



United States Department of Agriculture

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Food Safety and
Inspection Service

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Dr. Ulrich Herzog
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Head of BMG-II/B
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Austria

Dear Dr. Herzog,

The Food Safety and Inspection Service (FSIS) conducted an on-site audit of Austria's Meat inspection system from June 6 through June 14, 2013. Enclosed is copy of the final audit report.

If you have any questions regarding the FSIS audit or need additional information, please contact me at telephone number (202) 720-6400, by facsimile at (202) 720-7990, or electronic mail at international.audit@fsis.usda.gov

Sincerely,

A handwritten signature in blue ink, appearing to read "Shaukat H. Syed".

Dr. Shaukat H. Syed
Director
International Audit Staff
Office of Investigation, Enforcement and Audit

Enclosure

AUSTRIA
FINAL AUDIT REPORT

February 11, 2014
Food Safety and Inspection Service
United States Department of Agriculture

Executive Summary

This report describes the outcome of an onsite equivalence verification audit conducted by the Food Safety and Inspection Service (FSIS) from June 6 through June 14, 2013, to determine whether Austria's meat inspection system remains equivalent to that of the United States (U.S.), with the ability to produce products that are safe, wholesome, unadulterated, and properly labeled. Austria currently produces only not heat-treated, shelf-stable or fully-cooked, not shelf-stable pork products for the U.S., which are indirectly exported through U.S.-eligible establishments operating in Germany. The audit scope included the two establishments that are currently eligible to produce product for the United States, as well as the Central Competent Authority (CCA) headquarters (the Bundesministerium für Gesundheit), and one provincial office. As Austria currently uses a laboratory located in Germany for official analysis, a visit to this location was not included. However, verification of oversight activities and performance for this laboratory was accomplished through review of documents at the CCA headquarters, which included proof of accreditation as well as individual audit reports issued by Austria, Germany, and the European Commission's Food and Veterinary Office.

The audit focused on six main system components: (1) Government Oversight; (2) Statutory Authority and Food-Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Chemical Residue Control Programs; and (6) Microbiological Testing Programs. The auditor also verified that the corrective actions the CCA had implemented in response to the September 2008 audit finding – inadequate implementation regarding establishment adherence to pre-operational and operational Standard Operating Procedures (SSOPs) and Sanitation Performance Standards (SPS) – were still being correctly implemented.

While the audit determined that the equivalence criteria for the six components were met, and that Austria has maintained an average-performing equivalent food safety system, the following findings were identified that could ultimately impact the ability of the CCA to operate its program as intended:

- The CCA's system for documenting non-compliance did not give adequate detail of the non-compliances observed and did not record the actions taken by the establishment to resolve the non-compliances.
- At both establishments, the auditor observed that many of the carts used to move raw materials had cracks or unsmooth welds that would make them difficult to clean, and that both inspection and establishment personnel were only verifying the visible cleanliness of the carts and not routinely considering physical construction deficiencies.
- At one establishment, the FSIS auditor noted that the establishment records for CCP 6, cooking temperature, did not include documentation of ongoing verification activities.

These findings were discussed at the exit meeting on June 14, 2013, in Vienna, at which the CCA understood and accepted the need to address these findings to maintain its equivalence. Once FSIS receives corrective actions from the Austrian CCA, FSIS will further evaluate the effectiveness of the corrective actions provided.

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I. INTRODUCTION

Austria is eligible to export raw and processed pork products to the United States (U.S.). The products currently produced and exported are not heat-treated, shelf stable or fully-cooked, not shelf-stable pork products. At present, Austria exports all products destined for the United States to Germany. Some of this product is used by three German establishments for export to the United States; some is used by these German establishments for domestic production and other exports. Because all Austrian pork products are exported indirectly through Germany, the Food Safety and Inspection Service (FSIS) does not report import weights or point-of-entry (POE) violations for Austria. In addition, since Austria presently has no slaughter facilities certified eligible to export to the United States, all pork used in the processing must come from another country that is eligible to export to the United States. Austria currently imports pork for this purpose from Denmark and the Netherlands.

FSIS conducted an onsite verification audit of Austria's meat inspection system from June 6 through June 14, 2013. During the audit, FSIS verified that the inspection system maintained requirements equivalent to those of FSIS, in particular:

- The Federal Meat Inspection Act (21 U.S.C. 601 et seq.)
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end), which include the Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) regulations

The audit standards applied during this audit included all applicable legislation originally determined by FSIS as equivalent as part of the initial equivalence process and any subsequent equivalence determinations that have been made under provisions of the Sanitary/Phytosanitary Agreement.

II. AUDIT GOAL AND OBJECTIVES

FSIS' overall goal for the audit was to verify that Austria's food safety system governing meat products continues to be equivalent to that of the United States, with the ability to produce and export products that are safe, unadulterated, wholesome, and properly labeled. To achieve this goal, the audit focused on the following areas with the objective of determining whether each component continues to be equivalent to that of the U.S. The six equivalence components are: (1) Government Oversight; (2) Statutory Authority and Food-Safety Regulations; (3) Sanitation; (4) Hazard Analysis and Critical Control Points (HACCP) Systems; (5) Chemical Residue Control Programs; and (6) Microbiological Testing Programs. FSIS also verified that the corrective actions proffered by the Central Competent Authority (CCA), the Bundesministerium für Gesundheit (BMG), in response to the September 2008 FSIS audit, were being implemented.

III. AUDIT METHODOLOGY

For conducting this equivalence verification audit, FSIS utilized its established four-phase process: planning, execution (onsite), evaluation, and feedback. Each phase is described below.

The first phase involved document and data analysis of previous audit findings and other available information. Prior to conducting the June 2013 onsite audit, the FSIS auditor examined the CCA's performance within the six equivalence components, data on exported product types and volumes (to Germany) provided by the Austrian CCA, point-of-entry (POE) testing results (from review of POE violations from German companies' products that include Austrian product and then export to the United States), and other data collected by FSIS since the last FSIS onsite audit in 2008. All findings from this past audit centered on issues of government oversight and sanitation; those had been immediately corrected. This audit confirmed that those corrective actions are in place and effective. In addition, FSIS reviewed information obtained directly from the CCA, through the self-reporting tool, outlining the current structure of the inspection system and identifying any significant changes that have occurred since the last FSIS audit. This comprehensive analysis served as the basis for planning the onsite audit itinerary.

The second phase is the onsite or execution phase. FSIS conducted this onsite audit to verify that the CCA is conducting oversight activities through document reviews, interviews, observations, and site visits. The FSIS auditor was accompanied throughout the audit by representatives from the CCA, including members from the provincial or establishment inspection offices.

The auditor reviewed management, supervision, and administrative functions at the CCA headquarters, the Linz Provincial Office, and the only two establishments eligible for export to the United States [one pork processing (cutting) establishment and one pork processing, ready-to-eat (RTE) establishment] to verify that the national system of inspection, verification, and enforcement was being implemented as required to maintain equivalence. During the establishment visits, the auditor paid particular attention to the extent to which government and industry interact to control hazards and prevent program deficiencies that may threaten food safety, with an emphasis on the CCA's ability to provide oversight through supervisory reviews conducted in accordance with the Title 9 of the United States Code of Federal Regulations (CFR) section 327.2.

Since there are no certified slaughter establishments in Austria, all residue control takes place in the country of origin of the pork (the Netherlands or Denmark). The CCA has been using a laboratory in Germany for the microbiological analyses of the RTE products. The FSIS auditor assessed the CCA's oversight activities of the approved microbiology laboratory during both the planning and execution phases; however, no onsite visit was made during this audit to the approved laboratory in Germany. This laboratory was last reviewed in the FSIS audit of Germany in 2012, and there were no findings. The FSIS auditor reviewed laboratory-related data collected prior to the 2013 audit through analysis of documents in the self-reporting tool (SRT). Second, FSIS conducted onsite interviews of inspection personnel and reviewed the CCA's laboratory audit reports (third party - European Union and Germany reports) at the CCA's headquarters. Austria is now proposing the use of an Austrian microbiological laboratory

(AGES) for these analyses. An onsite visit to the proposed laboratory was conducted. Once Austria has solidified its oversight procedures for this new laboratory, a formal request will be made by Austria to transition from the German laboratory to the Austrian AGES laboratory. This request will include their new oversight procedures, which will then be evaluated for equivalence by FSIS and verified on the next FSIS audit.

The third phase of the audit is evaluation. FSIS conducted an evaluation of all data collected onsite to determine whether the CCA's performance is consistent with the information provided to FSIS in the SRT and other submitted documents. FSIS conducted an exit meeting with the CCA representatives to convey all findings and discuss next steps.

The final phase of the audit is feedback which begins with a draft audit report, which provides the CCA with an opportunity for comment. After reviewing the CCA's comments and responses to all findings, FSIS prepares a final report. Then, the CCA develops an action plan to address any issues raised by the audit. These issues will be monitored by FSIS until resolution.

IV. COMPONENT ONE: GOVERNMENT OVERSIGHT

The first of the six equivalence components that the auditor reviewed was Government Oversight. The FSIS import eligibility requirements state that an equivalent foreign inspection system must be organized and administered by the national government of the foreign country and must provide standards equivalent to those of the Federal system of meat inspection in the United States. The evaluation of this component included a review and analysis of documentation submitted by the CCA as support for the responses to the SRT and corrective actions in response to the FSIS 2008 audit, as well as onsite record reviews, interviews, and observations made by the FSIS auditor at government offices and audited establishments.

The CCA, the BMG, is the Federal Ministry of Health. The Chief Veterinary Officer (CVO) position is the head of subdivision II/B that is responsible for food and veterinary matters. Within BMG's Division II, department II/B/12 is responsible for food safety in primary production, veterinary residues, animal by-products, and animal welfare at slaughter. The Senior Firstline Inspector reports directly to the CVO. Personnel from this level along with those at the Provincial level (Firstline Inspectors) ensure uniform implementation of regulatory requirements and are responsible for oversight of the official activities of inspection personnel at establishments certified eligible to export to the United States.

The CCA's authority to enforce EU food safety inspection laws is specified in the Austrian statute, *Austrian Food Safety and Consumer Protection Act (LMSVG)*. The CCA has the legal authority and the responsibility to write, implement, and enforce requirements equivalent to those governing the U.S. system of meat inspection. To achieve these objectives, the CCA issues, distributes, and oversees a number of inspection-related instructions to its inspection personnel.

At the provincial level, the Linz Provincial Office represents the BMG. Austria only has two establishments certified to export pork products to the United States, owned by the same parent company and located within close proximity to each other within a single province. The Linz

Provincial Office operates within the scope of the inspection operations coordinated by the BMG and is responsible for the implementation and enforcement of inspection operations in the processing plants within the province. This is the level of government that also provides periodic supervisory reviews for the establishments certified eligible to export to the U.S. The Senior Firstline Inspector also conducts an annual supervisory review of the establishments. At the establishment level, the veterinarians hired by the provincial government have the responsibility to implement and enforce inspection requirements at the establishments eligible to export meat products to the United States.

The FSIS auditor reviewed non-compliance reports that were generated by in-plant inspection personnel at both audited establishments from January 1, 2012, to the day of the audit. This review identified that the non-compliance documentation system used by the Austrian inspection personnel did not give adequate detail on the non-compliances observed and did not record the actions taken by the establishment to resolve the non-compliances. The failure to include that information was primarily the result of a recent attempt to streamline these forms, which occurred since the last FSIS audit. During discussions held with the FSIS auditor, the CCA acknowledged that the absence of such information could ultimately impact their ability to analyze trends in non-compliance as they occur. Consequently, the CCA immediately revised the form to include the missing information, which was presented to the FSIS auditor at the exit meeting. In response to this finding, FSIS requests further information to demonstrate the effective implementation of these forms, including any training or other guidance provided to inspection personnel to ensure their accurate completion and that the included level of detail meets the expectations of the CCA.

The FSIS auditor also reviewed the last 12 months of written periodic supervisory reviews to assess the enforcement capability of the inspection personnel and the adequacy of the establishment's corrective actions. The conditions in the audited establishments matched the supervisory reviews, and no non-compliance trends related to Sanitation Standard Operating Procedures (SSOP), HACCP, or Sanitation Performance Standards (SPS) activities were observed.

In the two pork processing establishments audited, periodic supervisory reviews are conducted approximately every 60 days by the Linz Provincial Office veterinary supervisors (Firstline Inspectors) in accordance with the yearly Work Schedule provided by the BMG through the Senior Firstline Inspector. The Senior Firstline Inspector conducts an annual supervisory review.

In both establishments, the FSIS auditor verified that supervisory reviews were conducted using a standard format, "*Protokoll zur Inspektion*, Protocol for Inspection," that 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 9 CFR 327.2 and LMSVG Chapter 2, Section 1. The periodic supervisory review reports are distributed to the audited establishment's management, the veterinary personnel assigned to the establishments, the Linz Provincial Office, the Senior Firstline Inspector, and the BMG offices in Vienna. The in-plant veterinary personnel and the Firstline Inspectors are responsible for verification of corrective actions resulting from the reviews.

The Linz Provincial Office Firstline Inspectors and the Senior Firstline Inspector are responsible for analyzing the results of the review. The Linz Provincial Office and the Senior Firstline Inspector also review the establishment's action plans and verify the corrective actions by the Firstline Inspectors and the in-plant veterinary personnel in order to ensure the effectiveness and implementation of action plans.

After a thorough review of all documents, onsite observations, and interviews, the auditor concluded that Austria's government has in place an equivalent organizational structure for performing oversight. The FSIS auditor also confirmed compliance with the CCA's LMSVG Art. 64, which provides the regulatory framework for payment for inspection activities. The auditor verified, through document review (i.e., electronic pay statements) at the CCA and at the provincial office, that inspection personnel assigned to establishments certified eligible for export to the United States were employees of the government servicing agency, including national and provincial governments.

FSIS' onsite audit verification methodology, including observations, document reviews, and interviews in combination with FSIS' review of the SRT and document analysis of the CCA's control measures, demonstrates that the CCA continues to perform at an "average" level in meeting FSIS' equivalence criteria for this component.

V. COMPONENT TWO: STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS

The second of the six equivalence components that the FSIS auditor reviewed was Statutory Authority and Food Safety Regulations. The inspection system must provide an appropriate regulatory framework to demonstrate equivalence with FSIS' requirements, including, but not limited to, HACCP, sanitation, microbiological sampling, establishment construction, facilities, equipment, daily inspection, and periodic supervisory visits to establishments certified eligible to export to the United States. The evaluation of this component included an analysis of information provided by the CCA, the SRT, interviews, and observations during the onsite portion of the audit. The FSIS auditor verified that official inspection and verification activities were in accordance with the responses in the SRT and supporting documentation.

During the CCA's headquarters audit, the FSIS auditor verified the regulatory authority maintained by the CCA as outlined in official legislation, protocols, and other instructions issued in accordance with the BMG inspection law. The auditor confirmed that the CCA provided the provincial and establishment inspection offices with the appropriate regulatory authority to enforce requirements for HACCP, sanitation, microbiological sampling, establishment construction, facilities, equipment, daily inspection and periodic supervisory visits to establishments certified eligible to export to the United States. In particular, the FSIS auditor verified that the CCA exercises its legal authority to require that the establishments certified eligible to export to the United States develop, implement, and maintain sanitation programs sufficient to prevent direct product contamination or insanitary conditions. The CCA has adopted FSIS' sanitation regulatory requirements prescribed in 9 CFR Part 416 along with the requirements of the European Union (EU), which have previously been deemed equivalent by FSIS. The in-plant inspection personnel at both audited establishments verified sanitary

conditions in accordance with methodology described in the EU Directives and in the CCA's Manual on Inspection of SPS, SSOP, and HACCP, which is based on the FSIS Directive 5000.1, Rev. 3 (Manual).

During the onsite audit of the two pork processing establishments, the FSIS auditor accompanied inspection personnel and observed the in-plant inspection verification activities for pre-operational and operational sanitation procedures (described under Component Three) and HACCP verification activities (described under Component Four). In addition, during the onsite audit of one pork processing establishment, the FSIS auditor reviewed and observed the in-plant inspection verification activities for RTE sampling and testing (described under Component Six). The FSIS auditor observed the functions of the in-plant veterinary personnel and their records to ensure daily inspection verification activities in both audited establishments. These daily verification activities included direct observation, measurement, and review of each establishment's records, including HACCP, SSOP, and SPS, and sampling for, and results of, *Salmonella* and *Listeria monocytogenes (Lm)* in finished RTE product records (in one establishment).

The FSIS auditor also assessed the adequacy of HACCP program verification activities conducted by inspection officials and establishment personnel by observing verification activities as well as reviewing monitoring and verification records generated by establishment and in-plant inspection personnel at both audited establishments.

Through Austria's implementation of the requirements of the EU legislation, the LMSVG, and the Manual, Austria's meat inspection system has legal authority and a well-documented regulatory framework to implement requirements equivalent to those governing the U.S. FSIS' system of meat inspection. The analysis and onsite verification activities indicate that the CCA continues to perform at an "average" level in meeting FSIS' equivalence criteria for this component.

VI. COMPONENT THREE: SANITATION

The third of the six equivalence components that the FSIS auditor reviewed was Sanitation. An equivalent inspection system must provide requirements for all areas of sanitation, sanitary handling of products, and SSOPs. Prior to the onsite portion of the audit, the auditor reviewed the CCA's Manual on Inspection of SPS, SSOP, and HACCP. Once onsite, the auditor gathered additional information to assess sanitation equivalence at the government offices and at both of the establishments certified eligible to export to the United States.

The FSIS auditor reviewed sanitation plans and records related to the design and implementation of sanitation programs at both audited establishments. At these establishments, the FSIS auditor verified the actual pre-operational inspection by shadowing and observing the in-plant inspector conducting pre-operational sanitation verification of processing areas. Then, establishment personnel conducted their pre-operational sanitation inspection and determined that the facility was ready for the in-plant inspector's pre-operational sanitation verification activities. The in-plant inspection personnel conducted this activity in accordance with the established equivalent procedures from the Austrian Inspection Manual cited previously. In particular, to verify

operational sanitation, the FSIS auditor followed the inspector and observed in-plant inspection verification of operational sanitation procedures at the two audited establishments. These verification activities included direct observation of operations and review of the establishment's associated records. The FSIS auditor also reviewed the establishment's sanitation monitoring and corresponding inspection's verification records. The auditor noted that the inspection and establishment records mirrored the actual sanitary conditions of the establishment. The establishment employees who are responsible for the implementation and monitoring of the SSOP procedures correctly authenticated these records with initials or signatures and the date.

One area for improvement identified by the FSIS auditor at both establishments concerns the methodology by which maintenance of production equipment is verified. During the tour of these establishments, the auditor noted that many of the carts used to move raw materials had cracks or unsmooth welds that would make them difficult to clean and could possibly lead to the formation of biofilms. Neither establishment's sanitation records nor inspection records at the establishment or supervisory levels noted these conditions. Rather, the auditor noted that both inspection and establishment personnel were only verifying the visible cleanliness of the carts (which were clean at the time of the audit) and not routinely considering physical construction deficiencies.

In accordance with the FSIS audit procedures, discussions were held with local inspection personnel and other members of the CCA regarding this finding. At both facilities, the inspection force demonstrated the knowledge and ability to take proper enforcement action and immediately began working with establishment management personnel to address the issue. This included a plan to conduct an audit of all remaining carts, replace or repair equipment as appropriate, and establish an on-going maintenance program. Furthermore, inspection personnel proposed to verify the effectiveness of these corrective actions and the efficiency of the new establishment maintenance program once complete.

The FSIS auditor verified ongoing maintenance of the corrective actions provided and implemented by the CCA in response to the September 2008 audit findings in the two eligible establishments—inadequate implementation of pre-operational and operational Standard Operating Procedures (SSOPs) and Sanitation Performance Standards (SPS)—were still in place and effective in preventing contamination of product. The previous findings in sanitation included two situations. In the first, when the wheeled carts were being lifted to dump into mixers and other batch equipment, the wheels carried water up from the floor, which could fall into the mixer as the last of the product was transferred. The corrective action was to make the wheels and the cart separate pieces of equipment so that only the cart was lifted. The second finding was that an operator walked under an elevated cart with another cart of product, and drips from the elevated cart fell into the lower one. Several different corrective actions were taken to prevent this from occurring again such as creating painted floor pathways, small curbs, and redesigning the physical set-up of the areas where carts were being lifted so no traffic could go below them. The BMG in-plant personnel continue to monitor these situations, and no new NRs were written about these. The 2013 audit reaffirmed that those corrective actions were in place and were still effectively being implemented.

The FSIS auditor determined that the CCA's inspection system provides requirements equivalent to those of FSIS' system for sanitary handling of products, as well as development and implementation of SSOPs. In-plant veterinary officials and provincial supervisors enforce the regulatory requirements and monitor the ability of the establishments to maintain sanitary conditions. Therefore, the audit findings support that the CCA continues to perform at an "adequate" level in meeting FSIS' equivalence criteria for this component.

VII. COMPONENT FOUR: HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEMS

The fourth of the six equivalence components that the FSIS auditor reviewed was HACCP. The inspection system needs to require a HACCP plan or similar type of preventative control plan to maintain equivalence. Austria's meat inspection system has equivalent HACCP requirements to FSIS, as described in the LMSVG. It imposes regulatory requirements for the development, implementation, and maintenance of HACCP programs as set forth in this regulation on the establishments certified eligible to export to the United States. The FSIS auditor verified through record review and observation that the in-plant inspection personnel at certified establishments conducted daily verification of HACCP plans in accordance with methodology described in the CCA's Manual which included the evaluation of written HACCP programs, monitoring, verification, corrective actions, recordkeeping, and hands-on verification inspection. The in-plant daily inspection verification included Critical Control Points (CCP) verification for all production shifts with results entered into the Inspection Log.

No non-compliance trends were detected as the result of the document reviews. Furthermore, the FSIS auditor verified the physical CCP locations by observing inspection personnel conducting HACCP hands-on verification activities. Neither the inspection personnel nor the FSIS auditor observed any deviation from the critical limits.

During onsite document reviews and interviews of establishment personnel at one establishment, the FSIS auditor noted that the establishment records for CCP 6, cooking temperature, did not include documentation of ongoing verification activities. Missing elements 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 records were signed at the bottom, but lacked indication as to what the signature signified. Discussions with the CCA indicated that they clearly understood the nature of the problem and demonstrated efficient enforcement mechanisms leading to its resolution, for which an updated record format was presented to the auditor prior to the exit meeting.

The establishment's verification activities were mostly likely occurring as intended, as specific instructions were included in the associated HACCP plan, and that the ongoing verification for other CCPs within the establishment was being documented correctly. The CCA is expected to periodically verify the implementation of each HACCP system operating within the facility. The lack of complete documentation for CCP6 had not been previously identified by the Frontline or Firstline Inspectors.

In conclusion, with the exception of the above finding, the overall results of the assessment of the HACCP programs demonstrated that the CCA's inspection system provides requirements equivalent to those of FSIS' HACCP regulatory requirements. In-plant (Frontline) veterinary officials and provincial supervisors monitor, verify, and enforce the implementation of the HACCP regulatory requirements in the audited establishments. The analysis and onsite audit verification of the HACCP component indicated that the CCA's meat inspection system continues to perform at an "average" level in meeting FSIS' equivalence criteria for this component.

VIII. COMPONENT FIVE: CHEMICAL RESIDUE CONTROL PROGRAMS

The FSIS auditor reviewed Chemical Residue Control Programs as the fifth of the six equivalence components. FSIS criteria for this component include the design and implementation of a program managed by the CCA that conducts effective regulatory activities to prevent chemical residue contamination of food products. To be equivalent, the program needs to include random sampling of internal organs and fat of carcasses for chemical residues that have been identified as potential contaminants by the exporting countries and FSIS. The inspection system must identify the laws, regulations, or other decrees that serve as the legal authority for the implementation of this program. The CCA must provide a description of its residue plan and the process used to design the plan; provide a description of the actions taken to deal with unsafe residues as they occur; and provide oversight of laboratory capabilities and analytical methodologies to ensure the validity and reliability of test data.

Austria, in accordance with EU regulations—EC Directive 96/23—develops and implements a national residue program each year. This program is furnished to FSIS each year along with the previous year's results. However, since no slaughterhouses are currently certified 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 the Netherlands or Denmark. 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 this product in Austria as trade between member states is not considered an import from a third country (EU Regulation 884/2004 for the development of the trans-European transport network). The FSIS auditor reviewed records of incoming raw product to assure that products that were for use in product destined for the United States came from establishments certified for export to the United States from either the Netherlands or Denmark.

FSIS auditor's review found no concerns with the CCA's chemical residue control program. The CCA's meat inspection system has regulatory requirements for a chemical residue control program that continue to demonstrate the ability to meet the core equivalence requirements for this component.

IX. COMPONENT SIX: MICROBIOLOGICAL TESTING PROGRAMS

The last of the six equivalence components that the FSIS auditor reviewed was Microbiological Testing Programs. This component pertains to the microbiological testing programs organized and administered by the CCA to verify that products destined for export to the United States are safe, wholesome, and meet all equivalence criteria.

The evaluation of this component included a review and analysis of the CCA's LMSVG and EU Regulation 2073/2005 on Microbiological Criteria for Foodstuffs. Austria has microbiological testing programs for *Salmonella* and *Listeria monocytogenes (Lm)* in Ready-to-Eat (RTE) products, and *Lm* on product-contact surfaces and non-product contact surfaces (environmental). The FSIS auditor verified that the CCA has implemented sampling and testing programs to ensure that meat products produced for export to the United States meet the equivalence criteria.

The microbiological laboratory used by the Austrian government is located in Lower Saxony in Germany. The name of the laboratory is the Exporting Establishment Certifying Authority in the Federal State of Lower Saxony (Niedersächsisches Landesamt für Verbraucherschutz und Lebensmittelsicherheit, Lower Saxony State Office of Consumer Protection and Food Safety). The laboratory in Germany uses the FSIS Microbiological Lab Guide methods and is regularly audited during FSIS audits as well as by the German third-party accreditation body and the EC Food and Veterinary Office (FVO) audits. The laboratory was audited during the FY2012 FSIS audit of Germany from June 27 to July 13, 2012. Neither FSIS nor the European Union has made negative findings in recent audits of the laboratory.

In addition, the FSIS auditor reviewed the accreditation for ISO 17025 for the German laboratory, laboratory reports for destined products including one report that had a positive result for *Lm*, the Senior Firstline Inspector's supervisory review for 2012, the General Schedule for Sampling letter, and the Authorization for Sampling letter. These letters authorize the sampling to occur and give a yearly sampling schedule for *Salmonella* and *Lm*. The letters are issued by BMG in Vienna to the Provincial Office in accordance with the LMSVG requirements. The review of these documents describing the programs Austria has in place to assure that the RTE products produced are not exported containing either *Salmonella* or *Lm* showed that these programs remain equivalent.

The LVMSG contains requirements that establishments eligible to export to third countries are required to fulfill the requirements of these countries. It is this legislation that ensures zero tolerance for *Salmonella* and *Lm* for exports to the United States. Austria completed the SRT for RTE and presented it to the FSIS auditor at the entrance meeting. An analysis of the SRT reaffirmed Austria's equivalence for this component. This same requirement also provides 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 U.S. standards. The applicable lethality and cooling requirements are checked during the daily inspection by the Frontline Inspectors as well as during the reviews by the Firstline Inspectors.

In addition, the auditor verified the implementation of *Salmonella* and *Lm* sampling for the RTE program in the processing establishments. *Lm* control measures are a part of the HACCP plan and are verified by the Frontline and Firstline Inspectors on a regular basis. All batches of finished pork products intended for the United States are officially tested prior to shipping for *Lm* and *Salmonella*. Since product eligible for the United States is shipped to Germany, the trucks are sealed. The seal cannot be broken in Germany until a representative of the government of Germany has a copy of a laboratory report showing negative results for both pathogens.

All laboratory report results are forwarded to the Senior Firstline Inspector who, along with the provincial Firstline Inspectors, review all results throughout the year. Establishment self-check testing results are also reviewed by the Frontline and Firstline Inspectors and enforcement actions are taken as necessary.

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 *Listeria monocytogenes (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. Based on the FSIS auditor's interviews and review of inspection documents at the CCA headquarters in Vienna, the Linz Provincial Office, and at the one audited processing establishment that produces RTE product, the auditor had no negative findings for this component.

No slaughterhouses certified for export to the United States operate in Austria, and therefore no review for generic *Escherichia coli (E. coli)* or *Salmonella* Performance Standards was conducted. Also, since beef export is not approved for Austria, there are no programs for *E. coli* O157:H7 or non-O157 *Shiga*-toxin producing *Escherichia coli* (STECs). As provided for in the LVMSG and the Manual, Austria's meat inspection system includes a microbiological testing program that provides sufficient controls for the RTE products produced for export to the United States in Austria's certified establishments. At this time, the CCA continues to perform at an "average" level in meeting FSIS' equivalence criteria for this component.

X. CONCLUSIONS AND NEXT STEPS

In conclusion, this audit found that the Austrian CCA demonstrated that they continue to perform at an "average" level in maintaining their equivalence. The inspection program met the established core criteria for all six equivalence components. However, the following findings were identified that could ultimately impact CCA's ability to operate its program as intended:

- The CCA's system for documenting non-compliance did not give adequate detail of the non-compliances observed and did not record the actions taken by the establishment to resolve the non-compliances; a new form resolving this issue was presented to the FSIS auditor at the exit meeting. In response to this audit report, FSIS requests further information to demonstrate the effective implementation of these forms, including any

training or other guidance provided to inspection personnel to ensure that they are accurately completed and that the included level of detail meets the expectations of the CCA.

- At both establishments, the auditor observed that many of the carts used to move raw materials had cracks or unsmooth welds that would make them difficult to clean. They also observed that both inspection and establishment personnel were only verifying the visible cleanliness of the carts and not routinely considering physical construction deficiencies. In response to the condition of the carts, plant management proposed a plan to conduct an audit of all remaining carts, to replace/repair equipment as appropriate, and to establish an on-going maintenance program.
- At one establishment, the FSIS auditor noted that the establishment records for CCP 6, cooking temperature, did not include documentation of ongoing verification activities and an updated record format was presented to the auditor prior to the exit meeting. However, it is FSIS' expectation that the CCA periodically verifies the implementation of each HACCP system operating within the facility in its entirety, for which the incomplete documentation for this particular CCP is relevant in that these forms had been in use for some time and had not been previously identified by the Frontline or Firstline Inspectors. Consequently, FSIS requests further information to demonstrate how the CCA ensures that all HACCP systems operating within U.S.-eligible establishments are verified by inspection personnel, including how often it occurs.

These findings were discussed at the exit meeting on June 14, 2013, in Vienna. The CCA understood and accepted the need to address these findings to maintain its equivalence. Once the FSIS receives corrective actions from the Austrian CCA, FSIS will further evaluate the effectiveness of the corrective actions.

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 Hochreiter Fleischwaren GmbH A-4190 Bad Leonfelden (Reichenthal)	2. AUDIT DATE 6/10/2013	3. ESTABLISHMENT NO. AT40735EG	4. NAME OF COUNTRY AUSTRIA
5. NAME OF AUDITOR(S) Rori K. Aaron, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT	

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		Part E - Other Requirements	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions.		42. Plumbing and Sewage	
16. Records documenting implementation and monitoring of the HACCP plan.		43. Water Supply	
17. The HACCP plan is signed and dated by the responsible establishment individual.		44. Dressing Rooms/Lavatories	
Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements		45. Equipment and Utensils	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		Part F - Inspection Requirements	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. 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		Part G - Other Regulatory Oversight Requirements	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
Salmonella Performance Standards - Basic Requirements		58. <input style="width:100%;" type="text"/>	
30. Corrective Actions		59. <input style="width:100%;" type="text"/>	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Austria Est. AT40735 EG 06/10/2013

45/51 During pre-operational sanitation verification inspection, it was noted by the auditor that many (approximately one out of 10) of the stainless steel carts used to move raw materials had cracks and/or unsmooth welds making them difficult to clean and possibly leading to the formation of biofilms in these areas. This had not been noted in either establishment sanitation records for pre-operational or operational sanitation or in the records of inspection personnel either at the establishment or supervisory levels. Establishment management personnel stated that they will do an audit of these carts, remove and replace or repair as appropriate, and establish an on-going maintenance program for the oversight of these carts. Inspection personnel will verify the effectiveness of this corrective action and of the efficiency of the new establishment maintenance program. EC Reg. 852/2004 Annex II, Chapter V, 1.b

51 The non-compliance documentation system used by Austrian inspection personnel at the establishment level did not give adequate detail of the non-compliances observed and did not record corrective actions taken by the establishment or preventive measures proposed and put into place by the establishment. CCA personnel will design and implement a new format for the documentation of non-compliances. EC Reg. 852/2004 Article 5 2(3); 9 CFR 417.5

61. NAME OF AUDITOR

Rori K. Aaron, DVM

62. AUDITOR SIGNATURE AND DATE

 06/10/2013

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Hochreiter Fleischwaren GmbH Kommunestrasse 1 A-4190 Bad Leonfelden	2. AUDIT DATE 6/11/2013	3. ESTABLISHMENT NO. AT40776EG	4. NAME OF COUNTRY AUSTRIA
	5. NAME OF AUDITOR(S) Rori K. Aaron, DVM		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

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

60. Observation of the Establishment

Austria Est. AT40776 EG 06/11/2013

22/51 Establishment records for CCP 6, cooking temperatures for fully cooked product, did not include documentation of ongoing verification including the event (record review, instrument calibration, or observation of the monitor), the result, the date and time, and the initials of the verifier. The record was signed at the bottom, but there was no indication what that signature signified. Instructions for the verification events were included in the HACCP plan for fully cooked, not shelf stable products. This missing documentation had not been noted in establishment records or in the records of the frontline or firstline inspection personnel. Establishment management stated that they will modify the record so that verification events are documented. Inspection personnel will verify this addition to the records and the successful completion of the documentation in future CCP records. EC Reg. 852/2004 Article 5, 2(f); 9 CFR 417.5

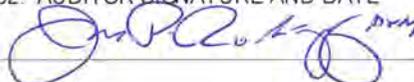
45/51 During operational sanitation verification inspection, it was noted by the auditor and the CCA personnel that many (approximately one out of 10) of the stainless steel carts used to move raw materials had cracks and/or unsmooth welds making them difficult to clean and possibly leading to the formation of biofilms in these areas. This had not been noted in either establishment sanitation records for pre-operational or operational sanitation or in the records of inspection personnel either at the establishment or supervisory levels. Establishment management personnel stated that they will do an audit of these carts, remove and replace or repair as appropriate, and establish an on-going maintenance program for the oversight of these carts. Inspection personnel will verify the effectiveness of this corrective action and of the efficiency of the new establishment maintenance program. EC Reg. 852/2004 Annex II, Chapter IX, 3

51 The non-compliance documentation system used by Austrian inspection personnel at the establishment level did not give adequate detail of the non-compliances observed and did not record corrective actions taken by the establishment or preventive measures proposed and put into place by the establishment. CCA personnel will design and implement a new format for the documentation of non-compliances. EC Reg. 852/2004 Article 5, 2(e); 9 CFR 417.5

61. NAME OF AUDITOR

for Rori K. Aaron, DVM

62. AUDITOR SIGNATURE AND DATE



06/11/2013

APPENDIX B: Foreign Country Response to Draft Final Audit Report (when available)