



United States Department of Agriculture

Food Safety and
Inspection Service

September 23, 2024

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Washington, D.C.
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GERMANY

Dear Dr. Lhafi,

The U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an onsite verification audit of Germany's inspection system April 15–May 7, 2024. 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.

Sincerely,

**MARGARET
BURNS RATH**

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Margaret Burns Rath, JD, MPH
Acting International Coordination Executive
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Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED OF

GERMANY

APRIL 15–MAY 7, 2024

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING

PROCESSED PORK PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

September 23, 2024

Food Safety and Inspection Service
U.S. Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit of Germany conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) April 15–May 7, 2024. The purpose of the audit was to verify whether Germany's food safety inspection system governing processed pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. Germany currently exports pork products under the following Hazard Analysis and Critical Control Point (HACCP) process categories to the United States: Thermally processed/Commercially Sterile, Not Heat Treated-Shelf Stable, Fully Cooked-Not Shelf Stable, Heat Treated-Not Fully Cooked-Not Shelf Stable, and Products with Secondary Inhibitors-Not Shelf Stable.

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.

FSIS concluded that Germany's processed pork products inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL), as the Central Competent Authority, requires that establishments certified as eligible to export processed pork products to the United States implement sanitation requirements and a HACCP system designed to improve the safety of their products. In addition, BVL has implemented an official microbiological testing program that is organized and administered by the national government to verify its system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

TABLE OF CONTENTS

I.	INTRODUCTION.....	1
II.	AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY	1
III.	BACKGROUND.....	4
IV.	COMPONENT ONE: GOVERNMENT OVERSIGHT (e.g., ORGANIZATION AND ADMINISTRATION)	4
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)	9
VI.	COMPONENT THREE: GOVERNMENT SANITATION.....	12
VII.	COMPONENT FOUR: GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM	13
VIII.	COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS	15
IX.	COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS	15
X.	CONCLUSIONS AND NEXT STEPS	17
	APPENDICES	18

Appendix A: Individual Foreign Establishment Audit Checklists

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

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) conducted an onsite audit of Germany's food safety inspection system April 15–May 7, 2024. The audit began with an entrance meeting April 15, 2024, in Berlin, Germany, during which the FSIS auditor discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL). Representatives from the USDA's Foreign Agricultural Service, Federal Ministry of Food and Agriculture (Bundesministerium für Ernährung und Landwirtschaft - BMEL) and representatives from the Competent Authority (CA) of the Federal States of Lower Saxony, Baden-Württemberg and Bavaria, including officials from their respective regions and districts, were also present during the meeting. Representatives from BVL accompanied the FSIS auditor throughout the entire audit. The audit concluded with an exit meeting conducted May 7, 2024.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to verify whether the food safety inspection system governing processed pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. Germany is eligible to export the following categories of products to the United States:

Process Category	Product Category	Eligible Products ¹
Thermally Processed - Commercially Sterile (TPCS)	Thermally Processed, Commercially Sterile	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	Ready-to-Eat (RTE) Acidified / Fermented Meat (without cooking)	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	RTE Dried Meat	Pork - All Products Eligible
Not Heat Treated - Shelf Stable	RTE Salt-Cured Meat	Pork - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE Fully-Cooked Meat	Pork - All Products Eligible
Fully Cooked - Not Shelf Stable	RTE Meat Fully-Cooked Without Subsequent Exposure to the Environment	Pork - All Products Eligible
Heat Treated - Not Fully Cooked - Not Shelf Stable	Not Ready-to-Eat (NRTE) Otherwise Processed Meat	Pork - All Products Eligible
Products with Secondary Inhibitors - Not Shelf Stable	RTE Salt-Cured Meat	Pork - All Products Eligible

¹ All source meat used to produce products must originate from eligible countries and establishments certified to export to the United States.

The USDA's Animal and Plant Health Inspection Service (APHIS) recognizes Germany as free from foot-and-mouth disease with special restrictions specified in Title 9 of the U.S. Code of Federal Regulations (9 CFR) 94.11; free from swine vesicular disease with special restrictions specified in 9 CFR 94.13; and part of the APHIS-defined European classical swine fever region subject to restrictions specified in 9 CFR 94.31. Germany is not free from African swine fever and is subject to regionalization restrictions specified in 9 CFR 94.8.

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed Germany's Self-Reporting Tool (SRT) responses and supporting documentation, including official microbiological sampling plans and results. During the audit, the FSIS auditor conducted interviews, reviewed records, and made observations to verify whether Germany's food safety inspection system governing processed pork products is being implemented as documented in the country's SRT responses and supporting documentation.

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, port-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 3-year period, in addition to information obtained directly from BVL through the 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 BVL's headquarters, two regional offices, two district offices, and eight local inspection offices within the establishments. 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 documented in the country's SRT responses and supporting documentation.

A sample of 8 establishments was selected from a total of 15 establishments certified to export to the United States. All eight selected establishments were processed pork establishments that produce and export to the United States products under the following HACCP process categories: TPCS; Not Heat Treated-Shelf Stable, Fully Cooked-Not Shelf Stable, Heat Treated-Not Fully Cooked-Not Shelf Stable, and Products with Secondary Inhibitors-Not Shelf Stable.

During the establishment visits, the FSIS auditor paid particular attention to the extent to which industry and government interacted to control hazards and prevent noncompliance that threatens food safety. The FSIS auditor assessed BVL'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.

The FSIS auditor also audited one microbiological laboratory to verify that the laboratory is capable of providing adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> • BVL, Berlin
	Federal State Authority included: Ministry, Provincial, and District levels	2	<ul style="list-style-type: none"> • Bavaria, Ansbach • Baden-Württemberg, Karlsruhe
Laboratory		1	<ul style="list-style-type: none"> • Lower Saxony State Office for Consumer Protection and Food Safety (LAVES) Microbiology Laboratory, Oldenburg
Pork processing establishments		8	<ul style="list-style-type: none"> • EV-34, Meica Ammerländische, Fleischwarenfabrik Fritz Meinen GmbH & Co. KG, Edewecht • AEV-35, Bell Deutschland GmbH & Co. KG, Edewecht • EV-717, HoWe Wurstwaren KG, Nürnberg • DE NI 18210 EG, H. Klümper GmbH & Co. KG, Schüttorf • BW 03330 Freiburger Lebensmittel GmbH & Co. Produktions- und Vertriebs KG, Muggensturm • BW 05068 Schinkenhof GmbH & Co. KG (Currently named as Adler Schwarzwald GmbH & Co. KG Werk Schinkenhof), Achern • BY 50008 Hans Kupfer & Sohn GmbH & Co. KG, Heilsbronn • BY50567 Gebrüder Kupfer GmbH & Co. KG, Nürnberg

FSIS performed the audit to verify that Germany's food safety inspection system meets 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.) Section 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 inspection system for processed pork products included: (1) all applicable legislation originally determined by FSIS as equivalent as part of the initial review process, and (2) any subsequent equivalence determinations that have been made by FSIS under provisions of the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures.

III. BACKGROUND

From November 1, 2020, to October 31, 2023, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 15,924,317 pounds of processed pork products exported by Germany to the United States.

Additional types of inspection were performed on 1,653,096 pounds of processed pork products. These additional types of inspection included physical examination, condition of container examination for TPCS products, chemical residue analysis, and testing for microbiological pathogens including *Listeria monocytogenes* (*Lm*) and *Salmonella* in RTE products. As a result of this additional testing, no products were rejected for issues related to public health, and 23,643 pounds were refused for other issues not related to public health, including shipping damage, labeling, or other miscellaneous issues.

On April 24, 2024, approximately 85,984 pounds of RTE sliced prosciutto ham product produced at German establishment DE NI 18210 EG, H. Klümper GmbH & Co. KG, were recalled after BVL notified FSIS that the establishment produced and exported to the United States a portion of the prosciutto without the benefit of equivalent inspection.²

The previous FSIS audit in 2021, conducted remotely, did not identify any systemic findings representing an immediate threat to public health.

The FSIS final audit reports for Germany's food safety inspection system are available on the FSIS website at: www.fsis.usda.gov/foreign-audit-reports.

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

The first equivalence component the FSIS auditor reviewed 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.

On matters related to food safety inspection systems, the Federal Republic of Germany (Germany) is comprised of a CCA and CAs within its 16 Federal States (Länder). Germany draws its authority to operate its inspection system related to food and feed safety from overarching European Union (EU) regulations as well as from national laws and regulations. Germany monitors and verifies that requirements in Regulation European Commission (EC) No.

² As part of corrective actions, BVL and the Federal State authority of Lower Saxony ensured that government inspection personnel were retrained on requirements for at least once-per-shift inspection for production of products intended for export to the United States. Additionally, the establishment implemented similar training for its personnel. Lastly, BVL received and verified production schedules for products intended for export to the United States to ensure all shifts received inspection.

178/2002 are complied with by establishments at all stages of production, processing, and distribution. Furthermore, the CCA and CAs manage regulatory oversight and inspection activities as required per Article 5(5) of Regulation (EU) 2017/625 when more than one unit is competent to perform official controls or other official activities. Germany's Basic Law of 1949 outlines the respective competence for Federal and Federal States levels pertaining to food and feed safety, animal health, animal welfare, and plant health. Germany's National Food Hygiene Regulation (LMHV) requires that approval of establishments for export to other countries, such as the United States, is subject to compliance with the sanitary requirements of the importing country. In addition to establishing official controls designed to ensure compliance with the EC legislation, the CAs of the Federal States, with oversight by BVL, are also responsible for ensuring compliance with FSIS import requirements and certification of eligible establishments.

At the national level, the Federal Ministry of Food and Agriculture (Bundesministerium für Ernährung und Landwirtschaft - BMEL) is responsible for issuing statutory regulations relating to food safety under the Food, Feed and Consumer Goods Code and Animal Health Act. BVL, an agency within BMEL, is recognized as the CCA on matters of food safety and consumer protection at the national level. BMEL also oversees the Federal Institute for Risk Assessment, the Federal Agency for Agriculture and Food, the Friedrich Loeffler Institute, the Julius Kühn Institute, and the Max Rubner Institute. Additionally, BMEL collaborates with the Federal Ministry for Environment, Nature Conservation, Building and Nuclear Safety, the Federal Ministry of Finance, and the Federal Ministry of Justice and Consumer Protection on certain aspects of food safety. The FSIS auditor confirmed that there have not been any organizational changes within BVL since the previous FSIS audit in 2021.

BVL exerts its legislative and regulatory authority to enforce rules and regulations for food and feed safety, animal health, and animal welfare. BVL coordinates the development and implementation of food monitoring and supervisory controls between Federal and Federal States authorities in food safety and consumer protection. In this context, BVL coordinates with the Federal States Working Group for Foods of Animal Origin (LAV) and updates the Implementation Instructions for Carrying Out Official Controls in Food Businesses that Export Meat Products to the USA (hereinafter referred to as German Guidelines) as needed. The current version of German Guidelines, version 2.1, was put into effect on June 1, 2023. BVL is also the competent authority responsible for the national residue control plan and is the national point of contact for the Rapid Alert System for Food and Feed (RASFF). BVL plays a key role in managing its inspection-centered communication portal, the Specialised Information System for Consumer Protection and Food Safety intranet (FIS-VL). Within BVL, Unit 180 oversees all export-related affairs including requirements for export of products to the United States.

As noted earlier, there are 16 Federal States in Germany also known as Länder. Each Federal State is a CA within their state. In each Federal State, the CA is organized in three levels in relation to the management of official inspection, oversight, and administration of food safety controls: 1. Supreme State Authority (e.g., a ministry within Federal State); 2. Higher State Authority (e.g., provincial or regional); and 3. Lower Authority (e.g., district, municipal or independent city). BMEL in its federal ministerial capacity is responsible for the control, coordination, and issuance of guidance on the implementation of federal laws and the applicable EU laws and regulations. Within the Federal States, the provincial or regional level is an

intermediate administrative level between the ministry and district levels. The district level is responsible for the control of food-producing establishments within the respective district. All official controls concerning implementation of food safety requirements are carried out in the context of each Federal State's Quality Management System (QMS). The objective of the QMS is to provide documented procedures and instructions for government inspection personnel on verifying the effectiveness of official controls required by Regulation (EU) 2017/625. The current audit included three Federal States, Baden-Württemberg, Lower Saxony, and Bavaria, and their region, district, and municipality (or independent city) offices to assess the CA's authority and ability to administer the inspection system as well as organizational structure in their respective Federal State. The FSIS auditor verified there has not been any change in organizational structure pertaining to the inspection system at the Federal States level since the previous FSIS audit in 2021.

The FSIS auditor conducted interviews and reviewed documents to verify procedures when an establishment requests to gain eligibility to export meat products to the United States. Germany maintains the legal authority and responsibility to certify and remove the certification of establishments per Article 4 of Regulation (EC) No. 853/2004 and Article 148 of Regulation (EU) 2017/625, which require the CCA to establish procedures for approvals and withdrawal of approvals of establishments, and further requires the CCA to review and ensure establishments' compliance with the relevant requirements of food law. Certification of a new establishment, recertification, or withdrawal of certification occur at the Federal States level in communication with BVL. The FSIS auditor verified documents related to an establishment seeking eligibility through an informal request through the inspector-in-charge (IIC) to the regional approving authority in Bavaria. The requesting establishment submitted information regarding the origin of raw products, including health certificates for raw products from the country of origin and the profile of products intended for export. Prior to the issuance of the approval certificate, the regional approving authority visited the establishment and verified the establishment's preparedness and compliance with U.S. import requirements. The IIC followed up on noncompliance observed during the approving authority's establishment visit prior to finalizing the certification process. Once approved, BVL notified FSIS of the update to the list of establishments certified to export to the United States. Generally, regional approving authorities visit establishments at the time of certification and annually thereafter to assess the ability of the establishment to maintain eligibility. The FSIS auditor's review did not raise any concerns.

Pursuant to Article 18 of Regulation (EC) No. 178/2002, which requires traceability to be established at all stages of production, processing, and distribution, the CA at each Federal State requires that establishments must have procedures in place for recall and traceability in their food safety program to protect consumers when adulterated products enter commerce. The establishments are to immediately inform the CA of the affected Federal State. Part B.II.6 of German Guidelines outlines the key elements in handling recalls for example implicated consignments, lot identification for traceability, as well as product seizure in the event the establishment fails to conduct a recall. The Federal States or BVL release public warnings and information on the internet portal in accordance with Article 40 of the Food, Consumer Goods and Feed Act (LFGB). The FSIS auditor reviewed documentation at each audited establishment and verified that the establishments have developed procedures as part of their food safety system to ensure adulterated product, once identified, can be traced back and recalled.

Germany utilizes an online database, Zentrale Tierseuchendatenbank, which houses the template for the export certificate to be used by the certification authority, who issues unique certificate numbers prior to completing shipment information on the export certificate. BMEL's Information About the Issuing of Official Veterinary Certificates for Exportation provides instructions for the issuance of export certificates that must be adopted by each Federal State. The FSIS auditor verified that tracking systems on health certificates are in place by the district inspection office and updated by the front-line supervisor (FLS) who signs, issues, and maintains all paper-based export health certificates, government seals, and security accountability logs in a secured, locked location. The FSIS auditor further evaluated inspection verification activities and establishment's controls for ensuring the safety and wholesomeness of incoming raw materials that are sourced from certified establishments in countries that are eligible to export pork products to the United States. The FSIS auditor reviewed shipment documents and interviewed government officials as well as establishment responsible personnel for verifying accuracy of documents and product safety. The FSIS auditor verified that raw pork products were received from certified slaughter establishments in the Netherlands and Denmark and that processed pork products were received from a certified establishment in Austria for further processing in Germany. Incoming raw or processed product loads to be used on the production of products destined for export to the United States are received in the presence of the IIC, who either breaks the seal or witnesses the establishment employee breaking the seal and is responsible for checking the hygiene of the truck, physical condition of products, and taking product temperatures upon receiving the loads. The IIC verifies that the number on the accompanying health certificate matches the number on the seal. In one audited establishment producing NRTE products for export to the United States, the FSIS auditor noted that the RTE meat component (salami/pepperoni) originated from a certified establishment in Austria. The German establishment further processes the meat component by assembling with other components and packaging and labeling the final product. The FSIS auditor did not identify any concerns either with export certification or safety of sourced raw or processed materials.

The communication between BVL and various parts of the inspection system at the Federal States level is maintained through FIS-VL. This digital platform allows for the quick and secure exchange of information between the authorized users within all parts of the inspection system across all Federal States. The site managed by BVL provides access to real-time data, including inspection and technical documents. All government inspection personnel assigned to the certified establishments have access to FIS-VL through the intranet. They can access or upload documents, so the supervisors and higher authorities are informed in real time. FIS-VL also provides users email notifications when new documents have been uploaded to the system. BVL forwards new and existing U.S. requirements to the CAs which then forward them to the official staff in the Federal States. Updates on FSIS requirements are instantly available through FIS-VL. The FSIS auditor received temporary access to the site and was able to review the extent of communication, collaboration, and cooperation the FIS-VL provides to the users of the site. The LAV holds workgroup meetings to address any issues concerning all Federal States with the certified establishments. One major objective of LAV is to discuss when an amendment or a revision of German Guidelines is required. LAV meetings between BVL and CAs at all levels of the Federal States are utilized to achieve uniform application of FSIS requirements across

Germany's inspection system. The FSIS auditor did not identify any concerns.

The FSIS auditor confirmed that the inspection operations are funded by the state budget. Government inspection personnel assigned to the establishments certified to export to the United States are hired and paid by the government. In each Federal State, the authority for hiring and assigning competent, qualified inspection personnel lies with the regions and districts. All official veterinarians in the certified establishments are graduates of an accredited college of veterinary medicine with a doctor of veterinary medicine degree who took courses in meat inspection within the curriculum of their formal education. Upon graduation, veterinarians wishing to pursue a career in food safety continue their training by taking special courses in meat inspection including 4 weeks of practical training. In accordance with Commission Delegated Regulation (EU) 2019/624, non-veterinary inspector "auxiliaries" attend courses involving 400 hours of practical training and 500 hours of theoretical training, after which they must pass specific examinations before being qualified to work in exporting establishments. The FSIS auditor reviewed the hiring process for new entrants into the inspection system and verified that incoming candidates are required to disclose all possible conflicts of interest that might interfere in performance of duties once the inspector assumed his or her responsibilities. No concerns were identified.

The FSIS auditor assessed BVL's measures to ensure that adequate administrative and technical support is available to its laboratory system. Although each Federal State has a network of its own laboratories conducting analytical testing for chemical residues or microbiological pathogens, BVL has designated the Lower Saxony State Office for Consumer Protection and Food Safety - Food and Veterinary Institute (LAVES-FVI), located in Oldenburg, as an official laboratory. LAVES-FVI receives samples from establishments certified to export to the United States to conduct official analytical testing for microbiological pathogens in meat products. Section 23 (Bacteriology and Sanitary Testing Branch) of LAVES-FVI is responsible for analysis of official samples received from establishments certified to export to the United States. The FSIS audit of the laboratory functions included interviews with the head of Section 23, and document reviews to verify the implementation of procedures and standards described in the quality control manual (QCM). BVL requires the official laboratory to use methods in FSIS' Microbiological Laboratory Guidebook (MLG) for product or environmental samples being tested for *Lm* and *Salmonella*. The FSIS auditor verified that the LAVES-FVI laboratory implements FSIS' MLG methods for analysis of environmental and RTE products for *Lm* and *Salmonella* as required by BVL and described in Chapter 7 of German Guidelines.

Pursuant to requirements contained in Regulation (EC) No. 765/2008 for accreditation and market surveillance, LAVES-FVI is accredited by the German Accreditation Body, Deutsche Akkreditierungsstelle GmbH (DAkkS) according to standards in International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025. The FSIS auditor verified inclusion of FSIS MLG methods for detection of *Lm* (FSIS MLG Chapter 8) and *Salmonella* (FSIS MLG Chapter 4) in the scope of the accreditation for the laboratory. The laboratory has ongoing training program as well as training for the new analyst as part of the QCM. New analysts shadow the senior analyst and undergo training on the FSIS MLG for *Lm* and *Salmonella* methods prior to independently analyzing samples of products intended for export to the United States. The FSIS auditor also assessed the competence, skills, knowledge, and ongoing training of analysts assigned to the microbiological laboratory by reviewing the

recent proficiency test (PT) reports. The laboratory participates annually in PT schemes offered by the Food Analysis Performance Assessment Scheme using FSIS MLG methods for detection of *Lm* and *Salmonella*. The analysts participate in PT schemes on a rotating basis to ensure each analyst is evaluated over time. The FSIS auditor reviewed PT scheme results and found that PT was implemented as described and that the results of the PT scheme were acceptable. The laboratory conducts internal audits and maintains a calibration plan for all instruments and equipment, including incubators and thermometers. The FSIS auditor's review of proficiency testing, and quality assurance procedures did not raise any concerns.

Samples that screen positive for *Lm* or *Salmonella* are reported immediately to the CA of the implicated Federal State, and again when the result is confirmed utilizing confirmation methods as laid out in MLG for *Lm* and *Salmonella*. BVL requires product to be held until acceptable results are received. RTE finished products and RTE products exposed to food contact surfaces (FCS) that test positive for *Lm* are excluded from export to the United States. Retesting of samples with unacceptable results is not allowed. The FSIS auditor did not identify any concerns during the review.

The FSIS auditor evaluated the procedures for receipt of samples and observed the process. At receiving, laboratory personnel verify sample integrity, review the accompanying laboratory form for accuracy, and verify chain of custody for the sample. The sample temperatures are obtained and recorded at receiving. Acceptable samples are logged into the laboratory's database and assigned an order number. A unique laboratory identification number is assigned to accompany the sample through completion of the analysis for the purpose of traceability. The laboratory maintains sample discard records, which explain the reasons a sample is discarded and if a follow-up should be collected by government inspection personnel.

The FSIS auditor verified that Germany's food safety inspection system governing processed pork products has the organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements for this component.

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 equivalence component the FSIS auditor reviewed 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 every carcass and its parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once-per-shift inspection during processing operations; and periodic supervisory visits to official establishments.

There are currently no slaughter establishments in Germany that are certified to export product to the United States. Therefore, requirements for humane handling and slaughter of livestock; ante-mortem inspection of animals; and post-mortem inspection are not applicable to the FSIS audit of Germany's meat inspection system.

Pursuant to national laws and overarching EU regulations, Germany has implemented periodic supervision in all certified establishments eligible to export to the United States. Germany's Lebensmittel-Hygieneverordnung (Animal Food Hygiene Regulation -Tier-LMHV) implements Regulation (EC) No. 852/2004, Regulation (EC) No. 853/2004, Commission Implementing Regulation (EU) 2019/627, and Regulation (EU) 2017/625. Article 148 of Regulation (EU) 2017/625 mandates that the competent authority must perform onsite visits as well as meet the analogous requirements laid out in Regulation (EC) No. 852/2004 and Regulation (EC) No. 853/2004. German Guidelines describes the procedure for conducting supervisory reviews, the frequency and scope of the review, and methods of documentation of the review findings. The documents reviewed and interviews conducted at local and district offices of Baden-Württemberg and Bavaria as well as local inspection offices in Lower Saxony, indicate that at the establishments certified to export to the United States the official veterinarian (OV), who is employed by the districts or cities/municipalities as a FLS, is responsible for conducting periodic supervisory reviews. Reviews are conducted utilizing checklists covering sanitation standard operating procedures (Sanitation SOPs), HACCP, prerequisite programs including personal hygiene, temperature control, pest control, water hygiene, condemned waste, product hygiene, traceability, and microbiological testing, as well as compliance with labeling requirements. Per German Guidelines, the reviews are conducted monthly. However, in newly certified establishments reviews are conducted more frequently until establishments demonstrate full compliance with FSIS import requirements. In addition to supervisory reviews, the FLS is also responsible for conducting internal audits per the relevant section of the General Administrative Regulation on the Principles for Carrying Out Official Monitoring of Compliance with The Provisions of Food Law, the Law on Animal By-Products, Wine Law, Feed Law and Tobacco Law, which indicates the competent authorities must perform internal audits and take appropriate measures considering the results of internal audits. The FSIS auditor's review of FLS supervisory reviews and internal audits in each visited Federal State did not raise any concerns.

The FSIS auditor verified that sufficient staffing was available to provide the required inspection. At establishments that are certified for export to the United States, depending on the district or independent municipality within a Federal State, an IIC could be either a food inspector or a meat inspector with responsibility for the daily inspection, which meets requirements for inspection by government inspection personnel once per production shift in pork processing establishments when producing product for export to the United States. The IIC conducts inspection activities including visual observation of operations and review of establishment food safety records, including Sanitation SOPs, sanitation performance standards (SPS), and HACCP, in accordance with Chapters 3 and 4 of German Guidelines, respectively. The daily pre-operational and operational sanitation verification inspection activities are conducted through direct observation and document review to ensure pre-operational and operational sanitation procedures are properly implemented on all food contact and non-food contact surfaces in the production areas.

The IICs document the results of their inspection activities in forms developed by each CA in alignment with the checklist provided in the German Guidelines. A sample of official daily monitoring checklists reviewed at the audited establishments indicated that IICs record the results of inspection and document any noncompliance or deviation from the HACCP requirements requiring corrective actions. All shifts in which products for export to the United

States are produced and any shift changes or changes to the product being produced are noted in the checklists. The FLS ensures that government inspection personnel perform verification procedures at the frequency required in the monitoring plan and that results are documented in the district specific forms or electronically, if applicable. The FSIS auditor's review and correlation of inspection records and establishment records did not raise any concerns.

Relating to requirements for complete separation of eligible meat from ineligible meat during production of processed pork products destined for export to the United States, the FSIS auditor observed the IIC review the health certificate accompanying a load of raw product prior to breaking its seal. Through the facility tour of each audited establishment and the document review the FSIS auditor verified that product intended for export to the United States is segregated and stored in dedicated locations conspicuously marked with "US Export" signs in freezers and coolers from the time of receipt of raw materials to the shipment of finished products. The FSIS auditor noted that the competent authorities in Federal States and BVL ensure that meat products intended for export to the United States are not subject to animal health restrictions by regularly visiting APHIS' website. Additionally, source material eligibility is reviewed by checking the FSIS Import/Export library product eligibility charts for individual countries from which Germany sources raw or processed pork products, which also summarizes APHIS restrictions. The FSIS auditor's review of this requirement concluded that Germany has procedures in place as described in relevant sections of German Guidelines to ensure complete separation of eligible processed pork products from other ineligible products during production of processed pork products intended for export to the United States. No concerns were identified by the FSIS auditor.

The FSIS auditor verified through interviews and record reviews that BVL requires certified establishments to properly label products intended for export to the United States. Per Chapter 8 of German Guidelines, establishments eligible to export to the United States must meet FSIS labeling requirements. Establishments must request approval from FSIS for labels that cannot be generically approved and must maintain records for all labels whether they are sketch-approved labels by FSIS or approved by FSIS through generic labeling regulations. German Guidelines further provides instruction to the IIC or FLS to verify the accuracy of labels during routine monitoring or as part of their pre-shipment verification activity. During the facility tour of several audited establishments producing a variety of product types, including NRTE products, the FSIS auditor performed a random check of labels on products intended for export to the United States and determined that labels on the products were in compliance with FSIS labeling requirements. The auditor further noted that the label on an NRTE pizza product intended for export to the United States had validated cooking instructions. The inspection documents as well as establishment records pertaining to products labels indicated that the IIC and FLS perform labeling verification of each lot of products intended for export to the United States.

Germany implements Regulation (EC) No. 852/2004, Regulation (EC) No. 853/2004, and Regulation (EU) 2017/625 to ensure condemned materials are controlled until they are destroyed or removed, and that inedible products are segregated from edible products. The CA in each Federal State requires each establishment in their respective state to maintain receptacles that are specifically designated for inedible or condemned materials. Control and disposal of those materials are required by Regulation (EC) No. 1069/2009 and Regulation (EC) No. 142/2011.

The proper control of inedible product is verified and documented routinely in the pertinent daily routine checklist. Measures to control condemned material are also evaluated during the initial certification process by the regional approving authority on their audit report as well as by the FLS during their documented monthly reviews. The FSIS auditor's review of documents and interviews with government inspection personnel did not raise any concerns.

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. An isolated finding pertaining to labeling requirements in one audited establishment has been captured in the Appendix A of this report.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component the FSIS auditor reviewed was Government Sanitation. The food safety inspection system is to require that each official establishment develop, implement, and maintain written Sanitation SOPs to prevent direct product contamination or insanitary conditions, and to maintain requirements for SPS.

The FSIS auditor assessed sanitation programs implemented and enforced at all audited establishments. In Germany, BVL requires all establishments certified to export to the United States to develop, implement, and maintain Sanitation SOPs, and to comply with the requirements laid out in overarching EC sanitary regulations, which include Regulation (EC) No. 852/2004, Regulation (EC) No. 853/2004, and Regulation (EU) 2017/625. These regulations require that the certified establishments' premises must allow for the cleaning and disinfecting of equipment, utensils, and FCS of equipment, as well as food production environment, and to avoid the creation of insanitary conditions. National laws and regulations, mainly LFGB and the Ordinance on the Enforcement of Food Acts of the European Community, give ability to CA in Federal States to require corrective actions and to take additional enforcement measures when noncompliance occurs. In the event an establishment is not in compliance with the laws and regulations or fails to implement effective corrective actions, the regional approving authority can take additional enforcement actions in accordance with Article 9 of the LMHV, which range from suspension to decertification, or withdrawal of inspection.

Through record reviews and interviews conducted with the FLS and IIC in audited establishments, the FSIS auditor confirmed that establishments certified to export to the United States have developed, implemented, and maintained Sanitation SOPs per part B. II sections 2.1.3.1. of German Guidelines. The audited establishments' Sanitation SOPs and monitoring documents also include pre-operational and operational sanitation verification activities. All equipment and utensils coming in contact with food undergo daily cleaning and sanitization prior to operation. The FSIS auditor noted that cleaning-in-place programs have been developed for metal pipes that run food between equipment and rooms. The FSIS auditor also observed that the establishments producing post-lethality exposed (PLE) RTE products and controlling *Lm* through a sanitation program implement extensive cleaning procedures. In addition to extensive cleaning, these establishments implement microbiological testing programs for *Lm* or *Listeria* species or

other indicator organisms for FCS and non-FCS in the production environment to verify the adequacy of their sanitation program. SPS-related requirements, such as for outside premises and pest management, have been addressed and are monitored at a specified frequency. The FSIS auditor was able to correlate his observations of outside premises and verification of SPS-related requirements with establishments' monitoring records and did not identify any concerns.

The FSIS auditor reviewed official documents related to sanitation verification by government inspection personnel and determined that the IIC routinely verifies establishments' implementation and monitoring of their sanitation programs including Sanitation SOPs. The IIC documents the verification outcome on district's provided checklists. The IIC and FLS in all audited establishments have included pre-operational sanitation verification with frequencies sufficient to ensure that establishments are adhering to their sanitation plan and effectively prevent insanitary conditions or product adulteration. The FSIS auditor's review of a sample of completed checklists of official verification activities indicated that all elements in the verification checklist aligned with sanitation requirements, which are consistent with the requirements in 9 CFR part 416. The checklist has provisions for remarks which must be completed when a noncompliance requiring corrective action is detected. Whenever "No" is entered on the checklist because of sanitation verification, a corresponding remark detailing the nature and extent of the noncompliance is recorded and followed until the noncompliance record is closed. Sanitation SOPs and SPS requirements are also captured during monthly supervisory visits by the FLS. Noncompliance noted by the FLS are followed up either by the FLS or IIC. In addition to supervisory verification, sanitation requirements are verified by regional approving authorities at the time of establishment certification and annually thereafter. No concerns arose as result of the FSIS auditor's verification.

The FSIS auditor assessed the adequacy of the pre-operational inspection verification by observing the IIC conducting pre-operational sanitation verification inspection in one of the audited establishments. The in-plant government inspection personnel's hands-on verification procedures started after the establishment had conducted its pre-operational sanitation and informed the IIC that the facility was ready for pre-operational sanitation verification inspection. The FSIS auditor's assessment of the pre-operational sanitation verification did not raise any concerns, except for isolated observations recorded in establishment checklists in Appendix A of this report.

FSIS onsite audit verification activities indicate that BVL requires establishments certified to export to the United States to develop, implement, and maintain sanitation programs to ensure that the establishment's construction, facilities, and equipment prevent the contamination or adulteration of meat products destined for export to the United States. The FSIS auditor observed isolated noncompliances related to the inspection verification of sanitation requirements. These are noted in the individual establishment checklists provided in Appendix A of this report.

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

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

The specific provisions of Regulation (EC) No. 852/2004 forms the legal basis for implementation of overarching HACCP requirements in all certified establishments in Germany. BVL has incorporated HACCP requirements consistent with 9 CFR part 417 into Chapter 4 of part B of German Guidelines. Establishments certified to export to the United States must develop, implement, and maintain HACCP systems per provisions outlined in Chapter 4 of part B of German Guidelines referenced above. In addition, the CA in Federal States having jurisdiction over establishments certified to export to the United States verifies compliance according to the requirements of Chapter 4 of part B of German Guidelines.

The FSIS auditor verified implementation of government verification of HACCP systems in all audited establishments. Each audited establishment maintains product description records, including information such as the HACCP process category, product shelf life, and targeted consumer. Establishments' hazard analyses matched the flow diagrams for each processing step, and considered all microbiological, chemical, and physical hazards associated with each processing step. Any hazard in the hazard analysis that is determined to be likely to occur is addressed with a critical control point (CCP). For hazards that were identified as not reasonably likely to occur, establishments provided documentation to support their decision, including scientific studies or technical papers, as applicable. The FSIS auditor noted that chemical hazards associated with incoming raw materials are addressed through letters of guarantee from the supplier of the raw material. Imported raw product used to prepare products for export to the United States originates from certified establishments in Denmark and the Netherlands. Each establishment developed HACCP plans that corresponded to the hazard analysis and identified CCPs with supportable critical limits (CLs).

The FSIS auditor confirmed that establishments handling PLE RTE products control the microbiological hazard of *Lm* by adopting one of three alternative controls consistent with those described in 9 CFR 430.4. The FSIS auditor also verified that establishments producing non-PLE RTE or NRTE products also identified all known microbiological, chemical, and physical hazards including allergens associated with their products. The FSIS auditor's review of establishments' HACCP-related documents included monitoring and verification records, decision-making documents, and scientific and in-house data did not identify any concerns, except for isolated observations recorded in establishment checklists in Appendix A of this report.

The FSIS auditor conducted interviews and reviewed government records related to HACCP system verification in all visited Federal States having jurisdiction over establishments certified to export to the United States. The daily inspection records reviewed at each local inspection office indicate inspectors routinely verify HACCP related control measures including CCPs, control points, verification records, and pre-shipment reviews, and any noncompliance or deviations from the CL are documented and followed up until resolved. For instance, where a deviation from a CL occurs, the corrective actions employed are in accordance with the requirements of Section 4.2.4 of Chapter 4 of German Guidelines, which are consistent with 9 CFR 417.3. While touring the audited facilities, the FSIS auditor observed an establishment employee monitoring CCPs and recording the reading on establishment monitoring records. The FSIS auditor also observed government inspection personnel verifying the plant employee's

monitoring of the CCP. In another establishment, the FSIS auditor observed the IIC conducting hands-on verification of a CCP followed by record review of the establishment's monitoring record.

The IIC, who may be a meat inspector or food inspector, is supervised by the FLS during monthly visits to assess inspectors' performance in verifying compliance of establishments with HACCP requirements. HACCP requirements are also verified at the time the regional approving authority makes an initial verification visit to any establishment requesting to be certified as eligible to export to the United States. If approval is granted, compliance with HACCP requirements is verified annually to ensure the establishment continues to maintain the eligibility requirements. The FSIS did not identify any concerns during the review of documents pertaining to supervisory visits and approving authorities' verification for HACCP system compliance.

The FSIS onsite verification activities indicate that BVL requires establishments to develop, implement, and maintain a HACCP system for each processing category. FSIS concludes that BVL continues to meet the core requirements for this component. However, the FSIS auditor identified isolated establishment noncompliances related to verification of HACCP basic and ongoing requirements. These findings are noted in the individual establishment checklists provided in appendix A of this report.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth equivalence component the FSIS auditor reviewed 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, or muscle of carcasses for chemical residues identified by the exporting country's meat products inspection authorities or by FSIS as potential contaminants.

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 the 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. BVL routinely reviews the results of chemical residue monitoring from the countries providing source materials. BVL also monitors RASFF for any documented cases of product exceeding established chemical residue levels.

There have not been any POE violations related to this component since the previous FSIS audit in 2021.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component the FSIS auditor reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and

testing programs to ensure that meat prepared for export to the United States is safe and wholesome.

BVL has drawn its definition for ready-to-eat (RTE) product from Commission Regulation (EC) No. 2073/2005, which states, “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.” BVL considers *Lm* and *Salmonella* adulterants in RTE products as described in Chapter 7 of German Guidelines. If RTE product tests positive for *Lm* or if RTE product comes into direct contact with a food contact surface that has tested positive for *Lm*, the RTE product is considered adulterated. BVL defines a production lot in Chapter 7 of German Guidelines and directs establishments producing PLE RTE products to refer to the FSIS guideline, Controlling *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products, for further guidance on how to maintain microbiological independence of shipment lots intended for export to the United States.

Germany has adopted requirements consistent with 9 CFR 430.4, and requires establishments certified to export to the United States to identify and implement control programs designed to prevent adulteration of RTE products with *Lm*. Through observations, document reviews, and interviews with the government inspection officials, the FSIS auditor verified that the audited establishments that produce PLE RTE products have adopted one of the three alternatives to control *Lm*, consistent with 9 CFR 430.4. The FSIS auditor also verified that the audited establishments tailored their microbiological sampling programs in accordance with the alternative applied to PLE RTE products to verify the efficacy of *Lm* controls.

The FSIS auditors reviewed records and verified that establishments producing fully cooked products ensure their cooking process achieves a 6.5-log reduction for *Salmonella*, followed by a stabilization step to prevent germination of spore-forming pathogens. These measures are consistent with the performance standard for *Salmonella* in fully cooked products as described in German Guidelines, which also references FSIS’ guidelines for cooking (Revised Appendix A) and stabilization (Revised Appendix B). In addition to the requirements in German Guidelines, establishments must implement applicable microbiological testing as described in Commission Regulation (EC) No. 2073/2005. The FSIS auditor verified the audited establishments adhere to BVL requirements and no issues were identified.

The FSIS auditor verified through interviews and record reviews that BVL and CA in all Federal States with jurisdiction over establishments certified to export to the United States conduct verification sampling of both PLE and non-PLE RTE products for *Lm* and *Salmonella*. All government verification sampling is conducted by government inspection personnel who ship the samples to the BVL-designated laboratory for analysis. BVL implements RTE sampling programs for both routine and risk-based sampling consistent with FSIS verification sampling programs described in FSIS Directives 10240.3, 10240.4, 10240.5, and 10300.1. The FSIS auditor verified through review of official records maintained at the local and district inspection offices that the frequency of official verification testing is based on each establishment’s selected *Lm* alternatives, consistent with requirements in German Guidelines. In one audited establishment, the FSIS auditor verified that government inspection personnel collected official

RTE verification samples following the sampling instructions provided in Chapter 7 of German Guidelines. No concerns were identified.

German Guidelines indicates that establishments producing PLE RTE products under processed classified as Alternative 2b or 3 are required to implement sampling of FCS for *Lm* or *Listeria* species, consistent with FSIS requirements in 9 CFR part 430. The IIC verifies that the establishment's written programs meet BVL requirements, including the location of sampling, randomness of sampling, and sample integrity. The IIC also ensures that the establishment takes appropriate corrective actions when an analytical test returns a positive result.

The FSIS audit included one establishment producing TPCS products. Regulation (EC) No. 852/2004 forms the basis for the application of HACCP principles in establishments producing TPCS products. The HACCP system requirements to address microbiological hazards associated with the production of hermetically-sealed products are described in Article 5 of Regulation (EC) No. 852/2004. Further requirements for hermetically-sealed containers are contained in Annex 2, Chapter XI of Regulation (EC) No. 852/2004, which describes minimum time and temperature parameters to ensure lethality for the product. BVL and CAs in each Federal State also require establishments producing TPCS products for export to the United States to follow instructions outlined in Codex Alimentarius CAC/RCP 23-1979 2.9, Commercial Sterility of Thermally Processed Food.

The FSIS auditor verified that the audited TPCS establishment implements a HACCP system in accordance with BVL and Federal State requirements to ensure commercial sterility is achieved. 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, product incubation data) conducted in thermal processing areas. No concerns were identified.

The FSIS auditor found that Germany's inspection system for processed pork products includes a microbiological testing program organized and administered by the national government and that BVL has implemented the necessary microbiological sampling and testing programs that meet the core requirements of this component. There have not been any POE violations related to this component since the previous FSIS audit in 2021.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held May 7, 2024, with BVL and representatives of the CA for each Federal State with jurisdiction over the audited establishments. FSIS concluded that Germany's processed pork products inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. BVL requires that establishments certified as eligible to export products to the United States implement sanitation requirements and a HACCP system designed to improve the safety of their products. In addition, BVL implements an official microbiological testing program that is organized and administered by the national government to verify its system. An analysis of each component did not identify any systemic findings representing an immediate threat to public health.

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 Meica Ammerländische Fleischwarenfabrik Fritz Meinen GmbH & Co. KG Meicastraße 6 26188 Edewecht (Lower Saxony)	2. AUDIT DATE 04/17/2024	3. ESTABLISHMENT NO. A-EV-34	4. NAME OF COUNTRY Germany
	5. OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

Establishment Operations:	Pork processing.
Prepared Products:	

60. Observation of the Establishment

39. A rubber hose around a steel pipe carrying brine to fill glass jars was degrading and cracking around its edges, if left unchecked could shed rubber pieces into the product.
41. During the tour of the facility, the auditor observed overhead beaded condensation in multiple processing rooms. Over the product condensation was observed on steel pipes feeding ground meat into mixing hoppers.
42. A drain in a cooler where meat for the US export is stored had a pool of stagnant water. Residues of meat and fat was also observed deposited around the drain cover was creating insanitary condition and providing ideal condition for bacterial harborage. No meat for the US export was stored at the time of observation.

The establishment management corrected all identified issues immediately.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Schinkenhof GmbH & Co., KG Severinstr 12 77855 Achern	2. AUDIT DATE 04/24/2024	3. ESTABLISHMENT NO. BW 05068	4. NAME OF COUNTRY Germany
	5. OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

Establishment Operations:	Pork processing.
Prepared Products:	

60. Observation of the Establishment

In ham salting room the auditor observed the following:

41. Overhead condensation, a leaking pipe, and frayed/eroding rubber sleeves around plumbing fittings was observed in the salting room. No product adulteration observed during the audit.

46.

- Perforations and openings by design of plastic meat containers would allow meat to get wedged in holes or perforations of containers. In one such container the auditor observed a portion of ham product protruding out and touching the exterior of the crate.
- In multiple coolers around the door-floor junction dirt and debris was collected which was creating insanitary conditions. In one cooler, the door-floor junction had water and dirt that appeared to be neglected for days.
- In one drying room where palletized containers of ham products for the US export were stored, the products in outer containers of the bottom layer were not fully covered in protective plastic sheets and thus exposed to potential contamination.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Freiberger Lebensmittel GmbH & Co. Produktions- und Vertriebs KG Werk Muggensturm Draisstrasse 1-5 Muggensturm Baden-Württemberg	2. AUDIT DATE 04/23/2024	3. ESTABLISHMENT NO. BW-03330	4. NAME OF COUNTRY Germany
	5. OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

Establishment Operations:	Pork processing.
Prepared Products:	

60. Observation of the Establishment

There were no findings after consideration of extent, degree, and nature of all observations

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Hans Kupfer & Sohn GmbH & Co.KG Mausendorfer Weg 11 91560 Heilsbronn	2. AUDIT DATE 04/26/2024	3. ESTABLISHMENT NO. BY 50008	4. NAME OF COUNTRY Germany
	5. OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

Establishment Operations:	Pork processing.
Prepared Products:	

60. Observation of the Establishment

25. In the mixing room the auditor observed a plastic tote containing salts and/or spices did not have any label as to the contents in the container.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Gebrüder Kupfer GmbH & Co. KG Marburger Str. 8 90427 Nürnberg	2. AUDIT DATE 04/30/2024	3. ESTABLISHMENT NO. BY 50567	4. NAME OF COUNTRY Germany
	5. OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

Establishment Operations:	Pork processing.
Prepared Products:	

60. Observation of the Establishment

- 15.
- The following findings were identified pertaining to HACCP system requirements:
- Neither product description document nor establishment’s HACCP plan identify the correct HACCP process category for the US export. The review of HACCP plan identified that the establishment produces cooked sausages under the HACCP process category “fully cooked-not shelf stable.”
 - The establishment’s flow diagram did not include a cooling step after pasteurization step and consequently failed to conduct hazard analysis for the cooling step.
 - The establishment’s hazard analysis did not specify the core temperature or time the product should be held in the water heating tunnel for the fully cooked sausages.
 - The establishment’s hazard analysis or HACCP plan did not identify the known microbiological hazard (Clostridium perfringens and Clostridium botulinum) at the product cooling step.

41. In the establishment’s filling room, overhead beaded condensation was observed in multiple locations including over the product condensation at one of the sausage filling stations.

The FLS leading the audit committed to correcting the findings immediately.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION EG, H. Klümper GmbH & Co. KG Niedersachsenstr. 22 48465 Schüttorf	2. AUDIT DATE 04/19/2024	3. ESTABLISHMENT NO. DE NI 18210 EG	4. NAME OF COUNTRY Germany
	5. OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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8. Records documenting implementation.		34. Species Testing	
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Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
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14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

Establishment Operations:	Pork processing.
Prepared Products:	

60. Observation of the Establishment

There were no findings after consideration of extent, degree, and nature of all observations.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION HoWe Wurstwaren KG Regenstrasse 1 Nurnberg Bayern	2. AUDIT DATE 04/29/2024	3. ESTABLISHMENT NO. EV-717	4. NAME OF COUNTRY Germany
	5. OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Establishment Operations:	Pork processing.
Prepared Products:	

60. Observation of the Establishment

41. During operational sanitation verification the auditor observed beaded condensation at various locations in the filling room where product for US export was being prepared. At one location condensation was directly above the sausage product. No dripping of condensate was noted at the time the observation was made. The front-line supervisor leading the audit required immediate corrective action when this situation was pointed out.

46. During the pre-operational verification:

- The FSIS auditor noted that ready-to-be used clean steel totes were stored in a manner where one of their edges were resting on the floor thereby posing a potential for contamination.
- The commercial sized plastic containers used to transport incoming raw pork meat to be used for the US export appeared not being subject to routine washing. A frequency for cleaning of these containers was not specified in the SSOP. A stack of containers containing meat, although covered with plastic sheet on the top, collected visible dirt all around their top portions. Some of the plastic containers had rough jagged edges which would be difficult to sanitize properly.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Bell Deutschland GmbH & Co. KG Osterschepser Str. 40 Edewecht Niedersachsen	2. AUDIT DATE 04/18/2024	3. ESTABLISHMENT NO. A-EV-35	4. NAME OF COUNTRY Germany
	5. OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
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16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
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21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	O
25. General Labeling		53. Animal Identification	O
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic E. coli Testing		55. Post Mortem Inspection	O
27. Written Procedures	O	Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis	O	56. European Community Directives	
29. Records	O	57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions	O	59.	
31. Reassessment	O		
32. Written Assurance	O		

Establishment Operations:	Pork processing.
Prepared Products:	

60. Observation of the Establishment

41. Beaded condensation was observed at multiple locations where product was being processed. In the mixing room condensation above a conveyor belt carrying meat product to the mixer was quite noticeable throughout its entire length. The establishment management immediately shut the belt off and retained the product for further evaluation for possible contamination and dispositon accordingly.
46. Visible dirt collected around on various parts on multiple totes containing incoming raw meat products was posing risk for product adulteration. No product contamination was observed at the time of audit.

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



Federal Office of
Consumer Protection
and Food Safety

Federal Office of Consumer Protection and Food Safety (BVL)
Berlin Office • P.O. Box 11 02 60 • 10832 Berlin • Germany

InternationalCoordination@usda.gov
Office of International Coordination
USDA, FSIS
1400 Independence Avenue, SW
Washington, D.C. 20250, USA
copy:
AgBerlin@fas.usda.gov
USDA FAS
Clayallee 170, 14195 Berlin

la-1@wash.auswaertiges-amt.de
Botschaft der Bundesrepublik Deutschland
4645 Reservoir Rd. NW,
Washington, D.C. 20007

324@bmel.bund.de
Bundesministerium für Ernährung und
Landwirtschaft (BMEL)
Postfach 14 02 70, 53107 Bonn

Via e-mail only

Comments on the “draft final report of an audit conducted of Germany April 15 – May 07, 2024”

Dear Margaret Burns Rath,

Please find the response of the CCA Germany, the Federal Office of Food Safety and Consumer Protection (BVL) and the Competent Authorities (CAs) of the Federal States attached to this letter. Attachment 1 contains a table with comments related to the draft final report of the audit conducted April 15 – May 7, 2024 of Germany evaluating the food safety systems governing processed pork products exported to the United States of America. The action plan in Attachment 2 is informing about corrective actions related to the findings mentioned in the draft final report which have been implemented by the establishments concerned. All corrective actions have been officially verified.

Dr. Soumaya Lhafi
Head of Unit

COMPOSED BY Stefanie Roth
PHONE +49 3018 444-18010
FAX +49 3018 444-89999
E-MAIL 180@bvl.bund.de

YOUR REFERENCE
YOUR MESSAGE FROM

OUR REFERENCE 180.16450.0.16461
(specify when answering)

DATE September 10, 2024

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

Yours sincerely,
on behalf of BVL



Dr. Soumaya Lhafi

Attachment

01a_Comments Germany.docx

01b_Comments Germany.pdf

02a_Action Plan Germany.docx

02b_Action Plan Germany.pdf

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 15. April 2024 bis 07. Mai 2024 durchgeführt. Ziel des Audits war es zu überprüfen, ob die Äquivalenzanerkennung des deutschen Überwachungssystems hinsichtlich der Hygiene bei der Gewinnung von Schweinefleisch 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 April 15 2024 to May 07 2024. 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
ii	“BVL has implemented an official microbiological testing program that is organized and administered by the national government to verify its system”	BVL has implemented an official microbiological testing program that is organized and administered by the national government to verify its system, the national “Zoonoses Monitoring Programme”: Link to the national zoonoses program on the BVL Homepage.	Name and Link to the testing program
2	“The FSIS auditor assessed BVL’s ability to provide oversight through supervisory reviews ...”	The FSIS auditor assessed CA’s ability to provide oversight through supervisory reviews	Supervisory visits of authorities lies within the responsibility of the Federal State CA’s and not the BVL
3	“Federal State Authority included: Ministry, Provincial, and District levels, • Bavaria, Ansbach • Baden-Württemberg, Karlsruhe“	Federal State Authority included: Ministry, Provincial, and District levels, Lower Saxony • ML (Highest Federal State Authority) • LAVES (Approval Authority) • Landkreis Ammerland (Inspection Office) • Grafschaft Bentheim (Inspection Office) Baden-Württemberg • MLR, Stuttgart (Highest Federal State Authority) • Regierungspräsidium Karlsruhe (Approval Authority) • Landratsamt Rastatt (Inspection Office) • Regierungspräsidium Freiburg (Approval Authority) • Landratsamt Ortenaukreis (Inspection Office) Bavaria • StMUV (Highest Federal State Authority) • Ansbach, Regierung Mittelfranken (Approval Authority) • Veterinäramt Stadt Nürnberg (Inspection Office) • LGL (Approval Authority) • KBLV (Inspection Office)	There were more than two authorities audited
3	EV-34, Meica Ammerländische, Fleischwarenfabrik ...	EV 34, Meica Ammerländische Fleischwarenfabrik ...	proposed wording according to BLtU-list: Link to the BLtU-List. and the Annual Recertification 2024

3	AEV-35, Bell ...	A EV 35, Bell ...	proposed wording according to BLtU-list and the Annual Recertification 2024
3	DE NI 18210 EG, H. Klümper ...	DE NI 18210, H. Klümper ...	proposed wording according to the Annual Recertification 2024
3	BW 03330 Freiberger Lebensmittel GmbH & Co. Produktions- und Vertriebs KG, Muggensturm	BW 03330 Freiberger Lebensmittel GmbH	proposed wording according to BLtU-list and the Annual Recertification 2024
3	BY50567	BY 50567	proposed wording according to BLtU-list and the Annual Recertification 2024
4	“previous FSIS audit in 2022”	Previous FSIS audit in 2021	The previous FSIS audit in Germany took place in 2021
5	“Germany’s National Food Hygiene Regulation (LMHV) requires that approval of establishments for export to other countries, such as the United States, ...”	Germany’s National Food Hygiene Regulation (LMHV) requires an approval of establishments for export to other countries if necessary as it is the case for the United States	The USA are the only Third Country where such an approval is compulsory per law
5	“the CAs of the Federal States, with oversight by BVL, are also responsible for”	“the CAs of the Federal States are also responsible for”	Corrigendum concerning responsibilities
5	“the Federal Ministry for Environment, Nature Conservation, Building and Nuclear Safety”	the Federal Ministry for Environment, Nature Conservation, Nuclear Safety and Consumer Protection	Corrigendum of the name
5	“the Federal Ministry of Justice and Consumer Protection”	the Federal Ministry of Justice	Corrigendum of the name
5	“BVL exerts its legislative and regulatory authority to enforce rules and regulations for food and feed safety, animal health, and animal welfare.”	BVL exerts its legislative and regulatory authority to act as an advisory and coordinating body concerning rules and regulations for food and feed safety, animal health, and animal welfare.	Enforcement lies within the CA’s of the Federal States
5	“BVL coordinates with the Federal States Working Group for Foods of Animal Origin (LAV) and updates the Implementation Instructions for Carrying Out Official Controls in Food Businesses that Export Meat Products to the USA (hereinafter referred to as German Guidelines) as needed.”	BVL is chairing the Expert Working Group “Export to the USA” and updates the Implementation Instructions for Carrying Out Official Controls in Food Businesses that Export Meat Products to the USA (hereinafter referred to as German Guidelines) as needed. Once a new version of the German Guidelines is finalized, a vote within the Federal States Working Group for Foods of Animal Origin (LAV AFFL) for mandatory implementation in all Federal States is issued.	There are two different Working Groups involved in the Process: the “Expert Working Group “Export to the USA”” (finalizing a new version of the German Guidelines) and the Federal States Working Group for Foods of Animal Origin (LAV AFFL) (vote for a mandatory implementation in all Federal States)
6	“The current audit included two Federal States, ...”	The current audit included three Federal States, Bade-Wuerttemberg, Bavaria and Lower Saxony ...”	Corrigendum, three Federal States were audited

6	“which require the CCA to establish procedures for approvals and withdrawal of approvals of establishments, and further requires the CCA to review and ensure establishments’ compliance with the relevant requirements of food law.”	which requires Germany to establish procedures for approvals and withdrawal of approvals of establishments, and further requires the CA’s of the Federal States to review and ensure establishments’ compliance with the relevant requirements of food law.	Clarification of responsibilities
6	“Part B.II.6 of German Guidelines outlines the key elements in handling recalls ...”	Part B.III.6 of German Guidelines outlines the key elements in handling recalls	Corrigendum
7	“The communication between BVL and various parts of the inspection system at the Federal States level is maintained through FIS-VL.”	The communication between BVL and various parts of the inspection system at the Federal States level is maintained amongst other channels through FIS-VL.	Complementary information
7	“All government inspection personnel assigned to the certified establishments have access to FIS-VL through the intranet.”	All government inspection personnel assigned to the certified establishments have access to FIS-VL.	Corrigendum
7/8	“The LAV holds workgroup meetings to address any issues concerning all Federal States with the certified establishments. One major objective of LAV is to discuss when an amendment or a revision of German Guidelines is required. LAV meetings between BVL and CAs at all levels of the Federal States are utilized to achieve uniform application of FSIS requirements across Germany’s inspection system.”	The BVL holds expert (export to the USA) workgroup meetings to address any issues concerning all Federal States with the certified establishments. One major objective of the expert workgroup (export to the USA) is to discuss when an amendment or a revision of German Guidelines is required. Expert workgroup meetings between BVL and CAs at all levels of the Federal States are utilized to achieve uniform application of FSIS requirements across Germany’s inspection system.	The function described lies within the expert workgroup (export to the USA) and not within the responsibility of the Federal States Working Group for Foods of Animal Origin (LAV AFFL) where the vote for a mandatory implementation of the German Guidelines in all Federal States is conducted.
8	“with a doctor of veterinary medicine degree”	with an approbation certificate of veterinary medicine degree	Corrigendum
8	“including 4 weeks of practical training”	Each official veterinarian must undergo practical training for a probationary period of at least 200 hours before starting to work independently: Link to the english legal text on the website of the EU Commission.	Corrigendum using a citation of the original Regulation
8	“The FSIS auditor assessed BVL’s measures to ensure that adequate administrative and technical support is available to its laboratory system.”	The FSIS auditor assessed the CA’s measures to ensure that adequate administrative and technical support is available to its laboratory system.	This responsibility lies within the Federal State CA of Lower Saxony
8	“BVL has designated the Lower Saxony State Office for Consumer Protection and Food Safety - Food and Veterinary Institute (LAVES-FVI), located in Oldenburg, as an official laboratory.”	The Lower Saxony State Office for Consumer Protection and Food Safety - Food and Veterinary Institute (LAVES-FVI), located in Oldenburg, is the designated official laboratory for analyses using MLG Methods.	Corrigendum
8	“BVL requires the official laboratory to use methods in FSIS’ Microbiological Laboratory Guidebook (MLG)”	The official laboratory has, according to Article 12 of Regulation (EC) No 178/2002 in conjunction with FSIS legal requirements and as described in the German Guidelines to use methods in FSIS’ Microbiological Laboratory Guidebook (MLG)	Corrigendum

8	“The FSIS auditor verified that the LAVES-FVI laboratory implements FSIS’ MLG methods for analysis of environmental and RTE products for <i>Lm</i> and <i>Salmonella</i> as required by BVL and described in Chapter 7 of German Guidelines.”	The FSIS auditor verified that the LAVES-FVI laboratory implements FSIS’ MLG methods for analysis of environmental and RTE products for <i>Lm</i> and <i>Salmonella</i> as required and described in Chapter 7 of German Guidelines.	Corrigendum
9	“BVL requires product to be held until acceptable results are received.”	According to the German Guidelines, officially sampled product has to be held until acceptable results are received. This requirement is officially verified by the CA’s of the Federal states.	Corrigendum concerning responsibilities
11	“The FSIS auditor verified through interviews and record reviews that BVL requires certified establishments to properly label products intended for export to the United States.”	The FSIS auditor verified through interviews and record reviews that certified establishments are required to properly label products intended for export to the United States. This requirement is officially verified by the CA’s of the Federal states.	Corrigendum concerning responsibilities
12	“In Germany, BVL requires all establishments certified to export to the United States to develop, implement, and maintain Sanitation SOPs, ...”	In Germany, all establishments certified to export to the United States are required to develop, implement, and maintain Sanitation SOPs, ... This requirement is officially verified by the CA’s of the Federal states.	Corrigendum concerning responsibilities
12	“which range from suspension to decertification, or withdrawal of inspection.”	which range from suspension to decertification, or withdrawal of approval/certification.	Corrigendum concerning legal measures
13	“BVL requires establishments certified to export to the United States to develop, implement, and maintain sanitation programs”	establishments certified to export to the United States are required to develop, implement, and maintain sanitation programs. This requirement is officially verified by the CA’s of the Federal states.	Corrigendum concerning responsibilities
15	“BVL requires establishments to develop, implement, and maintain a HACCP system for each processing category.”	Approved establishments are required by EU and national law to develop, implement, and maintain a HACCP system for each processing category. The German Guidelines contain further information for establishments with US-approval concerning US legal requirements. This requirement is officially verified by the CA’s of the Federal states.	Corrigendum concerning responsibilities and legal requirements
15	“FSIS concludes that BVL continues to meet the core requirements for this component.”	“FSIS concludes that Germany continues to meet the core requirements for this component.”	Corrigendum concerning responsibilities
16	“BVL has drawn its definition for ready-to-eat (RTE) product from Commission Regulation (EC) No. 2073/2005, which states, “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 definition for ready-to-eat (RTE) product is defined in Commission Regulation (EC) No. 2073/2005, which states, “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.”	Corrigendum concerning responsibilities and legal requirements
16	“BVL considers <i>Lm</i> and <i>Salmonella</i> adulterants in RTE products as described in Chapter 7 of German Guidelines.”	As described in Chapter 7 of German Guidelines <i>Lm</i> and <i>Salmonella</i> are considered as adulterants in RTE products.	Corrigendum concerning responsibilities

16	“BVL defines a production lot in Chapter 7 of German Guidelines and directs establishments producing PLE RTE products to refer to the FSIS guideline, ...”	A production lot is defined in Chapter 7 of German Guidelines for establishments producing PLE RTE products the German Guidelines refer to the FSIS guideline, ...	Corrigendum concerning responsibilities
16	“The FSIS auditor verified the audited establishments adhere to BVL requirements and no issues were identified.”	The FSIS auditor verified the audited establishments adhere to the described requirements and no issues were identified.	Corrigendum concerning responsibilities and legal requirements
16	“The FSIS auditor verified through interviews and record reviews that BVL and CA in all Federal States with jurisdiction over establishments certified to export to the United States conduct verification sampling ...”	The FSIS auditor verified through interviews and record reviews that the CA's in all Federal States with jurisdiction over establishments certified to export to the United States conduct verification sampling	Corrigendum concerning responsibilities
16	“... who ship the samples to the BVL-designated laboratory for analysis.”	... who ship the samples to the designated laboratory for analysis.	Corrigendum concerning responsibilities
16	“BVL implements RTE sampling programs for both routine and risk-based sampling”	In Germany RTE sampling programs for both routine and risk-based sampling are implemented according to the German Guidelines ...	Corrigendum concerning responsibilities
17	“establishment's written programs meet BVL requirements, ...”	establishment's written programs meet the requirements described in the German Guidelines, ...	Corrigendum concerning responsibilities
17	“BVL and CAs in each Federal State also require establishments producing TPCS products for export to the United States to follow instructions outlined in Codex Alimentarius CAC/RCP 23-1979 2.9, ...”	establishments producing TPCS products for export to the United States are required to follow instructions outlined in Codex Alimentarius CAC/RCP 23-1979 2.9, ...	Corrigendum concerning responsibilities
17	“HACCP system in accordance with BVL and Federal State requirements to ensure ...”	HACCP system which ensures ...	Corrigendum concerning responsibilities
17	“and that BVL has implemented the necessary microbiological sampling and testing programs that meet the core requirements of this component.”	and that in Germany, there are implemented the necessary microbiological sampling and testing programs that meet the core requirements of this component.	Corrigendum concerning responsibilities
17	“BVL requires that establishments certified as eligible to export products to the United States implement sanitation requirements and a HACCP system designed to improve the safety of their products.”	BVL requires that establishments certified as eligible to export products to the United States implement sanitation requirements and a HACCP system designed to improve the safety of their products. This requirement is officially verified by the CA's of the Federal states.	Corrigendum concerning responsibilities
17	“BVL implements an official microbiological testing program that is organized and administered by the national government to verify its system.”	BVL implements an official microbiological testing program that is organized and administered by the national government to verify its system, the national “Zoonoses Monitoring Programme”: Link to the BLtU-list .	Name and Link to the testing program

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 15. April 2024 bis 07. Mai 2024 durchgeführt. Ziel des Audits war es zu überprüfen, ob die Äquivalenzanerkennung des deutschen Überwachungssystems hinsichtlich der Hygiene bei der Gewinnung von Schweinefleisch 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 April 15 2024 to May 07 2024. 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.

Anhang A**Betrieb, Zulassungsnummer: Meica Ammerländische Fleischwarenfabrik Fritz Meinen GmbH & Co. KG, Meicastraße 6, 26188 Edeweicht, EV 34**

Appendix A

Establishment, approval number: Meica Ammerländische Fleischwarenfabrik Fritz Meinen GmbH & Co. KG, Meicastraße 6, 26188 Edeweicht, EV 34

Seite Nr. Page No.	Beanstandung (Nr./Prüfkomponente) Finding (No./component)	Ursachenanalyse root cause analysis	Korrekturmaßnahmen, Präventivmaßnahmen corrective actions, preventive measures
2	39. A rubber hose around a steel pipe carrying brine to fill glass jars was degrading and cracking around its edges, if left unchecked could shed rubber pieces into the product.	The rubber hose was not recognized as defective by the employees.	The rubber hose was replaced immediately. The rubber hose will be checked in the future as part of pre-op and maintenance inspections.
2	41. During the tour of the facility, the auditor observed overhead beaded condensation in multiple processing rooms. Over the product condensation was observed on steel pipes feeding ground meat into mixing hoppers.	The condensation was not noticed by the employees and therefore not removed.	The condensation was removed immediately. The employees were trained to remove condensation immediately.
2	42. A drain in a cooler where meat for the US export is stored had a pool of stagnant water. Residues of meat and fat was also observed deposited around the drain cover was creating insanitary condition and providing ideal condition for bacterial harborage. No meat for the US export was stored at the time of observation.	The drain was not cleaned by employees according to the cleaning schedule.	The drain was cleaned immediately. The employees were trained to carry out the cleaning according to the specifications.
Landkreis Ammerland, Veterinär- und Lebensmittelüberwachungsamt Concerning the above mentioned findings the CA Landkreis Ammerland, Veterinär- und Lebensmittelüberwachungsamt has officially verified the following: The establishment's root cause analysis The establishment's corrective actions 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

Schinkenhof GmbH & Co., KG, Severinstr 12, 77855 Achern, BW 05068

Currently named as Adler Schwarzwald GmbH & Co. KG Werk Schinkenhof

Appendix A

Establishment, approval number: Schinkenhof GmbH & Co. KG, Severinstr 12, 77855 Achern, BW 05068

Currently named as Adler Schwarzwald GmbH & Co. KG Werk Schinkenhof

Seite Nr. Page No.	Beanstandung (Nr./Prüfkomponente) Finding (No./component)	Ursachenanalyse root cause analysis	Korrekturmaßnahmen, Präventivmaßnahmen corrective actions, preventive measures
2	41. <i>Overhead condensation, a leaking pipe, and frayed/eroding rubber sleeves around plumbing fittings was observed in the salting room. No product adulteration observed during the audit.</i>	Cause: condensation formed on the evaporators due to existing cold bridges between the neighboring rooms.	Measures: A drainage option was created under the evaporators, which drains the condensation directly and the drained condensation water is removed daily. There is no open raw material allowed under the affected area. In addition, a special ceiling cleaning device was purchased so that further spray and condensation water can be removed immediately. The employees were trained on this regard on May 3rd, 2024. The broken parts were repaired, new replacement parts were installed. The Ventilation situation will also be improved by purchasing new machines in the neighboring room this year.
2	46 <i>-Perforations and openings by design of plastic meat containers would allow meat to get wedged in holes or perforations of containers. In one such container the auditor observed a portion of ham product protruding out and touching the exterior of the crate.</i>	Cause: the raw material is delivered to the plant in that manner.	Measures: The responsible suppliers have been informed by the company. The employees responsible for incoming goods have already been made aware of this as part of a training course on May 3rd, 2024. From now on, every pallet of raw material will be circled and checked for pieces of meat hanging out. These will be removed immediately. Broken Boxes will be sorted out and returned to the supplier.

	<p><i>-In multiple coolers around the door-floor junction dirt and debris was collected which was creating insanitary conditions. In one cooler, the door-floor junction had water and dirt that appeared to be neglected for days.</i></p>	<p>Cause: The area was forgotten during cleaning and disinfection. The affected area was not explicitly listed in the SSOP-Plans.</p>	<p>Measures: The employees responsible for this area have been trained on this topic on May 3rd, 2024. The SSOP plans were adjusted and the area was included in the regular cleaning and disinfection schedule.</p>
	<p><i>-In one drying room where palletized containers of ham products for the US export were stored, the products in outer containers of the bottom layer were not fully covered in protective plastic sheets and thus exposed to potential contamination.</i></p>	<p>Cause: The intermediate layers on each salting boxes layer do not completely cover the salting boxes.</p>	<p>Measures: In future, the racks for the USA goods/products will be completely covered in protective plastic sheets after each stratification. The employees responsible for this task have been trained on May 3rd, 2024.</p>
<p>Concerning the above mentioned findings the District Authority Ortenaukreis, Office for Veterinary Affairs and Food Control has officially verified the following:</p> <p>The establishment's root cause analysis The establishment's corrective actions 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.</p>			

Anhang A

Betrieb, Zulassungsnummer: Hans Kupfer & Sohn GmbH & Co.KG, Mausendorfer Weg 11, 91560 Heilsbronn, BY 50008

Appendix A

Establishment, approval number: Hans Kupfer & Sohn GmbH & Co.KG, Mausendorfer Weg 11, 91560 Heilsbronn, BY 50008

Seite Nr. Page No.	Beanstandung (Nr./Prüfkomponente) Finding (No./component)	Ursachenanalyse root cause analysis	Korrekturmaßnahmen, Präventivmaßnahmen corrective actions, preventive measures
2	25. In the mixing room the auditor observed a plastic tote containing salts and/or spices did not have any label as to the contents in the container.	Employee removed the label to early to prevent foreign object trap in the cutter.	Immediate actions: The box without a label was blocked and the content disposed of. Preventive measures: Employee was instructed to the incident, labels remain on the boxes just before use in cutter.
Concerning the above mentioned findings the CA Kontrollbehörde für Lebensmittelsicherheit und Veterinärwesen has officially verified the following: The establishment's root cause analysis The establishment's corrective actions 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

Gebrüder Kupfer GmbH & Co. KG, Marburger Str. 8, 90427 Nürnberg, BY 50567

Appendix A

Establishment, approval number: Gebrüder Kupfer GmbH & Co. KG, Marburger Str. 8, 90427 Nürnberg, BY 50567

Seite Nr. Page No.	Beanstandung (Nr./Prüfkomponente) Finding (No./component)	Ursachenanalyse root cause analysis	Korrekturmaßnahmen, Präventivmaßnahmen corrective actions, preventive measures
2	15. <i>The following findings were identified pertaining to HACCP system requirements:</i> -Neither product description document nor establishment's HACCP plan identify the correct HACCP process category for the US export. The review of HACCP plan identified that the establishment produces cooked sausages under the HACCP process category "fully cooked-not shelf stable."	The establishment was aware of the process category but used the general German designation for it.	The establishment has revised the HACCP plan and the product description and adopted the relevant product category of the United States of America.
	-The establishment's flow diagram did not include a cooling step after pasteurization step and consequently failed to conduct hazard analysis for the cooling step.	The pasteurizer of the establishment is a combined system containing heating and cooling. Therefore, the process step „Cooling“ was not listed separately.	The process step was added to both the flow diagram and the hazard analysis. Cooling has been assessed according to its microbiological hazard. To verify adequate cooling, temperature controls are documented after leaving the combined system. The limit value for the core temperature was set at < 7°C.
	-The establishment's hazard analysis did not specify the core temperature or time the product should be held in the water heating tunnel for the fully cooked sausages.	The core temperature is measured by default as a routine during the steam-cooking process of the sausages using a temperature logger; documentation in the hazard analysis was missing.	The process of steam-cooking the sausages was recently added to the hazard analysis, holding time and temperature of the hot waterbed have been adjusted specifically. The lethality value [German: F-value] was used as reference. The lethality value is obtained on the basis of the measurements of the temperature logger (F>30, setpoint 82 °C, 18 min boiling time).
	-The establishment's hazard analysis or HACCP plan did not identify the known microbiological hazard (<i>Clostridium perfringens</i> and <i>Clostridium botulinum</i>) at the product cooling step.	The risk posed by spore formers was not recorded in writing. Due to the process steps conducted, their occurrence is not to be classified as reasonably likely.	The risk and control of spore formation of <i>Clostridium botulinum</i> and <i>Clostridium perfringens</i> was added to the hazard analysis. The "Meat and Poultry Hazards and Controls Guide" (FSIS, 03/2018) was used for the revision of the hazard analysis.

			As an additional measure, the contents of the HACCP plan will be reviewed at every quarterly meeting of the establishment that takes place in the future.
2	<i>41. In the establishment's filling room, overhead beaded condensation was observed in multiple locations including over the product condensation at one of the sausage filling stations.</i>	Due to structural thermal bridges and the steam-cooking process, condensation forms in the filling room.	The establishment created a new SOP to address condensation. Condensation with droplet formation on structural components above the product is removed in shorter intervals. Employees were made aware of the risk of condensate formation in training courses on how to conduct SSOP checks. In the future, condensation formation will be documented and the quantity analyzed. Smaller amounts of condensation can also be controlled by preventive measures and are classified as an unavoidable residual risk.
<p>Veterinary Inspection Office City of Nuremberg has officially verified the following:</p> <ol style="list-style-type: none"> 1. The establishment's root cause analysis 2. The establishment's corrective actions 3. The establishment's preventive measures <p>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.</p> <p><u>Further comments by the competent authority</u></p> <p>An official additional protocol was drawn up by the FLS regarding the findings during the audit 04/30/2024 Page 2, No. 15 and 41. The additional protocol was sent to the establishment and deadlines were set for addressing the pending issues. The FLS checked and documented that the establishment addressed the findings in due time.</p> <p>Regarding No. 15: The root cause analysis of the establishment is acceptable. As corrective actions, several new operational documents have been created and reviewed by the FLS (HACCP list dated 08/03/24 with hazard analysis, checklist Verification_Validation HACCP, 240619). A HAV task to check the new risk assessment of the establishment by CCA and CA will take place in September 2024.</p> <p>Regarding No. 41: The CA agrees to the root cause analysis of the establishment. If condensation occurs, the operational corrective measures (SOP) are monitored more often by the FLS and the IIC and the formation of condensate is documented. Small amounts of condensation and aerosols in the room of the sausage filling stations are classified as low risk for the raw sausage meat due to the subsequent process steps of cooking and pasteurization for the category: "Fully Cooked-Not Shelf Stable". The measures taken by the establishment are assessed as effective. No concerns were identified.</p>			

Anhang A

HoWe Wurstwaren KG, Regenstrasse 1, 90451 Nürnberg, EV 717

Appendix A

Establishment, approval number: HoWe Wurstwaren KG, Regenstrasse 1, 90451 Nürnberg, EV 717

Seite Nr. Page No.	Beanstandung (Nr./Prüfkomponente) Finding (No./component)	Ursachenanalyse root cause analysis	Korrekturmaßnahmen, Präventivmaßnahmen corrective actions, preventive measures
2	<i>41. During operational sanitation verification the auditor observed beaded condensation at various locations in the filling room where product for US export was being prepared. At one location condensation was directly above the sausage product. No dripping of condensate was noted at the time the observation was made. The front-line supervisor leading the audit required immediate corrective action when this situation was pointed out.</i>	Due to the high need of warm water in combination with the cooling of the room, condensation can occur. At the time of the audit, the removal by an employee was not done with sufficient frequency.	During the audit, condensation was removed immediately. The competent division heads have been made aware and the intervals for removal will be increased depending on the need. Excessive abnormalities are documented in the SSOP or shift records. The hazard analysis has been analyzed accordingly. The residual risk, unavoidable despite root cause analysis and adjustment (condensation in the filling station) is acceptable due to the subsequent steam-cooking process. Possible microbiological contamination is reduced to an acceptable level by the process step fully cooking.
2	<i>46. During the pre-operational verification: -The FSIS auditor noted that ready-to-be used clean steel totes were stored in a manner where one of their edges were resting on the floor thereby posing a potential for contamination. -The commercial sized plastic containers used to transport incoming raw pork meat to be used for the US export appeared not being subject to routine washing. A frequency for cleaning of these containers was not specified in the SSOP. A stack of containers containing meat, although covered with plastic sheet on the top, collected visible dirt all around their top portions. Some of the plastic containers had rough jagged edges which would be difficult to sanitize properly.</i>	Improper handling by cleaning staff of steel totes that come into contact with food.	The clean steel totes are dried on clean H1 plastic pallets without floor contact. The cleaning staff has been instructed on the risks of contamination of food contact containers/surfaces.
<p>Veterinary Inspection office City of Nuremberg has officially verified the following:</p> <ol style="list-style-type: none"> The establishment's root cause analysis The establishment's corrective actions The establishment's preventive measures <p>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.</p>			

Further comments by the competent authority

An official additional record was drawn up by the FLS on the findings during the audit 04/29/2024 Page 2, No. 41 and 46. The additional record was sent to the establishment and deadlines were set for addressing the pending issues. The FLS checked that the establishment addressed the issues and documented it with pictures.

Regarding No. 41: The CA agrees to the root cause analysis of the establishment. If condensation occurs, the operational corrective measures are monitored more closely by the FLS and the IIC and the formation of condensation is documented. Small amounts of condensation and aerosols in the room of the filling stations are classified as low risk for the raw sausage meat due to the subsequent process steps of cooking and pasteurization for the category: "Fully Cooked-Not Shelf Stable". The measures taken by the establishment are assessed as effective. No concerns were identified.

Regarding No. 46: The root cause analysis of the establishment is plausible. The system for cleaning the steel totes was changed. A corrective action document with pictures was submitted to the CA by the establishment as supporting evidence. Follow-up inspections since May 24 have confirmed this. During the incoming goods inspection, the CA (FLS/ICC) will pay more attention to the condition of the meat supplier's transport containers. In the event of meat residues adhering to the outside of transport boxes, the CA will block them temporarily. For clearance, meat residues will be removed by the operating personnel in the cold room before the boxes will be tipped onto the processing belt in the blending area.

Anhang A

Bell Deutschland GmbH & Co. KG, Osterschepser Str. 40, 26188 Edewecht, A EV 35

Appendix A

Establishment, approval number: Bell Deutschland GmbH & Co. KG, Osterschepser Str. 40, 26188 Edewecht, A EV 35

Seite Nr. Page No.	Beanstandung (Nr./Prüfkomponente) Finding (No./component)	Ursachenanalyse root cause analysis	Korrekturmaßnahmen, Präventivmaßnahmen corrective actions, preventive measures
2	<i>41. Beaded condensation was observed at multiple locations where product was being processed. In the mixing room condensation above a conveyor belt carrying meat product to the mixer was quite noticeable throughout its entire length. The establishment management immediately shut the belt off and retained the product for further evaluation for possible contamination and disposition accordingly.</i>	Due to bad transportation during processing the employees poured water to wet the conveyor belt. This caused dripping water and beaded condensation.	The conveyor belt was changed to add more grip to the belt and a second motor was installed improve the transportation. Additionally, the employees are going to adapt the amount of meat on the conveyor belt to improve the transportation.
2	<i>46. Visible dirt collected around on various parts on multiple totes containing incoming raw meat products was posing risk for product adulteration. No product contamination was observed at the time of audit.</i>	Empty totes from the fresh meat delivery were stored together with totes with meat to be collected by the suppliers. The empty totes were not covered.	The empty totes to be collected are stored in separate room, separated from full totes with meat. They are covered with film to avoid any contamination.
<p>NI – Landkreis Ammerland, Veterinär- und Lebensmittelüberwachungsamt Concerning the above mentioned findings the CA Landkreis Ammerland, Veterinär- und Lebensmittelüberwachungsamt has officially verified the following: The establishment's root cause analysis The establishment's corrective actions 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.</p>			