USDA

United States Department of Agriculture

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Food Safety and
Inspection Service

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Washington, D.C.
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Dr. Klaus Lorenz, Head
Unit 106, Food of Animal Origin and Food Hygiene
Federal Office of Consumer Protection and Food Safety
Mauerstr. 39 – 42
PO Box 100214
D-10562 Berlin
Germany

Dear Dr. Lorenz,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Germany's meat inspection system from June 2 through June 19, 2015. Enclosed is a copy of the final audit report. The comments received from the Government of Germany are included as an attachment to the report.

In transmitting this report, FSIS requests that in response to Germany's January 16, 2016, request for an equivalence determination for Commission Regulation (EU) 219/2015, the Federal Office of Consumer Protection and Food Safety provide documentation to FSIS to evidence that Germany's implementation of risk-based visual post-mortem inspection in swine satisfies FSIS equivalence criteria outlined in the enclosed communication to the European Commission dated September 4, 2015.

For technical questions regarding the FSIS audit report, please contact Mr. Vincent Fayne, Acting Director of the International Audit Staff with the Office of Investigation, Enforcement and Audit (OIEA) at (202) 690-5662, or by electronic mail at international.audit@fsis.usda.gov.

If you have any other questions, please feel free to contact me directly.

Sincerely,

Jane H. Doherty

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosures:
Final Report of an Audit Conducted in Germany
EU - Letter Regarding Swine Inspection 090415.pdf

FINAL REPORT OF AN AUDIT CONDUCTED IN

GERMANY

June 2 to June 19, 2015

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

February 11, 2016

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from June 2 to June 19, 2015. The audit was conducted to determine whether Germany's food safety inspection system governing pork products continue to be equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Germany is eligible to export raw and processed pork to the United States.

The audit was designed to assess the equivalence of Germany's meat inspection system and focused on six main system components: (1) Government Oversight (Organization & Administration), (2) Statutory Authority and Food-Safety Regulations (Inspection System Operation and Product Standards), (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP) Systems, (5) Government Chemical Residue Control Programs, and (6) Government Microbiological Testing Programs.

The previous FSIS audit of Germany's meat inspection occurred from June 27 to July 13, 2012. During the course of the 2012 audit, FSIS identified findings within the equivalence components for Sanitation and Hazard Analysis and Critical Control Points (HACCP). During the current audit, FSIS verified that corrective actions proffered to FSIS by Germany to remedy the 2012 findings were implemented.

The 2015 FSIS audit identified some operational (or procedural) weaknesses related to sanitation and HACCP. The FSIS auditor also identified that the Central Competent Authority (CCA) implemented visual post-mortem inspection in 2014, based on Commission Regulation No. 219/2014. In order to be equivalent with FSIS requirements, Germany must demonstrate the effectiveness of alternative procedures to the incision and palpation of organs or lymph nodes required by FSIS during routine post-mortem examination. Germany is expected to continue performing organoleptic post-mortem inspection in swine until such time that FSIS has determined that Germany's implementation of visual post-mortem procedures is equivalent to the United States' food safety requirements. FSIS requests that the CCA provide a detailed response within 60 calendar days of receipt of this draft report.

An exit meeting was held on June 19, 2015, in Berlin, Germany with the CCA. The preliminary audit findings were presented by FSIS. FSIS will evaluate any information provided by the CCA, including an assessment of the CCA's proposed corrective actions submitted in response to the audit findings.

TABLE OF CONTENTS

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Germany's food safety system from June 2 to June 19, 2015.

The audit began with an entrance meeting held on June 2, 2015 in Berlin with the participation of representatives from the Central Competent Authority (CCA) – the Federal Office of Consumer Protection and Food Safety (BVL), the Federal Ministry of Food and Agriculture of the Länder visited during the audit, Foreign Agriculture Service (FAS), and the FSIS auditor.

II. OBJECTIVES, SCOPE, AND METHODOLOGY

This was a routine on-going equivalence verification audit. The objective of the audit was to ensure that the food safety system governing swine meat and meat products maintains equivalence to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged.

In pursuit of this objective, FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, results of prior audit-related site visits, Point-of-Entry (POE) testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process included an analysis of data collected by FSIS over a three-year timeframe, in addition to information obtained directly from the CCA, through a Self-Reporting Tool (SRT).

The FSIS auditor was accompanied throughout the entire audit by representatives from the CCA, Federal State Authorities, and staff from inspection offices located within the audited establishments.

Determinations concerning program effectiveness focused on performance within the following six equivalence components upon which system equivalence is based: (1) Government oversight (organization and administration), (2) Statutory authority and food safety regulations (inspection system operations and product standards), (3) Sanitation, (4) Hazard Analysis and Critical Control Points (HACCP), (5) Government chemical residues testing program, and (6) Government microbiological testing programs.

The auditor reviewed the administrative functions at the CCA headquarters in Berlin, four Federal State offices, six local inspection offices at audited establishments, and one government microbiology laboratory. During the review, the FSIS auditor evaluated implementation of the management control systems put in place to ensure that the national system of inspection, verification, and enforcement is implemented as intended. This evaluation included on-site verification of the implementation of those corrective actions proffered to FSIS by Germany to remedy the 2012 audit findings.

The auditor conducted reviews of the administrative functions of local inspection offices as part of the establishment review. The FSIS auditor assessed the administrative functions of sampling

and testing methodology through a review of records at the Federal State offices and one microbiology laboratory. The auditor selected a sample of six (6) establishments from 12 establishments certified to export to the United States. During the establishment visits, the auditor paid particular attention 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 Title 9 of the Code of Federal Regulation (CFR) part 327.2.

The Lower Saxony State Office for Consumer Protection and Food Safety (LAVES) Microbiology Laboratory, located in Oldenburg, was audited to verify its ability to provide adequate technical support to the inspection system. An audit of a chemical residue laboratory was not within the scope of this audit.

Audit Scope Summary

Competent Authority Visits	#	Locations
Central Competent Authority	1	• BVL headquarters office in Berlin
Federal State Authority: Ministry, Provincial, and District levels	4	• Bavaria, Ansbach • Baden-Württemberg, Karlsruhe • North Rhine-Westphalia, Gütersloh • Lower Saxony, Hannover
Government microbiology laboratory	1	• Lower Saxony State Office for Consumer Protection and Food Safety (LAVES) Microbiology Laboratory, Oldenburg
Swine slaughter establishment	1	• Est. 202 Tönnies Lebensmittel GmbH & Co., Rheda-Wiedenbrück
Swine cutting/processing establishments	5	• Est. 717, HoWe Wurstwaren KG, Nuremberg • Est. 03330, Freiberger Lebensmittel GmbH & Co. Produktions- und Vertriebs KG, Muggensturm • Est. 34, Meica Ammerländische Fleischwarenfabrik Fritz Meinen GmbH & Co. KG, Edewecht • Est. 917, Tönnies Lebensmittel GmbH & Co., KG, Rheda-Wiedenbrück • Est. 35, Bell Deutschland GmbH & Co. KG, Edewecht

The audit was undertaken under the specific provisions of United States' laws and regulations, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.),
- The Humane Methods of Livestock Slaughter Act (7 U.S.C. Title 7), and
- The Food Safety and Inspection Service Regulations for Imported Meat (9 CFR Part 327).

The audit standards applied during the review of Germany's inspection system for pork products included: (1) All applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the agreement on the application of Sanitary and Phytosanitary measures of the World Trade Organization. Currently, Germany has one equivalence determination in place that applies to *Enterobacteriaceae* testing in lieu of generic *E.coli* testing in swine slaughter establishments.

III. BACKGROUND

Germany is eligible to export raw and processed pork products to the United States. Between January 1, 2013 and July 1, 2015, FSIS import inspectors performed 100% re-inspection for labeling and certification on 6,221,844 pounds of pork products exported by Germany to the United States. FSIS also performed re-inspection on 2,504,379 pounds at point-of entry (POE) using additional types of inspection (TOI), of which a total of 545 pounds were refused entry for issues not involving food safety concerns (e.g. missing shipping marks, shipping container damage).

Previous FSIS final audit reports for Germany's food safety system are available on the FSIS website at:
http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT (ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components that the FSIS auditor reviewed was Government Oversight. FSIS import regulations require that the foreign inspection system be organized by the national government in such manner to provide ultimate control and supervision over all official inspection activities. The system must also ensure that there is uniform enforcement of requisite laws; provide sufficient administrative and technical support; and assign competent qualified inspection personnel at establishments where products are prepared for export to the United States. The evaluation of this component included an analysis of information provided by the CCA through the SRT, as well as interviews and observations during the on-site portion of the audit.

There has not been any major change in the organizational structures of the Central Competent Authority (CCA) since the last FSIS audit conducted in 2012. The Federal Republic of Germany is divided into 16 Federal States, known as Länder. At the national level, the Federal Ministry of Food and Agriculture (BMEL) is responsible for issuing statutory regulations relating to food safety under the Food, Feed and Consumer Goods Code (LFGB), Animal Health Act (TierGesG), and animal welfare under the Animal Welfare Act (TierSchG). The BMEL controls the lower-level Federal offices including the BVL.

FSIS recognizes the BVL in Berlin as Germany’s CCA. The BVL is a federal authority within the administrative domain of the BMEL and its responsibilities include:

1. BVL is the national contact point for the Rapid Alert System for Food and Feed,
2. BVL is the competent authority for the National Residue Control Plan including authorizing veterinary drugs on a national basis,
3. BVL supports data management including the flow of information between the national and Federal States authorities in the area of food safety and consumer protection, and
4. BVL coordinates the development and implementation of food monitoring and supervisory controls at national level.

The BVL oversight of the Federal States achieved through conducting correlation meetings with the Federal States authorities to ensure that equivalent EU food hygiene and special United States requirements are being uniformly applied and enforced in all United States-certified establishments. These requirements are outlined in the 2009 inspection document "Guidelines for the Supervisory Agencies of the Federal States of Germany for the Implementation of Official Control in Meat Processing Enterprises Licensed to Export to the United States." This collaboration includes providing the Federal States with logistical and organizational support; ensuring that the EU and national legislation is properly implemented in all Federal States; contributing to the drafting of general administrative regulations; coordinating control programs; providing training concerning the United States import requirements, and participating in meetings of the Federal States Working Group for Consumer Protection.

As of 2013, the BVL has taken on new responsibilities relating to export matters. This function encompasses managing the lists of approved establishments for export and accompanying foreign inspections and audits carried out in Germany by third-country authorities.

At the Federal State level, the system of the official controls, oversight, and administration of food safety consists of up to three levels: Ministry, Provincial, and District. The Federal State Ministry level is responsible for the control, coordination, and issuance of guidance on the implementation of Federal law. The Provincial level is an intermediate administrative level between the Federal State Ministry and the District level. The District level is responsible for the control of food producing establishments within their respective District. In addition, this level has responsibility for animal welfare monitoring and enforcement measures in accordance with the German Animal Welfare Act.

Each Federal State is a competent authority responsible for implementing official controls and supervision over official activities in all establishments within its territory, including those that are certified to export meat products to the United States. All official controls concerning implementation of food safety requirements are carried out in the context of each Federal State's Quality Management System (QMS). The objective of the QMS is to provide documented procedures and instructions for inspection personnel on verifying the effectiveness of official controls required by Regulation (EC) No 882/2004.

The coordination and implementation of the legal provisions between the Federal States is achieved through the "Federal States Working Committee for Consumer Protection." This committee meets regularly and is comprised of representatives from all Federal States as well as representatives from the BMEL, BVL, and the Federal Institute for Risk Assessment. Its aim is to harmonize implementation of regulatory requirements and official controls across all Federal

States in Germany. During the on-site review of the documents at four (4) audited Federal State offices, the FSIS auditor verified the implementation of the coordination and communication meetings between the BVL and the Federal States involved with the production of pork products destined for export to the United States.

The FSIS auditor confirmed that the inspection operations funded by the state budget and the inspection personnel assigned to United States-certified establishments are full-time employees of the government and perform their inspection activities under the administration of the respective Federal State Authority.

The Federal States are responsible for the approval of food establishments including meat-producing establishments certified to export to the United States. The rules governing establishment approval procedures are defined in the German General Administrative Provision on Food Hygiene (AVV-LmH) and include the following steps:

- Submitting an application by the respective establishment to its Federal State for approval,
- Examining the administrative and technical file,
- Reviewing the establishment (on-site visits and document review) by the approval authority,
- Approving the application based on the results of the document reviews, on-site visits, and verifying the implementation of any applicable corrective actions, and
- Notifying FSIS of the establishment approval process by the BVL.

At the establishment level, an official veterinarian/inspector-in-charge is responsible for supervising other veterinary or auxiliary inspectors in establishments approved (certified) to export to the United States. The inspector-in-charge is also responsible for conducting daily and weekly verification of the inspection activities. These verification activities include direct observation and review of establishment records, including HACCP, Sanitation Standard Operating Procedures (SSOP), Sanitation Performance Standards (SPS), and *Enterobacteriaceae* sampling techniques and records. The auditor confirmed that these verification activities were being conducted properly.

An official veterinarian at the District level, known as a frontline supervisor, performs periodic supervisory reviews at the United States-certified establishments. The CCA has set a minimum frequency of two supervisory reviews per year for United States-approved establishments. However, some of the audited Federal State Ministries have implemented a higher frequency for reviews (monthly) according to their own risk assessment and QMS program. The FSIS auditor noted that the frontline supervisors conduct these reviews as planned, document their findings, and verify the implementation of the corrective actions through document review or during the next on-site supervisory reviews.

The Federal States are also competent authorities for implementing enforcement strategies as described in the Regulation (EC) No. 882/2004. In addition, they have direct authority and responsibility to enforce special requirements set by importing countries or the CCA. The CCA issued a document in 2009 titled “Guidelines for the Supervisory Agencies of the Federal States of Germany for the Implementation of Official Control in Meat Processing Enterprises Licensed

to Export to the United States." The new edition of this guideline, covering export requirements for slaughter establishments, is currently under review and clearance process by the CCA.

Each Federal State has the authority and responsibility for hiring and assigning competent and qualified inspection personnel to perform inspection and enforcement activities at the regulated establishments including United States-certified establishments. The FSIS auditor confirmed that all official veterinarians in the United States-certified establishments are graduates of an accredited college of veterinary medicine with a Doctor of Veterinary Medicine degree who took courses in meat inspection within the curriculum of their formal education. After graduation, they continue their training by taking special courses in meat inspection including four weeks of practical training. In accordance with Regulation (EC) No. 854/2004, non-veterinary inspectors "auxiliaries" attend courses involving 400 hours of practical training and 500 hours of theoretical training, after which they must pass specific examinations before being qualified to work in exporting establishments. The auditor's review of employment process and qualification did not encounter any situation that could result in a conflict of interest.

Since the last FSIS audit in 2012, the CCA and Federal State Ministries have provided ongoing training programs for inspection personnel. These trainings have covered such subjects as Pathogen Reduction/HACCP, sanitation, animal welfare, sampling methodology, and specific export requirements concerning United States-certified establishments. The FSIS auditor interviewed a number of the inspection personnel to assess their knowledge, skills, and abilities and reviewed their training records from 2013 to 2015. The FSIS auditor confirmed that inspection personnel have attended the ongoing training and have sufficient training in performing inspection activities.

FSIS observations of inspection program activities, interviews of inspection personnel, and reviews of official inspection records during the on-site audit confirm that the CCA has administrative controls to support its inspection system, and that the CCA is enforcing applicable regulatory requirements.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS (INSPECTION SYSTEM OPERATION AND PRODUCT STANDARDS)

The second of six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; daily inspection; and periodic supervisory reviews to the official establishments certified to export to the United States. The evaluation of this component included an analysis of information provided by the CCA through the SRT, interviews, and observations during the on-site portion of the audit. There are no regulatory changes associated with the export meat products in the United States since the last audit that would have required changes by the CCA.

FSIS has determined that the European Commission's food hygiene legislation including Regulation (EC) No. 178/2002, No. 882/2004, No. 852/2004, No. 853/2004, No. 854/2004, and

No. 2073/2005 are equivalent as an overarching legislation, given that the CCAs of the European Union Member States address the implementation of these legislations and other United States import requirements through their national laws, regulations, and policies. Germany's national framework of the inspection and control programs mainly includes the Food, Feed and Consumer Goods Code (LFGB) and the 2009 CCA guidelines.

During the on-site audit of one slaughter and five processing establishments, the FSIS auditor verified that continuous inspection is provided daily at the audited slaughter establishment and at least once per day per shift at the audited processing establishments when producing product for export to the United States. The FSIS auditor interviewed inspection personnel; reviewed in-plant inspection generated records; and observed the functions of the in-plant inspectors while conducting their daily inspection verification activities. These daily verification activities included direct observation of the production process and review of the establishment records, including HACCP (monitoring, verification, and corrective action), SSOP, SPS, and *Enterobacteriaceae* (slaughter establishment) sampling techniques and records.

The FSIS auditor verified that in-plant inspection personnel at the only United States-certified slaughter establishment conduct ante-mortem inspection on the day of slaughter by reviewing the incoming registrations and identification documents. The inspection personnel also observe all animals from both sides at rest and in motion in designated holding pens before slaughter in order to determine whether they are fit for slaughter and for human food purposes. The designated holding pen for sick or suspect animals was maintained for further examination of these animals, as needed. The auditor noted that the in-plant inspection verification of the humane methods of handling and slaughter of swine were being conducted properly and in accordance with the CCA's requirements.

The FSIS auditor also assessed post-mortem inspection examinations through on-site record reviews, interviews, and observations of in-plant inspection personnel performing post-mortem examinations in the swine slaughter establishment. The auditor observed that the in-plant inspection personnel are implementing proper presentation, identification, and disposition of carcasses and parts. In addition, the FSIS auditor observed the performance of the in-plant inspection personnel as they examined the heads, viscera, and carcasses. The FSIS auditor identified that the CCA implemented visual post-mortem inspection in 2014, based on Commission Regulation No. 219/2014. In order to be equivalent with FSIS requirements, Germany must demonstrate the effectiveness of alternative procedures to the incision and palpation of organs or lymph nodes required by FSIS during routine post-mortem examination.

The FSIS auditor also accompanied and observed the function of inspection personnel responsible for conducting the periodic supervisory reviews. During the periodic supervisory reviews, the inspection personnel verify requirements for ante-mortem inspection, humane handling and slaughter, post-mortem inspection, microbiological sampling including *Salmonella* sample collection in raw product (slaughter establishment), microbiological verification sampling including *Listeria monocytogenes (Lm)* and *Salmonella* sample collections in ready to eat (RTE) product (processing establishments), verification of pre-operational and operational sanitation monitoring procedures, and HACCP verification activities including the review of Critical Control Points (CCP). The FSIS auditor noted that the overall sanitary condition of the audited establishments on the day of the on-site audit are the same as documented in the periodic

supervisory review reports except those conditions that are currently being reported as audit findings under the Sanitation component.

During the audit of the processing establishments, the FSIS auditor noted that the in-plant inspection personnel apply a traceability mechanism throughout the entire production process to ensure that products destined for export to the United States do not commingle with other products. The traceability process also included the inspection verification of the incoming products originating from an approved source.

FSIS observations of inspection program activities, interviews of inspection personnel, and reviews of official inspection records during the on-site audit confirms that the CCA's meat inspection system continues to have both legal authority and a regulatory framework to implement requirements equivalent to those governing the United States' system of meat inspection. However, FSIS has a concern regarding implementation of visual post-mortem inspection without this procedure first having received a determination of equivalence by FSIS as an alternate sanitary measure. The CCA is expected to continue performing organoleptic post-mortem inspection in swine until such time that FSIS has determined that Germany's implementation of visual post-mortem procedures is equivalent to the United States' food safety requirements. FSIS requests that the CCA provide a detailed response within 60 calendar days of receipt of this draft report.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components that FSIS reviewed was Sanitation. To be considered equivalent to FSIS' program, the CCA is to provide general requirements for sanitation, sanitary handling of products, and development and implementation of SSOP.

The evaluation of the sanitation component included an analysis of information provided by the CCA through the SRT, interviews, and observations during the on-site portion of the audit. The 2009 CCA guidelines provide instructions to both inspection and industry personnel to implement the contents of 9 CFR part 416 concerning sanitation requirements in all United States-certified establishments.

The FSIS auditor reviewed the establishments' sanitation programs and associated records related to the development, implementation, and maintenance of sanitation programs at the audited establishments. The auditor also assessed the inspection personnel's ability to verify and enforce the regulatory requirements for sanitation at the establishment level. The assessment included review of the official inspection verification records, of the establishment's sanitation monitoring records, of documented corrective actions generated by the establishment, and of the actual sanitary conditions in the production areas. The auditor verified that each audited establishment maintains a written sanitation program to prevent direct product contamination or adulteration. Each program includes maintenance and improvement of sanitary conditions through routine assessment of the establishment's hygienic practices. The FSIS auditor confirmed that the in-plant inspection personnel conduct daily verification procedures of the implementation of the establishments' sanitation programs. The inspection verification activities consist of a combination of document reviews and hands-on inspections.

In one audited processing establishment, the FSIS auditor verified the implementation of the pre-operational inspection verification by shadowing and observing the in-plant inspector conducting pre-operational sanitation verification inspection. The in-plant inspection personnel conducted this activity in accordance with the guidelines provided by the CCA.

The FSIS auditor also followed and observed the in-plant inspection personnel's verification of operational sanitation procedures at all of the audited establishments. These verification activities included direct observation of operations while product was being processed and review of the establishments' records for that process. The FSIS auditor reviewed the establishments' sanitation monitoring and corresponding inspections' verification records for the same time period. The auditor noted that the inspection and establishment records mirrored the actual sanitary conditions of the establishment. The audited establishments also documented the implementation and monitoring of sanitation procedures and any corrective actions taken. The inspection personnel also verified that the establishment employees responsible for the implementation and monitoring of sanitation procedures properly authenticated sanitation records with their initials or signatures and the date. No concerns arose as the result of these document reviews.

During the on-site tour of the establishments, the FSIS auditor observed the following SPS deficiencies in two of the audited establishments:

- In one establishment, the FSIS auditor observed beaded condensation on the overhead structures in a carcass cooler and in the cutting room over exposed products. No direct product contamination observed by the FSIS auditor at the time.
- In another establishment, the FSIS auditor observed several small holes in the ceiling and on the overhead structures in the processing area over exposed products. No direct product contamination observed by the FSIS auditor at the time.

Both establishments and the inspection personnel made commitments to take immediate action to correct these issues and address any potentially affected product. FSIS believes that the above isolated deficiencies may indicate a need to increase surveillance by the inspection personnel in verifying and enforcing regulatory requirements.

The analysis and on-site verification activities indicate that the CCA requires operators of official establishments to develop, implement, and maintain sanitation programs.

VII. COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP)

The fourth of six equivalence components that the FSIS auditor reviewed was HACCP. The inspection system requires that each official establishment develop, implement, and maintain a HACCP plan.

The evaluation of the HACCP component included an analysis of information provided by the CCA through the SRT, interviews, and observations made during the on-site portion of the audit. The 2009 CCA guidelines provide instructions to both inspection and industry personnel to

implement the contents of 9 CFR part 417 concerning HACCP requirements in all United States-certified establishments.

The FSIS auditor visited one swine slaughter and five processing establishments to assess the adequacy of the CCA's oversight and the adequacy of the verification procedures performed by the inspection personnel. At the establishment level, the auditor observed the actual verification activities conducted by the in-plant inspection personnel and reviewed the associated verification records generated by the in-plant inspection personnel. The auditor noted that the in-plant inspection personnel at the audited establishments conduct daily verification of the establishment's HACCP plans in accordance with the instructions described in the 2009 CCA guidelines. The in-plant inspection verification methodology includes such activities as the evaluation of the establishment's written HACCP programs and observing the establishment personnel perform monitoring, verification, corrective actions, and recordkeeping activities. The in-plant daily inspection verification activities also included direct observation or record review of CCPs with results of verification being entered in the associated inspection records.

The FSIS auditor conducted an on-site observation and document review of CCPs in all the audited establishments including the zero tolerance (feces, ingesta, and milk) CCP control records generated in the only United States-certified swine slaughter establishment. At the slaughter establishment, the FSIS auditor together with the in-plant inspection personnel observed the establishment's employee conducting hands-on HACCP monitoring and verification activities for the zero-tolerance CCP. Neither the FSIS auditor nor the CCA's inspection personnel observed any deviations from the critical limits. The FSIS auditor also reviewed the establishment and the in-plant inspections' zero tolerance records. Both establishment (monitoring, verification, and corrective action) and the in-plant inspection (verification) records documented a few deviations from the critical limits and related corrective actions taken by the establishment.

During the on-site document reviews and interviews of establishment and inspection personnel, the FSIS auditor identified the following HACCP findings:

- In two establishments, the HACCP plan did not include direct observation of monitoring procedures as part of its ongoing verification activities.
- In two establishments, the HACCP monitoring or verification records did not document the time of the monitoring or ongoing verification activities conducted by the establishment's personnel.
- In one establishment, the HACCP verification records did not document the results of the ongoing verification activities conducted by the establishment's personnel.
- In one establishment, the written corrective action plan or records did not include measures to identify and eliminate the cause of the deviation or measures to prevent the reoccurrence as part of its corrective action when there is a deviation from the critical limit.

The CCA informed FSIS that the above HACCP record-keeping findings would be corrected and verified immediately in order to comply with the regulatory requirements. FSIS believes that the HACCP findings may indicate a need to improve the knowledge base of inspection personnel concerning HACCP requirements.

The analysis and on-site verification activities indicate that the CCA requires operators of official establishments to develop, implement, and maintain HACCP programs for each processing category.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of the six equivalence components that the FSIS auditor reviewed was Government Chemical Residue Control Programs. To be equivalent to FSIS' inspection system, the inspection system must have a chemical residue control program designed and administered by the national government that functions to prevent chemical residue contamination of food products. In addition, the program must include random sampling of the internal organs, muscle, and fat of carcasses for chemical residues identified by the exporting countries and FSIS as potential contaminants. The CCA must provide a description of its residue sampling and testing plan and the process used to design the plan. The CCA must maintain oversight of laboratories to ensure the validity and reliability of test data.

Germany's National Residue Control Plan (NRCP) is based on Council Directive 96/23/EC and Commission Decision 97/747/EC. These legal provisions have set the framework for performance of residue controls. The plan is designed each year by the BVL in cooperation with the BMEL, the National Reference Laboratory (NRL), and the 16 Federal States. Each Federal State is responsible for the enforcement of legislations including the administration of the Residue Control Plan. Therefore, each Federal State develops a sampling plan for its state according to the requirements set out by the National Residue Control Plan. The annual slaughter and production figures and the size of the livestock populations constitute the basis for determining the level of sampling for each Federal State.

Based on the NRCP, residue samples are collected at slaughter establishments without prior notice over the whole calendar year; on different days of the week and at different times of the day; and distributed over the entire dates of slaughter so that as many as possible producers supplying slaughter animals are included. The official veterinarian in slaughter establishment collects samples in accordance with the provisions of Regulation (EC) No. 854/2004. The official veterinarian who collects the residue samples receives periodic training that includes such subjects as sampling methodology, identification of animals, traceability, avoiding contamination, and sample security.

Germany has one NRL for all commodities and all substance groups listed in Annex I to Council Directive 96/23/EC. The NRL does not perform any routine testing under the Residue Control Plan. The routine testing is the responsibility of the 29 official laboratories operating in the 16 Federal States. The German accreditation body (AkkStelleG) provides accreditation to laboratories in accordance with International Organization for Standardization (ISO) 17025.

The residue laboratory should follow the provisions of Decision 2002/657/EC and EU standard DIN EN ISO 17025 when analyzing residue samples. In particular, the processing of samples has to run parallel with at least one blank sample and one positive control sample per analytic series. The period between receipt of samples and report of final laboratory results should be

less than six weeks. A positive finding obtained by a screening method must be confirmed using a confirmation or reference method, according to Decision 2002/657/EC. All sampling results obtained under the NRCP must be reported to the BVL. FSIS reviewed Germany's National Residue Control Plan of 2015 and results of the 2014 program. This review identified no concerns. In addition, analytical testing conducted by FSIS at United States POE has not detected any violative level of chemical residues in meat products exported to the United States.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component that the FSIS auditor reviewed was Government Microbiological Testing Programs. The system is to organize and implement certain sampling and testing programs to ensure that meat products produced for export to the United States are safe, wholesome, unadulterated, and meet all relevant equivalence criteria. The evaluation of this component included an analysis of the information provided by the CCA through the SRT, review of the establishments' and the official inspection verification records, interviews with the inspection and laboratory personnel as well as observations during the on-site audit.

The CCA requires slaughter establishments to conduct *Enterobacteriaceae* testing in swine carcasses in accordance with Commission Regulation (EC) No 2073/2005- Annex I, Chapter 2, in lieu of testing for generic *E. coli* as a measure of sanitary process control. This testing program is equivalent to the FSIS requirements. The FSIS auditor reviewed the establishment's written program and sampling records and confirmed that the in-plant inspection personnel verify that the swine slaughter establishment complies with the CCA regulatory requirements cited in the aforementioned regulation including sampling frequency, technique, methodology, and maintaining records of analytical results. The auditor's review of the inspection personnel verification records identified no concerns.

During the on-site tour of the slaughter establishment, the FSIS auditor accompanied and observed the in-plant inspection personnel *Salmonella* sampling verification activities including the actual sample collection by the inspection personnel on the day of the audit. The auditor noted that the sampling and testing for *Salmonella* in raw products is in accordance with Commission Regulation (EC) No 2073/2005- Annex I, Chapter 2 that is equivalent to the FSIS requirements. The FSIS auditor confirmed that the inspection personnel collect official verification *Salmonella* samples and government laboratories conduct analytical testing using the ISO 6579-2002 methodology which FSIS determined to be equivalent. The *Salmonella* sets for testing of swine carcasses consist of 50 samples with a maximum allowed number of three positives per set according to EU Regulation No. 217/2014. The FSIS auditor's review of inspection records found that there have not been any *Salmonella* set failures for the past six months. The auditor's review of the inspection personnel verification records identified no concerns.

The requirements concerning ready-to-eat (RTE) product are cited in Commission Regulations including (EC) No. 2073/2005, No. 178/2002, No. 852/2004, No. 882/2004, and the 2009 CCA guidelines. Chapter 7 of this guideline provides instructions to the inspection personnel and United States-approved establishments concerning implementation of measures against *Lm* and *Salmonella* in RTE products in accordance with to 9 CFR part 430. The FSIS auditor noted that

the CCA's official verification sampling frequency is based on each establishment's selected alternatives. As a result, the CCA's official verification sampling of finished product for *Lm* and *Salmonella* is at least four samples per year for Alternative 1, at least six samples per year for Alternative 2, and sampling of each United States-export consignment for Alternative 3. The CCA's official verification sampling also included at least 10 food contact surfaces/year and 10 non-food contact surfaces/year. The FSIS auditor verified that the inspection personnel collect official RTE verification samples and a government laboratory conducts analytical testing using FSIS Microbiology Laboratory Guidebook (MLG) for RTE products destined for export to the United States. The auditor's review of the inspection personnel verification records identified no concerns.

During the on-site audit, the FSIS auditor visited Lower Saxony State Office Microbiology Laboratory (LAVES). This is an ISO 17025 accredited laboratory conducting microbiological analytical testing on products destined for export to the United States. The FSIS auditor interviewed the laboratory personnel and reviewed laboratory documents related to analyst trainings and qualifications, sample receipt, timely analysis, analytical methodologies, recording and reporting results, and check samples. The current analytical test portions for both *Lm* and *Salmonella* meets the CCA's export requirements of a minimum of 25 g (*Lm*) and 325 g (*Salmonella*) analytical test portions using MLG 8.09for testing *Lm* in RTE products and MLG 4.08for testing *Salmonella* in RTE products. The FSIS auditor's review of the provided documents found no concerns within the CCA's implementation of microbiological testing programs.

The analysis and on-site verification activities indicate that the CCA meat inspection system has a microbiological testing program organized and administered by the national government. Analytical testing conducted by FSIS at United States POE has not reported any violations.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on June 19, 2015, in Berlin, Germany with the CCA. The preliminary audit findings were presented by FSIS. The CCA understood and accepted the findings. FSIS identified some operational (or procedural) weaknesses related to sanitation and HACCP. The FSIS auditor also identified that the CCA implemented visual post-mortem inspection in 2014, based on EU Regulation No. 219/2014. In order to be equivalent with FSIS requirements, Germany must follow certain criteria that demonstrate the effectiveness of alternative procedures to the incision and palpation of organs or lymph nodes required by FSIS during routine post-mortem examination. Germany is expected to continue performing organoleptic post-mortem inspection in swine until such time that FSIS has determined that Germany's implementation of visual post-mortem procedures is equivalent to the United States' food safety requirements. FSIS requests that the CCA provide a detailed response within 60 calendar days of receipt of this draft report.

XI. ATTACHMENTS TO THE AUDIT REPORT

Attachment A: Individual Foreign Establishment Audit Checklist
Attachment B: Foreign Country Response to Draft Final Audit Report (when available)

Attachment A: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Meica GmbH & Co. KG Meicastraße 6, 26188 Edewecht	June 8, 2015	EV-34	Germany
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, DVM		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

22/51: HACCP – Ongoing Requirements

A) The establishment's HACCP plan did not include direct observation of monitoring procedures as part of its ongoing verification activities.

B) The establishment's HACCP verification records for review of records component did not document the results of the ongoing verification activities conducted by the establishment's personnel.

Species processed: porcine

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	June 8, 15

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Bell Deutschland GmbH & Co. KG Osterschepser Straße 40 26188 Edewecht	June 4, 2015	EV-35	Germany
	5. NAME OF AUDITOR(S) Nader Memarian, DVM		6. TYPE OF AUDIT [X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	X
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

22/51: HACCP – Ongoing Requirements
The establishment's HACCP monitoring and verification records did not document the time of the monitoring or ongoing verification activities conducted by the establishment's personnel.

Species processed: porcine

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	June 4, 15

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Tönnies Lebensmittel GmbH & Co. KG In der Mark 2, 33378 Rheda-Wiedenbrück	June 10, 2015	ES-202 & EZ-917	Germany
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, DVM		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	X
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	X
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	X
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

41/51: Other Requirements – Ventilation
Beaded condensation was observed on the overhead structures in a carcass cooler and in the cutting room over exposed products. No direct product contamination observed by the FSIS auditor at this time. While the establishment and the inspection personnel took action to correct the issue and address any potentially affected product, the amount and specific location of the condensation indicated a problem which was ongoing and recurring in nature, i.e., insufficient ventilation in these areas.

20/51: HACCP – Ongoing Requirements
The establishment's written corrective action plan did not include measures to identify/eliminate the cause of deviation or measures to prevent the reoccurrence as part of its corrective action when there is a deviation from the critical limit.

55: Inspection Requirements – Post Mortem Inspection
The CCA implemented visual inspection methodology for swine post-mortem inspection procedures. The CCA has not submitted to FSIS an equivalence determination request for visual post-mortem inspection.

Species slaughtered (ES-202) and processed (EZ-917): porcine

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
HoWe Wurstwaren KG Regenstraße 1, 90451 Nürnberg	June 16, 2015	EV-717	Germany
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, DVM		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
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16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
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18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

22/51: HACCP – Ongoing Requirements
A) The establishment's HACCP plan did not include direct observation of monitoring procedures as part of its on-going verification activities.
B) The establishment's HACCP monitoring records did not document the time of the monitoring conducted by the establishment's personnel.

Species processed: porcine

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Freiberger Lebensmittel GmbH & Co. Draisstraße 1-5, 76461 Muggensturm	June 12, 2015	BW-03330	Germany
	5. NAME OF AUDITOR(S)		6. TYPE OF AUDIT
	Nader Memarian, DVM		[X] ON-SITE AUDIT [ ] 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
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
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17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Enforcement	X
52. Humane Handling	
53. Animal Identification	
54. Ante Mortem Inspection	
55. Post Mortem Inspection	
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Monthly Review	
58.	
59.	

60. Observation of the Establishment

June 12, 2015 | Processing (Not RTE) Est# BW-03330 | Germany

39/51: Other Requirements – Establishment Construction/Maintenance
The FSIS auditor observed several small holes on the ceiling and on the overhead structures in the processing areas over exposed products. No direct product contamination observed by the FSIS auditor at this time. However, this condition may create an insanitary condition.

Species processed: porcine

61. NAME OF AUDITOR	62. AUDITOR SIGNATURE AND DATE
Nader Memarian, DVM	June 12, 15

Attachment B: Foreign Country Response to Draft Final Audit Report (when available)

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

-

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
Dienstsitz Berlin • Postfach 11 02 60 • 10832 Berlin

By e-mail only:
Shaukat H. Syed, DVM, Director
USDA, FSIS, OIA, IAS
1400 Independence Ave. SW, Room 2141-S
Washington, D. C. 20210, USA

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USDA Foreign Agricultural Service
American Embassy
Clayallee 170
D - 14195 Berlin

Dt. Botschaft Washington:
Botschaft der Bundesrepublik Deutschland
4645 Reservoir Road NW
Washington, D. C. 20007, USA

Ministerium für Ernährung und
Landwirtschaft
Rochusstr. 1
D - 53123 Bonn

Stefanie Roth
Scientific Officer

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E-MAIL Stefanie.Roth@bvl.bund.de
INTERNET www.bvl.bund.de

YOUR REFERENCE
YOUR LETTER OF

OUR REFERENCE 106.16461.0.362209
(Please quote with answer)

DATE 13. November 2015

Comments on draft final report of FSIS 2015 audit of German meat inspection system

Dear Dr. Syed

With this letter, I am sending you Germany's comments on the draft final report of the 2015 FSIS audit of the German meat inspection system for establishments eligible to export meat and meat products to the United States, conducted by senior program auditor Dr. Nader Memarian from June 02 to June 19, 2015.
I would like to express our appreciation of the report and the conclusions drawn by FSIS auditor Dr. Nader Memarian. Please find our comments attached to this letter.

I thank you again for the opportunity to comment on the report. Please let me know if any further information is needed.

Sincerely yours

signed

Dr. Ina More
Deputy Head of unit

Enclosure:

1. Comments Germany to the draft of the FSIS Audit report 2015

Comments Germany on 2015 FSIS Audit Draft Report

General comments on the report:

FSIS states under section V and in the conclusion under X that the personnel in the inspected slaughter establishment that were competent for the post-mortem inspection did not conduct any of the incisions and/or palpations of organs and lymph nodes in accordance with FSIS criteria. The report also notes that Germany has not submitted any equivalence determination request in respect of this post-mortem inspection procedure.

Germany draws attention to the fact that the slaughtering establishment complies with European Regulation (EC) No. 854/2004 as amended in Regulation (EU) No. 219/2014 in respect of the requirements for the post-mortem inspection of domestic pigs. This Regulation requires, in the case of domestic pigs, a risk-based post-mortem examination of the carcass to be carried out; it does not, however, provide for any incisions of organs or lymph nodes to be made. Additional procedures in the post-mortem inspection based on incisions and palpations must be carried out by the official veterinarian as part of the risk-based post-mortem inspection if a potential risk to human or animal health or to animal welfare is indicated.

Germany therefore requests that the wording "visual post-mortem inspection" should be replaced by the wording "risk-based post-mortem inspection" in the report.

Germany will contact FSIS in order to reach an interim solution until the equivalence determination and at the same time submit bilaterally an equivalence determination request for the above procedure for risk-based post-mortem inspections.

Specific comments on the report:

Page 1, paragraph 2:

Participating in the entrance meeting in Berlin were also officials of the Federal Ministry of Food and Agriculture of the *Laender* visited during the audit.

Page 2, Table:

The names Gütersloh and Rheda-Wiedenbrück are spelled with an "ü" (or –ue-), and Tönnies with an "ö" (or –oe-).

The approval numbers of the slaughter and the cutting plant of Toennies Lebensmittel GmbH & Co., Rheda-Wiedenbrueck, have been switched in cells 5 and 6 of column 3 of the table. The slaughter plant has the approval number 202, and the cutting plant approval number 917.

Page 3, Chapter IV, paragraph next to last:

The Animal Disease Act (TierSG) is outdated. The requisite law is the "Act on the prevention and control of animal diseases" (Animal Health Act – TierGesG).

As regards the attachment to the report concerning establishment EV 717, the two deficiencies described there have been corrected.

Page 4:

Paragraph 4 states:
"At the Federal State level, the system...consists of up to three levels:..." Lower Saxony would like to underline that the system in some Federals States consists of less than three levels.

Page 12:

Paragraph 4 on page 12 explains that the testing of swine carcasses for *Salmonella* according to Regulation (EC) No. 2073/2005 allows a maximum five samples to be positive in a set of 50 samples. Please note that, according to (amending) Regulation (EU) No. 217/2014 of 07 March 2014, which has amended Regulation (EC) No. 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs, only a maximum three out of a set of 50 samples may now be positive.

Page 13:

Paragraph 1 correctly states:
„The FSIS auditor verified that the inspection personnel collect official RTE verification samples and a government laboratory conducts analytical testing using FSIS Microbiology Laboratory Guidebook (MLG) for RTE products destined for export to the United States. The auditor's review of the inspection personnel verification records identified no concerns"

Paragraph 2 on the same pages says:
The current analytical test portions for both Lm and Salmonella meets the CCA's export requirements of a minimum of 25 g (Lm) and 325 g (Salmonella) analytical test portions using ISO 11290-1 for testing Lm in RTE products and ISO 6579:2002 for testing Salmonella in RTE products."

Please note that the Lower Saxony government laboratory uses FSIS methods MLG 4.08 for *Salmonella* testing and MLG 8.09 for *Lm* testing in official verification samples (as it is correctly stated in the prior paragraph), and not ISO methods.

Attachment A:

Concerning the establishment Freiberger, the competent Authority would like to state that the products that are exported at the moment to the United States of America by the establishment BW 03330, Freiberger Lebensmittel GmbH & Co. Produktions- und Vertriebs KG, Werk Muggensturm, are „not-ready-to-eat products", (NRTE).

United States Department of Agriculture

Food Safety and
Inspection Service

1400 Independence
Avenue, SW.
Washington, D.C.
20250

SEP 0 4 2015

Mr. Bernard Van Goethem
Director of Directorate G (Veterinary and International Affairs)
Health and Consumer Protection Directorate-General
European Commission
Rue Breydel 4 B-1040 Brussels, Belgium

Dear Mr. Van Goethem:

Thank you for your June 26, 2015, letter requesting that the Food Safety and Inspection Service (FSIS) recognize that the visual post mortem (pm) inspection of swine implemented by Commission Regulation (EU) No 219/2014, which amends Annex I of EC Regulation 854/2004, as equivalent to the organoleptic post-mortem inspection conducted in the US meat inspection system. FSIS has reviewed the Commission Regulation (EU) No 219/2014, and the associated 2011 scientific opinion by the European Food Safety Authority (EFSA), on the public health hazards to be covered by inspection of meat (swine). Additionally, FSIS has taken into account the live animal production data and risk-based evidence provided by Denmark in its petition for an FSIS equivalence determination on certain aspects of the visual post-mortem inspection of market hogs.

On this basis, FSIS has identified the following criteria for determining whether the implementation by EU Member States of Commission Regulation (EU) No. 219/2014 meets the U.S. level of protection:

Specifically, individual Member States must:

- provide risk assessment data to demonstrate that their implementation of visual post-mortem inspection of swine is as effective as traditional, organoleptic inspection in identifying and removing unhealthy animals and adulterated carcasses from the food chain;
- require the use of prerequisite programs that reduce the incidence of foodborne pathogens in market hog carcasses presented for inspection;
- specify whether visual post-mortem inspection is performed strictly on market-age hogs or on all swine animals;
- specify whether visual post-mortem inspection is performed on hogs raised indoors and/or outdoors;

- demonstrate that the incidence of diseases in market hogs, such as Tuberculosis (TB), is no higher than the incidence in the United States;
- describe food chain information reviewed by official veterinarians prior to making an ante-mortem inspection disposition, and explain circumstances in which official veterinarians are expected to decide that organoleptic (palpation and incision) post-mortem inspection is necessary to determine that swine meat is fit for human consumption;
- describe training programs and competency requirements for inspectors performing visual post-mortem inspection of swine;
- provide evidence demonstrating that market hogs subject to visual post-mortem inspection have been born and raised domestically; and
- provide elements of their national control plans that demonstrate how Commission Regulation (EU) 219/2014 requirements are implemented and verified in all swine slaughter establishments certified for U.S. export.

In addressing these criteria, EU Member States demonstrate that visual post-mortem inspection techniques can be equally as effective as traditional, organoleptic post-mortem inspection in identifying defects and disease conditions and removing unhealthy animals and adulterated carcasses from the food chain.

Until FSIS has received and reviewed this information and determined its equivalence to U.S. food safety requirements, Member States are expected to continue performing organoleptic post-mortem inspection of swine in establishments that export product to the United States. Member States should provide this documentation to Mr. Robert Tuverson, Senior Equivalence Officer. He can be reached by electronic mail at Robert.Tuverson @fsis.usda.gov or internationalequivalence@fsis.usda.gov.

As always, please feel free to contact me or Mary Stanley directly should you have any questions.

Sincerely,

Sharon McMurtrey
for Jane Henriques Doherty
International Coordination Executive
Office of the Administrator