



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

AUG 30 2002

Dr. Peter-Paul Hoppe, Chief Veterinary Officer  
Federal Institute for Health Protection  
of Consumers and Veterinary Medicine  
Lieter, Veterinarmedizin  
Mohrenstr, 62  
10117 Berlin, Germany

Dear Dr. Hoppe:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Germany's meat inspection system from July 18 through August 6, 2001. Enclosed is a copy of the final audit report. Comments by Germany on the draft final audit report have been included as Attachment "G" in the enclosed final audit report.

As you know, this audit revealed numerous inadequacies in implementing and enforcing the required programs, through all levels of authority, in the Germany meat inspection system. Numerous deficiencies were noted during the audit, pertaining to (1) the development and implementation of Hazard Analysis and Critical Control Point (HACCP) program requirements; (2) government monitoring/verifying of pre-operational sanitation adequacy and effectiveness (part of Sanitation Standard Operation Procedures (SSOP)); (3) inspection coverage; (4) monthly supervisory visits; (5) the control of inedible product; (6) HACCP verification activities by the government; (7) intra-laboratory and/or inter-laboratory check samples; and (8) the inclusion of *Listeria monocytogenes* in HACCP plans. Some of these concerns were also observed during the October 2000 audit.

In addition, FSIS has carefully reviewed your comments to the draft final audit report dated May 31, 2002, and the assurances provided at the exit conference of August 6, 2001, and appreciate your willingness to correct the deficiencies noted above. The FY 2002 audit of Germany's meat inspection was vastly improved over the previous two audits and indicates a successful effort to fully correct these deficiencies.

In your May 31, 2002 comments, you also raised some concerns regarding the nature of the deficiencies and their compatibility with international agreements. We would like to discuss these comments further and will contact you in the near future regarding a teleconference.

If I can provide further information regarding this audit or you have any questions regarding this letter, please do not hesitate to contact me at your convenience. I can be contacted by

Dr. Peter-Paul Hoppe

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e-mail at [sally.stratmoen@fsis.usda.gov](mailto:sally.stratmoen@fsis.usda.gov), by telephone at 202-720-3781, or by facsimile at 202-690-4040.

Sincerely,

A handwritten signature in cursive script that reads "Sally Stratmoen". The signature is written in black ink and is positioned above the typed name and title.

Sally Stratmoen, Chief, Equivalence Section  
International Policy Staff  
Office of Policy, Program Development  
and Evaluation

Enclosure

cc: Friedrich Wacker, Agricultural Counselor, German Embassy  
Richard Petges, Minister Counselor, American Embassy, Bonn  
Gerry Keily, Counselor (Agriculture), EU Mission to the U.S.  
Mary Revelt, Minister-Counselor, US Mission to the EU in Brussels  
John Wilson, FAS Area Officer  
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Donald Smart, TSC, FSIS  
Sally Stratmoen, IPS  
Karen Stuck, IPS  
Richard Brown, IPS  
Country File (FY 2001 Audit - #2)



## **AUDIT REPORT FOR GERMANY JULY 18 THROUGH AUGUST 6, 2001**

### **INTRODUCTION**

#### **Background**

This report reflects information that was obtained during an audit of Germany's meat inspection system from July 18 through August 6, 2001. The five establishments certified to export meat to the United States were audited. All five establishments were conducting processing operations.

The last audit of the German meat inspection system was conducted in October/November, 2000. Six establishments (Est's A-EV-218, A-EV-36, A-IV-21, A-IV-10, A-EV-139, and A-EV-15) were audited: four were acceptable, and two were evaluated as acceptable/re-review (Est's A-EV-15 and A-EV-218).

The German meat inspection officials removed eight establishments (Ests. A-EV-1277, A-EV-874, A-IV-23, A-EV-15, A-EV-30, A-EV-218, A-IV-21, and A-IV-23) from the list of establishments eligible to export meat and meat products to the United States prior to this new audit.

The major concerns from the October 2000, audit were the following:

- In nine establishments, the HACCP plan did not adequately specify critical limits for each CCP and the frequency with which these procedures will be performed.
- In ten establishments, the HACCP plan did not adequately address the corrective actions to be followed in response to deviations from critical limits.
- In nine establishments, the HACCP plan was not validated to determine that it was functioning as intended.
- In ten establishments, the HACCP plan did not adequately state the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequencies with which these procedures will be performed. The on-going verification activities of the HACCP program were not adequately performed by either the establishment personnel or by the GOG meat inspection officials.

- In five establishments, the HACCP plan's record-keeping system was not documenting the monitoring of CCPs.
- In three establishments, the HACCP plan was not dated and signed by a responsible establishment official.
- In two establishments, there was no documentation for the pre-shipment document reviews.
- The written SSOP procedures did not address operational sanitation in ten establishments.
- The written SSOP procedures did not address pre- operational sanitation in four establishments.
- The records for SSOP operational sanitation and any corrective actions taken were not being maintained in seven establishments
- GOG meat inspection officials were not monitoring pre-operational sanitation to verify the adequacy and effectiveness of the SSOP in eleven establishments.
- GOG meat inspection officials were not providing adequate daily inspection coverage in the processed products establishments. Inspectors were visiting establishments at variable frequencies such as once a week, twice a week, or once a month. The duration of the visits was between one to two hours in eleven establishments.
- GOG meat inspection officials were not providing inspection coverage for second shift operations in six establishments.
- Periodic supervisory visits were not performed monthly in two establishments. Only one to three internal reviews were conducted per year by local or regional officials. No internal review was conducted in Establishment A-IV-22.
- Product contact equipment (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) was found with fat, grease, dried pieces of meat, and dirt; with open seams that were broken and cracked in four establishments.
- 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 a processing room and a 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 while passing through these doors; a container of minced meat in the sausage filling room was too close to the hand washing facility creating the potential for cross contamination

from splash water; several containers for edible product ready-for-use and one container with edible product were stored under a catwalk creating the potential for dirt and waste to fall onto product. These deficiencies were observed in four establishments.

- Personnel were not using hygienic work habits to prevent product contamination. Several employees' were observed picking up pieces of meat, used packaging materials, dirty pallets, and a meat hook from the floor; cleaning the floor with a broom; handling dirty containers; and keeping an ax (used for edible product) on an employees' work platform without washing their hands or washing/sanitizing the dirty equipment (then handling edible product) in six establishments.
- Exposed product was not handled in a sanitary manner. Containers of edible product were stacked on each other and exposed product was contacting the dirty bottom of containers; and frozen meat was contacting dirty pallets in Establishment A-EV-139.  
*Corrected*
- Containers for edible and inedible product and pet food were not identified in four Establishments.

As of end of May 2001, German establishments exported 242,857 pounds of canned products containing processed pork, cured pork, and sausages to the U.S. Port-of-entry rejections were only for transportation damage (0.004 %).

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 establishment visits. The third involved the on-site visits to the establishments. The fourth 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*.

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.

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

Five establishments were audited (Ests. A-IV-10, A-IV-191, A-IV-22, A-EV-36, and A-EV-139). Four were acceptable and one establishment (A-EV-36) was judged Acceptable Subject to Re-review on the next audit. Details of the audit findings, including compliance with HACCP and SSOPs programs, are discussed later in this report.

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

As stated above, numerous major concerns were identified during the last audit of the German meat inspection system conducted in October/November 2000.

During this new audit, the auditor determined that some of the major concerns were not adequately addressed and were not corrected.

- The development and implementation of HACCP requirements was not properly implemented and enforced in all the establishments.
- GOG meat inspection officials were not adequately monitoring/verifying the adequacy and effectiveness of pre-operational sanitation in all of the five establishments.
- GOG meat inspection officials were not providing adequate daily inspection coverage in all five processed products establishments. Inspectors were visiting establishments at variable frequencies such as once a week, twice a week, or once a month. The duration of the visits was between one to two hours.
- GOG meat inspection officials were not providing inspection coverage for second shift operations in two establishments.
- No monthly supervisory visits were conducted in one establishment.
- One employee was not using hygienic work habits to prevent product contamination, such as cleaning the floor with a broom and, without washing hands, handling edible product in the processing room in one establishment. This is a repeat deficiency.

The major concerns during the new audit were the following.

- The development and implementation of HACCP requirements were not properly implemented and enforced in all of the five establishments.

- GOG meat inspection officials were not adequately monitoring/verifying the adequacy and effectiveness of pre-operational and operational sanitation (SSOP) in all of the establishments.
- The on-going verification activities of the HACCP program were not adequately performed by the GOG inspection officials in all five establishments.
- GOG meat inspection officials were not providing adequate daily inspection coverage in all five establishments. Inspectors were visiting establishments at variable frequencies, such as once a week, twice a week, or once a month. The duration of the visits was between one to two hours.
- GOG meat inspection officials were not adequately providing inspection coverage for second shift operations in two establishments.
- Monthly supervisory reviews were not conducted in one establishment.
- Inedible product destined for rendering was not denatured/decharacterized or under proper security before shipping in one establishment.
- Intralaboratory and/or interlaboratory check samples for the quality assurance programs were inadequate. In addition, when the percent recovery results for check samples were unacceptable or had fallen below the established acceptable limit, the corrective actions that were taken, if any, not documented.
- The control of *Listeria monocytogenes* is not included in the HACCP plan in establishments producing ready-to-eat products.
- Establishment officials have a surveillance program for *Listeria monocytogenes* testing between one to five samples per month in establishments producing ready-to-eat products. A few samples were also taken for environmental contamination in each establishment.
- The sanitizer was not maintained at the required temperature during the operation in the product receiving room in Establishment A-EV-36.
- Inedible product was not denatured/decharacterized or under secure conditions before shipping for rendering in Establishment A-EV-36.

### Entrance Meeting

On July 18, 2001, 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. Sabine Lieberz, Agricultural Specialist, Foreign Agricultural Service (FAS); Ms. Kerstin Kruger, Agricultural

Assistant, Foreign Agricultural Service (FAS), American Embassy in Berlin; Mr. Richard F. Brown, Senior Equivalence Officer, International Policy Staff, FSIS; Dr. Judd Giezentanner, International Audit Staff Officer, FSIS 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. Upon inquiry, it was determined that Germany does not make similar information available to the public.
5. The audit itinerary and travel arrangements. Subsequent to that meeting, the USDA team divided into two subgroups and pursued their individual audit goals.
6. Discussions regarding what BgVV can and cannot do in relation to the States, especially in the area of the listing and delisting 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 October/November 2000.

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 each establishment audited. These records reviews were conducted at each establishment. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors and laboratory personnel.
- Label approval records such as generic labels, and animal raising claims.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Compliance with SSOPs, HACCP programs.

- Sanitation and processing inspection procedures and standards.
- Control 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, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

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

- The development and implementation of HACCP requirements was not properly implemented and enforced in all the establishments.
- GOG meat inspection officials were not adequately monitoring/verifying the adequacy and effectiveness of pre-operational and operational sanitation (SSOP) in all establishments.

### Government Oversight

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

The German oversight system is potentially unique to countries that export to the United States. The responsibilities of the various levels of authority within Germany have been previously outlined in FSIS' report of the November 2000 audit of Germany and in the European Commission (EC) report from Directorate F, DG (SANCO)/1218/2000. The most relevant responsibilities of the central government are to participate and negotiate during new or revised EC legislation, to interpret and clarify EC Directives and federal laws and regulations, and to pass these documents on to the state governments. These are then passed on to the lower levels of authority by the state. However, although compliance is mandated, the states and the various lower levels of authority can create corresponding regulations, directives, and ordinances of their own, as long as they meet the minimum requirements mandated by the "higher" authority. These state-and local-level documents are normally used for clarification and administrative purposes only.

To understand the levels of authority that receive these regulatory documents, the organizational structure within Federal Republic of Germany needs to be understood. Germany consists of the sixteen Federal States of Germany. Each *Land* or state in Germany is further divided into smaller territories. Using terminology adopted by the EC, each state is divided into regions (or *Regierungsbezirk*) and each region is divided into local districts (or *Ländkreis*). In addition, each local district can have one or more city governments (or *Kreisfreie Städte*) within their borders. At the present time, there are only two states with establishments that are certified to export to the United States, Bavaria and Lower Saxony. The various levels of authority work together to implement Germany's meat inspection program.

The supervision and authority established or delegated by the state and by the local authorities varies. The inspectors and veterinarians that work within these levels of authority are not necessarily accountable to the “higher” levels. The meat inspectors, food inspectors and veterinarians that actually perform the daily inspection activities are not normally hired or paid by either the state or the region. Disciplining or firing resident inspectors and veterinarians can not be dictated by the state or regional governments. These “higher” levels of authority can only recommend action against a poor performing government employee working in an EC or U.S. approved establishment. In addition, the potential exists that the supervisor who performs monthly supervisory visits in these establishments is not an employee of either the state or the regional offices. However, in Lower Saxony, the state has the authority to replace a district-paid veterinarian with a state-paid veterinarian if the local district refuses to correct a performance problem.

Although direct and accountable supervision is different than it exists in the U.S., veterinarians within Germany all receive approximately the same training and operate at a high level of professionalism and trust. The additional experience, education, and examination of hired government veterinarians is used as a means of identifying performance weaknesses. The performance of responsibilities and duties of these veterinarians is, however, rarely questioned. Actual visits to determine competence by the “higher” levels of authority may not be routinely performed or documented and are not part of any written supervisory plan. Although there are detailed instructions of what to do when visiting a “lower” level authority, including visits to an establishment, the central and state governments rely heavily upon the results of EC and U.S. audits of their inspection system and appear to have a reactive system of maintaining compliance rather than a preventative system of maintaining compliance.

In addition, part of the responsibility of the regions is to approve establishments for EC and U.S. markets and to withdraw federal approval from these establishments. The regional office notifies the state office of each approval and withdrawal. The state office then notifies the Federal Institute in Berlin. The federal and state offices do not visit these establishments as a result of the approval and do not supervise or question the validity of a region’s decision to approve or withdraw an establishment. However, the regions work closely with the local veterinarians to secure compliance for the approvals and have extensive documentation of their pre-approval inspections of the establishments.

### Establishment Audits

Five establishments were certified to export meat products to the United States at the time this audit was conducted. All five establishments (Est’s A-IV-10, A-IV-22, A-IV-191, A-EV-36, and A-EV139) were visited for on-site audits. In all five of the establishments visited, both German inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products. Four establishments (Est’s A-IV-10, A-IV-22, A-IV-191, and A-EV-139) were found acceptable. Establishment A-EV-36 was rated acceptable subject to re-review on the next audit because of some 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 Staatliches Veterinarunter-suchungsamt, Federal Land der Lower Saxony, Laboratory for Residues of Veterinary Drugs and Microbiology in Hanover was audited on July 19, 2001. Another Veterinary Drug Residues Laboratory, Landesuntersuchungsanstalt für das Gesundheits- und Veterinarwesen Sachsen Standort, in Dresden (Saxony) was audited on July 20, 2001. Except as noted below, both laboratories had effective controls in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done.

The following concerns arose as a result of these laboratory audits:

- Intralaboratory and/or interlaboratory check samples for their quality assurance program was inadequate for chlorinated hydrocarbons, polychlorinated biphenyls, sulfonamides, organophosphates, trace elements, hormones, chloramphenicol, ivermectin, antibiotics, *Salmonella*, and *Listeria monocytogenes*.
- When percent recovery results for check samples of oxytetracycline were unacceptable (fallen below the established acceptable limit 80%), no corrective actions were taken and documented.

## Establishment Operations by Establishment Number

The following operations were being conducted in the five establishments:

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

Smoked and air dried, cured hams – two establishments (Ests. A-IV-191 A-IV-22)

## 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 controls; 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).

The SSOPs were found to meet the basic FSIS regulatory requirements.

### Basic Establishment Facilities

- The sanitizer was not maintained at the required temperature during the hog carcass trimming operation in the receiving room in Establishment A-EV-36. Establishment officials took corrective action immediately and preventive measures were proposed to GOG inspection officials to prevent recurrence.

### Condition of Facilities and Equipment

- A few racks for exposed frozen edible product ready-for-use in the product receiving room were found with old fat residue, black discoloration, and dirt in Establishment A-EV-36. Establishment officials took corrective action immediately and proposed corrective/preventive measures to meat inspection officials.

### Personnel Hygiene and Practices

- 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. Establishment officials took corrective action immediately.

### ANIMAL DISEASE CONTROLS

Germany's inspection system had no slaughter establishments that were U.S. certified. Therefore, with the exception listed below, the risk factors were not evaluated.

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

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

### RESIDUE CONTROLS

Germany's National Residue Testing Plan for 2001 was being followed and was on schedule. German inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and the storage and use of chemicals (see Attachment E).

## SLAUGHTER/PROCESSING CONTROLS

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

Currently there are no slaughter establishments certified for export to the United States.

### 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).

With the exceptions listed below, the HACCP programs were found to meet the basic FSIS regulatory requirements:

- The HACCP plan did not adequately conduct a hazard analysis that included food safety hazards likely to occur in Establishments A-EV-36, A-IV-191, and A-IV-22.
- The HACCP plan did not adequately specify critical limits, monitoring procedures, and the monitoring frequency performed for each CCP in Establishments A-IV-10, A-EV-36, and A-EV-139.
- The HACCP plan did not adequately address the corrective action to be followed in response to a deviation from a critical limit in Establishment A-IV-22.
- The HACCP plan was not validated to determine that it was functioning as intended in Establishments A-EV-36, A-EV-139, and A-IV-10.
- The HACCP plan did not adequately state the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequencies with which these procedures will be performed. The on-going verification activities of the HACCP program were not adequately performed by the establishment personnel. These deficiencies occurred in Establishments A-IV-10, A-EV-36, A-EV-139, and A-IV-191.
- The HACCP plan's record-keeping system was not documenting the monitoring of CCPs in Establishment A-IV-10.

### Testing for Generic *E. coli*

*E. coli* testing is not required in Germany's 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 regarding boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, and the importation of only eligible meat products from other countries 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

*Salmonella* testing is not 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 all establishments audited in accordance with FSIS requirements.

### *Listeria monocytogenes*

The following deficiencies were noted with Germany's testing program:

- The control of *Listeria monocytogenes* is not included in the HACCP plan in establishments producing ready-to-eat products.
- Establishment officials have a surveillance program for *Listeria monocytogenes* testing between one to five samples per month in establishments producing ready-to-eat products. A few samples were also taken for environmental contamination in each establishment.

## Monthly Reviews

These reviews were being performed by the City or District Veterinarians. These positions are similar to FSIS' Inspector-in-Charge and Circuit Supervisor, respectively.

The internal review program was applied equally to both export and non-export establishments. In four establishments, reviews were conducted monthly and in one establishment no monthly review was performed. The records of audited establishments were kept in the Regional or 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 Regional office is empowered by the State to conduct an in-depth review, and a 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 regional offices. This authority is delegated to them by the State. The Regions are thereby empowered by law to take corrective measures, penalize establishments and suspend or withdraw their licenses to operate. Other federal, state, and local 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 Fleischhygiene-Verordnung (FIH)- federal meat hygiene regulations. The district or city inspectors and veterinarians visit these establishments at variable frequencies: once a week, once a month and between one to two hours each visit. Adequate daily inspection coverage to processed products establishments is not provided. Second shift operations mostly are not covered in Establishments A-IV-10 and A-IV-191. The inspection and establishment system documents are maintained in the City, District, or Regional office. Information is not sent to the BgVV national headquarters in Berlin.

The inspectors, in addition to periodic meat inspection activities, are also responsible for the 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. They are also responsible for body-contact items, such as eyeglasses, cosmetics, drinking glasses, jewelry, and clothes.

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 August 6, 2001. 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; Ms. Sabine Lieberz, Agricultural Specialist, (FAS), U.S. Embassy in Berlin; Mr. Richard F. Brown, Senior Equivalence Officer, International Policy Staff, FSIS; Dr. Judd Giezentanner, International audit Staff Officer, FSIS, and Dr. Faiz R. Choudry, International audit Staff Officer, FSIS.

A second meeting was conducted with the European Commission (EC) in Brussels, Belgium on August 7, 2001. The EC participants were Dr. Paolo Dhostby, DG, Health and Consumer Protection Directorate General (SANCO), Unit E-3, Dr. Jennifer Egan, FVO, Veterinary Inspector Food of Animal Origin in Dublin. The participant from Germany was Dr. Peter-Paul Hoppe. The participants from FSIS were Mr. Richard F. Brown, Dr. Judd Giezentanner, and Dr. Faiz R. Choudry.

The following topics were discussed:

1. The SSOPs were found to meet the basic FSIS regulatory requirements in all five establishments audited, with the following variations:
  - GOG meat inspection officials were not adequately monitoring pre-operational and operational sanitation to verify the adequacy and effectiveness of the sanitation SSOP in all five establishments.
2. Sanitation Controls

Cross-Contamination: In the area of cross-contamination, actual product contamination and the potential for product contamination was found in one out of five of the establishments audited. GOG inspection officials took corrective actions. Specific findings for each establishment audited on-site can be found in Attachment F to this report. Examples of findings of actual product contamination include:

- A few racks for exposed frozen edible product in the product receiving room that were ready for use, were found with old fat residue, dirt, and black discoloration.
- The sanitizer was not maintained at the required temperature during the operation in the product receiving room.

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

- An employee was not using hygienic work habits to prevent product contamination such as cleaning floor with broom and, without washing her hands, handling edible product in one establishment. This is a repeat deficiency.

The HACCP programs were reviewed during the on-site audits of all five establishments. The auditor found the following deviations from FSIS regulatory requirements :

- The HACCP plan did not adequately conduct a hazard analysis that included food safety hazards likely to occur in three establishments.
- The HACCP plan did not adequately specify critical limits, monitoring procedures, and the monitoring frequencies performed for each CCP in three establishments.
- The HACCP plan did not adequately address the corrective action to be followed in response to a deviation from a critical limit in one establishment.
- The HACCP plan was not validated to determine that it was functioning as intended in three establishments.
- The HACCP plan did not adequately state the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequencies with which these procedures will be performed. The on-going verification activities of the HACCP program were not adequately performed by the establishment in four establishments.
- The HACCP plan's record-keeping system was not documenting the monitoring of CCPs in one establishment.

### 3. Inspection System Controls

- The ongoing verification activities of the HACCP program were not adequately performed by the GOG inspection officials in all five establishments.
- GOG meat inspection officials were not providing adequate daily inspection coverage in all five establishments. Inspectors were visiting establishments at variable frequencies, such as once a week, twice a week, or once a month. The duration of the visits was between one to two hours.
- GOG meat inspection officials were not adequately providing inspection coverage for second shift operations in two establishments.
- Monthly supervisory reviews were not conducted in one establishment.
- Inedible product destined for rendering was not denatured/decharacterized or under proper security before shipping in one establishment.

### 4. Laboratory Audits

- Intralaboratory and/or interlaboratory check samples for the quality assurance programs were inadequate. In addition, when the percent recovery results for

check samples were unacceptable or had fallen below the established acceptable limit, the corrective actions that were taken, if any, not documented.

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

The German meat inspection system had several repeat deficiencies and new deficiencies. One repeat deficiency of major concern was the lack of adequate daily inspection coverage. This current team audit was conducted as a result of the deficiencies found during the early FY 2001 audit. To secure a clear picture of the inspection system's response to observed non-compliances, all of the deficiencies noted above should be reviewed jointly with the facts presented under the Government Oversight section of this report. Potential weaknesses in the oversight system of the Federal Republic of Germany, as implemented by the Federal States of Germany, and enforced by the regions within each state may be evidenced by the findings presented in this report and summarized below.

Five establishments were audited: four were acceptable and one was evaluated as acceptable/re-review. During the on-site audits with establishment representatives and government officials from the regional and district offices, assurances were made to FSIS personnel that they would ensure prompt compliance. However, these assurances were also made during and/or at the conclusion of the FY 1999, FY 2000, and October/November 2000 audits with only minor corrective actions taking place between audits. In addition, the BgVV authorities in Berlin were not able to guarantee the immediate implementation of adequate daily inspection coverage of U.S. export establishments, as required by FSIS at the exit conference on August 6, 2001. State officials were faxed a letter during the exit conference in Berlin, requesting confirmation ("today, if possible") that adequate daily inspection coverage would be implemented on August 7, 2001.

Dr. Faizur R. Choudry  
International Audit Staff Officer

(signed) Dr. Faizur R. Choudry

## **ATTACHMENTS**

- A. Data collection instrument for SSOP
- B. Data collection instrument for HACCP programs
- C. Data collection instrument for *E. coli* testing.
- D. Data collection instrument for *Salmonella* testing
- 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	√	√	√	√	√	√	√	√
A-IV-191	√	√	√	√	√	√	√	√
A-IV-22	√	√	√	√	√	√	√	√
A-EV-36	√	√	√	√	√	√	√	√
A-EV139	√	√	√	√	√	√	√	√

Acceptable √

Deficiency \*

### Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. (except Est. 12, which was a cold-storage facility) 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-10	√	√	√	√	√	*	√	*	*	*	√	√
A-EV-191	√	*	√	√	√	√	√	√	*	√	√	√
A-IV-22	√	*	√	√	√	√	*	√	√	√	√	√
A-EV-36	√	*	√	√	√	*	√	*	*	√	√	√
A-EV-139	√	√	√	√	√	*	√	*	*	√	√	√

Acceptable

√

Deficiency

\*

U.S. DEPARTMENT OF AGRICULTURE  
 FOOD SAFETY AND INSPECTION SERVICE  
 INTERNATIONAL PROGRAMS

REVIEW DATE

7/19/01

NAME OF FOREIGN LABORATORY

Staatliches Veterinarunter-suchungsamt (State  
 Veterinary investigation Laboratory)

## FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY  
 Federal Lander Lower Saxony

CITY & COUNTRY  
 HANOVER, GERMANY

ADDRESS OF LABORATORY  
 Eintrachtweg 17 30173 Hanover

NAME OF REVIEWER  
 Dr. Faiz R. Choudry

NAME OF FOREIGN OFFICIAL  
 Dr. Peter Paul Hoppe

Residue Code/Name

100 111 300 400 500 200 203 800 923 Sal List

		100	111	300	400	500	200	203	800	923	Sal	List	
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE										
	Sample Handling	01											
	Sampling Frequency	02	A	A	A	A	A	A	A	A	A	A	A
	Timely Analyses	03	A	A	A	A	A	A	A	A	A	A	A
	Compositing Procedure	04	O	O	O	O	O	O	O	O	O	O	O
	Interpret Comp Data	05	O	O	O	O	O	O	O	O	O	O	O
Data Reporting	06	A	A	A	A	A	A	A	A	A	A	A	
ANALYTICAL PROCEDURES	Acceptable Method	07	A	A	A	A	A	A	A	A	A	A	
	Correct Tissue(s)	08	A	A	A	A	A	A	A	A	A	A	
	Equipment Operation	09	A	A	A	A	A	A	A	A	A	A	
	Instrument Printouts	10	A	A	A	A	A	A	A	A	O	O	
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	A	A	A	A	A	A	A	A	O	O	
	Recovery Frequency	12	A	A	A	A	A	A	A	A	O	O	
	Percent Recovery	13	A	A	A	A	A	A	A	A	O	O	
	Check Sample Frequency	14	A	A	A	A	A	A	A	A	A	A	
	All analyst w/Check Samples	15	C	C	C	C	C	C	C	C	C	C	
	Corrective Actions	16	A	A	A	A	A	A	A	A	A	A	
International Check Samples	17	O	O	O	O	O	O	O	O	O	O	O	
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	O	O	O	O	O	O	O	O	O	A	
OTHER REVIEW		19											
		20											

SIGNATURE OF REVIEWER

DATE

<b>FOREIGN COUNTRY LABORATORY REVIEW</b> <i>(Comment Sheet)</i>		<b>REVIEW DATE</b> 7/19/01	<b>NAME OF FOREIGN LABORATORY</b> Staatliches Veterinarunter-suchungsamt (State Veterinary investigation Laboratory)
<b>FOREIGN GOV'T AGENCY</b> Federal Lander Lower Saxony		<b>CITY &amp; COUNTRY</b> HANOVER, GERMANY	<b>ADDRESS OF LABORATORY</b> Eintrachtweg 17 30173 Hanover
<b>NAME OF REVIEWER</b> Dr. Faiz R. Choudry		<b>NAME OF FOREIGN OFFICIAL</b> Dr. Peter Paul Hoppe	

RESIDUE	ITEM	COMMENTS
100,200, 300,400, 500,203, 800,111, 923, Salmon- ella & Listeria	14	Intralaboratory and/or interlaboratory check samples for quality assurance program were not performed for chlorinated hydrocarbons, antibiotics, organophosphates, trace elements, hormones, chloramphenicol, sulfonamides, polychlorinated biphenyls, ivermectin, Salmonella and listeria monocytogenes. The laboratory is accredited by Staatliche Akkreditierungsstelle Hanover under the Europaischen Norm EN 45001 bzw. ISO/IEC 17025 on January 11, 2000. Laboratory officials indicated that after the accreditation they had two years to comply with all the requirements.

**FOREIGN COUNTRY LABORATORY REVIEW**

7/20/01

Landesuntersuchungsanstalt für das Gesundheits- u  
 Veterinarwesen Sachsen Standort Dresden

FOREIGN GOV'T AGENCY  
 Federal Lander Saxony

CITY & COUNTRY  
 Dresden, Germany

ADDRESS OF LABORATORY  
 Reichenbachstr. 71/73 01217 Dresden

NAME OF REVIEWER  
 Dr. Faiz R. Choudry & Dr. J. Gientanner

NAME OF FOREIGN OFFICIAL  
 Dr. Peter Paul Hoppe

Residue Code/Name			100	111	300	400	200	203	800	923					
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE												
	Sample Handling	01		A	A	A	A	A	A	A	A				
	Sampling Frequency	02		A	A	A	A	A	A	A	A				
	Timely Analyses	03		A	A	A	A	A	A	A	A				
	Compositing Procedure	04		O	O	O	O	O	O	O	O				
	Interpret Comp Data	05		O	O	O	O	O	O	O	O				
	Data Reporting	06	A	A	A	A	A	A	A	A					
ANALYTICAL PROCEDURES	Acceptable Method	07	A	A	A	A	A	A	A	A					
	Correct Tissue(s)	08	A	A	A	A	A	A	A	A					
	Equipment Operation	09	A	A	A	A	A	A	A	A					
	Instrument Printouts	10	A	A	A	A	A	A	A	A					
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	A	A	A	A	A	A	A	A					
	Recovery Frequency	12	A	A	A	A	A	A	A	A					
	Percent Recovery	13	A	A	A	A	C	C	A	A					
	Check Sample Frequency	14	A	A	A	A	A	A	A	A					
	All analyst w/Check Samples	15	C	C	C	C	A	A	C	C					
	Corrective Actions	16	A	A	A	A	A	A	A	A					
	International Check Samples	17	O	O	O	O	O	O	O	A					
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	O	O	O	O	O	O	O					
OTHER REVIEW		19	EVAL. CODE												
		20	EVAL. CODE												

SIGNATURE OF REVIEWER

DATE

<b>FOREIGN COUNTRY LABORATORY REVIEW</b> <i>(Comment Sheet)</i>		REVIEW DATE 7/20/01	NAME OF FOREIGN LABORATORY Landesuntersuchungsanstalt für das Gesundheits- und Veterinärwesen Sachsen Standort Dresden
FOREIGN GOV'T AGENCY Federal Lander Saxony	CITY & COUNTRY Dresden, Germany	ADDRESS OF LABORATORY Reichenbachstr. 71/73 01217 Dresden	
NAME OF REVIEWER Dr. Faiz R. Choudry & Dr. J. Gientanner		NAME OF FOREIGN OFFICIAL Dr. Peter Paul Hoppe	

RESIDUE	ITEM	COMMENTS
200,203	12	When percent recovery results for check samples of oxytetracycline were unacceptable (fallen below the established acceptable limit 80%), no corrective actions were documented.
100,111, 300 400, 500,800, 923	14	Intralaboratory and/or interlaboratory check samples for quality assurance program were not performed as programmed for chlorinated hydrocarbons, polychlorinated biphenyls, organophosphates, trace elements, hormones, sulfonamides, and ivermectin.

REVIEW DATE  
07/24/2001

ESTABLISHMENT NO. AND NAME  
Est. A-EV-36  
Schafft Fleischwerke

CITY  
Ansbach  
COUNTRY  
GERMANY

FOREIGN PLANT REVIEW FORM

NAME OF REVIEWER  
Dr. F. Choudry & Dr. J. Giezantanner

NAME OF FOREIGN OFFICIAL  
Dr. Peter P. Hoppe & Dr. Kathrin Leip

EVALUATION  
 Acceptable  Acceptable/  
Re-review  Unacceptable

CODES (Give an appropriate code for each review item listed below)

A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 A
Chlorination procedures	02 O	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 A
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	60 A
Sanitizers	05 M	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 M	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	2. DISEASE CONTROL		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 M	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 O	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 A	3. RESIDUE CONTROL		Export certificates	74 A
Product contact equipment	19 M	Residue program compliance	46 O	Single standard	75 A
Other product areas (inside)	20 A	Sampling procedures	47 O	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 A	HACCP	M
Personal hygiene practices	26 M	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE 07/24/2001	ESTABLISHMENT NO. AND NAME Est. A-EV-36 Schafft Fleischwerke	CITY Ansbach
			COUNTRY GERMANY
NAME OF REVIEWER Dr. F. Choudry & Dr. J. Giezantanner	NAME OF FOREIGN OFFICIAL Dr. Peter P. Hoppe & Dr. Kathrin Leip		EVALUATION <input type="checkbox"/> Acceptable <input checked="" type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable

COMMENTS:

05. The sanitizer was not maintained at the required temperature during the operation in the carcass receiving room. Establishment officials took corrective action immediately and measures were proposed to GOG inspection officials to prevent recurrence.

19. A few racks for exposed frozen edible product in the product receiving room were found with old fat residue, dirt, and black discoloration. Establishment officials took corrective action immediately.

26. One employee was observed cleaning floor with a broom and, without washing her hands, handling edible product in the processing room. Establishment officials took corrective action immediately.

43. Inedible product was not denatured/decharacterized or under security prior to leaving for rendering.

34,35. GOG meat inspector was monitoring/verifying the adequacy and effectiveness of pre-operational and operational SSOP monthly. Another meat inspector was visiting this establishment daily (one hour each visit) but inspection activity was limited only to meat and meat product that was received from outside. The daily continuous inspection coverage was not provided during the operation.

82. HACCP (please see attachment B).

FOREIGN PLANT REVIEW FORM

REVIEW DATE  
07/26/2001

ESTABLISHMENT NO. AND NAME  
Est. A-IV-10  
Meica Ammerlandische Fleischwarenfabrik Fritz

CITY  
Edeweicht  
COUNTRY  
GERMANY

NAME OF REVIEWER  
Dr. F. Choudry & Dr. J. Giezertanner

NAME OF FOREIGN OFFICIAL  
Dr. Peter Hoppe, Dr. Reinhard & Dr. Remmers

EVALUATION  
 Acceptable  Acceptable/  
Re-review  Unacceptable

CODES (Give an appropriate code for each review item listed below)

A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 A
Chlorination procedures	02 O	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 M	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 A
Pest control monitoring	09 A	2. DISEASE CONTROL		Filling procedures	65 A
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 A
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 A
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 A
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 A
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 A
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 A	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 O	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 A	3. RESIDUE CONTROL		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 O	Single standard	75 A
Other product areas (inside)	20 A	Sampling procedures	47 O	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 A	HACCP	M
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	07/26/2001	Est. A-IV-10 Meica Ammerlandische Fleischwarenfabrik Fritz	Edeweicht
			COUNTRY GERMANY
NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL		EVALUATION
Dr. F. Choudry & Dr. J. Giezertanner	Dr. Peter Hoppe, Dr. Reinhard & Dr. Remmers		<input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptabl

COMMENTS:

34, 35. GOG meat inspector was monitoring/verifying the adequacy and effectiveness of the pre-operational SSOP monthly and operational SSOP was not monitored/verified. Another inspector was visiting this establishment four times a month (two hours each visit) but inspection activity was limited only to meat and meat product that was received from outside. The daily continuous inspection coverage was not provided during the operation.

82. HACCP (please see attachment B).

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS		REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY	
<b>FOREIGN PLANT REVIEW FORM</b>		07/31/2001	Est. A-EV-139 Nestle Deutschland AG	Neuenkirchen	
NAME OF REVIEWER Dr. Faiz R. Choudry, DVM.		NAME OF FOREIGN OFFICIAL Dr. Peter Hoppe & Dr. Reinhard Dr. Schumacher		EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	
CODES (Give an appropriate code for each review item listed below) A = Acceptable    M = Marginally Acceptable    U = Unacceptable    N = Not Reviewed    O = Does not apply					
1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 A
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Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 M	Processing records	63 A
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Equipment approval	16 A	Condemned product control	43 A	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 O	Export product identification	72 A
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Other product areas ( <i>inside</i> )	20 A	Sampling procedures	47 O	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE 07/31/2001	ESTABLISHMENT NO. AND NAME Est. A-EV-139 Nestle Deutschland AG	CITY Neuenkirchen
			COUNTRY GERMANY
NAME OF REVIEWER Dr. Faiz R. Choudry, DVM.	NAME OF FOREIGN OFFICIAL Dr. Peter Hoppe & Dr. Reinhard Dr. Schumacher	EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	

COMMENTS:

34, 35. GOG meat inspector was visiting this establishment once a month and was not monitoring/verifying the adequacy and effectiveness of the pre-operational sanitation SSOP and operational SSOP was monitored/verified monthly. The daily continuous inspection coverage was not provided during the operation. GOG meat inspection officials did not make any commitment to increase inspection coverage.

82. HACCP (Please see attachment B.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS  <b>FOREIGN PLANT REVIEW FORM</b>	REVIEW DATE 07/27/2001	ESTABLISHMENT NO. AND NAME Est. A-IV-191 Abraham Schinken GmbH & Co. KG	CITY Barbel-Harkenbrugge  COUNTRY GERMANY
NAME OF REVIEWER Dr. F. Choudry & Dr. J. Giezentanner	NAME OF FOREIGN OFFICIAL Dr. Peter Hoppe & Dr. Reinhard Velleuer		EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable

CODES (Give an appropriate code for each review item listed below)

A = Acceptable    M = Marginally Acceptable    U = Unacceptable    N = Not Reviewed    O = Does not apply

1. CONTAMINATION CONTROL	Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES	Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	60 A
Sanitizers	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	Preoperational sanitation	34 M	Processing equipment	62 A
Pest --no evidence	Operational sanitation	35 M	Processing records	63 A
Pest control program	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	2. DISEASE CONTROL		Filling procedures	65 O
Temperature control	Animal identification	37 O	Container closure exam	66 O
Lighting	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	Condemned product control	43 A	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT	Restricted product control	44 O	Export product identification	72 A
Over-product ceilings	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	3. RESIDUE CONTROL		Export certificates	74 A
Product contact equipment	Residue program compliance	46 O	Single standard	75 A
Other product areas (inside)	Sampling procedures	47 AO	Inspection supervision	76 A
Dry storage areas	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING	Pre-boning trim	51 O	Imports	81 A
Personal dress and habits	Boneless meat reinspection	52 A	HACCP	M
Personal hygiene practices	Ingredients identification	53 A		
Sanitary dressing procedures	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	07/27/2001	Est. A-IV-191 Abraham Schinken GmbH & Co. KG	Barbel-Harkenbrugg
			COUNTRY
			GERMANY
NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL		EVALUATION
Dr. F. Choudry & Dr. J. Giezentanner	Dr. Peter Hoppe & Dr. Reinhard Velleuer		<input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptabl

COMMENTS:

34,35. GOG meat inspector was monitoring/verifying the adequacy and effectiveness of pre-operational and operational SSOP bimonthly. The daily continuous inspection coverage was not provided during the operation.

82. HACCP (please see attachment B).

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS  <b>FOREIGN PLANT REVIEW FORM</b>	REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
	08/03/2001	Est. A-IV- 22 Gebruder Abraham GmbH, Werk Seevetal	Seevetal
NAME OF REVIEWER		NAME OF FOREIGN OFFICIAL	COUNTRY
Dr. F. Choudry & Dr. J.Giezantanner		Dr. Peter P. Hoppe & Dr. Ekkehard Schubert IIC	GERMANY
		EVALUATION	
		<input checked="" type="checkbox"/> Acceptable	<input type="checkbox"/> Acceptable/ Re-review
			<input type="checkbox"/> Unacceptable

CODES (Give an appropriate code for each review item listed below)  
 A = Acceptable      M = Marginally Acceptable      U = Unacceptable      N = Not Reviewed      O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 O	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 A
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 M	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	2. DISEASE CONTROL		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 A	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 O	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 A	3. RESIDUE CONTROL		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 O	Single standard	75 A
Other product areas (inside)	20 A	Sampling procedures	47 O	Inspection supervision	76 M
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 A	HACCP	
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A		

FOREIGN PLANT REVIEW FORM (reverse)	REVIEW DATE 08/03/2001	ESTABLISHMENT NO. AND NAME Est. A-IV- 22 Gebruder Abraham GmbH, Werk Seevetal	CITY Seevetal
			COUNTRY GERMANY
NAME OF REVIEWER Dr. F. Choudry & Dr. J. Giezantanner	NAME OF FOREIGN OFFICIAL Dr. Peter P. Hoppe & Dr. Ekkehard Schubert IIC	EVALUATION <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Acceptable/ Re-review <input type="checkbox"/> Unacceptable	

COMMENTS:

34,35. GOG meat inspector was monitoring/verifying the adequacy and effectiveness of pre-operational and operational SSOP between 3 to 5 times per month. The daily continuous inspection coverage was not provided during the operation.

76. GOG inspection official did not conduct any monthly supervisory review this year. No change from last audit. GOG inspection officials indicated that it would be corrected immediately.

82. HACCP (*Please see attachment B*).

Federal Institute  
for Hygienic Consumer Protection and Veterinary Medicine

bgvv

bgvv. Postfach 33 00 13, D – 14191 Berlin

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D – 14191 Berlin

John C. Prucha, D.V.M., M.S., M.P.H.  
Food Safety and Inspection Service  
United States Department of Agriculture  
1400 Independence Avenue

Telephone 030/8412-0  
Telefax 030/8412-4741

USA – Washington, D.C. 20250

File No.: *In reply please refer to*  
5106-01/188313

Telephone Berlin  
0049-1888- 31 May 2002  
412-2114

**Export of Meat Products to the USA**

Specifically: Comment by the Federal Republic of Germany on the Final FSIS Report dated 6 November 2001 (Audit Report for Germany July 18 – August 6, 2001)

My Dear Dr. Prucha,

We hereby send you the enclosed Communication from the Federal Republic of Germany on the above-mentioned audit report for your information.

Cordially,  
By Order

[Signature illegible]

Dr. Hoppe

## **Communication**

by the Federal Republic of Germany to the Food Safety and Inspection Service Concerning the Audit Report for Germany dated 06 November 2001

### **Preface:**

1. This Communication is based on the comments coordinated between the monitored enterprises and the veterinary authorities that are responsible on site as well as the licensing authorities (supervisors) as well as the deficiency correction reports. The Audit Report mentions the deficiencies that were observed on site and that were addressed during the particular final conferences, although – and this is noted with a critical emphasis – this was frequently formulated in an unsystematic and generalizing fashion, in other words, in too much of a lump-sum approach. It is therefore suggested for the future that a more detailed list of deficiencies with a precise description of the deficiency be drafted for each monitored enterprise.
  
2. Upon critical evaluation of the described shortcomings, one can establish without any doubts that the overwhelming number of deficiencies involves so-called paperwork deficiencies and not any significant genuine hygienic deficiencies that could be the source of a health hazard to the consumer. Such shortcomings that were observed during the inspection as a rule were immediately corrected; others such as, for example, insufficient training of personnel, have in the meantime been remedied. It must, however, be noted at this point that all of the listed shortcomings are to be sanctioned according to the Community Law of the European Union. The concerns of the FSIS, expressed prior to the audit, likewise are no longer justified because one can just about rule out any health impairment of the consumer due to genuine and grave hygienic shortcomings.
  
3. The shortcomings under discussion have in the meantime been remedied. Here are further details:

With respect to Enterprise A/IV/10 Meica Ammerländische Fleischwarenfabrik in Edeweicht:

The following were challenged accordingly:

A. the HACCP Plan:

1. The HACCP Plan, it was charged, does not adequately define the boundary values, the measurement methods and the measurement frequency at the individual HACCP's;
2. the HACCP Plan, it was charged, was not examined for its functional efficiency and it was noted that it had not been validated;
  - the HACCP Plan, it was charged, does not contain any adequate description of the verification measures and the frequency with which these measures are implemented. The company personnel, it was noted, do not carry out constant verification measures (on-going verification) in the proper manner;
3. the monitoring measures at the CCP's, it was noted, were not being documented.

B. Official Supervision:

1. Official supervision was not done daily and monitoring from the start of work at the plant and during the second shift, it was charged, is not adequate;
2. the constant verification measures (on-going verification) reportedly are not being adequately carried out by Supervision.

Comment on A.1:

The HACCP Plan of Firma Meica has been spelled out very precisely, noting as to the methods that are to be employed and how frequently the prescribed monitoring parameters must be measured and documented at the CCP's.

Moreover, the boundary values are exactly defined at all CCP's and the measures that are to be taken when the boundary value is exceeded are spelled out. Corrective measures are governed by the provisions of § 417.2 of FSIS Directive 500.1, Attachment 1. One cannot recognize any deficiency here.

**Note:**

If the input temperature measurement considered as a deficiency by the FSIS is construed according to the Minimax principle, then this shortcoming has been remedied, although one might argue whether a Minimax measurement with many measurement points might not make more sense than an exact temperature documentation of just a few measurement points, in particular, because the HACCP system rests on the basis of the boundary value principle.

*With respect to A.2:*

Validation according to the Definition of the Codex Alimentarius, second edition, supplement to Volume 1, B-1997 is the "receipt of evidence that the elements of the HACCP Plan are in effect." FSIS Directive 5000.1, Attachment 1, in § 417.4, also describes "initial validation" as a summary of measures that must be mentioned in order to determine whether the HACCP Plan works as intended. Main points in validation – if the term is correctly interpreted in the Codex – must be the bacteriological safety in commercially sterile canned products. According to the view held here, the HACCP Plan is validated in terms of bacteriological stability when the monitoring is done in accordance with the provisions of the "Code of Federal Regulations -- § 318, Subpart 6." Firma Meica has regularly performed these monitoring functions for many years and prior to every boiling. Moreover, the effectiveness of the HACCP Plan has for years been validated with the help of external and internal bacteriological exams of the finished products. The validation of the HACCP Plan regarding the prevention of foreign bodies and residues naturally can be accomplished only in a restricted manner by means of regular checks on the integrity of materials that come into contact with foods (foreign bodies) as well as random sample examinations of finished products and, above all, analysis of official challenges and consumer complaints. All mentioned measures are documented and are part of the HACCP Plan. One cannot recognize a deficiency in the validation of the HACCP Plan of Firma Meica to the extent that the definition of the Codex and of the FSIS Directive were used as basis.

With respect to A.3:

According to the definition of the Codex Alimentarius, verification consists of “methods, processes, analyses and other evaluations implemented in addition to supervision by means of which it is to be determined whether the HACCP Plan is being complied with.” According to the view held here, verification cannot be neatly separated from the validation of the HACCP Plan. Verification, in particular, comprises control measures as part of the monitoring that is actually done, in other words, checks on measurements and measurement frequency on the HACCP. This is also indicated in FSIS Directive 5000.1 in § 417.4, No. 2 under the heading of “On-Going Verification Activities,” for example, lists the calibration of the measurement instrument, the direct monitoring of measurement activities and the corrective measures taken.

All mentioned measures are part of the HACCP Plan of Firma Meica and checked on and documented by the Quality Assurance section of the plant and by officials in Supervision. One cannot recognize a verification deficiency in the HACCP system in the documentation and the actual current practice pursued by Firma Meica. One cannot recognize any system deficiency.

With respect to B.1:

Until now, U.S. authorities had not prescribed any daily supervision; instead, they confined themselves to the supervision requirements of the FSIS representatives, above all for the time during U.S. production (constant supervision of incoming commodities up to shipment of commodities) throughout the time in which no commodities were produced for the U.S. market, in other words, official monitoring was performed only in accordance with the various national or European Union requirements. The just recently established requirement of the FSIS for daily checkups also outside the time during which products are being turned out for the U.S. market has in the meantime been properly taken into account. Accordingly, there has also been an increase in the frequency of monitoring prior to the start of work and during the second shift. According to views held here, the frequency of supervision actually bumps into a limit that remains yet to be justified in a meaningful manner (in-house monitoring) and that would still be economically bearable. Operational supervision for enterprises shipping experts to the USA is done free of charge; this creates a competitive disadvantage for German plants, something that is not compatible with the WTO Agreement according to views held here.

With respect to B.2:

The CCP's are being checked on and they are being monitored by Supervision at the start of work in the plant and are being properly documented. Additional checks are performed in the context of official sampling and external examinations in the state examination bureaus and, moreover, on a random sampling basis; the calibration of the used measurement instruments is checked with officially calibrated instruments at the monitoring points. All of these measures are documented in the reports. Here again, one cannot recognize any shortcoming.

Summarizing, it must be said that the report of the FSIS is entirely too general for anyone to be able to make any specific comments on the individual shortcomings. It is therefore suggested that a more detailed record be prepared for each individual monitored enterprise.

With respect to personnel facilities:

On the basis of new operating agreements (interference in the private sphere), personnel lockers will, effective immediately, be checked twice a year by Quality Assurance in the presence of representatives of the shop committee for hygienic conditions. Monitoring and results are documented.

With respect to Enterprise A/IV/191 – Abraham Schinken GmbH & Co. KG, Barsel-Harkebrügge:

The following was challenged accordingly:

1. SSOP
2. HACCP examination of CCP
3. General shortcomings that will be covered in detail.

Comment on 1. SSOP:

In-house documentation is compiled according to the recommendations of the representative of the FSIS on one sheet of paper per day and in the future will be handled by one person and no longer – as in the past – by the particular department head.

The in-house description of shortcomings hereafter will be presented in a more detailed form according to new instruments.

With respect to 2. HACCP:

The hazard analysis has in the meantime been performed including the designation of the anticipated practical use by the consumer.

The in-house verification of two CCP's has been accomplished.

The instruction concerning the review of the way in which the temperature measurement instrument works was supplemented by the addition of official calibration.

The HACCP system has in the meantime been validated.

The products were examined once a month for Listeria; besides, swab samples were taken (environmental exams). The examination results are documented.

*With respect to 3. SSOP – General Shortcomings:*

Fly screens were placed in the personnel facilities.

The manual scoop that was criticized was replaced by a scoop made of plastic material. Instructions were issued to clean the smoking car and a test paper was prepared. A corresponding cleaning machine was ordered to clean the rods used in suspending the hams. The wooden rods have not yet been completely exchanged against metal rods. A list of measures was drawn up. Overhead cleaning (pipelines, cable strands) was done; the hygiene plan was properly adjusted.

Specially marked waste containers are now available in adequate numbers.

For the slicer room: Effective measures were taken against the formation of condensation water at the evaporators. According to local estimates, the requirements (regulations) of the Reference Guide (status as of January 1998) of the USDA are being complied with.

With respect to Enterprise A/IV/22 – Gebrüger Abraham GmbH, Werk Seevetal:

All of the established, mostly minor shortcomings were remedied without question including the monthly checkup by the supervisor.

Concerning hazard analysis:

In chemical hazard analysis during Process Step 1, the national examination program was replaced by official plan samples in the nature of random samples.

With respect to the form entitled “Examination of Meat Raw Materials/Working Instruction,”  
“Examination of Temperature in Meat Raw Materials”:

The response when the boundary value is exceeded was revised. After coordination with Production, it was decided to facilitate after-refrigeration up to 7°C. At more than 4°C, the goods are locked in place until a temperature of 4°C has been attained. Documentation is applied upon the reverse side of the form entitled “Examination of Meat Raw Materials.”

Documentation regarding as to what is being done, for example, in case of soiled ham or ham that has fallen down, is provided on the form entitled “Examination of Meat Raw Materials.”

Regarding the working instruction “Examination of the Hygiene Status Before and After  
Production” as well as the pertinent forms:

This system was developed as suggested by FSIS. The interval was set at twice a month.

With respect to 4: Description of Work Procedures:

Here, consideration was given to the divisions of Goods Receipt, Salting and Cutting as discussed.

With respect to Enterprise A/EV/139 Herta, Werk Neuenkirchen:

Along with the communication from the appropriate authority to the effect that the shortcomings noted have all been remedied, it was announced officially that the enterprise has returned the U.S. permit. The enterprise emphasized the observation that the check on shortcomings necessitated a redrafting of the particular operating sheets of the Nestle Concern. This, among other things, necessitates a revision of the HACCP Plan that is to be done within 12 months.

The enterprise has been stricken from the roster of German enterprises holding export licenses to the USA.

With respect to Enterprise A/EV/36 Schafft Fleischwerke GmbH, Ansbach:

1. Sanitizers:

The facilities for knife sterilization were checked out on a random sample basis by the technical maintenance personnel as part of daily operating checks. There were no complaints.

2. Product contact equipment:

Personnel employed in the area of the frozen goods transport system as well as personnel responsible for cleaning were briefed accordingly. Random sample checks, conducted in the context of daily operating checkups, did not yield any new objections.

3. Personnel hygiene practices:

This topic was covered in detail as part of the general personnel training program. The department heads, moreover, were informed on the special requirements contained in the FSIS Regulation and were urged to pay more attention to those provisions.

4. Condemned product control:

Confiscated material is surrendered (according to regulations) from the enterprise along with a cover letter to the Carcass Elimination Plant. As for the rest, reference is made to the organization structure and regulation of competence of the German Veterinary Service. Accordingly supervision exercised by the official veterinarian according to the Meat Hygiene Law is confined to areas within the supervised enterprise.

5. Free operational/operational sanitation:

Random sample supervision of production not working for exports to the USA has recently also been instituted as part of the daily operating checkups and is documented in the check lists.

6. HACCP:

- a) The HACCP system was revised and was corrected with regard to the indicated points.
- b) The hazard analysis was performed and the potential hazards were identified.
- c) Supervision is described precisely; the frequencies of supervision have been inserted.
- d) The plan has been validated.
- e) Regarding the verification of the examination procedures, the department heads have now been included. The documentation of the HACCP system states that Listeria

monocytogenes, Salmonella spp. and enteropathogenic E. coli as well as Clostridium botulinum and its toxins must not be detectable in the end product. The products may not contain any risk regarding Staphylococcus aureus and its toxins. Any danger to the consumer from foreign bodies and chemical contamination must be excluded and must remain excluded effectively. The newly developed forms for daily hygiene monitoring as well as for the monitoring of the metal detectors are enclosed.

By request of the enterprise, it is stricken from the roster of German enterprises with export license to the USA.

## **Conclusion**

*Enterprises and the particular appropriate veterinary authorities noted rather critically that the Audit Report lists the deficiencies partly in an unsystematic and generalizing fashion. It is therefore suggested that a detailed record of deficiencies be drawn up for each individual enterprise and that duplicate listings of shortcomings be avoided in the summary (in the summary, page 4, point 1, "The development and implementation of HACCP...", point 1 is repeated on page 5; three times on page 5 under points 3, 8 and 13, there is listed the shortcoming "inedible product was not denatured..."). That at least creates the wrong optical impression.*

The practice of daily supervision, demanded for the first time by the FSIS during the audit in August 2001, means additional costs for the enterprises to the tune of between 8,000 and 21,000 € per year. In the USA, the Federal Government obviously takes care of these costs; this therefore constitutes a considerable competitive disadvantage for the local meat processing plants. The FSIS is therefore asked to reconsider whether the current procedure is compatible with the WTO Agreement or the Agreement of Equivalence between the European Union and the USA.

[Signature illegible]

Dr. Hoppe

Schafft Fleischwerke Ansbach  
Zweigniederlassung der Unilever Bestfoods Deutschland  
**Metal Detector Monitoring**

**HACCP Documentation Verification:**

CCP No. 1, 5, 10, 11, 13, 17, 18, 24, 25, 27

CCP in Work Division is to be marked by circling the corresponding number

**Metal detector monitoring interval: 1x per shift at start of shift**

**Monitoring of ejection plant: 1x per week at start of week**

**Calendar week from .....20 to .....20**

**Machine number:**

Day	Time	Metal detector	Ejection plant	Signature Examiner	Signature Division Chief
Sunday about	0530 hours				
	1400 hours				
	2230 hours				
Monday about	0530 hours				
	1400 hours				
	2230 hours				
Tuesday about	0530 hours				
	1400 hours				
	2230 hours				
Wednesday about	0530 hours				
	1400 hours				
	2230 hours				
Thursday about	0530 hours				
	1400 hours				
	2230 hours				
Friday about	0530 hours				
	1400 hours				
	2230 hours				
Saturday about	0530 hours				
	1400 hours				
	2230 hours				
<b>Prepared by:</b> [signature]		<b>Released by:</b> [Signature]		<b>Date:</b> [Illegible]	

**City of Ansbach – Public Order and Street Traffic Bureau  
 Division of Meat Hygiene**

Daily Hygiene Monitoring Fa. Schafft, EZ 54/EV 36											
Month/Year											
Date	Production Division										Signature Official Veterinarian
	Raw material acceptance	Breakup	Cutting	Spice chamber	Filling	Climate- conditioned chamber	Peeling chamber	Bake snack	Final packaging	Laboratory	
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											
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**Reviewed by:**

**State Supervisory Authority**

**Date**

**Signature**

**Stamp**