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Dear Dr. Lorenz:

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Germany's meat inspection system from June 27 through July 13, 2012. FSIS has received your comments and has incorporated the information into the report. Enclosed is a copy of the final report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-6400, by facsimile at (202) 720-7990, or electronic mail at [international.audit@fsis.usda.gov](mailto:international.audit@fsis.usda.gov).

Sincerely,

Dr. Shaukat H. Syed  
Director  
International Audit Staff  
Office of Investigation, Enforcement and Audit

Enclosure

MAY 30 2013

DRAFT FINAL REPORT OF AN ONGOING  
EQUIVALENCE ON-SITE AUDIT CONDUCTED IN  
GERMANY  
JUNE 27 THROUGH JULY 13, 2012

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING  
THE PRODUCTION OF MEAT PRODUCTS INTENDED FOR  
EXPORT TO THE UNITED STATES OF AMERICA

Food Safety and Inspection Service  
United States Department of Agriculture

## *Executive Summary*

This audit report describes the outcome of an on-site audit of Germany's meat inspection system conducted by the Food Safety and Inspection Service (FSIS), determining on-going equivalency of the German Meat inspection system in order to produce safe wholesome products from June 27 through July 13, 2012. The routine audit was conducted to determine if the German Meat inspection system remains equivalent with that of the U.S. meat inspection system. Between January 1 to December 31, 2011, Germany exported 1,391,722 pounds of processed pork products such as cooked sausages, hot dogs and pepperoni pizza to the United States.

Representatives from Germany's Federal Inspection Service as well as from State Ministries accompanied the FSIS auditors throughout the entire audit.

FSIS reviewed and verified the information provided by Germany's Central Competent Authority (CCA) in the latest revised, Self-Reporting Tool (SRT). The audit scope included the central, four Lander states, four Regional, and four local inspection offices; one swine slaughter and three pork processing establishments; and one government microbiology laboratory. Determinations concerning the effectiveness of Germany's meat inspection system focused on its performance associated with the following six components upon which FSIS' system equivalence is based: (1) Government Oversight, (2) Statutory Authority and Food-Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Points Systems, (5) Chemical Residue Control Programs and (6) Microbiological Testing Programs. The audit findings indicate the CCA met the all six components of the German inspection system continue to meet equivalence criteria.

The *Länder* maintains the legal authority and responsibility to enforce all applicable laws and regulations governing Germany and third-country requirements for the production of safe and wholesome pork products for export to the United States. The FSIS auditor verified that all prior systemic findings identified during the previous FSIS audit were appropriately addressed and corrected. The audit revealed improvement in all areas of Germany's meat inspection system, and there was no systemic non-compliances reported.

The audit outcome demonstrated that the CCA is able to provide sufficient oversight and to meet the principal requirements for all six equivalence components and, therefore, is operating an equivalent meat inspection system.

The final audit report will be developed after all FSIS comments as well as responses to any findings from the German inspection authorities are incorporated. Corrective actions reported during the 2009 audit were corrected and verified during the on-site audit of 2012.

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## ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

BfR	Federal Institute for Risk Assessment
BMELV	Federal Ministry of Food, Agriculture and Consumer Protection
BVL	Federal Office of Consumer Protection and Food Safety (CCA)
CCA	Central Competent Authority (German Food Safety Authority)
CFR	Code of Federal Regulations
CVO	Chief Veterinary Officer
FLS	First Line Supervisor
FS	Front Line Supervisor
<i>E. coli</i>	<i>Escherichia coli</i>
FSIS	Food Safety and Inspection Service
<i>Länder</i>	Particular Federal State Ministry
LAV	Lander Working Group for Consumer Protection
PA	Provincial authorities
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point System
PSR	Periodic Supervisory Review
<i>Salmonella</i>	<i>Salmonella</i> species
SPS	Sanitation Performance Standards
SSOP	Sanitation Standard Operating Procedures
U.S.	The United States of America

## 1. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of the Germany's meat inspection system from June 27 through July 13, 2012.

The last audit of the German Meat Inspection System was carried out from October 28 through November 18, 2009. Six (6) processing establishments (A-IV-10; A-EV-29; A-EV-35; A-IV-191; EV-717; AND EV-830) were visited.

The audit began with an entrance meeting held on June 27, 2012, in Berlin with the participation of representatives from the Central Competent Authority (CCA), the Federal Office of Consumer Protection and Food Safety (BVL), Federal States (*Länder*) and the FSIS, representatives from the United States Embassy in Germany, and Office of International Affairs (OIA), International Audit Staff (IAS).

## 2. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

The audit objective was to verify that Germany's food safety system governing meat inspection continues to be equivalent to that of the United States of America (U.S.), with the resultant capability to produce and export pork products that are safe, wholesome, unadulterated, and properly labeled.

In pursuit of this objective FSIS conducted a risk based assessment of the information provided by Germany in the CCA component of FSIS document entitled, "Self-Reporting Tool" (SRT) for On-going Equivalence, the new version from the April of 2012 with accompanying references, U.S.' port-of-entry (POE) testing results, other data collected by FSIS and relevant to Germany's food safety system, and the FSIS findings reported from on-site audits conducted in the last three years.

FSIS determinations concerning Germany's program effectiveness focused on performance associated with the following six components: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point Systems, (5) Chemical Residue Control Programs, and (6) Microbiological Testing Programs. The auditor was accompanied by the CCA/BVL and particular *Länder* state representative during this audit.

Administrative functions of the system were reviewed at the CCA headquarters in Berlin and four State/local inspection offices. During the review, the FSIS auditor evaluated the implementation of the management control systems put in place to ensure that the national system of inspection, verification, and enforcement is implemented as intended.

During the establishments reviews, particular attention was paid to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS regulation (9 CFR 327.2).

Additionally, one laboratory conducting microbiological testing was audited to verify the CCA's ability to provide adequate technical support to the inspection system.

Sectors Visited During the Audit		No. Sites	Locations
Competent Authority Offices	Central	1	<ul style="list-style-type: none"> <li>• BVL Headquarters office in Berlin</li> </ul>
	State Authority	4	<ul style="list-style-type: none"> <li>• Bavarian State Authority, Munich</li> <li>• Baden-Wuerttemberg State Authority, Stuttgart</li> <li>• North-Rhein Westfalia, Dusseldorf</li> <li>• Lower Saxony, Hannover</li> </ul>
	Regional Authority	4	<ul style="list-style-type: none"> <li>• Ansbach Regional Authority</li> <li>• Karlsruhe Regional Authority</li> <li>• Recklinghausen Regional Authority</li> <li>• Oldenburg/Wardenberg Regional Authority</li> </ul>
	Local offices	4	<ul style="list-style-type: none"> <li>• Nurnberg Local Office</li> <li>• Rastatt Local Office</li> <li>• Gutersloh Local Office</li> <li>• Westerstede Local Office</li> </ul>
Government Microbiological Laboratory	1	<ul style="list-style-type: none"> <li>• Oldenburg</li> </ul>	
Swine Slaughter Establishment	1	<ul style="list-style-type: none"> <li>• Est. 927 Toennies, Rheda-Wiedenbrueck</li> </ul>	
Swine Processing Establishments	3	<ul style="list-style-type: none"> <li>• Est. D-EW-717, HoWe, Nuremberg</li> <li>• Est. BW 03330, Freiburger, Muggensturm</li> <li>• Est. 34, Meica, Edewecht</li> </ul>	

### 3. LEGAL BASIS FOR THE AUDIT AND AUDIT STANDARDS

The audit was conducted under the specific provisions of the U.S. laws and regulations, in particular:

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

Currently, Germany has equivalence determinations in place for the following:

- Testing for *Enterobacteriaceae* and Total Viable Count in Lieu of testing for generic *E. coli* is acceptable for all EU exporting countries.

#### **4. BACKGROUND**

Germany is eligible to export raw and processed pork meat products to the U.S. Germany exported 1,391, 722 pounds of pork products in 2011. A total of 406, 875 pounds were re-inspected by FSIS at POE in which 567 pounds were rejected due to transportation damage. Germany has currently no certified slaughter establishments and obtains its raw materials from certified establishments in Denmark and Netherland.

APHIS has declared Germany as:

- Affected with Bovine Spongiform Encephalopathy (BSE).
- Free of Foot-and-Mouth Disease (FMD) and Rinderpest, with special restrictions.
- Free of Classical Swine Fever.
- Free of Swine Vesicular Disease with restrictions.

The previous FSIS routine audit of Germany's food safety and inspection system was conducted in October/November 2009. The FSIS auditor reported weaknesses in implementation of the European Union (EU) and FSIS requirements concerning Sanitation Standard Operating Procedures (SSOP), Sanitation Performance Standards (SPS), and Hazard Analysis and Critical Control Point (HACCP) in the audited establishments. During the audit, the CCA proffered corrective actions and all corrective actions were verified by the FSIS on-site audit. The 2009 FSIS audit concluded that Germany continued to operate a food safety system equivalent to that of the United States.

This audit (2012) included an on-site verification of corrective actions taken by the CCA in association with the previous audit conducted by FSIS in 2009. The auditor's review of the CCA documents indicated that the CCA has a system in place that addresses the correction and prevention of similar deficiencies identified in the 2009 audit through the documentation, implementation, and verification of the corrective actions.

The FSIS final audit reports for Germany's meat inspection system are available on the FSIS' website at:

[http://www.fsis.usda.gov/Regulations\\_&Policies/ForeignAuditReports/index.asp](http://www.fsis.usda.gov/Regulations_&Policies/ForeignAuditReports/index.asp)

#### **5. GOVERNMENT OVERSIGHT**

FSIS import eligibility requires that the inspection system be organized and administered by the national government and that the government provides standards equivalent to those of the federal system of meat inspection in the United States. The evaluation of this component included a review and analysis of documentation previously submitted by the CCA as support for the responses provided in the SRT, interview of government officials, and observations made by the FSIS auditor during the on-site audit of the inspection system, to include a review of daily inspection reports, periodic supervisory reports, sampling and oversight reports.

The FSIS review of the activities carried out at both; the BVL, federal and the *Länder*, state levels of the inspection system indicated the European Community regulations are the primary overarching laws for regulating meat inspection, enforcing inspection laws and ensuring adulterated or misbranded products are not exported to the United States. In addition, Germany issues national legislations to address the implementation of the inspection activities. The national legislations include the Basic Law. Under the Basic Law, the *Länders* are responsible for ensuring implementation of the laws.

The various *Länder* ministries and senate administrations coordinate monitoring activities within their respective, state, *Länder*. In some state, *Länder* with provincial authorities, the latter have responsibility for supervising individual monitoring agencies, e.g. the offices of veterinary medicine, food and health. These authorities are controlled by the Ministries of the Land.

Germany's food safety is organized under the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV) and works in conjunction with the Federal Office of Consumer Protection and Food safety (BVL).

The BVL is a federal authority in its own right within the administrative domain of the BMELV. The BVL/CCA core responsibilities include:

1. The European Rapid Alert System for Food and Feed
2. The coordination of food monitoring and surveillance programs
3. Technical Information System for Consumer Protection and Food Safety
4. Data management
5. National contact point for audits by the Food and Veterinary Office of the EC and third countries
6. Monitoring of zoonoses
7. National Residue Control Plan
8. Involvement in LAV working groups and coordination of duties resulting from LAV decisions

There is cooperation and coordination between competent authority as Germany's BMELV which has a scientific risk assessment and risk communication with its federal offices of the Federal Institute for Risk Assessment (BfR) and risk management with the BVL. The BVL assists BMELV by providing data and information. The BVL ensures that the legislation is properly implemented in all *Landers* and contributes to drafting the general administrative regulations, coordinates control programs and participates in meetings of the Lander Working Group for Consumer Protection (LAV).

Germany is comprised of 16 federal states. The *Landers* have their own parliaments, governments and administration. Federal states have 412 Districts and City Councils, and 27 Official Laboratories.

Veterinary and food safety legislation is largely harmonized across the EU and is a legal domain dealt with at federal level. However, the *Länders* are in charge of implementing the respective legal provisions and official inspection controls as well as food monitoring programs.

The system of the official controls and oversight on the *Länder* has the following three levels:

1. Supreme Federal State Ministry of the *Länders*, which is responsible for legislation and organization.
2. Intermediate, Middle level authorities, Regional Government. Some *Länder* are subdivided into provinces. The provincial authorities (PA) form an intermediate administrative level between the Land food, feed and veterinary control authority and the Districts and Municipal Authorities (DMAs). It exists as a subdivision in five *Länder*. The provincial authorities are governed by a provincial government. The provincial governor is the head of the province.
3. Lower, Local, Municipal, (District) Office level, responsible for:  
The execution of food surveillance; control of establishments, sampling, execution;  
contact point for consumers (appeal division for sampling).

The competent authorities in the *Länders* designate official laboratories for micro and residue samples to carry out the analysis of official food samples. Regional and Local governments send requests for analysis and receive results of analysis. Additionally, both governmental agencies are involved in establishment approval and official control. Within the Working Group, the *Länder* authorities responsible for consumer health protection and veterinary matters work together. The LAV is responsible for co-coordinating the implementation of legal provisions.

The federal government exercises supervision to ensure the *Länders* properly execute federal laws. Article 84 of the Basic Law enables the execution of federal laws, and the federal government may issue individual instructions for particular cases. These instructions must be addressed to the highest *Länder* authorities. In application of Article 84 of the Basic Law, four General Administrative Regulations (Allgemeine Verwaltungsvorschriften) have been adopted and are as follows:

The German Food and Feed Code (LFGB) issued for food and feed safety,

The Animal Diseases Act (TierSG) issued for animal health,

The Animal Welfare Act (TierSchG) issued for animal welfare

The Plant Protection Act (PflSchG) issued for plant health

The four General Administrative Regulations are controlled almost exclusively with the BMELV and its subordinated authorities. Its portfolio encompasses higher Federal authorities, institutions established under public law and Federal research institutions.

Within the federal government:

□ the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV) is responsible for drawing up legislative initiatives, general administrative regulations and statutory regulations in food, feed, animal health, animal welfare and plant health areas.

□ the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) has responsibility for minimizing risks to consumers resulting from environmental contaminants like cadmium, lead, mercury, dioxins, PCBs.

□ the Federal Office of Consumer Protection and Food Safety (BVL) works with BMELV, providing support and expertise in the areas of food safety, veterinary affairs and consumer protection.

□ the Federal Institute for Risk Assessment (BfR), a scientific body is responsible for risk assessment and risk communication in relation to food and feed safety.

The coordination and implementation of the legal provisions between the Federal States (FS') is assured through the "Federal States Working Committee for Consumer Protection". The committee meets regularly and is comprised of representatives from all FS' as well as guest representatives from the BMELV, BVL and Federal Institute for Risk Assessment (BfR). Its aim is to coordinate the implementation of the system of official controls in Germany.

Coordination in the FS is ensured through meetings of the districts on different issues and with the different CAs involved in official controls. Furthermore, each district in both FSs visited prepares an annual summary of activities and reports it to the FS Ministry.

The FSIS auditor verified by document review and CCA interview that the CCA operations are funded by the government State budget and inspection personnel are employees of the Federal State government, in accordance with the Regulation EC 882/2004 Annex IV (basic principles). The Federal State inspection service is funded by the Federal State administration and inspectors are paid directly by the *Länder* government. The FSIS auditor was shown the pay slip of the government inspection employee.

The funding of official veterinary and food control and inspection is based upon European law. All costs of official controls are funded by tax money, fees or charges of official control. The basic principles of financing of official controls by fees and charges and of level of expenses are laid down in the European Regulation (EC) No. 882/2004.

The official control staff is assigned by the government and paid according to public tariffs law resp. Federal Civil Service Remuneration Act. This arrangement meets U.S. requirements for ultimate control and supervision over the official activities of all employees or licensees of the system articulated by the FSIS import regulations (9 CFR 327.2).

In Germany, there is central registration for the U.S. export but not approval of establishments at the federal level. The *Länder* States are responsible for the registration and approval of establishments.

The German General Administration Provision on Food Hygiene (AVV-LmH) OF September 12, 2007 contains criteria for approval of food business operators (FBOs) in the context of Regulation (EC) 852/2004 and 853/2004.

In the Federal Republic of Germany various administrative institutions are involved in the licensing process in different ways. Because of the federative structure of the Federal Republic of Germany, the Federal States are in the charge of licensing establishments applying for approval for the export of meat products to the United States. Following the licensing of the respective establishment by an official notification in writing, the licensing authority grants the company a specific veterinary control number. After approval has been granted in writing, the licensing authority informs the BVL via the supreme State Authority. The BVL informs the FSIS of the veterinary control number.

Control and supervision over official activities for all establishments which export meat products to the U.S. rests with the Federal State Ministry in the respective Federal State. Federal Law in Germany does not allow the Federal Office to audit functions of the Federal State Ministry.

However, according to the Basic Law for the Federal Republic of Germany, Article 84 *Länder* administration-Federal oversight states:

(3) The Federal Government shall exercise oversight to ensure that the *Länder* execute federal laws in accordance with the law. For this purpose the Federal Government may send commissioners to the highest Land authorities and, with their consent or, where such consent is refused, with the consent of the Bundesrat, also to subordinate authorities.

(4) Should any deficiencies that the Federal Government has identified in the execution of federal laws in the *Länder* not be corrected, the Bundesrat, on application of the Federal Government or of the Land concerned, shall decide whether that Land has violated the law. The decision of the Bundesrat may be challenged in the Federal Constitutional Court.

(5) With a view to the execution of federal laws, the Federal Government may be authorized by a federal law requiring the consent of the Bundesrat to issue instructions in particular cases. They shall be addressed to the highest Land authorities unless the Federal Government considers the matter urgent.

The *Länder* is responsible for hiring and assigning qualified inspection personnel to perform inspection and enforcement activities at the regulated establishments. Applicants are required to take a written examination followed by an on-site examination by the senior veterinarian. Following this procedure, the final examination is taken. The applicant's performance is observed for a period of two years. If applicant passes this procedure, he /she are accepted as the *Länder* inspection personnel. All official veterinarians are graduates from an accredited college of veterinary medicine with a Doctor of Veterinary Medicine degree. These veterinarians take courses in meat inspection within the curriculum of their formal education. After graduation, they take further special courses in meat inspection including four weeks of practical training. Non-veterinary inspectors "auxiliaries", in accordance with EC regulation 854/2004, have courses involving 400 hours of practical training on the slaughter line and 500 hours of theoretical class work, after which they must pass specific examinations before being qualified to

work in meat export establishments. The *Länder* provides training for State government employees on a yearly basis. Both maintain records regarding training.

There is on-going training organized for all official veterinarians as well as all staff involved in official controls. There is a national correlation of training material organized at the BVL level in Berlin.

Each district is responsible for preparing its annual training program which includes subjects such as Pathogen Reduction Hazard Analysis and Critical Control Point system, sanitation, humane handling, slaughter and animal welfare, and food safety assessments. Additionally, BVL organizes technical training targeting the government veterinarians. Some training is provided on the Federal Ministry level and some on the State *Länder* level.

The FSIS auditor determined the *Länder* CCA provides an initial and ongoing training program intended to ensure inspection officials are aware of specific inspection requirements that pertain to meat exported to the United States. All of the above was verified by the FSIS auditor during the HQ and on-site inspection of the German Inspection System through a review of training documents, manuals, and participant list. The review indicated that in-plant inspection personnel have successfully completed their classroom training.

During the establishment audit, the FSIS auditor observed inspection personnel performance and concluded that in-plant inspection personnel had proper training to conduct their assigned responsibilities and their supervisors had provided adequate oversight to ensure the proper implementation of the inspection system.

The enforcement strategies as described in the relevant sections of EU Regs 882/2004 in place are based on EU regulation 882/2004, and German "Guidelines for the Supervisory Agencies of the Federal States of Germany for the Implementation of Official Control in Meat Processing Enterprises licensed for Export to the U.S." 2009.

In addition, exporting establishments must fulfill special requirements set by importing countries. Federal Lander States provide direct authority for inspection activities. Federal Ministries provide the Law and legal requirements but have no enforcement power.

The FSIS auditor reviewed the CCA issuances of EU regulation 882/2004 that provide procedures for documentation and verification of corrective actions related to SSOP, SPS, and HACCP non compliances. The audit included a review of SSOP, SPS, HACCP and micro analysis documents and reports which included deficiencies noted in respective components and corrective actions demonstrating compliance with regulatory requirements.

An official veterinarian, frontline supervisor (FS) is the inspector in charge and is responsible for the official veterinary auxiliary or foodstuffs inspector in the U.S. approved establishment.

The "frontline supervisor" should initially perform a weekly supervisory review and subsequently at time intervals of one month. The frequency of future inspections depends on the

results of these initial inspections. There is no predetermined number of initial inspections. The number of inspections is based on the risk of noncompliances.

At least thirty minutes of supervision by a first-line-supervisor (FLS), “inspector-in-charge” is required each day. All official supervisory measures must be documented. Supervisory measures include verifying corrective actions performed by establishment among them agency verification as referenced in 9 CFR, for sanitation 416.17 and HACCP 417.8. The auditor observed a supervisory review being performed and verified the application of periodic supervisory reviews at the CCA headquarters and local inspection offices. However the auditor made the following observation:

- The pre-shipment review was performed but did not include control of CCPs in one establishment.

Export certification is performed by the particular, of the sixteen state *Länder* offices. The FSIS auditor verified through the interviews that the CCA has controls including inventory log books, security checks, and duplicates in place to prevent fraud or misuse of export certificates. Export health certificates, seals and stamps are secured at the official inspection office in order to prevent fraud or misuse of export certificates, seals and stamps. The inspection system is also capable of tracking export certificates issued for a specific country. Therefore, the FSIS auditor determined that Germany maintains the security and integrity of the export certification process, and transportation between establishments and port facilities.

The FSIS audit included assessment of the oversight provided by the CCA to ensure that procedures for the country’s official laboratory were established and implemented as intended. Official samples to monitor the self-checking of establishments as well as Ready-To-Eat (RTE) samples must be taken at random and examined by the state-licensed laboratories.

The 16 *Länder* States have within their competence to approve and disapprove government laboratories for official food, feed, animal health and plant health analyses. All laboratories must be accredited. There is only one accreditation body in Germany which is located in Berlin. Currently, the laboratory system consists of one government laboratory (Oldenburg) for analytical testing of product destined for the United States. Several Federal State government laboratories are responsible for conducting residue analyses. Currently, there is no slaughter establishment approved for export to the U.S. and as a result there were no analytical results available for review.

The BVL has been identified as the National Reference Laboratory for all commodities and all substance groups listed in Annex 1 of Council Directive 96/23/EC. This laboratory is accredited according to ISO 17025 and is reviewed by Germany’ Accreditation Body (AKS) from Berlin. In the National Residue Control Plan (NRCP), there is a list of approved and accredited laboratories as well as capacity and the infrastructure of government services. The CCA Local veterinary authority also conducts verification and oversight of the micro laboratories which are responsible for testing of product destined for export to the U.S. The FSIS auditor verified that the CCA conduct these annual reviews of certified laboratories.

At the in-plant level, the FSIS auditor interviewed the *Länder* government representative to determine the knowledge about procedures for sample collection, sample identity, sample integrity, sample trace back, log book for incoming sample, sample shipment procedures, and sample analysis followed by a review of records including the laboratory analysis record, reporting form of “Positive residue findings”, micro analysis results, and micro-analysis of the sample collection process. Additionally, the FSIS auditor checked the handling and shipping of official samples to accredited government laboratories. The auditor checked requirements concerning the person responsible for sampling, identity of samples-labeling, sampling procedure-not to contaminate sample, sampling quantities, and sampling protocol which must meet requirements of Decision 98/197/EC. This process was under the oversight of the *Länder* and in accordance with the CCA sample collection protocols.

Germany has Rapid alert system food defense initiatives in place as an EU member state. There are EU-wide applicable provisions for the Rapid alert system, crisis management, emergencies and measures to be taken by the FBO [Reg. (EC) No. 178/2002] for implementation of the general plan for crisis management in Germany operational contingency plans setting out measures to be implemented when feed or food is found to pose a serious risk. These are drawn up pursuant the to article 13 of Reg. (EC) No. 882/2004 and the National legal provisions for crisis management in section 8 of the General Administration Regulation on Framework Control (Allgemeine Verwaltungsvorschrift Rahmen-Überwachung (AVVRUb).

During the operational sanitation inspection the following non-compliances were observed:

- Passing carcasses were contacting the establishment employee’s boots at the plant last check point for carcass inspection in the slaughter house at one establishment.
- Heavy grease for rail use was hanging over the product way in the boning room in one establishment.
- The plant employee, working in the freezer who was responsible for CCP 1, metal detector, picked-up the wrapping paper from the floor and continued to work without washing his hand in one establishment.

In conclusion, Germany’s meat inspection system is organized and administered by the Federal Ministries of the national government and by the oversight and enforcement activities of Federal States (*Länder*), which provides standards equivalent to those of the Federal system of meat inspection in the United States. Therefore, this component of the system continues to meet equivalence criteria with the exception of the following:

However there are government oversight concerns related to Statutory Authority and Food Safety Regulation, the implementation of Sanitation Procedures, and Hazard Analysis and Critical Control Point Systems. The specific concerns are identified in the appropriate equivalence component.

## **6. STATUTORY AUTHORITY AND FOOD SAFETY REGULATION**

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations (SAFSR). FSIS equivalence criteria require that the CCA has the legal authority and associated responsibility to ensure that adulterated or misbranded product is not prepared for export to the U.S. The evaluation of this component included a review and analysis of documentation previously submitted by the CCA as support for the responses provided in the SRT, interview of government officials, and observations made by the FSIS auditor during the on-site audit of the inspection system.

This evaluation demonstrated that the Germany's inspection system has the statutory authority to deliver inspection to all certified establishments and to provide requirements for humane handling and slaughter of livestock, ante and post-mortem inspection, control over establishment construction/ facility/equipment, control over inedible and condemned materials, as well as daily inspection and periodic supervisory reviews of the certified establishments. Furthermore, the CCA has regulatory requirements that require that official inspection personnel, laboratories, and establishments meet the requirements of importing countries.

The FSIS auditor verified that all animals presented for slaughter, in the one audited non-U.S. certified establishment, undergo ante-mortem inspection, which is conducted by the veterinary inspectors. The inspection personnel verify livestock arriving to slaughter establishments are accompanied by required documentation and identification that allow the traceability of the animal to its source. The official inspectors also evaluate the adequacy of ante-mortem facilities and assess compliance of operators with humane handling requirements imposed by EU regulations and importing country requirements. The FSIS auditor verified the identification and documentation of suspect and condemned animals. However, the FSIS auditor observed the following:

- When suspect carcasses are retained for veterinary disposition, the corresponding viscera are not retained. There were no provisions to identify the carcass with the corresponding viscera.

During the on-site audit of the non-certified slaughter establishment, FSIS assessed the technical aspects of post-mortem inspection. The auditor verified that proper presentation and identification of carcasses and parts were being implemented. In addition, the design of the inspection stations and the number of on-line veterinary inspectors met Germany's requirements. Veterinary inspectors, who were performing post-mortem examinations, demonstrated an acceptable level of proficiency to perform their duties. FSIS also observed and verified the functions of the off-line veterinary inspector who has an in-plant supervisory role to ensure that all applicable regulations are being implemented. Additionally, the FSIS auditor verified the required swine identification of carcasses and parts.

The following facilities were audited: (BV 03330, Freiburger, Lebensmittel GmbH & Co, Muggensturm; EV-717, HoWe Wurstwaren KG, Nurnberg; EV-34, Meica Meat Packing Plant of Ammerland, Edeweicht, Lower Saxony and non U.S. certified slaughter establishment, ES 202/ EZ 917Tonnies Fleischwerk GmbH & Co.KG, Rheda-Wiedenbruck-not certified for U.S. export).

The FSIS auditor's observations of the facilities of the audited establishments, interviews of the in-plant inspection officials, and the examination of the documentation of the periodic supervisory reviews provided objective evidence that the CCA maintains official oversight over the design and maintenance of the regulated slaughter facilities.

The CCA's *Länder* front-line supervisor conducts periodic supervisory reviews (PSR) of certified establishments in accordance with updated BVL's guidelines (2009) for inspection personnel. The *Länder* is performing the CCA/BVL requirements in States.

According to Article 85 Execution by the Länder on federal commission states following:

(1) Where the Länder execute federal laws on federal commission, establishment of the authorities shall remain the concern of the Länder, except insofar as federal laws enacted with the consent of the Bundesrat otherwise provide.

(2) The Federal Government, with the consent of the Bundesrat, may issue general administrative rules. It may provide for the uniform training of civil servants and other salaried public employees. The heads of intermediate authorities shall be appointed with its approval.

(3) The Land authorities shall be subject to instructions from the competent highest federal authorities. Such instructions shall be addressed to the highest Land authorities unless the Federal Government considers the matter urgent. Implementation of the instructions shall be ensured by the highest Land authorities.

The PSRs evaluate the adequacy of establishment food safety system and the performance of inspection personnel at certified establishments. The FSIS auditor reviewed the daily records that were generated by the in-plant inspection personnel and the CCA PSR records. FSIS verified that non-compliances were identified, documented, and corrected by the inspection personnel. The FSIS auditor also reviewed several supervisory follow-up reports to assess the enforcement capability of the inspection personnel and the adequacy of the establishment's corrective actions. This review indicated that the CCA maintained adequate regulatory oversight over the food safety systems of the audited establishments. The FSIS auditor also verified that all the non-compliances reported during the last FSIS audit were adequately addressed and corrected.

In conclusion, Germany's meat inspection system has legal authority and a regulatory framework to impose requirements equivalent to those governing the system of meat inspection organized and maintained by the United States. Therefore, this component of the system continues to meet equivalence criteria.

## 7. SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. The inspection system must provide requirements for sanitation, for sanitary handling of products, and for the development and implementation of sanitation standard operating procedures. The evaluation of this component included a review and analysis of documentation previously submitted by the CCA as support for the responses provided in the SRT, interview of government officials, and observations made by the FSIS auditor during the on-site audit of government offices and one slaughter and three processing establishments.

The FSIS auditor assessed and reviewed legislation, regulations and official instructions and verified that the CCA exercises its legal authority to require industry operators to develop, implement, and maintain sanitation programs sufficient to prevent direct product contamination and the creation of insanitary conditions at establishments intending to export to the U.S. Additionally, FSIS auditor verified that corrective actions were performed by establishments and verified by the CCA- *Länder* for all non-compliances of SSOP and SPS observed during the 2009 audit.

The CCA demonstrated that it enforces EU sanitary regulations which have been determined to be equivalent to FSIS requirements. German sanitation guidelines (Guidelines for the Supervisory Agencies for the Federal States of Germany the Implementation of Official Controls in Meat Processing Enterprises Licensed for Export to the U.S.) of 2003 and 2009 for official veterinarians of the U.S. eligible establishments provide instructions in order to meet FSIS sanitation requirements. The in-plant inspection personnel at certified establishments conducted verification of sanitary conditions in accordance with BVL's guideline, which included the evaluation of written sanitation programs, monitoring and implementation of sanitation procedures, record review and hands-on verification inspection of both pre-operational and operational procedures.

During the assessment of this component, the FSIS auditor reviewed the design and implementation of sanitation programs at the audited establishments. The FSIS auditor observed the inspection personnel as they performed pre-operational inspection verification in one certified processing establishment. In addition, the auditor evaluated the sanitary conditions of the audited establishments during operational process and reviewed sanitation monitoring records, documented non-compliances and verification of corrective actions by inspection personnel, training programs for inspection personnel, and an assessment of the actual conditions in the production areas.

In conclusion, the results of the assessment of the sanitation programs conducted by FSIS demonstrated that the CCA inspection system provides requirements equivalent to those of FSIS system for sanitary handling of products, and for the development and implementation of sanitation standard operating procedures. In-plant veterinary government officials and the CCA front-line supervisor enforce these regulatory requirements and monitor the ability of the establishments to maintain sanitary conditions but need to improve monitoring of SPS.

## **8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS**

The fourth of the six equivalence components reviewed by FSIS was the HACCP system. The inspection system must require that each official establishment develop, implement and maintain a HACCP plan. The FSIS auditor evaluated this component through review and analysis of documentation previously submitted by the CCA as support for the responses provided in the SRT, interview of government officials, and observations made by the FSIS auditor during the on-site audit of government offices, one non-U.S. certified slaughter and three certified processing establishments.

The *Länder* demonstrated that it enforces the German legislations, BVL guidelines 2003 and 2009 to meet U.S. requirements. Documents reviewed by the FSIS auditor included regulatory standards, training materials, and regulatory guidelines such as all relevant EU Regs, training manuals, “Guidelines for the Supervisory Agencies of the Federal States of Germany for the Implementation of Official Control in Meat Processing Enterprises licensed for Export to the U.S.” 2003 and 2009, which were issued by the CCA.

The FSIS auditor reviewed HACCP procedures, analysis, validation, corrective actions and verification records, and determined the in-plant inspection personnel at certified establishments conducted daily verification of the HACCP program in accordance with the BVL’s guidelines. Daily verification includes the evaluation of written HACCP plans and its contents, record review and hands-on inspection of monitoring and verification activities, and implementation of corrective actions when there is a deviation from the critical limits.

Additionally, the CCA-Lander provided documentation to the FSIS auditor which demonstrated that the CCA verified implementation of corrective actions for all non-compliances related to HACCP observed during the 2009 audit.

FSIS also assessed the adequacy of the HACCP program verification activities conducted by government officials and establishment operators at the establishment level, by observing on-site verification activities for time and temperature CCPs and reviewing, monitoring and verification records generated by establishment personnel and in-plant inspection officials. All records were found in order. The observations, reviews and analysis of information conducted by FSIS revealed that Germany’s meat inspection system imposes on operators of certified establishments, regulatory requirements for the development, implementation and maintenance of HACCP programs as set forth in the BVL guidelines and the FSIS regulations. The FSIS auditor reviewed the hazard analysis, CCP monitoring records, records of corrective actions for non compliances and deviations, record keeping and the on-going verification activities and the actual on-site observations indicated that official verification activities assesses the design and execution of the HACCP programs including adequacy of hazard analysis, monitoring of Critical Control Points, corrective actions, recordkeeping and verification activities were properly performed. However, the following non-compliances were observed during the audit of HACCP activities:

- The hazard analysis of the HACCP program did not include visible fecal contamination on carcasses as a hazard reasonably likely to occur; no CCP for this hazard was present in the non-certified establishment.

The CCA should review their process for assessing slaughter HACCP plans before certifying slaughter plants for export to the U.S and provide corrective actions that demonstrate the hazard analysis considers all physical, chemical and microbiological hazards. Please submit the corrective actions with the response to this audit before certifying slaughter establishments for export to the U.S.

In conclusion, the results of the assessment of the HACCP programs demonstrated that Germany’s inspection system provides requirements equivalent to those of FSIS regulatory

requirements. In-plant veterinary government officials and the front-line supervisor, monitor, verify and enforce the implementation of the regulatory requirements in the certified establishments.

## 9. CHEMICAL RESIDUES CONTROL PROGRAMS

The FSIS auditor reviewed Chemical Residues as the fifth of the six equivalence components. The FSIS criteria for chemical residues include a program managed by the CCA and established to carry out effective regulatory activities to prevent contamination of food products with chemical residues. The inspection system must identify the laws, regulations, or other decrees that serve as the legal authority for the implementation of this program. The CCA must provide a description of the basis for its residue plan and the process used to design the plan. The plan must describe the actual operations of its residue plan. The CCA must provide a description of the actions taken to deal with unsafe residues as they occur. The CCA must have access to and supervision of analytical laboratories that have the capability to assure the validity and reliability of test data.

During the on-site audit, FSIS conducted a review of Germany's Chemical Residue Control Programs at the CCA's headquarters, and one audited non-U.S. certified slaughter establishment to verify if Germany has regulatory authority to enforce requirements of the Chemical Residue Control Program equivalence component.

The FSIS auditor interviewed the CCA officials and reviewed National Residue Program, laboratory testing methods, enforcement strategies, and communication tools. The FSIS auditor verified that Germany's residue control program is based, designed and conducted in accordance with *Council Directive 96/23/EC of 29 April 1996* and *Commission Decision 97/747/EC*. Each of the federal *Länder* states is informed about their respective numbers of samples to be taken in the detailed form chosen for national purposes. The CCA of the respective state (Land) develops a sampling plan for its state according to the requirements set out by the National Residue Control Plan. If sample taking is not centralized, sample numbers are distributed among the lower administrative units responsible for sampling and controls. Sample numbers are broken down according to numbers of animal stocks, slaughter and production volume of the past 12 months. Regional or any other particularities can be considered when breaking down sample numbers. Sample collection should be distributed over the whole calendar year, while seasonal foci arising from the nature of production should be reflected. It is possible to define certain time periods for sampling. The states' sampling plans are entered in the professional information system in the file "National Residue Control Plan", sub-file "*Länder*, internally". The auditor concluded that Germany's residue plan was properly designed to include all compounds of concern to both Germany and the U.S.

The National Residue Control Plan for 2012 tested for the following compound/substances: stilbenes, thyreostats, steroids, bete-agonists, amphenicols (chloramphenicol), nitrofurans, sulfonamides, tetracyclines, quinolones, anti-bacterial substances (aminoglycoside), beta-lactam-antibiotics, cephalosporins, macrolides (erythromycin), polymyxins, antihelminthics (averomectins), benzimidazoles, carbamates, sedatives, organochlorine compounds, PCB's, organophosphorus compounds, chemical elements, mycotoxins.

Sample security requests that unauthorized persons must not have access to the samples. Both deep-frozen and uncoiled samples must be transferred to the laboratory within one week after sample taking. Samples which are not properly sealed are cancelled because analytical results obtained with such samples cannot be used in further administrative proceedings.

The Official State Residue Laboratory (CVUA) documents were audited by FSIS. The FSIS auditor reviewed sample handling, sampling frequency, timely analysis, data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, percent recoveries, intra-laboratories check samples, and quality assurance programs, including standards books, sample security, and corrective actions. No concerns arose as a result of this visit.

One non-certified slaughter establishment was audited to determine Germany's regulatory authority to implement and enforce the requirements of the Chemical Residue Control Programs equivalence component at the establishment level. Sample collection for the purposes of Directive 96/23/EC has to follow the provisions of Commission Decision 98/179/EC as well as German Food and Feed Code LFGB. Distribution of residue samples to the districts goes from BVL to Federal State *Länder*, to Middle authority and finally to District. Principally, one animal will give one sample for testing for an active substance or a substance group. A sample may consist of several matrices, such as muscle and liver or muscle and kidney.

Selection of animals to be sampled should be a state or official veterinarian's responsibility. The sample must be immediately labeled so that it is safely identifiable. The sample collecting individual has to prevent sample contamination and collect the required sampling quantities. The information on the sampling protocol must meet the requirements of Decision 98/179/EC. Each sample matrix must be packaged separately and labeled as belonging to a certain sample. Samples must be cooled down to 2-7C, immediately upon collection. Each should be packed for shipment only after cooling, and equipped with sufficient cooling elements to keep this temperature for the duration of transport. Sample analysis has to follow the provisions of Decisions 2002/657/EC and EU standard EN ISO 17 025. In particular, the processing of samples has to run parallel with at least one blank sample and one positive sample per analytical series, to check the efficiency of processing. A positive finding obtained by a screening method must be confirmed using a confirmation or reference method, according to Decision 2002/657/EC.

The FSIS auditor concluded that the program was effectively implemented by BVL/CCA-State/Lander, Intermediate, District, and Establishment Level and Germany's national residue testing program for 2012 was being followed and was on schedule. There were no POE residue violations reported by Germany, in conjunction with product exported to other countries from this establishment.

In conclusion, results of Germany's current year's residue sampling program were reviewed at the HQ, state offices and in-plant levels. The program was operating as specified, results were delivered on time, and results were available at all levels.

The 2012 Germany's residue program has been submitted to OIA and has been reviewed by the FSIS auditor. Germany's meat inspection system has a residue control program that includes random sampling of internal organs and fat of carcasses to detect chemical residues recognized by Germany and the FSIS as potential contaminants. Additionally, sample handling and frequencies, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective action control were properly performed. At the present, Germany has no U.S. certified slaughter establishment. Therefore, this component of the Germany meat inspection system meets equivalence requirements.

## 10. MICROBIOLOGICAL TESTING PROGRAMS

The last of the six equivalence components that the FSIS auditor reviewed was the Microbiological Testing Programs. This component pertains to regulatory requirements for the inspection system to have a microbiological testing program, organized and administered by the national government.

The microbiological sampling and testing program is intended to ensure that meat products produced for export to the U.S. are safe, wholesome and unadulterated. The criteria the FSIS used to assess microbiological testing programs included:

- The inspection system provides for a sampling and testing program for destructive method for *Enterobacteriaceae* in raw meat product, and the CCA uses the test results to verify establishment slaughter processing and dressing controls for fecal contamination. Sampling is in accordance with EU Regulation (EC) No. 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. The frequency of *Enterobacteriaceae* sampling is based on the aforementioned regulations.
- The inspection system provides for a sampling and testing program for *Salmonella* in raw product, and includes performance standards for *Salmonella*. The inspection system achieves pathogen reduction by ensuring that all slaughter establishments meet the *Salmonella* Performance Standards. *Salmonella* sampling is in accordance with national *Salmonella* regulation No. 20/EEO/2001. The frequency of *Salmonella* sampling is set by the CCA and it contains both carcass sampling and testing.

At the CCA headquarters, the FSIS auditor reviewed the microbiological sampling regulatory requirements and procedures, testing reports, and internal audit reports of government laboratory. This review was intended to determine whether the CCA was capable of designing and coordinating the conduction and reporting of the microbiological testing results, applying microbiological performance standards, and taking appropriate enforcement actions in response to nonconforming product.

Competent authorities in the *Länder* designate laboratories to carry out analysis of official food samples. The RTE-official product *Lm* and *Salmonella* samples are collected by the *Länder*. Additionally, there is an official sample of *Lm* collected for environment. There are also RTE samples for testing of *Lm* and *Salmonella* on product and environment by industry.

Carcass testing for *Enterobacteriaceae* and *Salmonella* is performed by industry. According of Regulation EC 882/2004, verification testing is performed by *Länder*.

At the establishment level, FSIS reviews were conducted to determine inspection personnel's ability to enforce the requirements of the Microbiological Testing Programs' equivalence component. The FSIS auditor reviewed Germany's legislation, inspection instructions, and in-plant inspection records maintained at one non-U.S. certified slaughter establishment. The CCA has regulatory requirements including sampling and enforcement strategies for testing programs related to *Enterobacteriaceae*, and *Salmonella* that meets the FSIS testing requirements. The inspection personnel and establishment employees' at all three audited processing establishments were following the inspection system's sampling protocol, which includes testing frequency, sample collection, and the delivery of RTE-samples of *Lm* and *Salmonella* to the approved government laboratory.

During a government microbiology laboratory visit, verification focused on the qualification of analysts, sample receiving and handling, analytical methodology, data reporting, maintenance of facilities and equipment, and corrective actions. FSIS reviewed the CCA's auditing procedures, checklists and results of past audits and verified that the CCA on a routine basis evaluated the functions of this laboratory. No concerns arose as a result of this visit.

## 11. EXIT MEETING

An exit meeting was held on July 13, 2012, in Berlin with the CCA representatives. At this meeting, the preliminary findings from the audit were presented by the FSIS auditor. The CCA understood and accepted the audit findings.

## 12. CONCLUSIONS AND NEED FOR FURTHER ACTIONS

The FSIS auditor confirmed that all prior systemic findings from the 2009 FSIS audit were appropriately addressed and corrected. In addition, the current audit did identify some findings in the non-certified slaughter establishment within three of the six equivalence components. Although findings were noted during this audit, FSIS has concluded that Germany's meat inspection system meets the FSIS import requirements.

Oto Urban, DVM  
Senior Program Auditor

  
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## 13. ATTACHMENTS TO THE AUDIT REPORT

Foreign Country Response to Draft Final Audit Report (when it becomes available)



United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION HoWe Wursthwaren KG Regenstrasse 1 DE - 90451 Nurnberg	2. AUDIT DATE 07/02/12	3. ESTABLISHMENT NO. EV-717	4. NAME OF COUNTRY Germany
	5. NAME OF AUDITOR(S) Oto Urban, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

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

60. Observation of the Establishment

Date: 07/02/2012 Est #: EV-717 (HoWe Wurstwaren [P]) (Numberg, Germany)

**Red meat processing establishment:**

*There are no significant findings to report concerning this establishment and the government oversight verification.*

All HACCP and SPS deficiencies from the last audit of 2009 were corrected by establishment and verified by the Inspection Service.

This establishment produces fully cooked not shelf stable sausages. It is a processing establishment with a cold storage. It has 350 employees and receives product from the US certified establishment in Denmark. Product is considered to be RTE.

Employee's dressing room was observed to have some dust on the employee dress cabinet. This deficiency was observed by the German Inspection service and immediate corrective action was performed by the establishment management.

I visited fresh meat receiving area where meat receiving procedure was explained by the IIC. No deficiencies were observed in this area. We continued to audit the cutting room where pieces of meat were found in the one of the drainages by the German Inspection service. Corrective action was immediately performed and deficiency corrected.

Production area had no sanitary and HACCP deficiencies. Inspection service performed on-site check of the CCP for time and temperature, and no deviation were observed. Cold store and shipping area were observed to be in the satisfactory condition.

Company produces RTE product which has no post-lethality exposure. Product is tested for *Salmonella* and *Listeria monocytogenes* in RTE product and analysis of the product is performed in ISO 17025 certified laboratories. No positive test results were reported in the last year.

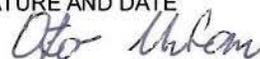
I audited several establishment documents, procedures and records (SSOP, SPS, HACCP, water control, insect and rodent control, label approval and RTE microbiology analysis results). All procedures and records were maintained as required.

Eventually, I checked on government oversight records for SSOP, SPS, and HACCP including pre-shipment review, export certificates control, and periodic supervisory reports. All reviewed records were found satisfactory.

61. NAME OF AUDITOR

Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE

 5-29-13

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Tonnies Fleischwerk GmbH & Co.KG 33378 Rheda-Wiedenbruck Germany	2. AUDIT DATE 07/06/2012	3. ESTABLISHMENT NO. ES 202/ EZ 917	4. NAME OF COUNTRY Germany
	5. NAME OF AUDITOR(S) Oto Urban, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

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

## 60. Observation of the Establishment

Date: 07/06/2012 Est #:Tonnie's Fleisch Rheda-Wiedenbruck

During this audit slaughter and cutting areas were visited: The following areas of the slaughter operation were audited and operations observed: the ante-mortem area where animal receiving procedure and movement and resting of animals was observed. The inspection personnel verify that livestock arrives to slaughter establishments are accompanied by required documentation and identification that allow the traceability of the animal to its source. Additionally, suspect pen was checked for presence of water supply. I verified the identification and documentation of suspect and condemned animals. I observed that the official inspectors also evaluated the adequacy of ante-mortem facilities and assessed compliance of operators with humane handling requirements imposed by the EU regulations and the importing country requirements.

The stunning and post-mortem rooms were inspected, bleeding-out, and carcass and viscera inspection was observed. I verified the carcasses disposition and whether they are under inspection control. I was assessing Inspection Service (veterinarians) performance, incision of mandibular lymph node, synchronization of carcasses with viscera and collection of samples for *Trichinella spiralis*. Additionally, I verified the required swine identification of carcasses and parts. I checked the final inspection station and operation performed by government inspection service.

Before the audit of the slaughter house the areas of the cutting room, coolers and freezers were inspected. That was my on-site audit. I also checked social facilities, dressing rooms, pest control, outside premises and potable water control.

I audited several establishment documents; both, procedures and records (SSOP, SPS, HACCP including the written hazard analysis, the written HACCP plan, records documenting the monitoring of CCP's and the pre-shipment review, potable water control, insect and rodent control, and carcass testing results).

I checked on government oversight records for SSOP, SPS, HACCP, and periodic supervisory reports.

*The following non-compliances of the establishment and inspection service procedures were observed:*

10/51/56 Passing carcasses were contacting the establishment employee's boots at the plant last check point for carcass inspection in the slaughter house. The Inspection Service and establishment officials started were informed about this non-compliance and started proceeding for corrective action Reg. EC 852/2004; 9 CFR 416.13(c).

15/51/56 Pre-shipment review was performed but did not include control of CCPs. The establishment management and Inspection official promised to take immediate corrective action and include missing CCPs to their records. 9 CFR 417.5(3)(c).

15 The hazard analysis of the HACCP program did not include visible fecal contamination on carcasses as a hazard, no CCP for this hazard was present 9 CFR 417.2(a).

39/51/56 Heavy grease for rail use was hanging over the product way in the boning room. This non-compliance was immediately corrected by the establishment management Reg. EC 852/2004; 9 CFR 416.3(a).

47/51/56 The employee, working in the freezer who was responsible for CCP 1, metal detector, picked-up the wrapping paper from the floor and continued to work without washing his hand. The establishment and Inspection service personnel were informed, corrected the non-compliance, and promised preventive measures to be implemented by re-training the employee Reg. EC 852/2004 and 9 CFR 416.5 (a).

55/56 When suspect carcasses are retained for veterinary disposition, the corresponding viscera is not retained. There were no provisions to identify the carcass with the corresponding viscera. (Reg. EC 853/2004 Annex III, Section I Chapter IV; and FSIS Directive 6100.2 Chapter II, no. 4e to 5a).

61. NAME OF AUDITOR

Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE


 5-29-13

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Freiberger, Lebensmittel GmbH & Co Productions-u. Vertriebs-KG, Draisstr. 1-5-D-76461 Muggensturm Germany	2. AUDIT DATE 07/04/2012	3. ESTABLISHMENT NO. BV 03330	4. NAME OF COUNTRY Germany
	5. NAME OF AUDITOR(S) Oto Urban, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

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

60. Observation of the Establishment

Date: 07/04/2012 Est #: BV-03330, processing, Muggensturm, Germany

**Red meat processing establishment:**

*There are no significant findings to report concerning this establishment and the government oversight verification.*

I performed an audit of this pizza producing establishment. This establishment receives pepperoni toppings from a US certified establishment in Austria and exports the final product to the US.

I observed and followed the German Inspection service while performing the inspection. Inspection started in the employee's dressing room where we observed separation of dressing rooms for work and street clothes.

We followed by visiting the pizza processing area where the inspection service observed flaking paint in the processing room but not over the product contacting area. This deficiency was scheduled for corrective action. Cooking and freezing procedures were continued as required at prescribed temperature.

We followed the inspection by auditing the storage room where Inspection service observed cob webs in one corner of the room. This deficiency was scheduled for corrective action. The packaging area had assigned a US destined product place.

I followed the Inspection service to the shipping room where no deficiencies were observed.

The establishment produces pizza products and tests for *Salmonella* and *Listeria monocytogenes* in RTE products and analyzes products in ISO 17025 certified laboratories. No positive test results were reported in the last year.

I checked the previous corrective action verification by the country inspection service and concluded that it was done properly.

I reviewed the establishment documentation, procedures and records including the SSOP, SPS, HACCP, water control, insect and rodent control, label approval and NRTE microbiology analysis results. All procedures and records were maintained as required.

Eventually, I reviewed government oversight records for SSOP, SPS, and HACCP including pre-shipment review, export certificates control, and periodic supervisory reports. Supervisory reviews are performed twice a year. All reviewed records were found as satisfactory.

61. NAME OF AUDITOR

Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE

Oto Urban 5-29-13

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Meica Meat Packing Plant of Ammerland Postfach 1160 Edeweicht, Lower Saxony D-26188	2. AUDIT DATE 07/10/12	3. ESTABLISHMENT NO. EV-34	4. NAME OF COUNTRY Germany
	5. NAME OF AUDITOR(S) Oto Urban, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

Place an X in the Audit Results block to indicate noncompliance with requirements. Use O if not applicable.

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

60. Observation of the Establishment

Date: 07/10/2012 Est #: EV-34(Meica Meat Packing Plant of Ammerland [P]) (Edeweicht, Germany)

**Red meat processing establishment:**

*There are no significant findings to report concerning this establishment and the government oversight verification.*

All HACCP and SPS deficiencies from the last audit of 2009 were corrected by establishment and verified by the Inspection Service.

I audited pre-operation sanitation of the sausage filling, mincing and sausage glass filling and distribution area with German inspection service leading the audit. Several pieces of dry meat on the filling and mincing machine were found by the Inspection service of Germany. Water residue on processing tables was cleaned and cracked plastic part for filling machine was replaced. These deficiencies were corrected immediately by the establishment management.

Also, I visited the processing area most of the filling, mixing, mincing and sausage filling machines. No contamination of product, no condensation, no employees mishandling of product was observed. Three establishment employees were sent to change to the proper dressing code (hair caps) and hematoma was found and removed by the Inspection service.

The raw meat arrival area was audited. The Inspection service checked the arriving meat temperature with satisfactory results. One damaged plastic meat container was rejected by the country Inspection service.

Dust on some cartons and grease on the floor was observed in the packaging department. These deficiencies were corrected immediately by the establishment employees.

Dressing rooms and outside premises were audited with satisfactory results. Rodent and insect control and water control and testing were performed at required frequency with no microbiological or chemical residue violations.

The establishment produces commercially sterile product and test for *Salmonella* and *Listeria monocytogenes* in RTE product and analysis product in ISO 17025 certified laboratories. No positive test results were reported in the last year.

I audited several establishment documents, procedures and records (SSOP, SPS, HACCP, water control, insect and rodent control, label approval and RTE microbiology analysis results). All procedures and records were maintained as required.

Eventually, I checked on government oversight records for SSOP, SPS, and HACCP including pre-shipment review, export certificates control, and periodic supervisory reports. All reviewed records were found satisfactory.

61. NAME OF AUDITOR

Oto Urban, DVM

62. AUDITOR SIGNATURE AND DATE

 5-29-13