



United States Department of Agriculture

Food Safety and
Inspection Service

MAY 10 2022

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Dear Dr. Lhafi,

The United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) conducted a remote verification audit of Germany's inspection system from October 19 to November 30, 2021. 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,

A handwritten signature in blue ink, appearing to read "Michelle Catlin".

Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF A REMOTE AUDIT CONDUCTED OF
GERMANY

OCTOBER 19–NOVEMBER 30, 2021

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING
PROCESSED PORK PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

May 10, 2022

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of a remote ongoing equivalence verification audit of Germany conducted by the U. S. Department of Agriculture Food Safety and Inspection Service (FSIS) from October 19 to November 30, 2021. Due to the global COVID-19 pandemic, FSIS conducted the audit remotely using video conferences for interviews and records review. The purpose of the audit was to determine 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 correctly labeled and packaged. Germany currently exports 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 to the United States.

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

FSIS concluded that Germany's meat 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 (CCA), has required that establishments certified as eligible to export products to the United States implement sanitation and HACCP requirements to ensure the safety of their products. In addition, BVL has implemented requirements for microbiological testing programs that are organized by the national government to verify its food safety inspection system. An analysis of each component did not identify any findings representing an immediate threat to public health.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted a remote audit of Germany's food safety system from October 19 to November 30, 2021. The audit began with an entrance meeting held via videoconference on October 19, 2021, with the Central Competent Authority (CCA)— Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL). Representatives from BVL participated throughout the entire audit.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

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

Process Category	Product Category	Eligible Products ¹
Thermally Processed - Commercially Sterile	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
Product With Secondary Inhibitors - Not Shelf Stable	RTE Salt-Cured Meat	Pork - All Products Eligible

The USDA's Animal and Plant Health Inspection Service recognizes Germany as free from foot-and-mouth disease with special restrictions specified in Title 9 of the Code of Federal Regulations (9 CFR) part 94.11; free from swine vesicular disease with special restrictions specified in 9 CFR part 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 subject to regionalization restrictions specified in 9 CFR 94.8.

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

Prior to the remote equivalence verification audit, FSIS reviewed and analyzed Germany's Self-Reporting Tool (SRT) responses and supporting documentation. During the audit, the FSIS auditor conducted interviews and reviewed records to determine whether Germany's food safety inspection system governing processed meat 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, point-of-entry (POE) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a three-year period, in addition to information obtained directly from 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 records related to administrative functions and oversight at BVL headquarters, government verification records from two regional offices, and verification records from three district offices overseeing three local inspection offices within the establishments. The remote audit involved meetings with government personnel and laboratory staff. FSIS scheduled up to two meetings each week over a six-week period. Through records review, the FSIS auditor evaluated the implementation of control systems that ensure the national system of inspection, verification, and enforcement is being implemented as documented in the SRT and supporting documentation.

A sample of three establishments was selected for the remote audit from a total of 13 establishments certified to export to the United States. All three selected establishments were processed pork establishments that produce and export to the United States the products under following product categories: not ready-to-eat (NRTE) otherwise processed meat; RTE acidified/fermented meat (without cooking); RTE dried meat; RTE salt-cured meat; RTE fully-cooked meat; RTE fully-cooked meat without subsequent exposure to the environment. Establishments producing TPCS meat products for export to the United States were not included in this audit. BVL's TPCS inspection activities were audited in the previous FSIS audit conducted in 2019 and FSIS did not identify any concerns. Currently there are no pork slaughter establishments certified to export to the United States.

This remote audit focused on a review of records associated with official government verification activities conducted at the selected establishments. It did not include review of establishments' conditions or records. The FSIS auditor assessed the ability of BVL to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence

requirements for foreign food safety inspection systems outlined in Title 9 of the Code of Federal Regulations (CFR) 327.2.

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

Remote Audit Scope		#	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> • BVL, Berlin
	Regions	3	<ul style="list-style-type: none"> • Freiburg Regional Authority (overseeing the district office Ortenaukreis), Freiburg • Karlsruhe Regional Authority (overseeing Rastatt Local District Office), Karlsruhe • Higher Thuringian State Office of Consumer Protection (overseeing the District Office Altenburger Land) Bad Langensalza
	Districts	3	<ul style="list-style-type: none"> • Ortenaukreis District Office, Offenburg • Rastatt District Office, Rastatt • Altenburger Land District Office, Altenburg
Laboratory		1	<ul style="list-style-type: none"> • Lower Saxony State Office for Consumer Protection and Food Safety (LAVES) (government laboratory-microbiological), Oldenburg
Pork processing establishments		3	<ul style="list-style-type: none"> • BW-05068, Schinkenhof GmbH & Co., KG, Achern • BW-03330, Freiburger Lebensmittel GmbH & Co., Muggensturm • TH 01531, Wolf GmbH, Schmölln

FSIS performed the audit to verify that the 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 meat 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 May 1, 2018, to July 9, 2021, FSIS import inspectors performed 100 percent re-inspection for labeling and certification on 17,242,043 pounds of processed pork products exported by Germany to the United States. Additional types of inspection were performed on 1,993,106 pounds of processed pork products. These additional types of inspection included physical examination, condition of container examination for thermally processed/commercially sterile (TPCS) products, chemical residue analysis, and testing for microbiological pathogens *Listeria monocytogenes* (*Lm*) and *Salmonella* in ready-to-eat (RTE) products. FSIS rejected 25 pounds of RTE, salt-cured unsliced pork products and 4,480 pounds of RTE, salt-cured, not sliced pork products due to product implication in a foreign country recall. Another 7 pounds of RTE, salt-cured, sliced pork was rejected due to testing positive for the presence of *Lm*. Concerning heat treated-not fully cooked-not shelf stable pork products, 14 pounds of pizza products were rejected for reasons unrelated to public health.

In accordance with FSIS procedures for evaluating and verifying implementation of corrective actions in response to rejected product, FSIS conducted a review of BVL's written responses to these violations, which included intensified official verification sampling of product, food contact surfaces, and environmental surfaces for *Lm* and *Salmonella*, and determined these responses were acceptable. In addition, as part of FSIS risk-based audit methodology, the FSIS auditor selected the implicated establishment in this remote audit, for which no further concerns were identified.

The last FSIS audit in 2019 identified the following findings:

Summary of Findings from the 2019 FSIS Audit of Germany	
Component 4: Government Hazard Analysis and Critical Control Point (HACCP) System	
<ul style="list-style-type: none"> • In two of the six audited establishments, there was inadequate government verification of HACCP requirements. The inspection personnel failed to identify that the written HACCP plan did not include one or more of the following elements required by the German Guidelines 2.0, which are consistent with 9 CFR 417.2: monitoring procedures and frequencies, and ongoing verification procedures and frequencies. • In two of the four audited establishments that produce ready-to-eat dry cured hams, there was inadequate government verification of HACCP requirements. The hazard analyses did not identify microbiological controls for <i>Salmonella</i> within all process steps; however, the establishment process had validated/scientific documentation. 	

The FSIS auditor verified through records review that the corrective actions for the previously reported findings were implemented and effective in resolving the findings.

The most recent 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.

The legal basis of Germany's inspection system is grounded in EU's overarching regulations as well as Germany's own laws and regulations governing food safety and consumer protection. Article 17 of Regulation European Commission (EC) No. 178/2002 requires Germany to: (1) enforce food law and monitor and verify that the relevant requirements of food law are fulfilled by the establishments at all stages of production, processing, and distribution; and (2) maintain a system of official controls and other activities covering all stages of production, processing, and distribution. Provisions in Regulation (EU) 2017/625 authorize BVL of the inspection system to ensure that establishment corrects the observed deficiencies when identified and further allows BVL to take enforcement actions that can include suspension or withdrawal of approval in the event corrective actions are not effective in remedying deficiencies. Article 12 of Regulation (EC) No. 178/2002, and Section 9 on "Export Approval" of Germany's National Food Hygiene Regulation (LMHV) state that approval of establishments for export to other countries, such as the United States, is dependent on compliance with the sanitary requirements of the importing country. In addition to establishing official controls designed to ensure compliance with the EC legislation, Federal States are also responsible for ensuring compliance with FSIS requirements and certification of eligible establishments.

The FSIS auditor verified that the inspection system is organized and administered by the national government of Germany. The Federal Republic of Germany is divided into 16 Federal States, known as Länder. At the national level, the Federal Ministry of Food and Agriculture (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, and animal welfare under the Animal Welfare Act. One of the major agencies within BMEL's oversight is BVL, which FSIS recognizes as the CCA on matters of food safety including exportation of pork meat products. BVL is part of Division 314 within BMEL and is led by the president whose office is supported by the vice president and a team of administrative staff. Structurally, BVL is organized into departments which are further divided into groups and units, each of which are charged with specific functions and areas of responsibility. The list of some of the important programs that lie within BVL's authority includes Food Safety, Plant Protection Products, Veterinary Drugs, Genetic Engineering and Biotechnical Processes, Methods Standardization, Reference Laboratories, and Antibiotic Resistance. There have not been any significant changes within the organization of BVL since the last FSIS audit in 2019 except that Unit 180, which deals mainly on export related affairs and was once part of the food safety department, is now an independent unit and directly reports to the vice president of BVL. In matters of food safety, BMEL receives extensive collaboration within the ministry and with other ministries of the government. Notably, the Federal Institute for Risk Assessment of BMEL, advises the ministry on the subjects of risk assessments and research, while the Federal Ministry for Environment, Nature Conservation, Building and

Nuclear Safety, through its Division IG 11 2, collaborates on protecting public health from exposure to food contaminants and environmental pollutants.

Through document review and interviews with BVL's officials, the FSIS auditor further verified that BVL is the competent authority in the following areas of food safety:

- Advising and coordinating on policies and issues on exporting of animals, animal products, and feed to various non-EU countries;
- Implementing export requirements for the United States, through BVL's Unit 180 (The Export Affairs Unit);
- Managing of approval (and listing) procedures of establishments that seek approval to export to the United States;
- Overseeing registration of official stamps, export certificates, and signatures for annual certification of eligibility;
- Handling of complaints made by official authorities (e.g., POE violations);
- Managing audits by countries outside the EU or monitoring of inspections of the Federal States authorities by non-EU country authorities;
- Responding and managing questionnaires from non-EU countries food safety system authorities (e.g., FSIS SRT);
- Coordinating of the Working Group for United States Export of BVL and the Federal States;
- Training official inspection staff;
- Maintaining of the Technical Information System for Consumer Protection and Food Safety (FIS-VL) program, specifically export and non-EU country information; and
- Serving as contact point (BVL) for the National Residue Control Plan including authorizing veterinary drugs on a national basis and as the national contact point for the Rapid Alert System for Food and Feed (RASFF).

The next level of inspection in Germany is structured at the level of Federal States, also known as Länder. Each Federal States has its own ministry for agriculture and allied functions including food safety. It is the competent authority (CA) in a Federal States who is responsible for implementing official controls and supervision over official activities in all establishments within its territory, including those that are certified to export products to the United States. At the Federal States level, the system of official controls, oversight, and administration of food safety is divided into three levels: ministry, provincial or regional, and district or municipal authorities. Inspection controls, coordination, issuance of guidance on the implementation of Federal laws and the applicable EU laws are exerted at the ministerial level. The provincial or regional level is an intermediate administrative level between the ministry and the district or municipal level. The routine day-to-day inspection activities at all establishments, including the certified establishments eligible to export to the United States, are conducted at the district or municipal level depending upon Federal State organizational structure in the Federal State. In addition, this level has responsibility for animal welfare monitoring and enforcement measures in accordance with the Animal Welfare Act. For this report, the term region will be broadly used to cover provinces and likewise, district will also imply municipal authority when applicable. The presentations provided by the higher Federal States authorities and the district inspection staff in conjunction with document review from two Federal States indicate that there have not been any

changes in the organizational structure of the inspection system at the Federal States level since the last FSIS audit in 2019.

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 uniform documented procedures and instructions for inspection personnel on verifying the effectiveness of official controls required by Regulation (EU) 2017/625. The auditor reviewed QMS related documents and did not identify any concerns.

BVL oversight of Federal States is achieved through conducting correlation meetings with the Federal States authorities to ensure that FSIS requirements are being uniformly applied and enforced in all establishments certified to export to the United States. These requirements are outlined in the inspection guidelines for the supervisory authorities of the Federal States to carry out official controls in meat processing plants approved for U.S. export Version 2.0 March 27, 2018 (hereafter referred to as German Guidelines). This collaboration includes providing the Federal States with logistical and organizational support; ensuring that the EU and national legislation is properly implemented in all Federal States; contributing to the drafting of general administrative regulations; coordinating control programs; providing training concerning United States import requirements; and participating in meetings of the Federal States Working Group for Consumer Protection. The working group for food of animal origin (LAV) holds workgroup meetings to tackle issues concerning all Federal States and with a focus on mutual objectives and cooperation on resolving issues relating to food of animal origin. The LAV meets twice a year and publishes its documentation in the FIS-VL, a communication platform discussed in more detail later under this component. Through the LAV-AFFL (LAV working group on meat and poultry meat hygiene and technical issues of food of animal origin) platform, BVL and the Federal States engage in discussions on technical concerns which includes future updates and revisions of the German Guidelines, new information on FSIS requirements, and upcoming trainings. The Food Hygiene and Food of Animal Origin Research Group is another platform of BVL and Federal States interface through which BVL and Federal States work on food hygiene, exchange of scientific information and opinion, food pathogens, and the National Residue Control Plan. The auditor verified that the last meeting of LAV-AFFL was held May 11–12, 2021 in Potsdam, Germany, and was attended by BMEL and representatives from Federal States across the country. BVL officials informed the auditor that the current version of the German Guidelines is presently under revision to align with recently new or revised EU regulations and Directives.

Germany requires certified establishments to have effective procedures to deal with any food safety hazard and to enable the complete, rapid recall of any implicated lot of the finished food from the market in accordance with Article 50, Chapter IV of Regulation (EC) No. 178/2002, which establishes the RASFF. Notification procedures for recalls are contained in the General Administrative Rules for the Implementation of the Rapid Alert System for Food and Feed Notifications. These general administrative rules set out clear responsibilities and criteria in relation to the preparation of notifications regarding food, food contact materials, and feeding stuffs. Section 6 of the German Guidelines describes the mechanisms for recall of consignments, lot identification for traceability, and seizure. As noted above, BVL is a contact point for RASFF in Germany. Inspection documents reviewed from the district offices provide adequate evidence that the establishments eligible for export to the United States have developed procedures as part

of their food safety system to ensure adulterated product, once identified, can be traced back and recalled.

The FSIS auditor confirmed that the inspection operations are funded by the state budget and the inspection personnel assigned to establishments certified to export to the United States are full-time employees of the government and perform their inspection activities under the administration of the respective Federal State Authority. Authority for hiring and assigning competent, qualified inspection personnel lies at the regional and district levels within regions and district level office. Inspection personnel are recruited according to applicable Federal State, regional, or local laws governing hiring of public officials. One head of the regional office walked the auditor through the hiring process and pointed to clauses where 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. The auditor was provided with a redacted, government-issued salary slip of an inspector as documented evidence that inspection personnel are government paid employees.

Through document review and interviews conducted with regional and district officials, the FSIS auditor verified that inspection personnel have the appropriate educational credentials and training to perform their inspection tasks. In accordance with relevant clauses of Commission Delegated Regulation (EU) 2019/624 and Regulation (EU) 2017/625 specifying specific minimum requirements for the official veterinarians (OVs) and for official auxiliaries (OAs), Germany ensures that official inspection personnel have appropriate education credentials, and necessary training and experience to perform inspection tasks. OVs must have a doctor of veterinary medicine or equivalent degree and receive practical training for a probationary period of at least 200 hours before starting to work independently. OAs, including food inspectors (FIs), are required to have at least 500 hours of theoretical training and at least 400 hours of practical training, after which they must pass specific examinations before being qualified to work in export meat establishments.

One point of focus for the current remote audit was to verify BVL's procedures and requirements for certification of establishments in compliance with, and decertification of establishments not in compliance with, the FSIS import requirements. The auditor reviewed the documents related to certification of a new establishment and adding a new product category for export to an existing certified establishment. The rules governing establishment approval procedures are defined in the German General Administrative Regulation on the implementation of the supervision of compliance with hygiene rules for food and method for testing for guides to good practice (AVV-LmH) hereafter referred to as General Administrative Regulation, and the procedures are outlined in a special section under the German Guidelines. The approval process begins with document reviews followed by an onsite visit, and subsequent visit if needed, to verify the implementation of any applicable corrective actions. Each Federal State at the regional level has the sole authority to grant final certification of a new establishment or to permit an existing certified establishment to maintain its eligibility for export to the United States. However, BVL also conducts an audit of all establishments prior to initial certification and if there are any findings, the Federal State approval authority verifies appropriate corrective actions and determines final eligibility. The auditor was provided with documents outlining step-by-step procedures that led to final certification and inclusion of an establishment producing NRTE

product into the list of the certified establishments eligible to export to the United States. As noted above, in addition to playing a role in the final certification process, BVL also notifies FSIS upon certification of a new establishment as well as annual updates of establishment certification. No issues arose in the auditor's verification of this requirement.

As Germany currently does not have certified slaughter establishments, it sources raw pork products from eligible slaughter establishments in Denmark and the Netherlands, which are then processed in Germany for export to the United States. The auditor verified the inspection documents for all three establishments selected for the current audit, which provide evidence that these establishments have control measures in place that ensure the safety of incoming raw product. The auditor also verified that the OV or inspector-in-charge (IIC) reviews the accompanying shipping document and health certificates, and verifies product temperature, sanitation of trucks, and integrity of truck seals by corroborating the physical product seal to seal entry on the shipping document. Through inspection records reviews, the auditor verified that the inspector is present at the time a shipment arrives to break the seal and oversee that the establishment's controls are implemented as described in the procedure of receipt of product. The FSIS auditor examined a copy of the health certificate and corroborated the information on the inspector daily record. The auditor's review of inspection records further revealed that raw pork was not the only product sourced from outside Germany, but that one establishment purchased processed pork products (salami) from an eligible establishment in Austria to be used in NRTE products for export to the United States. The auditor's review did not raise any concern.

The FSIS auditor verified that BVL and Federal States ministries have implemented training programs for new inspection personnel as well as routine ongoing training intended to ensure that inspection personnel are aware of specific food safety and inspection requirements of FSIS import regulations and of Germany's regulations for pork products exported to the United States. BVL plans training activities for the official inspection personnel of all the Federal States and provides training on the spot at establishments. Each Federal State and district office also conducts training with specific topics related to United States requirements typically attended by the Front Line Supervisor (FLS). The FLS subsequently trains deputy FLS, OVs, and FIs based on the same training materials. BVL's Unit 180 organized and delivered a training within and across Federal States in response to a violation identified by FSIS at a U.S. POE concerning RTE product that tested positive for *Lm*. These trainings were delivered in the Federal States of Lower Saxony, Baden-Württemberg, and Bavaria.

BVL administers and manages the FIS-VL centralized document management and information intranet portal for food safety and consumer protection utilized by BVL and official personnel in each Federal State. BVL disseminates uniform instructions to the Federal States' CAs, including information about the required approval and eligibility certification, templates for certification of establishment eligibility, relevant FSIS legislation and policy, guidelines and training material developed by the Working Group for the United States Export, and minutes of the workgroup's meetings. The Working Groups maintain their own sites within FIS-VL to provide information related to their own work, meetings, and reports, etc. Their information is available to anyone with access to FIS-VL site. FIS-VL also provides users email notifications when new documents have been uploaded to the system. BVL granted temporary access to the FSIS auditor to gain insight of this inspection wide communication platform. The FSIS auditor verified access and

routine use of FIS-VL by the audited district offices and was able to view all features of the program described above. The auditor was also shown how exchange of information and documents related to the current audit were available to everyone with authorized access.

As required under Articles 109 and 110 of Regulation (EU) 2017/625, BVL develops and submits a Multiannual National Control Plan (MANCP). One of the principal objectives that member states must include in the plan is controlling compliance with food and feed law with regard to animal and plant health. The plan must specify that the member state has resources and infrastructure including what is necessary to achieve the MANCP's underlying objectives. BVL shared the current framework of the MANCP for Germany, which appears to be meeting the objectives and target set for the plan.

The FSIS auditor assessed BVL's measures in ensuring that adequate administrative and technical support is available to its laboratory system. In Germany, BVL has designated the Food and Veterinary Institute (FVI) Lower Saxony State Office for Consumer Protection and Food Safety (LAVES) in Oldenburg as the laboratory conducting official analytical testing on product destined to the United States. The FSIS remote audit included a review of the laboratory's functions in relation to testing of products intended for export to the United States. The audit included interviews with the laboratory management and document reviews including the Quality Control Manual (QCM).

The FSIS auditor verified that LAVES is accredited to the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025 standards by Germany's national accreditation body, the Deutsche Akkreditierungsstelle GmbH (DAkkS). The auditor reviewed the most recent organization chart of the FVI issued in October 2021. Section 23 (Bacteriology and Sanitary Testing Branch) in Department 2 of the FVI is responsible for analysis of samples received under the sanitary and slaughter testing program which includes samples received from all certified establishments. The review 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 QCM. Section 23 of FVI is staffed with 13 trained employees, including two scientific experts supported by 11 assistants, each responsible for defined duties. The FSIS auditor verified that Section 23 of FVI conducts testing for *Salmonella* and *Lm* in RTE meat products destined for export to the United States, as well as environmental sponge samples from producing establishments.

The FSIS auditor reviewed the most recent accreditation audit report by of the laboratory issued to FVI by DAkkS on March 7, 2019. The audit report provided detailed assessments of how all departments of FVI are meeting ISO/IEC 17025 standards, focusing on requirements of FVI's QCM, equipment, analytical methods, and qualifications of laboratory personnel. The auditor noted the DAkkS audit findings reported during the laboratory audit were addressed by the relevant departments of the institute in a timely manner and were followed up by the DAkkS auditor who accepted the corrective actions proffered by the laboratory. The next accreditation audit is within five years of the previous audit and is expected to be conducted in September 2022. In addition to the DAkkS report, the auditor also evaluated the laboratory's internal audit report dated November 9, 2021. The internal audit covered all facets of the laboratory's management functions, including document review and analyst performance. The FSIS auditor did not identify any concerns.

To assess the competence, skills, knowledge, and ongoing training of analysts assigned to the microbiological laboratory, the FSIS auditor reviewed analysts' most recent proficiency reports. The review of the proficiency testing (PT) program indicated that the PT is conducted annually. Furthermore, the auditor confirmed that analysts assigned to conduct analyses on samples drawn from the product intended for the United States export are rotated to ensure that each analyst is evaluated over time. The auditor further reviewed the laboratory's QCM records related to quality assurance procedures and the documents pertaining to analytical methods were implemented as described in the manual. Additionally, the auditor reviewed examples of analyst worksheets, participation in workshops, and refresher courses as part of their continuing education. The auditor's review of PT and quality assurance procedures did not raise any concerns

The FSIS auditor verified that the microbiology laboratory has implemented FSIS' MLG methods for analysis of environmental and RTE products for *Lm* and *Salmonella* and continues to update the test versions as these methods are modified or updated by FSIS. The laboratory has recently updated its MLG methods and aligned its analytical methods for official verification sampling for RTE products analysis for *Salmonella* (325g sample size) according to MLG 4.11 and *Lm* analysis (25g sample size) in accordance with FSIS MLG 8.13. Since the laboratory is in the process of transitioning to the newer versions of methods, the reviewed certificates of analysis for official routine food contact and environmental surfaces and intensified verification sampling analysis for *Lm* indicated that FSIS' MLG 8.11 and MLG 4.10 methods were used to detect *Lm* and *Salmonella*, respectively.

Lastly, the auditor verified the sample receipt, sample registration issuance, Laboratory Information Management System generated sample ID, sample traceability and examples of laboratory test reports. The laboratory has documented standard operating procedures for each facet of sample handling, documenting as the sample travels through the laboratory and until the laboratory report is generated and issued. When a sample tests positive, the laboratory immediately alerts the FLS of the district where the sample originated via e-mail or phone.

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

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

The second equivalence component the FSIS auditor reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for 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 certified slaughter establishments in Germany. Therefore, requirements for humane handling and slaughter of livestock; ante-mortem inspection of animals; and post-mortem inspection are not applicable to Germany's inspection system.

The FSIS auditor verified that each certified establishment is under official supervision pursuant to Article 148 of Regulation (EU) 2017/625. Article 148 mandates that the competent authority must perform onsite visits to ensure that food establishments have demonstrated that they meet the relevant requirements of Regulation (EC) No. 852/2004 and Regulation (EC) No. 853/2004 and other relevant requirements of the (EC) No. 178/2002. Germany's LMHV implements Regulation (EC) No. 852/2004, Regulation (EC) No. 853/2004, and Regulation (EC) and Regulation (EU) 2017/625. The FSIS criteria for periodic supervisory visits are achieved through procedures contained in relevant sections of the German Guidelines which are implemented per requirements detailed in section 5 of General Administrative Regulation (AVV LMH). The document reviewed, in conjunction with interviews conducted with supervisory staff from Federal States Baden-Württemberg and Thuringia, show that the supervisory chain of command exists at two levels which are responsible for conducting supervisory reviews at defined frequencies which may be increased if warranted. The regions at the first level conduct annual visits to the establishments and are involved with the process of maintenance of certification as well as with new approval requests. Their visits include a comprehensive evaluation of the establishment's food safety program and the review of government documents. Regions follow up with the districts on concerns identified during the audit. A follow-up onsite visit, if warranted, is completed and documented with the outcome of the visit. The auditor reviewed examples of these reviews conducted at the regional authority level. In one region, the report reviewed was the official form FOB 20/05.11.2020/V5 and the auditor did not identify any concerns.

The next level of supervision is at the district level and FLS in the districts are responsible to carry out these supervisory visits at least once a month, but more frequently when needed in response to compliance or performance issues in the establishment. The auditor noted some variation from monthly frequencies of FLS visits; for example, one FLS was conducting weekly visits, and in another district the FLS was conducting quarterly, biannual, and annual visits in addition to conducting routine monthly supervisory visits. FLS in each district document their reports on official forms and make these forms available to their superior. These forms are essentially a checklist designed to verify the establishment's compliance with requirements consistent with the 9 CFR Parts 416, 417, and 430 as mandated through specific sections of the German Guidelines. The checklist requires detailed descriptions as to the nature and extent of noncompliance if the box is checked "not met." The FLS' review also includes the evaluation of performance of OV's, IICs and FIs, which is accomplished through shadowing them while they are doing routine inspections and documenting their work on the inspection forms. The auditor reviewed examples of weekly, monthly, quarterly, biannual, and annual checklists from the Ortenaukreis, Rastatt, and Altenburger Land District Offices. The records examined covered both the establishment's documents and the result of onsite visits as well as descriptions of any noncompliance observed and any follow-up reports.

Daily routine inspections are conducted by either OV or IICs assigned to the establishments certified to export to the United States. The German Guidelines describe the requirement that inspection by the OV or IIC must be carried out at least once per day at certified establishments during the production of products intended for export to the United States. The inspection must be conducted in all shifts as well as during any changes in shifts or products. The OV or IIC documents their inspection verification using a government-controlled checklist which aligns with the requirements listed in the German Guidelines. For example, in one district the checklist for preoperational checks is on form FOB: 10a/05.02.2020/V2n and operational sanitation checks are documented on FOB: 10b/05.02.2020/V2. The FSIS auditor verified that staffing plans were adequate to ensure official inspection coverage during each production period of eligible product. The FSIS auditor's reviews of these records verified that an FLS, deputy FLS, OV, or an IIC was present at each audited establishment at least once per production shift during the processing of meat intended for export to the United States.

The criteria for the separation of eligible pork meat products from non-certified products are prescribed in section 8 of the German Guidelines, which requires food business operators to clearly identify each batch of product destined for the United States. The record reviewed during the audit indicated that there are procedures designed to ensure separation of product intended for export to the United States. Incoming product that is intended for export is processed separately by time or space as per the German Guidelines. The OV or IIC verify that the operators comply with the requirements for separation of product destined for the United States. The FLS in one district office pictorially demonstrated the dedicated space in freezer and storage for product to be exported to the United States.

The FSIS auditor verified that each establishment had programs in place that ensure the traceability of all products destined for the United States as well as properly identifying, labeling, and segregating product. Prior to export certification, the FLS and other inspection personnel are responsible for verifying the implementation of pre-shipment procedures as required in the German Guidelines, section 8. The pre-shipment review includes a complete document package for each production lot from receiving raw meat through packaging and labeling. The pre-shipment review includes the review and confirmation of testing results from samples of products tested for adulterants (such as residue, and microbiological samplings), species identification, and the verification of the unique identification of the batch (e.g., labels, lot markings, and shipping marks). An export certificate is not issued until all testing results are received and are negative for any tested pathogens or any contaminants of public health concern. The FSIS auditor verified that measures designed to ensure segregation were effectively implemented in each audited establishment.

The FSIS auditor verified that BVL ensures that pork exports are not subject to animal health restrictions by receiving notifications via APHIS' Email Subscription Service or through official channels such as the Federal Ministry or the German Embassy (Animal Disease Notification System), as well as by regularly visiting the relevant APHIS website. BVL communicates newly issued import requirements to the CAs which then forward them to the official staff in the district either by direct e-mails or through posting on the FIS-VL website. To ensure that only meat not restricted by APHIS is exported to the United States, the FLS or designee at certified

establishments verify the product and species when receiving the product and prior to signing the export certificate.

The FSIS auditor verified controls over inedible materials and products in each certified establishment through interviews conducted and documents reviewed from three district offices. The auditor confirmed that the OV or IIC verifies each establishment's programs to ensure proper identification, control, and disposition of inedible materials in accordance with Regulation (EC) No. 1069/2009 and Regulation (EU) No. 142/2011. Furthermore, the auditor reviewed documents and images shared during a presentation on the topic by an FLS and confirmed that proper identification, handling, and segregation of these materials in specially marked containers are ensured and the inspection personnel routinely verify documentation of inedible materials according to the instruction in Annex 2 of the German Guidelines.

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

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third equivalence component the FSIS auditor reviewed was Government Sanitation. The FSIS auditor verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation standard operating procedures (Sanitation SOPs) to prevent direct product contamination or insanitary conditions, and to maintain requirements for sanitation performance standards (SPS).

All food handling businesses in Germany are required to follow and enforce overarching EC sanitary regulations, including Regulation (EC) No. 852/2004, Regulation (EC) No. 853/2004, and Regulation (EU) 2017/625. The ultimate objective of these regulations is to ensure that each official establishment operates in a sanitary manner to always prevent insanitary conditions throughout the operation. In addition to meeting EC sanitary regulations, Germany requires those establishments certified to export to the United States to develop, implement, and maintain Sanitation SOPs in their establishments. The German Guidelines, section 3, provides requirements for the implementation of Sanitation SOPs which are consistent with 9 CFR 416.

Through record reviews and interviews conducted with FLS in three district offices, the FSIS auditor confirmed that inspection personnel use routine inspection forms to verify and document that certified establishments implement sanitation requirements consistent with the requirements in 9 CFR 416. The auditor reviewed examples of completed inspection verification forms in all three districts. In one district, for example, FOB: 10a/06-02-2019/V3 is used to document the outcome of pre-operational sanitation checks and form FOB: 10b/06-02-2019/V3 is used to document operational sanitation verification results. The inspection verification activities include ensuring that the establishment's general maintenance practices, outside premises, walls and floor conditions, pest control management, and drainage meet sanitation requirements. Through review of inspection records from a district with jurisdiction over an establishment processing post lethality exposed (PLE) RTE products, the auditor confirmed that the establishment swabs

the food contact surfaces (FCS) and non-FCS for *Lm*, *Salmonella*, and other indicator organisms to verify the adequacy of the establishment's sanitation. The review of these examples demonstrated that OV's or their designees, document any noncompliance found during their sanitation verification inspection and follow up with the establishment on efficacy of the corrective action in preventing further recurrence. Similar completed sanitation inspection forms were also reviewed for the other two districts which had different formats designed to address sanitation practices in the production room where PLE products are packaged, while also capturing all essential elements required in section 3 of the German Guidelines on sanitation requirements. Discussion on the microbiological verification of the establishment's sanitation in relation to *Listeria* control is included in component 6 of the government microbiological testing in this report.

FLS in each of the three districts audited verify the requirement of sanitation to their assigned establishment with a defined frequency to ensure all production areas and the exterior of the facility are covered during the year. The visit includes onsite and document review components. FLS' review also includes the evaluation of performance of OV's and IICs, which are accomplished through shadowing them while they are doing routine inspections and documenting their work on the inspection forms. The auditor reviewed examples of FLS' generated reports, which may be weekly, monthly, quarterly, biannual, or annual reports depending on district. The FLS in one district provided evidence of corrective action taken in response to isolated SPS findings during FSIS' 2019 onsite audit. The document reviewed was supplemented with pictures that were taken before and after the corrective actions were implemented. No concerns arose as a result of the auditor's review.

The FSIS auditor concluded that BVL requires establishments certified to export to the United States to develop, implement, and maintain sanitation programs, including requirements for SPS and Sanitation SOPs. FSIS concluded that BVL continues to meet the core requirements for this component.

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.

BVL has adopted FSIS' regulatory requirements for HACCP and controlling *Lm* and *Salmonella*. Section 4 of the German Guidelines prescribes the HACCP system requirements which are consistent with 9 CFR 417. Through review of government verification records, the auditor confirmed that BVL inspection personnel verified that the certified establishments producing RTE products identified all physical, chemical, and biological hazards associated with each eligible product; conducted a hazard analysis; and developed critical control points (CCP) in the HACCP plan to address hazards that were identified as reasonably likely to occur. The auditor also confirmed through records review that the establishment eligible to export NRTE product adequately identified all hazards associated with the product and developed and implemented the HACCP plan in compliance with the German Guidelines. The auditor reviewed examples of

HACCP verification tasks performed by the OV or IIC which include among others, verifying the establishment's product profiles and production flow charts. FLS in each district also verify during their routine supervisory visits that certified establishments are complying with HACCP requirements. No concerns arose as a result of review of these requirements.

The auditor also evaluated how certified establishments comply with the requirements included in section 4.2.3 of the German Guidelines for developing and implementing the HACCP plan which is consistent with regulatory requirements of 9 CFR 417. Additionally, if RTE product is exposed to production areas after receiving lethality treatment, the establishment must meet *Listeria* control requirements. The official verification documents maintained at the three districts provide evidence that the OV or IIC routinely verifies their respective establishment's HACCP plan, and reviews establishment monitoring records, pre-shipment reviews, ongoing verification, and validation documents which include HACCP decision-making documents, scientific support and in-plant data. These food safety requirements are also verified during FLS' scheduled visits.

The FLS supervisory reviews are consistent with instructions in the German Guidelines and evaluate the establishment decision-making documents and ensure that any hazards reasonably likely to occur are appropriately addressed in the HACCP plan. The FLS reports reviewed demonstrate all the decisions made in the HACCP plan to address identified hazards and the corresponding controls are well supported based on either historic data, by already established measures, or through challenge studies. The auditor verified the establishment's support and inspection records regarding *Listeria* control and had no concerns.

The FSIS auditor verified government records related to HACCP activities in another district with jurisdiction over an establishment producing RTE fully cooked, not shelf stable products and confirmed the HACCP plan addressed physical and microbiological hazards reasonably likely to occur through validated CCPs. The auditor further noted the time and temperature lethality for the CCP for cooking follows scientifically supported data. The OV's daily inspection record indicates that establishment HACCP related control measures including CCPs, control points, verification records and pre-shipment reviews are routinely verified, and any findings of noncompliances are documented and followed up until resolved. The FSIS auditor further verified the IIC's inspection records for an establishment producing NRTE products are maintained at the district office with jurisdiction over the establishment. The document reviewed demonstrated that the establishment had controls in place to ensure the food safety of products exported to the United States. No concerns were identified by the auditor.

Through document reviews and interviews with the FLS, the FSIS auditor determined that the corrective actions taken in response to the 2019 FSIS audit findings related to the HACCP system were effective in resolving the issues.

The FSIS analysis and remote verification activities indicate that BVL requires operators of certified establishments to develop, implement, and maintain a HACCP system. FSIS concludes that BVL continues to meet the core requirements for this component.

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 monitoring results of these countries as well as RASFF for any documented cases of product exceeding accepted residue levels.

Prior to the remote audit, and as part of the annual SRT review for ongoing equivalence determination, FSIS reviewed the German National Residue Control Program (NRCP) for 2020, associated methods of analysis, reported results of the testing program, and additional SRT responses outlining the structure of Germany's chemical residue testing program.

Germany's NRCP includes testing imported meat products for the presence of chemical residues. Germany's NRCP is based on EU legislation (Council Directive 96/22/EC of 29 April 1996 and Regulation (EU) 2017/625 and Commission Delegated Regulation (EU) 2019/2090 which require the member countries to develop and implement a national residue plan. These documents prescribe conditions of chemicals used in the production of meat, including animal feed; provide authority to prohibit the use of compounds that may present public health risks; and provide the ability to control and monitor industrial and environmental chemicals. These documents also indicate that Germany maintains the legal authority to regulate, plan, and execute activities aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in the tissues of livestock slaughtered for human consumption.

The FSIS auditors' review of government records indicates establishments' hazard analyses addressed potential hazards associated with chemical and environmental residues. Through interviews and record reviews, the FSIS auditor verified that BVL is meeting the core requirements of this component.

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 products prepared for export to the United States are safe and wholesome.

In accordance with Regulation (EC) No. 2073/2005 microbiological criteria for foodstuffs, BVL defines RTE product as “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 of micro-organisms of concern.” BVL’s requirements for RTE products are contained in section 7 of the German Guidelines. This document indicates that RTE products that test positive for either *Salmonella* or *Lm* will be deemed adulterated and will be excluded for export to the United States. Per section 7, BVL requires certified establishments producing RTE-
PLE products to identify and implement control programs designed to prevent adulteration of RTE products with *Lm*. The control program must ensure that all finished RTE products are free from *Salmonella* and *Lm*.

Section 5 of the German Guidelines emphasizes the importance of product hygiene and describes procedures for lethality treatment and stabilization of product which has undergone heat treatment. It also sets performance standards for pathogens and their toxins in finished products. The review of government documents indicates that the establishment producing fully cooked-not shelf stable products adheres to the product lot definition and testing frequencies described in the guidelines. The amount of RTE product that could be affected by a positive test result is normally defined as all product produced from clean-up to clean-up.

The inspection records reviewed in addition to interviews conducted with inspection personnel from all three district offices provided evidence that FLS or their designees routinely verified the implementation and effectiveness of establishments’ microbiological testing programs that export RTE products to the United States. The documents reviewed indicated that the establishments sample RTE products eligible for the United States export irrespective of export schedule. The establishment’s sampling programs also include collecting FCS, non-FCS, and environmental swab samples as well as any applicable testing program required under Regulation (EC) No. 2073/2005. Selected product lots are tested to ensure product entering commerce is free of *Lm*, *Salmonella*, and other pathogens of public concern. The auditor reviewed examples of inspectors’ verification documents, which encompass a range of activities that include reviewing the microbiological testing plan, laboratory results, and establishment’s corrective action(s). Although OV’s or IICs assigned to the establishments are responsible for daily verification, FLS also conducts weekly, monthly, quarterly, and annual visits to the certified establishments eligible to export to the United States and generates reports to document the outcome of their evaluation. The review of OV reports and FLS reports did not identify any concerns.

The CCA has designed and implemented governmental verification testing programs for RTE products (including products exposed to post lethality production areas) which are consistent with FSIS verification testing program requirements as specified in section 7 of the German Guidelines. All samples under the governmental verification testing programs are collected by the government employed inspection personnel who ship these samples to the designated government laboratory for analysis. The records pertaining to official testing maintained at one of the district offices, which has jurisdiction over the establishment producing both PLE and non-
PLE RTE products, indicate that the sampling protocols are implemented as documented in the German Guidelines. The sampling protocols referenced above are consistent with FSIS’ risk based and random sampling programs. The reviewed records demonstrated that annually, either

FLS or the designated official inspection personnel collects at least nine product samples to test for the presence of *Lm* and *Salmonella*. Of these nine samples, six are tested under the risk-based program and three are tested under a random testing program to cover all product types.

The FSIS auditor reviewed a recent sampling and test results from June 28, 2021, and the auditor confirmed that the number of samples, type of product and testing program were in line with the BVL's testing program for the RTE product producing establishments as outlined in section 7 of the German Guidelines. The auditor also reviewed an example of sampling data for FCS, non-FCS and environmental testing for the establishment producing RTE-PLE products. The sample submission form and the laboratory results dated August 16, 2021, indicated that 15 swabs covering a wide range of food contact surfaces were sampled for *Lm* and 13 swabs were sampled for *Salmonella*. Environmental testing includes collecting five samples per production line, as well as collecting chilling water samples that have indirect or no contact with the finished product. All samples for *Lm* are tested utilizing FSIS' Microbiology Laboratory Guide (MLG) chapter 8.11; and for *Salmonella* detection, the Laboratory used MLG method described in chapter 4.10. The auditor's review of documents related to testing programs, testing frequencies and the laboratory test results did not raise any concerns.

The FSIS analysis and remote verification activities indicate that BVL requires and verifies microbiological sampling and testing programs to ensure that meat products are safe and wholesome. FSIS concludes that BVL continues to meet the core requirements for this component.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on November 30, 2021, by videoconference with BVL. FSIS concluded that Germany's processed pork products inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. BVL has required that establishments certified as eligible to export processed pork products to the United States implement sanitation and HACCP requirements to ensure the safety of their products. Additionally, BVL has implemented microbiological testing programs that are organized and administered by the national government to verify its food safety inspection system. An analysis of each component did not identify any findings representing an immediate threat to public health.

Appendix: Foreign Country Response to the Draft Final Audit Report



Federal Office of
Consumer Protection
and Food Safety

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YOUR REFERENCE
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OUR REFERENCE 180.16461.0
(please indicate in reply)

DATE May 09, 2022

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Comments on the “draft final report of a remote Audit conducted of Germany October 19 – November 30, 2021”

Dear Michelle Catlin

With this letter, I am sending you the response of the German Central Competent Authority (CCA) to on the “draft final report of a remote Audit conducted of Germany October 19 – November 30, 2021” which was conducted by the senior program auditor [REDACTED]

Please find the response of the German CCA and the Competent Authorities (CAs) of the Federal States attached to this letter. The table provided contains comments like corrigenda and remarks related to the draft final report of the remote audit evaluating the food safety systems governing processed pork products exported to the United States of America.

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

Kind regards

A handwritten signature in blue ink, appearing to read 'Dr. Soumaya Lhafi', with a stylized, cursive script.

Dr. Soumaya Lhafi
Head of Unit

Enclosure:

Comments CAs and CCA of the Federal Republic of Germany

Stellungnahme

comments

Antwort der zuständigen Behörden der Bundesrepublik Deutschland bezüglich der Korrekturen und Anmerkungen in Bezug auf die Ausführungen des Entwurfs des Auditberichts zur Überprüfung des Überwachungssystems (Fleischhygiene), die in der nachfolgenden tabellarischen Übersicht aufgeführt werden. Das Audit wurde durch das Food Safety and Inspection Service (FSIS) des US Departments of Agriculture (USDA) der Vereinigten Staaten von Amerika im Zeitraum 19. Oktober 2021 bis 30. November 2021 als Remote Audit 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 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 October 19 2021 to November 30 2021 as a Remote Audit. 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
i	The Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL), as the Central Competent Authority (CCA), has required that establishments certified as eligible to export products to the United States implement sanitation and HACCP requirements to ensure the safety of their products.	<u>According to the German Guidelines for US Export of pork products it is required</u> that establishments certified as eligible to export products to the United States implement sanitation and HACCP requirements to ensure the safety of their products.	Clarification

i	In addition, BVL has implemented requirements for microbiological testing programs that are organized by the national government to verify its food safety inspection system.	In addition, BVL has implemented requirements for microbiological testing programs that are organized by the national government, <u>the “Zoonoses Monitoring”</u> , to verify its food safety inspection system.	Clarification concerning the name of the program
1	The audit began with an entrance meeting held via videoconference on October 19, 2021, with the Central Competent Authority (CCA) - Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL).	The audit began with an entrance meeting held via videoconference on October 19, 2021, with the Central Competent Authority (CCA) - Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) <u>and representatives of the Foreign Agricultural Service (FAS), the Federal Ministry of Food and Agriculture Bundesministerium für Ernährung und Landwirtschaft (BMEL) and the ministries of the participating Federal States Baden-Württemberg, Lower-Saxony and Thuringia.</u>	Corrigendum concerning the participants
2	The FSIS auditor reviewed records related to administrative functions and oversight at BVL headquarters, government verification records from two regional offices, ...	The FSIS auditor reviewed records related to administrative functions and oversight at BVL headquarters, government verification records from <u>three</u> regional offices,...	Corrigendum concerning the number of the regional offices audited
2	...and verification records from three district offices overseeing three local inspection offices within the establishments.	...and verification records from three district offices overseeing three local inspection offices within the establishments <u>and an official laboratory.</u>	Corrigendum, there was also an official laboratory audited
2	BVL's TPCS inspection activities were audited in the previous FSIS audit conducted in 2019 and FSIS did not identify any concerns.	<u>TPCS inspection activities of the competent authorities of the Federal States</u> were audited in the previous FSIS audit conducted in 2019 and FSIS did not identify any concerns.	Corrigendum concerning the responsibility of inspection activities

2	It did not include review of establishments' conditions or records.	<u>Establishment's records were shown and uploaded to FIS-VL since they were requested by the Auditor during the Audit.</u>	Corrigendum concerning the review of establishment's records
2	The FSIS auditor assessed the ability of BVL to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in Title 9 of the Code of Federal Regulations (CFR) 327.2.	The FSIS auditor assessed the ability of <u>the competent authorities of the Federal States</u> to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign food safety inspection systems outlined in Title 9 of the Code of Federal Regulations (CFR) 327.2.	Corrigendum concerning the supervisory visit responsibilities, this issue has already been clarified in the comments to the draft of the last audit report 2019
3	Regions	Regions <u>[higher state authorities]</u>	Corrigendum of the designation of the "Competent Authority"
3	Higher Thuringian State Office of Consumer Protection (overseeing the District Office Altenburger Land) Bad Langensalza	Thuringian State Office of Consumer Protection (overseeing the <u>Altenburger Land District Office; overseen by the Ministry of Labour, Social Welfare, Health, Women and Family Affairs of Thuringa, Erfurt</u>), Bad Langensalza	Complement regarding oversight responsibilities
3	Districts	Districts <u>[Lower state authorities]</u>	Corrigendum of the designation of the "Competent Authority"
3	BW-03330, Freiburger Lebensmittel GmbH & Co., Muggesnsturm	BW-03330, Freiburger Lebensmittel GmbH, Muggesnsturm	Corrigendum concerning the name of the company
5	Provisions in Regulation (EU) 2017/625 authorize BVL of the inspection system to ensure that establishment corrects the observed deficiencies when identified and further allows BVL to take enforcement actions that can include suspension or withdrawal of approval in the event corrective actions are not effective in remedying deficiencies.	Provisions in Regulation (EU) 2017/625 authorize <u>the competent authorities of the Federal States</u> of the inspection system to ensure that establishments correct the observed deficiencies when identified and further allows <u>the competent authorities of the Federal States</u> to take enforcement actions that can include suspension or withdrawal of approval in the event corrective actions are not effective in remedying deficiencies.	Corrigendum concerning the responsibilities

5	The FSIS auditor verified that the inspection system is organized and administered by the national government of Germany.	The FSIS auditor verified that the inspection system is organized and administered by the national government of Germany <u>and the competent authorities of the Federal States.</u>	Corrigendum concerning the responsibilities
5	BVL is part of Division 314 within BMEL and is led by the president whose office is supported by the vice president and a team of administrative staff.	<u>BVL is a higher Central Authority within BMEL's oversight</u> and is led by the president whose office is supported by the vice president and a team of administrative staff.	Corrigendum concerning the role of BVL
5	Notably, the Federal Institute for Risk Assessment of BMEL,...	Notably, the Federal Institute for Risk Assessment <u>within BMEL's oversight</u> ,...	Corrigendum concerning the role of BfR
6	Implementing export requirements for the United States, through BVL's Unit 180 (The Export Affairs Unit);	Implementing <u>together with BMEL and the competent authorities of the Federal States</u> export requirements for the United States, through BVL's Unit 180 (<u>Export Affairs - Export regulations and listing procedures</u>);	Corrigendum concerning the responsibilities
6	Each Federal States has its own ministry for agriculture and allied functions including food safety.	Each Federal State has its own ministry for agriculture, <u>health</u> or consumer protection and allied functions including food safety.	Corrigendum concerning the portfolio of the ministry of the federal state. In Thuringia, food surveillance is located in the Thuringian Ministry of Labour, Social Affairs, Health, Women and Family. Agriculture is located in another Thuringian ministry.
6	At the Federal States level, the system of official controls, oversight, and administration of food safety is divided into three levels: ministry, provincial or regional, and district or municipal authorities.	At the Federal States level, the system of official controls, oversight, and administration of food safety is divided into two or three levels respectively: supreme state authority (ministry), in most Länder a higher state authority (e.g. provincial or regional), and lower (district or municipal) authorities.	Corrigendum to describe the administrative levels more precisely.

7	This collaboration includes providing the Federal States with logistical and organizational support; ensuring that the EU and national legislation is properly implemented in all Federal States; contributing to the drafting of general administrative regulations; coordinating control programs; providing training concerning United States import requirements; and participating in meetings of the Federal States Working Group for Consumer Protection.	This collaboration includes providing the Federal States with <u>advisory support; contributing to the drafting of general administrative regulations; coordinating control programs; providing training concerning United States import requirements; and participating in meetings of the Federal States Working Group for Consumer Protection.</u> <u>The competent authorities of the Federal States are ensuring that the EU and national legislation is properly implemented in all Federal States.</u>	Corrigendum concerning the responsibilities and role of BVL and the competent authorities of the Federal States
7	The working group for food of animal origin (LAV) holds workgroup meetings to tackle issues concerning all Federal States and with a focus on mutual objectives and cooperation on resolving issues relating to food of animal origin.	The <u>LAV-AFFL (LAV working group on meat and poultry meat hygiene and technical issues of food of animal origin)</u> holds workgroup meetings to tackle issues concerning all Federal States and with a focus on mutual objectives and cooperation on resolving issues relating to food of animal origin.	Corrigendum of the name of the working group
7	Through the LAV-AFFL (LAV working group on meat and poultry meat hygiene and technical issues of food of animal origin) platform, BVL and the Federal States engage in discussions on technical concerns which includes future updates and revisions of the German Guidelines, new information on FSIS requirements, and upcoming trainings.	Through the LAV-AFFL (LAV working group on meat and poultry meat hygiene and technical issues of food of animal origin) platform, <u>BMEL, BMU (Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection), BMVG (Federal Ministry of Defence), BVL, BfR (Federal Institute for Risk Assessment), ALB (LAV Working Group for Food, commodities, Wine and Cosmetics), ALTS (Working Group in the area of Food Hygiene and Food of Animal Origin working Experts)</u> and the Federal States engage in discussions on technical concerns which includes <u>amongst others votes and recommendations for implementation of future updates and revisions of the German Guidelines</u>	Corrigendum concerning the participants

		containing new information on FSIS requirements.	
7	The Food Hygiene and Food of Animal Origin Research Group is another platform of BVL and Federal States interface through which BVL and Federal States work on food hygiene, exchange of scientific information and opinion, food pathogens, and the National Residue Control Plan.		This passage should be deleted due to misunderstandings.
7	The auditor verified that the last meeting of LAV-AFFL was held May 11–12, 2021 in Potsdam, Germany, and was attended by BMEL and representatives from Federal States across the country.	The auditor verified that the last meeting of LAV-AFFL was held May 11–12, 2021 in Potsdam, Germany, and was attended by BMEL, <u>BMU</u> , <u>BMVG</u> , <u>BVL</u> , <u>BfR</u> , <u>ALB</u> , <u>ALTS</u> and representatives from Federal States across the country.	Corrigendum concerning the participants
7	Notification procedures for recalls are contained in the General Administrative Rules for the Implementation of the Rapid Alert System for Food and Feed Notifications. These general administrative rules set out clear responsibilities and criteria in relation to the preparation of notifications regarding food, food contact materials, and feeding stuffs. Section 6 of the German Guidelines describes the mechanisms for recall of consignments, lot identification for traceability, and seizure. As noted above, BVL is a contact point for RASFF in Germany.	Uniform notification procedures for the use of the rapid alert system are laid down in the General Administrative Regulation for the implementation of the rapid alert system for food, food contact materials and feed. This general administrative regulation establishes clear responsibilities and criteria for the preparation of RASFF notifications and specifies that the BVL acts as the national contact point. Section 6 of the above-mentioned German Guidelines describes the mechanisms for recall of consignments, lot identification for traceability, and seizure.	Clarification of the function of the General Administrative Regulation for the Rapid Alert System (the RASFF is not necessarily about recalls) and demarcation of the RASFF from the German Guidelines mentioned above
8	The FSIS auditor confirmed that the inspection operations are funded by the state budget and the inspection personnel assigned to establishments certified to export to the	The FSIS auditor confirmed that the inspection operations are funded by the state budget and the inspection personnel assigned to establishments certified to export to the United	Clarification concerning the working time of the employees

	United States are fulltime employees of the government and perform their inspection activities under the administration of the respective Federal State Authority.	States are fulltime <u>or part-time</u> employees of the government and perform their inspection activities under the administration of the respective Federal State Authority.	
8	OVs must have a doctor of veterinary medicine or equivalent degree...	OVs must be licensed Veterinarians or have an equivalent degree...	Clarification concerning Official Veterinarians, this issue has already been clarified in the comments to the draft of the last audit report 2019
8	One point of focus for the current remote audit was to verify BVL's procedures and requirements for certification of establishments in compliance with, and decertification of establishments not in compliance with, the FSIS import requirements.	One point of focus for the current remote audit was to verify <u>BVL's procedures and coordination of activities as well as the requirements of the German competent authorities</u> for certification of establishments in compliance with, and decertification of establishments not in compliance with, the FSIS import requirements.	Clarification concerning the responsibilities and role of BVL and the competent authorities of the Federal States
8	The rules governing establishment approval procedures are defined in the German General Administrative Regulation on the implementation of the supervision of compliance with hygiene rules for food and method for testing for guides to good practice (AVV-LmH).	The rules governing establishment approval procedures are defined in the <u>German Food Hygiene Regulation (LMHV) § 9 and § 5</u> of the German General Administrative Regulation on the implementation of the supervision of compliance with hygiene rules for food and method for testing for guides to good practice (AVV-LmH).	Corrigendum concerning the legal basis
8	..., BVL also conducts an audit of all establishments prior to initial certification...	..., BVL also <u>accompanies</u> the final audit of establishments prior to initial certification...	Clarification concerning the role of BVL concerning accompanying of audits prior to initial certification, this issue has already been clarified in the comments to the draft of the last audit report 2019
9	BVL administers and manages the FIS-VL centralized document management and	BVL administers and manages the FIS-VL centralized document management and	Corrigendum concerning the users of FIS-VL

	information intranet portal for food safety and consumer protection utilized by BVL and official personnel in each Federal State.	information intranet portal for food safety and consumer protection utilized by <u>BfE, BVL and other Higher Central Authorities as well as</u> official personnel in each Federal State.	
9	BVL disseminates uniform instructions to the Federal States' CAs, including information about the required approval and eligibility certification, templates for certification of establishment eligibility, relevant FSIS legislation and policy, guidelines and training material developed by the Working Group for the United States Export, and minutes of the workgroup's meetings.	BVL disseminates uniform <u>advice and support</u> to the Federal States' CAs, including information about the required approval and eligibility certification, templates for certification of establishment eligibility, relevant FSIS legislation and policy, guidelines developed by the Working Group for the United States Export, minutes of the workgroup's meetings <u>and training material</u> .	Clarification concerning the role and responsibilities of BVL
10	The FSIS auditor assessed BVL's measures in ensuring that adequate administrative and technical support is available to its laboratory system.	The FSIS auditor assessed that adequate administrative and technical support is available to <u>the</u> laboratory system.	Corrigendum concerning the role and responsibilities of BVL
10	In Germany, BVL has designated the Food and Veterinary Institute (FVI) Lower Saxony State Office for Consumer Protection and Food Safety (LAVES) in Oldenburg as the laboratory conducting official analytical testing on product destined to the United States.	In Germany, <u>the Food and Veterinary Institute (LVI) of the Lower Saxony State Office for Consumer Protection and Food Safety (LAVES) in Oldenburg is the designated</u> laboratory conducting official analytical testing on product destined to the United States.	Clarification, this issue has already been clarified this issue has already been clarified in the comments to the draft of the last audit report 2019
10	The auditor reviewed the most recent organization chart of the FVI issued in October 2021. Section 23 (Bacteriology and Sanitary Testing Branch) in Department 2 of the FVI is responsible for analysis of samples received under the sanitary and slaughter testing program which includes samples received from all certified establishments. The review of the laboratory functions included interviews with	The auditor reviewed the most recent organization chart of the <u>LVI</u> issued in October 2021. Section 23 (Bacteriology and Sanitary Testing Branch) in Department 2 of the <u>LVI</u> is responsible for analysis of samples received under the sanitary and slaughter testing program which includes samples received from all certified establishments. The review of the laboratory functions included interviews with the head of	Corrigendum of the name of the LVI

	<p>the head of Section 23, and document reviews to verify the implementation of procedures and standards described in the QCM. Section 23 of FVI is staffed with 13 trained employees, including two scientific experts supported by 11 assistants, each responsible for defined duties. The FSIS auditor verified that Section 23 of FVI conducts testing for <i>Salmonella</i> and <i>Lm</i> in RTE meat products destined for export to the United States, as well as environmental sponge samples from producing establishments. The FSIS auditor reviewed the most recent accreditation audit report by of the laboratory issued to FVI by DAkkS on March 7, 2019. The audit report provided detailed assessments of how all departments of FVI are meeting ISO/IEC 17025 standards, focusing on requirements of FVI's QCM, equipment,...</p>	<p>Section 23, and document reviews to verify the implementation of procedures and standards described in the QCM. Section 23 of <u>LVI</u> is staffed with 13 trained employees, including two scientific experts supported by 11 assistants, each responsible for defined duties. The FSIS auditor verified that Section 23 of <u>LVI</u> conducts testing for <i>Salmonella</i> and <i>Lm</i> in RTE meat products destined for export to the United States, as well as environmental sponge samples from producing establishments. The FSIS auditor reviewed the most recent accreditation audit report by of the laboratory issued to <u>LVI</u> by DAkkS on March 7, 2019. The audit report provided detailed assessments of how all departments of <u>LVI</u> are meeting ISO/IEC 17025 standards, focusing on requirements of <u>LVI's</u> QCM, equipment,...</p>	
12	<p>... of the German Guidelines which are implemented per requirements detailed in section 5 of General Administrative Regulation (AVV LMH).</p>	<p>... of the German Guidelines which are implemented per <u>official vote with the recommendation for implementation by the LAV AFFL.</u></p>	<p>Corrigendum concerning the implementation of the German Guidelines</p>
13	<p>The FSIS auditor verified that BVL ensures that pork exports are not subject to animal health restrictions by receiving notifications via APHIS' Email Subscription Service or through official channels such as the Federal Ministry or the German Embassy (Animal Disease Notification System),...</p>	<p>The FSIS auditor verified that <u>BMEL</u> ensures that pork exports are not subject to animal health restrictions by receiving notifications via APHIS' Email Subscription Service or through official channels such as the Federal Ministry or the German Embassy <u>or the Animal Disease Notification System</u>,...</p>	<p>Corrigendum concerning the responsibility for Animal Health issues</p>
13	<p>BVL communicates newly issued import requirements to the CAs which then forward them to the official staff in the district either by</p>	<p><u>Concerning Animal Health issues BMEL</u> communicates newly issued import requirements to the CAs which then forward</p>	<p>Corrigendum concerning the responsibility for Animal Health issues</p>

	direct e-mails or through posting on the FIS-VL website.	them to the official staff in the district either by direct e-mails or through posting on the FIS-VL website.	
14	... confirmed that proper identification, handling, and segregation of these materials in specially marked containers are ensured and the inspection personnel routinely verify documentation of inedible materials according to the instruction in Annex 2 of the German Guidelines.	... confirmed that proper identification, handling, and segregation of these materials in specially marked containers are ensured and the inspection personnel routinely verify documentation of inedible materials according to the instruction in <u>section 3.6 and Annex 2</u> of the German Guidelines.	Clarification concerning the relevant sections of the German Guidelines
14	The FSIS auditor verified that the CCA requires each official establishment to develop, implement, and maintain written sanitation standard operating procedures (Sanitation SOPs)...	The FSIS auditor verified that <u>it is required and officially verified according to the German Guidelines section 3, that</u> each official establishment to develop, implement, and maintain written sanitation standard operating procedures (Sanitation SOPs)...	Clarification concerning the role and responsibilities of BVL
15	The FSIS auditor concluded that BVL requires establishments certified to export to the United States to develop, implement, and maintain sanitation programs, including requirements for SPS and Sanitation SOPs. FSIS concluded that BVL continues to meet the core requirements for this component.	The FSIS auditor concluded that establishments certified to export to the United States <u>are, according to the German Guidelines section 3, required</u> to develop, implement, and maintain sanitation programs, including requirements for SPS and Sanitation SOPs. FSIS concluded that <u>Germany</u> continues to meet the core requirements for this component.	Clarification concerning the role and responsibilities of BVL
15	Through review of government verification records, the auditor confirmed that BVL inspection personnel verified that the certified establishments producing RTE products...	Through review of government verification records, the auditor confirmed that <u>government</u> inspection personnel verified that the certified establishments producing RTE products...	Corrigendum concerning the responsibility for inspection activities
16	The FSIS analysis and remote verification activities indicate that BVL requires operators	The FSIS analysis and remote verification activities indicate that operators of certified	Clarification concerning the role and responsibilities of BVL

	of certified establishments to develop, implement, and maintain a HACCP system. FSIS concludes that BVL continues to meet the core requirements for this component.	establishments <u>are, according to the German Guidelines section 4, required</u> to develop, implement, and maintain a HACCP system. FSIS concludes that <u>Germany</u> continues to meet the core requirements for this component.	
17	BVL routinely reviews the monitoring results of these countries as well as RASFF for any documented cases of product exceeding accepted residue levels.	NL and DK routinely review their monitoring results. <u>Should products exceed accepted residue levels and therefore pose a risk for human and/or animal health and should these products have been placed on the market in other Member States or Third Countries, this would be communicated via the RASFF.</u>	Corrigendum concerning monitoring and communication channels
17	Council Directive 96/22/EC of 29 April 1996	Council Directive 96/23/EC of 29 April 1996	Corrigendum of the Title of the Council directive
17	Through interviews and record reviews, the FSIS auditor verified that BVL is meeting the core requirements of this component.	Through interviews and record reviews, the FSIS auditor verified that <u>Germany</u> is meeting the core requirements of this component.	As mentioned in the Executive summary of the report the audit was a remote ongoing equivalence verification audit of Germany and Germany's food safety inspection system
18	In accordance with Regulation (EC) No. 2073/2005 microbiological criteria for foodstuffs, BVL defines RTE product as...	In accordance with Regulation (EC) No. 2073/2005 microbiological criteria for foodstuffs, <u>a RTE product is defined in the German Guidelines section 7.2 as...</u>	Clarification concerning the role and responsibilities of BVL
18	BVL's requirements for RTE products are contained in section 7 of the German Guidelines.	<u>The</u> requirements for RTE products are contained in section 7 of the German Guidelines.	Clarification concerning the role and responsibilities of BVL
18	BVL requires certified establishments producing RTEPLE products to identify and implement control programs...	Certified establishments producing RTEPLE products <u>are, according to the German Guidelines section 7.2 required</u> to identify and implement control programs...	Clarification concerning the role and responsibilities of BVL

18	The CCA has designed and implemented governmental verification testing programs for RTE products...	<u>Germany has designed and implemented governmental verification testing programs for RTE products, as described in the German Guidelines section 7.3.3,...</u>	As mentioned in the Executive summary of the report the audit was an remote ongoing equivalence verification audit of Germany and Germany's food safety inspection system
19	...designated official inspection personnel collects at least nine product samples to test for the presence of <i>Lm</i> and <i>Salmonella</i> . Of these nine samples, six are tested under the risk-based program and three are tested under a random testing program to cover all product types.	...designated official inspection personnel collects product samples to test for the presence of <i>Lm</i> and <i>Salmonella</i> . <u>Under the risk-based program the sampling is the following:</u> <u>Alternative 1: 1 sample/year</u> <u>Alternative 2a: 3 samples/year</u> <u>Alternative 2b: 6 samples/year</u> <u>Alternative 3: 12 samples/year</u> <u>Under the random testing program (to cover all product types) the sampling is the following:</u> <u>At least 3 samples/year</u>	Corrigendum concerning the official product sampling required according to the German Guidelines section 7.3.3
19	were in line with the BVL's testing program for the RTE product producing establishments as outlined in section 7 of the German Guidelines.	were in line with the testing program for the RTE product producing establishments as outlined in section 7 of the German Guidelines.	Clarification concerning the role and responsibilities of BVL
19	Environmental testing includes collecting five samples per production line, as well as collecting chilling water samples that have indirect or no contact with the finished product.	<u>Official Environmental Routine Testing includes the following sampling:</u> <ul style="list-style-type: none"> <u>establishments (>500 employees): up to 3 production lines/year</u> <u>establishments (10-499 employees): up to 2 production lines/year</u> <u>establishments (<10 employees): 1 production line/year</u> <u>FCS (Food Contact Surfaces):</u> <u>10 sponge samples/production line</u>	Corrigendum concerning the official environmental sampling required according to the German Guidelines section 7.3.3

		<p><u>(FCS as well as collecting chilling water samples that might have contact with the finished product)</u></p> <p><u>NFCS (Non Food Contact Surfaces):</u> <u>5 sponge samples/production line</u> <u>(NFCS as well as collecting chilling water samples that have indirect or no contact with the finished product)</u></p>	
19	The FSIS analysis and remote verification activities indicate that BVL requires and verifies microbiological sampling and testing programs to ensure that meat products are safe and wholesome. FSIS concludes that BVL continues to meet the core requirements for this component.	The FSIS analysis and remote verification activities indicate <u>the German competent authorities require and verify</u> microbiological sampling and testing programs to ensure that meat products are safe and wholesome. FSIS concludes that <u>Germany</u> continues to meet the core requirements for this component.	As mentioned in the Executive summary of the report the audit was an remote ongoing equivalence verification audit of Germany and Germany's food safety inspection system
19	An exit meeting was held on November 30, 2021, by videoconference with BVL.	An exit meeting was held on November 30, 2021, by videoconference with <u>FAS, BMEL, BVL and representatives from the Federal States Baden-Württemberg, Lower-Saxony and Thuringia.</u>	Corrigendum concerning the participants
19	BVL has required that establishments certified as eligible to export processed pork products to the United States implement sanitation and HACCP requirements to ensure the safety of their products. Additionally, BVL has implemented microbiological testing programs that are organized and administered by the national government to verify its food safety inspection system.	<u>It is required and officially verified</u> that establishments certified as eligible to export processed pork products to the United States implement sanitation and HACCP requirements to ensure the safety of their products. Additionally, BVL has implemented microbiological testing programs, <u>the "Zoonoses Monitoring"</u> , that are organized and administered by the national government to verify its food safety inspection system.	Clarification concerning the role and responsibilities of BVL and the name of the microbial testing program

