



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

NOV 14 2005

Mr. Cheng Fang
Deputy Chief Administrator
Certification and Accreditation Administration
9 Madian East Road, Tower B
Haidian District, Beijing 100088
P.R. China

Dear Mr. Cheng:

This letter transmits the final report of the Food Safety and Inspection Service's audit of China's poultry inspection system conducted July 27 through August 12, 2005. Comments from the government of China have been included as an attachment to the final report.

If you have any questions or need additional information regarding the enclosed report, please contact me by telephone at 202-720-3781, by fax at 202-690-4040, or by electronic mail at sally.white@fsis.usda.gov.

Sincerely,

for Sally White
Director
International Equivalence Staff
Office of International Affairs

Enclosure

cc:

Maurice House, Minister Counselor, PRC
Casey Bean, Agricultural Attaché, PRC
Zhao Baoqing, First Secretary, Embassy of the PRC
Barbara Masters, Administrator, FSIS
Linda Swacina, Executive Director, FSIA, OIA
Susan Schayes, FAS Area Officer
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Bob Macke, Assistant Deputy Administrator, ITP, FAS
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Mary Stanley, Director, IID, OIA
Armia Tawadrous, Director, FSIS CODEX, OIA
Todd Furey, IES
Country File

FINAL

NOV 04 2005

FINAL REPORT OF AN INITIAL EQUIVALENCE AUDIT CARRIED
OUT IN CHINA COVERING CHINA'S POULTRY SLAUGHTER
INSPECTION SYSTEM

JULY 27 THROUGH AUGUST 12, 2005

Food Safety and Inspection Service
United States Department of Agriculture

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ABBREVIATIONS AND SPECIAL TERMS USED IN THE REPORT

| | |
|-------------------|--|
| AQSIQ | General Administration of Quality Supervision, Inspection and Quarantine |
| CCA | Central Competent Authority [AQSIQ] |
| CIQ | Provincial Branches of AQSIQ |
| CNCA | Certification and Accreditation Administration, AQSIQ |
| DVO | District Veterinary Officer |
| <i>E. coli</i> | <i>Escherichia coli</i> |
| FSB | Food Safety Bureau, AQSIQ |
| FSIS | Food Safety and Inspection Service |
| MoA | Ministry of Agriculture |
| PR/HACCP | Pathogen Reduction/Hazard Analysis and Critical Control Point Systems |
| <i>Salmonella</i> | <i>Salmonella</i> species |
| SSOP | Sanitation Standard Operating Procedures |

1. INTRODUCTION

The audit took place in China from July 27 through August 12, 2005.

An opening meeting was held on July 27, 2005 in Beijing with the Central Competent Authority (CCA). At this meeting, the lead auditor confirmed the objective and scope of the audit, the auditors' itineraries, and requested additional information needed to complete the audit of China's poultry slaughter inspection system.

The auditors were accompanied during the entire audit by representatives from the CCA and representatives from the regional and local inspection offices.

2. OBJECTIVE OF THE AUDIT

This audit was an initial equivalence audit. The objective of the audit was to evaluate the performance of the CCA with respect to controls over the slaughter establishments proposed for certification by the CCA as eligible to export poultry products to the United States.

In pursuit of the objective, the following sites were visited: the headquarters of the CCA, three provincial entry-exit inspection and quarantine bureau (CIQ) offices and four poultry slaughter establishments.

| Competent Authority Visits | | | Comments |
|----------------------------------|---------|---|---------------------|
| Competent Authority | Central | 1 | |
| | Local | 3 | Establishment level |
| Laboratories | | 0 | |
| Poultry Slaughter Establishments | | 4 | |

3. PROTOCOL

This on-site audit was conducted in three parts. One part involved visits with CCA officials to discuss oversight programs and practices, including enforcement activities. The second part involved an audit of a selection of records in the country's inspection headquarters or regional offices. The third part involved on-site visits to four poultry slaughter establishments.

Program effectiveness determinations of China's inspection system focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP), (2) animal disease controls, (3) slaughter controls, including the implementation and operation of HACCP programs and a testing program for generic *E. coli*, (4) residue controls, and (5) enforcement controls, including

a testing program for *Salmonella*. China's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditor also assessed how inspection services are carried out by China and determined if establishment and inspection system controls were in place to ensure the production of poultry products that are safe, unadulterated and properly labeled.

At the opening meeting, the lead auditor explained that China's poultry inspection system would be audited against two standards: (1) FSIS regulatory requirements and (2) any equivalence determinations made for China. FSIS requirements include, among other things, daily inspection in all certified establishments, monthly supervisory visits to certified establishments, humane handling and slaughter of animals, ante-mortem inspection of animals and post-mortem inspection of carcasses and parts, the handling and disposal of inedible and condemned materials, sanitation of facilities and equipment, residue testing, species verification, and requirements for HACCP, SSOP, and testing for generic *E. coli* and *Salmonella*.

Equivalence determinations are those that have been made by FSIS for China under provisions of the Sanitary and Phytosanitary Agreement. At this time, FSIS is currently reviewing equivalence determination requests submitted by China.

4. LEGAL BASIS FOR THE AUDIT

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

- The Poultry Products Inspection Act (21 U.S.C. 451 et seq.)
- Poultry Products Inspection Regulations (9 CFR Part 381]

5. SUMMARY OF PREVIOUS AUDITS

This is the second on-site audit of China's poultry slaughter inspection system.

During the first audit, the FSIS auditor found:

Sanitation Controls

- In one establishment, during preoperational sanitation, grease, blood, fat, pieces of dry meat and foreign particles were observed on product contact areas of conveyor belts, plastic containers.
- In one establishment, over product dripping condensation was observed in several areas.
- In two establishments, edible and inedible containers were not segregated in the cut-up area.

- In three establishments, there was inadequate light at the re-inspection stations.
- In one establishment, tables were missing at the re-inspection station.
- In three establishments, the conveyor belt used for edible product transfer had several deep cuts.
- In one establishment, a rusty pipe with flaking paint was observed over the exposed chiller.
- In one establishment, product contact areas were continuously wiped off by a dirty cloth which was not cleaned.
- In one establishment, non-food contact surfaces of processing tables were observed with heavy grease in the raw meat area.
- In two establishments, employees designated for floor duties were handling edible product duties.

Slaughter/Processing Controls

- In one establishment, monitoring activities were not adequately addressed in the HACCP plan.
- In one establishment, generic *E. coli* testing on whole birds was not being performed.
- In one establishment, no testing for *Salmonella* species on whole birds was performed.
- In two establishments, there was no pre-chill or post-chill operation performed by the establishment employees and/or inspection service.

6. MAIN FINDINGS

6.1 Government Oversight

The primary laws for regulating poultry inspection and entry-exit inspection and quarantine in China are the *Food Hygiene Law of the PRC*; *Law of the PRC on Import and Export Commodity Inspection*; *Law of the PRC on the Entry and Exit Animal and Plant Quarantine*; *Law of the PRC on Animal Disease Prevention*; and *Product Quality Law of the PRC*. These laws provide the operational and regulatory authorities to carry out China's poultry inspection system.

6.1.1 CCA Control Systems

According to relevant Chinese laws and regulations, currently there are three governmental bodies involved in animal health, animal and plant protection and food

safety. These three ministries are: the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), the Ministry of Agriculture (MoA), and the Ministry of Health (MoH).

AQSIQ is a law-enforcement administrative part of the State Council in the field of quality, metrology, entry-exit commodities inspection, entry-exit health quarantine, entry-exit animal and plant quarantine, certification and accreditation and standardization. AQSIQ has 35 CIQ bureaus which are responsible for the entry-exit quarantine and quality inspection of animals and animal products, issuing health certificates and control of food processing plants producing products for export. Within AQSIQ there are two responsible sections for food safety.

The first is the Entry-Exit Food Safety Bureau (FSB). The FSB executes the supervision and implementation of the food safety regulations in China.

The second is the Certification and Accreditation Administration (CNCA). CNCA is authorized to exercise administrative responsibilities by undertaking unified management, supervision and overall coordination of certification and accreditation activities throughout China.

MoA, Bureau of Animal Production and Health is responsible for animal health and veterinary public health in China. Its scope of responsibility includes animal disease prevention and diagnosis, epidemic control and notification, veterinary drug management, residue control and quarantine of livestock and poultry and their products.

Finally, MoH is comprised of health supervision centers, health administrative departments and China's Center for Disease Control (CDC). The health supervision centers are administrative, executive bodies, while China's CDC is responsible for technical support. The MoH plays a crucial role in the food safety area. MoH is responsible for drafting regulations and standards related to the hygienic code of practice of food manufacturing.

6.1.2 Ultimate Control and Supervision

The *Law of the People's Republic of China on Import and Export Commodity Inspection*, states that AQSIQ is the law-enforcement administrative part of the state council in the field of quality, metrology, entry-exit commodities inspection, entry-exit health quarantine, entry-exit animal and plant quarantine, certification and accreditation and standardization.

During this audit, FSIS found that in all four establishments, ante-mortem inspection, post-mortem inspection and carcass disposition were performed by establishment veterinarians.

6.1.3 Assignment of Competent, Qualified Inspectors

During 2005, AQSIQ has sent four representatives to participate in FSIS training seminars in the United States. Upon their return, they have used course material to provide further training to their colleagues.

In addition, China has conducted three separate training sessions during 2005 throughout the country. The focus of the sessions has been all FSIS laws and regulations.

The CIQ does employ official veterinarians in each establishment. Their role in the establishment is oversight of the complete operation. However, FSIS found that, in all four establishments, ante-mortem inspection, post-mortem inspection and carcass disposition were performed by establishment veterinarians.

6.1.4 Authority and Responsibility to Enforce the Laws

AQSIQ has the authority and responsibility to enforce the laws. AQSIQ has 35 CIQ bureaus nationwide. These 35 CIQ bureaus are responsible for the entry-exit quarantine and quality inspection of animals and animal products, issuing health certificates and control of food processing plants producing products for export.

6.1.5 Adequate Administrative and Technical Support

AQSIQ appears to have adequate administrative and technical support to support its inspection system.

6.2 Headquarters Audit

The auditor conducted a review of inspection system documents at Headquarters. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that will be certified to export to the United States
- Training records for inspectors and laboratory personnel.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sanitation, slaughter and processing inspection procedures and standards.
- Enforcement records, including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

No concerns arose as a result the examination of these documents.

6.3.1 Audit of Regional and Local Inspection Sites

The auditor visited three local CIQ inspection offices. No concerns arose as a result of these visits.

7. ESTABLISHMENT AUDITS

The FSIS auditor visited a total of four slaughter establishments.

Specific deficiencies are noted in the attached individual establishment review forms.

8. LABORATORY AUDITS

During this audit, no microbiological or residue laboratories were visited.

9. SANITATION CONTROLS

As stated earlier, the FSIS auditor focuses on five areas of risk to assess China's poultry slaughter inspection system. The first of these risk areas that the FSIS auditor reviewed was Sanitation Controls.

Based on the on-site audits of establishments, and except as noted below, China's inspection system had controls in place for SSOP programs, all aspects of facility and equipment sanitation, the prevention of actual or potential instances of product cross-contamination, good personal hygiene practices, and good product handling and storage practices.

In addition, and except as noted below, China's inspection system had controls in place for water potability records, chlorination procedures, back-siphonage prevention, separation of operations, temperature control, work space, ventilation, ante-mortem facilities, welfare facilities, and outside premises.

9.1 SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the United States' domestic inspection program. The SSOP in the four establishments were found to meet the basic FSIS regulatory requirements. However, the following deficiencies were noted for SSOP ongoing requirements:

- In one establishment, dripping condensation in the over-product contact area (cut-up tables) and in the hallways in front of the cold stores was observed during the pre-operational sanitation.

9.2 Sanitation Performance Standards

The following deficiency was noted:

- In one establishment, outside rodent control traps are regularly removed from their sites during the day's operation and moved back to their position after the end of the shift. This practice might allow rodents to enter to the establishment through areas with inadequate sealing and door closure, such as the product transport area.

10. ANIMAL DISEASE CONTROLS

The second of the five risk areas that the FSIS auditor reviewed was Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. The auditor determined that China's inspection system had adequate controls in place. No deficiencies were noted.

China is affected with Avian Influenza subtype H5N1.

11. SLAUGHTER/PROCESSING CONTROLS

The third of the five risk areas that the FSIS auditor reviewed was Slaughter/Processing Controls. The controls include the following areas: ante-mortem inspection procedures; humane handling and humane slaughter; ante-mortem disposition; post-mortem inspection procedures; and post-mortem disposition.

The controls also include the implementation of HACCP systems in all establishments and implementation of a generic *E. coli* testing program in slaughter establishments.

11.1 Humane Handling and Humane Slaughter

No deficiencies were noted.

11.2 HACCP Implementation.

All establishments approved to export poultry products to the United States are required to have developed and adequately implemented a HACCP program. Each of these programs was evaluated according to the criteria employed in the United States' domestic inspection program.

The HACCP programs were reviewed during the on-site audits of the four establishments. Three establishments had adequately implemented the HACCP basic requirements.

In one establishment, the following deficiencies were noted:

- In the HACCP plan, one CCP included biological and chemical hazards as well as the corrective action for both hazards. A CCP cannot control two hazards at once. All hazards should be identified individually.
- In the HACCP plan, the verification procedure did not identify the on-site verification of the monitoring activity.

11.3 Testing for Generic *E. coli*

China has adopted the FSIS regulatory requirements for generic *E. coli* testing.

All of the establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing and were evaluated according to the criteria employed in the United States' domestic inspection program.

Testing for generic *E. coli* was properly conducted in all four poultry slaughter establishments.

11.4 Testing of Ready to Eat Products

Since this was an audit of China's poultry slaughter inspection system, FSIS did not review any establishments that produce ready-to-eat products.

12. RESIDUE CONTROLS

The fourth of the five risk areas that the FSIS auditor reviewed was Residue Controls. These controls include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

No labs were reviewed during this audit. However, FSIS is reviewing the submission by AQSIQ for an equivalence determination of their residue program. The review is still in progress.

13. ENFORCEMENT CONTROLS

The fifth of the five risk areas that the FSIS auditor reviewed was Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella* in raw product.

13.1 Daily Inspection

Inspection was being conducted daily in all four establishments.

13.2 Testing for *Salmonella* on Raw Product

China has adopted the FSIS regulatory requirements for testing for *Salmonella*.

All of the establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing and were evaluated according to the criteria employed in the United States' domestic inspection program.

Testing for *Salmonella* was properly conducted in all four poultry slaughter establishments.

13.3 Species Verification

Since this was an audit of China's poultry slaughter inspection system, species verification was not required.

13.4 Monthly Reviews

During this audit, monthly supervisory reviews were being performed and documented as required.

13.5 Inspection System Controls

The CCA did have controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the United States with product intended for the domestic market.

During the audit, FSIS found that in all four establishments, ante-mortem inspection, post-mortem inspection and disposition were performed by establishment veterinarians.

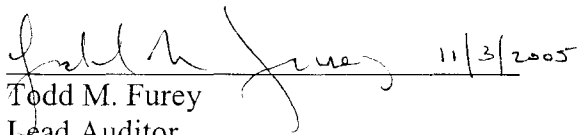
Controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other countries for further processing.

Lastly, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

14. CLOSING MEETING

A closing meeting was held on August 12, 2005 in Beijing, China with the CCA. At this meeting, the preliminary audit findings were presented by the lead auditor.

The CCA understood and accepted the findings.


Todd M. Furey
Lead Auditor

15. ATTACHMENTS

Individual Foreign Establishment Audit Forms

Foreign Country Response to Draft Final Audit Report (when it becomes available)

Foreign Establishment Audit Checklist

| | | | |
|--|---------------------------------|---|-----------------------------|
| 1. ESTABLISHMENT NAME AND LOCATION Beijing Huadu Broiler Co, Xiao Tangshan, Changping, Beijing, China | 2. AUDIT DATE 07 - 29 - 2005 | 3. ESTABLISHMENT NO. 1100/03013 | 4. NAME OF COUNTRY China |
| 5. NAME OF AUDITOR(S) Dr. Oto Urban | | 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 | O |
| 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 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 | |
| Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements | | 40. Light | |
| 14. Developed and implemented a written HACCP plan. | | 41. Ventilation | |
| 15. Contents of the HACCP list the food safety hazards, critical control points, critical limits, procedures, corrective actions. | | 42. Plumbing and Sewage | |
| 16. Records documenting implementation and monitoring of the HACCP plan. | | 43. Water Supply | |
| 17. The HACCP plan is signed and dated by the responsible establishment individual. | | 44. Dressing Rooms/Lavatories | |
| Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements | | 45. Equipment and Utensils | |
| 18. Monitoring of HACCP plan. | | 46. Sanitary Operations | |
| 19. Verification and validation of HACCP plan. | | 47. Employee Hygiene | |
| 20. Corrective action written in HACCP plan. | | 48. Condemned Product Control | |
| 21. Reassessed adequacy of the HACCP plan. | | Part F - Inspection Requirements | |
| 22. Records documenting the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. | | 49. Government Staffing | X |
| Part C - Economic / Wholesomeness | | 50. Daily Inspection Coverage | |
| 23. Labeling - Product Standards | O | 51. Enforcement | X |
| 24. Labeling - Net Weights | O | 52. Humane Handling | |
| 25. General Labeling | O | 53. Animal Identification | |
| 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture) | O | 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 | O |
| 29. Records | | 57. Monthly Review | |
| Salmonella Performance Standards - Basic Requirements | | 58. | |
| 30. Corrective Actions | | 59. | |
| 31. Reassessment | | | |
| 32. Written Assurance | | | |

60. Observation of the Establishment

China, Est. 1100/03013

7-29-05

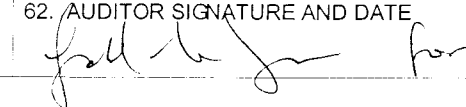
49/51 Post-mortem inspection has been performed by establishment veterinarians. Disposition has also been performed by the establishment veterinarians 9 CFR 381.34 (a), and 381.37 (a).

* If this establishment was certified to export to U.S., this establishment would be immediately delisted.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE



11/3/2005

Foreign Establishment Audit Checklist

| | | | |
|---|---------------------------------|---|-----------------------------|
| 1. ESTABLISHMENT NAME AND LOCATION Jilin Deda Co., Ltd. Meat, hanqian Street Dehui City Jilin Province China | 2. AUDIT DATE 08 - 05 - 2005 | 3. ESTABLISHMENT NO. 2200/03026 | 4. NAME OF COUNTRY China |
| 5. NAME OF AUDITOR(S) Dr. Oto Urban | | 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.

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

60. Observation of the Establishment

China, Est. 2200/03026

8-5-05

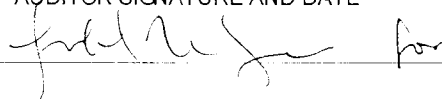
49/51 Ante-mortem and post-mortem inspection have been performed by establishment veterinarians. Disposition has also been performed by the establishment veterinarians 9 CFR 381.34 (a), and 381.37 (a).

* If this establishment was certified to export to U.S., this establishment would be immediately delisted.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

 for 11/3/2005

Foreign Establishment Audit Checklist

| | | | |
|---|---------------------------------|---|-----------------------------|
| 1. ESTABLISHMENT NAME AND LOCATION Qingdao Nine – Alliance Group Co., Ltd, Laixi, Qingdao, China | 2. AUDIT DATE 08 - 02 - 2005 | 3. ESTABLISHMENT NO. 3700/03359 | 4. NAME OF COUNTRY China |
| 5. NAME OF AUDITOR(S) Dr. Oto Urban | | 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 | |
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| 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 | X |
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| Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements | | 40. Light | |
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| 16. Records documenting implementation and monitoring of the HACCP plan. | | 43. Water Supply | |
| 17. The HACCP plan is signed and dated by the responsible establishment individual. | | 44. Dressing Rooms/Lavatories | |
| Hazard Analysis and Critical Control Point (HACCP) Systems - Ongoing Requirements | | 45. Equipment and Utensils | |
| 18. Monitoring of HACCP plan. | | 46. Sanitary Operations | |
| 19. Verification and validation of HACCP plan. | | 47. Employee Hygiene | |
| 20. Corrective action written in HACCP plan. | | 48. Condemned Product Control | |
| 21. Reassessed adequacy of the HACCP plan. | | Part F - Inspection Requirements | |
| 22. Records documenting: the written HACCP plan, monitoring of the critical control points, dates and times of specific event occurrences. | | 49. Government Staffing | X |
| Part C - Economic / Wholesomeness | | 50. Daily Inspection Coverage | |
| 23. Labeling - Product Standards | O | 51. Enforcement | X |
| 24. Labeling - Net Weights | O | 52. Humane Handling | |
| 25. General Labeling | O | 53. Animal Identification | |
| 26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture) | O | 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 | O |
| 29. Records | | 57. Monthly Review | |
| Salmonella Performance Standards - Basic Requirements | | 58. | |
| 30. Corrective Actions | | 59. | |
| 31. Reassessment | | | |
| 32. Written Assurance | | | |

60. Observation of the Establishment

China, Est. 3700/03359

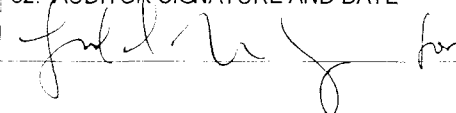
8-2-05

- 10/51 Dripping condensation in the over-product contact area (cut-up tables) and in the hallways in front of the cold stores was observed during the pre-operational sanitation. 9 CFR 416.13 (c).
- 15/51 This establishment HACCP plan was unclear, the same CCP included biological and chemical hazard and corrective action to both hazards under one CCP was confusing. No on-site verification of monitoring activities 9 CFR 417.3 (a) and 417.4 (2)(ii).
- 38/51 Outside rodent control traps are regularly removed from their sites during the day operation and moved back to their position after the end of the shift. This practice might allow rodent enter to the establishment through areas with inadequate sealing and door closure, such as the product transport area. This deficiency was scheduled for correction by the establishment management 9 CFR 416.2 (a).
- 49/51 Ante-mortem and post-mortem inspection have been performed by establishment veterinarians. Disposition has also been performed by the establishment veterinarians 9 CFR 381.34 (a), and 381.37 (a).
- * If this establishment was certified to export to U.S., this establishment would be immediately delisted.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

 for 11/2/2005

Foreign Establishment Audit Checklist

| | | | |
|---|---------------------------------|---|-----------------------------|
| 1. ESTABLISHMENT NAME AND LOCATION Shandong Kaijia Food Co. LTD, Xiazhuang, Gaomi, Shandong, China | 2. AUDIT DATE 08 - 03 - 2005 | 3. ESTABLISHMENT NO. 3700/03364 | 4. NAME OF COUNTRY China |
| 5. NAME OF AUDITOR(S) Dr. Oto Urban | | 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.

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

60 Observation of the Establishment

China, Est. 3700/03364

8-3-05


49/51 Ante-mortem and post-mortem inspection have been performed by establishment veterinarians. Disposition has also been performed by the establishment veterinarians 9 CFR 381.34 (a), and 381.37 (a).

* If this establishment was certified to export to U.S., this establishment would be immediately delisted.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE

 11/3/2005

The Translation for Reference

**Comments to the FSIS Draft Final Report of an Initial
Equivalence Audit Carried out in China Covering China's
Poultry Slaughter Inspection System**

NOV. 01, 2005

Madame Sally White
Director
International Equivalence Staff
Office of International Affairs
Food Safety and Inspection Service
United States Department of Agriculture

Dear Madame Sally White,

On October 21, 2005 Beijing time, I received your letter dated October 14, 2005 with the enclosed FSIS/USDA Draft Final Report of an Initial Equivalence Audit Carried out in China Covering China's Poultry Slaughter Inspection System from July 27 through August 12, 2005.

The Chinese side has conducted serious study on the FSIS/USDA Draft Final Report of an Initial Equivalence Audit Carried out in China Covering China's Poultry Slaughter Inspection System (hereinafter referred to as "Report" and "Attachments to the Report"), and hereby submits the comments on the said "Report" and "Attachments to the Report" as follows.

The issues not mentioned in the comments merely indicate that the Chinese side reserves the right to raise any doubts about those covered in

the “Report” and “Attachments to the Report”.

1. Comments of the Chinese Side on the “Report”

(1) Comments of the Chinese Side on “5. SUMMARY OF PREVIOUS AUDITS” in the “Report”

a. The Chinese side has attached great importance to the problems found during the previous FSIS audits. The relevant establishments, under the supervision and guidance of the General Administration of Quality Supervision, Inspection and Quarantine of PRC (AQSIQ), Certification and Accreditation Administration of PRC (CNCA) and the related provincial branches of AQSIQ (CIQ), have immediately taken corrective actions and passed the official verification by CNCA/CIQ.

b. In order for more establishments to prevent the similar problems from occurrence and take corrective actions at any time, CNCA has notified all the establishments applying for exporting cooked poultry meat to the U.S. and the relevant CIQs of the findings from the previous FSIS audits, and requested the establishments to conduct self-inspection and take corrective actions.

c. As for the problem of “ In two establishments, employees designated for floor duties were handling edible product duties” mentioned in Part 5 of the “Report”, the Chinese side makes correction and explanation as follows:

According to the on-site record of the Chinese representatives

accompanying the FSIS auditors, one establishment (2100/03086) has the above problem as described in the “Report”, while the other establishment (1100/03039) does not have the same problem. For this, the Chinese side has identified the cause why the establishment was mistaken as having the above problem, as the working clothes of the employees designated for floor duties are almost the same as those of the employees designated for handling edible product duties, thus leading to the misunderstanding by the FSIS auditors. Both CNCA/CIQ and establishments have made it a rule that the employees designated for floor duties are not allowed to handle edible product duties. Now the establishment has made clear marking on the working clothes of the employees designated for floor duties, so as to distinguish from the employees handling edible product duties. The Chinese side wishes that FSIS would make correction in its final report.

(2) Comments of the Chinese Side on “9.1 SSOP” and “9.2 Sanitation Performance Standards” in the “Report”

a. The Chinese side suggests that the “9.1 SSOP” in the “Report” shall be supplemented as follows:

After the “dripping condensation” was observed by the FSIS auditors during the preoperational sanitation, the establishment conducted cleaning and disinfection immediately, and developed preventive measures.

b. The Chinese side would supplement the “9.2 Sanitation Performance Standards” in the “Report” as follows:

After the FSIS auditors noted that the “outside rodent control traps” were removed from their sites during the day’s operation, the establishment has made correction immediately by placing the rodent control traps on their sites 24 hours a day, and passed the official verification by CNCA/CIQ.

c. The establishment’s report concerning the above rectification has been submitted to the FSIS auditors.

**(3) Comments of the Chinese Side on “11.2 HACCP Implementation”
in the “Report”**

The Chinese side suggests that the “11.2 HACCP Implementation” in the “Report” shall be supplemented as follows:

After the deficiencies were noted by the FSIS auditors, the establishment has promptly made an overall revision on the HACCP plan, added the on-site verification of monitoring activities in the HACCP plan and implementation and also passed the official verification by CNCA/CIQ.

The above rectification report of the establishment has been submitted to the FSIS auditors.

**(4) Suggestion of the Chinese Side on “12. RESIDUE CONTROLS”
in the “Report”**

The Chinese side wishes that FSIS would complete the evaluation on the residue controls in China and send back the results to the Chinese side as

soon as possible.

(5) Comments of the Chinese Side on “13. ENFORCEMENT CONTROLS” in the “Report”

In view of the problem that “FSIS found that in all four establishments, ante-mortem inspection, post-mortem inspection and disposition were performed by establishment veterinarians” as raised in the “Report”, the Chinese side would explain the problem of “the ante-mortem inspection, post-mortem inspection and disposition performed by establishment veterinarians” as follows:

a. The Chinese side reiterates that: First, the export foodstuffs in China are subject to lot-by-lot inspection and quarantine prior to export so as to ensure the sanitary quality of the final products, and this procedure is different from that of the US. Second, China Entry-Exit Inspection and Quarantine authorities (CIQ) dispatch veterinarians to export-oriented establishments, and they are civil servants. The Chinese government has legal provisions regarding the recusal of public service for civil servants, such as the Law of Civil Servants of the People’s Republic of China (Articles 70 and 71) and the Provisions for Recusal of Post and Public Service of Civil Servants. The disciplinary provisions of the Chinese government for civil servants are basically the same as the provisions of the US Code of Federal Regulations for official inspectors. Third, the supervision of export food establishments in China is jointly performed

by CIQ and establishments. The establishment inspectors are supervised by CIQ, and receive pre-service training and regular re-training by CIQ. Fourth, China applies for exporting cooked poultry meat to the US, and the processing temperature and time therein can effectively prevent epidemic disease and unsafe factors. Fifth, the Chinese side has noticed that the inspection of “pizza containing poultry meat” (fit for consumption after being cooked) in the Federal Poultry Products Inspection Act 464(d) may apply “exemption” clause; The Chinese side has also noticed that FSIS “Import Procedures for Meat, Poultry and Egg Products” points out that “The US requests that these countries do not have to apply the same inspection system, provided that their inspection systems are equivalent”; The Chinese side stresses that the “Preface” and “Article 4” of the WTO/SPS Agreement also points out that the policies developed by the importing countries shall minimize the adverse impact on or obstacles to trade. Based on the above reasons, the Chinese side thinks that the US side should consider acknowledging the equivalence of the current inspection and quarantine system in China with that of the US.

b. In order to export cooked poultry meat to the US at the earliest possible date, the Chinese side hereby expresses that: as required by the US CFR, and as proposed by you at the teleconference with CNCA on September 20, 2005, the Chinese side will dispatch CIQ official inspectors to the slaughter and processing establishments certified to export cooked

poultry meat to the US, responsible for ante-mortem inspection, post-mortem inspection and disposition. The Chinese side will develop and implement the operational procedures for official inspectors to conduct inspection and quarantine in establishments that meet the requirements of the US CFR.

The Chinese side stresses that it will not automatically terminate (or give up) its application for equivalence due to the afore-mentioned commitment, and will continue its application, and request the US side to accelerate its equivalence review on the inspection and quarantine system in China.

2. Comments of the Chinese Side on the “Attachments to the Report”

(1) Comments of the Chinese Side on FSIS “Observation of the Establishment” of Qingdao Nine-Alliance Group Co., Ltd., China. (3700/03359)

a. In view of the observation of the establishment as raised in the “Attachments to the Report”: “ 10/51 Dripping condensation in the over-product contact area (cut-up tables) and in the hallways in front of the cold stores was observed”, the establishment has taken the corrective measures indicated below:

(a) Add solid dehumidifier at the air vent of the air-conditioner in the processing workshop, so as to avoid condensation in humid climate.

(b) Remove moisture from the hallways in front of the cold stores by adopting dedicated airways to get rid of condensation.

(c) In case of humid air in the ambient environment, arrange dedicated employees to clear the condensation on the ceilings and air diffusing outlets during preoperational sanitation in the workshop, so as to ensure that no dripping condensation occurs.

(d) Duly adjust the air flow in the workshop.

The above measures have been officially verified by CNCA/CIQ.

b. In view of the Observation of the Establishment as raised in the “Attachments to the Report”: “15/51 This establishment HACCP plan was unclear, the same CCP included biological and chemical hazard and corrective action to both hazards under one CCP was confusing. No on-site verification of monitoring activities 9CFR 417.3(a) and 417.2(ii)”, the establishment has revised the CCPs in the HACCP plan, developed corrective measures respectively for the biological and chemical hazard included in the same CCP, and added the on-site verification of monitoring activities in the HACCP plan and implementation.

The above measures have been officially verified by CNCA/CIQ.

c. In view of the Observation of the Establishment as raised in the “Attachments to the Report”: “38/51 Outside rodent control traps are regularly removed from their sites during the day operation and moved back to their position after the end of the shift. This practice might allow

rodent to enter the establishment through areas with inadequate sealing and door closure, such as product transport area 9CFR 416.2(a)”, the establishment has placed the rodent control traps on their sites round the clock, and requested the pest control group to take charge of carrying it out and the quality inspectors to conduct daily inspection, so as to ensure that the rodent control traps are in service 24 hours a day.

(2) Comments of the Chinese side on the FSIS findings that in all four Chinese establishments (1100/03013, 2200/03026, 3700/03359, 3700/03364), “ante-mortem inspection, post-mortem inspection and disposition were performed by establishment veterinarians”.

In view of the Observation of the Establishment as raised in the “Attachments to the Report” for the four establishments: “49/51 Ante-mortem and post-mortem inspection have been performed by establishment veterinarians. Disposition has also been performed by the establishment veterinarians”, CNCA/CIQ has expressed that it will dispatch CIQ official inspectors to the slaughter and processing establishments certified to export cooked poultry meat to the US, responsible for ante-mortem inspection, post-mortem inspection and disposition. The Chinese side will develop and implement the operational procedures for official inspectors to conduct inspection and quarantine in establishments that meet the requirements of 9CFR 381.34(a) and 381.37(a).

If you have any questions concerning the above comments and reply from the Chinese side, please contact me.

Your contribution to promoting Sino-US trade and inspection and quarantine cooperation is highly appreciated.

Sincerely,

Cheng Fang
Deputy Chief Administrator
Certification and Accreditation Administration of PRC

cc:

Import and Export Food Safety Bureau, AQSIQ

Mr. Zhao Baoqing, Commercial Division, Embassy of the PRC in the US

Agriculture Division, Embassy of the US in the PRC

Foreign Agricultural Service, USDA