



United States Department of Agriculture

Food Safety and
Inspection Service

October 11, 2024

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Avenue, SW.
Washington, D.C.
20250

Dr. Ulrich Herzog
Chief Veterinary Officer
Federal Ministry of Social Affairs, Health, Care and Consumer Protection
Radetzkystrasse 2
A-1030 Vienna, Austria

Dear Dr. Herzog,

The United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) conducted an onsite verification audit of Austria's inspection system March 11–25, 2024. Enclosed is a copy of the final audit report. The comments received from the Government of Austria are included as an attachment to the report.

Sincerely,

**MARGARET
BURNS RATH**

Digitally signed by
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Margaret Burns Rath, JD, MPH
Acting International Coordination Executive
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Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED OF
AUSTRIA

MARCH 11 – 25, 2024

EVALUATING THE FOOD SAFETY SYSTEM GOVERNING
PROCESSED PORK PRODUCTS

EXPORTED TO THE UNITED STATES OF AMERICA

October 8, 2024

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

Executive Summary

This report describes the outcome of an onsite equivalence verification audit of Austria conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) March 11-25, 2024. The purpose of the audit was to verify whether Austria's food safety inspection system governing processed pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. Austria currently exports Not Heat Treated – Shelf Stable, Heat Treated – Shelf Stable, Heat Treated but Not Fully Cooked – Not Shelf Stable and Fully Cooked – Not Shelf Stable pork products to the United States.

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

An analysis of the findings noted below did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM

- Government inspection personnel did not verify that establishment HACCP plans complied with BMSGPK's requirements. Ongoing verification activities (e.g., calibration of the process monitoring instrument, direct observation of monitoring activities, and review of records) or their frequencies were not included in the establishments' HACCP plans, as required by BMSGPK.
- Government inspection personnel did not verify that the corrective actions included in the establishments' HACCP plans for deviations met BMSGPK's requirements.

During the audit exit meeting, BMSGPK officials committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of the BMSGPK's documentation of proposed corrective actions and base future equivalence verification activities on the information provided.

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I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) conducted an onsite audit of Austria's food safety system March 11-25, 2024. The audit began with an entrance meeting held March 11, 2024, in Vienna, Austria, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – The Federal Ministry of Social Affairs, Health, Care and Consumer Protection (Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz - BMSGPK). Representatives from BMSGPK accompanied the FSIS auditors throughout the entire audit. The audit concluded with an exit meeting conducted March 25, 2024.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

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

Process Category	Product Category	Eligible Products ¹
Not Heat Treated - Shelf Stable	Ready-to-eat (RTE) Acidified / Fermented Meat (without cooking)	Pork - All Products Eligible
Heat Treated - Shelf Stable	RTE Acidified / Fermented Meat (without cooking)	Pork - All Products Eligible
Heat Treated - Not Fully Cooked - Not Shelf Stable	Not-ready-to-eat (NRTE) Otherwise Processed 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

The USDA's Animal and Plant Health Inspection Service (APHIS) subjects pork imported from Austria to African swine fever requirements specified in Title 9 of the U.S. Code of Federal Regulations (9 CFR) 94.8, classical swine fever requirements specified in 9 CFR 94.31, swine vesicular disease requirements specified in 9 CFR 94.13, and foot-and-mouth disease requirements specified in 9 CFR 94.11.

Prior to the onsite equivalence verification audit, FSIS reviewed and analyzed BMSGPK's Self-Reporting Tool (SRT) responses and supporting documentation. During the audit, the FSIS auditors conducted interviews, made observations, and reviewed records to verify whether

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

Austria's food safety inspection system governing processed pork products is being implemented as documented in the country's SRT responses and supporting documentation.

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, 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 3-year period, in addition to information obtained directly from BMSGPK 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 auditors reviewed administrative functions at BMSGPK's headquarters in Vienna, two provincial veterinary offices, and three local inspection offices within the audited establishments. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

The FSIS auditors selected all three pork processing establishments certified as eligible to export to the United States for the audit. The products these establishments produce and export to the United States include RTE fully-cooked pork; RTE acidified / fermented pork (without cooking); and NRTE otherwise processed pork. Austria's raw pork inspection system has not been determined to be equivalent to FSIS' inspection system; therefore, the pork processing establishments source raw pork products from certified slaughter establishments in other eligible countries that have equivalent raw products inspection systems.

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

The FSIS auditors did not visit any laboratories to verify the adequacy of technical support to the food safety system because BMSGPK utilizes an accredited laboratory located in Germany for the analysis of all official microbiological samples.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	<ul style="list-style-type: none"> • BMSGPK Headquarters, Vienna
	Provincial Offices	2	<ul style="list-style-type: none"> • Upper Austrian Provincial Veterinary Services, Linz • Tyrol Provincial Veterinary Services, Innsbruck
Pork processing establishments		3	<ul style="list-style-type: none"> • Establishment No. AT40776EG, Hochreiter Fleischwaren GmbH, Bad Leonfelden • Establishment No. AT41586EG, Hochreiter Fleischwaren GmbH, Reichenthal • Establishment No. AT71088EG, Handl Tyrol GmbH, Haiming

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

III. BACKGROUND

From October 1, 2020, to September 30, 2023, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 102,239 pounds of processed pork products from Austria. This included 102,239 pounds of NRTE otherwise processed pork exported by Austria to the United States. Of these amounts, additional types of inspection were performed on 7,840 pounds of processed pork products, including physical examination. As a result of this additional inspection, 53 pounds of processed pork products were refused for other issues not related to public health, such as shipping damage, labeling, or other miscellaneous issues. No product was refused entry for issues related to public health.

The previous FSIS audit in 2021, conducted remotely, did not identify any systemic findings.

The most recent FSIS final audit reports for Austria'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 auditors 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.

Austria's national government organizes and manages the food safety system governing processed pork products that are exported to the United States. As previously noted, BMSGPK is Austria's CCA. BMSGPK consists of a central office located in Vienna and 9 provincial veterinary service (PVS) offices overseeing 94 district veterinary services (DVS) offices. The PVS offices are led by Provincial Veterinary Officers (PVO) while the DVS offices are run by District Veterinary Officers (DVO). BMSGPK also includes seven sections as part of its continuous chain of command. Section III (Consumer Policy and Consumer Health) includes Divisions A and B. Division B plays a key role in the oversight and administration of the national inspection system and consists of seven departments that are responsible for consumer health and veterinary services. Those seven departments are:

1. Department III/8/9, which oversees crisis coordination for veterinary and food safety related affairs;
2. Department III/B/10, which handles animal health and disease control, border control service as well as trade of live animals;
3. Department III/B/11, which is responsible for animal welfare;
4. Department III/B/12, which manages hygiene in meat production, animal by-products and export affairs;
5. Department III/B/13, which oversees food safety and consumer protection-control, hygiene, and quality;
6. Department III/B/15, which is responsible for zoonosis, international coordination, and the execution of the Risk-based Multiannual Control Plan; and
7. Department III/B/16, which handles legal affairs for the veterinary profession, animal health, animal welfare, and veterinary services.

Department III/B/12 is led by the Central Veterinary Officer and governs processed pork products exported to the United States. This department also organizes trainings and audits in coordination with provincial and district offices. BMSGPK derives its authority and responsibility to enforce the laws and regulations governing meat inspection and to certify processed pork products for export to the United States from the 2021 Austrian statute Complete Statutory Regulations for the Food Safety and Consumer Protection Act (hereinafter referred to as LMSVG). Furthermore, as a European Union (EU) Member State, Austria implements the overarching food safety controls mandated by the EU.

The FSIS auditors verified that there was one notable organizational change in the structure of BMSGPK with the creation in January 2022 of the Federal Office of Consumer Health (BAVG) per Section 51(3) of LMSVG. BAVG is led by the Head of Export Permits and is responsible for import control, export authorization, internet sales of LMSVG-regulated goods, and promotion of a uniform process in the implementation of third country specifications in addition to the EU

specifications for animal products. BAVG conducts onsite inspections to verify that import requirements of third countries are met and, after that, issues an export license. The head of BAVG also conducts at least one supervisory review visit per year to all establishments certified as eligible to export processed pork to the United States. The FSIS auditors reviewed reports of supervisory reviews for all audited establishments and found no concerns with the frequency or content of these reviews.

There are nine PVS offices headed by PVO who supervise firstline veterinarians who, in turn, oversee frontline veterinarians assigned to establishments certified to export to the United States. PVS offices are responsible for the implementation and organization of official controls regarding meat inspection. There are 94 DVS offices, which are headed by DVO. The three establishments certified to export to the United States fall under the jurisdiction of the Upper Austria and Tyrol PVO.

As an EU Member State, Austria has adopted Regulation (EC) No. 178/2002 regarding the definition of adulterated and misbranded products. Regulation (EC) No. 178/2002 establishes overarching guiding principles and legitimate objectives for food law to ensure a high level of health protection and the effective functioning of the internal market. The regulation includes requirements related to (a) the responsibilities of establishments (Article 17); (b) product traceability (Article 18); (c) the withdrawal, recall, and notification for food and feed (Articles 19 and 20) in relation to food and feed safety (Articles 14 and 15); and (d) imports and exports (Articles 11 and 12). Adulterated and misbranded products are also defined under Article 5 of LMSVG, which prohibits such products from being placed on the market. Establishments bear the legal responsibility to market only safe and unadulterated products and must recall any adulterated product that has entered commerce. If frontline veterinarians identify that any adulterated or misbranded product has been shipped, the PVO is notified and then the PVO notifies BMSGPK's central office. Austria also utilizes the EU Rapid Alert System for Food and Feed (RASFF) to notify other EU countries to which the product has shipped, and BMSGPK's central office notifies FSIS if adulterated or misbranded product is shipped to the United States. The FSIS auditors verified that there have not been any recalls at the establishments eligible to export to the United States. All establishments certified as eligible to export processed pork to the United States conduct mock recalls at least once a year, as per BMSGPK's requirement.

The FSIS auditors verified that BMSGPK ensures that the same set of laws, regulations, and policies is applied consistently to all establishments certified to export to the United States. Specifically, Commission Implementing Regulation (EU) 2019/627 governs official controls for meat, and Regulation (EC) No. 178/2002 and Regulation (EU) 2017/625 govern export approval. BMSGPK further implements Austrian national legislation and LMSVG. The national legislation fully implements the EU requirements concerning food, which includes a requirement that establishments intending to export to a third country must comply with the minimum requirements of both the country of origin (Austria) and country of destination (e.g., United States). Additionally, meat inspection requirements implemented per EU requirements and LMSVG are further supplemented by and detailed in the Meat Inspection Regulation of 2006.

The FSIS auditors verified the process for certifying establishments as eligible to export to the United States as defined in Article 51 of LMSVG and National Implementing Decree No. 9,

which outline approval procedures. Establishments that intend to export to the United States must have an official veterinarian from the PVS office review their requests and verify that the establishments meet U.S. import requirements. The FSIS auditors reviewed the approval records and decree for the establishment in the Tyrol province recently listed as eligible and identified no issues of concern.

The FSIS auditors reviewed the export certification process as outlined in Article 52 of LMSVG and National Implementing Decree No. 10, which require establishments to meet the requirements of the country to which they are exporting. Frontline veterinarians verify that these requirements are met by reviewing the establishment's pre-shipment review, conducting a visual inspection of products being certified for export, and checking the traceability records. If any noncompliance is identified, the frontline veterinarian requires and verifies the implementation of acceptable corrective actions before resuming the export verification activity. Additionally, the frontline veterinarians review and ensure that test results of all samples (official and establishment samples) are acceptable. Once the review is complete, the frontline veterinarians forward the export package to the firstline veterinarian located at the PVS office. As per Articles 24.3 and 24.4 of LMSVG, appointed or authorized veterinarians and official veterinarians from the competent DVS offices are legally authorized to perform export certification. Regarding shipments intended for direct U.S. export, the export certification is performed by the appointed firstline veterinarians from the competent DVS office. In accordance with the National Implementing Decree No. 10, only authorized government personnel have access to export certificates, which are kept in the exporting establishment or in the office of the competent DVS office after export clearance.

At the audited establishments, the FSIS auditors verified that BMSGPK ensures that only source materials from establishments and countries certified as eligible to export to the United States can be used. Frontline veterinarians verify during the export certification process that only eligible source materials from certified establishments are utilized for each shipment. Austrian establishments that are certified as eligible to export processed pork products to the United States are sourcing raw products from certified slaughter establishments in the Netherlands or Denmark and some processed pork products from Germany. The FSIS auditors verified the list of supplying establishments from Denmark, Germany, and the Netherlands and confirmed their eligibility to export to the United States.

At the audited establishments, the FSIS auditors reviewed examples of noncompliance documented by frontline veterinarians, records documenting corrective actions and verification of corrective actions by the frontline veterinarians. The PVS office and the BAVG official reviews noncompliance records during supervisory review visits. The FSIS auditors verified that there have been no enforcement actions or delistments of certified establishments eligible to export to the United States since the previous FSIS audit in 2021.

The FSIS auditors reviewed the qualifications of frontline veterinarians assigned to certified establishments and verified that government inspection personnel are required to hold a degree in veterinary medicine to qualify for the position, in accordance with EU legislation and the Austrian Law on Training and Education. Frontline veterinarians assigned to certified establishments that export to the United States are trained on FSIS import requirements and must

complete both practical and theoretical training prior to starting their assignment. Ongoing training is held by BMSGPK headquarters for frontline and firstline veterinarians once per year. The FSIS auditors reviewed the most recent training records and confirmed that firstline veterinarians, frontline veterinarians, BMSGPK headquarters officials and BAVG authorities have participated in FSIS' September 2023 Seminar for International Government Officials, which covered the FSIS regulatory process, inspection methods, control of food pathogens, the national residue program, laboratory modernization, labeling and ingredients approval system, import requirements, sanitation standard operating procedures (Sanitation SOPs) and HACCP verification, and microbiological sampling.

The FSIS auditors reviewed duty rosters and verified that BMSGPK ensures frontline veterinarians are assigned at least once per shift to inspect and verify that all FSIS import requirements are met for processed pork products intended for export to the United States. The schedules additionally have a back-up frontline veterinarian assigned at least once per shift if any unplanned absences arise. The FSIS auditors confirmed through a review of inspection records that most of BMSGPK's inspection personnel are employees of the Austrian government who are hired and paid by the provincial government. In addition, the FSIS auditors verified that BMSGPK also utilizes some privately contracted frontline veterinarians to perform official inspection duties. These privately contracted frontline veterinarians are supervised by firstline veterinarians (who are civil servants) and are subject to the same deontological and ethical rules as other civil servants, including the avoidance of conflicts of interest in the discharge of their professional duties.

The FSIS auditors verified that information regarding FSIS requirements is conveyed to government inspection personnel and establishments certified to export to the United States through email communication, regular seminars, and trainings provided to PVS offices, DVS offices, and frontline veterinarians. Furthermore, BMSGPK also uses the service of the Austrian Chamber of Commerce and a public website with export information to disseminate U.S. import requirements to government inspection personnel.

The sole laboratory responsible for analyzing official samples of product intended for export to the United States is the Lower Saxony State Office for Consumer Protection and Food Safety (LAVES) laboratory in Germany. LAVES is accredited annually by a German accreditation body, the Deutsche Akkreditierungsstelle (DAkkS), according to International Organization for Standardization/International Electrotechnical Commission 17025 standards. BMSGPK receives and reviews the accreditation certificates and associated annexes, which include the methods in the scope of the accreditation, on an annual basis. The EU additionally audits this laboratory, and BMSGPK regularly receives and reviews these audit reports.

The FSIS auditors also verified that once the sample results are available, the laboratory emails the certificate of analysis (COA) to the DVO, the firstline veterinarians, the frontline veterinarians, and the establishment where the sample was collected. The FSIS auditors reviewed an email from the laboratory about the COA of a sample collected from one of the audited establishments and confirmed that the results are issued in a timely fashion.

The FSIS auditors reviewed the most recent accreditation certificate and verified that it included FSIS analytical methods used for products exported to the United States. The FSIS auditors reviewed BMSGPK laboratory submission and sample result reports for product intended for export to the United States for *Salmonella* and *Listeria monocytogenes* (*Lm*) verification testing and the sampling schedule and sampling plan for all eligible establishments. The FSIS auditors reviewed a positive result and verified that corrective actions were taken by the establishment and verified by both the frontline and firstline veterinarians. The FSIS auditors also verified that follow-up sampling was performed, and the product was condemned. The FSIS auditors also verified the contractual agreement between LAVES and BMSGPK and confirmed that it included all the specifications regarding sample analysis from sample shipping to issuance of the COA. No concerns were identified regarding the contract.

The FSIS auditors verified that BMSGPK's processed pork inspection system meets the core requirements of this component because it is organized and administered by the national government and has the organizational structure to provide ultimate control, supervision, and enforcement of regulatory requirements.

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 auditors 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.

The FSIS auditors verified that firstline veterinarians from the PVS offices conduct supervisory reviews four times per year at establishments that are eligible to export to the United States, one of which is conducted together with a representative from BAVG. The reviews include verification of HACCP, Sanitation SOPs, sanitation performance standards (SPS), microbiological sampling, and labeling. The reports of these reviews are distributed to BMSGPK headquarters, firstline veterinarians, frontline veterinarians, and the establishment. If findings are identified, orders are issued to the establishment to implement corrective actions and to the frontline veterinarians to verify corrective action. Additionally, a performance appraisal of the frontline veterinarian is conducted once per year. The FSIS auditors reviewed the periodic supervisory review reports and verified that when findings were identified, corrective actions were taken and verified by frontline veterinarians.

The FSIS auditors verified that establishments maintain identity of product and control and segregate product intended for export to the United States from other products by designating "USA Products" zones in the storage rooms. Additionally, the source materials are identified as intended for export to the United States. Frontline veterinarians verify once per shift that establishments certified to export to the United States are maintaining separation and identity of product intended for export to the United States. If applicable, labeling requirements are verified

upon initial approval for export of the product by the firstline veterinarians and BMSGPK headquarters.

The FSIS auditors verified that establishments maintain FSIS-approved labels. BMSGPK's Work Instructions US-EXP-3-Export Clearance requires that all products intended for export to the United States meet FSIS labeling requirements, in accordance with National Implementing Decree No. 10. The FSIS auditors reviewed examples of label sketches and corresponding label approvals at each establishment and confirmed that FSIS labeling requirements are met and verified by frontline veterinarians verify for each shipment of product.

Frontline veterinarians verify that each shipment of product intended for export to the United States meets APHIS requirements. BMSGPK receive regular animal health updates from the EU, including through market access databases. Austria's Department of Animal Health and Animal Disease also has access to the World Organization for Animal Health (WOAH) database and receives animal health notifications from WOAH's World Animal Health Information System, the global reference platform for the publication of official data on epidemiologically important diseases in domestic and wild animals.

Austria's export certificate includes an animal health attestation stating that APHIS regulations are complied with for applicable diseases for the live animal source region of the Netherlands and Denmark. The FSIS auditors reviewed export certificates that include health attestations from the certifying veterinarian from the Netherlands and did not identify any concerns. The FSIS auditors verified through records review that condemned and inedible materials are categorized and disposed of in accordance with Regulation (EC) No. 1069/2009 and Austria's National Regulation on Animal Materials. Frontline veterinarians verify proper disposal and identification of condemned materials once per shift.

The FSIS auditors concluded that Austria's food safety inspection system governing processed pork products meets the core requirements of this component because it provides 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.

VI. COMPONENT THREE: GOVERNMENT SANITATION

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

The FSIS auditors reviewed the legislation, regulations, official instructions, decrees, and guidelines of BMSGPK and verified that BMSGPK uses its legal authority in LMSVG to require that certified establishments develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions. BMSGPK's authority to enforce EU food safety inspection laws is outlined in LMSVG. Article 4 of LMSVG states that the applicable legislative acts of the EU listed in the annex of LMSVG shall be implemented.

Additionally, Article 24 (2) of LMSVG sets forth that the official controls must be conducted according to Regulation (EC) No. 178/2002 and Regulation (EU) 2017/625. Lastly, Version 2.0.24 of Work Instructions # 1 for Performing Ongoing Controls in Certified U.S. Establishments including HACCP and Specific Hazard Control (hereinafter denoted as Work Instructions # 1) described the sanitation verification activities that frontline veterinarians are to conduct on the day an establishment produces products intended for export to the United States. The FSIS auditors verified the records associated with products exported to the United States and found no concerns.

LMSVG requires exporters to meet the requirements of the countries they are exporting to and therefore requires that establishments implement, develop, and maintain Sanitation SOPs to prevent product contamination. BMSGPK implements National Decree No. 7, which describes the official control for hygiene and describes the inspection procedure to be performed. In addition, the Manual on Inspecting SPS, Sanitation SOP and HACCP includes instructions for verifying sanitation requirements that are consistent with the instructions provided in FSIS Directive 5000.1. The FSIS auditors verified through records review that government inspection personnel at all audited establishments conduct verification of sanitary conditions. These verification activities are in accordance with the Manual on Inspecting SPS, Sanitation SOP, and HACCP.

The FSIS auditors verified that frontline veterinarians conduct the review and observation component of pre-operational sanitation once a month and review all sanitation records during export inspections. The FSIS auditors observed frontline veterinarians conduct pre-operational and operational sanitation verification at one establishment and confirmed that government inspection personnel perform an organoleptic inspection of food-contact surfaces of equipment, facilities, overhead structures, and non-food contact surfaces and review pre-operational sanitation records. The FSIS auditors observed SPS-related deficiencies during pre-operational sanitation inspection and Sanitation SOP design issues, both of which are documented on the individual establishment checklists in Appendix A of this report.

The FSIS auditors verified through records review that these verification activities are documented at the frequencies required by BMSGPK. Government inspection personnel have the option to increase the frequency of these inspection activities based on the establishment's regulatory compliance.

The FSIS auditors' verification activities included a review of noncompliance reports issued by frontline veterinarians when SPS and Sanitation SOP deficiencies were identified and verified corrective actions were taken as appropriate. The FSIS auditors also examined reports of supervisory reviews for each establishment and confirmed that establishments brought themselves back into compliance through corrective actions that were satisfactory to the supervisory reviewers.

The FSIS auditors verified that BMSGPK requires each official establishment to develop, implement, and maintain written Sanitation SOPs to prevent direct product contamination or insanitary conditions and to maintain requirements for SPS.

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

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

BMSGPK requires establishments to develop, implement, and maintain a HACCP system in accordance with Regulation (EC) No. 852/2004. Additionally, Article 51 of LMSVG contains requirements that establishments eligible to export food to countries outside the EU are required to fulfill the requirements of these countries. Furthermore, Work Instructions # 1 also lays down the HACCP verification activities that frontline veterinarians are to perform and document during the production of products intended for export to the United States. BMSGPK has also developed the Manual to control the SPS, Sanitation SOP, and HACCP, which is consistent with FSIS Directive 5000.1, as guidance about U.S. import requirements for government inspection personnel and establishments certified as eligible to export to the United States.

BMSGPK reviews the design and implementation of all certified establishments' HACCP programs quarterly, and again annually prior to granting export certification renewal. BMSGPK verification includes the review of all aspects of the written HACCP programs based on LMSVG and the Manual on Inspecting SPS, Sanitation SOP and HACCP. This verification includes evaluation of written HACCP programs in accordance with the Manual on Inspecting SPS, Sanitation SOP and HACCP, and observation of establishment personnel during monitoring, verification, corrective actions activities, and recordkeeping activities. The FSIS auditors identified the following HACCP inspection findings at the audited establishments:

- Government inspection personnel did not verify that establishment HACCP plans complied with BMSGPK's requirements. Ongoing verification activities (e.g., calibration of the process monitoring instrument, direct observation of monitoring activities, and review of records) or their frequencies were not included in the establishments' HACCP plans, as required by BMSGPK.
- Government inspection personnel did not verify that the corrective actions included in the establishments' HACCP plans for deviations met BMSGPK's requirements.

The frontline veterinarian's verification activities include daily verification of the establishment's HACCP monitoring, verification, and corrective actions activities to ensure adequate implementation of HACCP requirements. The FSIS auditors reviewed daily and weekly reports and verified that frontline veterinarians document their verification of HACCP requirements as required by BMSGPK in accordance with National Implementing Decrees No. 9 and 10. In addition, the FSIS auditors verified that certified establishments must receive and confirm acceptable test results from all products tested for adulterants, as defined by FSIS, prior to presenting the shipment to the government for export certification. The review of documents showed that BMSGPK requires establishments to maintain a written hazard analysis for each step in the process, a flow chart, and a HACCP plan.

The FSIS auditors reviewed BMSGPK's supervisory review reports of the audited establishments and verified that BMSGPK further reviews the establishments' HACCP systems during its audit process. The quarterly supervisory review includes verification that the establishments are implementing HACCP verification procedures per their HACCP plan. In addition, these reviews include verification that the establishment is meeting HACCP requirements.

Except for the HACCP inspection findings listed above, the FSIS auditors concluded that BMSGPK continues to meet the core requirements of this component because it requires operators of establishments certified to export to the United States to develop, implement, and maintain HACCP plans for each processing category and government inspection personnel verify that certified establishment meet these requirements.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

The fifth equivalence component the FSIS auditors 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 inspection authorities or by FSIS as potential contaminants.

Although Austria maintains a national residue control plan, raw and processed pork materials are sourced from establishments in other countries that are eligible to export pork products to the United States (the Netherlands or Denmark). FSIS evaluates the chemical residue programs of those countries separately from Austria's inspection system. The Netherlands and Denmark implement requirements in accordance with Regulation (EU) 2017/625 and Commission Delegated Regulation (EU) 2019/2090, which require the development and implementation of a national residue control plan. If a positive residue is detected in product from Member States, such as the Netherlands or Denmark, the country is required to inform affected Member States through the RASFF notification system. There have not been any POE violations related to this component since the previous FSIS audit in 2021.

The FSIS auditors concluded that BMSGPK continues to meet the core requirements for this component.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The sixth equivalence component the FSIS auditors reviewed was Government Microbiological Testing Programs. The food safety inspection system is to implement certain sampling and testing programs to ensure that processed pork products prepared for export to the United States are safe and wholesome.

BMSGPK enforces a microbiological sampling program for *Salmonella* and *Lm* in RTE products consistent with Commission Regulation (EC) No. 2073/2005. Austria's national regulations

outlined in LMSVG also require that establishments eligible to export food to countries outside the EU meet the requirements of the importing country. This legislation requires establishments certified to export to the United States to implement measures against *Lm* and *Salmonella* in RTE products consistent with FSIS requirements in 9 CFR part 430 and ensures zero tolerance for *Lm* and *Salmonella* in RTE products intended for export to the United States.

The FSIS auditors verified that BMSGPK has official verification testing in place to meet FSIS' equivalence criteria for RTE products. As required by Work Instructions US-EXP-1 Microbiological Investigations (Working Instructions for Microbiological Testing Parameters and Procedure for Detection as part of US Export), BMSGPK conducts official verification testing for *Lm* and *Salmonella* in RTE products. Each production lot exported to the United States is sampled by both the establishment and frontline veterinarian for *Lm* and *Salmonella*, and lots are placed on hold pending receipt of acceptable test results. BAVG officials do not sign export certificates for product intended for export to the United States until acceptable results are received.

In accordance with the 2024 Work Instructions US-EXP-1 Microbiological Investigations, frontline veterinarians also collect samples of the processing environment (food contact surfaces and non-food contact surfaces) to test for *Lm*.

The FSIS auditors observed frontline veterinarians collect an *Lm/Salmonella* RTE product sample and confirmed that they follow the sample collection procedures described in Work Instructions US-EXP-1 Microbiological Investigations for sampling preparation, sample size, sample integrity, and sample submission to the LAVES laboratory.

The FSIS auditors also confirmed that Austria enforces the requirements of Commission Regulation (EC) No. 2073/2005 regarding RTE products that test positive for *Lm*. These products are not eligible for export to the United States but may be marketed to the EU if they meet the required EU evaluation criteria for the results. In addition, the FSIS auditors verified that RTE products that were produced on equipment that had an *Lm*-positive result on a food-contact surface are considered adulterated and not eligible for export to the United States.

The FSIS auditors confirmed through review of inspection records that establishments are meeting the requirements in National Implementing Decree No. 10, which requires establishments to implement *Lm* control measures consistent with FSIS requirements in 9 CFR part 430. Government inspection personnel send samples for analysis to the LAVES laboratory, which implements FSIS' Microbiological Laboratory Guide methods for *Lm* and *Salmonella* analyses in RTE products and environmental samples.

The FSIS auditors concluded that BMSGPK continues to meet the core requirements of this component because it has implemented sampling and testing programs to ensure that processed pork products intended for export to the United States are safe and wholesome. There have not been any POE violations related to this component since the previous FSIS audit in 2021.

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on March 25, 2024 with BMSGPK officials. At this meeting, the FSIS auditors presented the preliminary findings from the audit. An analysis of the findings noted below did not identify any deficiencies that represented an immediate threat to public health. The FSIS auditors identified the following findings:

GOVERNMENT HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) SYSTEM

- Government inspection personnel did not verify that establishment HACCP plans complied with BMSGPK's requirements. Ongoing verification activities (e.g., calibration of the process monitoring instrument, direct observation of monitoring activities, and review of records) or their frequencies were not included in the establishments' HACCP plans, as required by BMSGPK.
- Government inspection personnel did not verify that the corrective actions included in the establishments' HACCP plans for deviations met BMSGPK's requirements.

During the exit meeting, BMSGPK committed to address the preliminary findings as presented. FSIS will evaluate the adequacy of BMSGPK's documentation of proposed corrective actions once received and base future equivalence verification activities on the information provided.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Hocheiter Fleischwaren GmbH Reichenthal	2. AUDIT DATE 03/13/2024	3. ESTABLISHMENT NO. 41586EG	4. NAME OF COUNTRY Austria
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

Establishment Operations:	Pork processing.
Prepared Products:	Lasagne Bolognese

60. Observation of the Establishment

9. *SSOP Program signature*

- Establishment’s SSOP program was not signed by an official with overall authority on site.

13. *SSOP records authentication*

- Establishment’s pre-operational and operational sanitation records were not authenticated by the employee(s) who generated them.

19. *HACCP ongoing verification*

- Ongoing verifications for metal detection did not include record review and frequency and calibration of process monitoring device (metal detector) and frequency for the Lasagne Bolognese HACCP plan

20. *HACCP corrective actions*

- Corrective actions for deviations covered by critical limits did not include all CCA requirements for the Lasagne Bolognese HACCP plan.

48. *Condemned product control*

- Edible and inedible containers were not separated by space or time in the deboning room. The FSIS auditors observed an inedible container and an edible container stacked on top of each other during production with edible product in the edible container.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	03/13/2024

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Hochreiter Fleischwaren GmbH Bad Leonfelden	2. AUDIT DATE 03/14/2024	3. ESTABLISHMENT NO. AT40776EG	4. NAME OF COUNTRY Austria
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

Establishment Operations:	Pork processing
Prepared Products:	Lasagne Bolognese

60. Observation of the Establishment

9. *SSOP Program signature*

- Establishment’s SSOP program was not signed by an official with overall authority on site.

13. *SSOP records authentication*

- Establishment’s pre-operational and operational sanitation records were not authenticated by the employee(s) who generated them.

17. *HACCP plan signature*

- The master HACCP plan for all three HACCP plans (Cooked cured pork; Cooked sausages; Fermented salami products) was not signed by an individual with authority on-site.

19. *Ongoing verification*

- The three HACCP plans under which products exported to the United States were produced did not include as ongoing verification activities direct observation of monitoring activities; review of the monitoring records, and calibration of the pH meters, the water activity meters, and thermometers.

20. *HACCP Corrective actions*

- The corrective actions listed in the three HACCP plans under which products exported to the United States were produced did not include all CCA requirements.

39. *Establishment construction & maintenance*

- Numerous overhead structures and pieces of equipment were observed with heavy rust build up in the raw meat receiving area,
- Numerous cracks and crevices were observed on the floor leading up to the smoking rooms
- The air vent above the autoclaves in the laboratory had heavy dust and dirt build up on it.
- A cooling unit in the receiving area had a rusty grill, unsanitary fan blades and rusty bolts as well.
- Three tiles were missing on the ceiling in the smoking room exposing insulated pipes.
- The insulation above the meat grinder was in advanced disrepair.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Handl Tyrol Tyrol	2. AUDIT DATE 03/18/2024	3. ESTABLISHMENT NO. AT71088EG	4. NAME OF COUNTRY Austria
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

Establishment Operations:	Pork processing
Prepared Products:	Cured ham

60. Observation of the Establishment

7. *SSOP program design*

- The SSOP program did not include operational sanitation procedures and frequencies.

16. *SSOP records requirements*

- The establishment was not generating operational sanitation records.

19. *HACCP ongoing verification requirements*

- Direct observation and calibration of process monitoring device are not listed under ongoing verification in the Cured Ham HACCP Plan

39. *Establishment construction and maintenance*

After observing government inspector's pre-operational sanitation inspection, the FSIS auditors following the following SPS deficiencies:

- Cracks and crevices on the floor in the product storage room.

46. *Sanitary operation*

After observing government inspector's pre-operational sanitation inspection, the FSIS auditors following the following SPS deficiencies:

- Fat residue was behind the control panel in the drying room.
- Product debris and salt residues on the salting machine from the previous day’s production.

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

USDA Food Safety and Inspection Service
Office of International Coordination
zH Margaret Burns Rath, JD, MPH
1400 Independence Avenue, SW.
Washington, D.C. 20250
USA

Our Ref: 2024-0.689.134

Response to the FSIS Draft Final Report of an Audit conducted of Austria from March 11-25, 2024

Dear Ms. Margaret Burns Rath, JD, MPH,

On behalf of the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection (BMSGPK), we would like to express our thankfulness for granting a grace period for submitting the written response to the FSIS Draft Final Audit Report as submitted by July 1, 2024.

As requested by FSIS, the BMSGPK provides comments regarding the information in the FSIS Draft Final Audit Report as following: Attachment 1 (*"Austria FY24 Draft Final Audit Report_reviewed by BMSGPK"*) contains yellow markings, which refer to corrective comments in Attachment 2 (*"Written comments to the Austria FY24 Draft Final Audit Report"*).

Additionally, we hereby submit the new Standard Operating Procedure (SOP) No. 5 on the official control implementation of the HAV Task, the HACCP Verification Task as well as the Verification Task of Lethality and Stabilization as Attachment 3 (*"Arbeitsanweisung US-EXP-5 - HAV und HACCP Kontrolle, spezifische Gefahrenkontrolle V1.0.24"*) to FSIS. We prepared this detailed SOP No. 5 in order to sufficiently address the HACCP inspection findings of the FSIS Audit Team. The SOP No. 5 should therefore assist Austrian Inspection Program Personnel (IPP, Frontline Veterinarians) in charge to verify and ensure compliance with respective US legal requirements in establishments approved for export

of processed pork products to the USA in detail. A checklist is complementing SOP No. 5 in order to document compliance or non-compliance in accordance with FSIS Directive 5000.1 Rev.7 (Attachment 4: “*Annex I zu US-EXP-5 (Checkliste)*”).

As central competent authority, the BMSGPK approved this new SOP No. 5 together with the Austrian Federal Office for Consumer Health (BAVG) and all involved Firstline Veterinarians (Provincial Veterinary Services) on September 20, 2024 during an online meeting for its further implementation. Since we would like to ensure more detailed skills on the HAV Task and the HACCP Verification Task of the responsible Frontline Veterinarians, we would like to take this opportunity to hereby politely request FSIS for support in the provision of an online training on the issues of HAV and HACCP Verification in order to enhance the according implementation process.

Findings as indicated in the “Foreign Establishment Audit Checklists” were already communicated by BMSGPK (in cooperation with BAVG) to the audited establishments and the verification of corrective actions taken by the establishments to revert to compliance is conducted by BAVG and BMSGPK in upcoming official controls.

Concerning the “Foreign Establishment Audit Checklist” of the establishment with the approval no. AT 40776 EG (Hochreiter Fleischwaren GmbH), there is still one question left from our side: Audit Result No. 9 states that *establishment’s SSOP program was not signed by an official with overall authority on site*. We subsequently wonder whether in general the establishment’s documentation of the SSOP program has indeed to be signed by the Inspection Program Personnel after verification. If so, could you please provide us the FSIS Directive reference for this US requirement in order to incorporate it correctly into our Standard Operating Procedures designated to the Frontline Veterinarians as IPP? So far, we, together with responsible Firstline Veterinarians, assumed that SSOP documentation and respective records have to be signed and approved by the responsible employee of the company and in this context, the Frontline Veterinarians as IPP have to exclusively sign the inspection report for the verification of SSOP compliance.

The BMSGPK would like to thank FSIS in advance for the clarification of open questions and feedback concerning the adequacy of BMSGPK’s proposed corrective actions to be incorporated in the Final Report to the past audit. Looking forward to the continuation of the successful collaboration between the Republic of Austria and the United States of America, we remain respectfully, 1. October 2024

On behalf of the Federal Minister:

Mag. Andreas Wunsch

Enclosure: Attachment 1 (Austria FY24 Draft Final Audit Report_reviewed by BMSGPK)


Attachment 2 (Written comments to the Austria FY24 Draft Final Audit Report)

Attachment 3 (Arbeitsanweisung US-EXP-5 - HAV und HACCP Kontrolle, spezifische Gefahrenkontrolle V1.0.24)

Attachment 4 (Annex I zu Arbeitsanweisung US-EXP-5)

Elektronisch gefertigt

(signed electronically)

	Unterzeichner	Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz
	Datum/Zeit	2024-10-01T11:26:39+02:00
	Aussteller-Zertifikat	CN=a-sign-corporate-05,OU=a-sign-corporate-05,O=A-Trust Ges. f. Sicherheitssysteme im elektr. Datenverkehr GmbH,C=AT
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