R. Choudry, International audit Staff Officer, FSIS.

A second meeting was conducted with European Commission (EC) in Brussels, Belgium on November 21. The EC participants were Dr. Paolo Dhostby, DG, Health and Consumer Protection Directorate General (SANCO), Unit E-3; Dr. T. E. Golden, DG, SANCO, Unit D-2; MS. Caroline Hommez, Agricultural Specialist, United States Mission to the European Union in Brussels and Dr. Faiz R. Choudry, International audit Staff Officer, FSIS.

The following major deficiencies were discussed:

The HACCP programs were audited and the following noncompliance with FSIS regulatory requirements were found:

1. The HACCP plan did not specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP adequately in nine establishments (Ests. A-IV-10, A-EV-15, A-IV-21, A-EV-139, A-EV-1277, A-IV-26, A-IV-23, A-IV-22, and A-EV-874).

1. The HACCP plan did not address adequately, the corrective action to be followed in response to a deviation from a critical limit in ten establishments (Ests. A-IV-10, A-EV-15, A-IV-21, A-EV-36, A-EV-139, A-EV-218, A-EV-1277, A-IV-26, A-IV-23, and A-IV-22).

3. The HACCP plan was not validated to determine that it is functioning as intended in nine establishments (Ests. A-EV-15, A-IV-21, A-EV-36, A-EV-139, A-EV-218, A-EV-1277, A-IV-26, A-IV-23, and A-IV-22).

4. The HACCP plan did not state adequately 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 ongoing verification activities of the HACCP program were not performed adequately either by the establishment personnel or by the GOG meat inspection officials in ten establishments (Ests. A-IV-10, A-IV-21, A-EV-36, A-EV-139, A-EV-218. A-EV-1277, A-IV-26, A-IV-23, A-IV-22, and A-EV-874).

5. The HACCP plan's record-keeping system was not documenting the monitoring of CCPs in five establishments (Ests. A-EV-15, A-IV-21, A-EV-1277, A-IV-23, and A-IV-22).

6. The HACCP plan was not dated and signed by a responsible establishment official in three establishments (Ests. A-EV-36, A-EV-218, and A-IV-26).

7. Establishments A-IV-22, and EV-36 that were active exporters to the United States, were not performing and documenting pre-shipment document review as required.

<u>The SSOPs programs were audited and the following noncompliance with FSIS regulatory requirements were found:</u>

1. The written SSOP procedure did not address pre-operational sanitation in four establishments (Ests. A-EV-218, A-EV-15, A-EV-874, and A-EV-1277).

2. The written SSOP procedure did not address operational sanitation in ten establishments (Ests. A-IV-10, A-EV-15, A-IV-21, A-IV-22, A-EV-36, A-EV-139, and A-EV-218. A-EV-1277, A-IV-26, and A-EV-874).

3. The written SSOP procedure did not indicate the frequency of the tasks to be conducted in one establishment (Est. A-EV-218).

4. The written SSOP procedure did not identify the individuals responsible for implementing and maintaining the activities in two establishments (Ests. A-EV-15, and A-EV-218).

5. The records for SSOP operational sanitation and any corrective action taken were not being maintained in seven establishments (Ests. A-IV-10, A-EV-15, and A-EV-218, A-EV-1277, A-IV-26, A-IV-22, and A-EV-874).

6. GOG meat inspection officials were not monitoring pre-operational sanitation to verify the adequacy and effectiveness of the sanitation SSOP in all eleven establishments (Ests. A-IV-10, A-EV-15, A-IV-21, A-EV-36, A-EV-139, and A-EV-218. A-EV-1277, A-IV-26, A-IV-23, A-IV-22, and A-EV-874).

7. GOG meat inspection officials were not providing continuous inspection coverage to processed products establishments. Inspectors were visiting establishments at variable frequencies such as once a week, twice a week, or once a month and between one to two hours each visit in all eleven establishments (Ests. A-EV-874, A-EV-1277, A-IV-23, A-IV-26, A-IV-22, A-EV-36, A-EV-218, A-EV-15, A-IV-21, A-EV-139, A-IV-10).

8. GOG meat inspection officials were not providing inspection coverage for second and/or third shift operations in six establishments (Ests. A-EV-874, A-IV-23, A-IV-26, A-EV-15, A-IV-21, A-IV-10).

9. Periodic supervisory visits were not performed monthly in Establishments A-IV-22, which was active exporter to the United States. No internal reviews were conducted by the local or regional officials.

10. Equipment in contact with product such as containers of edible product, working tables, racks for processed product, edible product conveyor belts, and plastic bins for edible product ready for use in the processing room, product receiving room and boning rooms were found with fat, grease, dried pieces of meat, dirt, with open seams, broken and cracked in four establishments (Ests.A-EV-218, A-EV-139, A-EV-15, and A-IV-10).

11. Cross Contamination of product such as dripping condensate, from overhead refrigeration units, ceilings, pipes, and air socks that were not cleaned/sanitized daily, was falling onto exposed edible product in the processing rooms; several doors between equipment washing and processing rooms, between edible product receiving and product grinding rooms, between raw product and grinding rooms, and between processing room and cooler were opened upwards and puddles of water below the door resulted in dripping dirty water that was observed to fall onto exposed edible product and employees' clothes during passing through these doors; container of minced meat in the sausages filling room, was too close to hand washing facility potential for cross contamination from splash water; several containers for edible product ready for use and one container with edible product, were stored under catwalk potential for any fallout onto product. These deficiencies were observed in four establishments (Ests.A-IV-10, A-IV-21, A-EV-139, and A-EV-218)

12. Personnel were not using hygienic work habits to prevent product contamination such as several employees' were observed picking up pieces of meat, used packaging materials and dirty pallets, meat hook, from the floor, cleaning floor with broom, handling dirty containers, keeping an ax (used for edible product) on employees' work platform and, without washing their hands and washing/sanitizing dirty equipment, handling edible product in six establishments (Ests. A-IV-10, A-EV-15, A-IV-21, A-EV-36, A-EV-139, and A-EV-218).

13. Exposed product was not handled in a sanitary manner such as containers of edible product were stacked on each other and exposed product was contacting dirty bottom of containers; frozen meat was contacting dirty pallets in four establishments (Ests. A-EV-15, A-IV-21, A-EV-139, and A-EV-218).

14. Containers for edible and inedible product and pet food were not identified in four Establishments (Ests. A-EV-218, A-EV-139, A-EV-15, and A-IV-10).

Dr. Ekkehard Weise, Director and Professor, Food Safety and Hygiene, BGVV and Dr. Peter Paul Hoppe, Deputy Director, Food Safety and Hygiene, indicated that they would take the necessary steps to ensure that corrective actions and preventive measures, including HACCP and SSOP programs as promised during the audits and exit meetings in individual establishments, would be implemented.

CONCLUSION

Six establishments were audited: four were acceptable, two were evaluated as acceptable/re-review. The deficiencies encountered during the on-site establishment audits, in those establishments which were found to be acceptable, were adequately addressed to the auditor's satisfaction at the time of the audit. GOG officials made assurances that the deficiencies which were not addressed at the time of on-site audit would be rectified promptly.

The Federal Government has no direct authority to monitor periodically on-site audit of meat inspection programs run by individual states. However, Dr. Ekkehard Weise, Director and Professor, BGVV, indicated that he would ensure that corrective actions and preventive measures, including HACCP and SSOP programs as promised during the audits and exit meetings in all the establishments visited, would be implemented.

Dr. Faizur F. Choudry (signed)Dr. Faizur F. Choudry
International Audit Staff Officer

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
E. Laboratory audit form
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report (No response provided by country)

Attachment A

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. Fre-quency addressed	6. Respons-ible indiv. identified	7. Docu-mentation done daily	8. Dated and signed
A-IV10	√	√	*	√	√	√	*	√
A-EV15	√	*	*	√	√	*	*	√
A-IV21	√	√	*	√	√	√	√	√
A-EV36	√	√	*	√	√	√	√	√
A-EV139	√	√	*	√	√	√	√	√
A-EV218	√	*	*	√	*	*	*	√

√-Acceptable *-Deficiency

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respons-ible indiv. identified	7. Docu-mentation done daily	8. Dated and signed
A-IV22	√	√	*	√	√	√	*	√
A-IV23	√	√	√	√	√	√	√	√
A-IV26	√	√	*	√	√	√	*	√
A-EV874	√	*	*	√	√	√	*	√
A-EV1277	√	*	*	√	√	√	*	√

Attachment B

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 and documenting pre-shipment document reviews as required.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Haz. analysis –all ID'ed	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. reviews
A-IV	√	√	√	√	√	*	*	√	*	√	√	√
A-EV15	√	√	√	√	√	*	*	*	√	*	√	*
A-IV21	√	√	√	√	√	*	*	*	*	*	√	√
A-EV36	√	√	√	√	√	√	*	*	*	√	*	*
A-EV139	√	√	√	√	√	*	*	*	*	√	√	√
A-EV218	√	√	√	√	√	√	*	*	*	√	*	*

√-Acceptable *-Deficiency

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

Est. #	1. Flow diagram	2. Haz. analysis –all ID'ed	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. proced-ures	10. Adequate documentation	11. Dated and signed	12. Pre-shipment doc. reviews
A-IV22	√	√	√	√	√	*	*	*	*	*	√	*
A-IV23	√	√	√	√	√	*	*	*	*	*	√	*
A-IV26	√	√	√	√	√	*	*	*	*	√	*	*
A-EV874	√	√	√	√	√	*	√	√	*	√	√	*
A-EV1277	√	√	√	√	√	*	*	*	*	*	√	*