FINAL REPORT OF AN AUDIT CONDUCTED OF POLAND

MAY 8–31, 2023

EVALUATING THE FOOD SAFETY SYSTEMS GOVERNING RAW AND PROCESSED PORK PRODUCTS EXPORTED TO THE UNITED STATES OF AMERICA

October 5, 2023

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

Executive Summary

This report describes the outcome of an onsite equivalence verification audit of Poland conducted by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) from May 8–31, 2023. The purpose of the audit was to verify whether Poland's food safety inspection system governing raw and processed pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. Poland currently exports thermally processed, commercially sterile (TPCS) pork; ready-to-eat (RTE) pork fully-cooked without subsequent exposure to the environment; RTE fully-cooked pork; RTE dried pork; RTE salt-cured meat; RTE acidified/fermented pork (without cooking); raw intact pork; and not ready-to-eat (NRTE) otherwise processed pork to the United States.

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

FSIS concluded that Poland's food safety inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. The General Veterinary Inspectorate (GVI), Poland's Central Competent Authority, has required that establishments certified as eligible to export pork products to the United States implement sanitation requirements and a HACCP system designed to improve the safety of their exported products. In addition, GVI has implemented official microbiological and chemical residue testing programs that are organized and administered by the national government to verify its food safety inspection system. An analysis of each component did not identify any findings representing an immediate threat to public.

TABLE OF CONTENTS

I. INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) conducted an onsite audit of Poland's food safety inspection system May 8–31, 2023. The audit began with an entrance meeting held May 8, 2023, in Warsaw, Poland, during which the FSIS auditors discussed the audit objective, scope, and methodology with representatives from the Central Competent Authority (CCA) – the General Veterinary Inspectorate (GVI). Representatives from GVI accompanied the FSIS auditors throughout the entire audit. The audit concluded with an exit meeting conducted remotely via videoconference May 31, 2023.

II. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY

This was a routine ongoing equivalence verification audit. The audit objective was to verify whether the food safety inspection system governing raw and processed pork products remains equivalent to that of the United States, with the ability to export products that are safe, wholesome, unadulterated, and properly labeled and packaged. Poland is eligible to export the following categories of products to the United States:[1]

Process Category	Product Category	Eligible Products[2]
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Pork	Pork - all products eligible except Mechanically Separated and Advanced Meat Recovery Product (AMR)
Raw - Intact	Raw Intact Pork	Pork - all products eligible
Raw - Intact	Raw Intact Chicken	Chicken - all products eligible except boneless and/or skinless parts and poultry parts (including necks/feet & giblets)
Raw - Intact	Raw Intact Turkey	Turkey - all products eligible
Raw - Intact	Raw Intact Poultry-Other (Ducks, Geese, Squab)	Duck, goose, and guinea - all products eligible
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Chicken	Chicken - all products eligible except ground product, mechanically separated and sausage
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Turkey	Turkey - all products eligible except ground product, mechanically separated and sausage

[1] On October 7, 2021, Poland became eligible to export raw and processed poultry products to the United States. There have been no exports of raw or processed poultry products to the United States since Poland became eligible, nor has Poland certified any establishments as eligible to export these products prior to or during this audit.

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

Process Category	Product Category	Eligible Products[2]
Raw - Non Intact	Raw Ground, Comminuted, or Otherwise Non-intact Poultry-Other (Ducks, Geese, Squab)	Duck, goose, and guinea - all products eligible except mechanically separated
Thermally Processed - Commercially Sterile (TPCS)	Thermally Processed, Commercially Sterile	Pork, chicken, turkey, and goose - all products eligible
Not Heat Treated - Shelf Stable	Ready-to-Eat (RTE) Acidified / Fermented Meat (without cooking)	Pork - all products eligible
Not Heat Treated - Shelf Stable	RTE Dried Meat	Pork - all products eligible
Not Heat Treated - Shelf Stable	Not Ready-to-Eat (NRTE) Otherwise Processed Poultry	Chicken, turkey, duck, goose, and guinea - all products eligible
Not Heat Treated - Shelf Stable	RTE Acidified / Fermented Poultry (without cooking)	Chicken, turkey, duck, goose, and guinea - all products eligible
Not Heat Treated - Shelf Stable	RTE Dried Poultry	Chicken and turkey - all products eligible
Not Heat Treated - Shelf Stable	RTE Salt-Cured Poultry	Chicken, turkey, duck, goose, and guinea - all products eligible
Heat Treated - Shelf Stable	RTE Dried Meat	Pork - all products eligible
Heat Treated - Shelf Stable	RTE Salt-Cured Meat	Pork - all products eligible
Heat Treated - Shelf Stable	NRTE Otherwise Processed Poultry	Chicken, turkey, duck, goose, and guinea - all products eligible
Heat Treated - Shelf Stable	RTE Acidified / Fermented Poultry (without cooking)	Chicken, turkey, duck, goose, and guinea - all products eligible
Heat Treated - Shelf Stable	RTE Dried Poultry	Chicken, turkey, duck, goose, and guinea - all products eligible
Heat Treated - Shelf Stable	RTE Salt-Cured Poultry	Chicken, turkey, duck, goose, and guinea - all products eligible
Heat Treated - Not Fully Cooked - Not Shelf Stable	NRTE Otherwise Processed Meat	Pork - all products eligible
Fully Cooked - Not Shelf Stable	RTE Fully-Cooked Meat	Pork - all products eligible
Fully Cooked - Not Shelf Stable	RTE Meat Fully-Cooked Without Subsequent Exposure to the Environment	Pork - all products eligible
Fully Cooked - Not Shelf Stable	RTE Fully-Cooked Poultry	Chicken, turkey, duck, goose, and guinea - all products eligible
Fully Cooked - Not Shelf Stable	RTE Poultry Fully-Cooked Without Subsequent Exposure to the Environment	Chicken, turkey, duck, goose, and guinea - all products eligible

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

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

FSIS applied a risk-based procedure that included an analysis of country performance within six equivalence components, product types and volumes, frequency of prior audit-related site visits, point-of-entry (POE) reinspection and testing results, specific oversight activities of government offices, and testing capacities of laboratories. The review process included an analysis of data collected by FSIS over a 3-year period, in addition to information obtained directly from GVI through the SRT.

Determinations concerning program effectiveness focused on performance within the following six components upon which system equivalence is based: (1) Government Oversight (e.g., Organization and Administration); (2) Government Statutory Authority and Food Safety and Other Consumer Protection Regulations (e.g., Inspection System Operation, Product Standards and Labeling, and Humane Handling); (3) Government Sanitation; (4) Government Hazard Analysis and Critical Control Point (HACCP) System; (5) Government Chemical Residue Testing Programs; and (6) Government Microbiological Testing Programs.

The FSIS auditors reviewed administrative functions at GVI headquarters, one regional office, and five district offices, in addition to government verification records from nine local inspection offices. The FSIS auditors evaluated the implementation of control systems in place that ensure the national system of inspection, verification, and enforcement is being implemented as intended.

The FSIS auditors selected a sample of nine establishments from a total of 16 establishments certified to export pork products to the United States. This included six pork slaughter and processing establishments, and three establishments conducting solely processing activities. These establishments produced raw intact pork; RTE dried pork; RTE fully-cooked pork; and TPCS pork products.

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

The FSIS auditors also audited two government laboratories (one conducting both microbiological and chemical testing, the other conducting solely chemical residue testing) to verify that these laboratories provide adequate technical support to the food safety inspection system.

Competent Authority Visits		#	Locations
Competent Authority	Central	1	• General Veterinary Inspectorate, Warsaw
	Regional Veterinary Inspectorate (RVI)	1	• RVI, Gdańsk
	District Veterinary Inspectorate (DVI)	5	• DVI, Kutno • DVI, Ostróda • DVI, Ostrzeszów • DVI, Trzebnica • DVI, Starachowice
Government Laboratories		2	• National Veterinary Research Institute (NVRI), Pulawy (chemical residue testing) • Regional Veterinary Hygiene Institution (ZHW), Łódź (microbiological and chemical residue testing)
Swine slaughter and processing establishments		6	• Establishment No. 10 02 38 02, Animex Foods Sp. zo.o. Oddzial K4 w Kutnie, Kutno • Establishment No. 14 29 02 01, Sokołów S.A. Oddział w Sokołowie Podlaskim, Sokołów Podlaski • Establishment No. 22 02 38 01, Zakłady Mięsne Skiba S. A. Oddział Ubojnia Trzody Chlewnej w Chojnicach, Chojnice • Establishment 22 03 02 07, Goodvalley Sp. z o.o., Przechlewo • Establishment 26 11 02 01, Animex Foods Spółka z ograniczoną odpowiedzialnością ul. T Chałubińskiego 8, Starachowice • Establishment No. 32 62 02 01, Animex Foods Sp. zo.o. ul. T. Chalubinskiego 8 00-613 Warszawa, Oddzial w Szczecinie, ul. Pomorska 115 B, 70-812 Szczecin
Swine processing establishments		3	• Establishment No. 02 20 03 03, Tarczyński S.A., Trzebnica • Establishment No. 28 15 40 03, Animex Foods sp. z o.o. ul. T. Chałubińskiego 8 00-613 Warszawa Oddział w Morlinach, Ostróda • Establishment No. 30 18 41 03, Profi Spółka Akcyjna, Grabów nad Prosną

FSIS performed the audit to verify that Poland's food safety inspection system meets requirements equivalent to those under the specific provisions of United States laws and regulations, in particular:

- The Federal Meat Inspection Act (21 United States Code (U.S.C.) Section 601 et seq.);
- The Humane Methods of Slaughter Act (7 U.S.C. Sections 1901-1906); and
- The Meat Inspection Regulations (9 CFR parts 301 to the end).

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

III. BACKGROUND

From January 1, 2020, to December 31, 2022, FSIS import inspectors performed 100 percent reinspection for labeling and certification on 213,002,933 pounds of meat from Poland. This included 3,608,060 pounds of TPCS pork; 6,667 pounds of RTE salt-cured pork; 50,904,957 pounds of RTE pork fully-cooked without subsequent exposure to the environment; 10,712,752 pounds of RTE fully-cooked pork; 392,996 pounds of RTE dried pork; 71,900 pounds of RTE acidified/fermented pork (without cooking); 145,489,564 pounds of raw intact pork; 414,693 pounds of raw non-intact pork; and 1,401,344 pounds of NRTE otherwise processed pork exported by Poland to the United States.

Of these amounts, additional types of inspection were performed on 21,795,135 pounds of meat products. These products included 284,378 pounds of TPCS pork; 6,173,724 pounds of RTE fully-cooked pork without subsequent exposure to the environment; 1,502,742 pounds of RTE fully-cooked pork; 65,151 pounds of RTE dried pork; 9,534 pounds of RTE acidified / fermented pork (without cooking); 13,645,791 pounds of raw intact pork; 51,770 pounds of raw non-intact pork; and 62,045 pounds of NRTE otherwise processed pork.

These additional types of inspection included physical examination, condition of container examination for TPCS products, chemical residue analysis, and testing for microbiological pathogens (*Listeria monocytogenes* [*Lm*] and *Salmonella* in RTE products). As a result of this additional testing, no lots of product were rejected for issues related to public health. An additional 303,545 pounds of pork were refused for other issues not related to public health including shipping damage, labeling or other miscellaneous issues.

FSIS conducted the previous audit of Poland remotely May 25–July 8, 2021, and did not identify any systemic findings representing an immediate threat to public health. The most recent FSIS final audit reports for Poland's food safety inspection system are available on the FSIS website at: www.fsis.usda.gov/foreign-audit-reports.

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

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

The European Commission (EC) Regulations No. 178/2002 and Regulation (EU) 2017/625 provide GVI with the legal and enforcement authority and responsibility to ensure that adulterated product is not eligible for export to the United States. Article 3 of Poland's Act of January 29, 2004, on Veterinary Inspection and Poland's Instruction of the Chief Veterinary Officer (ICVO) No. GIWhig-500-4/08 of April 1, 2008, provide instructions for implementing and documenting the official controls at the supervised establishments.

Poland's meat inspection system is organized into three levels. At the first level is GVI, which is headed by the Chief Veterinary Officer (CVO). The CVO is appointed by the Prime Minister following recommendation by the Minister of Agriculture and Rural Development. The CVO has direct authority over all levels, including government inspection personnel at the establishments certified to export to the United States.

The second level includes the Regional Veterinary Inspectorate (RVI), headed by the regional veterinary officer (RVO). There are 16 regions in Poland, and each region has between 15 and 32 districts. The third level is the District Veterinary Inspectorate (DVI), headed by the district veterinary officer (DVO). The district is responsible for all veterinary related activities, including meat inspection and periodic supervisory reviews at each establishment certified to export to the United States.

The EC regulations are the primary overarching laws for regulating meat inspection in Poland. To standardize the uniform application of requirements, inspection, and supervision in establishments certified to export to the United States, GVI published the document Requirements for Establishments in the Red Meat, Poultry, or Egg Processing Sector Approved for Export to the United States of America or Applying for Such Approval (hereafter referred to as Requirements for Establishments). In the document, GVI has mandated compliance with certain provisions consistent with those in 9 CFR Parts 317, 319, 416, 417, 430, and 431 in their entirety in order to meet FSIS import requirements.

Poland maintains definitions of adulteration (Article 14 of Regulation (EC) No. 178/2002) and misbranding (Article 8 of Regulation (EC) No. 178/2002) in accordance with European Union (EU) regulations. Additionally, under Sections 7.3.1 and 7.3.2 of the Requirements for Establishments, Poland adopts requirements consistent with the FSIS definition in 9 CFR 317.8 that provides that products are "misbranded" when their labels are false or misleading (9 CFR 317.8). Article 18 of Regulation (EC) No. 178/2002 describes the general requirements for traceability of food, feed, food-producing animals, and any other substance intended to be, or

expected to be, incorporated into a food or feed at all stages of production, processing, and distribution. Article 19 of Regulation (EC) No. 178/2002 requires establishments to immediately initiate procedures to recall food products when the products are not in compliance with food safety requirements. The FSIS auditors confirmed that each visited establishment maintains a written recall plan in accordance with these requirements.

During the audit, the FSIS auditors reviewed GVI's procedures for certification of establishments for eligibility to export to the United States. No additional establishments have been certified to export to the United States since the previous FSIS audit in 2021. Establishment certification for the United States market requires registration at DVI. Establishments must successfully implement procedures that meet FSIS import requirements for three months before they are recommended for certification. The DVO has the authority to accept or reject the application based on the outcome of the onsite inspection verification of establishment compliance with FSIS import requirements. If approved at this level, the DVO submits the application to the RVO, who delegates an RVI official to conduct an additional inspection and affirm certification. RVI then sends recommendations for the certification to GVI headquarters. GVI reviews the documents prior to updating the list of eligible establishments and then submits the list to FSIS.

The FSIS auditors verified that government inspection personnel maintain export certificates and an accountable item inventory of all issued certificates in a secure environment. A review of export certificates and accompanying documents associated with lots of product previously exported to the United States demonstrated that establishments routinely provide certifying government inspection personnel with their HACCP pre-shipment reviews, as well as the results of any product testing conducted as part of their HACCP verification procedures. The FSIS auditors' review of records indicated that government inspection personnel routinely confirm acceptable test results of official microbiological and chemical residue sampling prior to certifying product for export to the United States.

The FSIS auditors verified that supervisory veterinarians (SV) at establishments certified to export to the United States are full-time government employees of DVI. These individuals are assigned to establishments certified to export to the United States on a permanent basis, providing continuous inspection coverage on each shift, including both slaughter and processing operations. SVs are responsible for coordination and direct verification of the inspection activities performed by the appointed official veterinarians (AOV), which are contracted employees; informing the DVO of identified noncompliance, suspension of production, and reporting suspect infectious animal diseases; conducting administrative proceedings and enforcement proceedings in the event of noncompliance; controlling the implementation of the national control program for prohibited substances, including chemical residues; controlling the proper storage of veterinary stamps by the AOVs; checking the validity of the declarations of the AOVs on the absence of conflicts of interest; organizing meetings with AOVs in order to ensure consistent inspection methodology; and controlling fulfilment of inspection requirements in the entire facility, including those resulting from FSIS requirements (e.g., sanitation, HACCP, and humane handling and slaughter requirements).

Poland follows Regulation (EU) 2017/625, which requires GVI to ensure that all government inspection personnel or contracted employees are paid by the government. This regulation requires GVI to ensure that adequate financial resources are available to provide the necessary staff and other resources for official inspection controls by whatever means considered appropriate, including through general taxation or establishing fees or charges. Industry is assessed fees for meat inspection and directly pays the Polish government. Salaries for SVs and other civil service employees are in accordance with the Regulation of the Minister of Agriculture and Rural Development of 15 January 2018 and paid from the state budget as described in Article 8 of the Act of 21 November 2008 on Civil Service. Budget expenditures for wages are financed from Section 4020 of this Act. Payment of AOVs is conducted in accordance with Articles 12 and 16 of the Act of 29 January 2004 on Veterinary Inspection and is also paid from the state budget. The FSIS auditors were able to confirm direct payment of government inspection personnel by reviewing invoices maintained by each DVI's accounting department.

The FSIS auditors confirmed that all official veterinarians (OV), including SVs and AOVs, must have a Doctor of Veterinary Medicine or equivalent degree, and the official auxiliaries (OA) must have specialized experience or education that allows them to perform their assigned duties. Through Article 18 of the Veterinary Inspection Act, On Products of Animal Origin, GVI implements the provisions of Articles 17–18 of Regulation (EU) 2017/625, which state the inspection staff performing official control must receive appropriate training. Only those inspectors that have undergone training and passed an examination are eligible for employment. In addition, GVI provides ongoing training covering FSIS import requirements. The FSIS auditors verified that all assigned OVs had received specific training regarding requirements for export to the United States.

The OVs attending training sessions organized by GVI are certified as trainers of cascade training (i.e., train the trainer) and are then made responsible for delivering cascade training to government inspection personnel working in establishments certified to export to the United States. GVI customizes cascade training sessions for veterinary upper-level staff, who in turn disseminate the information among the OAs. Continuous training focuses on refreshing and adding to the knowledge and skills of government inspection personnel responsible for enforcing regulatory requirements at establishments certified to export to the United States. The FSIS auditors verified documentation of the training and written examination results at multiple levels of the inspection system (e.g., RVI, DVI, and local inspection offices) and did not identify any concerns.

GVI maintains a communication system to convey requirements related to products intended for export to the United States throughout its inspection system. The FSIS auditors verified that GVI disseminates information related to regulatory and administrative affairs to all levels of the inspection system by mail, e-mail, and by posting it on its website.

GVI also maintains administrative and technical support to operate its laboratory system through issuance of the Act on Veterinary Inspection. The FSIS auditors visited the National Veterinary Research Institute (NVRI) and Łódź Regional Veterinary Hygiene Institution (ZHW). The NVRI is a government chemical residue testing laboratory that is responsible for providing technical support and auditing of the ZHW laboratories. The NVRI also serves as a designated chemical

residue reference laboratory. The ZHW- Łódź is a government laboratory that is responsible for conducting analytical testing, including *Salmonella* on swine carcasses and in RTE products; and *Lm* in RTE products and environmental samples for official verification of products destined for export to the United States. These laboratories are accredited by the Polish Centre for Accreditation in accordance with International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Guide 17025 standards. The FSIS auditors' scope in each laboratory included review of sample receipt, timely analysis, analytical methodologies, analytical controls, analyst qualifications and trainings, proficiency testing, and recording and reporting of results. No concerns were identified.

FSIS determined that GVI organizes and administers its food safety inspection system and that government inspection personnel enforce laws and regulations governing production and export of raw and processed pork at establishments certified to export to the United States.

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

The second equivalence component the FSIS auditors reviewed was Government Statutory Authority and Food Safety and Other Consumer Protection Regulations. The system is to provide for humane handling and slaughter of livestock; ante-mortem inspection of animals; post-mortem inspection of every carcass and its parts; controls over condemned materials; controls over establishment construction, facilities, and equipment; at least once per shift inspection during processing operations; and periodic supervisory visits to official establishments.

The EU regulations mandate that the inspection authority at each EU Member State requires handling and humane slaughter of livestock. GVI adopted the Regulation (EC) No. 853/2004, Council Regulation (EC) No. 1/2005, and Council Regulation (EC) No. 1099/2009 to meet the requirement of humane handling and humane slaughter of animals. Article 34 of the Act on the Protection of Animals of August 21, 1997, indicates the regulatory requirements for the slaughter of animals at the slaughterhouses. In addition, Poland has developed humane handling verification instructions consistent with FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock, and made them available on the GVI website. The ICVO No. BP.0200.1.2.2022 describes the frequency of the government inspection personnel animal welfare verification activities. The FSIS auditors, through records reviews and interviews with government inspection personnel, confirmed that humane handling and slaughter of livestock are conducted in accordance with the requirements.

The FSIS auditors confirmed that all livestock presented for slaughter receive ante-mortem examination in accordance with Articles 17–18 of Regulation (EU) 2017/625; and Article 11 of Commission Implementing Regulation (EU) 2019/627. The ICVO No. GIWbż-500-1/13 provides guidance to the official veterinarians that carry out ante-mortem inspection activities and the ICVO No. BP.0200.1.11.2022 outlines the rules for the recordkeeping of such activities. Records review indicated that at least one government veterinarian conducts ante-mortem examination of all swine prior to slaughter. GVI provided inspection documentation to show that the AOV conducting the ante-mortem examination verified the accompanying health certificate

of the lot issued by another OV at the farm, and traceability documents identifying all the required information for the livestock. The FSIS auditors confirmed that the AOV performs ante-mortem examination at the time of unloading of swine and documents inspection observations in accordance with GVI requirements.

The FSIS auditors verified that each audited slaughter establishment is staffed with a sufficient number of government inspectors. The post-mortem inspection requirements to be performed by government inspection personnel are laid out in the repealed Regulation (EC) No. 854/2004 (Version 01/07/2013). Although Regulation (EU) 2017/625 repealed Regulation (EC) No. 854/2004, government inspection personnel follow EC-specific requirements in order to be comparable to the FSIS requirements. The FSIS auditors confirmed that post-mortem inspection is conducted on every carcass by online AOVs during all hours of slaughter. This included reviews of supervisory records to verify the implementation of inspection requirements regarding proper presentation and identification; examination of heads, viscera, and carcasses; and disposition of affected carcasses and parts.

The control of animal by-products, including condemned materials, is accomplished through the application of Regulation (EC) No. 1069/2009 and Commission Regulation (EU) 142/2011. In addition, the ICVO No. GIWpr.0200.1.12.2020 provides procedures for the supervision of animal by-products by government inspection personnel. GVI provided inspection documentation to demonstrate that relevant portions of this regulation were applied, including: (a) appropriate identification in accordance with the categories described therein, (b) segregation in specially marked or otherwise secure containers, and (c) documented final disposal of these materials at nearby rendering facilities. Receipts documenting the cost of final disposal were maintained by each establishment and routinely reviewed by government inspection personnel, as indicated by the presence of an official stamp.

Section 5, Note 7 of the Requirements for Establishments indicates that the DVO or the person(s) authorized by him or her are responsible for verifying on an ongoing basis that certified meat and meat products at any stage of their production and/or storage are separated from non-certified products. This document also includes requirements for the complete separation of establishments certified to export to the United States from those that are not certified, stating that raw materials used for the preparation of products intended for export to the United States must come from approved sources (i.e., eligible countries and establishments certified to export to the United States). The FSIS auditors verified that SVs maintain documentation to demonstrate that each shipment of source meat originated only from establishments certified to export to the United States. As indicated previously, SVs are assigned to establishments certified to export to the United States on a permanent basis, providing inspection coverage on each shift, including both during all slaughter operations and at least once per shift during processing operations.

GVI ensures that meat exports are not subject to animal health restrictions by regularly consulting the relevant sections of the APHIS website in addition to FSIS' foreign establishment eligibility table for individual countries, which also outlines current APHIS restrictions in place for these establishments. Poland is affected with ASF and has adopted the definitions of zones as determined by the EU.

The periodic supervisory reviews of official establishments are conducted monthly in accordance with GVI requirements. The supervisory reviews include an assessment of the establishment's sanitary operations and HACCP records generated and maintained by the establishment, and examination of the official inspection records. The reviews are documented using a uniform detailed checklist entitled Control Report of the Establishment Approved for Export to the United States – Form 5000-6. Supervisory reviews are conducted by direct observations and complemented with records review activities by DVIs and RVIs. Periodic visits at the establishments certified to export to the United States are conducted monthly by DVI officials, and quarterly by RVI officials.

Section 5, Note 2 of the Requirements for Establishments indicates that during the monthly supervisory visit, the DVI officials also evaluate the performance of the government inspection personnel at the establishments certified to export to the United States. This evaluation is conducted and documented using the Control Sheet of the Designated Official Veterinarian. The objective of this supervisory procedure is to evaluate all the OVs assigned to establishments that export products to the United States during a calendar year. Some of the topics that are verified during the supervisory visits are inspection staffing, work rotations, work schedules, previous training on FSIS requirements, findings of previous audits, official documentation, and knowledge of FSIS requirements.

The FSIS auditors reviewed periodic supervisory reports conducted by representatives of DVI and RVI for selected establishments for this audit. All findings are documented on GVI's Form 5000-6 as described. If findings result in noncompliance, the process ensures documentation on noncompliance records (NR) and issuance of an administrative decision instructing the establishment to correct the findings. Only when the DVI officials have verified resolution of the noncompliance is the administrative decision repealed, indicating closure of the issue. The FSIS auditors also verified that the annual evaluations of government inspection personnel were conducted by representatives of DVI as intended and documented on the Control Sheet of the Designated Official Veterinarian. The FSIS auditors confirmed that these reviews were performed and documented in accordance with GVI requirements.

FSIS analysis and onsite audit verification activities indicate that GVI continues to maintain the legal authority, a regulatory framework, and adequate verification procedures to ensure sufficient official regulatory control using statutory authority consistent with criteria established for this component.

VI. COMPONENT THREE: GOVERNMENT SANITATION

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

The EC legislation outlines the criteria and standards for good hygiene practices. The legislation also requires the CCA in each EU Member State to be responsible for enforcing the EC food

regulations by maintaining a system of official controls and other verification activities appropriate to each situation. Chapter IV of Regulation (EC) No. 853/2004 describes the requirements for sanitary dressing (slaughter hygiene) of livestock throughout the slaughter operations. Chapter IV of Regulation (EC) No. 853/2004, states that the carcass must not contain visible fecal material and that any visible contamination must be removed immediately by trimming or alternative means. Through onsite interviews, the FSIS auditors confirmed that government inspection personnel routinely verify that the establishment implements sanitary dressing procedures throughout the slaughter process in accordance with the instructions provided in Guidelines for Official Veterinarians on Checks in Slaughterhouses in Good Hygiene Practices and Animal Welfare, ICVO No. GIWbż-500-2/12 (1).

GVI follows Regulation (EC) Nos. 852/2004 and 853/2004 to maintain official controls over establishment construction, facilities, and equipment. Annexes II and III of Regulation (EC) No. 852/2004 stipulate that food premises are to be kept clean and maintained in good repair and condition. The layout, design, and construction of the establishment facilities must permit adequate maintenance to prevent conditions that can lead to insanitary conditions. Equipment and utensils must be maintained in a sanitary manner. Chapter II, Section I, Annex III of Regulation (EC) No. 853/2004 stipulates specific requirements for food business operators to ensure that the construction, layout, and equipment of slaughterhouses prevent the contamination or adulteration of meat.

GVI has adopted provisions consistent with 9 CFR 416 to meet requirements pertaining to sanitation in the establishments certified to export to the United States, which are documented in Section 3 of the Requirements for Establishments. The FSIS auditors verified through direct observation and review of records that each audited establishment has implemented Sanitation SOP requirements and has food safety programs to ensure that SPS requirements are addressed. The design of written Sanitation SOPs includes operational and pre-operational sanitation procedures and monitoring of these procedures with some defined frequencies. The FSIS auditors also reviewed a sample of NRs generated by in-plant government inspection personnel to verify that in-plant government inspection personnel had identified deficiencies during pre-operational and operational verification activities. The in-plant government inspection personnel closed the NRs after verifying the adequacy and effectiveness of the establishment's corrective actions and preventive measures. The FSIS auditors' review of this documentation determined that government inspection personnel adequately described noncompliance and verified the effectiveness of the establishment's corrective actions.

The FSIS auditors observed the in-plant government inspection personnel conducting pre-operational sanitation verification of slaughter and processing areas. The in-plant government inspection personnel's hands-on verification procedures began after the establishment personnel completed their pre-operational sanitation inspection and determined that the facility was ready for government pre-operational sanitation verification activities. Additionally, the FSIS auditors followed the offline government inspection personnel and observed inspection verification of operational sanitation procedures at all audited establishments. These verification activities included direct observation of operations and review of the establishments' associated records. The FSIS auditors confirmed that the results of the government's verification are documented on Form 5000.1-6, Weekly Verification List in the Establishment.

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

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

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

The FSIS auditors conducted interviews and reviewed documents in conjunction with direct observation at nine establishments certified to export to the United States to verify whether Poland continues to maintain equivalence with respect to the HACCP system requirements. The FSIS auditors assessed the implementation and effectiveness of GVI's requirements and verification procedures in ensuring that HACCP requirements are effectively and fully implemented in each certified establishment. The FSIS auditors observed the critical control points (CCP), and reviewed the establishment hazard analyses, flow charts, and HACCP plans. The FSIS auditors also reviewed the supporting documents and results of official veterinary verification activities to verify compliance. Each audited establishment had performed a hazard analysis and addressed the expected hazards for appropriate steps of the process. The establishments had developed flow charts that aligned with the process.

The FSIS auditors verified that OVs routinely review the establishments' implementation of their HACCP systems. GVI requires OVs to follow instructions in Section 4 of the Requirements for Establishments. This section addresses verification methodology to ensure that the design and implementation of HACCP systems in the establishments certified to export to the United States meet requirements. Any noncompliance is documented on a noncompliance record. At each audited establishment, the FSIS auditors reviewed a sample of noncompliance records to assess whether inspectors are applying methodology in accordance with instructions provided in the GVI instruction document referenced in the Government Oversight Component in this report.

The FSIS auditors reviewed the zero tolerance (i.e., for visible fecal material, ingesta, and milk) CCP at six swine slaughter and processing establishments. The auditors verified the physical CCP locations by observing government inspection personnel conducting HACCP hands-on verification activities. The FSIS auditors also verified that these establishments maintained additional controls to ensure that carcasses were chilled in a manner sufficient to prevent the outgrowth of microbial pathogens.

At those establishments producing RTE products, the FSIS auditors reviewed the HACCP programs for these processes with a special emphasis on lethality for *Salmonella* and other relevant pathogens. Establishments producing cooked pork products followed the lethality and

stabilization performance standards consistent with Appendices A and B of the FSIS Compliance Guidelines for Cooking/Cooling Meat and Poultry Products.

The audit results show that GVI verifies that operators of official establishments comply with GVI's requirement to develop, implement, and maintain HACCP programs for each processing category. The FSIS auditors identified isolated noncompliances related to the inspection verification of HACCP systems. These are noted in the individual establishment checklists provided in Appendix A of this report.

VIII. COMPONENT FIVE: GOVERNMENT CHEMICAL RESIDUE TESTING PROGRAMS

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

Regulation (EU) 2017/625, Regulation (EC) No. 178/2002, and Commission Implementing Regulation (EU) 2022/1646 mandate the development, content, implementation and reporting of a national chemical residue control program, which includes random and targeted sampling for chemical residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants. These EU legislations require Poland to annually design and submit an acceptable residue plan that follows EU guidelines.

Poland's National Residue Control Plan (NRCP) relies on the NVRI and six ZHW laboratories. According to EU legislations, Poland's NRCP provides instructions to its inspection system on method of sampling (strategy and criteria of sampling choice), type and quantity of samples, directions for performed examinations, regulatory action in case of detection of chemical residues that are prohibited or in excess of maximum residue limits (MRL), residues and medicinal products, and method of documentation of the regulatory actions taken for violative samples. Poland's NRCP specifies type and size of samples, sampling strategy, location, species, tissues, target compounds, and MRLs. Depending on the target compounds, the matrices of samples consist of muscles, liver, kidney, fat, urine, or blood. The sampling location includes farms and slaughterhouses.

The FSIS auditors' verification of this component occurred at all levels of the inspection system, which included interviews with central, regional and district offices, local inspection offices at establishments, and at the NVRI. The FSIS auditors reviewed documents, including certificates of analysis, interviewed government officials and OVs, and reviewed the chemical residue testing program to confirm that the type and size of samples, sampling method, method of analysis, and location of sample collection for the targeted compounds were consistent with the information included in GVI's SRT submission.

The FSIS auditors further confirmed that Poland's enforcement programs include: (1) procedures to document the disposition of contaminated product, (2) enforcement action against violators,

and (3) measures to prevent recurrence of the same or similar violations. Samples collected under the NRCP that are prohibited or exceed defined MRLs are deemed violative upon confirmatory analysis verification.

The following actions are taken for violative results in accordance with Article 19 of Regulation (EC) No. 178/2002, which initiates a Rapid Alert System for Food and Feed notification and an on-farm investigation conducted by a DVO for every violative result. The source farms are subject to more frequent sampling at slaughter; traceable products are removed from the market by the establishment; and if deemed a significant threat to public health, the government would conduct a recall and inform consumers.

Using GVI's information technology system, e-Klient, the FSIS auditors reviewed the government chemical residue sampling records for the six audited swine slaughter and processing establishments. This review indicated that the 2023 sampling program was being adhered to as scheduled. The FSIS auditors verified that residue samples are collected by government personnel and are shipped under inspection seal. Samples are shipped to the laboratory in accordance with protocols outlined in ICVO No. GIWpr-02010-8/2019, which includes requirements and controls for sample collection, including procedures used to ensure sample integrity and chain of custody, packaging, storage, and transportation to the laboratory.

During review of ante-mortem inspection procedures at the swine slaughter establishments, the FSIS auditors verified that an OV verifies all lots of animals are accompanied by records documenting their veterinary health examination, including proper withdrawal periods for medications used prior to slaughter.

There have not been any POE violations related to this component since the last FSIS audit in 2021. The result of the onsite audit activities indicates that GVI continues to maintain the legal authority to regulate, plan, and execute activities of the inspection system that are aimed at preventing and controlling the presence of residues of veterinary drugs and chemical contaminants in pork products intended for export to the United States.

IX. COMPONENT SIX: GOVERNMENT MICROBIOLOGICAL TESTING PROGRAMS

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

The FSIS auditors verified that GVI requires all slaughter establishments certified to export product to the United States to collect and analyze carcass samples for indicator organisms in a manner consistent with the FSIS regulatory requirements referenced in 9 CFR 310.18. The FSIS auditors verified that the six selected slaughter establishments for this audit conducted sampling for generic *Escherichia coli* at both pre-evisceration and post-chill points of the slaughter and dressing process at a frequency of one sample for every 1,000 swine carcasses. No concerns were identified.

GVI continues to implement a *Salmonella* sampling and testing program for performance standards in swine carcasses. Poland's Rules of *Salmonella* Testing in the Process of Verification Control at Pig Slaughterhouses According to USDA-FSIS describes *Salmonella* carcass sampling procedures and instructions for government inspection personnel regarding sampling frequency, and for collection sites regarding pork carcasses, randomized selection, sampling techniques, submission of samples to the designated laboratory, laboratory testing methods, interpretation of test results, and enforcement strategies. All samples are collected by government inspection personnel and analyzed at official laboratories. The FSIS auditors reviewed government sampling results from six slaughter establishments and concluded that GVI is implementing their *Salmonella* carcass testing program as intended.

The Requirements for Establishments contains provisions for control of *Lm* in post-lethality exposed (PLE) RTE products that are consistent with 9 CFR Part 430, as well as verification activities conducted by OVs and official sampling programs. According to these provisions, establishments certified to export PLE RTE pork products to the United States must comply with the requirements by employing one of the three alternatives to address *Lm.* This document provides detailed procedures and instructions to government inspection personnel on how to collect RTE product and environmental samples, including food contact and non-food contact surfaces. In addition, Poland has adopted sampling and testing programs for *Lm* and *Salmonella* in non-PLE RTE products by implementing procedures consistent with FSIS Directive 5000.1, Verifying an Establishment's Food Safety System and FSIS Directive 10,240.4, Microbial Sampling of Ready-To-Eat (RTE) Products for the FSIS Verification Testing Program. The FSIS auditors confirmed that all official sampling is organized, scheduled, and collected by OVs, and all analyses are conducted at official laboratories. Product intended for export to the United States is maintained under official control pending acceptable laboratory results. The FSIS auditors verified that the audited laboratories were implementing the analytical methodologies consistent with ISO 6579 for detection of *Salmonella* and ISO 11290-1 for detection of *Lm*.

GVI maintains a regulatory definition for TPCS product as product subjected to heat treatment under specified time and temperature parameters and placed on the market in hermetically sealed containers. Poland has adopted the FSIS regulatory requirements consistent with 9 CFR Part 431, in their entirety, and conveys these requirements to all establishments certified to export TPCS product to the United States and to government inspection personnel in the Requirements for Establishments. Government inspection personnel verify implementation of these requirements by following instructions that are consistent with FSIS Directive 7530.2, Verification Activities in Canning Operations that Choose to Follow the Canning Regulations. In the event of a processing deviation leading to contamination or adulteration of product, GVI implements the provisions in Article 19 of Regulation (EC) No. 178/2002 to include market withdrawal and recall procedures.

The FSIS auditors interviewed GVI officials regarding verification activities and reviewed related documentation addressing process schedules for products exported to the United States; procedures to address operations (e.g., posting of processes, retort traffic control, initial temperature) in thermal processing areas; incubation records; retort heat-distribution tests; and procedures to ensure proper closure of containers, including training of closure technicians.

The FSIS auditors verified that GVI maintains overall authority to implement an official microbiological sampling program organized and administered by the national government to verify that meat products intended for export to the United States are unadulterated, safe, and wholesome. There have not been any POE violations related to this component since the last FSIS audit in 2021.

X. CONCLUSIONS AND NEXT STEPS

A remote exit meeting was held May 31, 2023, with representatives from GVI. FSIS concluded that Poland's food safety inspection system is organized to provide ultimate control, supervision, and enforcement of regulatory requirements. GVI has required that establishments certified as eligible to export pork products to the United States implement sanitation requirements and a HACCP system designed to improve the safety of their exported products. In addition, GVI has implemented official microbiological and chemical residue testing programs that are organized and administered by the national government to verify its food safety inspection system. An analysis of each component did not identify any findings representing an immediate threat to public.

APPENDICES

Appendix A: Individual Foreign Establishment Audit Checklists

United States Department of Agriculture
Food Safety and Inspection Service

Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION	2. AUDIT DATE	3. ESTABLISHMENT NO.	4. NAME OF COUNTRY
Tarczynski S.A. Trzebnica	05/13/2023	02 20 03 03	Poland
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[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.	X
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.	X
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	
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	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57.	
58.	
59.	

Establishment Operations:	Pork processing.
Prepared Products:	RTE Dried Sausage and Hot-dog Products

60. Observation of the Establishment

The following non-compliances were not identified by Poland's inspection officials during the establishment review:

12. The establishment’s written sanitation standard operating procedures (SSOP) did not include specific instruction to a) ensure appropriate disposition of products that may be contaminated; and b) prevent the recurrence of direct contamination or adulteration of product.

15. The establishment’s hazard analyses addressing the production of RTE fully cooked dried sausage and hot-dog products did not accurately identify all the potential hazards associated with the cooling of product after cooking. These analyses did not address the possible germination and subsequent toxin production of spore-forming organisms such as *Clostridium* during the cooling step. While these are cured products with either a low water activity or rapid cooling step, the failure to address all potential hazards within the establishment`s hazard analysis does not meet the export requirements outlined in the General Veterinary Inspectorate’s (GVI) “Requirements for Establishments Exporting to the United States.”

15. The establishment’s written HACCP plans did not include “direct observation of monitoring activities and corrective actions” as a specific ongoing verification activity.

15. The establishment’s written HACCP plans did not include specific instruction to ensure that all four parts of corrective actions are taken in response to a deviation from a critical limit.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	05/13/2023

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
Zaklady Miesne Skiba S.A. Oddzial Ubojnia Trzody Chlewnej w Chojnicach	05/16/2023	22023801	Poland
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[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.	X
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	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

Establishment Operations:	Swine slaughter and processing.
Prepared Products:	Raw product – intact

60. Observation of the Establishment

The following non-compliances were not identified by Poland's inspection officials during the establishment review:

22) The establishment’s HACCP ongoing verification records for the calibration of process-monitoring instruments (thermometers) did not include the times of the calibration activities.

39) Gaps between the ceiling and protruding pipes in the ceiling above exposed products and food contact surfaces in the production areas.

41) Presence of beaded condensate on overhead structures in carcass coolers where exposed swine carcasses were present. No direct product adulteration observed.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	05/16/2023

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
10 02 38 02, Animex Foods Sp. zo.o. Oddzial K4 w Kutnie, Kutno	05/12/2023	10023802	Poland
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[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	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

Establishment Operations:	Swine slaughter and processing.
Prepared Products:	Raw product – intact

60. Observation of the Establishment

The following non-compliances were not identified by Poland's inspection officials during the establishment review:

39) Presence of numerous holes in the ceiling and rusted areas on overhead structures in production areas and carcass coolers where exposed product was present. No direct product adulteration observed.

40) Lighting of good quality and sufficient intensity was not provided after the post-mortem rail inspection station where in-plant inspectors perform a livestock zero tolerance verification inspection task.

41) Presence of beaded condensate on overhead structures in a cooler where exposed swine carcasses were present. No direct product adulteration observed.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	05/12/2023

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
Sokolow S.A. Oddzial w Sokolowie Podlaskim	05/22/2023	14290201	Poland
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[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	
Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements		**Part E - Other Requirements**	
10. Implementation of SSOP's, including monitoring of implementation.		36. Export	
11. Maintenance and evaluation of the effectiveness of SSOP's.		37. Import	
12. Corrective action when the SSOP's have failed to prevent direct product contamination or adulteration.		38. Establishment Grounds and Pest Control	
13. Daily records document item 10, 11 and 12 above.		39. Establishment Construction/Maintenance	X
Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements		40. Light	
14. Developed and implemented a written HACCP plan .		41. Ventilation	
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.	X	49. Government Staffing	
Part C - Economic / Wholesomeness		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Periodic Supervisory Reviews	
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
Part D - Sampling Generic *E. coli* Testing		55. Post Mortem Inspection	
27. Written Procedures		**Part G - Other Regulatory Oversight Requirements**	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57.	
Salmonella Performance Standards - Basic Requirements		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

Establishment Operations:	Swine slaughter and processing.
Prepared Products:	Raw intact pork (primals and subprimals); RTE acidified / fermented pork (without cooking) (sausage/salami - not sliced); RTE fully-cooked pork (ham, not sliced, other fully cooked not sliced product, other fully cooked sliced product, and sausage products); RTE pork fully-cooked without subsequent exposure to the environment (ham, not sliced, and sausage products)

60. Observation of the Establishment

The following non-compliances were not identified by Poland's inspection officials during the establishment review:

22) The establishment’s HACCP verification records for calibration of process-monitoring instruments (thermometers) did not include the times or the results of the verification activities.

39) Presence of several rusted areas on the overhead structures above exposed swine carcasses in the carcass coolers. No direct product contamination observed.

46) The establishment did not maintain adequate separation between swine carcasses on the main slaughter line. The FSIS auditor observed that swine carcasses, identified by the government inspection personnel for rail-out due to pathology or dressing defects, were in direct contact with other carcasses resulting in cross-contamination between carcasses.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	05/22/2023

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
Goodvalley Sp. z o.o., . Przechlewo	05/18/2023	22030207	Poland
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[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.	X
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	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

Establishment Operations:	Swine slaughter and processing.
Prepared Products:	Raw product – intact

60. Observation of the Establishment

The following non-compliances were not identified by Poland's inspection officials during the establishment review:

22) The establishment’s HACCP system did not include its return product procedures in its flowchart or resulting hazard analysis.

22) The establishment’s HACCP plan did not include "review of records" as part of its ongoing verification activities.

38) Presence of a defective seal under an exterior shipping door that did not provide a tight seal when closed and could facilitate the entrance of vermin into production areas.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	05/18/2023

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
Animex Foods Spolka z Ograniczona Odpowiedzialnoscia ul. T. Chalubinskiego 8,00 - 613 Warszawa Oddzial w Starachowicach ul. Krancowa 4 27-200 Starachowice	05/12/2023	26 11 02 01	Poland
	5. AUDIT STAFF		6. TYPE OF AUDIT
	OIEA International Audit Staff (IAS)		[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.	X
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	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	Raw-intact (pork ribs); RTE PLE sausage products

60. Observation of the Establishment

The following non-compliances were not identified by Poland's inspection officials during the establishment review:

15. The hazard analysis addressing the production of RTE products did not accurately identify all the potential hazards associated with the cooling of product after cooking. This document did not address the possible germination and subsequent toxin production of spore-forming organisms such as *Clostridium* during the cooling step. While these are cured products with a low water activity, the failure to address all potential hazards within the establishment`s hazard analysis does not meet the export requirements outlined in the General Veterinary Inspectorate's (GVI) "Requirements for Establishments Exporting to the United States."

39. A tile wall in the slaughter area presented numerous cracks and fissures which could impact cleanability of the surface and permit the accumulation of blood and other insanitary substances.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	05/12/2023

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
Animex Foods Sp. zo.o. ul. T. Chalubinskiego 8, 00-613 Warszawa Oddzial w Morlinac	05/10/2023	28154003	Poland
	5. AUDIT STAFF: OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT: [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	
Part E - Other Requirements	
36. Export	
37. Import	
38. Establishment Grounds and Pest Control	
39. Establishment Construction/Maintenance	X
40. Light	
41. Ventilation	
42. Plumbing and Sewage	
43. Water Supply	
44. Dressing Rooms/Lavatories	
45. Equipment and Utensils	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57.	
58.	
59.	

Establishment Operations:	Pork processing
Prepared Products:	RTE fully-cooked pork

60. Observation of the Establishment

The following non-compliance was not identified by Poland's inspection officials during the establishment review:

39. Presence of numerous gaps between the ceiling and protruding pipes or metal bars holding attached structures in the ceiling in RTE production areas where product was present. No direct product adulteration observed.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	05/10/2023

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
Wielkopolska Wytwornia Zywnosci Profi 63-520 Grabow n/Prosna ul. Kolejowa 3	5/18/2023	30 18 41 03	Poland
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [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.	X
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	
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	
46. Sanitary Operations	
47. Employee Hygiene	
48. Condemned Product Control	
Part F - Inspection Requirements	
49. Government Staffing	
50. Daily Inspection Coverage	
51. Periodic Supervisory Reviews	
52. Humane Handling	O
53. Animal Identification	O
54. Ante Mortem Inspection	O
55. Post Mortem Inspection	O
Part G - Other Regulatory Oversight Requirements	
56. European Community Directives	
57.	
58.	
59.	

Establishment Operations:	Pork processing
Prepared Products:	TPCS Pork Pâté

60. Observation of the Establishment

The following non-compliance was not identified by Poland's inspection officials during the establishment review:

15. The establishment hazard analysis for thermally processed, commercially sterile (TPCS) pork products did not sufficiently address the proliferation of pathogenic microorganisms during the tempering of raw materials (blocks of frozen pork). The establishment had identified the proliferation of pathogenic microorganisms as a potential hazard at this step and instituted a control point (CP) for core temperature. However, as tempering occurred at near room temperature levels, the concern in this case is proliferation of microorganisms on the surface (rather than core) of the product. Furthermore, the establishment did not maintain any further documentation (e.g., temperature correlation studies) to support that the measurement of core temperature at this step in itself would be sufficient to address the identified potential hazard.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	11/21/2019

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
Animex Foods 70-812 Szczecin ul. Pomorska 115b	05/22/2023	32 62 02 01	Poland
	5. AUDIT STAFF OIEA International Audit Staff (IAS)		6. TYPE OF AUDIT [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.	X
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.	X
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.	X
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	
28. Sample Collection/Analysis	
29. Records	
Salmonella Performance Standards - Basic Requirements	
30. Corrective Actions	
31. Reassessment	
32. Written Assurance	

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

Establishment Operations:	Pork slaughter and processing.
Prepared Products:	Raw-intact; Fully-cooked not PLE; TPCS pork

60. Observation of the Establishment

The following non-compliances were not identified by Poland's inspection officials during the establishment review:

10. Presence of beaded condensate on overhead structures in the deboning room, directly above exposed product. Although no direct product contamination was observed, the establishment took immediate corrective action to address the restoration of sanitary conditions and appropriate disposition of potentially affected product when notified of the non-compliance by the FSIS auditor.

19. A review of records documenting the "direct observation of monitoring" component of the establishment's ongoing verification procedure for CCP1 (zero tolerance for the presence of bile, ingesta, milk, and feces on swine carcasses) indicated that the procedure was not always implemented as intended. Whereas the HACCP monitoring procedure specified a visual assessment of 100 total carcasses, an instance was identified where only a portion of these carcasses was observed during the "direct observation of monitoring" activity.

22. The establishment’s ongoing verification HACCP records for the calibration of process-monitoring instruments (thermometers) did not include the times of the calibration activities.

39. Presence of defective rubber stripping under an exterior shipping door that did not provide a tight seal when closed and could facilitate the entrance of vermin into production areas.

61. AUDIT STAFF	62. DATE OF ESTABLISHMENT AUDIT
OIEA International Audit Staff (IAS)	05/22/2023

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

REPUBLIC OF POLAND
VETERINARY INSPECTION
CHIEF VETERINARY OFFICER
Paweł Niemczuk

Warsaw, 19 September 2023 r.

To:
Michelle Catlin, PhD
International Coordination Executive
Office of International Coordination
Food Safety and Inspection Service
United States Department of Agriculture
1400 Independence Avenue, SW
Washington, D. C., 20250

Our reference: BUEiWZ.071.42.2023 1
Subject: FSIS audit of Poland's meat inspection system in 2023

Dear Dr. Catlin,

with reference to the Draft Final Report of the FSIS Audit conducted in Poland on May 8-31, 2023 please be informed that I do not submit any remarks on the report.

Moreover please find attached the document Corrective Actions taken by the local veterinary authorities and establishments with reference to the non-compliances listed in Annex A to the Report. Annexes to the above-mentioned document are available at:

https://wetcloud.wetgiw.gov.pl

Yours sincerely,

Paweł Niemczuk

[signed electronically]

CC (electronic version only):
Ms. Dorota Białczak, Director of International Cooperation Department, MARD,

Annex 1

CORRECTIVE ACTIONS TAKEN BY THE LOCAL VETERINARY AUTHORITIES AND ESTABLISHMENTS WITH REFERENCE TO THE NON-COMPLIANCES LISTED IN "ANNEX A" TO THE FSIS AUDIT REPORT FROM THE AUDIT CONDUCTED IN POLAND May, 8-31, 2023

The draft report has been prepared with great understanding of the meat inspection system in Poland and of the implementation of US law by the Polish pork sector establishments approved for export to the US market.

At the same time, below I present a brief description of the corrective and preventive actions taken by the local authorities of Veterinary Inspection and establishments with reference to the non-complaiances listed in Annex A to the FSIS report. The Annexes mentioned in the text are attached in the folder “Corrective actions_annexes.”

1. Est. No 02200303, Tarczyński S.A.

Non-compliances:

12. The establishment’s written sanitation standard operating procedures (SSOP) did not include specific instruction to a) ensure appropriate disposition of products that may be contaminated; and b) prevent the recurrence of direct contamination or adulteration of product.

15. The establishment’s hazard analyses addressing the production of RTE fully cooked dried sausage and hot-dog products did not accurately identify all the potential hazards associated with the cooling of product after cooking. These analyses did not address the possible germination and subsequent toxin production of spore-forming organisms such as Clostridium during the cooling step. While these are cured products with either a low water activity or rapid cooling step, the failure to address all potential hazards within the establishment`s hazard analysis does not meet the export requirements outlined in the General Veterinary Inspectorate’s (GVI) “Requirements for Establishments Exporting to the United States.”

General Veterinary Inspectorate, 30 Wspólna Street, 00-930 Warszaw, POLAND
phone: (+48 22) 623-20-88, fax: (+48 22) 623-14-08, e-mail: wet@wetgiw.gov.pl, www.wetgiw.gov.pl

15. The establishment's written HACCP plans did not include "direct observation of monitoring activities and corrective actions" as a specific ongoing verification activity.

15. The establishment's written HACCP plans did not include specific instruction to ensure that all four parts of corrective actions are taken in response to a deviation from a critical limit.

Corrective actions:

1) The establishment documentation was updated:

- Annex 1. IS5 PS2 B4/1 Monitoring CCP1 Control of heat treatment parameters of US assortments:

• extension of point 3.3 with information contained in 9 CFR part §417.3(a)

• making point 3.4 more precise by: verifying the correctness of records, description of the method of verifying detectors, observation of employees

- Annex 2. F4 IS5 PS2 B4/1 Product Temperature Verification Sheet - Heat Treatment CCP1 USA:

• adding of description of the monitoring observation

- Annex 3. IS15 PS C3/1 Performing pre-operational and inter-operational activities USA

• development of SSOP terms to cover the product itself

• adding of point 5.2.4 - product corrective actions

- Annex 4. F4 PS A1/2 Hazard Analysis USA – Cooling down, chilling - Homogenized pork sausages (homogenized sausages, frankfurters).

• adding of hazards: definition of hazard - presence of Clostridium perfringens and Clostridium botulinum. Risk at the cooling/chilling stage after heat treatment and after packaging of pasteurized products.

2) Training was conducted for DVO in Trzebnica and supervising veterinarians in the scope of STANDARD SANITARY PROCEDURES (SPS) AND STANDARD SANITARY OPERATIONAL PROCEDURES (SSOP). The training took place on May 16, after the audit (presentation attached - Annex 5).

General Veterinary Inspectorate, 30 Wspólna Street, 00-930 Warszaw, POLAND
phone: (+48 22) 623-20-88, fax: (+48 22) 623-14-08, e-mail: wet@wetgiw.gov.pl, www.wetgiw.gov.pl

2. Est. No 22023801, Zakłady Mięsne Skiba S. A. Oddział Ubojnia Trzody Chlewnej w Chojnicach

Non-compliances:

22) The establishment's HACCP ongoing verification records for the calibration of process-monitoring instruments (thermometers) did not include the times of the calibration activities.

39) Gaps between the ceiling and protruding pipes in the ceiling above exposed products and food contact surfaces in the production areas.

41) Presence of beaded condensate on overhead structures in carcass coolers where exposed swine carcasses were present. No direct product adulteration observed.

Corrective actions:

1) Due to the detection of condensates on the piping of chiller units 1 and 3, documented with the NR form, the following actions were implemented:

- carcasses located under the above-mentioned units were subjected to separate cutting and, in accordance with the DVO decision, the meat was heat-treated; due to the fact that the condensates froze, they were removed immediately after emptying the cold chambers, then the surfaces of the cold stores were washed and disinfected;

- on May 17, 2023, the refrigeration system settings were verified, the control system settings were adjusted;

- the frequency of checking the formation of condensates in post-slaughter cold stores was increased to 1x/2 hours;

- an external company (GEA), measured the humidity in all post-slaughter cold chambers and prepared the report with the list of recommendations. In connection with the above, heated protective trays have been installed under the aggregates. Additionally, the frequency of automatic defrosting of the aggregates has been increased from 1x/6 hours to 1x/4 hours, and all cable exits to the cooling chambers were insulated.

2) In connection with the detection of structural defects: the partial lack of ceiling collars securing the cable entry to the ceiling on the ceiling pipes in the main cutting hall, and the

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presence of three unsecured holes in the wall of the meat packing compartment, the establishment took corrective actions completed on May 27-28, 2023 i.e. holes in the wall were blinded and cables going to the ceiling were secured with collars (Annexes 1-3).

3) On May 17, 2023, the template of the list "List of measurement equipment" 3/PR11 2nd edition, documenting the results of thermometer calibrations, was changed by adding a column informing about the time of calibration activities (Annex 4).

3. Est. No 10023802, Animex Foods Sp. z o.o. Oddział K4 w Kutnie

Non-compliances:

39) Presence of numerous holes in the ceiling and rusted areas on overhead structures in production areas and carcass coolers where exposed product was present. No direct product adulteration observed.

40) Lighting of good quality and sufficient intensity was not provided after the post-mortem rail inspection station where in-plant inspectors perform a livestock zero tolerance verification inspection task.

41) Presence of beaded condensate on overhead structures in a cooler where exposed swine carcasses were present. No direct product adulteration observed.

Corrective actions:

1) Action taken immediately during the audit:

- Condensation on the ceiling in the area of the second fan in the Carcass Storage Chamber No. 37

• the condensation in the indicated area was removed immediately;

• half-carcasses were removed from the area of condensation;

• a decision was made to conduct training for employees responsible for monitoring the SSOP and SPS system in the area of post-slaughter storage and to double the monitoring frequency;

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[according to the explanations of the establishment, the appearance of condensation was the result of temporary disassembly of the ventilation sleeves for periodic washing. Ventilation sleeves were reinstalled in the Carcass Storage Chamber No. 37];

2. Actions taken after the audit:

- traces of corrosion on the ceiling above the bacon line No. 14 (Cutting and Trimming Hall No. 29) were removed from the ceiling by fixing glasboards (Annex 1);

- the holes above the bacon line No. 13, 14 and 15 (Cutting and Trimming Hall No. 29) on the ceiling, after the previous lighting was uninstalled, were sealed (Annex 2);

- the holes after removing the lighting and disassembly of the pipes in the Packing Hall No. 31 were secured and the pipes from the ceiling and the flanges without the installed pipes were protected;

- the station with insufficient lighting (at the CCP 1 monitoring station when assessing the cleanliness of heads in the slaughter hall, clean part No. 60) was illuminated, lighting at head height was measured and the result was 620 lux (Annexes 3-4);

- the corroded reel on the line of clean containers was repaired, corrosion was removed and new covers on the engine on the line of clean containers were installed.

In connection with the identification of the above-mentioned non-compliances, the DVO in Kutno prepared a Control Report of the Establishment Approved for Export to the USA of May 12, 2023 and based on it the inspection report SPIWET- 00 and initiated administrative proceedings (Annexes 5-7).

4. Est. No 14290201, „SOKOŁÓW” S.A. Oddział w Sokołowie Podlaskim

Non-compliances:

22) The establishment’s HACCP verification records for calibration of process-monitoring instruments (thermometers) did not include the times or the results of the verification activities.

39) Presence of several rusted areas on the overhead structures above exposed swine carcasses in the carcass coolers. No direct product contamination observed.

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46) The establishment did not maintain adequate separation between swine carcasses on the main slaughter line. The FSIS auditor observed that swine carcasses, identified by the government inspection personnel for rail-out due to pathology or dressing defects, were in direct contact with other carcasses resulting in cross-contamination between carcasses.

Corrective actions:

1) On May 22, 2023, two NR forms were issued for the non-compliances found (1 form - structural defects / conveyor belt chain and contact of carcasses at slaughter / 1 form in relation to the verification of the measuring device) and a SPIWET report was issued as well (Annexes 1-3).

2) On May 25, 2023, administrative proceedings were initiated by DVO regarding the identified non-compliance with food law (Annex 4).

3) Sokołów Service was commissioned to calibrate the conveyors, which was performed on May 26, 2023. Additionally, a guide was installed, which slows down the half-carcasses on the turn, in order to eliminate contact between the half-carcasses as much as possible. In addition, the slaughter foremen was obliged to observe the synchronization on a daily basis during the start of the slaughter. In case of deficiencies, the foremen informs Sokołów Service in order to make corrections.

4) The control card for measuring instruments was adapted, elements required for proper verification were added. Employees responsible for verification have been informed adequately.

5) On May 29, 2023, the establishment delivered information about the implementation of the revised measuring device control sheet and the completion of the modification of the suspended conveyor belt at slaughter. The actions taken were verified by the inspection on May 30, 2023 - verification of the control records of the measuring device sheet is carried out correctly and the introduced changes in conveyor belt under ceiling prevent the carcasses from touching each other (Annexes 5-7).

6) On June 1, 2023, the DVO in Sokołów Podlaski issued an administrative decision ordering the proper technical condition of the overhead conveyor chain in the pork chilling room 061, 062, 186. On June 19, 2023, the establishment delivered information that the chain was technically inspected and brought to acceptable technical condition. The inspection carried

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out on June, 20 and August, 31, 2023 confirmed that the above-mentioned chain is in good technical condition and there is no contact between the half-carcasses, which means that the actions taken are effective and should prevent the repetition of the non-compliance (Annex 8).

5. Est. No 22030207, Goodvalley Sp. z o.o.

Non-compliances:

22) The establishment's HACCP system did not include its return product procedures in its flowchart or resulting hazard analysis.

22) The establishment's HACCP plan did not include "review of records" as part of its ongoing verification activities.

38) Presence of a defective seal under an exterior shipping door that did not provide a tight seal when closed and could facilitate the entrance of vermin into production areas.

Corrective actions:

1) As for a defective seal in the shipping ramp No. 5, temporary corrective actions were implemented (installation of the seal, discontinuation of using of the ramp) and the service was called to regulate the device (Annex 1-3).

2) With regard to the non-compliances in documentation:

- CCP 1 monitoring - the documentation of zero tolerance monitoring was carried out correctly, however, in the verification section there were no records / entries regarding the checks of documentation from the monitoring records carried out as part of the verification. In addition, the document did not include a section for preventive actions - there was only a section for introducing corrective actions in the event of carcass contamination;

- CCP 2 monitoring – measuring a temperature before carcasses are introduced for cutting - the document did not include a section for corrective and preventive actions in the event of deviations, in the verification section lack of records / entries regarding verification of documentation of monitoring

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→ corrective actions were implemented - the procedure and monitoring sheets were updated (Annexes 4-6). Quarterly checks performed by the DVO confirmed that the updated forms are used.

3) With regard to the non-compliance in the procedure of permitted product returns [the establishment have a possibility to accept the return only in the event of errors in loading, without unloading at the destination, using the same means of transport] the establishment updated the block diagrams and carried out the hazard analysis for these products; all hazards were identified (concerns the product being outside the establishment and at the entrance) a risk assessment was carried out (the documentation in Annex 7).

6. Est. No 26110201, ANIMEX FOODS Spółka z ograniczoną odpowiedzialnością, ul. T. Chałubińskiego 8, 00 - 613 Warszawa, Oddział w Starachowicach

Non-compliances:

15. The hazard analysis addressing the production of RTE products did not accurately identify all the potential hazards associated with the cooling of product after cooking. This document did not address the possible germination and subsequent toxin production of spore-forming organisms such as Clostridium during the cooling step. While these are cured products with a low water activity, the failure to address all potential hazards within the establishment`s hazard analysis does not meet the export requirements outlined in the General Veterinary Inspectorate's (GVI) "Requirements for Establishments Exporting to the United States."

39. A tile wall in the slaughter area presented numerous cracks and fissures which could impact cleanability of the surface and permit the accumulation of blood and other insanitary substances.

Corrective actions:

1. Non-compliances found during pre-operational activities were removed before the premises were released for production (Annex 1 – Pre-operational SPS Verification Sheet).

2. After the DVO in Starachowice had forwarded the comments of the FSIS auditor to the Managing Director, the establishment submitted to the DVO the new edition of Risk analysis

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for the KABANOSY USA product in which, at the cooling stage, Clostridium botulinum, Clostridium perfringens are included as microbiological hazards (Annex 2).

7. Est. No 28154003, Animex Foods sp. z o.o. ul. T. Chałubińskiego 8 00-613 Warszawa, Oddział w Morlinach

Non-compliances:

39. Presence of numerous gaps between the ceiling and protruding pipes or metal bars holding attached structures in the ceiling in RTE production areas where product was present. No direct product adulteration observed.

Corrective actions:

1) On May 10, 2023, the supervising veterinarian (NLW) issued Form 5000.1-5 Non-compliance record Form No. 2/2023 in the scope of the above non-compliance and confirmed the removal of the identified risk (Annex 1).

2) The establishment took corrective and preventive actions (Annex 2-4).:

- the holes in the ceiling, through which the water and electrical installations are run, were immediately secured with collars;

- the non-compliances found during the audit were analysed with the employees of the technical department responsible for the technical condition and proper maintenance of the production premises in the establishment.

8. Est. No 30184103, PROFI SPÓŁKA AKCYJNA

Non-compliances:

15. The establishment hazard analysis for thermally processed, commercially sterile (TPCS) pork products did not sufficiently address the proliferation of pathogenic microorganisms during the tempering of raw materials (blocks of frozen pork). The establishment had identified the proliferation of pathogenic microorganisms as a potential hazard at this step and instituted a control point (CP) for core temperature. However, as tempering occurred at near room temperature levels, the concern in this case is proliferation of microorganisms on the surface (rather than core) of the product. Furthermore, the establishment did not

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maintain any further documentation (e.g., temperature correlation studies) to support that the measurement of core temperature at this step in itself would be sufficient to address the identified potential hazard.

Corrective actions:

The HACCP team re-analyzed the risk associated with the excessive multiplication of microorganisms on the surface of thawed raw materials in the thawing process and decided to perform internal tests of temperature distribution. The team recommended possible changes in the establishment's documentation and performing system validation after changes made to the HACCP system. These activities were aimed at ensuring that conditions conducive to excessive multiplication of microorganisms would not arise during the dethawing of raw materials.

In order to demonstrate the elimination of the hazard, PROFI S.A. conducted tests to check the temperature distribution in meat raw materials intended for products for the US market, in the superficial layers of blocks thawed at a temperature of max. 20oC, and compared them with the temperatures measured at the center of the meat block, which are measured at a designated control point in the establishment. Measurements were made using an electronic Tesco comfort device that automatically records the temperature every 30 minutes, equipped with two probes, and a Testo calibrated thermometer with a probe screwed into a block.

It was assumed that during the tests the temperature in the outer layers of thawed blocks of raw meat: in case of pork shoulder, pork meat and fat should would not exceed 7oC, in case of pork liver 3oC.

The test results presented by the establishment to the DVO in Ostrzeszów showed that in the case of thawing blocks of frozen pork shoulder, pork meat and pork liver, at the time of thawing, the temperature in the surface layers of meat raw materials did not exceed the assumed temperature, i.e. 7oC for pork shoulder, pork meat pork and 3oC for pork liver, with temperatures measured in the middle of the blocks ranging from -1.7oC to +2.6oC for pork shoulder, from -0.8oC to -0.5oC for pork and from -2.0oC to -1.7oC for pork liver. The measurements inside the blocks of meat raw material were carried out within the designated control point.

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However, in the case of fat in blocks dethawed in dethawing hall, it was found that the assumed temperature of 7oC was exceeded in the superficial layers of the block, after a few hours from the start of the dethawing process, with the temperature measured in the center of the blocks at the level of 2oC.

The establishment's and the supervisory authority analysis of the temperature limits at the establishment's designated control point showed that the limits are too high for measurements inside thawed blocks of meat raw materials and should be lowered or the location where the temperature will be measured should be changed to ensure that the listed in the hazard analysis, the potential hazard will be under control.

In connection with the results of the tests carried out and the analysis of temperature limits at the control point, the establishment took the following actions:

Frozen fat in blocks are thawed in a cooling room at a temperature of +2oC to +4oC.

The temperature during thawing of meat raw materials of pork shoulder, pork meat, pork liver measured at the designated control point are measured in the surface layers of the thawed blocks with maximum limits of up to 7oC for pork shoulder, pork meat and up to 3oC for pork liver.

The Workplace Instructions were changed: I 02.01.USA 01.3 Unpacking meat raw materials from packaging and preparing them for thawing and I 02.01.USA 01.1 Unpacking raw materials from foil after thawing, taking into account the above-mentioned handling of the raw material and the method of measuring the temperature of meat raw materials.

A requirement was introduced to verify the thawing temperature of meat raw materials using the Tesco comfort device, which automatically registers the temperature level, once a quarter, and to present the results of these verifications to the DVO in Ostrzeszów.

After collecting the appropriate number of checks on the temperature of thawed meat raw materials intended for products for the US market, the establishment is going to validate the HACCP system after changes made to the system.

9. Est. No 32620201 Animex Foods Sp. z o. o. ul. T. Chałubińskiego 8 00-613 Warszawa, Oddział w Szczecinie

Non-compliances:

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10. Presence of beaded condensate on overhead structures in the deboning room, directly above exposed product. Although no direct product contamination was observed, the establishment took immediate corrective action to address the restoration of sanitary conditions and appropriate disposition of potentially affected product when notified of the non-compliance by the FSIS auditor.

19. A review of records documenting the "direct observation of monitoring" component of the establishment's ongoing verification procedure for CCP1 (zero tolerance for the presence of bile, ingesta, milk, and feces on swine carcasses) indicated that the procedure was not always implemented as intended. Whereas the HACCP monitoring procedure specified a visual assessment of 100 total carcasses, an instance was identified where only a portion of these carcasses was observed during the "direct observation of monitoring" activity.

22. The establishment’s ongoing verification HACCP records for the calibration of process-monitoring instruments (thermometers) did not include the times of the calibration activities.

39. Presence of defective rubber stripping under an exterior shipping door that did not provide a tight seal when closed and could facilitate the entrance of vermin into production areas.

Corrective actions:

1) In connection with the identified non-compliances, three non-compliance reports were issued (NR 3, NR 4, NR 5 - Annexes 1-4):

- NR 3 - the external door (loading ramp No. 12) in the Cooked Meat and Canned Products Dispatch Area is not constructed and maintained in a way that protects against the intrusion of pests such as rats, mice or insects; the leak of the door was found, consisting in the lack of a seal in the connection of the curtain with the wall, which may result in the possibility of pests entering the production area. The persons responsible in the establishment were informed about the non-compliance;

- NR 4 - in the cutting room (C24/1) condensation was found above the conveyor belt above the line of heads. The condensate was on the metal elements of the structure, above the product zone. After finding the non-compliance, production on the line was immediately stopped and the Quality Representative present during the audit was immediately informed;

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- NR 5 - non-compliance regarding the verification requirement, which concerned the direct observation of monitoring activities in CCP 1 - Final Control of Zero Tolerance for Faecal Contamination on May 8, 2023. The document "Verification Form at Critical Control Points" showed that a responsible employee did not carry out verification activities in direct observation according to the HACCP plan. The cleanliness of the carcass is monitored for 100 carcasses per hour of slaughter, and the form showed that only 5 carcasses were monitored (from 1011 to 1015).

2) On May 22, 2023, immediately after finding the non-compliance, an employee of the technical department was called, who supplemented the missing fragment of the seal in the loading ramp No. 12.

3) On May 23, 2023, the supervisory staff of the Cooked Meat and Canned Products Dispatch Area were trained on the principles of GMP and GHP, with particular emphasis on the need to take immediate action to prevent pests from entering the establishment (Annex 5).

4) On May 23, 2023, the remaining external doors located in the Cooked Meat and Canned Products Dispatch Area were inspected by employees of the technical department, during which the tightness of the remaining loading ramps was confirmed.

5) Condensation above the secured raw material was removed; the conveyor belt was washed and disinfected. The raw materials were sent for disposal as category III. Production supervision was trained in the ANX-SZ-KS-INS instruction Rules of Conduct for Removing Condensation and Water Stagnation (Annexes 6-7).

6) Employees employed as a quality management system specialists were trained in the Monitoring and Verification Procedure of CCP 1 Final Control of Zero Tolerance for Faecal Contamination (Annex 8).

7) Changes were made to the instructions and to the records of the control cards by adding, apart from the date, also the time of checking the thermometers. The corrective actions were verified during the establishment inspection and assessed as correct (Annex 9).

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