United States Department of Agriculture

Food Safety and
Inspection Service

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OCT 23 2019

Dr. Soumaya Katherine Lhafi
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Dear Dr. Lhafi,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an on-site verification audit of Germany's inspection system from March 18 through March 29, 2019. 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.

For any questions regarding the FSIS audit report, please contact the Office of International Coordination at InternationalCoordination@usda.gov.

Sincerely,

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

GERMANY

MARCH 18 THROUGH 29, 2019

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

PROCESSED MEAT PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

September 25, 2019

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 United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) from March 18 through 29, 2019. The purpose of the audit was to determine whether Germany's food safety inspection system governing processed meat products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and correctly labeled and packaged. Germany currently exports processed pork products to the United States.

The audit focused on six system equivalence components: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditor identified the following findings:

GOVERNMENT HACCP SYSTEM

- In two of the six audited establishments, there was inadequate government verification of HACCP requirements. The Inspection personnel did not identify that the written HACCP plan did not include one or more of the following elements required by the *German Guidelines 2.0*, which are consistent with 9 CFR § 417.2: monitoring procedures and frequencies, and ongoing verification procedures and frequencies.

- In two of the four audited establishments that produce ready-to-eat dry cured hams, there was inadequate government verification of HACCP requirements. The hazard analyses did not identify microbiological controls for *Salmonella* within all process steps; however, the establishment process had validated/scientific documentation.

The audit findings did not represent a potential to endanger public health because they involved recordkeeping and necessary technical clarifications. During the audit exit meeting, the Central Competent Authority (CCA) committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

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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 inspection system from March 18-29, 2019. The audit began with an entrance meeting held on March 18, 2019, in Berlin, Germany, during which the FSIS auditor discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – Federal Office of Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)). Representatives from the CCA accompanied the FSIS auditor throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to determine whether Germany's food safety inspection system governing processed meat products remains 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 currently eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products
Thermally Processed - Commercially Sterile	Thermally processed - commercially sterile	Beef, Veal, Goat, Lamb, Mutton, and Pork- All Products Eligible
Not Heat Treated - Shelf Stable	Ready-to-eat (RTE) acidified/fermented meat (without cooking)	Beef, Veal, Goat, Lamb, Mutton, and Pork- All Products Eligible
Not Heat Treated - Shelf Stable	RTE dried meat	Beef, Veal, Goat, Lamb, Mutton, and Pork- All Products Eligible
Not Heat Treated - Shelf Stable	RTE salt-cured meat	Beef, Veal, Goat, Lamb, Mutton, and Pork- All Products Eligible
Fully Cooked - Not Shelf Stable	RTE fully-cooked meat	Beef, Veal, Goat, Lamb, Mutton, and Pork- All Products Eligible
Fully Cooked - Not Shelf Stable	RTE meat fully-cooked without subsequent exposure to the environment	Beef, Veal, Goat, Lamb, Mutton, and Pork- All Products Eligible
Heat Treated but Not Fully Cooked - Not Shelf Stable	Not ready-to-eat (NRTE) otherwise processed meat	Beef, Veal, Goat, Lamb, Mutton, and Pork- All Products Eligible
Product with Secondary Inhibitors - Not Shelf Stable	RTE salt-cured meat	Beef, Veal, Goat, Lamb, Mutton, and Pork- All Products Eligible

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes that beef and veal imported from Germany are subject to foot-and-mouth disease (FMD) requirements specified in Title 9 of the United States Code of Federal Regulations (9 CFR) § 94.11, and the bovine spongiform encephalopathy (BSE) requirements specified in 9 CFR § 94.18 and/or § 94.20. Additionally, pork imported from Germany is subject to African swine fever (ASF) requirements specified in 9 CFR § 94.8, classical swine fever (CSF) requirements specified in 9 CFR § 94.31, swine vesicular disease (SVD) requirements specified in 9 CFR § 94.13, and FMD requirements specified in 9 CFR § 94.11. Germany is eligible to export only processed meat products to the United States.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from the CCA through the self-reporting tool (SRT).

Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditor reviewed administrative functions at the CCA headquarters, one regional (district) office, and six local inspection offices. The FSIS auditor evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

The FSIS auditor visited a sample of six establishments from 13 establishments certified as eligible to export meat products to the United States. Eight of these 13 establishments are actively involved with exporting to the United States. The remaining five establishments have not exported to the United States in at least the last three years. Processed pork products are produced at the six processing establishments for export to the United States.

During the establishment visits, the FSIS auditor paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliances that threaten food safety. The FSIS auditor assessed the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in 9 CFR § 327.2.

Additionally, the FSIS auditor audited one government microbiological laboratory to verify its ability to provide adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• Federal Office of Consumer Protection and Food Safety (BVL), Berlin
	Regional (District) Office	1	• District Office (Landratsamt) Ortenaukreis - Office of Veterinary and Food Supervision Ortenaukreis, Offenburg
Laboratory		1	• Lower Saxony State Office for Consumer Protection and Food Safety (LAVES) (government laboratory - microbiological), Oldenburg
Pork processing establishments		6	• EV-34, Meica Ammerländische, Fleischwarenfabrik Fritz Meinen GmbH & Co. KG, Edewecht • AEV-35, Bell Deutschland GmbH & Co. KG, Edewecht • DE-EV-717EG, HoWe Wurstwaren KG, Nürnberg • BW-03330, Freiberger Lebensmittel GmbH & Co. Produktions-und Vertriebs KG Werk Muggensturm, Muggensturm • BW-05068, Schinkenhof GmbH & Co., KG, Achern • BY-50008, Hans Kupfer & Sohn GmbH & Co. KG, Heilsbronn

FSIS performed the audit to verify the food safety inspection system met requirements equivalent to those under the specific provisions of United States' laws and regulations, in particular:

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] 601 *et seq.*); and
- The Meat Inspection Regulations (9 CFR Parts 301 to the end).

The audit standards applied during the review of Germany's food safety inspection system for processed meat 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 World Trade Organization's *Agreement on the Application of Sanitary and Phytosanitary Measures* and includes the following regulations and directives for the European Union (EU):

- Regulation European Commission (EC) No. 178/2002;
- Regulation (EC) No. 852/2004;
- Regulation (EC) No. 853/2004;
- Regulation (EC) No. 854/2004;
- Regulation (EC) No. 882/2004;
- Regulation (EC) No. 1/2005;
- Regulation (EC) No. 2073/2005;
- Regulation (EC) No. 1069/2009;
- Regulation (EC) No. 1099/2009;

- Regulation (EC) No. 142/2011;
- EC Directive No. 93/119/EC;
- EC Directive No. 96/22/EC; and
- EC Directive No. 96/23/EC.

III. BACKGROUND

From January 1, 2016, to December 31, 2018, FSIS import inspectors performed 100 percent reinspection for certification, labeling, and general conditions on 10,311,410 pounds of processed pork products exported by Germany to the United States. FSIS also performed additional types of inspection on 1,845,183 pounds of processed pork products, including laboratory testing for chemical residues and microbiological pathogens (e.g., *Listeria monocytogenes* (*Lm*) and *Salmonella*). As a result, FSIS rejected seven pounds of RTE, salt-cured, sliced pork product for the presence of *Lm* and 4,505 pounds of RTE, salt-cured, unsliced, and sliced pork product implicated in a foreign country recall due to *Lm*. An additional 332 pounds of process pork products were rejected for reasons other than public health.

The current audit included a visit to the establishment implicated in the above-referenced POE violations, for which FSIS concluded that BVL had satisfactorily worked with the food business operator to identify the root causes of the problem and institute appropriate corrective actions. These actions included a) verification of the establishment's traceability program to properly identify processing dates and other implicated product; b) review of HACCP records for the specific dates; c) follow-up review and official intensified verification sampling of product, food contact surfaces (FCS), and environmental surfaces for *Lm* and *Salmonella*; and d) review of the establishment's microbiological testing records.

The previous FSIS audit conducted in 2017 included visits to the central headquarters, three regional (district) offices, two laboratories, and five pork processing establishments. The on-site verification audit results indicated that Germany's food safety inspection system remains equivalent. However, findings were identified within the following equivalence components:

GOVERNMENT OVERSIGHT

- The CCA's *Working Group for United States* Export did not meet at a frequency sufficient to coordinate export activities across Federal States, including analysis of inspection results, identification of system-wide trends, and revision of written export guidelines.
- The CCA's training plan did not adequately ensure that inspection personnel throughout the inspection system are sufficiently trained to ensure United States requirements are met. This was a repeat finding.
- The CCA did not routinely conduct audits of official laboratories with a special emphasis on testing activities related to United States requirements. Several deficiencies related to the implementation of testing methods and reporting of results were identified.

GOVERNMENT SANITATION

- Inadequate government verification of sanitation standard operating procedure (sanitation SOP) requirements was identified in three of the six audited establishments.

GOVERNMENT HACCP SYSTEM

- Inadequate government verification of HACCP requirements (e.g., monitoring, corrective actions, and ongoing verification) was identified in all six audited establishments.
- Two of the three establishments preparing RTE products did not maintain validated scientific support demonstrating *Salmonella* lethality, although the processes had inherent controls (e.g., water activity) and microbiological sampling was conducted to demonstrate the safety of their product.
- Two of the three establishments conducting RTE product sampling to validate their food safety systems were analyzing 25 gram samples for *Salmonella*. The CCA had not assessed whether the sample portion provided equivalent results to German official methods (e.g., 325 gram) and supported the HACCP system.

GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

- Written programs for the control of *Lm* were incomplete at all three establishments producing RTE products. The written programs lacked the identification of the control alternative being used; identification of sampling locations; indication of the conditions for which hold-and-test procedures would be implemented; and justification of testing frequencies.
- The CCA's guidelines for conducting government verification testing of FCS did not clearly describe the size (area) of the surface to be tested and the sampling frequencies.

In response to the 2017 findings, BVL proffered corrective actions to develop and implement adequate policies and written procedures for conducting verification procedures for verifying sanitation, HACCP, and microbiological testing programs. The FSIS auditor verified that all actions taken by BVL were completed.

Prior to the 2019 on-site equivalence verification audit, FSIS reviewed and analyzed Germany's SRT responses and supporting documentation. During the on-site audit, the FSIS auditor conducted interviews, reviewed records, and made observations to determine whether Germany's food safety inspection system governing processed meat products is being implemented as documented in the country's SRT responses and supporting documentation.

The FSIS final audit reports for Germany's food safety inspection 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 (E.G., ORGANIZATION AND ADMINISTRATION)

The first of six equivalence components reviewed by the FSIS auditor was Government Oversight. FSIS import regulations require the foreign food safety inspection system to be organized by the national government in such a manner as to provide ultimate control and supervision over all official inspection activities; ensure the uniform enforcement of requisite laws; provide sufficient administrative technical support; and assign competent qualified inspection personnel at establishments where products are prepared for export to the United States.

The FSIS auditor verified that the inspection system is organized and administered by the national government of Germany. There have been no major changes in the CCA's organizational structure since the last FSIS audit conducted in 2017.

The Federal Republic of Germany is divided into 16 Federal States, known as Länder. Each Federal State has its own parliament, government, and administration. The *Basic Law of 1949* describes the respective authority for Federal and Federal State levels including the areas of food and feed safety, animal health, animal welfare, and plant health. The Federal level is responsible for federal legislation, whereas the Federal States are responsible for implementation and enforcement. At the national level, the primary federal legislation relating to food safety is the *Food, Consumer Goods and Feed Act* (LFGB), and animal health and welfare are governed under the *Animal Health Act* and the *Animal Welfare Act*, respectively.

Two ministries share responsibilities at the Federal level in the area of food: the Federal Ministry of Food, Agriculture and Consumer Protection (BmEL) and the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMUB). Within BmEL are the Federal Office of Consumer Protection and Food Safety (*Bundesamt für Verbraucherschutz und Lebensmittelsicherheit*, BVL) and the Federal Institute for Risk Assessment (BfR). The BfR provides scientific counsel to BmEL. FSIS recognizes BVL as Germany's CCA for food safety.

BVL acts essentially as an advisor and coordinator in relation to the exporting of animals, animal products, and feed to various third countries. The Export Affairs Unit (Unit 180) within BVL has the responsibility for implementing export requirements for the United States. These responsibilities include: Administration of approval (and listing) procedures of establishments; Organization and communication of lists of eligible establishments; Registration of official stamps, export certificates, and signatures for annual certification of eligibility; Handling of complaints made by official authorities (e.g., POE violations); Organization of audits by third countries (i.e., countries outside the EU) authorities or monitoring of inspections of the Federal States authorities; Coordination of the answers to third country questionnaires (e.g., FSIS SRT); Coordination of the *Working Group for United States Export* of BVL and the Federal States; Training for official inspection staff; and Maintenance of the Technical Information System for Consumer Protection and Food Safety (FIS-VL) program, specifically export and third country information.

The EC regulations are the primary overarching laws for regulating meat inspection in Germany. *Regulation (EC) No. 178/2002*, *Regulation (EC) No. 852/2004*, *Regulation (EC) No. 854/2004*, and *Regulation (EC) No. 882/2004* provide Germany with the legal and enforcement authority and responsibility to ensure that adulterated or misbranded products are not eligible to be exported to the United States. *Regulation (EC) No. 178/2002, Article 12* and Germany's *National Food Hygiene Regulation (LMHV), § 9 Export Approval*, state that approval of establishments for export to third countries, such as the United States, is dependent on compliance with the sanitary requirements of the importing country. In addition to establishing official controls designed to ensure compliance with the EC legislation, Federal States are also responsible for ensuring compliance with United States requirements and certification of eligible establishments.

The *General Administrative Provision on Food Hygiene* (AVV LmH) § 5 *Approval of Establishments for Export,* provides the legal authority requiring the Federal States to apply the *Guidelines for the Supervisory Agencies of the Federal States of Germany for the Implementation of Official Control in Meat Processing Enterprises Licensed for Export in the U.S.,* hereafter the "*German Guidelines 2.0.*" The AVV LmH, therefore, establishes the requirements within the *German Guidelines 2.0* as mandatory provisions under German federal authority.

BVL achieves oversight of the Federal States through conducting correlation meetings with the Federal State competent authorities (CAs) to ensure that equivalent EU food hygiene and United States requirements are being uniformly applied and enforced in all certified establishments. The *Working Group for United States Export* consists of representatives of BmEL, BVL, and the CAs in the Federal States and its objective includes coordination with the Federal States on meat hygiene and technical issues of food of animal origin.

The workgroup is intended to meet regularly for the purposes of issuance and maintenance of the *German Guidelines 2.0* (recently updated), evaluation of audits and inspections of third countries, general issues concerning export to third countries, and preparation of training concepts. These meetings are also designed to include review of inspection information and data across the Federal States. The workgroup is also responsible for disseminating relevant information to Federal State district veterinary offices. The FSIS auditor verified that the workgroup has met approximately twice each year to ensure coordination among Federal States including analysis of data and results for the purpose of identifying trends to adjust procedures or training.

Each Federal State, typically at the District Veterinary Authority level, is responsible for developing, issuing, and implementing guidelines and instructions specific to United States requirements in accordance with the *German Guidelines 2.0.* These instructions include the frequency of supervisory reviews and report format; the verification frequencies; procedures and recordkeeping system for official verification results; ongoing training and training plans; export certifications; and microbiological sampling plans.

Regulation (EC) No. 178/2002, Chapter IV, Article 50 establishes the Rapid Alert System for Food and Feed (RASFF) and the *Commission Regulation (EU) No. 16/2011* lays down the implementing measures for the RASFF. RASFF is utilized to inform the public of a direct or indirect risk to human health that is derived from food. The system is a network to share information among the food safety authorities of the EU Member States, the Commission, and some European countries that are not members of the EU. Germany requires certified establishments to have effective procedures to deal with any food safety hazard and to enable the complete, rapid recall of any implicated lot of the finished food from the market.

The German provision *General Administrative Rules for the Implementation of the Rapid Alert System for Food and Feed Notifications (AVV SWS)* lays down the procedures for notification. These general administrative rules set out clear responsibilities and criteria in relation to the preparation of notifications regarding food, food contact materials, and feeding stuffs. The *German Guidelines 2.0*, Section 6 describes the mechanisms in place concerning recall of consignments, lot identification for traceability, and seizure. The FSIS auditor noted that each audited certified establishment maintained comprehensive recall procedures and records to conduct trace-back activities if adulterated product were exported to the United States.

The *German Guidelines 2.0* contain the export requirements for all establishments certified as eligible for export to the United States, including control procedures to ensure that the source meat products used in processing operations originate only from certified establishments in eligible countries. At each audited establishment, the FSIS auditor verified the process and records used to ensure and document that source pork meat originated from animals slaughtered in certified establishments in eligible countries. Each shipment received at certified establishments in Germany is under official seal and accompanied by certification from the national government of the originating country. In addition, at the time of export certification, official inspection personnel verify the implementation of pre-shipment procedures conducted by the establishment, which includes review of all source documentation along with production records to ensure all products certified for export to the United States meet requirements. The FSIS auditor directly observed the inspection personnel's verification process and verified that inspection personnel were familiar with and routinely reference the FSIS country and establishment eligibility lists on the FSIS website.

LMHV, *Article 9*, provides the national legal basis for certification of establishments for export and states that Germany will implement *Regulation (EC) No. 178/2002, Article 12*. The Federal States are responsible for certifying the eligibility of establishments for export to the United States. The establishment approval procedures are defined in the AVV LmH. The *German Guidelines 2.0, Section B, Chapter I*, contains a flow diagram that shows the step-by-step approval process for designating establishments eligible for export to the United States.

Approval is based on the results of the document reviews, on-site visits, and verifying the implementation of any applicable corrective actions. Each Federal State has the sole authority to grant final certification of a new establishment or to permit an existing certified establishment to maintain its eligibility for export to the United States. However, the CCA also conducts an audit of all establishments prior to initial certification and if there are any findings, the Federal State

approval authority verifies appropriate corrective actions and determines final eligibility. BVL provides an initial and annual establishment eligibility certification to FSIS.

The FSIS auditor verified that Germany prevents fraud or misuse of export health certificates by issuing export health certificates using an online database, *Zentrale Tierseuchendatenbank* (TSN). TSN provides the export certificate template and the certification authority issues unique certificate numbers and completes shipment information. The BmEL issued written procedures, *Information about the Issuing of Official Veterinary Certificates for Exportation* that provide instructions for issuance of export certification that must be adopted by each Federal State. The FSIS auditor verified that tracking systems are in place by the district inspection office and updated by the Frontline Supervisor (FLS) who signs, issues, and maintains all export health certificates (paper-based), government seals, and security accountability logs in a secured, locked environment. BVL requires establishments to hold all product that undergoes sampling for microbiological testing until results are received and found negative as instructed in the *German Guidelines 2.0.*

BVL administers the FIS-VL central document management and information platform for food safety and consumer protection. The platform is secure and accessible by the CCA and official personnel in each Federal State and includes restricted areas for the working groups. The CCA disseminates uniform instructions to the Federal States including information about the approval and eligibility certification, templates for certification of establishment eligibility, relevant FSIS legislation and policy, guidelines and training material developed by the *Working Group for United States Export*, and minutes of the workgroup's meetings. FIS-VL also provides users email notification when new documents have been uploaded to the system. The FSIS auditor verified access and routine use of FIS-VL by the audited district office.

The FSIS auditor verified that official inspection personnel assigned to certified establishments exporting pork products to the United States are government employees paid by the German government. The Federal State inspection service is funded by the Federal State administration, and inspectors are paid directly by the Federal State authorities. Within each Federal State, the FSIS auditor verified documentation demonstrating government employment. Each Federal State has the authority and responsibility for hiring and assigning competent, qualified inspection personnel to perform inspection and enforcement activities at the regulated establishments, including establishments certified as eligible to export product to the United States, and for discharging inspection personnel.

To comply with *Regulation (EC) No. 882/2004, Article 4 (subparagraph 2b),* the CAs in the Federal State ensure that personnel who conduct official inspection tasks are free from any conflict of interest and are not permitted to seek employment outside of their official capacity for the government. The FLS is always an Official Veterinarian (OV) that meets the EC requirements for education and training. The FLS is responsible for implementing and enforcing inspection requirements at establishments certified as eligible for export to the United States. The FLS is also responsible for ensuring adequate staffing coverage during operations requiring inspection. Each official establishment has assigned an inspector-in-charge (IIC) that may be an OV or Food Inspector (FI) under the supervision of the FLS. In addition, each district inspection office also includes one or more deputy FLSs and deputy IICs.

The FLS and IIC are responsible for carrying out all required daily inspection activities in certified establishments. The *German Guidelines 2.0* describes the requirement that inspection by the IIC must be carried out at least once per day at certified establishments during the production of products for export to the United States. The inspection must be conducted in all shifts as well as during any changes in shifts or products. The FSIS auditor verified that staffing plans were adequate to ensure official inspection coverage during each production period of eligible product. The FSIS auditor's reviews of these records verified that an FLS and IIC were present at each audited establishment at least once per production shift during the processing of meat intended for export to the United States.

The FSIS auditor verified that inspection personnel have the appropriate educational credentials and training to perform their inspection tasks. In accordance with *Regulation (EC) No. 854/2004, Annex I, Section III, Chapter IV*, Germany ensures that official inspection personnel have appropriate education credentials, and necessary training and experience to perform inspection tasks. OVs must have a Doctor of Veterinary Medicine or equivalent degree and receive practical training for a probationary period of at least 200 hours before starting to work independently. Official Auxiliaries, including FIs, are required to have at least 500 hours of theoretical training and at least 400 hours of practical training, after which they must pass specific examinations before being qualified to work in export meat establishments. The FSIS auditor reviewed documentation for a select number of OVs at establishments certified to export to the United States to verify that they had the required veterinary degrees.

The FSIS auditor verified that BVL and Federal State ministries have implemented and conducted initial and yearly ongoing training programs intended to ensure that inspection personnel are aware of specific food safety and inspection requirements of FSIS import regulations and of Germany's regulations for pork export to the United States. BVL plans training activities for the CAs and the official inspection personnel of all the Federal States and provides training on the spot at establishments. Each Federal State and district office also conducts training with specific topics related to United States requirements typically presented by the FLS. The FLS subsequently trained deputy FLSs, OVs, and FIs based on the same training materials.

The FSIS auditor verified the training records of FLSs and IICs in addition to observing official inspection personnel while they were conducting their inspection activities. The FSIS auditor reviewed the recent training provided by BVL and the districts, which included requirements for sanitation SOPs; Good Manufacturing Practices; HACCP; and collection of microbiological samples for *Salmonella* and *Lm*. All trainings include a success control (e.g., test) after receiving the training to monitor and to assess whether the participants understood and assimilated the content of the trainings. The FSIS auditor verified that ongoing training materials, including program updates in inspection-related issues and procedures, and training participation records were maintained at all levels of authority.

Germany ensures that adequate administrative and technical support is available to its laboratory system in accordance with the EU regulations. BVL has designated one official microbiology laboratory to conduct analyses of official samples from all establishments certified for export to the United States. The official laboratory is the LAVES in Oldenburg. The laboratory is

organized into four professional and technical departments along with one administrative department. The laboratory performs microbiological analyses for *Salmonella* and *Lm* in RTE meat products and from environmental sponge samples. LAVES maintains administrative and technical support staff to operate its laboratory system.

The FSIS auditor visited LAVES and verified that the laboratory conducting analyses of processed pork products exported to the United States operates in accordance with the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025, *General requirements for the competence of testing and calibration laboratories,* standard. The ISO/IEC 17025 accreditation standard covers the management and quality assurance aspects of the functions of the laboratory to ensure that it has the capability to support BVL's inspection program for certified establishments eligible to export to the United States.

The government laboratory is ISO/IEC 17025 accredited by the German Accreditation Service, *Deutsche Akkreditierungsstelle GmbH (DAkkS*) with three audits carried out per each five-year accreditation cycle. The FSIS auditor verified that the DAkkS accreditation certificate, dated March 7, 2019, included FSIS methods of analysis used in the official laboratory were included in the scope of accreditation for the laboratory: *Microbiology Laboratory Guidebook* (MLG) 4.10: *Isolation and Identification of Salmonella from Meat, Poultry and Egg products*; and *MLG 8.11: Isolation and Identification of Lm from Red Meat, Poultry, Egg, and Environmental Samples*.

The FSIS auditor verified LAVES's oversight functions and the ability to evaluate laboratory performance, including proficiency testing for analyses and evaluations of the quality controls maintained by laboratory managers. FSIS also verified that laboratory analysts possess relevant academic and technical credentials as analysts in their specialty areas. Documentation on file also demonstrated that the analysts possess the academic qualifications, technical credentials, and accreditations required to conduct analysis within their accreditation scope. In addition, the FSIS auditor reviewed the DAkkS accreditation audits and internal annual laboratory audit program reports generated for the previous year and its related follow-up reviews and verified that corrective actions were documented in an action plan and were adequate to address the findings, which demonstrated that LAVES provides technical support to the laboratories. No concerns arose as the result of these reviews.

The FSIS auditor determined that Germany's government continues to organize and administer the country's food safety inspection system to provide ultimate control, supervision, and enforcement of regulatory requirements. BVL officials enforce laws and regulations governing production and export of processed pork at establishments certified as eligible to export to the United States.

V. COMPONENT TWO: GOVERNMENT STATUTORY AUTHORITY AND FOOD SAFETY AND OTHER CONSUMER PROTECTION REGULATIONS (E.G., INSPECTION SYSTEM OPERATION, PRODUCT STANDARDS AND LABELING, AND HUMANE HANDLING)

The second of six equivalence components reviewed by the FSIS auditor was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of each and every carcass and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; periodic supervisory visits to official establishments; and requirements for thermally processed/commercially sterile (TPCS) products.

Germany's *LMHV* implements *Regulation (EC) No. 852/2004, Regulation (EC) No. 853/2004,* and *Regulation (EC) No. 854/2004*. As previously noted, the AVV LmH requires that each Federal State apply the *German Guidelines 2.0* for certified establishments that export products to the United States. The *German Guidelines 2.0* reference the requirements for consistency with 9 CFR Parts 416, 417, and 430 and reference FSIS policies including *FSIS Directive 5000.1, Verifying an Establishment's Food Safety System*.

The FSIS auditor reviewed records maintained at BVL headquarters, district inspection office (supervisory) records, and local inspection records for each audited establishment. The FSIS auditor verified whether BVL provides appropriate oversight and direction to inspection personnel for them to use their regulatory authority to enforce requirements for Germany's meat food safety system. The FSIS auditor, accompanied by BVL, Federal State ministry representatives, and district office FLS' observed the performance of verification activities by the inspection personnel.

The FSIS auditor verified that a BVL representative of the government meat inspection system conducts periodic supervisory visits to each certified establishment to evaluate the performance of inspection personnel. Supervisory visits (supervisor reviews) are conducted to verify each certified establishment's continued conformance with *Regulation (EC) No. 178/2002*, *Regulation (EC) No. 852/2004*, and *Regulation (EC) No. 854/2004*. The *German Guidelines 2.0* describe the procedure for supervisory review and specifies who performs the supervisory visits, the review frequency, the scope of the review, and methods of documentation of the review findings.

The FLS, an OV at the district inspection office, is responsible for oversight of the official activities of inspection personnel and for conducting supervisory visits to meet 9 CFR § 327.2 requirements. Periodic supervisory visits are conducted in the form of an audit at certified establishments eligible for export to the United States. The *German Guidelines 2.0* set a minimum frequency of two supervisory visits per year for certified establishments. However, some of the audited Federal States have implemented a higher frequency for reviews, up to monthly.

The *German Guidelines 2.0* also establishes weekly monitoring frequencies for FLS' in newly certified establishments, decreasing to monthly with subsequent frequencies dependent on conditions in the establishment. The scope of the audit is in accordance with *Regulation (EC) No. 854/2004, Article 4*. The scope includes: receiving food products (goods receipt), hygiene in the establishment, sanitation SOP, personal hygiene, temperature control, pest control, water hygiene, disposal of substances unfit for human consumption, HACCP, product hygiene, emergency concept of the establishment (crisis management traceability), finished food products (goods shipping), and *Lm* and *Salmonella* measures.

The FSIS auditor assessed the procedures and completion of multiple periodic supervisory visit reports and inspection-related records of certified establishments eligible for export to the United States. The FSIS auditor concluded that the FLS' conduct these reviews at the intended frequencies, document their findings, and verify the implementation of the corrective actions through document review or during the next on-site supervisory review.

The FSIS auditor verified that there are procedures designed to ensure separation of product eligible for export to the United States and that official inspection personnel verify that operators comply with the requirements for separation of product destined for the United States. The *German Guidelines 2.0*, *Chapter 8*, requires food business operators to clearly identify each batch of product and that strict protocols are implemented at each certified establishment for official verification of every lot of raw product received at the certified processing establishments. The IIC verify that operators comply with the requirement for separation of product destined for the United States.

The *German Guidelines 2.0* contain the export requirements for all establishments certified as eligible for export to the United States, including control procedures to ensure that the source meat products used in processing operations originate only from certified establishments in eligible countries. The FSIS auditor verified that the audited establishments processed only meat from swine that were slaughtered from an approved source that is eligible to export to the United States. Currently, Germany's certified establishments eligible to export product to the United States only use raw pork products received from Denmark and Netherlands (approved sources) for processed product produced in Germany for export to the United States.

The FSIS auditor verified that each establishment had implemented programs designed to ensure traceability of all product destined for the United States and identification labeling and segregation in time and/or space. In addition, the FLS and other inspection personnel verify the implementation of pre-shipment procedures according to the *German Guidelines 2.0, Chapter 8*, prior to certification. The pre-shipment review includes a complete document package for each production lot from receiving raw meat through packaging and labeling. The pre-shipment review includes the review and confirmation of testing results from samples of products tested for adulterants (such as residue, species identification, raw material/product, and microbiological samplings) and the verification of the unique identification of the batch (e.g., labels, lot markings, and shipping marks). No export certification will be issued if any deficiencies in eligible source product or segregation procedures are identified. The FSIS auditors verified that measures designed to ensure segregation were effectively implemented in each audited establishment.

The FSIS auditor verified that BVL ensures that pork exports are not subject to animal health restrictions by regularly consulting the relevant sections of the APHIS website in addition to FSIS' product eligibility chart for individual countries, which also considers current APHIS restrictions, and APHIS Email Subscription Service or via official channels such as the Federal Ministry or the German Embassy (TSN – Animal Disease Notification System). BVL communicates newly issued import requirements to the CAs which then forward them to the official staff in the district. This communication includes animal disease status as defined by APHIS regulations and restrictions of products to be exported to the United States. Consequently, only those products previously identified by BVL as meeting both FSIS and APHIS requirements can be certified for export to the United States. To ensure that only meat not restricted by APHIS is exported to the United States, the IICs at certified establishments verify the product and species when receiving the product and prior to signing the export certificate.

The FSIS auditor verified controls over inedible materials and products in each certified establishment. The IIC verifies that each establishment is responsible for implementing programs to ensure proper control and disposition of inedible material and product not fit for human consumption in accordance with *Regulation (EC) No. 1069/2009* and *Regulation (EC) No. 142/2011.* The FSIS auditor verified the proper handling of inedible materials, that they were appropriately identified and segregated in specially-marked containers, and that the IIC verified documentation according to the *German Guidelines 2.0, Annex 2*.

Germany's food safety system continues to maintain the legal authority, a regulatory framework, and adequate verification procedures to ensure sufficient official regulatory control actions to prevent products from contamination when insanitary conditions or practices are present, which as described, is consistent with criteria established for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of six equivalence components reviewed by the FSIS auditor was Government Sanitation. The FSIS auditor verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation SOPs to prevent direct product contamination or insanitary conditions.

Germany follows and enforces overarching EC sanitary regulations, including *Regulation (EC) No. 852/2004*, *Regulation (EC) No. 853/2004*, and *Regulation (EC) No. 854/2004*. *Regulation (EC) No. 852/2004* ensures that each official establishment operates in a sanitary manner to prevent insanitary conditions. The inspection system focuses on the aspects of the establishment's sanitation that pose a risk of causing direct product contamination. In addition, the *German Guidelines 2.0, Chapter 3*, provides requirements for the implementation consistent with 9 CFR § 416 and requires that each certified establishment eligible for export to the United States develop, implement, and maintain written sanitation SOPs. Germany requires that establishments have an effective enforcement program that includes corrective actions being taken, and actions taken to prevent product contamination when insanitary conditions or contaminated products are found.

The *German Guidelines 2.0*, *Chapter 3,* provides general instructions for inspection personnel at certified establishments for the verification consistent with 9 CFR § 416 sanitation requirements. The verification methods include monitoring and implementation of sanitation procedures, record review, and hands-on verification inspection of both pre-operational and operational sanitation procedures. The frequency of sanitation SOP verification tasks is set as daily for IICs in certified establishments during the production of products for export to the United States. Deficiencies observed during the official verification task must be recorded, appropriate measures must be taken, and follow-up verification tasks are to be conducted to confirm that the deficiencies were eliminated and properly documented. Additionally, it indicates that IICs are to conduct ongoing inspection that includes the examination and evaluation of the documents generated by the certified establishments.

The FSIS auditor assessed the adequacy of pre-operational sanitation by observing official inspection personnel conducting pre-operational verification of the establishment's sanitation program at one of the audited establishments. The in-plant inspection personnel conducted this activity in accordance with the established procedures including an organoleptic inspection of FCS of facilities, equipment, and utensils, as well as an assessment of sanitation performance standards (SPS) requirements (e.g., ventilation, condensation, and structural integrity).

The FSIS auditor also observed in-plant inspection personnel's verification of operational sanitation in all six audited establishments. The FSIS auditor's verification activities included direct observation of production operations, overall sanitary conditions of production and storage areas, interviews with inspection personnel, and review of the establishments' written sanitation programs and related records at all establishments. The FSIS auditor also examined documentation of inspection verification results and noncompliance records in addition to supervisory review reports. The FSIS auditor's review of records demonstrated that upon the identification of a noncompliance, the establishment took corrective actions and inspection personnel verified that the corrective actions were implemented and effective.

The FSIS auditor also noted that the government inspection and establishment records were representative of the actual sanitary conditions of the establishment, although isolated findings that are noted on the individual establishment checklists attached to this report (Appendix A). The FSIS auditor concluded that BVL requires establishments certified to export to the United States to develop, implement, and maintain sanitation programs consistent with 9 CFR § 416 to ensure that establishment construction, facilities, and equipment prevent the contamination or adulteration of meat products destined for United States export.

VII. COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM

The fourth of six equivalence components reviewed by the FSIS auditor was Government HACCP System. The food safety inspection system is to require that each official establishment develop, implement, and maintain a HACCP system.

Germany follows and enforces overarching EC sanitary regulations, including *Regulation (EC) No. 852/2004* and *Regulation (EC) No. 854/2004*. *Regulation (EC) No. 852/2004 Chapter II, Article 5* requires each establishment to develop, implement, and follow procedures based on the HACCP principles. *Article 5, Section 1(a)* requires establishments to identify hazards which can be prevented, eliminated, or reduced to an acceptable level. *Article 5, Sections (e)* and *(f)* of this same EC regulation requires that food business operators take corrective actions if a critical control point (CCP) is not under control, and they must develop and implement procedures to routinely ensure that the procedures based on the HACCP principles (HACCP plan) are efficient.

The CCA adopted FSIS requirements cited in 9 CFR § 417 for the implementation of HACCP. The *German Guidelines 2.0, Chapter 4*, contains provisions that are consistent with the HACCP requirements cited in 9 CFR § 417 which requires that establishments certified eligible for export to the United States: (1) identify food safety hazards that can affect the safety of products, and institute the controls necessary to prevent those hazards from occurring or keep them within acceptable limits and (2) develop, implement, and maintain a HACCP system. In addition, the CAs must verify compliance according to the requirements defined in 9 CFR § 417.8. The initial certification audit process includes an evaluation of establishment HACCP systems including the flow chart, hazard analysis, and HACCP plans by the responsible district office as well as the CCA.

Once certified, the annual review of each certified establishment's HACCP system is conducted by the responsible district office by means of a HACCP Activity Verification (HAV)-Task of the *German Guidelines 2.0, Annex 11,* prior to the granting of annual export certification renewal, communicated to FSIS by the CCA. This verification activity is conducted at least once a year or more often if determined to be necessary by the CA's quarterly examination. The frequency of HACCP inspection verification tasks of CCPs conducted by the IIC is at least once per day at certified establishments during the production of products for export to the United States. The inspection must be conducted in all shifts as well as during any changes in shifts or products.

The FSIS auditor also observed in-plant inspection personnel's implementation of government verification of HACCP systems in all six audited establishments. The IICs are responsible for performing verification activities that include the review of the establishment's written HACCP plans and their contents, review of establishment-generated HACCP monitoring and verification records, and direct observation verification of those procedures by the establishment to assess the adequacy of implementation of HACCP plans on the part of the establishments.

The FSIS auditor's verification activities included direct observation, interviews with inspection personnel and review of the establishments' HACCP systems, including flow charts, hazard analyses, HACCP plans, and related records at all establishments. The FSIS auditor examined documentation of inspection verification results and noncompliance records as well as supervisory review reports. The FSIS auditor also confirmed that inspection personnel were conducting verification activities in accordance with the aforementioned documents.

The FSIS auditor's review of records demonstrated that, upon the identification of a noncompliance, the establishment took corrective actions and preventive measures and

inspection personnel verified that those actions were implemented and effective. However, the FSIS auditor identified the following findings:

- In two of the six audited establishments, there was inadequate government verification of HACCP requirements. The Inspection personnel did not identify that the written HACCP plan did not include one or more of the following elements required by the *German Guidelines 2.0*, which are consistent with 9 CFR § 417.2: monitoring procedures and frequencies, and ongoing verification procedures and frequencies.

- In two of the four audited establishments that produce RTE dry cured hams, there was inadequate government verification of the HACCP requirements. The hazard analyses did not identify microbiological controls for *Salmonella* within all process steps; however, the establishment process had validated/scientific documentation. A Challenge Study and inherent controls were in place that monitored (e.g., water activity and pH) and verified (microbiological sampling) product to demonstrate the safety of the product.

The FSIS auditor's on-site verification activities and analysis indicate that BVL requires operators of establishments certified to export to the United States to develop, implement, and maintain HACCP systems. However, the current audit identified noncompliance with basic HACCP requirements at two audited establishments. The FSIS auditor analyzed these findings at each establishment including the production processes, sampling results, export history, and overall food safety controls before concluding there were not any immediate concerns regarding the safety of products destined for export or of those previously exported to the United States.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth of six equivalence components reviewed by the FSIS auditor was Government Chemical Residue Testing Programs. The food safety inspection system is to present a chemical residue testing program, organized and administered by the national government, which includes random sampling of internal organs, fat, and muscle of carcasses for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants.

Prior to the on-site visit, FSIS' residue experts reviewed the German National Residue Control Program (NRCP) for 2018, associated methods of analysis, and additional SRT responses outlining the structure of Germany's chemical residue testing program. Germany's NRCP includes testing imported meat products for the presence of chemical residues. Germany's NRCP is based on EU legislation (*Council Directive 96/22/EC of 29 April 1996* and *Council Directive 96/23/EC of 29 April 1996*). These documents prescribe conditions of chemicals used in the production of meat, including animal feed; provide authority to prohibit the use of compounds that may present public health risks; and provide the ability to control and monitor industrial and environmental chemicals. These documents also indicate that Germany maintains the legal authority to regulate, plan, and execute activities aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in the tissues of livestock slaughtered for human consumption.

Germany does not currently have any pork slaughter establishments certified as eligible to export product to the United States, and all raw source materials are imported from eligible establishments in Denmark and Netherlands. Consequently, Germany is reliant on the national residue monitoring programs of these countries and also conducts random testing of imported raw meat products under its "Import Residue Control Plan". Germany's CCA routinely reviews the monitoring results of these countries as well as RASFF for any documented cases of product exceeding accepted residue levels.

The FSIS auditor verified that the audited establishments' hazard analyses addressed potential hazards associated with chemical and environmental residues. The FSIS audits of the meat inspection systems for both Denmark (2018) and the Netherlands (2017) did not identify significant findings related to the control of chemical residues. Furthermore, there have not been any POE violations for chemical residues from Germany, Denmark, or the Netherlands since their last FSIS audits.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth of six equivalence components reviewed by the FSIS auditor was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that meat products prepared for export to the United States are safe and wholesome.

The FSIS auditor verified Germany's microbiological sampling and testing programs through direct observation, document reviews, and interviews of CAs and microbiological laboratory personnel to verify government microbial testing programs. The FSIS audit included five establishments producing post-lethality exposed (PLE) RTE products, and one establishment producing TPCS products. In addition, the official LAVES microbiology laboratory in Oldenburg was audited. BVL maintains the regulatory definition for RTE product provided in *Regulation (EC) No. 2073/2005*, "RTE means food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level micro-organism of concern".

The *German Guidelines 2.0, Chapter 7, Measures Against Listeria monocytogenes and Salmonella*, adopts the United States controls consistent with 9 CFR § 430.4, by requiring the certified establishments producing PLE RTE product to identify and implement control programs designed to prevent adulteration of RTE products with *Lm*. BVL considers *Salmonella* and *Lm* to be adulterants in RTE products and considers RTE products that test positive for *Lm* and RTE products that come into direct contact with an FCS that has tested positive for *Lm* to be adulterated and requires that establishments take appropriate corrective action in response to positive sample results. The *German Guidelines 2.0* provide a definition of "Product Lot" as the amount of product that could be affected by a positive test result, normally defined as all product produced from clean-up to clean-up.

These guidelines also describe the official verification responsibilities and official sampling programs designed to ensure the requirements are met. On an ongoing basis, the official

inspection personnel verify the implementation and effectiveness of the control measures in certified establishments that export RTE products to the United States. The official inspection personnel conduct verification activities in RTE establishments by conducting verification sampling of PLE RTE products, product contact surfaces, and the environment at a frequency that ensures that the establishments' control measures are effective for both adulterants. The official inspection personnel verify that the establishment's written programs meet requirements including the location of sampling, randomness of sampling, and sample integrity.

The BVL microbiological sampling program provides sampling and testing for *Lm* and *Salmonella* in RTE meat products and FCS for *Lm*. The *German Guidelines 2.0*, *Chapter 7* identifies the frequency for product samples. Government testing of RTE product is both risk-based and random and the minimum number of samples are specified in the *German Guidelines 2.0*. Additional samples are taken as determined appropriate by the CA. The FSIS auditor verified the results of the official RTE product samples for each audited establishment. The FSIS auditor identified that the CCA's official verification sampling frequency is based on each establishment's selected *Lm* alternatives.

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 for Alternative 3. The CCA's official *Lm* verification sampling also included at least ten food contact surfaces/year and five non-food contact surfaces/year. In most cases, the number of samples greatly exceeded the number defined in the *German Guidelines 2.0*. The FSIS auditor verified that the official inspection personnel collected official RTE verification samples at the required frequency and as described by the *German Guidelines 2.0, Chapter 7.* Additionally, the FSIS auditor reviewed the hazard analyses and written sanitation programs in the five PLE RTE audited establishments and verified that all elements required were met. No concerns were identified.

FSIS identified one POE violation for *Lm* for RTE, salt-cured, sliced pork since the last FSIS audit conducted in 2017. In response, the producing establishment investigated and revised the HACCP plan to include a validated/scientifically supported post-packaging treatment step in the process to prevent recurrence. The CAs also investigated the establishment in response to the violation and verified effectiveness of the corrective actions. The FSIS auditor verified implementation of the corrective actions and official verification activities in the establishment. No concerns were identified.

The FSIS auditor conducted an on-site audit of the LAVES, the only microbiological laboratory providing technical support to Germany's food safety inspection system. The audit included interviews with the laboratory management, document reviews including the Quality Control Manual, and observations of the laboratory. The FSIS auditor verified that the laboratory conducting microbiological analytical testing for products destined for export to the United States was accredited by DAkkS as meeting ISO/IEC 17025 standard.

The FSIS auditor reviewed the most recent accreditation audit report of the laboratory dated March 7, 2019, and verified that the findings reported during laboratory audits were promptly addressed and documented as required by the ISO/IEC 17025 standard with corrective action

plans in response to the audits. The audit reports reviewed at the laboratory demonstrated that the technical and organizational aspects of the functions of the laboratory were periodically evaluated by the laboratory quality control manager (internal audits), and by a third-party accrediting institution.

The FSIS auditor verified that the LAVES microbiology laboratory has implemented FSIS MLG methods for analysis of environmental and RTE products for *Lm* and *Salmonella* as described in the *German Guidelines 2.0*. The laboratory methods for official verification sampling for RTE products analysis for *Salmonella* (325g sample size) is performed according to MLG 4.10 and for *Lm* analysis (25g sample size) is performed in accordance with FSIS MLG 8.11. Official routine food contact and environmental surfaces verification sampling and intensified verification sampling analysis for *Lm* is performed in accordance with FSIS MLG 8.11 and *Salmonella* is performed according to MLG 4.10 using the sponge or swab method.

The FSIS auditor verified that analysts assigned to the microbiological laboratory have documentation of analysts' proficiency evaluations and testing results, specialized training logs that qualify them to conduct the analytical methods for detection and quantification in their scope of accreditation. In addition, the laboratory conducts Fapas® proficiency tests annually using FSIS MLG methods for *Lm* and *Salmonella*. The analysts conducting the analyses are rotated to ensure each analyst is evaluated over time. The FSIS auditor reviewed documented results and found that proficiency testing was implemented, as well as testing associated with the methods and found the results to be acceptable. A calibration plan was included for all instruments and equipment. The FSIS auditor confirmed the use of calibrated thermometers on relevant equipment such as incubators.

The handling of samples to ensure sample integrity and chain of custody is required by *Regulation (EC) No. 882/2004, Article 11*, Methods of Sampling and Analysis. The FSIS auditor evaluated the procedures for receipt of samples and observed the process. At receiving, laboratory personnel verify that the sample shipment box is sealed with an official seal. In addition, the sample temperatures are obtained and recorded at receiving. Acceptable samples are logged into the laboratory's system database and assigned an order number. Once the sample proceeds for analysis, a unique laboratory identification number is assigned to accompany the sample through completion of analysis.

The FSIS auditor verified that the audited laboratory maintained appropriate discard criteria to ensure the integrity of the sample and testing results and traceability throughout sample receipt, analysis, and reporting per the laboratory Quality Control Manual; the laboratory performs a timely analysis of samples, and it reports the results in a timely manner to submitting officials. The laboratory results are distributed either via facsimile, email, or postal mail. The FSIS auditor evaluated results for certified establishments. The results reports maintained in the laboratory included all relevant paperwork and documentation from submission receipt through the analytical results report, including photographs of the RTE product samples (e.g., whole, packaged product) at receiving. No concerns arose from these observations and reviews.

The FSIS audit included one establishment producing TPCS products. Establishments in Germany producing TPCS product are required to address the hazards using HACCP principles

according to *Regulation (EC) No. 852/2004, Article 5*. In addition, *Regulation (EC) No. 852/2004, Annex 2, Chapter XI*, sets requirements for food placed on the market in hermetically sealed containers by stating that the heat treatment process used to process an unprocessed product or to process further a processed product is: (a) to raise every part of the product treated to a given temperature for a given period of time; and (b) to prevent the product from becoming contaminated during the process. The CCA advised that the requirements as documented in Codex Alimentarius CAC/RCP 23-1979 2.9, Commercial Sterility of Thermally Processed Food, apply to all certified establishments producing TPCS products for export to the United States.

The FSIS auditor verified that the TPCS establishment has implemented a HACCP system including a CCP for a validated thermal process to meet commercial sterility requirements. The FSIS auditor also verified requirements related to closure of containers (glass jars), training of technicians, and additional operations (e.g., filling, posting of processes, retort traffic control, initial temperature) conducted in thermal processing areas. No concerns were identified.

In TPCS establishment, the CAs take official samples for verification. The analysis is conducted in official laboratories. Test procedures are set in the *German General Administrative Provision for Meat Hygiene (AVV), Annex 4, No 2 Bacterioscopic Investigation of Meat Products (includes thermally processed - commercially sterile)* and in the German Collection of Laboratory Methods as mentioned in *German Food Law 64*, (e.g., *Salmonella*, *Lm*, *Clostridium botulinum*, total viable colony count, *E. coli*, etc.). The FSIS auditor verified laboratory results documenting these analyses. No concerns were identified.

The FSIS auditor verified that Germany's food safety inspection system continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system aimed at controlling the presence of microbiological pathogens in pork (meat) products exported to the United States to ensure the products are unadulterated, safe, and wholesome in accordance with United States requirements. The CCA's food safety system continues to meet the core requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held with BVL on March 29, 2019, in Berlin, Germany. At this meeting, the FSIS auditor presented the preliminary findings from the audit. An analysis of the findings within each component did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditor identified the following finding:

GOVERNMENT HACCP SYSTEM

- In two of the six audited establishments, there was inadequate government verification of HACCP requirements. The Inspection personnel did not identify that the written HACCP plan did not include one or more of the following elements required by the *German Guidelines 2.0*, which are consistent with 9 CFR § 417.2: monitoring procedures and frequencies, and ongoing verification procedures and frequencies.

- In two of the four audited establishments that produce RTE dry cured hams, there was inadequate government verification of HACCP requirements. The hazard analyses did not identify microbiological controls for *Salmonella* within all process steps; however, the establishment process had validated/scientific documentation.

The audit findings did not represent a potential to endanger public health because they involved recordkeeping and necessary technical clarifications. During the audit exit meeting, the Central Competent Authority (CCA) committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the CCA's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

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 Ammerlandische Fleischwarenfabrik Fritz Meinen GmbH & Co. KG Meicastrasse 6 26188 Edewecht Niedersachsen	03/25/2019	EV-34	Germany
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[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.	
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	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	O
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	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/25/2019

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 Str. 40 26188 Edewecht Niedersachsen	03/26/2019	A-EV-35	Germany
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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.	X
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.	
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	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	O
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	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

The following non-compliances were not identified by Germany's inspection officials during the establishment review:

HACCP – Basic Requirements:

15/51 Hazard Analysis:

The establishment's written HACCP Hazard Analysis did not identify *Salmonella* lethality controls for dry curing RTE ham processing steps although the processes had a scientific supporting documentation including a Challenge Study in place and inherent controls in place that were monitored (e.g., water activity, and pH) and verification activity (microbiological sampling) that was conducted to demonstrate the safety of the product.

Sanitation SPS

The FSIS auditor observed the following non-compliances during the establishment tour.

39/51 Facility Construction/Maintenance:

In the post hot smoke ham maturing storage room: a water drain line that protrudes from the ceiling was observed to showed signs of leaking. This storage room contains ham product that has been hot smoked and which once reaching the end of the maturing stage will proceed to the cubing department. All product is in immediate casing that are stripped from the product prior to cubing. No product was directly under the drain and the establishment had not product produced for the United States at the time of the audit.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/26/2019

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 Nurnberg Bayern	03/20/2019	EV-717	Germany
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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.	X
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.	
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	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	O
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	X
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	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

The following non-compliances were not identified by Germany's inspection officials during the establishment review:

HACCP – Basic Requirements:

15/51 The establishment's written HACCP plan did not include or adequately describe the following elements required by 9 CFR Part 417.2(c):

- The procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the CCPs to ensure compliance with the critical limits.

Sanitation SPS

The FSIS auditor observed the following non-compliances during the establishment tour.

45/51 Establishment Maintenance:
Post packaging pasteurization room: developing rust

- On structures that support the conveyor belt system that carries the vacuum packaged product through the post packaging pasteurization process.
- On conveyor belt sides that maintains the product on the belts around curves which makes incidental contact with packaged product.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/20/2019

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
Schinkenhof GmbH & Co., KG Severinstraße 12 77855 Achern	03/21/2019	BW 05068	Germany
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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.	X
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.	
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	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

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	X
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	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	X
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

The following non-compliances were not identified by Germany's inspection officials during the establishment review:

HACCP – Basic Requirements:

15/51 The establishment's written HACCP plan did not include or adequately describe the following elements required by 9 CFR Part 417.2(c):

- The procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the CCPs to ensure compliance with the critical limits,
- The procedures, and the frequency with which those procedures will be performed that will be used in verification of CCPs monitoring.

- Hazard Analysis:
  The establishment's written HACCP Hazard Analysis did not identify *Salmonella* lethality controls for dry curing RTE ham processing steps although the processes had scientific supporting documentation including a Challenge Study in place and inherent controls in place that were monitored (e.g., water activity, and pH) and verification activity (microbiological sampling) that was conducted to demonstrate the safety of the product.

Sanitation SPS

The FSIS auditor observed the following non-compliances during the establishment tour.

41/51 Ventilation:
Beaded condensation was observed on the ceiling in the product transfer area between the ham second application of brine and the ham racking area for cold smoke. No product was present at the time passing through the area.

45/51 Equipment and Utensils:
Gray plastic spacers that are placed in containers between layers of exposed raw dry cured pork product were observed to have chipped frayed edges that laid directly over the product.

46/51 Sanitary operations:

- In the area were pork product is applied the first application of a dry salt cure, gray plastic spacers that are placed in containers between layers of exposed raw dry cured pork product were observed to be staged in close proximity to the floor creating an insanitary condition for the cross contamination of product from organic material on the floor or employee boots.
- In the ham "maturing room" where vacuum pack hams (immediate container) were stored in containers to further the process of "maturing" - red plastic containers holding the product were observed to be stacked with having a gray plastic pallet directly over the products in the middle of the stacked product creating an insanitary condition. There was no secondary covering of the product to preclude any cross contamination from the pallet onto the product's immediate container (covering).

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/21/2019

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. Produktions- und Vertriebs KG Draisstraße 1-5 76461 Muggensturm	03/22/2019	BW-03330	Germany
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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.	
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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 .	
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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	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	O
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	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/22/2019

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
Hans Kupfer & Sohn GmbH & Co. KG Mausendorfer Weg 11 91560 Heilsbronn	03/19/2019	BY-50008	Germany
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		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
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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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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.	
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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	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

Part D - Continued Economic Sampling	Audit Results
33. Scheduled Sample	
34. Species Testing	
35. Residue	O
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	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57. Periodic Supervisory Reviews	
58.	
59.	

60. Observation of the Establishment

There were no significant findings to report after consideration of the nature, degree, and extent of all observations.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/19/2019

Appendix B: Foreign Country Response to the Draft Final Audit Report

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

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

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Landwirtschaft
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Scientific Officer

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E-MAIL 180@bvl.bund.de

YOUR REFERENCE
YOUR LETTER OF

OUR REFERENCE 180.16461.0
(Please quote in answer) answering)

DATUM 18 September 2019

Comments on draft final report of FSIS 2019 audit of German meat inspection system

Dear Michelle Catlin

With this letter, I am sending you the response of the German Central Competent Authority (CCA) to the draft final report of the 2019 FSIS audit of the German meat inspection system for establishments eligible to export pig meat and meat products to the United States. The audit was conducted by the senior program auditor Dr Kenneth Witek from March 18 to March 29, 2019.

Please find the response of the German CCA and the Competent Authorities (CAs) of the Federal States attached to this letter.

Enclosure 1 shows a table mentioning comments like corrigenda and remarks related to the draft final report of the on-site audit of Germany's Meat Inspection System.
Enclosure 2 is listing all the corrective actions, including a root cause analysis as well as preventive measures to address the findings mentioned in the draft final report.

I thank you for the opportunity to comment on the report. Please let me know should you have remarks or require any further information.

Kind regards

Dr. Soumaya Lhafi
Head of Unit

Enclosure:

1. Comments CAs and CCA of the Federal Republic of Germany
2. Action Plan CAs and CCA of the Federal Republic of Germany

Stellungnahme

comments

Antwort der zuständigen Behörden der Bundesrepublik Deutschland bezüglich der Korrekturen und Anmerkungen in Bezug auf die Ausführungen des Entwurfs des Auditberichts zur Überprüfung des Überwachungssystems (Fleischhygiene), die in der nachfolgenden tabellarischen Übersicht aufgeführt werden. Das Audit wurde durch das Food Safety and Inspection Service (FSIS) des US Departments of Agriculture (USDA) der Vereinigten Staaten von Amerika im Zeitraum 18. März 2019 bis 29. März 2019 durchgeführt. Ziel des Audits war es zu überprüfen, ob die Äuivalenzanerkennung des deutschen Überwachungssystems hinsichtlich der Hygiene bei der Gewinnung von Schweinfleisch mit Bezugnahme auf § 327.2 des Code of Federal Regulations (CFR) aufrechterhalten werden kann.

Response of the competent authorities of the Federal Republic of Germany, concerning corrigenda and remarks related to the draft of the report of the on-site audit of Germany's Meat Inspection System, mentioned in the following table. The audit was carried out by the Food Safety and Inspection Service (FSIS) of the US Department of Agriculture (USDA) of the United States of America and was conducted from March 18 2019 to March 29 2019. The purpose of the audit was to determine, referring to § 327.2 of the Code of Federal Regulations (CFR), whether Germany's food safety system governing processed pork meat remains equivalent to that of the United States.

Bericht Teile I-X:

Report parts I-X:

Seite Nr. Page No.	**Text im Berichtsentwurf** Text in the draft report	**Formulierungsvorschlag** Proposed wording	**Begründung** Reasoning
4	… two laboratories, and five pork processing establishments	….one laboratory, and six pork processing establishments	Corrigendum in accordance with the final report of the audit 2017
6	Two ministries share responsibilities at the Federal level in the area of food: the Federal Ministry of Food, Agriculture and Consumer Protection (BmEL) and the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMUB). Within BmEL are the Federal Office of Consumer Protection and	Two ministries share responsibilities at the Federal level in the area of food: the Federal Ministry of Food, Agriculture and Consumer Protection (BMEL) and the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMUB). Within BMEL are the Federal Office of Consumer Protection and Food	Corrigendum of the Name The name of the Ministry is BMEL and not BmEL

	Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, BVL) and the Federal Institute for Risk Assessment (BfR). The BfR provides scientific counsel to BmEL….	Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, BVL) and the Federal Institute for Risk Assessment (BfR). The BfR provides scientific counsel to BMEL….	
6			Clarification concerning the responsibilities of the BVL
7	The *Working Group for United States Export* consists of representatives of BmEL,…	The *Working Group for United States Export* consists of representatives of BMEL,…	Corrigendum of the Name
8	RASFF is utilized to inform the public of a direct or indirect risk to human health that is derived from food. The system is a network to share information among the food safety authorities of the EU Member States, the Commission, and some European countries that are not members of the EU.	RASFF is utilized to inform the public of a direct or indirect risk to human health that is derived from food. The system is a network to share information among the food safety authorities of the EU Member States, the Commission, some European Countries that are not members of the EU and Third countries, e. g. the USA, as far as they are concerned.	Clarification concerning the sharing of information: the information is also shared with Third Countries concerned.
8	However, the CCA also conducts an audit of all establishments prior to initial certification and if there are any findings,…	However, the CCA also accompanies the audit of establishments prior to initial certification and provides advice concerning US requirements and if there are any findings,	Clarification concerning the accompanying of audits prior to initial certification
9	The BmEL issued written procedures, *Information about the Issuing of Official Veterinary Certificates for Exportation* that provide instructions for issuance of export certification that must be adopted by each Federal State.	The BMEL issued written procedures, *Information about the Issuing of Official Veterinary Certificates for Exportation* that provide instructions for issuance of export certification that is recomended to be adopted by each Federal State.	Corrigendum and Clarification
9	The FSIS auditor verified that tracking systems are in place by the district inspection office and updated by the Frontline Supervisor (FLS) who signs, issues, and maintains all export health	The FSIS auditor verified that tracking systems are in place by the district inspection office and updated by *either the Frontline Supervisor (FLS) or the Inspector in Charge (IIC) who* signs, issues,	Clarification concerning the responsibilities.

	certificates (paper-based), government seals, and security accountability logs in a secured, locked environment.	and maintains all export health certificates (paper-based), government seals, and security accountability logs in a secured, locked environment.	
9	…requires establishments to hold all product that undergoes sampling for microbiological testing until results are received and found negative as instructed in the German Guidelines 2.0.	…requires establishments to hold all product that undergoes official sampling for microbiological testing until results are received and found negative as instructed in the German Guidelines 2.0.	"Test and Hold" applies for official sampling
9	The FSIS auditor verified that official inspection personnel assigned to certified establishments exporting pork products to the United States are government employees paid by the German government. The Federal State inspection service is funded by the Federal State administration, and inspectors are paid directly by the Federal State authorities.	The FSIS auditor verified that official inspection personnel assigned to certified establishments exporting pork products to the United States are government employees paid by the government. Each Federal State has its own government and budegtary resources. The Federal State inspection service is funded by the Federal State budget, and inspectors are paid directly by the Federal State authorities.	Clarification
10	OVs must have a Doctor of Veterinary Medicine or equivalent degree	OVs must be licensed Veterinarians or have an equivalent degree	Clarification concerning Official Veterinarians
10	BVL has designated one official microbiology laboratory to conduct analyses of official samples…	There is one designated official microbiology laboratory which conducts analyses of official samples….	Clarification
11	BVL officials enforce laws and regulations governing production and export of processed pork at establishments certified as eligible to export to the United States.	Government officials enforce laws and regulations governing production and export of processed pork at establishments certified as eligible to export to the United States.	Clarification concerning the officials to enforce laws and regulations

12	The FSIS auditor verified whether BVL provides appropriate oversight and direction to inspection personnel for them to use their regulatory authority to enforce requirements for…	The FSIS auditor verified whether BVL provides appropriate oversight and direction to inspection personnel for them to use their regulatory authority to coordinate the enforcement of requirements for…	Clearer description of the BVL responsibilities
12	The FSIS auditor verified that a BVL representative of the government meat inspection system conducts periodic supervisory visits to each certified establishment to evaluate the performance of inspection personnel.	The FSIS auditor verified that Federal State representatives of the government meat inspection system conducts periodic supervisory visits to each certified establishment to evaluate the performance of inspection personnel. In specific cases, e. g. a POE Violation, the BVL can be asked for advice and coordination including accompanying the supervisory visits.	Clarification concerning the supervisory visit responsibilities
12	The *German Guidelines 2.0* set a minimum frequency of two supervisory visits per year for certified establishments. However, some of the audited Federal States have implemented a higher frequency for reviews, up to monthly.	The *German Guidelines 2.0* set a minimum frequency of one visits per year for certified establishments by the approval authority. However, the Federal States have implemented a higher frequency for reviews, up to monthly, conducted by the FLS.	Clarification
19	The FSIS auditor conducted an on-site audit of the LAVES, the only microbiological laboratory providing technical support to Germany's food safety inspection system.	The FSIS auditor conducted an on-site audit of the LAVES, the only official microbiological laboratory in Germany that provides the FSIS methods.	Clarification
20	The FSIS auditor verified that analysts assigned to the microbiological laboratory have documentation of analysts' proficiency evaluations and testing results, specialized training logs that qualify them to conduct the analytical methods for detection and quantification in their scope of accreditation.	The FSIS auditor verified that the laboratory has a documentation of proficiency evaluations and testing results as well as specialized training logs of the analysts assigned to the microbiological laboratory, as qualification for conducting the analytical methods for detection and quantification in the scope of the accreditation.	Clarification
21	…. as mentioned in *German Food Law 64*,	… as mentioned in § 64 of the German Food and Feed Law (LFGB)	Clarification

Anhang A
Appendix A

Seite Nr. Page No.	**Text im Berichtsentwurf** Text in the draft report	**Formulierungsvorschlag** Proposed wording	**Begründung** Reasoning
Foreign Establishment Audit Checklist EV-34			
1	Meica Ammerlandische Fleischwarenfabrik Fritz…	Meica Ammerländische Fleischwarenfabrik Fritz…	Corrigendum of the name: it is an ä and not an a
Foreign Establishment Audit Checklist BW 05068			
1	Hazard Analysis: The establishment's written HACCP Hazard Analysis did not identify Salmonella lethality controls for dry curing RTE ham processing steps although the processes had scientific supporting documentation including a Challenge Study in place and inherent controls in place that were monitored (e.g., water activity, and pH) and verification activity (microbiological sampling) that was conducted to demonstrate the safety of the product.	Hazard Analysis: The establishment's written HACCP Hazard Analysis did not identify Salmonella lethality controls for dry curing RTE ham processing steps although the processes had scientific supporting documentation including a Challenge Study in place and inherent controls in place that were monitored (e.g., water activity) and verification activity (microbiological sampling) that was conducted to demonstrate the safety of the product.	Clarification concerning the pH measurement: The pH value is measured at the incoming of goods before the further processing. The measurement is conducted for quality safety reasons (detection of PSE and DFD meat)

Maßnahmenplan
Action plan

Antwort der zuständigen Behörden der Bundesrepublik Deutschland bezüglich der Korrekturmaßnahmen in Bezug auf die Feststellungen des Entwurfs des Auditberichts zur Überprüfung des Überwachungssystems (Fleischhygiene), die in der nachfolgenden tabellarischen Übersicht aufgeführt werden. Das Audit wurde durch das Food Safety and Inspection Service (FSIS) des US Departments of Agriculture (USDA) der Vereinigten Staaten von Amerika im Zeitraum 18. März 2019 bis 29. März 2019 durchgeführt. Ziel des Audits war es zu überprüfen, ob die Äuivalenzanerkennung des deutschen Überwachungssystems hinsichtlich der Hygiene bei der Gewinnung von Schweinfleisch mit Bezugnahme auf § 327.2 des Code of Federal Regulations (CFR) aufrechterhalten werden kann.

Response of the competent authorities (CCA and CAs of the Federal States) of the Federal Republic of Germany, concerning the corrective actions related to the findings of the draft of the report of the on-site audit of Germany's Meat Inspection System, mentioned in the following table. The audit was carried out by the Food Safety and Inspection Service (FSIS) of the US Department of Agriculture (USDA) of the United States of America and was conducted from March 18 2019 to March 29 2019. The purpose of the audit was to determine, referring to § 327.2 of the Code of Federal Regulations (CFR), whether Germany's food safety system governing processed pork meat remains equivalent to that of the United States.

Bericht Teile I-X:
Report parts I-X:

Seite Nr. Page No.	**Beanstandung (Nr./Prüfkomponente)** Finding (No./component)	**Ursachenanalyse** root cause analysis	**Korrekturmaßnahmen, Präventivmaßnahmen** corrective actions, preventive measures
i, 17, 21	**1. Component Four: Government HACCP System** In two of the six audited establishments, there was inadequate government verification of HACCP requirements. The	The inspection personnel did identify that the establishment has not implemented monitoring procedures and	BVL: Translation of the Audit Report and official E-Mail to all Federal States visited during the Audit 2019.

	Inspection personnel did not identify that the written HACCP plan did not include one or more of the following elements required by the German Guidelines 2.0, which are consistent with 9 CFR § 417.2: monitoring procedures and frequencies, and ongoing verification procedures and frequencies.	frequencies as well as verification procedures and frequencies as required according to the German Guidelines Version 2.0.	Follow-up training in Bavaria (August 2019) for inspection personnel of different Federal States including an on-site visit. Topics of the training were besides others: - Follow-up to the FSIS Audit 2019 - Official verification of HACCP requirements including monitoring and verification requirements according to 9 CFR § 417.2. Follow-up training in Baden-Württemberg (October 2019) for inspection personnel of different Federal States. Topics of the training were besides others: - Follow-up to the FSIS Audit 2019 - Official verification of HACCP requirements including monitoring and verification requirements according to 9 CFR § 417.2. - Processing of Third Country Complaints/POE Violations Presentation at the Annual Conference organized by the German Veterinary Chamber, Working Group Food Hygiene and Consumer Protection on US requirements (9 CFR § 430) concerning RTE and measures against *Listeria monocytogenes* (participation of the FAS, US Embassy Berlin and CAs and CCAs of Germany, Austria, Italy, Switzerland).

			Telephone-Conference with all Federal States visited and discussion of the findings including discussion of corrective actions and preventive measures by CAs of the Federal States to prevent a (re)occurrence of the findings. CAs: Federal State 1: The local authority in Lower Saxony which is competent for an establishment, also approved for US-Export that was not part of the audit this year, was informed about the outcome of the audit and received the draft final report for their information. A follow-up including a discussion of the FSIS findings with the local authorities and the establishments is planned within the next yearly control of the approval authority for re-certification. Federal State 2: Planned training in Bavaria for inspection personnel in November 2019 Topics: - Guidelines - HACCP - *Listeria monocytogenes* – Rule - Results of FSIS-Audit 2019 Instruction of inspection personnel directly after FSIS-audit on March 25th, that remarks

			and findings concerning HACCP must be checked again and regularly verified. Training in Bavaria for inspection personnel with BVL and on-site-visit (August 2019) - Topics: - Guidelines - HACCP - *Listeria monocytogenes* – Rule - Results of FSIS-Audit 2019 Sending Official E-Mails to Local Competent Authorities including the Audit-Report and translation of the Audit Report and also all other information coming from the CCA concerning the FSIS-Audit. Establishment A – no finding concerning HACCP; FS and IC meeting after the audit and recheck of monitoring and verification frequencies including responsibilities. Establishment B - The establishment HACCP plan was corrected by the establishment personnel. Inspection personnel was instructed to check regularly if the establishment HACCP plan is in accordance with 9 CFR §417.2 and to record the results (the corresponding checklist was extended and is conducted quarterly)

			Federal State 3: Discussion of the findings including discussion of corrective actions and preventive measures with the inspection personnel of the district administration and the supervisory personnel of the regional council in Baden-Württemberg. Furthermore a Follow- up training session in Stuttgart is planned on October, 16 2019 (including the contribution of the CCA). The official inherent documentation is available on demand.
i, 17, 21	**2. Component Four: Government HACCP System** In two of the four audited establishments that produce RTE dry cured hams, there was inadequate government verification of the HACCP requirements. The hazard analyses did not identify microbiological controls for Salmonella within all process steps; however, the establishment process had validated/scientific documentation. A Challenge Study and inherent controls were in place that monitored (e.g., water activity and pH) and verified (microbiological sampling) product to demonstrate the safety of the product.	The inspection personnel did identify that the establishment's hazard analysis did not identify microbiological controls for Salmonella within all process steps (however there was validated scientific documentation/a Challenge Study) as required according to the German Guidelines Version 2.0.	BVL: Translation of the Audit Report and official E-Mail to all Federal States visited during the Audit 2019. Follow-up training in Bavaria for inspection personnel of different Federal States including an on-site visit. Topics of the training were besides others: - Follow-up to the FSIS Audit 2019 - Official verification of HACCP requirements including hazard analysis requirements according to 9 CFR § 417.2. Follow-up training in Baden-Württemberg (October 2019) for inspection personnel of different Federal States. Topics of the training were besides others:

			- Follow-up to the FSIS Audit 2019 - Official verification of HACCP requirements including monitoring and verification requirements according to 9 CFR § 417.2. - Processing of Third Country Complaints/POE Violations Presentation at the Annual Conference organized by the German Veterinary Chamber, Working Group Food Hygiene and Consumer Protection on US requirements (9 CFR § 430) concerning RTE and measures against *Listeria monocytogenes* (participation of the FAS, US Embassy Berlin and CAs and CCAs of Germany, Austria, Italy, Switzerland). Telephone-Conference with all Federal States visited and discussion of the findings including discussion of official verification of the hazard analysis by CAs of the Federal States as well as corrective actions and measures to prevent a (re)occurrence of the findings. CAs: Federal State 1: The local authority in Lower Saxony which is competent for an establishment, also approved for US-Export that was not part of the audit this year, was informed about the

			outcome of the audit and received the draft final report for their information. A follow-up including a discussion of the FSIS findings with the local authorities and the establishments is planned within the next yearly control of the approval authority for re-certification. Federal State 2: Discussion of the findings including discussion of corrective actions and preventive measures with the inspection personnel of the district administration and the supervisory personnel of the regional council in Baden-Württemberg. Furthermore a training session in Stuttgart is planned on October 2019. Federal State 3: Discussion of the findings including discussion of corrective actions and preventive measures with the inspection personnel of the district administration and the supervisory personnel of the regional council in Baden-Württemberg. Furthermore a Follow- up training session in Stuttgart is planned on October, 16 2019 (including the contribution of the CCA). The official inherent documentation is available on demand.

Anhang A
Betrieb, Zulassungsnummer: Bell Deutschland GmbH & Co. KG, Osterschepser Str. 40, 26188 Edewecht, Niedersachsen

Appendix A
Establishment, approval number: Bell Deutschland GmbH & Co. KG, Osterschepser Str. 40, 26188 Edewecht, Niedersachsen

Seite Nr. Page No.	**Beanstandung (Nr./Prüfkomponente)** Finding (No./component)	**Ursachenanalyse** root cause analysis	**Korrekturmaßnahmen, Präventivmaßnahmen** corrective actions, preventive measures
2	*1. HACCP – Basic requirements* *15/51 Hazard Analysis* The establishment's written HACCP Hazard Analysis did not identify Salmonella lethality controls for dry curing RTE ham processing steps although the processes had a scientific supporting documentation including a Challenge Study in place and inherent controls in place that were monitored (e.g., water activity, and pH) and verification activity (microbiological sampling) that was conducted to demonstrate the safety of the product.	The establishment has, concerning the HACCP Analysis, looked taken into account pathogenic Microorganisms in general what has led to misunderstandings during the Audit. The establishment is to work over the Hazard Analysis.	The establishment has revised the HACCP Plan concerning the lethality controls and included the supporting documentation in the HACCP Plan (Challenge Study, scientific analysis concerning the inactivation of *Salmonella* in raw ham after HPP treatment and microbiological product analyses). The Hazard Analysis has been revised: a register of supporting documentation was assembled and linked to the Hazard Analysis. There will be a training provided in the next HACCP Team Meeting. A Follow-up (discussion and assessment of Audit findings) of past Audits is also part of such Team Meetings. Should there be, like in this Audit, new considerations, they are elaborated centrally and adapted for all sites affected.

			Concerning the above mentioned findings the CA Landkreis Ammerland, Veterinär- und Lebensmittelüberwachungsamt, 26655 Westerstede has officially verified the following: **1.** The establishment's root cause analysis **2.** The establishment's corrective actions **3.** The establishment's preventive measures 1. -3. Have been officially verified as effective and fully implemented as described. No concerns were identified. The documentation of official verification activities is available on demand.
2	*2. Sanitation SPS* The FSIS auditor observed the following non-compliances during the establishment tour: *39/51 Facility Construction/Maintenance* In the post hot smoke ham maturing storage room: a water drain line that protrudes from the ceiling was observed to showed signs of leaking. This storage room contains ham product that has been hot smoked and which once reaching the end of the maturing stage will proceed to the cubing department. All product is in immediate casing that are stripped from the product prior to cubing. No product was directly under the drain and the	It was not a leakage of the pipe but the pipe opening did not end at the floor.	The pipe was sealed, prolonged and with stainless steel-faced. No adulteration of product will be possible. Concerning the above mentioned findings the CA Landkreis Ammerland, Veterinär- und Lebensmittelüberwachungsamt, 26655 Westerstede has officially verified the following: **1.** The establishment's root cause analysis **2.** The establishment's corrective actions **3.** The establishment's preventive measures 1. -3. Have been officially verified as effective and fully implemented as described. No

	establishment had not product produced for the United States at the time of the audit.		concerns were identified. The documentation of official verification activities is available on demand.

NI-local authority: The deadlines given the establishment after the audit were fulfilled. (10 days after the audit for construction measures and until May 25 for modification of the HACCP Plan.

Concerning the above mentioned findings the CA Landkreis Ammerland, Veterinär- und Lebensmittelüberwachungsamt, 26655 Westerstede has officially verified the following:

1. The establishment's root cause analysis
2. The establishment's corrective actions
3. The establishment's preventive measures

1. -3. Have been officially verified as effective and fully implemented as described. No concerns were identified. The documentation of official verification activities is available on demand.

Anhang A
Betrieb, Zulassungsnummer: HoWe Wurstwaren KG, Regenstrasse 1, 90451 Nürnberg, Bayern
Appendix A
Establishment, approval number: HoWe Wurstwaren KG, Regenstrasse 1, 90451 Nürnberg, Bayern

Seite Nr. Page No.	**Beanstandung (Nr./Prüfkomponente)** Finding (No./component)	**Ursachenanalyse** root cause analysis	**Korrekturmaßnahmen, Präventivmaßnahmen** corrective actions, preventive measures
2	*1. HACCP – Basic Requirements* *15/51* The establishment's written HACCP plan did not include or adequately describe the following elements required by 9 CFR Part 417.2(c): • The procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the CCPs to ensure compliance with the critical limits.	**1. Root cause analysis**: The monitoring of the CCPs was performed regularly and the results were documented. The description and the written determination of the frequencies of these monitoring procedures were incomplete respectively could not be presented by the establishment personnel.	**2. Corrective actions**: The required documents were completed according to 9 CFR 417.2 (c): Procedures are described and the frequencies are fixed (verification schedule). 1.-2. Have been verified as effective and fully implemented as described. No concerns were identified. The documentation of official verification activities is available on demand.
2	*2. Sanitation SPS* The FSIS auditor observed the following non-compliances during the establishment tour: *45/51 Establishment Maintenance* Post packaging pasteurization room: developing rust • On structures that support the conveyor belt system that carries the vacuum packaged	**1. Root cause analysis**: Cause of the rust was a defective ball bearing in the roll of the conveyor belt. Therefore rust was developing and was spreading on belts, the pasteurizer basin and the frame.	**2. Corrective actions**: It was checked if rust was contaminating the packing of the sausages (immediately after realizing this non-compliance); possible contamination was removed. The defective ball bearing was replaced. Rust was removed from the conveyor belt, the frame, incl. the curves and the rusty pieces e.g. screws, hose fittings were replaced (20.-23.03.2019).

	product through the post packaging pasteurization process. • On conveyor belt sides that maintains the product on the belts around curves which makes incidental contact with packaged product.		A renovation concept for the whole pasteurizer was developed: Replacement of all chains and bearings (until 30.04.2019). **3. Preventive measures**: As a preventive measure it was determined that the condition of the conveyor system is to be checked daily during operation by the operational supervisor. 1.-3. have been verified as effective and fully implemented as described. No concerns were identified. The documentation of official verification activities is available on demand.

Anhang A
Betrieb, Zulassungsnummer: Schinkenhof GmbH & Co. KG, Severinstraße 12, 77855 Achern

Appendix A
Establishment, approval number: Schinkenhof GmbH & Co. KG, Severinstraße 12, 77855 Achern

Seite Nr. Page No.	**Beanstandung (Nr./Prüfkomponente)** Finding (No./component)	**Ursachenanalyse** root cause analysis	**Korrekturmaßnahmen, Präventivmaßnahmen** corrective actions, preventive measures
2	*1. HACCP – Basic Requirements 15/51* The establishment's written HACCP plan did not include or adequately describe the following elements required by 9 CFR Part 417.2(c): • The procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the CCPs to ensure compliance with the critical limits, • The procedures, and the frequency with which those procedures will be performed that will be used in verification of CCPs monitoring. • Hazard Analysis: The establishment's written HACCP Hazard Analysis did not identify Salmonella lethality controls for dry curing RTE ham processing steps	*1. HACCP - Basic Requirements 15/51* Deficiencies in the HACCP-plan of the establishment.	*1. HACCP Basic Requirements 15/51* Corrective actions: The following elements have been amended and adequately described in the written HACCP plan: • The procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the CCPs to ensure compliance with the critical limits, • The procedures, and the frequency with which those procedures will be performed, that will be used in verification of the CCPs monitoring. Preventive measures: The findings and the corrective measures to be taken have been discussed with the official control personnel with special focus on the requirements of 9 CFR Part 417.2(c).

	although the processes had scientific supporting documentation including a Challenge Study in place and inherent controls in place that were monitored (e.g., water activity, and pH) and verification activity (microbiological sampling) that was conducted to demonstrate the safety of the product.		Hazard Analysis: Corrective actions: The written HACCP Hazard Analysis is being corrected accordingly. We would like to point out, that the measuring of ph-value is exclusively performed after the receipt of the raw meat and before further treatment for reasons of quality control (PSE, DFD). Preventive measures: The findings and the corrective measures to be taken have been discussed with the official control personnel with special focus on the requirements of 9 CFR Part 417.2(c). The establishment's inherent documentation is available on demand.
2	*2. Sanitation SPS* The FSIS auditor observed the following non-compliances during the establishment tour: *41/51 Ventilation:* Beaded condensation was observed on the ceiling in the product transfer area between the ham second application of brine and the ham racking area for cold smoke. No product was present at the time passing through the area.	*45/51 <u>Ventilation</u>* After further investigation it turned out that the water found on the ceiling was not due to condensation	*2. Sanitation SPS* *45/51 <u>Ventilation</u>* Corrective actions: The rinsing place was adopted edificial to avoid splash water on the ceiling.

		but was splash water. Pallets had been rinsed there.	Preventive measures: The SSOP-Plan has been adopted.
	45/51 Equipment and Utensils: Gray plastic spacers that are placed in containers between layers of exposed raw dry cured pork product were observed to have chipped frayed edges that laid directly over the product.	*45/51 <u>Equipment and Utensils:</u>* Fault in the SSOP-plan.	*45/51 <u>Equipment and Utensils :</u>* Corrrective actions: The damaged spacers have been sorted out. Preventive measures: The SSOP-Plan has been adopted.
	46/51 Sanitary operations: • In the area were pork product is applied the first application of a dry salt cure, gray plastic spacers that are placed in containers between layers of exposed raw dry cured pork product were observed to be staged in close proximity to the floor creating an insanitary condition for the cross contamination of product from organic material on the floor or employee boots.	*46/51 <u>Sanitary operations:</u>* Fault in the SSOP-plan.	*46/51 <u>Sanitary operations:</u>* Corrective actions: The stand on which the plastic spacers have been stored was replaced by another one with greater distance to the floor to avoid cross contamination. Preventive measures: The SSOP-Plan has been adopted.
	• In the ham “maturing room” where vacuum pack hams (immediate container) were stored in containers to further the process of “maturing” - red plastic containers holding the product were observed to be stacked with having a gray plastic pallet	Fault in the SSOP-plan.	Corrective actions: The product in the immediate red container is now covered aditionnaly with a plastic sheet. Preventive measures: The SSOP-Plan has been adopted.

	directly over the products in the middle of the stacked product creating an insanitary condition. There was no secondary covering of the product to preclude any cross contamination from the pallet onto the product's immediate container (covering).		The establishment's inherent documentation is available on demand.

Concerning the above mentioned findings the CA Regierungspräsidium Freiburg has officially verified the following:

1. The establishment's root cause analysis
2. The establishment's corrective actions
3. The establishment's preventive measures

1. -3. Have been officially verified as effective and fully implemented as described. No concerns were identified. The documentation of official verification activities is available on demand.