USDA

United States Department of Agriculture

Food Safety and
Inspection Service

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JAN 12 2017

Dr. Ulrich Herzog
Chief Veterinary Officer, Head of BMG-II/B (Consumer Health)
Bundesministerium für Gesundheit (Federal Ministry of Health)
Radetzkystrasse 2
A-1030 Vienna, Austria

Dear Dr. Herzog,

The Food Safety Inspection Service (FSIS) onsite audit conducted from July 12 through July 22, 2016, supports that Austria's inspection system continues to remain equivalent to that of the United States. 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.

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

Sincerely,

Jane H. Doherty

Jane H. Doherty
International Coordination Executive
Office of International Coordination

Enclosure

FINAL REPORT OF AN AUDIT CONDUCTED IN

AUSTRIA

JULY 12 – 22, 2016

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING

MEAT

EXPORTED TO THE UNITED STATES OF AMERICA

Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an on-site equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from July 12 – 22, 2016. The purpose of the audit was to determine whether Austria's food safety system governing meat remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and accurately labeled and packaged. Austria currently is eligible to export pork within the following product categories: not heat-treated, shelf stable; and fully-cooked, not shelf stable.

The audit focused on six system equivalence components: Government Oversight (Organization and Administration); Government Statutory Authority and Food Safety Regulations (Inspection System Operation, Product Standards and Labeling, and Humane Handling); Government Sanitation; Government Hazard Analysis and Critical Control Points (HACCP) System; Government Chemical Residues Testing Programs; and Government Microbiological Testing Programs.

During the audit, the following findings were identified:

- The Central Competent Authority (CCA) has not provided adequate procedures for the implementation of official regulatory control actions associated with sanitation, HACCP systems, and food safety non-compliances.
- The CCA in-plant officials failed to identify and enforce compliance with the Sanitary Performance Standards (SPS) as they relate to sanitary operations for product handling or equipment maintenance at both the audited establishments.
- The CCA has not provided adequate instruction to inspection personnel that would ensure product that has tested positive for *Listeria monocytogenes* (*Lm*) or product that has come into contact with food contact surfaces that have tested positive for *Lm*, whether sampled by the CCA or the establishment, is not exported to the United States.

The analysis did not identify any significant findings representing an immediate threat to public health for those products that Austria is currently eligible to export to the United States. During the audit exit meeting, the CCA committed to addressing the findings as presented. FSIS received a written response from the CCA addressing all outstanding concerns within 60 days of communication of the draft final audit report.

TABLE OF CONTENTS

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site audit of Austria's food safety system from July 12 – 22, 2016. The audit began with an entrance meeting held on July 12, 2016, in Vienna, Austria with the participation of the FSIS auditors and representatives from the Central Competent Authority (CCA), the Bundesministerium für Gesundheit (BMGF) (i.e., Ministry of Health and Women).

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

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

In pursuit of this objective, FSIS applied a risk-based procedure, which 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) testing results, and specific oversight activities and testing capacities of government offices and laboratories. The review process included an analysis of data collected by FSIS over a 3-year timeframe, in addition to information obtained directly from the CCA through a self-reporting process.

The FSIS auditors were accompanied throughout the entire audit by representatives from the CCA, the Linz Provincial Office, and local inspection offices. Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (Organization and Administration); (2) Government Statutory Authority and Food Safety Regulations (Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Points (HACCP) System; (5) Government Chemical Residues Testing Programs; and (6) Government Microbiological Testing Programs.

Administrative functions were reviewed at the CCA headquarters, the Linz Provincial Office, and two local inspection offices, during which the FSIS auditors evaluated the implementation of in-place control systems that ensure that the national system of inspection, verification, and enforcement is being implemented as intended.

Two establishments are certified to export to the United States and both were audited. During the establishment visits, the auditors paid particular attention to the extent to which industry and government interact to control hazards and prevent non-compliances that threaten food safety. Additionally, the auditors focused on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with FSIS equivalence requirements for foreign inspection systems outlined in Title 9 of the United States Code of Federal Regulations (9 CFR) § 327.2, the FSIS regulations addressing equivalence determinations for foreign country inspection systems.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	BMGF/Vienna
	Regional	1	Linz Provincial Office/Linz
Establishments: Meat Processing		2	• Reichenthal • Bad Leonfelden

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

- The Federal Meat Inspection Act (21 United States Code [U.S.C.] 601, et seq.), and
- The Food Safety and Inspection Service Regulations for Imported Meat (9 CFR Part 327).

The audit standards applied during the review of Austria'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 Sanitary/Phytosanitary Agreement.

In addition, the FSIS auditors verified that the system implemented and enforced United States equivalent European Commission (EC) regulations and directives:

- EC Regulations 852/2004; 853/2004; 854/2004; 882/2004; 2073/2005; and
- Council Directives found equivalent under the Veterinary Equivalence Agreement 96-22 and 96-23.

Currently, Austria has an equivalence determination in place for the following procedure:

- Species Verification Analytical Method - BIOKITS (Cooked) Species Identification Kit (Tepnel)

III. BACKGROUND

Austria is eligible to export processed pork products to the United States. The establishments are currently certified as eligible to export to the United States within the following product categories: not heat-treated, shelf stable; and fully-cooked, not shelf-stable pork products. Austria exports the majority of the products destined for the United States indirectly through Germany.

From January 1, 2013 through December 31, 2015, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 13,650 pounds of processed pork products exported directly by Austria to the United States. FSIS also performed reinspection on 6,578 pounds at POE for additional types of inspection, none of which were rejected for food safety reasons.

In addition, since Austria presently has no slaughter facilities certified as eligible to export to the United States, all pork used in the processing of product for export to the United States is sourced from another country that is eligible to export to the United States. Austria currently imports pork for this purpose for Denmark and the Netherlands.

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

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

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

The FSIS auditors verified that the inspection system is organized and administered by the national government of Austria. There have been no major changes in the CCA's organizational structure since the last FSIS audit. At the national level, the BMGF is Austria's CCA.

The BMGF has one central and nine provincial offices. At the central level within BMGF, the Chief Veterinary Officer (CVO) is the head of Sector II/B - the Consumer Health and Veterinary Affairs and is responsible for food and veterinary matters in addition to exports to the United States. Within Sector II/B there are seven sectors with Department B/12 Hygiene in Meat Production, Animal by-Products and Export Certification responsible for food safety in primary production, veterinary, animal by-products, and exports certification. In addition, Sector II/B issues all food law, national regulations, veterinary legislation, decrees, and guidelines concerning meat export to third party countries; certifies or decertifies establishments for export; and is responsible for the translation, distribution, and implementation of the United States' requirements in establishments certified as eligible to export to the United States.

The BMGF administers the Austrian meat inspection system and is responsible for directing, planning, and carrying out food safety and animal health and welfare controls. The CCA's authority to enforce European Union (EU) food safety inspection laws is outlined in the Austrian statute *Austria Food Safety and Consumer Protection Act (LMSVG*). Austria has issued national legislation to address the design and implementation of the inspection activities. The legislation delineates responsibilities for each of the inspection levels, as well as enforcement of the *LMSVG*. The CCA has the legal authority and responsibility to develop and oversee the implementation of inspection-related procedures in accordance with national standards, in addition to those standards imposed by importing countries.

The provincial level consists of nine offices across the country. Only the Linz Provincial Office has establishments (two) certified eligible to export processed pork products to the United States. Firstline Veterinarians from the provincial level ensure uniform implementation of regulatory requirements and are responsible for oversight of the official activities of inspection personnel and for conducting supervisory reviews (audits) at establishments certified eligible to export to the United States. The Senior Firstline Veterinarian within BMGF also conducts an annual

supervisory review (audit) of the establishments and official control (inspection) and reports directly to the CVO.

At the local government level (establishment level), there are three Frontline Veterinarians who have the responsibility to implement and enforce inspection requirements at the establishments eligible to export meat product to the United States. They are part-time government employees hired by the provincial government but authorized and appointed by the BMGF for these inspection duties. The national and provincial governments pay inspection personnel salaries. The FSIS auditors verified compliance through document review at the CCA headquarters and compliance with the CCA's *LMSVG Article 64*, which provides the regulatory framework for payment for inspection activities, which includes in-plant inspection personnel at establishments eligible to export meat product to the United States.

The Frontline Veterinarians assigned to the establishment are the in-plant inspection personnel responsible for carrying out all daily inspection activities. These Frontline Veterinarians are assigned using a monthly duty roster. Under this roster, two of the Frontline Veterinarians are assigned to one establishment each and the third is rotated into the schedule or serves as relief when the assigned Frontline Veterinarian is not able to cover the assignment. These duty rosters were reviewed at both the Linz Provincial Office and establishments. In addition, Frontline Veterinarian control task records that document inspection activity, which are used to collect reimbursement from establishments for inspection services, were also reviewed. These records indicate that a Frontline Veterinarian was at each audited establishment each day of the week that inspection was required.

The BMGF issues guidelines and instructions that deal with the frequency of supervisory reviews and the procedures for registration, approval, or suspension. It also provides instructions on the withdrawal of approval of regulated establishments; the verification of the microbiological sampling program; and how to perform official inspection tasks. The CCA disseminates inspection information related to the regulatory and administrative affairs electronically by email to the Linz Provincial Office and to inspection personnel and establishments certified to export product to the United States.

The audit of the CCA headquarters included an examination of its oversight activities, including the verification of audits of establishments conducted by the Senior Firstline Veterinarian. These audits represent an additional layer of supervisory reviews beyond the provincial office supervisory reviews. In addition, FSIS examined enforcement activities, verification activity reports, and training records for official personnel by interviewing departmental personnel and reviewing documentation.

The CCA has a written National Legislation, *LMSVG §51 and §52, and National Decrees No. 9 Export Control - Approval Procedure for Export and Related Controls (Annex on United States specific issues) and No. 10 Export Certification,* which describes the procedures that establishment operators should follow to obtain and maintain approval from BMGF to be certified to export. In addition, it describes actions taken by the CCA to verify establishments for approval. The CCA has the sole authority to grant final certification of a new establishment

or to permit an existing United States-certified establishment to maintain its eligibility to export to the United States or decertify the establishment.

The FSIS auditors verified elements of the certification and decertification of establishments by the CCA headquarters, including certification/decertification documents and annual audits of the establishments that included relevant sections that correspond to the sanitation requirements, facility maintenance, Sanitation Standard Operating Procedures (SSOP) and HACCP programs, and microbial testing. The FSIS auditors verified that the CCA officials have conducted the approval process in accordance with Austria's prescribed procedures. The certification/decertification documents and yearly audit of the establishments demonstrated that the CCA audited the facilities and evaluated their ability to meet regulatory requirements before granting certification to export meat to the United States.

During this audit, the FSIS auditors verified that the CCA has implemented and routinely conducted ongoing training programs intended to ensure that in-plant inspection personnel are aware of specific food safety and inspection requirements that pertain to production of product for export to the United States. Frontline Veterinarians complete specific training, provided by the CCA and provincial offices, in food safety controls and meat inspection techniques. All training is presented to inspection personnel as a maintenance program, including training related to program updates on inspection-related issues and procedures. In addition, inspection personnel are sent to FSIS training seminars as the seminars become available. The FSIS auditors verified the training records of in-plant inspection personnel and observed in-plant inspection personnel while they were conducting their inspection activities and identified no issues of concern.

The CCA uses a system to assess the technical competence and performance of individual in-plant inspection personnel in conducting official inspection activities at establishments that export to the United States. The Senior Firstline Veterinarian conducts an audit of establishments yearly, which includes an audit evaluation of in-plant inspection activity (inspection personnel as a whole). In addition, the in-plant inspection personnel are formally evaluated every 4 years on their performance. The FSIS auditors' verification of documents associated with these evaluations identified no issues of concern.

The CCA maintains adequate administrative and technical support to operate its meat inspection system. The CCA employs a German government laboratory, the Lower Saxony State Office Microbiology Laboratory (LAVES). This is an International Organization for Standardization (ISO) 17025 accredited laboratory that conducts microbiological analytical testing on ready-to-eat (RTE) products destined for export to the United States. The CCA relies on the German government to conduct audits of the laboratory quality system. The CCA oversight includes the review of LAVES laboratory audit reports provided by the German CCA, which includes administrative and technical aspects of the analytical methodology, laboratory personnel qualifications, training, and maintenance of the laboratory equipment. In addition, the CCA reviews the accreditation and third party audit reports (EU and United States) of the microbiological laboratory.

The FSIS auditors reviewed the third party reviews and audit reports generated for the previous year at CCA headquarters. No concerns arose as the result of these reviews. FSIS included this laboratory during FSIS' 2015 on-site audit of Germany's meat inspection system and did not identify any issues with the government microbiological laboratory. The audit determined that the Austrian government organizes and administers the country's meat inspection system, and that CCA officials enforce laws and regulations governing production and export of meat at certified establishments.

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

The second of six equivalence components that the FSIS auditor reviewed was Government Statutory Authority and Food Safety Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of carcasses and parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; daily inspection; periodic supervisory visits to official establishments; and requirements for thermally processed/commercially sterile products.

The FSIS auditors verified that the CCA maintains regulatory authority as outlined in official legislation, regulations, decrees, and guidelines issued in accordance with the *LMSVG*. The document outlines Austria's sanitation policies and sanitary measures to protect public health and animal products, and HACCP requirements. Since the last audit, there have been no other regulatory changes associated with the export of meat products to the United States that would have required changes by the CCA.

The FSIS auditors performed on-site observations and reviewed records maintained by inspection personnel at CCA, the Linz Provincial Office, and in-plant BMGF inspection offices. The FSIS auditors verified that the CCA provides appropriate oversight and direction to inspection personnel for them to use their regulatory authority to enforce requirements for Austria's food safety system governing meat products exported to the United States. The FSIS auditors, accompanied by the CCA representatives, observed the performance of verification activities by the in-plant inspection personnel. The verification activities observed included inspection control tasks associated with the verification of pre-operational and operational sanitation verification procedures, HACCP verification activities, and analysis of establishment *Listeria monocytogenes* (*Lm*) program and sample results including CCA verification sample results.

Additionally, the FSIS auditors assessed the performance evaluation of in-plant inspection personnel and the completion of supervisory reviews of establishments certified eligible to export to the United States. The FSIS auditors determined that regulatory verification and inspection activities were consistently implemented at all establishments audited. Inspection officials use the authority conferred upon them by the laws of Austria to enforce the rules of their meat inspection system, to identify and document non-compliances, and to verify the adequacy of corrective actions and preventive measures.

The FSIS auditors verified through direct observation, on-site record reviews, and interviews that in-plant inspection personnel's inspection activities complied with Austria's *BMGF Manual on Inspecting Sanitation Performance Standards (SPS), SSOP, and HACCP based on FSIS Directive 5000.1*. Inspection personnel verified the monitoring of the incoming product critical control points (CCP) and the traceability control task of incoming meat identification of each load/truck, with the receiving documents.

In-plant inspection personnel verify that operators comply with the requirement for separation of product destined for the United States. Each audited establishment maintains a procedure that contains a designated holding area for product that is to be used for or used in the production of product exported to the United States. At the time of the audit there was no product designated for export to the United States, so FSIS auditors were unable to verify the process.

The FSIS auditors also observed the in-plant inspectors in both audited establishments as they conducted the daily inspection verification activities. These in-plant daily verification activities include direct observation and record review procedures related to SSOP, SPS, HACCP critical control point verification, and *Lm* sampling, in accordance with the BMGF inspection verification outlined in the *BMGF Manual on Inspecting SPS, SSOP, and HACCP based on FSIS Directive 5000.1*. The FSIS auditors did not observe any non-compliance related to CCP deviations on the day of the audit.

The FSIS auditors verified at CCA headquarters, the Linz Provincial Office, and the audited establishments that the CCA implemented adequate corrective actions to address the finding reported during the FSIS 2013 audit related to government documentation of non-compliances (detail), SPS implementation, and HACCP verification recordkeeping.

The FSIS auditors verified that the CCA has developed written standards that instruct inspection personnel on how to document non-compliance reports in *NR-Report and Manual* and on how inspection verification activities are to be performed as described within the *BMGF Manual on Inspecting SPS, SSOP, and HACCP based on FSIS Directive 5000.1*. The FSIS auditors also verified that Firstline Veterinarians were aware of this standard, and that they had verified that in-plant inspection personnel were adequately documenting non-compliance reports in the quarterly supervisory reviews.

Additionally, the FSIS auditors assessed the performance evaluation of in-plant inspection personnel and the completion of supervisory reviews of establishments certified eligible to export to the United States. The FSIS auditors determined that regulatory verification and inspection activities were consistently implemented at all audited establishments, using *BMGF Manual on Inspecting SPS, SSOP, and HACCP based on FSIS Directive 5000.1*, as written. Inspection officials use the authority conferred upon them by the laws of Austria to enforce the rules of their meat inspection system, to identify and document non-compliances, and to verify the adequacy of corrective actions and preventive measures.

In one establishment, the inspection personnel did not take adequate official regulatory control action when the FSIS auditors identified insanitary conditions during production to preclude use

of equipment and retain product that were unacceptable, or when the possibility of product contamination occurred.

It was further determined, through interviews with CCA officials and in-plant inspection personnel, that the CCA has not fully developed procedures for the implementation of adequate official regulatory control actions (the rejection of equipment or retention of product) associated with sanitation, HACCP, and food safety non-compliances. Inspection personnel only verbally notify the establishment at the time of the incident, losing regulatory control of equipment or product to the establishment.

The FSIS auditors also reviewed and verified the application of the CCA's supervisory reviews at certified establishments. The reviews of records demonstrated that government officials evaluate the adequacy of the establishments' food safety system and the capability of inspection as a whole in conducting inspection activities at certified establishments. These reviews are conducted by the Firstline Veterinarians from the Linz Provincial Office and Senior Firstline Veterinarians in accordance with the *LMSVG*.

The FSIS auditors verified that the Senior Firstline and Firstline Veterinarians had documented outcomes of supervisory reviews, which are conducted annually and quarterly, respectively, for establishments that are eligible to export to the United States. The Firstline supervisory reviews are conducted using a standardized format, "*Protocol for Inspection (Protokoll zur lnspektion),"* which consists of differing emphases for each review and related report, assuring that all areas are included in the supervisory reviews during the year, as required by the *LMSVG* and 9 CFR 327.2.

The supervisory review report is distributed to the management of the audited establishment, the Firstline Veterinarian assigned to the establishment, the Senior Firstline Veterinarian, the Linz Provincial Office, and the BMGF in Vienna. The in-plant inspection personnel are responsible for verification of corrective actions resulting from the supervisory reviews. The provincial office is responsible for analyzing the results of the review and for conducting follow-up verification of the corrective actions proposed by the establishment. The Senior Firstline Veterinarian is also responsible for verifying that the in-plant inspection personnel had verified those corrective actions and the effectiveness and implementation of the establishment's action plan. The provincial office submits a copy of the quarterly supervisory reviews to the CCA headquarters and Senior Firstline Veterinarian for further review and analysis. The FSIS auditors reviewed the supervisory reviews and inspection related records and concluded that they were consistent with observations at the establishments.

The FSIS auditors identified that the CCA needs to improve procedures for the implementation of adequate official regulatory control actions associated with sanitation, HACCP, and food safety non-compliances.

VI. COMPONENT THREE: GOVERNMENT SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Government Sanitation. To be considered equivalent to FSIS' program, the CCA is to provide general

requirements for sanitation, sanitary handling of products, and development and implementation of SSOP.

FSIS reviewed the legislation, regulations, official instructions, decrees, and guidelines of the CCA and verified that the BMGF uses its legal authority in the *LMSVG* to require that certified establishments develop and maintain sanitation programs to prevent direct product contamination and the creation of insanitary conditions.

The CCA demonstrated that it enforces overarching EU sanitary requirements, including *EC Regulations 852/2004 Article 4 no 2 cf.; EC Regulations 852/2004 Article 4 no 3 cf.* and *Annex II; EC Regulations 853/ 2004 Article 3 cf. Annex II Chapter I-VII*, and *Annex III; and EC Regulations 854/2004 Article 4(2)*, which have been determined to be equivalent to FSIS requirements. There are no fundamental differences between the United States and EU sanitary risk control systems. In addition, Austria incorporated FSIS regulations in 9 CFR Part 416 into its requirements for export to the United States. The *BMGF Manual on Inspecting SPS, SSOP and HACCP based on FSIS Directive 5000.1* provides instructions in order to meet FSIS sanitation requirements.

The FSIS auditors verified that the in-plant inspection personnel at both audited establishments exercise their official authority as prescribed by the regulations of the system and follow guidance provided by BMGF to conduct verification of sanitary conditions. These actions are in accordance with the *BMGF Manual on Inspecting SPS, SSOP, and HACCP based on FSIS Directive 5000.1*.

The CCA demonstrated that it enforces these requirements in that the in-plant inspection personnel at certified establishments conduct verification of sanitary conditions in accordance with the *BMGF Manual on Inspecting SPS, SSOP, and HACCP based on FSIS Directive 5000.1*, including the evaluation of written sanitation programs; verification of both pre-operational and operational sanitation implementation and monitoring of sanitation procedures including hands-on verification inspection; and records reviews. The FSIS auditors observed that inspection personnel perform verification of SSOP and SPS procedures daily, with pre-operational verification at least monthly at all visited establishments.

The FSIS auditors assessed the adequacy of pre-operational inspection by directly observing the in-plant inspection personnel conducting pre-operational verification of the establishment's sanitation program at both of the audited establishments. The in-plant inspection personnel conducted this activity in accordance with the established procedures at least once a month, including a pre-operational record review of the establishment's monitoring results and an organoleptic inspection of food contact surfaces of facilities, equipment, and utensils; as well as an assessment of sanitation performance standard requirements (e.g., ventilation, condensation, and structural integrity). Inspection personnel have the option to increase the frequency of these inspection activities based on the regulatory compliance of the establishment.

In addition, the FSIS auditors observed in-plant inspection personnel's verification of operational sanitation procedures in both audited establishments, comparing the overall sanitary conditions of all audited establishments to the BMGF inspection verification documentation. The FSIS

auditors' verification activities included direct observation of operations and review of the establishments' sanitation monitoring and corrective action records over a 3-month period at all establishments. The auditors also examined the BMGF documentation of inspection verification results documented on *BMGF Pre-Op and Op Checklist, Documentation of the Daily Control* (*Dokumentation der taglichen Kontrolle*) report, including the non-compliance report and BMGF supervisory reviews (audits) of each establishment. The FSIS auditors noted that the inspection and establishment records mirrored the actual sanitary conditions of the establishment, and that there were no major concerns identified during the document reviews.

The FSIS auditors identified SPS findings at both audited establishments concerning the CCA's ability to exercise regulatory control over maintenance of direct product contact equipment, and sanitary operations in raw processing areas of establishments eligible to export to the United States.

- In one establishment, maintenance of direct product contact equipment was found to be deficient. The establishment has a maintenance program in place to address this finding; however, it failed to identify and take immediate measures to prevent the possible cross-contamination of product.
    - Numerous sections of white plastic fiberboards attached to equipment along various sections of the production line had extensive areas that were jagged, cracked, and frayed.
    - Several cutting boards had loose plastic fiber particles.
    - Many plastic fiber red totes (carts) used to store and move raw product (direct contact) within the establishment, and ship raw product to their sister plant, had cracks and broken edges. This issue is a repeat finding from the previous FSIS audit.

FSIS also observed that inspection personnel did not exercise regulatory control when SPS sanitary operation implementation deficiencies were identified at one audited establishment eligible to export to the United States.

- In one establishment, sanitary operational procedures were found to be deficient. In the raw product formulation and stuffing areas, the establishment failed to take measures to prevent the possible cross-contamination of product from unsanitary conditions.
    - The improper staging of raw meat products used in the formulation of sausage product, exposed raw product to non-food contact surfaces.
    - Equipment (lug) used in lifting formulated product into stuffing equipment (hopper) had condensate on the outside of lug which was directly over exposed product.

The CCA required that corrective actions be taken to address the FSIS auditors' observations of possible product contamination and issued instructions for the establishment to take actions to prevent recurrence. However, the CCA did not take adequate official regulatory control action of the equipment and product that was involved in the reported events as documented in Component Two of this report. Discussions with inspection personnel, verification of records, and supervisory reviews did not show that the establishment or the BMGF inspection personnel had observed similar findings in the previous 3 months.

Note: The establishment was not processing product that would be used in the production of product for export to the United States on the day of the FSIS audit.

The FSIS auditors identified several deficiencies. These deficiencies included inspection personnel failing to identify SPS equipment maintenance issue of food contact surfaces, insanitary operational conditions, and inadequate official regulatory control actions related to sanitation non-compliances and the insanitary operational conditions and possible product contamination. The CCA provided FSIS with immediate corrective actions taken by the establishments and will verify that the implementation of those actions to meet sanitation standards.

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

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

The verification and evaluation of this component included the documents that BMGF issued as instructions for the implementation of HACCP programs in establishments eligible to export to the United States. These documents included the *LMSVG* and *BMGF Manual on Inspecting SPS, SSOP, and HACCP based on FSIS Directive 5000.1*. These documents require that establishments exporting to the United States develop, implement, and maintain HACCP programs. The *LVMSG* contains requirements that establishments eligible to export to third countries are required to fulfill the requirements of these countries. This legislation requires that the establishments use *Appendix A - FSIS Compliance Guidelines for Meeting Lethality Performance Standards for Certain Meat and Poultry Products* and *Appendix B - FSIS Compliance Guidelines for Cooling Heat-Treated Meat and Poultry Products (Stabilization)* to ensure that products are meeting United States standards.

The CCA reviews the design and implementation of all certified establishments' HACCP programs yearly, prior to granting of export certification renewal. The CCA verification includes the review of all aspects of the written HACCP programs, based on the *LMSVG* and *BMGF Manual on Inspecting SPS, SSOP and HACCP based on FSIS Directive 5000.1*. This verification includes such activities as the evaluation of written HACCP programs based on procedures in 9 CFR Part 417 and observing the establishment personnel perform monitoring, verification, corrective actions, and recordkeeping activities. The BMGF Senior Firstline Veterinarian conducts this verification, which also includes the review of the Linz Provincial Office's quarterly supervisory reviews (audits) of the certified establishments. The quarterly supervisory review includes inspection/verification of procedures of the HACCP program that are performed by the establishment and in-plant inspection personnel.

The FSIS auditors verified through record review and direct observation that in-plant inspection personnel conducted daily verification of HACCP plans in accordance with the *BMGF Manual on Inspecting SPS, SSOP, and HACCP based on FSIS Directive 5000.1*. In-plant inspection personnel document verification results in the *Documentation of the Daily Control*

(*Dokumentation der taglichen Kontrolle*) report. The in-plant inspection personnel verification of HACCP plans includes daily verification of establishment generated HACCP monitoring, verification and corrective action records for CCP, and direct observation of those procedures by the establishment to assess the adequacy of implementation of HACCP plans on the part of the establishments. There was no indication of any non-compliance trends resulting from the review of these documents.

At the two processing establishments audited, the FSIS auditors conducted an on-site review of CCP records generated during the past 3 months. In addition, the FSIS auditors reviewed the in-plant inspection verification records associated with CCP inspection tasks documented in the *Documentation of the Daily Control* (*Dokumentation der taglichen Kontrolle*) report. The review of the establishments' corrective actions in response to a few deviations associated with incoming product temperature critical limit indicated that all four parts of the corrective actions were correctly addressed in accordance with the *BMGF Manual on Inspecting SPS, SSOP and HACCP based on FSIS Directive 5000.1* and 9 CFR 417.

In addition, the FSIS auditors reviewed the CCA's verification of the non-compliance identified during FSIS' 2013 audit of the establishment verification records associated with CCP 6, cooking temperature. FSIS verified that all documentation of ongoing verification activities was included: the specific event (record review, instrument calibration, or direct observation of monitoring) and the result; the date and time; and the initials of the verifier.

The FSIS auditors' analysis and on-site verification activities indicate that the CCA requires operators of establishments certified to export to the United States to develop, implement, and maintain HACCP programs for each processing category. It further indicates that the CCA continues to demonstrate the ability to effectively implement and verify its regulatory requirement for products that Austria is currently eligible to export to the United States.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUES TESTING PROGRAMS

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

Austria, in accordance with *EC Regulation Directive 96-23*, develops and implements a national residue program each year. However, since no slaughterhouses are currently certified as eligible to export to the United States, this residue program does not apply to product eligible to be exported to the United States.

All pork used in the manufacture of products destined for the United States is imported by Austria from either Denmark or the Netherlands. Both of these countries, also member states of the EU, have residue plans that are acceptable by EU standards and therefore acceptable to FSIS

criteria. Neither country has had a residue violation in the past 3 years. No import testing is done of raw pork product from Denmark or the Netherlands in Austria, as trade between member states is not considered an import from a third country (*EC Regulation 884 /2004* for the development of the trans-European transport network).

The FSIS auditors reviewed records of incoming raw product to assure that products intended for use in product destined for the United States came from establishments certified for export to the United States from either Denmark or the Netherlands. The FSIS auditor's review found no concerns with the CCA's chemical residue control program. Austria's meat inspection system has regulatory requirements for a chemical residue control program that is organized and administered by the national government.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

The last equivalence component that the FSIS auditor reviewed was Government Microbiological Testing Programs. The system is to implement certain sampling and testing programs to ensure that meat or poultry products produced for export to the United States are safe and wholesome.

The evaluation of this component included a review and analysis of requirements concerning RTE product cited in *EC Regulations 178/2002; 852/2004; 882/2004; and 2073/2005 on Microbiological Criteria for Foodstuffs* in addition to the *LMSVG*. The *LVMSG* contains a requirement that establishments eligible to export to third countries are required to fulfill the requirements of these countries. This legislation provides instruction to the inspection personnel and establishments certified to export to the United States concerning implementation of measures against *Lm* and *Salmonella* in RTE products in accordance with 9 CFR 430 and ensures zero-tolerance for *Salmonella* and *Lm* for export to the United States.

FSIS' equivalence criteria for RTE *Lm* control programs require that the CCA verify implementation and effectiveness of control measures in each establishment certified for export to the United States, as stated in "Notification of Changes to the FSIS' Equivalence Criteria - Control Program for *Lm* in Ready-to-Eat (RTE) Products," dated July 13, 2011. This notification stipulates verification sampling of post-lethality exposed RTE products, food contact surfaces, and the environment for *Lm* at a frequency that ensures that the establishments' control measures are effective.

The FSIS auditors verified that the CCA has a verification-testing program in place per FSIS' equivalence criteria for RTE products. The CCA conducts official verification testing for *Lm* and *Salmonella* in RTE products and *Lm* on product contact surfaces and non-product contact surfaces (environmental). The CCA's official sampling frequency of finished product for *Lm* and *Salmonella* is at least 9 samples per year, in addition to environmental sample testing of at least 16 food contact surfaces per year and 8 non-food contact surfaces per year. The FSIS auditors verified that in-plant inspection personnel collect official sampling of finished product and the Firstline Veterinarian collects all environmental samples during supervisory reviews

(audit). All samples are shipped to the laboratory in a security-sealed bag that is labeled and numbered.

Although there is no explicit requirement within Austria's inspection system for product to be held in association with government testing, the FSIS auditors noted that this was a common practice at the establishments audited. However, it was identified that the CCA has not provided adequate instruction to inspection personnel that would ensure product that has tested positive for *Lm*, or product that has come in contact with food contact surfaces that has tested positive for *Lm*, whether sampled by the CCA or the establishment, is not exported to the United States.

The FSIS auditors additionally verified that the only establishment that produces RTE products for export to the United States has a program in place to meet FSIS equivalence criteria for control of *Lm* per 9 CFR 430, as required by the CCA. A review of the establishment's RTE prerequisite program identified that the establishment produces only one product (a salami-type product) that is post-lethality environment exposed for export to the United States. The salami-type product is produced in accordance with Alternative-2 of 9 CFR 430 and the establishment has identified verification sampling of the product, product contact surfaces, and non-product contact surfaces (environmental) twice a month per production line that meets the requirements per 9 CFR 430. The establishment tests and holds all product lots produced for export to the United States pending a negative test result.

The FSIS auditors reviewed both CCA official verification sampling results and establishment results and found no positive *Lm* sample results for product produced for export to the United States within the last year. The Austrian government and establishments certified to export to the United States employ LAVES which uses the FSIS Microbiological Laboratory Guide (MLG) methods.

The FSIS auditors reviewed the LAVES accreditation for ISO 17025. It was verified that the current analytical test portions for both *Lm* and *Salmonella* meet the export requirements of a minimum of 25 g (*Lm*) and 325 g (*Salmonella*) analytical test portions using MLG 8.09 for testing *Lm* in RTE products and MLG 4.08 for testing *Salmonella* in RTE products.

In addition, the FSIS auditors reviewed the CCA laboratory submission and sample result reports for product destined to the United States for *Salmonella* and *Lm* verification testing, CCA General Schedule for Sampling letter, and the Authorization for Sampling letter. These documents authorize the sampling and give a yearly sampling schedule for *Salmonella* and *Lm*. The letters are issued by BMGF in Vienna to the Linz Provincial Office in accordance with the *LMSVG* requirements. The review of these documents found no concerns within the CCA's implementation of microbiological testing programs for the verification of RTE products.

All laboratory report results are forwarded by the laboratory to the Senior Firstline Veterinarian who, along with the provincial Firstline Veterinarian, reviews all results throughout the year. The establishment conducted verification testing results are also reviewed by the in-plant inspection personnel and Firstline Veterinarians. Enforcement actions are taken as necessary.

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

X. CONCLUSIONS AND NEXT STEPS

An exit meeting was held on July 22, 2016, in Vienna, Austria with BMGF. At this meeting, the FSIS auditor presented the preliminary findings from the audit. The CCA accepted the findings.

During the audit, the following findings were identified:

- The CCA has not provided adequate procedures for the implementation of official regulatory control actions associated with sanitation, HACCP systems, and food safety non-compliances.
- The CCA in-plant officials failed to identify and enforce compliance with the SPS as they relate to sanitary operations for product handling or equipment maintenance at both the audited establishments.
- The CCA has not provided adequate instruction to inspection personnel that would ensure product that has tested positive for *Lm*, or product that has come into contact with food contact surfaces that have tested positive for *Lm*, whether sampled by the CCA or the establishment, is not exported to the United States.

The analysis did not identify any significant findings representing an immediate threat to public health for those products that Austria is currently eligible to export to the United States. During the audit exit meeting, the CCA committed to addressing the findings as presented. FSIS received a written response from the CCA addressing all outstanding concerns within 60 days of communication of the draft final audit report.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklist

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Hocheiter Fleischwaren GmgH Gewerbepark Sud 1 Reichenthal	07/15/2016	AT 41586 EG	Austria
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results
7. Written SSOP	
8. Records documenting implementation.	
9. Signed and dated SSOP, by on-site or overall authority.	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements	
10. Implementation of SSOP's, including monitoring of implementation.	
11. Maintenance and evaluation of the effectiveness of SSOP's.	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.	
13. Daily records document item 10, 11 and 12 above.	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements	
14. Developed and implemented a written HACCP plan .	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.	
16. Records documenting implementation and monitoring of the HACCP plan.	
17. The HACCP plan is signed and dated by the responsible establishment individual.	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements	
18. Monitoring of HACCP plan.	
19. Verification and validation of HACCP plan.	
20. Corrective action written in HACCP plan.	
21. Reassessed adequacy of the HACCP plan.	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.	
Part C - Economic / Wholesomeness	
23. Labeling - Product Standards	
24. Labeling - Net Weights	
25. General Labeling	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	
Part D - Sampling Generic *E. coli* Testing	
27. Written Procedures	O
28. Sample Collection/Analysis	O
29. Records	O
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	O
31. Reassessment	O
32. Written Assurance	O

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

60. Observation of the Establishment Hocheiter Fleischwaren GmgH, Est. AT 41586 EG, Processing, 07/15/2016

45/51 Equipment Maintenance:

1. Cutting/Trimming Department:

Cutting boards had lose plastic fiber particles on several boards, in addition the white plastic fiber rails that hold the boards in place and that are exposed to product had jagged and cracked edges.

2. Processing Department:

There were numerous sections of white plastic fiber boards attached to equipment along various sections of the production line had extensive areas that were jagged, cracked and frayed. These boards come in direct contact with product.

In addition many plastic fiber red totes (carts) used to store and move raw product (direct contact) within the establishment, in addition to the shipment of raw product to their sister plant had cracks and broken edges.

These deficiencies observed creates surfaces that could not be readily cleaned creating an insanitary condition which could result in the contamination of product through fiber particles that could become dislodge and embedded in to product. No direct product contamination was observed as these observations were observed during pre-operational verification of inspection personnel.

A review of establishment and inspection verification records provided little evidence that these deficiencies were previously identified for the magnitude of deficiencies observed. Immediate corrective actions were taken by the establishment and verified by CCA inspector additional measure to prevent the re-occurrence will be provide to inspection personnel.
[Regulatory reference: 9CFR 416.3(a), 416.4 (d), 327(a)(2)(i)(D); Council Directive 64/433/EEC, Annex I; and EU 852/2004, Annex II]

It should be noted that the establishment was not processing product that would be used in the production of product for export to the United States on the day of the FSIS audit.

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Hocheiter Fleischwaren GmgH KommunestraBe 1 Bad Leonfelden	07/18/2016	AT 40776 EG	Austria
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff		[X] ON-SITE AUDIT [ ] DOCUMENT AUDIT

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

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

60. Observation of the Establishment Hocheiter Fleischwaren GmgH, Est. AT 40776 EG, Processing, 07/18/2016

46/51/56 Sanitary Operations:

The following two (2) deficiencies observed created insanitary operation conditions and the possible cross contamination of product.

1. Formulation Department:

The FSIS auditors observed that the establishment was using plastic fiber floor pallets that are used to transport boxed product as a platform to stage product. FSIS auditors observed a deficiency in that numerous blocks of unwrapped raw pork fat used in the formulation of sausage product was placed on a plastic fiber floor pallet with only a sheet of plastic between the pallet and the product. Areas of the product were in direct contact with the surface of the pallet a non-product contact surface.

2. Stuffing Department:

The FSIS auditors observed that a stainless steel lug of formulated product was stretched out over the hopper of a sausage stuffing machine and possible contamination from the bottom of the lug.

A review of establishment and inspection verification records; Firstline-Vet quarterly audits; and Senior Firstline-Vet yearly audit reports provided no evidence that these deficiencies were previously identified. The establishment took no immediate corrective actions and the CCA inspection personnel failed to take appropriate regulatory control action at the time of the observation.
[Regulatory reference: 9CFR 327.3(a), 9CFR 416.4(d); and EU 852/2004, Annex II]

It should be noted that the establishment was not processing product that would be used in the production of product for export to the United States on the day of the FSIS audit.

Appendix B: Foreign Country Response to Draft Final Audit Report

MINISTERIUM FRAUEN GESUNDHEIT

Federal Ministry of Health and Women's Affairs

Ms. Jane H. Doherty
USDA - Food Safety and Inspection Service

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United States of America

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Ref.No.:	BMGF-74430/0062-BvZert/2016
Date:	22.12.2016
Ex. Ref.:	

FSIS - Draft Audit Report on Austria's Meat Inspection System 2016; Austrian Statement and Information on Corrective Actions

Dear Ms. Jane Doherty,

the Austrian Federal Ministry of Health and Women´s Affairs refers to your draft final report of October 26, 2016 on the audit conducted by FSIS from July 12 to 22, 2016 in Austria and would like to inform you about the measures and corrective actions taken with regard to the findings addressed in the report:

The frontline-vet as well as the firstline-vets were informed immediately after the closing meeting about the findings during the FSIS-audit and were instructed to focus in particular on the non-compliances registered by the US-auditors during their daily inspection tasks. When available a copy of the draft final audit report was provided to them.

Already on July 20, 2016 a letter from the regional competent authority in Linz, Upper Austria, instructed the frontline vets as well as the district vet, who is certifying exports to the US, that no US-certification may be granted in case *Listeria monocytogenes (Lm)* has been detected on food contact surfaces. The district vet has to check before each certification, if there was a positive result of *Lm* testing on food contact surfaces. In case there was finding of *Lm* he has to verify, that US-products were only produced and handled after another testing for *Lm* with negative results. Please refer to:

Annex I - Brief intern/extern ESV Kaltenböck Martin, Dr

The following measures have been taken immediately after the audit by the company Hochreiter:

During the FSIS-audit it was noted that the establishment failed to take measures to prevent the possible cross-contamination of product from unsanitary conditions as the improper staging of raw meat products (speck) used in the formulation of sausage product, exposed raw product to non-food contact surfaces. The raw product of this supplier is not used for US-production.

As an immediate action the company changed the supplier of speck and speck is now delivered only in red tote boxes and fully wrapped on the pallets.

In addition, the company requires now from ALL supplier that raw product for US-production is only shipped in red tote boxes and is fully wrapped on the pallets. There is also a new SOP for the handling of US-raw product - please see:

Annex II - QM-AA Fleisch-SpeckschlichtungUSA

The implementation of this measure was checked during the senior firstline audit conducted on December 13, 2016 and could be verified (see attached **image IX**).

As a measure with regard to the findings, that in both establishments, maintenance of direct product contact equipment was partly found to be deficient because of

- Numerous sections of white plastic fiberboards attached to equipment along various sections of the production line had extensive areas that were jagged, cracked, and frayed;
- Several cutting boards had loose plastic fiber particles;
- Many plastic fiber red totes (crates) used to store and move raw product (direct contact) within the establishment, and ship raw product to their sister plant, had cracks and broken edges

the company included the check of conveyer belts and cutting boards in their pre-op checklist and changed their maintenance program for the crates. On reception of raw product, the tote boxes or crates have to be visually checked and loose parts have to be clipped off. All internal used totes have to be checked before using them in the production area. Please refer to:

Annexes III, IV – PreOps; **Annex V** – QM-AA Surfaces; **Annexes VI, VII** – QM-AA Crates;

At the pre-op check during the senior firstline inspectors audit on December 13, 2016 it was verified, that no damaged or broken totes were used and fiber boards and conveyer belts were in good condition (please see attached **image X**)

Concerning the non-compliance with the lug that had condensate on the outside and was directly situated over exposed product the company implemented immediately after the FSIS audit a new SOP with instructions for personnel how to perform in case of condensation on the lug. All lugs have to be cleaned and dried with a disinfection tissue and residues of product in the lug have to be scratched out by using the provided equipment. Please refer to:

Annex VIII - QM-AA Umgang mit kondensierten Bräthubwagen

During the senior firstline inspectors audit on December 13, 2016 no condensation could be found on the lugs.

We kindly ask you to consider the information above and the attached documents demonstrating details of the implementation of the corrective actions and would very much appreciate if you could accept the taken measures as appropriate.

Sincerely,

For the Minister:

Dr. med.vet. Ulrich Herzog

Enclosures: