



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

Li Chunfeng  
Deputy Director General  
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Beijing, People's Republic of China

AUG 30 2013

Dear Dr. Li:

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site verification audit of the People's Republic of China (PRC) poultry processing inspection system from March 4-19, 2013. FSIS submitted the draft audit report on June 28, 2013 and PRC responded on August 29, 2013 with a few minor suggestions. The draft audit report was update with your suggestions. Enclosed is a copy of the final audit report for poultry processing inspection system. This report was published on the FSIS website (<http://www.fsis.usda.gov>) on August 30, 2013.

As all outstanding issues have been resolved, the PRC may proceed with certifying a list of poultry processing establishments as meeting the FSIS requirements. These certified establishments may then begin exporting processed (heat-treated/cooked) poultry products to the United States under the conditions established in FSIS' April 2006 final rule; i.e. only processed poultry products produced from poultry slaughtered under FSIS inspection in the United States or in a country eligible to export slaughtered poultry to the United States.

If you have any questions, please contact me at telephone number 202-720-6400, facsimile number 202-720-7990, or by e-mail at [internationalequivalence@fsis.usda.gov](mailto:internationalequivalence@fsis.usda.gov).

Sincerely,

Andreas Keller

Director  
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FINAL REPORT OF AN AUDIT CONDUCTED IN  
THE PEOPLE'S REPUBLIC OF CHINA

March 4 through 19, 2013

FSIS AUDIT OF THE FOOD SAFETY SYSTEM GOVERNING  
THE PRODUCTION OF PROCESSED POULTRY  
INTENDED FOR EXPORT TO  
THE UNITED STATES OF AMERICA

Food Safety and Inspection Service  
United States Department of Agriculture

## *Executive Summary*

This audit report describes the outcome of an on-site corrective action verification audit conducted by the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) on March 4-19, 2013, to determine whether the People's Republic of China's (PRC) food safety system governing poultry processing remains equivalent to that of the United States (U.S.), with the ability to produce products that are safe, wholesome, unadulterated, and properly labeled. This audit was necessary to assess the effectiveness of the corrective actions the PRC submitted in response to the December 1-21, 2010, verification audit. The March 2013 poultry processing audit was conducted concurrently with an equivalence audit of the PRC's poultry slaughter inspection system, for which the observed findings are included in a separate report. Representatives from the Certification and Accreditation Administration (CNCA), China Inspection and Quarantine (CIQ) Shandong province, and USDA's Foreign Agricultural Service (FAS) accompanied the FSIS auditors during the audit.

The audit focused on the ability of the Central Competent Authority (CCA), the General Administration for Quality and Safety Inspection and Quarantine (AQSIQ), to regulate processed poultry production. FSIS audited four poultry processing establishments, the CCA headquarters, and the CIQ Shandong province government offices. Determinations concerning the effectiveness of the PRC's food safety program focused on performance within the following six equivalence components: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point Systems, (5) Chemical Residue Programs, and (6) Microbiological Testing Programs.

Based on the analysis of the corrective actions submitted by the PRC in response to the 2010 audit and the results of the 2013 audit, FSIS concludes that the CCA has adequately addressed all previously identified concerns. Therefore, the PRC's processed poultry inspection system meets the equivalence components for FSIS equivalence criteria. Because all outstanding issues have been resolved, the PRC may proceed with certifying a list of establishments eligible to export processed (heat-treated/cooked) poultry products to the United States, as long as the raw poultry is sourced from countries that FSIS determined to have a poultry slaughter inspection system equivalent to the U.S. system.

FSIS submitted the draft audit report to PRC on July 1, 2013 and PRC responded on August 29, 2013 with no substantive issues with the report.

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## ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

AHVB	Animal Husbandry and Veterinary Bureau
AQSIQ	Administration of Quality and Supervision and Inspection Quarantine
CCA	Central Competent Authority (AQSIQ)
CFR	Code of Federal Regulations
CIQ	China Inspection and Quarantine Authority (Branch and Provincial)
CNAS	China National Accreditation Service for Conformity Assessment
CNCA	Certification and Accreditation Administration
<i>E. coli</i>	<i>Escherichia coli</i>
FSB	Entry-Exit Food Safety Bureau
FSL	PRC Food Safety Law
FSIS	Food Safety and Inspection Service
GB	Guobiao
HACCP	Hazard Analysis and Critical Control Point
<i>Lm</i>	<i>Listeria monocytogenes</i>
MOA	Ministry of Agriculture
MOH	Ministry of Health
PPIA	Poultry Products Inspection Act
PRC	People's Republic of China
RTE	Ready-to-Eat
<i>Salmonella spp.</i>	<i>Salmonella</i> species
SSOP	Sanitation Standard Operating Procedures
U.S.C.	United States Code

USDA

United States Department of Agriculture

VIC

Veterinarian-in-Charge

## **1. INTRODUCTION**

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) conducted an on-site corrective action verification audit of the People's Republic of China's (PRC) poultry processing inspection system on March 4-19, 2013. This audit was conducted simultaneously with an FSIS on-site equivalency verification audit of the PRC's poultry slaughter inspection system, for which the observed findings are included in a separate report.

The audit began with an entrance meeting on March 4, 2013, in Beijing with the participation of representatives from the General Administration of Quality Supervision, Inspection and Quarantine's (AQSIQ) Central Competent Authority (CCA); the Certification and Accreditation Administration (CNCA); Inspection and Quarantine (CIQ) from the Shandong province; representatives from USDA's Foreign Agricultural Service (FAS) at the United States Embassy-Beijing; and the FSIS audit team. The FAS provided assistance with translations and travel logistics.

## **2. AUDIT OBJECTIVE, SCOPE, AND METHODOLOGY**

FSIS' objective for the audit was to verify that the PRC's food safety system governing poultry processing is equivalent to that of the United States (U.S.), with the ability to produce and export products that are safe, wholesome, unadulterated, and properly labeled. In pursuit of this objective and prior to the on-site verification audit, FSIS reviewed and analyzed the proffered corrective actions and accompanying references submitted by the CCA to address findings FSIS identified in the 2010 audit as not being equivalent for each of the components of the poultry processing inspection system.

Representatives from the CNCA, CIQ-Shandong, and FAS-Beijing accompanied the FSIS auditors throughout the audit. Determinations concerning program effectiveness focused on performance within the following six equivalence components upon which system equivalence is based: (1) Government Oversight, (2) Statutory Authority and Food Safety Regulations, (3) Sanitation, (4) Hazard Analysis and Critical Control Point (HACCP) Systems, (5) Chemical Residue Programs, and (6) Microbiological Testing Programs.

FSIS auditors evaluated the implementation of management control systems developed by the PRC to ensure that poultry inspection verification and enforcement activities are standardized. The government offices audited included the CCA headquarters in Beijing, and the CIQ Shandong Provincial office along with interviews of representatives from three CIQ local offices in the Shandong province.

To verify the CCA's ability to provide consistent government oversight, FSIS visited four poultry processing establishments identified by the CCA as eligible to export poultry products to the United States. During establishment visits, FSIS placed its emphasis on the CCA's ability to provide oversight of inspection personnel through supervisory reviews conducted in accordance

with Title 9 U.S. Code of Federal Regulations (CFR), Part 381.196 and the in-plant inspectors' ability to verify industry compliance with the associated laws and regulations.

This 2013 verification audit did not include visits to the analytical laboratories because the auditors did not report systemic deficiencies with the technical support of the poultry processing inspection system in the 2010 audit report. A copy of the 2010 report can be viewed on the FSIS Web site at [www.fsis.usda.gov/OPPDE/FAR/China/China2010\\_Poultry\\_Processing.pdf](http://www.fsis.usda.gov/OPPDE/FAR/China/China2010_Poultry_Processing.pdf)

### Audit Scope Summary

Sectors Audited		No.	Locations
Competent Authority Offices	Central Authority	1	AQSIQ, Beijing
	Provincial Office	1	Shandong Entry-Exit Inspection and Quarantine Bureau, Qingdao
	Local Offices	3	Qingdao, Weifang, Dezhou
Poultry Processing Establishments		4	<ul style="list-style-type: none"> <li>• Qingdao 9-Alliance Group, Ltd</li> <li>• Zhucheng Waimao Co., Ltd</li> <li>• Weifang Legang Food Co., Ltd</li> <li>• Zhong' AO Holdings Group Co., Ltd</li> </ul>

### 3. LEGAL BASIS FOR THE AUDIT AND AUDIT STANDARDS

The audit was conducted under the specific provisions of the United States' and the PRC's laws and regulations, specifically:

U.S. Poultry Products Inspection Act, Title 21 United States Code (U.S.C.) 451, et seq.)

U.S Poultry Products Inspection Regulations regarding eligibility to import to the United States (9 CFR 381.196)

PRC Food Safety Law (FSL), 2009

PRC Administrative Rules on Quarantine of Animal (Decree No. 6), January 21, 2010

While the audit standards include applicable legislation and procedures submitted to FSIS by the PRC, this audit included a review of the proffered corrective actions submitted to FSIS by the PRC in response to the 2010 audit findings as part of the of the document review and the equivalence determination process.

#### 4. BACKGROUND

The PRC first requested an initial equivalence determination of its poultry processing inspection system in May 2004, for which FSIS conducted on-site audits in 2004. In 2006, FSIS determined that the PRC's poultry processing inspection system was equivalent to that of the U.S. The PRC was added to the list of countries eligible to export processed poultry to the United States with the following stipulation: processed heat-treated poultry products must be derived from flocks slaughtered under (1) the U.S. inspection system or (2) the inspection system of another country eligible to export slaughtered poultry products to the United States. Only such poultry would be permitted to be imported into the United States in accordance with 9 CFR § 94.6 (b), 9 CFR 381, and the Poultry Products Inspection Act (PPIA). This restriction is in place because USDA's Animal and Plant Health Inspection Service (APHIS) does not consider the PRC to be free of Highly Pathogenic Avian Influenza (HPAI) and Exotic Newcastle Disease (END). As a result of this APHIS animal disease status designation, exports to the United States of raw poultry from AI and END affected regions of the PRC are prohibited.

After conducting a comprehensive analysis of the PRC's Food Safety Law 2009 and all relevant legislation supporting the PRC's poultry processing inspection system, FSIS conducted a verification audit in 2010 to reaffirm the ongoing equivalence status of the PRC's processed poultry inspection system, which is required to reinstate their export eligibility. However, there were several findings that needed corrective actions, which are detailed in the 2010 audit report ([www.fsis.usda.gov/OPPDE/FAR/China/China2010\\_Poultry\\_Processing.pdf](http://www.fsis.usda.gov/OPPDE/FAR/China/China2010_Poultry_Processing.pdf)).

The PRC submitted corrective actions in response to the 2010 findings. In July 2011, the PRC submitted two manuals, *Inspection Quarantine Manual for Poultry Exported to America (IQMPES)* and *Microorganism Monitoring Program for Export Poultry Products (MMEPP)*. FSIS reviewed and analyzed the corrective actions and these manuals as a precursor to conducting the 2013 verification audit. During the 2013 audit, the PRC submitted revisions to the manuals, changing the name, content, and version numbers of both manuals, while improving many sections from earlier versions. The inspection manual has been changed to *Inspection Quarantine and Supervision Work for Poultry Products Exported to the U.S. Handbook* (IQSWPPEUH version 1.1). The microbe manual has been changed to *Monitoring Program for Microbes in Export Poultry Products (MPMEPP version 1.0)*.

FSIS auditors verified the adequacy of the corrective actions that the CCA had proffered in response to the 2010 audit findings and then reassessed FSIS' prior determination of equivalence for the PRC's poultry processing inspection system.

#### 5. GOVERNMENT OVERSIGHT

The first of the six components that the FSIS auditors reviewed was Government Oversight. The evaluation included a review and analysis of corrective actions the CCA submitted in response to the 2010 audit findings. Based on the analysis of the corrective actions the PRC submitted in response to the 2010 audit and the results of the verification activities conducted in the 2013

audit, FSIS concludes that the CCA has adequately addressed the identified concerns reported for this equivalence component. Therefore, the PRC's poultry processing inspection system continues to meet FSIS equivalence criteria for this component.

In the 2010 audit, the FSIS auditors confirmed that the State Council of the PRC delegates to AQSIQ the authority to administer the poultry processing inspection system for exports. AQSIQ serves as the CCA responsible for the safety of food products, promulgation of regulations on food inspection, and the sole authority to enforce the laws and regulations governing the export system. Registration and certification of import/export food enterprises is conducted by two major bureaus of the CCA: the Certification and Accreditation Administration (CNCA) and the Entry-Exit Food Safety Bureau (FSB). These bureaus verify that establishments fulfill official requirements before they grant the establishments' certification to export. Funding for CCA operations is provided by the central government and supplemented by fees assessed by the government on exported products.

The auditors also determined that the PRC Ministry of Agriculture (MOA) and the Ministry of Health (MOH) interact with the CCA to maintain appropriate regulation of the production of poultry products for export. Under this arrangement, the China National Accreditation Service for Conformity Assessment (CNAS) and the CCA, have promulgated the national standard that provides the general requirements for laboratory quality systems. FSIS auditors observed that the CCA delegates to inspection and quarantine bureaus (CIQ) located throughout the country the responsibility to implement inspection of animals and animal products and to regulate poultry processing activities at establishments producing products for export. The organizational structure for the delegation of authority has not changed since the 2010 audit.

In the 2010 audit, the auditors reported that the CCA allowed establishment-paid inspectors to conduct regular pre-operational sanitation verification at processing establishments. The use of establishment-paid inspectors conducting inspection activities could result in biased decisions leading to the export of unsafe poultry products to the United States. This arrangement constituted a conflict of interest and did not meet the requirements for ultimate control and supervision over the official activities of all employees of the system, as articulated by FSIS import regulations (9 CFR 381.196). As a corrective action, AQSIQ proposed to employ government officials to conduct all official sanitation verification.

During the 2013 audit, FSIS auditors verified that the CCA has implemented measures to ensure that employees of the PRC government perform official enforcement of regulatory requirements through cross referencing the ID badges and names of the CIQ inspectors observed performing inspection work with the following: the CIQ office employment database; an employee pay stub; training records; and a list of names of CIQ employees, including those interviewed.

The employment records demonstrated that personnel conducting inspection activities were employees of the PRC government. The CCA hires and utilizes official employees to conduct inspection duties, including sanitation. The CIQs hire official staff assigned to work at establishments producing cooked poultry products destined for the United States and retain employee records. PRC employees are issued ID cards, with or without photos, and assigned specific numbers that correlate to the respective CIQ Bureau database. Based on review of the

documentation, FSIS auditors determined that inspection personnel who are performing government oversight are employees of CIQ.

In the 2010 audit, the auditors found that the provincial CIQs oversaw the inspection system by designing and implementing inspection procedures as per PRC's national standards. The PRC's standards are in addition to those standards imposed by other importing countries. Auditors also found that CIQ procedures were not consistently applied throughout the country. FSIS concluded that this autonomy created significant variation in the application of these standards among provinces. FSIS auditors reported that a recurring finding in the PRC's system was the lack of standardized inspection procedures and thus the lack of government oversight of its inspection personnel.

In July 2011, the PRC submitted its response to this finding with two manuals, *Inspection Quarantine Manual for Poultry Exported to America (IQMPES)* and *Microorganism Monitoring Program for Export Poultry Products (MMEPP)*. The purpose of the manuals is to implement consistent inspection and verification activities of the systems across provinces that have establishments identified as eligible to export poultry products to the United States. To maintain consistency in the implementation of inspection procedures across all the provinces, the CCA trained inspectors assigned to eligible establishments on these manuals.

In the 2013 audit, the CCA identified one province (Shandong) with three branch CIQ Offices as having four eligible establishments to export poultry products to the United States. The auditors noted that the CCA revised the manuals it had provided to FSIS in the 2011 response, creating the new the *Inspection and Quarantine and Monitoring Manual for Poultry Exported to America (IQMMPEA)*, and the *Microorganism Monitoring Program for Export Poultry Products (MMEPP)*. The auditors confirmed that the CCA had disseminated the two newly revised manuals, *IQMMPEA* and *MMEPP*, to the CIQ offices and establishments and reviewed training records for inspection personnel at the provincial CIQ, and local CIQ offices. FSIS auditors confirmed consistent application of inspection procedures in all establishments.

During the 2013 audit, the PRC submitted revisions to the previous manuals, changing the name, content, and versions numbers of both manuals while improving many sections from earlier versions. The inspection manual was changed to *Inspection Quarantine and Supervision Work for Poultry products Exported to the U.S. Handbook (IQSWPPEUH version 1.1)*. The microbe manual was changed to *Monitoring Program for Microbes in Exported Poultry Products (MPMEPP version 1.0)*. Based on analysis of the current revised manuals, the auditors concluded that the CCA had standardized inspection procedures across the CIQ offices and the four establishments within the Shandong province.

In the 2010 audit, the auditors observed that the CCA provided training to the newly hired inspection personnel and developed provisions for ongoing training. However, the auditors observed that the CIQ inspectors did not demonstrate an ability to verify that implementation of Hazard Analysis and Critical Control Point (HACCP) and microbiological testing programs was consistent with PRC requirements. In response, AQSIQ provided training on HACCP, Sanitation Standard Operating Procedures (SSOP), *Listeria monocytogenes (Lm)*, and sanitation in 2012.

In the 2013 audit, the auditors interviewed CCA officials and CIQ supervisory and in-plant officials on the contents of the two manuals, inspection procedures, HACCP, sanitation, microbiological hazards for Ready-to-Eat (RTE) products, and microbiological sampling and testing procedures and practices. The FSIS auditors confirmed that inspection personnel were trained on the fundamentals of the aforementioned inspection activities. The inspection personnel were able to identify all components of the written HACCP programs maintained by the establishments, including microbiological hazards for RTE products. To further assess inspection personnel's knowledge of HACCP, RTE programs, and supervisory assessment, the auditors developed mock scenarios seeking projected actions expected for each scenario. CIQ personnel were able to successfully demonstrate the knowledge required to make decisions and take actions in accordance with the regulations of the system.

Also during the verification activities, FSIS confirmed that CIQ supervisory personnel conducted and documented periodic evaluations of employee performance. Supervisors were interviewed and asked to describe: (1) their preparation work/method prior to conducting subordinate evaluation; (2) the types of questions asked of an employee during the evaluation regarding inspection duties and knowledge of HACCP principles; (3) whether or not the evaluation included onsite observation in the performance of inspection activities and any sample questions that are asked during the observation; (4) whether or not establishment written programs and testing results are reviewed with the employee; and (5) the type of feedback (oral or written) provided to an employee. The auditors determined that the supervisors were knowledgeable on these five items.

Auditors reviewed and discussed with the supervisors a sample of a completed evaluation form, *Official Patrolling Supervision Record*. The auditor noted that the form did not contain the employee's name, but instead contained the establishment number. The auditors asked how one would know which employee was evaluated. CIQ supervisor explained that the employee's name appears in the body of the document.

Supervisors were asked to describe the procedures to handle employees who demonstrate an inability to perform inspection duties at a satisfactory level. It was explained that for an employee deemed unfit for duty, CIQ provides additional training and the employee's weaknesses are discussed. If the employee continues to be unable to perform inspection duties adequately, the person is transferred to another agency. The auditors concluded that supervisors had the ability to effectively assess a subordinate's knowledge, skills, and ability in the performance of inspection activities and had a process to remove an employee who is not able to satisfactorily perform inspection duties.

Based on the analysis of the corrective actions the PRC submitted in response to the 2010 audit and the results of the current verification activities conducted in the 2013 audit, FSIS concludes that the CCA has adequately addressed previously identified concerns. The CCA has hired government inspectors to conduct verification activities and trained those employees to perform the work. The CCA has also created and disseminated two manuals that can be uniformly implemented across all establishments exporting processed poultry to the United States. FSIS also determined that supervisory staff demonstrated the ability to effectively assess a

subordinate's knowledge, skills, and ability in the performance of inspection activities and had a process to remove an employee who was not able to satisfactorily perform official duties. Therefore, the PRC's poultry process inspection system meets FSIS equivalence criteria for this component.

## **6. STATUTORY AUTHORITY AND FOOD SAFETY REGULATIONS**

The second of the six equivalence components that FSIS auditors reviewed was Statutory Authority and Food Safety Regulations. This component pertains to the legal authority and the regulatory framework utilized by the CCA to impose requirements equivalent to those governing the system of processed poultry inspection organized and maintained in the United States. Based on analysis of the corrective action submitted by the PRC in response to the 2010 audit and the results of the current verification activities conducted in the 2013 audit, FSIS concludes that the CCA has adequately addressed previously identified concerns reported with this equivalence component. Therefore, the PRC's poultry processing inspection system meets FSIS equivalence criteria for this component.

In 2010, FSIS auditors reported that the PRC's inspection system of processed poultry provided requirements for processed poultry inspection activities; establishment construction; control over inedible and condemned materials; and daily inspection and periodic supervisory reviews of official establishments. In the 2013 audit, FSIS auditors confirmed that these requirements had not changed.

In the 2010 audit, the auditors reported that establishment-paid inspectors were conducting official pre-operational sanitation verification at processing establishments. This finding was presented to the CCA as an issue that constituted a potential conflict of interest. As a corrective action, AQSIS proposed to employ government officials to conduct all official sanitation verification activities.

In 2013, FSIS auditors verified that the CCA has implemented measures to ensure that employees of the PRC perform official enforcement of regulatory requirements through cross referencing the ID badges and names of the CIQ inspectors observed performing inspection work with CIQ office employment database, an employee pay stub, training records and a list of names of CIQ employees, including those interviewed. The employment records demonstrated that personnel conducting inspection were PRC employees. The CCA hires and utilizes official employees to conduct inspection duties, including sanitation. The CIQs hire official staff assigned to work at establishments producing cooked poultry products destined for the United States and retain employee records. PRC employees are issued ID cards, with or without photos and assigned specific numbers that correlate to the respective CIQ Bureau database. This potential conflict of interest involving establishment-paid officials conducting inspection activities has apparently been resolved.

In the 2013 audit, FSIS auditors interviewed supervisory and in-plant CIQ personnel to verify their knowledge of U.S. requirements, CCA regulations, and the two manuals, as well as to determine their ability to conduct supervisory reviews. The auditors also observed and

interviewed in-plant CIQ inspectors as they performed their assigned duties related to the verification of the adequacy of the establishments' HACCP and operational sanitation programs. During an observation assessment of inspection activities, an auditor discussed the operational cooking records with the CIQ inspectors and asked the inspectors to describe specific features within the record that aid in determining compliance and accuracy of the records. Inspectors were asked to provide the critical control point (CCP) process step, the critical limit and frequency of monitoring for each CCP of the records reviewed, and the number of CCPs within the HACCP plan. Upon returning to the establishment's conference room, the auditors reviewed with the inspectors the HACCP plan for each of the CCPs against the records reviewed during the plant tour. The inspectors were also asked to describe the components of a HACCP program and the type of training received. FSIS auditors found that supervisory and in-plant inspectors were knowledgeable about their responsibilities and had the competency to perform their duties.

A minor one-time observation occurred at one establishment regarding a design flaw of the establishment's recordkeeping form; the form did not account for additional temperature verification checks being conducted by the establishment Quality Control personnel. These additional temperature verification checks were not described in the HACCP plan. During the discussions with the inspector, he articulated measures expected to be taken by both the plant and himself regarding compliance of critical limits and product safety, which would correct the recordkeeping form and the HACCP plan to account for the additional temperature verification checks. He was able to demonstrate through the additional temperature verification checks that the product had met the critical limit and was safe. However, he failed to say he would document the noncompliance though he had earlier described as part of his training the need for documentation of the noncompliance along with the name of the noncompliance form to be used. It is unclear why he did not list this activity during the discussion; however, the inspector eventually stated he would document the noncompliance. A noncompliance record was produced for this incident.

The auditors also reviewed and discussed the revised form *Pre-Operational Inspection Official Onsite Verification of Cooked Plants*, which deals with sanitation and is generated and maintained by the CIQ officials, and verified that officials prepared detailed documentation of observed findings, which includes preventive measures by the establishment and verification notation for corrective actions and signatures of the CIQ inspectors. The CCA introduced this revised official form for completion by the CIQ inspectors conducting pre-operational sanitation inspections and verification. The establishment must complete the form *Pre-Operational Record of Cooked Plants* to document pre-operational facility reviews. During an observation assessment of sanitation activities, the inspectors were asked to describe the specific sanitation reviews conducted before and during operations, as well as specifics regarding the establishment procedures. The auditors were able to observe, in one plant, scheduled hand washing and sanitizing via a portable cart wheeled into each room by two Quality Assurance (QA) employees. Employees washed their hands at the cart, and the QA employee sprayed a sanitizer on their gloved hands before they returned to work. This activity occurred every 30 minutes. The inspector stated that poultry meat, which falls on the floor, is placed inside plastic lined inedible trash cans and only designated plant employees discard the trash into a locked chamber compartment at the end of the day.

In accordance with the analysis of the corrective action submitted by the PRC in response to the 2010 audit and the results of the verification activities conducted in the 2013 audit, FSIS concludes that the CCA has adequately addressed previously identified concerns reported with this equivalence component. Therefore, the PRC's poultry processing inspection system meets FSIS equivalence criteria for this component.

## 7. SANITATION

The third of the six equivalence components that the FSIS auditors reviewed was sanitation. FSIS requires that the inspection system provide requirements for sanitation, for sanitary handling of products, and for the development and implementation of sanitation standard operating procedures. In the 2010 audit, there were no major findings with this component and FSIS had concluded that the CCA had effectively implemented its requirements for sanitation and sanitary handling of poultry products intended for export to the United States. As a result, the PRC had met the requirements for this equivalence component.

In the 2013 audit, the auditors verified this observation and concluded that there were no concerns. Therefore, the PRC's poultry processing inspection system meets FSIS equivalence criteria for this component.

In the 2010 audit, the FSIS auditors reviewed legislation, regulations, and official instructions and confirmed that the CCA exercised its legal authority to require establishments to develop and implement sanitation programs and ensure sanitary handling of products. The auditors found that the establishments were maintaining sanitary conditions in accordance with AQSIQ Directive No. 20, 2002, *Regulation on Administration of Sanitary Registration and Enrollment for Establishments of Food for Export*, and GB/T 20094-2006, AQSIQ National Standard, *Code of Hygienic Practice for Registration on Abattoir and Meat Processing Establishments*. In 2010, the auditors observed that the CCA required establishments to conduct biannual sanitation audits, as required by the PRC regulation. During review of the biannual sanitation audit records, FSIS suggested improvements for in-depth reviews of these audits.

During the 2013 audit, FSIS auditors found no systemic issues with this component. Establishments identified, documented, and corrected sanitation deficiencies noted during pre-operational and operational inspection. The updated versions of the inspection manual had been distributed to the government offices and establishments. CIQ officials effectively verified the adequacy of the implementation of the sanitation program, documented their findings, and verified adequacy of the corrective actions. The FSIS auditors conducted onsite observations of the facilities and operational activities and concluded that, overall, the establishment's facilities were well maintained and in good repair, and sanitary controls were effectively implemented to prevent the development of insanitary conditions.

FSIS concludes that the CCA effectively implements its requirements for sanitation and sanitary handling of poultry products intended for export to the United States. As a result, the PRC meets the requirements for this equivalence component.

## 8. HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

The fourth of the six equivalence components reviewed by FSIS was HACCP systems. The inspection system must require that each official establishment develop, implement, and maintain a HACCP plan. Based on the analysis of the corrective action submitted by the PRC in response to the 2010 audit and the results of the verification activities conducted in the 2013 audit, FSIS concludes that the CCA has adequately addressed the previously identified concerns reported with regard to this equivalence component. Therefore, the PRC's poultry processing inspection system meets FSIS equivalence criteria for this component.

In the 2013 audit, the FSIS verified that the CCA had issued regulations that require each official establishment develop, implement, and maintain a HACCP system. The auditors evaluated the design and implementation of HACCP programs at four certified processing establishments. The auditors observed that the CCA exerts its legal authority by requiring operators to comply with HACCP system rules.

In the 2010 audit, FSIS conducted an onsite audit and reported to the CCA the following findings related to this component of the system:

Establishments failed to specifically identify *Listeria monocytogenes (Lm)* in their hazard analysis as a potential biological hazard reasonably likely to occur in the post-lethality processing environment. However, establishments did have sanitary controls in place controlling the post-lethality environment.

The stabilization step for heat-treated products was not identified in the hazard analysis in some establishments.

Establishments omitted processing steps in the product flowchart, thus the hazard analysis of the entire process was incomplete.

CIQ officials did not recognize inadequacies of the HACCP plans that included omitted processing steps in the flow chart, identifying missing stabilization steps, and identifying *Lm* as a potential biological hazard.

The national standard outlining requirements for HACCP systems (GB/T 19538-2004) does not require preventive measures as part of the corrective actions to deviations from critical limits.

In response, the CCA proposed that as corrective actions, it would develop and distribute manuals containing inspection procedures to ensure the uniform implementation of regulatory requirements at establishments that produce cooked poultry products for export to the United States. The CCA also indicated that it would train CIQ personnel on the contents of the manuals and would require that establishments comply with the HACCP regulations of the system.

In the 2013 audit, the auditor verified that the corrective actions proffered by the CCA to address the 2010 audit findings had been adequately implemented. Specifically, the CCA had provided to CIQ officials and establishments a copy of the updated inspection manual requiring that establishments recognize *Lm* as a biological hazard likely to occur in the post-lethality processing environment. The auditors verified that the establishment's HACCP plan did include *Lm* as a biological hazard. In the *Inspection Quarantine and Supervision Work for Poultry products Exported to the U.S. Handbook* version 1.1, (IQSWPPEUH) manual Section 3.4.2.2.2, the CCA has referenced 9 CFR 381.150 for lethality of *Salmonella* and stabilization for *Clostridium perfringens* in cooked poultry products as well as FSIS Appendix B for additional controls of *Clostridium perfringens*. Furthermore, the inspection manual requires that establishments identify, in their Sanitation Standard Operating Procedures (SSOP) or in their pre-requisite program, *Clostridium perfringens* as a pathogen to be controlled during stabilization of cooked poultry product destined for the United States. FSIS auditors conducted on-site observations and verified that recordkeeping maintained by the establishments adequately documented monitoring of cooking and cooling temperatures of products. The auditors reviewed establishments' HACCP programs and determined that all steps were included in the flow chart to permit analysis of each step in the process.

In addition, the CCA updated the inspection manual with a requirement for establishments to provide preventive measures when a deviation occurs. The auditors reviewed records for documented deficiencies and found that the establishments' stated preventive measure for the deviations was noted. These records included verification statements and the signature of the CIQ inspector verifying acceptability of the corrective action. FSIS auditors also verified that the establishments received a copy of the inspection manual.

The auditors interviewed inspection officials and reviewed records maintained by these officials assigned to provide inspection at the audited establishments. FSIS auditors found that a series of controls was in place to ensure that only raw poultry products that arrive from eligible poultry slaughter establishments are accepted by further processing establishments. Authorized establishments are poultry slaughter plants that have implemented systems to ensure that slaughtered flocks meet regulatory requirements regarding health management, husbandry practices, and compliance with drug withdrawal protocols. CIQ officials at the slaughter establishments verify during ante mortem inspection that the aforementioned requirements are met by reviewing the *Record of Veterinary Ante-Mortem Inspection of Export Poultry Processing Plant and Quarantine Certificate*. The processing establishments include a "receiving of raw materials" step in their hazard analysis and receive the *Quarantine Certificate* as proof of raw material originating from an approved source plant. Additionally, CIQ officials conduct verification activities associated with the receipt of raw products.

Based on the above analysis, FSIS concluded that the PRC's inspection system meets the requirement for this equivalence component.

## 9. CHEMICAL RESIDUE PROGRAMS

The fifth of the six equivalence components reviewed by FSIS was Chemical Residues. The inspection system must have a chemical residue control program that is organized and administered by the national government. This includes random sampling of internal organs and fat of carcasses for chemical residues as identified by the exporting country's meat and poultry inspection authorities or by FSIS as potential contaminants, as well as methods to deter recurrence of chemical residue violations.

CIQ officials verify that the raw poultry received at the poultry establishments comes from an approved source and meets the residue control program requirements. FSIS auditors verified that raw products utilized by the poultry processing establishments are derived from authorized poultry slaughter establishments that comply with the AQSIQ residue control program for exported poultry products.

This component will be further discussed in the draft audit report for initial equivalence for poultry slaughter inspection.

## 10. MICROBIOLOGICAL TESTING PROGRAMS

The last of the six equivalence components that the FSIS auditors reviewed was Microbiological Testing Programs. This component pertains to regulatory requirement for the inspection system to have a microbiological testing program, organized and administered by the national government. Both the CCA and the establishments certified for export to the United States are to employ control measures to prevent adulteration of both post-lethality exposed and non-exposed Ready-to-Eat (RTE) products by *Lm* and *Salmonella spp*. Furthermore, the CCA must conduct verification sampling and testing for *Lm*, and *Salmonella spp* in post-lethality exposed RTE products, product contact surfaces, and environmental surface samples, to verify that an establishment's control measures are effective in controlling these pathogens. Based on the analysis of the corrective actions submitted by the PRC in response to the 2010 audit and the results of the current verification activities conducted in the 2013 audit, FSIS concludes that the CCA has adequately addressed previously identified concerns reported with this equivalence component. Therefore, the PRC's China's processed poultry inspection system meets FSIS equivalence criteria for this equivalence component. The following analysis explains this decision.

In 2010 audit, FSIS conducted an audit and reported to the CCA the following findings related to this component of the system:

- The CCA needed to provide clear direction concerning the FSIS definition of RTE products as outlined in 9 CFR 430.1.
- Among the provinces audited, CIQ officials had not uniformly implemented sampling protocols to assess effective establishment control measures for *Lm* in the post-lethality

processing environment. CIQ officials did not verify that the methods used by the establishments to test the product and the environmental samples were adequate for the intended analysis of *Lm*. During the audit, the PRC discussed a zero tolerance policy for *Lm* and *Salmonella spp.* in RTE products. However, the auditors were unable to identify any specific legislation or written procedures describing a zero tolerance policy. The auditors observed that a 25g test portion was used for *Salmonella*, though FSIS requires a minimum of 325g test portion.

In response to the 2010 audit findings, the CCA proffered corrective actions to address each of the findings reported. The CCA indicated that it would develop a *Microorganism Monitoring Program for Export Poultry Products* (MMPEPP), which would specifically describe the method required to monitor microorganisms, including *Lm* in products and in the processing environment.

The CCA also indicated that in the newly issued regulations, *Listeria* and *Salmonella* were specifically mentioned as pathogens of concern to be controlled in the production of cooked products. Furthermore, the CCA stated that the MMPEPP would include the requirement for *Lm* and *Salmonella*, testing and would clearly state that there is a zero tolerance for *Lm* and *Salmonella* in cooked poultry products and require uniform monitoring of pathogen controls for *Lm* in products and the processing environment. The manual was revised to require a 325g sample for detecting *Salmonella* in cooked poultry products for export. Finally, the CCA indicated in its response that it would implement training of officials on each of the items included in the proffered corrective action.

During the 2013 audit, the auditors verified that the CCA had included the FSIS definition of RTE, as written verbatim in 9 CFR 430.1, in its *Inspection, Quarantine and Supervision Work for Poultry Products Exported to the U.S. Handbook* (IPSWPPEH) version 1.1, and that the CIQ inspectors were knowledgeable of this definition. The CCA developed the *Monitoring Program for Microbes in Export Poultry Products* (MPMEPP) version 1.0 which includes provisions for mandatory testing for *Lm* and *Salmonella* and states that there is zero tolerance for these pathogens in RTE products in Appendices 2 and 4. The auditors also verified that the CCA has updated the manual to include 325g test portion for *Salmonella* testing.

FSIS auditors, interviewed CIQ inspectors and found that they conduct product testing for *Lm* and *Salmonella* on a monthly basis. If a positive sample is found, either by government testing or by establishment testing, the CCA will initiate additional testing of food contact and environmental surfaces. The auditors verified that this is consistent with the official instructions contained in Appendix 2, Section 3.1.1.1 of the MPMEPP version 1.0. Product that is positive is either destroyed or reheated to destroy the pathogens and retested in a manner consistent with the instructions contained in Section 3.1.6 of the MPMEPP version 1.0. The CCA will also conduct an in-depth verification assessment of an establishment that produced product that tested positive for *Lm* or *Salmonella*. In addition, the establishments are required to initiate enhanced cleaning and sanitizing of the environment and food contact surfaces.

After analysis of the MPMEPP version 1.0 manual, FSIS determined that the CCA developed requirements and responsibilities for both regulatory verification and establishment

implementation of microbiological controls. Specifically, in Section 3, *Monitoring Procedures*, of the MPMEPP version 1.0, the CCA references the 10,000 series of FSIS directives covering RTE products, *Lm* testing, and intensified verification sampling, as well as 9 CFR 430.4, and PRC's GB 16869. In MPMEPP version 1.0, Appendix 2 and Appendix 4, the CCA provides instructions for control and verification of *Lm* testing of product, food contact surfaces and the environment for the CCA and establishments.

The CCA conducts three types of sampling as described in Appendix 2: regular, enhanced, and conventional. In the MPMEPP version 1.0, Section 3.1.1.1, the CCA provides instructions to inspection personnel to conduct regular product sampling on a monthly basis. When a positive result occurs from either regular product sampling or conventional sampling, the CCA initiates enhanced monitoring once every 2 weeks (Section 3.1.7.1), collecting samples from 10 FCS, 5 environment, 3 product, and 1 brine sample (if needed) while citing FSIS Directive 10,300.1 (Section 3.1.7.2).

In conventional sampling, all plants are sampled once every 4 years similar to FSIS sampling described in Directive 10,240.5. MPMEPP version 1.0, Section 3.2.3, describes the conventional frequency at which the CCA will sample food contact surfaces and processing environment. MPMEPP, Section 3.1.7.3 provides enhanced monitoring and comprehensive testing for seasonal facilities that have not undergone continuous regular sampling.

For the establishments, the CCA provides instructions in MPMEPP version 1.0, Appendix 4, regarding sampling and testing for *Lm*. In Section 2, the CCA mandates sampling of product, food contact surfaces, and environmental surfaces. Furthermore, Section 4.1 mandates that establishments control *Lm* hazards through HACCP, SSOP, or prerequisite programs. The rest of Appendix 4 provides mandates for what to do when a positive sample is detected: sampling size, frequency, sampling method, recordkeeping, and enhanced procedures. The CCA is responsible for evaluating the establishment's *Lm* control plans and verifies the adequacy of its implementation.

Based on the above analysis, FSIS concluded that the PRC's inspection system meets the requirement for this equivalence component.

## **11. EXIT MEETING**

An exit meeting was held on March 19, 2013, in Beijing with AQSIQ. At this meeting, the FSIS auditors presented their observations made during the audit.

## **12. CONCLUSIONS**

In the 2013 audit, FSIS analyzed and verified the PRC's proffered corrective actions to previous findings of systemic impact that were identified in the 2010 audit. This audit involved the following equivalence components: (1) Government Oversight; (2) Statutory Authority and Food Safety Regulations; (4) Hazard Analysis and Critical Control Point (HACCP) Systems; and (6) Microbiological Testing Programs. FSIS found that the PRC adequately addressed each of

the findings. Component 5, Chemical Residue Programs, is discussed in the draft audit report for initial equivalence for poultry slaughter inspection.

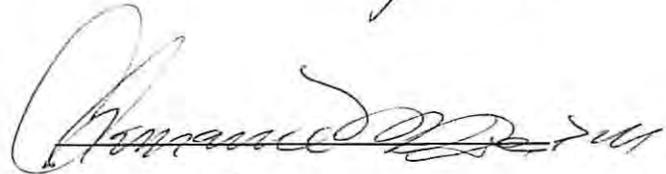
Based on the analysis of the corrective actions submitted by the PRC in response to the 2010 audit and the results of the verification activities conducted in the 2013 audit, FSIS concludes that the CCA has adequately addressed all previously identified concerns reported. Therefore, the PRC's poultry processing inspection system meets FSIS equivalence criteria for all system components. With all outstanding issues resolved, the PRC may certify a list of establishments eligible to export processed (heat-treated/cooked) poultry products to the United States, as long as the raw poultry is sourced from countries that have been determined by FSIS to have an equivalent poultry slaughter inspection system.

**Audit Team:**

Francisco Gonzalez, DVM  
Senior Program Auditor  
(On-site auditor)



Charmaine McGee, DVM  
Export Program Staff  
(On-site auditor)



Priya Kadam, Ph.D  
Senior Microbiologist/Senior Equivalence Officer



**13. ATTACHMENTS TO THE AUDIT REPORT**

None at this time.

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Zhucheng Waimao Co., LTD/Shandong Delicate Food Co., Ltd. East end of Mizhou Road Zhucheng, Shandong, PRC	2. AUDIT DATE March 8, 2013	3. ESTABLISHMENT NO. 3700/03409	4. NAME OF COUNTRY People's Republic of China
	5. NAME OF AUDITOR(S) Drs. Gonzalez and McGee		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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 SSOPs 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
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

## 60. Observation of the Establishment

## Processing Establishment No. 3700/03409

FSIS auditors observed electrical cords bundled on top of several workstations' lamps, one overhead electrical outlet with exposed wires and frayed conduit that had been rendered difficult to clean.

FSIS auditors received copies of documented corrective actions and official verification prior to the completion of the audit. The evidence provided demonstrated an effective corrective action and adequate official verification.

61. NAME OF AUDITOR

Drs. Gonzalez and McGee

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Weifang Legang Food Co., Ltd. Honghe Town of Changle County Shandong, PRC	2. AUDIT DATE March/12/2013	3. ESTABLISHMENT NO. 3700/03435	4. NAME OF COUNTRY People's Republic of China
	5. NAME OF AUDITOR(S) Drs. Gonzalez and McGee		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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 SSOPs 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
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

## 60. Observation of the Establishment

Processing Establishment No. 3700/03435

39. FSIS auditors identified structural deficiencies that included accumulation of residue on the outer surfaces of a tumbler in the raw product area and coils of electrical cords on workstation lamps in the cooked product area.

FSIS auditors received copies of documented corrective actions and official verification prior to the completion of the audit. The evidence provided demonstrated an effective corrective action and adequate official verification.

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61. NAME OF AUDITOR

Drs. Gonzalez and McGee

62. AUDITOR SIGNATURE AND DATE

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United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Zhongao Holdings Group Co., Ltd No. 1999 Central Street Qingyun County Shandong, PRC	2. AUDIT DATE March/14/2013	3. ESTABLISHMENT NO. 3700/03439	4. NAME OF COUNTRY People's Republic of China
	5. NAME OF AUDITOR(S) Drs. Gonzalez and McGee		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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 SSOPs 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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Processing Establishment No. 3700/03439

The sanitary conditions and general operations of the establishment currently meet FSIS's requirements and appear to comply with the PRC requirements.

61. NAME OF AUDITOR  
Drs. Gonzalez and McGee

62. AUDITOR SIGNATURE AND DATE

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Qingdao Nine-Alliance Group Co., Ltd. Weihai West Road Laixi, Qingdao Shandong, PRC	2. AUDIT DATE March 7, 2013	3. ESTABLISHMENT NO. 3700/03447	4. NAME OF COUNTRY People's Republic of China
	5. NAME OF AUDITOR(S) Drs. Gonzalez and McGee		6. TYPE OF AUDIT <input checked="" type="checkbox"/> ON-SITE AUDIT <input type="checkbox"/> DOCUMENT AUDIT

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

Part A - Sanitation Standard Operating Procedures (SSOP) Basic Requirements	Audit Results	Part D - Continued Economic Sampling	Audit Results
7. Written SSOP		33. Scheduled Sample	
8. Records documenting implementation.		34. Species Testing	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
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 SSOPs 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
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		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	
<b>Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements</b>		45. Equipment and Utensils	
18. Monitoring of HACCP plan.		46. Sanitary Operations	
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<b>Part F - Inspection Requirements</b>	
22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences.		49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	
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	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	
29. Records		57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions		59.	
31. Reassessment			
32. Written Assurance			

60. Observation of the Establishment

Processing Establishment No. 3700/03447

39. Establishment Construction/Maintenance

FSIS auditors observed several long electrical cords bundled with pieces of wire and repaired with electrical tape that rendered them difficult to clean. There was also one frayed electrical cord near exposed frozen RTE products. CIQ officials documented these structural deficiencies and ensured implementation of adequate corrective action within 48 hours.

An air-line water trap was not adequately closed and sealed causing its contents to spray in the surrounding area.

FSIS auditors received copies of documented corrective actions and official verification prior to the completion of the audit. The evidence provided demonstrated an effective corrective action and adequate official verification.

61. NAME OF AUDITOR

Drs. Gonzalez and McGee

62. AUDITOR SIGNATURE AND DATE