



United States  
Department of  
Agriculture

Food Safety  
and Inspection  
Service

Washington, D.C.  
20250

MAY 23 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 December 1 through 17, 2004. Comments from the government of China have been included as an attachment to the final report.

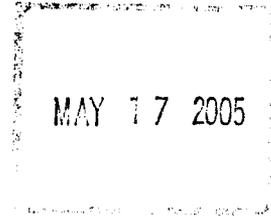
If you have any questions or need additional information regarding the enclosed report, please contact me by telephone at 202-720-3781, by fax at 202-690-4040, or by electronic mail at [sally.white@fsis.usda.gov](mailto:sally.white@fsis.usda.gov).

Sincerely,

Sally White  
Director  
International Equivalence Staff  
Office of International Affairs

Enclosure

**FINAL**



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

DECEMBER 1 THROUGH 17, 2004

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 of the People's Republic of China
CCA	Central Competent Authority [AQSIQ]
CIQ	Provincial Branches of AQSIQ
CNCA	Certification and Accreditation Administration of the People's Republic of China
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
MoH	Ministry of Health
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 December 1 through 17, 2004.

An opening meeting was held on December 1, 2004 in Beijing, China 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 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 and processing 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, four provincial offices, four microbiological laboratories, four residue laboratories, three slaughter establishments and four processing establishments.

Competent Authority Visits			Comments
Competent Authority	Central	1	
	Provincial	4	
Microbiological Laboratory		4	
Residue Laboratory		4	
Slaughter Establishment		3	
Processing Establishment		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 seven slaughter and processing 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, (2) animal disease controls, (3) slaughter/processing 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 auditors evaluated the nature, extent and degree to which findings impacted on food safety and public health. The auditors 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.

During the opening meeting, the auditors explained that China's inspection system would be audited against two standards. First, the auditors would audit against FSIS requirements. These include daily inspection in all certified establishments, humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, species verification testing, and FSIS' requirements for HACCP, SSOP, testing for generic *E. Coli*.

Second, the auditors would audit against any equivalence determinations that have been made by FSIS for China under provisions of the Agreement on the Application of Sanitary and Phytosanitary Measures.

- At this time, FSIS is reviewing several requests for equivalence determinations 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.)
- The Poultry Products Inspection Regulations (9 CFR Part 381)
- The Federal Meat Inspection Regulations (9 CFR Parts 301 to end) which include the PR/HACCP regulations.

#### 5. SUMMARY OF PREVIOUS AUDITS

Final audit reports are available on FSIS' website at:  
[http://www.fsis.usda.gov/regulations/foreign\\_audit\\_reports/index.asp](http://www.fsis.usda.gov/regulations/foreign_audit_reports/index.asp)

This is an initial equivalence audit.

## 6. MAIN FINDINGS

### 6.1 Legislation

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.

### 6.2 Government Oversight

#### 6.2.1 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 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 CDC is responsible for technical support. The MoH plays a crucial role in the food safety arena. MoH is responsible for drafting regulations and standards related to the hygienic code of practice of food manufacturing.

## 6.2.2 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.

However, in one CIQ, FSIS found that AQSIQ did not have adequate control and supervision over the establishments.

## 6.2.3 Assignment of Competent, Qualified Inspectors

Prior to the FSIS audit, AQSIQ/CNCA sent two representatives to participate in an FSIS training seminar. Upon return from their trip, AQSIQ/CNCA completed a three-day training seminar for the fourteen CIQ bureaus that would oversee establishments eligible to export product to the United States. The focus of the course included all FSIS laws and regulations and a detailed discussion of FSIS Directive 5000.1, Rev. 1. Translated copies of these documents were given to all CIQ inspection personnel that attended the course and were available to the FSIS auditors during each visit.

A similar course is scheduled for early 2005. In addition to the topics covered in the last training seminar, AQSIQ/CNCA will discuss the corrective actions taken by the CIQ bureaus as a result of the FSIS audit. The training seminar will include on-site visits to establishments to ensure that the information that is theoretically presented in the classroom can be practically applied in the workplace.

Additionally, the 35 CIQ bureaus develop training programs for inspection personnel every year. The topics include: ante- and post- mortem inspection, sampling and testing technique for microorganisms, residue detection techniques and training courses for auditors.

During the audit, in one CIQ, the official veterinarians had shown no evidence of an understanding of FSIS requirements.

## 6.2.4 Authority and Responsibility to Enforce the Laws

The AQSIQ has 35 CIQ bureaus nationwide. These 35 CIQ bureaus are responsible for entry-exit quarantine and quality inspection of animals and animal products, issuing health certificates and enforcing supervision and control of food processing establishments for export.

In one CIQ, the official veterinarians did not adequately enforce FSIS standards.

## 6.2.5 Adequate Administrative and Technical Support

AQSIQ had adequate administrative and technical support and has the ability to support a third party audit.

### 6.3 Audit of Headquarters and Local Offices

The auditors conducted a review of inspection system documents at the headquarters of the inspection service and in three district offices. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sanitation, slaughter and processing inspection procedures and standards.
- Export product inspection and control including export certificates.

The only concern that arose as a result of the examination of these documents was in the one CIQ in which the FSIS auditors found an inadequate understanding and implementation of FSIS standards.

## 7. ESTABLISHMENT AUDITS

The FSIS auditors visited a total of seven establishments. Three of the establishments were slaughter establishments. The other four were processing establishments. Since this was an initial equivalence audit, no establishments were delisted or received a notice of intent to de-certify. At this time, China is ineligible to ship poultry products to the United States.

## 8. MICROBIOLOGY LABORATORY AUDITS

During laboratory audits, emphasis was placed on the application of procedures and standards that are equivalent to United States requirements.

Residue laboratory audits focus on sample handling, sampling frequency, timely analysis data reporting, analytical methodologies, tissue matrices, equipment operation and printouts, detection levels, recovery frequency, percent recoveries, intra-laboratory check samples, and quality assurance programs, including standards books and corrective actions.

Microbiology laboratory audits focus on analyst qualifications, sample receipt, timely analysis, analytical methodologies, analytical controls, recording and reporting of results, and check samples. If private laboratories are used to test United States samples, the auditor evaluates compliance with the criteria established for the use of private laboratories under the FSIS Pathogen Reduction/HACCP requirements.

The following government laboratories were reviewed:

Beijing CIQ  
Liaoning, Dalian CIQ  
Shandong, Qingdao CIQ  
Shanghai CIQ

No deficiencies were noted. At this time, FSIS is reviewing several requests for equivalence determinations submitted by China.

## 9. SANITATION CONTROLS

As stated earlier, the FSIS auditors focused on five areas of risk to assess an exporting country's meat inspection system. The first of these risk areas that the FSIS auditors 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 and 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 three establishments were found to meet the basic FSIS regulatory requirements. However, three deficiencies were noted:

Preoperational sanitation:

- In one establishment, grease, blood, fat, pieces of dry meat and foreign particles were observed on product contact areas of conveyor belts, plastic containers in the poultry raw meat area and in the fried poultry processing area.

Operational Sanitation:

- 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.

### 9.2 Other Sanitation Deficiencies

- 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.

## 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. There had been no outbreaks of animal diseases with public health significance since our last visit in May 2004.

## 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, ante-mortem disposition, humane handling and humane slaughter, post-mortem inspection procedures, post-mortem disposition, ingredients identification, control of restricted ingredients, formulations, processing schedules, equipment and records, and processing controls of cured, dried, and cooked products.

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

### 11.1 Humane Handling and Humane Slaughter

No deficiencies were noted.

### 11.2 HACCP Implementation

All establishments approved to export meat 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.

- In two establishments, monitoring activities were not adequately addressed in the HACCP plan.
- In two establishments, pre-shipment review was not being performed.

### 11.3 Testing for Generic *E. coli*

- In one establishment, generic *E. coli* testing on whole birds was not being performed.

### 11.4 Testing for *Listeria monocytogenes*

No deficiencies were noted. At the time of the audit, FSIS was in the process of reviewing the submission by AQSIQ for an equivalence determination on the testing method used for *Listeria monocytogenes*. That review is still in process.

## 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.

The following residue labs were reviewed:

Beijing CIQ  
Liaoning, Dalian CIQ  
Shangdong, Qingdao CIQ  
Shanghai CIQ

- Differences in residue testing methods were found. At the time of the audit, FSIS was in the process of reviewing the submission by AQSIQ for an equivalence determination on the different testing methods. That review is still in process.
- In one CIQ, sampling handling procedures could have lead to cross-contamination of samples.

## 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*.

### 13.1 Daily Inspection in Establishments

Inspection was being conducted daily in all slaughter and processing establishments.

### 13.2 Testing for *Salmonella*

- In one establishment, no testing for *Salmonella* species on whole birds was performed.
- At the time of the audit, FSIS was in the process of reviewing the submission by AQSIQ for an equivalence determination on the testing method used for

*Salmonella*. China is presently using national standards to test for *Salmonella*. The review is still in process.

### 13.3 Species Verification

Species verification was being conducted in those establishments in which it was required.

### 12.4 Monthly Reviews

During this audit it was found that in all establishments visited, monthly supervisory reviews of certified establishments were being performed and documented as required.

### 12.5 Inspection System Controls

The CCA had 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.

In addition, 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.

However, in two establishments, there was no pre-chill or post-chill operation performed by the establishment employees and/or inspection service.

## 14. CLOSING MEETING

A closing meeting was held on December 17, 2004 in Beijing, China with the CCA. At this meeting, the primary findings, conclusions, and recommendations from the audit were presented by the lead auditor.

The CCA understood and accepted the findings.



Todd M. Furey  
USDA, FSIS, OIA

## 15. ATTACHMENTS TO THE AUDIT REPORT

Residue Laboratory Audit Forms

Individual Foreign Establishment Audit Forms

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

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY	CITY & COUNTRY Beijing, China	ADDRESS OF LABORATORY
NAME OF REVIEWER .O'Keefe	NAME OF FOREIGN OFFICIAL	

Residue Code/Name			CA	SUL														
	REVIEW ITEMS	ITEM #	EVALUATION CODE															
SAMPLING PROCEDURES	Sample Handling	01	C	C														
	Sample Frequency	02	A	A														
	Timely Analysis	03	A	A														
	Compositing Procedure	04																
	Interpret Comp Data	05	A	A														
	Data Reporting	06	A	A														
ANALYTICAL PROCEDURES	Acceptable Method	07	C	C														
	Correct Tissue(s)	08	C	A														
	Equipment Operation	09	A	A														
	Instrument Printouts	10	A	A														
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	C	A														
	Recovery Frequency	12	A	A														
	Percent Recovery	13	A	C														
	Check Sample Frequency	14	A	A														
	All Analyst W/Check Samples	15	A	A														
	Corrective Actions	16	A	A														
International Check Samples	17	C	C															
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE															
OTHER REVIEW		19	EVAL. CODE															
		20	EVAL. CODE															

Signature of reviewer *Margaret O'Keefe*

Date 1/18/05

Comments: Beijing CIQ

**SAMPLE HANDLING:**

Samples are in single ziplock bags. This will lead to cross-contamination of samples.

It would be preferable to have a computerized system for sample receipt.

**METHODS:**

Methods still need to be translated.

The methods for both CAP and Sulfas are different than the U.S.

The laboratory uses ELISA and HPLC methods. The U.S. uses GC and TLC methods.

It appeared that the sulfa method was not validated for liver, but muscle.

**TISSUE:**

China uses liver to test for CAP. U.S. uses muscle.

**MINIMUM DETECTION LEVELS:**

U.S. needs to confirm that China will only take regulatory action on CAP levels > 0.3 ppb.

**PERCENT RECOVERY:**

Some sulfa recoveries were low.

**INTERNATIONAL CHECK SAMPLES:**

The laboratory does not participate in international proficiency samples for these compounds.

**OTHER COMMENTS:**

The laboratory does not have control charts.

Pipets and balances are monitored between service. This needs to be documented.

The working standard preparation log should have name of individual who prepared the solution.

Maintenance logs should be more inclusive. Include column changes etc.

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FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOVT AGENCY	CITY & COUNTRY Dalian, China	ADDRESS OF LABORATORY
NAME OF REVIEWER O'Keefe	NAME OF FOREIGN OFFICIAL	

Residue Code/Name			TET	SUL	CA P	OC	ELE			
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE							
	Sample Handling	01		A	A	A	A	A		
	Sample Frequency	02		A	A	A	A	A		
	Timely Analysis	03		A	A	A	A	A		
	Compositing Procedure	04								
	Interpret Comp Data	05		A	A	A	A	A		
Data Reporting	06	A	A	A	A	A				
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	C	C	C	C	C		
	Correct Tissue(s)	08		C	A	C	C	C		
	Equipment Operation	09		A	A	A	A	A		
	Instrument Printouts	10		A	A	A	A	A		
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	C	A	A	C	C		
	Recovery Frequency	12		A	A	A	A	C		
	Percent Recovery	13		A	A	A	A	C		
	Check Sample Frequency	14		C	A	A	A	C		
	All Analyst W/Check Samples	15		C	A	A	A	C		
	Corrective Actions	16		A	A	A	A	A		
	International Check Samples	17		C	A	C	C	C		
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE							
OTHER REVIEW		19	EVAL. CODE							
		20								

Signature of reviewer *Margaret A. Keefe*

Date 1/18/05

Comments: Dalian CIQ

**METHODS:**

Methods still need to be translated.

The U.S. uses different methods:

Bioassay for tetracyclines, with HPLC identification.

TLC for sulfonamides.

GC for CAP in muscle.

GC for OCs in fat.

**TISSUE:**

China uses liver to test for tetracyclines. U.S. uses kidney.

China uses liver to test for CAP. U.S. uses muscle.

China uses liver to test for OCs. U.S. uses fat.

China uses kidney for arsenic. U.S. uses liver.

**MINIMUM DETECTION LEVELS:**

Tetracyclines: China- CHARM LOD 100 ppb, HPLC LOD 50/100 ppb. U.S. 80 ppb.

MRL China- 300 ppb.

MRL U.S. -12 ppm in poultry fat, 2 ppm in meat, 6 ppm in liver, 12 ppm in kidney.

OCs:

MRL China- BHC 300 ppb, DDT 1000 ppb, HCB 200 ppb

MRL U.S.- BHC 0.3 ppm in poultry fat, DDT 5.0 ppm, HCB 0.5 ppm

Elements:

MRL China- Pb 500 ppb, Cd- 500 ppb, As 1000 ppb.

MRL U.S.- no MRL for Pb and Cd (we can detect Pb 25 ppb, Cd 10 ppb. As- 0.5 ppm in poultry meat, 2 ppm in edible tissue.

U.S. needs to confirm that China will only take regulatory action on CAP levels > 0.3 ppb.

**PERCENT RECOVERY/CHECK SAMPLES:**

Need to have clear percent recoveries for elements, along with check samples.

Need to have more check samples for tetracyclines (HPLC).

**INTERNATIONAL CHECK SAMPLES:**

The laboratory does international check samples for sulfonamides.

**OTHER COMMENTS:**

The laboratory does not have control charts.

The method for elements only appears to be validated in chicken liver.

The CHARM II methods appear to be validated at one level.

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOV'T AGENCY	CITY & COUNTRY Qingdao, China	ADDRESS OF LABORATORY
NAME OF REVIEWER O'Keefe	NAME OF FOREIGN OFFICIAL	

Residue Code/Name			CA P	SUL	PC B	OC	ELE					
SAMPLING PROCEDURES	REVIEW ITEMS Sample Handling	ITEM # 01	EVALUATION CODE	A	A	A	A	A				
	Sample Frequency	02		A	A	A	A	A				
	Timely Analysis	03		A	A	A	A	A				
	Compositing Procedure	04										
	Interpret Comp Data	05		A	A	A	A	A				
	Data Reporting	06		A	A	A	A	A				
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	C	C	C	C	C				
	Correct Tissue(s)	08		C	A	C	C	C				
	Equipment Operation	09		A	A	A	A	A				
	Instrument Printouts	10		A	A	A	A	A				
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	C	A	C	C	C				
	Recovery Frequency	12		A	A	A	A	A				
	Percent Recovery	13		C	A	A	A	A				
	Check Sample Frequency	14		A	A	A	A	A				
	All Analyst W/Check Samples	15		A	A	A	A	A				
	Corrective Actions	16		A	A	A	A	A				
	International Check Samples	17		C	C	C	C	A				
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE									
OTHER REVIEW		19	EVAL. CODE									
		20										

Signature of reviewer *Margaret O'Keefe*

Date 11/15/05

Comments: Qingdao CIQ

**METHODS:**

Methods still need to be translated.

The U.S. uses different methods:

TLC for sulfonamides.

GC for CAP in muscle.

GC for OCs in fat.

GC for PCB in fat.

AAS for As in liver.

**TISSUE:**

China uses liver to test for PCBs. U.S. uses fat.

China uses liver to test for OCs. U.S. uses fat.

China uses kidney for arsenic. U.S. uses liver.

**MINIMUM DETECTION LEVELS:**

PCB:

MRL China- not set, LOQ 10 ppb

MRL U.S. – 3 ppm in poultry fat. LOQ 0.5 ppm

OCs:

MRL China- BHC 300 ppb, DDT 1000 ppb, HCB 200 ppb

MRL U.S.- BHC 0.3 ppm in poultry fat, DDT 5.0 ppm, HCB 0.5 ppm

Elements:

MRL China- Pb 500 ppb, Cd- 500 ppb, As 1000 ppb.

MRL U.S.- no MRL for Pb and Cd (we can detect Pb 25 ppb, Cd 10 ppb). As- 0.5 ppm in poultry meat, 2 ppm in edible tissue.

U.S. needs to confirm that China will only take regulatory action on CAP levels > 0.3 ppb.

**PERCENT RECOVERY/CHECK SAMPLES:**

Recoveries for CAP a little low.

**INTERNATIONAL CHECK SAMPLES:**

The laboratory does international check samples for elements.

**OTHER COMMENTS:**

The method for elements only appears to be validated in certified reference materials (CRMs).

REVIEW DATE  
 12/7/04

NAME OF FOREIGN LABORATORY  
 CIQ, Shanghai, China

FOREIGN COUNTRY LABORATORY REVIEW

FOREIGN GOVT AGENCY	CITY & COUNTRY Shanghai, China	ADDRESS OF LABORATORY
NAME OF REVIEWER O'Keefe	NAME OF FOREIGN OFFICIAL	

Residue Code/Name			ZE R	SUL	OCs	ELE							
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE										
	Sample Handling	01		C	C	C	C						
	Sample Frequency	02		A	A	A	A						
	Timely Analysis	03		A	A	A	A						
	Compositing Procedure	04											
	Interpret Comp Data	05		A	A	A	A						
	Data Reporting	06	A	A	A	A							
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	C	C	C	C						
	Correct Tissue(s)	08		A	A	C	C						
	Equipment Operation	09		A	A	A	A						
	Instrument Printouts	10		A	A	A	A						
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	A	A	C	C						
	Recovery Frequency	12		A	A	A	A						
	Percent Recovery	13		C	C	A	A						
	Check Sample Frequency	14		C	C	C	C						
	All Analyst W/Check Samples	15		A	A	A	A						
	Corrective Actions	16		A	A	A	A						
	International Check Samples	17		C	A	C	C						
REVIEW	Corrected Prior Deficiencies	18	EVAL. CODE										
OTHER REVIEW		19	EVAL. CODE										
		20											

Signature of reviewer

*Meghan O'Keefe*

Date

1/15/05

Comments: Shanghai CIQ

**SAMPLE HANDLING:**

Lab uses single ziplock bags. This could lead to cross contamination of samples.

**METHODS:**

Methods still need to be translated.

The U.S. uses different methods:

ELISA, GC-MS for zeranol.

TLC for sulfonamides.

GC for OCs in fat.

As in liver.

**TISSUE:**

China uses liver to test for OCs. U.S. uses fat.

China uses kidney for arsenic. U.S. uses liver.

**MINIMUM DETECTION LEVELS:**

OCs:

MRL China- BHC 300 ppb, DDT 1000 ppb, HCB 200 ppb

MRL U.S.- BHC 0.3 ppm in poultry fat, DDT 5.0 ppm, HCB 0.5 ppm

Elements:

MRL China- Pb 500 ppb, Cd- 500 ppb, As 1000 ppb.

MRL U.S.- no MRL for Pb and Cd (we can detect Pb 25 ppb, Cd 10 ppb). As- 0.5 ppm in poultry meat, 2 ppm in edible tissue.

**PERCENT RECOVERY/CHECK SAMPLES:**

Recoveries for sulfa and zeranol a little low.

Lab will decrease number of check samples if acceptable.

**INTERNATIONAL CHECK SAMPLES:**

The laboratory does international check samples for sulfa.

**OTHER COMMENTS:**

United States Department of Agriculture  
Food Safety and Inspection Service

## Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Shanghai Hushi Food Company Ltd., Tiading District, Shanghai, China	2. AUDIT DATE 12-10-04	3. ESTABLISHMENT NO. 3100/03032	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	0
8. Records documenting implementation.		34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	0
<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 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	
<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	0
25. General Labeling		53. Animal Identification	0
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	0
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	0
27. Written Procedures	0	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	0	56. European Community Directives	0
29. Records	0	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	0	59.	
31. Reassessment	0		
32. Written Assurance	0		

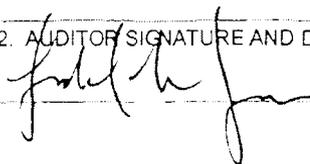
60. Observation of the Establishment

China, Est. 2100/03032 12-10-04

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE



1/24/2005

United States Department of Agriculture  
Food Safety and Inspection Service

**Foreign Establishment Audit Checklist**

1. ESTABLISHMENT NAME AND LOCATION Beijing Jia Yi Food Joint Factory, Xiao Tang Shan, Chang Ping, Beijing China	2. AUDIT DATE 12-02-04	3. ESTABLISHMENT NO. 1100/03039	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	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	0
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.	X	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	
<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.	X	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	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	X
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	X
24. Labeling - Net Weights		52. Humane Handling	0
25. General Labeling		53. Animal Identification	0
26. Fin. Prod. Standards/Boneless (Defects/AQL/Park Skins/Moisture)		54. Ante Mortem Inspection	0
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	0
27. Written Procedures	0	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	0	56. European Community Directives	0
29. Records	0	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	0	59.	
31. Reassessment	0		
32. Written Assurance	0		

## 60 Observation of the Establishment

China, Est. 1100/03039 12-02-04

- 10/51 Metal plates assigned for edible product were used for both; edible and inedible product handling in the cut up area. This deficiency was scheduled for correction by the establishment officials 9CFR 416.13.
- 16/51 Pre-shipment review was not performed by the establishment. This deficiency was scheduled for correction by the establishment management 9CFR 417.5(3)(c).
- 46/51 Conveyor belt, used for exposed edible product transfer had many deep cuts in it. This deficiency was scheduled for correction by the establishment management 9CFR 416.4(d).
- 47/51 Establishment employees designated for floor duties were handling edible product duties. This deficiency was scheduled for corrective action by the establishment officials 9CFR 416.5(a).

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE



1/24/2005

United States Department of Agriculture  
Food Safety and Inspection Service

**Foreign Establishment Audit Checklist**

1. ESTABLISHMENT NAME AND LOCATION Great Wall Food Co. Ltd. Dalian, China	2. AUDIT DATE 12-03-04	3. ESTABLISHMENT NO. 2100/03086	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	O
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.	X	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.	X	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	X
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.	X	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	X
18. Monitoring of HACCP plan.		46. Sanitary Operations	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	X
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	O	51. Enforcement	X
24. Labeling - Net Weights	O	52. Humane Handling	O
25. General Labeling	O	53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)	O	54. Ante Mortem Inspection	N
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	X
27. Written Procedures	X	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	X	56. European Community Directives	O
29. Records	X	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	X	59.	
31. Reassessment	X		
32. Written Assurance	X		

60. Observation of the Establishment

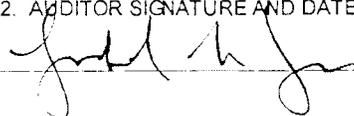
China, Est. 2100/03086 12-03-04

- 10/12/51 Over product dripping condensation was observed in several areas of the slaughter house. Improper corrective action was taken by the establishment officials. Condensation was wiped off on exposed product 9CFR 416.13 and 416.15(a,b).
- 10/51 Plastic white containers and metal plates assigned for edible product were used for both; edible and inedible product handling in the cut up area. This deficiency was improperly corrected by the establishment officials 9CFR 416.13.
- 16/51 Frequencies of verification of direct observation of monitoring activities was missing in the HACCP plan. This deficiency was scheduled for correction by the establishment management 9CFR 417.2.
- 27/28/29/51 No testing for verifying process control, for generic *E. coli* (biotype 1) on whole birds was performed either by the establishment officials or inspection service personnel. This was scheduled for corrective action by the inspection service officials 9CFR 381.93(a).
- 30/31/32/51 No testing for *Salmonella* species performance standards on whole birds was performed either by the establishment officials or inspection service officials. This was scheduled for correction by the inspection service officials 9CFR 381.93(b).
- 40/45/51 Tables and 200 foot-candles light were missing at the re-inspection stations. This deficiency was scheduled for correction by the establishment officials 9CFR 381.76(c)(iv).
- 46/51 Product contact areas were continuously wiped off by a dirty cloth, which was not cleaned. This deficiency was corrected by the establishment officials, where it was being observed, in the cut up product area 9CFR 416.4(a,d).
- 47/51 Establishment employees designated for floor duties were handling edible product duties. This deficiency was scheduled for corrective action by the establishment officials 416.5(a).
- 55/51 There was no pre-chill and no proper post-chill operation performed by the establishment employees and inspection service. The corrective action was scheduled by both; establishment and inspection service 9CFR 381.76.
- 54 Ante-mortem area was not audited due to lack of time.
- \* If approved, this establishment would have been delisted for SSOP, SPS, PR/HACCP and Enforcement deficiencies.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE



1/24/2005

United States Department of Agriculture  
Food Safety and Inspection Service

**Foreign Establishment Audit Checklist**

1. ESTABLISHMENT NAME AND LOCATION Dacheng Food Co. Ltd. Dalian, China	2. AUDIT DATE 12-03-04	3. ESTABLISHMENT NO. 2100/03129	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	
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	0
<b>Sanitation Standard Operating Procedures (SSOP) Ongoing Requirements</b>		<b>Part E - Other Requirements</b>	
10. Implementation of SSOP's, including monitoring of implementation.	X	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	
<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.	X	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	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<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.	X	49. Government Staffing	
<b>Part C - Economic / Wholesomeness</b>		50. Daily Inspection Coverage	
23. Labeling - Product Standards		51. Enforcement	X
24. Labeling - Net Weights		52. Humane Handling	0
25. General Labeling		53. Animal Identification	0
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	0
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	0
27. Written Procedures	0	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	0	56. European Community Directives	0
29. Records	0	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	0	59.	
31. Reassessment	0		
32. Written Assurance	0		

60. Observation of the Establishment

China, Est. 2100/03129 11-5-04

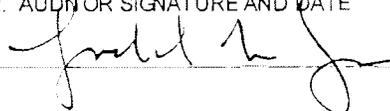
- 10/51 During the preoperational sanitation several deficiencies such as grease, blood, fat, pieces of dry meat and foreign particles were observed on product contact areas of conveyor belts and plastic containers in the poultry raw meat area and fried poultry processing area. These deficiencies were corrected by the establishment officials immediately in some cases, in others, with delay and not sufficiently 416.13, 15(a).
- 46/51 Non-food-contact surfaces of processing tables were observed with heavy grease in raw meat area. This deficiency was not corrected by the establishment officials at the time of the Auditor visit 416.4(b).
- 16/51 Direct observation of monitoring activities and their frequencies were not addressed in the HACCP plan. This deficiency was scheduled for corrective action 417.2.
- 22/51 The pre-shipment review was not performed and was not documented. This deficiency was scheduled for correction 417.5(3c).

\* This establishment was issued an NOID because of SSOP, SPS and HACCP deficiencies.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE



1/24/2005

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Shandong Delicate Food Stuff Co. Ltd., Shandong, China	2. AUDIT DATE 12-6-04	3. ESTABLISHMENT NO 3700/03260	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	0
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 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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	X
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	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<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	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<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	0
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

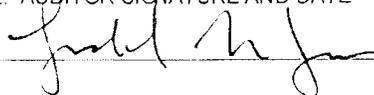
China, Est. 3700/03260 12-6-04

- 40/51 Intensity of 200 foot-candles light was missing at the re-inspection stations. This deficiency was scheduled for correction by the establishment officials 9CFR 381.76(c)(iv).
- 46/51 Conveyor belt, used for exposed edible product transfer had many deep cuts in it. This deficiency was scheduled for correction by the establishment management 9CFR 416.4(d).

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE



1/24/2005

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Qingdao Chia Tai Co. Ltd., Qingdao, China	2. AUDIT DATE 12 -7 - 04	3. ESTABLISHMENT NO. 3700/03262	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	0
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 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	
<b>Part B - Hazard Analysis and Critical Control Point (HACCP) Systems - Basic Requirements</b>		40. Light	X
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	X
19. Verification and validation of HACCP plan.		47. Employee Hygiene	
20. Corrective action written in HACCP plan.		48. Condemned Product Control	
21. Reassessed adequacy of the HACCP plan.		<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	X
24. Labeling - Net Weights		52. Humane Handling	
25. General Labeling		53. Animal Identification	
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	X
27. Written Procedures		<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis		56. European Community Directives	0
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

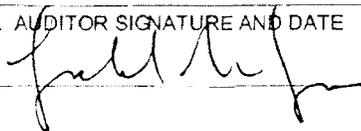
China, Est. 3700/03262 12-7-04

- 40/51 Intensity of 200 foot-candles light was missing at the re-inspection stations. This deficiency was scheduled for correction by the establishment officials 9CFR 381.76(c)(iv).
- 46/51 During the pre-operational sanitation it was observed that the conveyor belt, used for exposed edible product transfer had several deep cuts in it in the cut-up room. This deficiency was scheduled for correction by the establishment management 9CFR 416.4(d).
- 46/51 During the pre-operational sanitation, rusty pipe with flaking paint was observed over the exposed chiller. This deficiency was scheduled for corrective action by the establishment officials 9CFR 416.4.
- 46/51 Flaking paint from the ceiling, some of it found on the table used for edible product was observed in the several areas of the cut-up room during the pre-operational sanitation. This deficiency was corrected by the establishment officials 9CFR 416.4.
- 55/51 There was no pre-chill and no proper post-chill operation performed by the establishment employees and inspection service. The corrective action was scheduled by both; establishment and inspection service 9CFR 381.76.

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE



1/24/2005

United States Department of Agriculture  
Food Safety and Inspection Service

### Foreign Establishment Audit Checklist

1. ESTABLISHMENT NAME AND LOCATION Shandong Zhucheng Foreign Trade Cold Storage, No.2 Workshop, Shandong, China	2. AUDIT DATE 12-6-04	3. ESTABLISHMENT NO. 3700/03373	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	0
8. Records documenting implementation.		34. Species Testing	0
9. Signed and dated SSOP, by on-site or overall authority.		35. Residue	0
<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 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	
<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	0
25. General Labeling		53. Animal Identification	0
26. Fin. Prod. Standards/Boneless (Defects/AQL/Pork Skins/Moisture)		54. Ante Mortem Inspection	0
<b>Part D - Sampling Generic E. coli Testing</b>		55. Post Mortem Inspection	0
27. Written Procedures	0	<b>Part G - Other Regulatory Oversight Requirements</b>	
28. Sample Collection/Analysis	0	56. European Community Directives	0
29. Records	0	57. Monthly Review	
<b>Salmonella Performance Standards - Basic Requirements</b>		58.	
30. Corrective Actions	0	59.	
31. Reassessment	0		
32. Written Assurance	0		

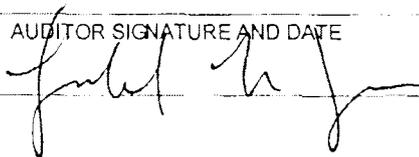
60. Observation of the Establishment

China, Est. 3700/03373 12-6-04

61. NAME OF AUDITOR

Dr. Oto Urban

62. AUDITOR SIGNATURE AND DATE



1/24/2005

Certification and Accreditation Administration of the People's Republic of China  
(CNCA)

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**Re: Evaluation Opinion regarding U. S. Department of Agriculture, Food Safety and  
Inspection Service  
Equivalence and Review Report**

Dear Ms. Sally White:

Your January 24, 2005, letter and follow-up to the December 2004 FSIS work group trip to China to review and report on the equivalence of China's poultry and meat inspection system was received February 7. We then immediately arranged for the relevant Center for Inspection and Quarantine (CIQ) industry and accompanying personnel to evaluate the review report. This evaluation of the report is hereby attached, please review.

Thank you to you and your colleagues for your tremendous work on behalf of China-U.S. poultry and meat inspection system equivalence efforts. I hope we continue to strengthen our cooperation in China's heat treatment procedures of poultry and meat for export to the United States.

If you require additional information related to the evaluation report, please contact me in a timely manner. Telephone: 0086-10-8226-2759 or 82262760, fax: 0086-10-8226-0753, email: chengf@cnca.gov.cn.

Respectfully yours,

Attached: China's evaluation of the U.S. Food Safety and Inspection Service initial review of China's meat and poultry inspection system equivalence

Certification and Accreditation Administration of the People's Republic of China

Administration Vice-Chairman      Cheng Fang

March 29, 2005

**Copies sent to:** U.S. Department of Agriculture, Food Safety and Inspection Service, Assistant Administrator **Ms. Karen Stuck** and Deputy Assistant Administrator **Mr. Bill James**; International Review Staff Director **Mr. Donald Smart**, Senior International Equivalence Staff Member **Mr. Todd Furey**; U.S. Embassy in China Agriculture Minister Mr. Fang Mosi; U.S. Embassy in China Agriculture Specialist Mr. Bi Kaixian; U.S. Embassy in China Senior Agriculture Assistant Ms. Zhang Jianjing; Chinese Embassy in the United States Secretary Mr. Zhao Baoqing.

AQSIQ: Food Products Division.

This department: Office, Archives (2).

Attachment:

**China's evaluation of the final draft of the U.S. Food Safety and Inspection Service initial review of China's meat and poultry inspection system equivalence**

U.S. Department of Agriculture, Food Safety and Inspection Service, Equivalence and Review Group (below, FSIS), from December 1 to 17, 2004, came to China and visited AQSIQ headquarters, Certification and Accreditation Administration of the People's Republic of China (CNCA) headquarters, four entry-exit inspection and quarantine (CIQ) stations and four microbiology laboratories and four medication residue laboratories, three slaughter sites and four processing factories to conduct equivalence review of poultry and meat inspection and quarantine systems. Through inspection and review, the U.S. review group was considering whether the AQSIQ, from its central administration to its local administration in the areas of professional qualifications, organization and staff, was able to ensure supervision and control of export industries and able to ensure export food product safety. On February 7, 2005, CNCA Administration Vice Chairman Cheng Fang received the FSIS final draft report. Now the Chinese side's evaluation of the report and report attachments (1, 2) follows in reply. If an issue has not been raised in this evaluation opinion then for the time being the Chinese side has no questions about these sections.

**One. Chinese side evaluation and opinion regarding review report**

**(One) Legislation and government supervision (review report, items 1-6)**

**-- Report "6.2.2 In a certain CIQ, FSIS discovered that AQSIQ does not have adequate supervision and control procedures for the factory."**

Chinese side evaluation and response: AQSIQ supervision of enterprises is based on the *Law of the People's Republic of China on Import and Export Commodity Inspection*, the *Law of the People's Republic of China on Entry and Exit Animal and Plant Quarantine* and AQSIQ *Administrative Procedures for Sanitation Registration of Food for Export* (AQSIQ 2002 decree no. 20) and *Supervisory Program for Import and Export Food Product Enterprises*.

For the enterprise involved in this situation, the Chinese side's CIQ staff has taken steps to withdraw the current position, and conduct retraining; half-hearted industrial supervision and control and existing problems were immediately rectified.

**-- Report "6.2.3 During the review period, official veterinarians at certain CIQs did not express understanding of FSIS requirements."**

**6.2.4 "Official veterinarians at certain CIQs did not have properly and thoroughly implement FSIS standards."**

**6.2.3 After inspecting these review documents, the only concern was that CIQ and FSIS inspectors**

**had poor understanding and implementation of FSIS standards.”**

Chinese side evaluation and response: In August 2004 the Chinese side conducted training of 14 CIQ official veterinarians in FSIS regulations and technical standards. In the first half of 2005, they also conducted retraining of CIQ official veterinarians and enterprise quality personnel (QA) with reference to the FSIS review report.

**(Two) Hygiene controls (Item 9)**

**-- Report “9.1: Pre-processing hygiene operations are inadequate: In one factory poultry food products and the hot food treatment area conveyer belt contact surface and plastic containers were found to have oil, blood, grease and air-dried meat and foreign bodies.”**

**-- Report “9.1: Hygiene operations are inadequate: In one factory, in several places it was discovered that there were too many products with oil spatter concentrations.**

**In two factories, decorative food and non-food product containers used were not stored in a separate area.”**

Chinese side evaluation and response: Regarding inadequate pre-processing hygiene operations and inadequate operating hygiene, cleaning and disinfecting were implemented immediately, and a series of prevention measures were formulated (for details refer to the evaluation and response to U.S. review report attachment 2).

The enterprise reform report has already been reviewed and submitted to the FSIS review group.

**-- Report “9.2 Other operating hygiene is inadequate: during reinspection of three factories, the lights were substandard; during reinspection of one factory the tables were misplaced; in three factories deep cracks were found in conveyer belts used to move edible food products; in one factory the cold storage container pipes were rusted and the oil paint was separating from the pipes; in one factory the products directly rubbed against dirty clothing that had not been cleaned; in one food production factory a processing platform for non-food products had a surface that was discovered to come into contact with an excessive amount of grease; in two factories the employee who cleaned the operating floor also worked in food processing.”**

Chinese side evaluation and response: The Chinese side has already completely repaired the problems discovered by FSIS (for details refer to the evaluation and response to U.S. review report attachment 2).

Problems that require explanation: “The two factories in which the employee who cleaned the operating floor also performed food processing.” According to the record of the persons at the site from the Chinese side, one Liaoning enterprise (2100/03086) was described above; in the other Beijing enterprise (1100/03039) the situation was not described in the report: the work of the employee cleaning the operating floor and the employee processing the food products were equivalent (it has now been clearly

differentiated), however the person cleaning the floor did not prepare food products (for details refer to the evaluation and response to U.S. review report attachment 2).

**(Three) Slaughter/processing controls (Items 11 – 13)**

**-- Report: "11.2 In two enterprises the HACCP program did not fully clarify the supervisory procedures. Two factories did not conduct preassembly re-inspections."**

Chinese side evaluation and response: The preceding situation was entirely corrected right away. The correction report has already been submitted to the FSIS review group.

**-- Report: "11.3 One factory did not conduct sampling of all chickens for E. COLI testing."**

Chinese side evaluation and response: Sampling of all chickens for E. COLI testing has now been implemented.

**-- Report "11.4 FSIS is now evaluating the equivalence of LISTERIA MONOCYTOGENES testing methods provided by AQSIQ. This evaluation is in process."**

Chinese side evaluation and response: In accordance with the recommendations of the U.S. side, the Chinese side has already adopted ISO11290-1 test methods for Listeria Monocytogenes. This method was provided to the U.S. review group on December 1, 2004. We hope that the U.S. side can conclude the equivalence evaluation regarding Listeria Monocytogenes as soon as possible.

**(Four) Medication residue controls (Item 12)**

**-- Report "12.0 Medication residue testing methods are not the same. During the approval process, FSIS is now evaluating the equivalence of various testing methods provided by AQSIQ."**

Chinese side evaluation and response: The medication residue inspection methods adopted by the Chinese side are not exactly the same as the U.S. methods, however the minimum detection quantities in China's medication residue methods are able to fully satisfy the demands of U.S. regulations, and the inspection results are equal, some Chinese medication residue methods are superior to those of the United States. We hope that the U.S. side can communicate the evaluation results as soon as possible.

**-- Report "12.0 In one CIQ the sampling procedure might possible create cross-contamination in the sample."**

Chinese side evaluation and response: Already completely repaired. This was the situation at one CIQ. China's residue inspection laboratory sample processing procedures are scientifically rigorous.

In addition, for the opinion from the Chinese side at the four Beijing, Liaoning, Shandong and Shanghai CIQ residue laboratories

reviewed, see review report attachment 1.

**(Five) Measures to strengthen controls (Item 13)**

-- Report "13.2 One factory did not conduct sampling of all chickens to test for SALMONELLA.

FSIS is now evaluating the equivalence of various SALMONELLA testing methods provided by AQSIQ. China is now at the stage of using national standards to conduct SALMONELLA testing. The equivalence evaluation is still in progress."

Chinese side evaluation and response: Said enterprise has already changed to conduct Salmonella testing on all chickens. The Chinese side has already adopted the recommendations of the U.S. side, and has adopted ISO6579 for testing Salmonella and standards for export of chicken food products to the United States in accordance with U.S. requirements, to use a cultured sample product quantity of 325 grams. We hope that the U.S. side can complete evaluation of the Chinese side's Salmonella testing methods as soon as possible.

**Two. Chinese side attachment 1 regarding the review report: *Final Report regarding the Initial Review of China's Poultry and Meat Inspection System Equivalence* -- Refer to the residue portion evaluation opinion.**

The Chinese side believes that in many locations in the *Final Report regarding the Initial Review of China's Poultry and Meat Inspection System Equivalence* the word "equal" replaces the word "equivalence" and it must be clarified. The specific evaluation opinion is as follows:

**1. Attachment 1: "8 Evaluation of hygiene laboratories"**

Chinese side evaluation: Should be changed to read "8 Evaluation of laboratories," because the text in this section refers to both hygiene laboratories and residue laboratories.

**2. Attachment 1: "12 Medication residue detection methods are not equal."**

Chinese side evaluation: FSIS is still in the process of evaluating the equivalence of various detection methods provided by AQSIQ. The lowest detectable quantities in China's medication residue methods are able to fully satisfy the requirements of relevant U.S. regulations, some of China's medication residue methods may be superior to those of the United States. Although China's methods are not equal to U.S. methods, the detection results are equivalent.

**3. Attachment 1: "12 In one CIQ the sample processing procedure may cause cross-contamination to the sample."**

Chinese side evaluation: The CIQ has already completely changed. This is a singular situation, China's residue detection laboratory sample processing procedures are scientifically rigorous.

#### **4. Attachment 1: “Residue laboratory review table (Beijing)”**

**-- Attachment 1: “4.1 Sample processing” “Sample placed in a single layer bag with a zipper, this sample will cause cross-contamination.”**

Chinese side evaluation: The Chinese side has thoroughly corrected the situation. As for the recommendation that an electronic recordkeeping system be used for sample collection, the Chinese side is actively pursuing adoption of such methods, and in fact China’s laboratories are now promulgating the LRP laboratory management system, which has already been successfully implemented in many laboratories.

-- Attachment 1: “4.2 Methods” “The methods of the Chinese side are still in the translation process. CAP and sulfanilamide testing used by the U.S. and Chinese sides are not the same. The Chinese side uses the ELISA and HPLC test methods. The table shows that the sulfanilamide test method is not suited for use with liver testing but is suitable for testing muscle.”

Chinese side evaluation: Beijing CIQ uses the ELISA method to conduct filter testing of CAP residue, positive samples (detected quantity  $\leq 0.1$  ppb) will be sent to the basic standards laboratory to mass spectrum analysis for verification. In China gas chromatography (GC) cannot serve to detect prohibited medications. As for detection of sulfanilamide medications, Beijing CIQ uses HPLC. The United States uses thin-layer chromatography, in China thin-layer chromatography is generally used for quantitative testing and semi-quantitative analysis, its quantitative testing ability is less than that of HPLC.

-- Attachment 1: “4.3 Tissue” “China uses liver for detection, the United States uses muscle.”

Chinese side evaluation: China uses the liver for sulfanilamide testing, and the United States uses muscle. China believes that it is easier to gather chloromycetin from liver than from muscle, and so it makes sense that China uses liver to test chloromycetin.

-- Attachment 1: “4.4 The United States requires confirmation that China only takes legal action when CAP detected quantity is  $> 0.3$  ppb.”

Chinese side evaluation: Chloromycetin is a prohibited medication and should not be detected. Because different laboratory equipment and test methods have definite differences, CAP must be detected in quantities no greater than 0.3ppb, and it is our understanding that in Europe and the United States and other developed nations the detected chloromycetin limit is also 0.3ppb, thus China’s detection limits may also satisfy the importing requirements of U.S. and various European nations. However, China not only takes action when CAP levels are greater than 0.3ppb, it also verifies that the test sample contains chloromycetin residue. China also will take investigatory action.

## **5. Attachment 1: “Residue laboratory review table (Dalian)”**

### -- Attachment 1: “5.1.1 Tetracycline”

Chinese side evaluation: Dalian CIQ uses radioimmunoassay (CHARM II method) testing and HPLC assay and the United States “uses biological testing and HPLC assay” methods, and clearly they are not the same. In the future all will use HPLC assay.

### -- Attachment 1: “5.1.2 Sulfanilamide”

Chinese side evaluation: As for detection of sulfanilamide medication, Dalian CIQ uses HPLC and the United States uses thin-layer chromatography. In China generally the thin-layer chromatography method is used for quantitative testing and semi-quantitative analysis, its quantitative testing function may be less than that of HPLC.

### -- Attachment 1: “5.1.3 Chloromycetin”

Chinese side evaluation: Dalian CIQ uses radioimmunoassay (CHARM II method) to perform filter testing of chloromycetin residue. Positive samples are sent to standards laboratories for verification and in China gas chromatography cannot serve as a method to detect prohibited medications.

### -- Attachment 1: “5.1.4 Organic chlorine”

Chinese side evaluation: Dalian CIQ similarly uses gas chromatography (GC) to detect organic chlorine, so this method should not have a clear distinction; it is only that the tissue detected is different.

-- Attachment 1: 5.2 Tissue “5.2.1 China uses liver to conduct tetracycline testing. The United States uses kidney.”

Chinese side evaluation: Liver and kidney are both tissues from which it is easy to gather tetracycline residue, so it makes sense that China uses liver tissue.

-- Attachment 1: “5.2.2 China uses liver to conduct CAP testing. The U.S. uses muscle.”

Chinese side evaluation: It is easier to gather chloromycetin from the liver, so it makes sense that China uses the liver rather than muscle to detect chloromycetin.

-- Attachment 1: “5.2.3 China uses liver to detect OCs. The U.S. uses fat.”

Chinese side evaluation: Fat and liver are both tissues from which it is easy to gather OC residue, so either liver or fat achieve the goal of detecting organic chlorine residue. However, by comparison, it is easier to gather OC residue in fats than in liver, so the Chinese side believes that it makes more sense to use fats as the U.S. does and in 2005 China will change and use fat to detect organic chlorine.

-- Attachment 1: "5.2.4 China uses kidney to detect arsenic. The United States uses the liver."

Chinese side evaluation: Kidney and liver are both tissues with which it is easy to detect elements, so it makes sense to use either the kidney or the liver to detect arsenic.

-- Attachment 1: "5.3 Minimum detectable quantity"

Chinese side evaluation: As for maximum residue limits for tetracycline and organic chlorine, China's requirements are far more rigorous than those of the United States, especially in terms of the maximum quantity of tetracycline, and it may initiate control of medication residues.

China has established maximum residue quantities for the elements lead, arsenic, cadmium and mercury. We ask the U.S. side to note that the U.S. does not have maximum residue quantities for lead and cadmium. The U.S. side provided detection capacities of 25ppb and 10ppb for lead and cadmium, respectively; however, the detection methods provided by U.S. FSIS officials on their web site do not test to verify the minimum limit, the U.S. side's controls for these two elements are not sufficient for detection. We ask that the U.S. side provide an explanation. If the U.S. side has clear MRL requirements, the Chinese side will take steps to ensure U.S. requirements for export products.

-- Attachment 1: "5.4 Element detection methods appear to only be suitable for testing chicken liver"

Chinese side evaluation: The element methods are not only suited to testing chicken liver samples, they are also suited to testing other tissue samples. Because organic ions are eliminated during preprocessing for the element testing method, when sample quality is unclear (for example, when it is both animal and plant tissue), the sample substrate has no impact on the final test results.

-- Attachment 1: "5.5 CHARM II method indicates that it only verifies at one level"

Chinese side evaluation: The CHARM II method is only needed to conduct verification at one concentration level, because the CHARM II method is a cut-off type of standard used for test filtering.

6. Attachment 1: "Residue laboratory review table (Qingdao)"

-- Attachment 1: "6.1.1 Sulfanilamide"

Chinese side evaluation: As for detection of sulfanilamide medications, Qingdao CIQ uses HPLC and the U.S. side uses thin-film chromatography. In China thin-film chromatography is generally used for quantitative testing and semi-quantitative testing, its quantitative testing function is poor compared to HPLC.

-- Attachment 1: "6.1.2 Chloromycetin"

Chinese side evaluation: Qingdao CIQ uses the ELISA and GC to filter test for chloromycetin, it uses GC/MS method or

LC/MS/MS method to conduct verification testing. In China the GC method cannot serve as the verification method for prohibited medications.

-- Attachment 1: "6.1.3 OCs and polychlorinated biphenyls (OCs) [T.N. sic]"

Chinese side evaluation: Qingdao CIQ similarly uses GC to detect OCs or polychlorinated biphenyls, so there is no clear deviation from the preceding method – it is just that a different tissue is used.

-- Attachment 1: "6.1.4 Arsenic (As)"

Chinese side evaluation: The United States uses atomic absorption spectrometry (AAS) to detect arsenic, and Qingdao CIQ may use AAS, it also may use ICP-MS to detect arsenic, and it should be explained that CIQ possesses more detection procedures, and it is not that the methods are different.

-- Attachment 1: "6.2.1 China uses liver to conduct OC and PCB detection. The United States uses fat."

Chinese side evaluation: Fat and liver are both tissues from which it is easy to gather OC and PCB residue. Thus using fat or liver makes it possible to achieve the goal of detecting OC and PCB residue. However, relatively speaking, it is easier to gather OC and PCB residue from fat, so the Chinese side believes that the U.S. use of fat makes more sense. In 2005 the Chinese side will use fat to conduct OC and PCB residue testing.

-- Attachment 1: "6.2.2 China uses kidney to conduct arsenic testing. The U.S. uses liver."

Chinese side evaluation: Kidney and liver are both tissues with which it is easy to detect elements, so it makes sense to use either the kidney or the liver to detect arsenic.

-- Attachment 1: "6.3 Minimum detectable quantity"

Chinese side evaluation: As for maximum residue limits for organic chlorine, China's requirements are more rigorous than those of the United States, so China fully meets the requirements regulated by the U.S.

China has established maximum residue quantities for lead, arsenic, cadmium and mercury, and the U.S. does not have maximum residue quantities for lead and cadmium. The U.S. does not control residues for these two elements, and it is not permitted to test them, so we ask the U.S. side to provide a clear explanation. The U.S. side provided detection capabilities of 25ppb and 10ppb for lead and cadmium, respectively; however, the detection methods provided by U.S. FSIS officials on their web site do not verify the minimum limit. If the U.S. side has clear MRL requirements, the Chinese side will take steps to ensure U.S. requirements for export products.

-- Attachment 1: "6.4 Chloromycetin collection rates tend to be low"

Chinese side evaluation: Because chloromycetin detection concentrations were lower than 1ppb, at such a low concentration a low collection rate is normal, it is only necessary that quality control provisions be followed to be acceptable. Qingdao CIQ laboratory has an average collection rate of 87.3% for chloromycetin, which is fully in compliance with the specified requirements.

7. Attachment 1: “Residue laboratory review table (Shanghai)”

-- Attachment 1: “7.1 Sample processing” “Sample is placed inside a single-layer zipper bag, this may cause cross-contamination.”

Chinese side evaluation and response: This issue has been fully corrected at the Shanghai CIQ, and double-layer bags are being used to store samples.

-- Attachment 1: “7.2.1 Sulfanilamide”

Chinese side evaluation: As for detection of sulfanilamide medication, the Shanghai CIQ uses HPLC and the U.S. uses thin-layer chromatography. In China thin-layer chromatography is generally used for quantitative testing and semi-quantitative analysis, its quantitative testing ability is less than that of HPLC.

-- Attachment 1: “7.2.2 Organic chlorine”

Chinese side evaluation: Shanghai CIQ similarly uses gas chromatography (GC) to detect organic chlorine, so this method should not have a clear distinction; it is only that the tissue detected is different.

-- Attachment 1: “7.3.1 China uses liver to conduct OCs testing. The United States uses fat.”

Chinese side evaluation: Fat and liver are both tissues from which it is easy to gather OC residue (OCs), so either liver or fat achieve the goal of detecting organic chlorine residue. However, by comparison, it is easier to gather OC residue in fats than in liver, so the Chinese side believes that it makes more sense to use fats as the U.S. does and in 2005 China will change the residue inspection and control program and use fat for the detection of organic chlorine.

-- Attachment 1: “7.3.2 China uses kidney to detect arsenic. The United States uses liver.”

Chinese side evaluation: Kidney and liver are both tissues from which it is easy to gather element residue, so it makes sense to use either the kidney or the liver to detect arsenic.

-- Attachment 1: “7.4 Minimum detectable quantity”

Chinese side evaluation: As for maximum residue limits for organic chlorine, China’s requirements are far more rigorous than those of the United States, and thus can fully meet the provisions of U.S regulations.

China has established maximum residue quantities for the elements lead, arsenic,

cadmium and mercury, and the United States does not have maximum residue quantities for lead and cadmium. The United States does not exercise controls for these two elements, and they are not permitted to be detected. We ask that the U.S. side provide a clear explanation. The U.S. side provides 25ppb and 10ppb detection capacities, respectively, for lead and cadmium but the U.S. FSIS official web site does not provide methods for verifying detection of such elements. If the United States has clear MRL requirements, then the Chinese side will take steps to guarantee products for export comply with U.S. requirements.

-- Attachment 1: "7.4 Sulfanilamide and ZERANOL collection rates tend to be low"

Chinese side evaluation: Shanghai CIQ testing of sulfanilamide and ZERANOL complies with the requirements of relevant Chinese law.

-- Attachment 1: "7.5 If it is possible to accept laboratory will properly reduce sample quantities for review"

Chinese side evaluation: Shanghai CIQ has strengthened review of sample focus and detection quality control effectiveness, testing personnel have properly reduced the frequency of continuous retesting of sample test results when reviewed samples pass the test; testing personnel have increased the frequency of sample review when reviewed samples do not pass or test results are not stable.

Three. Chinese side evaluation and response to review report attachment 2: : *Final Report regarding the Initial Review of China's Poultry and Meat Inspection System Equivalence*  
-- FSIS reviews seven Chinese enterprises observed.

1. 1100/03039 Beijing Jiayi Food Products Factory (inspection date December 2, 2004)

-- Attachment 2: "10/51 A metal dish on which many food-use products were placed was also used for placement of non-food-use products, and the food-use products and the non-food-use products were processed in the carving area. This inadequacy was already noted in the factory veterinarian review for correction report, 9CFR416.13."

Chinese side evaluation and response: The matter was corrected prior to December 4, 2004. The correction report was submitted to the FSIS review team.

-- Attachment 2: "16/51 The factory does not conduct inspection prior to transport. This inadequacy was already noted in the factory control personnel review for correction report. 9CFR417.5 (3) (c)."

Chinese side evaluation and response: The matter was corrected prior to December 4, 2004. The correction report was submitted to the FSIS review team.

-- Attachment 2: "46/51 A conveyor belt used to move unpackaged food-use products had deep cracks embedded in it. This inadequacy was already noted in the factory control personnel review for correction report. 9CFR416.4 (d)."

Chinese side evaluation and response: The matter was corrected prior to December 4, 2004. The correction report was submitted to the FSIS review team.

-- Attachment 2: "47/51 In the factory, the worker responsible for the hygienic condition of the floor was also responsible for processing food-use products, this inadequacy was already noted in the factory veterinarian review for correction report. 9CFR416.5 (a)."

Chinese side evaluation and response: Actual feedback at time of review was: The job duties of the worker cleaning the floor and the worker washing the food products were the same, and not easy to distinguish; however, the person cleaning the floor did not also come into contact with cleaned food products. The matter was corrected prior to December 4, 2004, and the correction report was submitted to the FSIS review team.

2. 2100/03086, China Dalian Great Wall Food Products Company, Ltd. (inspection date December 3, 2004)

-- Attachment 2: "10/12/51 In the slaughterhouse, quite a few products were discovered to have drops of condensed water on them, and the factory veterinarian's rectification efforts did not meet standards. Eliminate condensed water from the unpackaged product. 416.13, 416.15 (a, b)."

Chinese side evaluation and response: The enterprise has enrolled in a correction program, to further establish a warm-air ventilation system, to further establish a system to draw out the air and to prevent the formation of condensed water.

-- Attachment 2: "10/51 A plastic dish on which many food-use products were placed was also used for placement of non-food-use products, and the food-use products and the non-food-use products were processed in the carving area. Factory veterinarian rectification was improper, 9CFR416.13."

Chinese side evaluation and response: The enterprise has completely corrected the problem, the non-food-use products will use a special red basket.

-- Attachment 2: "16/51 Monitoring frequency as established in the HACCP program. This item is not in compliance with the rectification records of factory control personnel. 9CFR417.2"

Chinese side evaluation and response: The enterprise has completely corrected the problem, and in the HACCP verification column further established product control personnel to directly review the frequency of worker monitoring and control efforts; added HACCP operating verification record; and conducted training of all laboratory testing personnel. Passed Liaoning CIQ verification.

-- Attachment 2: "27/28/29/51 Factory officials or inspection officials do not test E. Coli in all chickens and verify that this test is controlled during the production process. This item of non-compliance was already in the correction records of the factory veterinarian. 9CFR381.93 (a)."

Chinese side evaluation and response: The Chinese side has already started to implement testing of all chicken for E. Coli.

-- Attachment 2: "30/31/32/51 Factory officials or inspection officials do not test the products of all chickens for Salmonella. This item of non-compliance was already in the correction records of the factory veterinarian. 9CFR381.93 (b)."

Chinese side evaluation and response: The Chinese side has already started to implement testing of all chicken for Salmonella.

-- Attachment 2: "40/45/51 pretest site did not have adequate tables and sufficient illumination (200 feet of candlepower). This item of non-compliance was already in the correction records of the factory veterinary. 9CFR381.76 (c) (iv)."

Chinese side evaluation and response: The enterprise has established additional pretest site testing platforms; pretest location illumination has been increased to 656LUX.

-- Attachment 2: "46/51 workers use a dirty, unclean cloth to wipe down the product contact area. This situation occurs in the carving area. This item of non-compliance was already in the rectification records of the factory veterinarian."

Chinese side evaluation and response: The enterprise has already eliminated this operating method.

-- Attachment 2: "47/51 In the factory, the worker responsible for the hygienic condition of the floor was also responsible for processing food-use products. This item of non-compliance was already in the rectification records of the factory veterinarian. 416.5 (a)."

Chinese side evaluation and response: The enterprise has established an additional position for a worker to maintain the hygienic condition of the floor.

-- Attachment 2: "55/51 Factory workers and inspection personnel have not conducted the correct pre-cooling and post-cooling operations. This item of non-compliance was already in the rectification records of the factory and inspection agencies. 9CFR381.76."

Chinese side evaluation and response: Pre-cooling and post-cooling operations have been implemented.

-- Attachment 2: "54 Because of time considerations, the pre-slaughter area has not been reviewed."

Chinese side evaluation and response: The pre-slaughter area of the slaughterhouse is very small, the hygienic conditions are poor, instrument washing and disinfecting is inadequate, the transportation vehicle has not had cleaning and disinfectant implemented. CIQ has already required the enterprise to enlist in a full rectification program, at present the enterprise is in the middle of this process.

3. 2100/03129. China Dacheng Food Products (Dalian) Company, Ltd. (inspection date December 3, 2004)

Although China Dacheng Food Products (Dalian) Company, Ltd., has already implemented complete rectification in compliance with the complete rectification program, it is still necessary to have a short period of time to observe the transformation. The Chinese side has decided to temporarily recommend that this enterprise not register with the United States.

-- Attachment 2: "10/51 Preprocessing hygiene operations are insufficient in several areas, for example the product contact surface was found to have foreign bodies, for example: oil, blood, grease, dried meat and miscellaneous microscopic foreign bodies. These contact surfaces include the raw meat area and the frying area's conveyor belt and plastic dish. After discovery by the factory veterinarian, some issues were corrected right away and some were not fully corrected in a timely manner. 416.134.15(a)."

Chinese side evaluation and response: The enterprise is now correcting preprocessing hygiene review, strictly in accordance with the implementation of the *Operating Procedures for Hygiene Standards*, the hygiene state of the workroom is very good; the raw product control manager has resigned; and training of the worker's SSOP system was strengthened.

-- Attachment 2: "46/51 It was discovered that the non-food-product contact surface of the raw meat area operating platform had a great deal of oil and fat.

When inspected by the review officials, the factory veterinarian had not rectified this non-compliant item in a timely fashion. 416.4 (b)."

Chinese side evaluation and response: The enterprise has already reviewed the nature of this preprocessing review. When CIQ conducted a re-inspection, oil and fat was not found on the non-food-product contact surface.

-- Attachment 2: "16/51 direct monitoring and control actions and frequency are not recorded in the HACCP program. Already enrolled in a correction program. 417.5.2."

Chinese side evaluation and response: During the HACCP management process, increased monitoring efforts to correct the issue, conducted CCP testing and records using product control personnel, verified and recorded CCP monitoring personnel records, monitoring frequency and operating methods.

-- Attachment 2: "22/51 does not implement pre-transport review, and also does not have corresponding records. Already enrolled in a correction program. 417.5.3 (c)."

Chinese side evaluation and response: The enterprise has already formulated a pre-transport review process, implemented a pre-transport review and established a corresponding record.

4. 3100/03032 Shanghai Fuxi Food Products Company Ltd. (inspection date December 10, 2004)

FSIS on-site check found no items of non-compliance

5. 3700/03260 Shandong Jinmei Food Products Company Ltd. (review date December 6, 2004)

-- Attachment 2: "40/51 at re-inspection point lacked 200 candlepower light source. This inadequacy was noted in the factory veterinarian correction report. 381.76 (c) (iv)."

Chinese side evaluation and response: This inadequacy was completely corrected on December 8, 2004.

-- Attachment 2: "46/51 The conveyor belt on which the food-use products were placed had many deep cracks. This inadequacy was already noted in the enterprise control correction program. 416.4 (d)."

Chinese side evaluation and response: This inadequacy was completely corrected December 8, 2004. The correction report was submitted to the FSIS review team.

6. 3700/03262 Shandong Qingdao Zhengda Company, Ltd. (review date December 7, 2004)

--Attachment 2: "40/51 Light source at the reinspection point was not 200 candlepower. This inadequacy was noted in the factory veterinarian correction report. 381.76 (c) (iv)."

Chinese side evaluation and response: Additional light was placed at the reinspection point to reach luminosity of 540LUX or higher. Completed December 11, 2004.

-- Attachment 2: "46/51 Hygiene operations prior to processing were found that in the carving workroom there were several places with deep cracks on the conveyor belt on which the export product was placed directly. The enterprise management is already in a program to correct this inadequacy. 416.4 (d)."

Chinese side evaluation and response: The enterprise reviewed all of the workroom conveyor belts and thoroughly replaced all belts with large defects or grooves. Corrections were completed December 9, 2004.

-- Attachment 2: "46/51 During the preprocessing review the exposed precooling pond had rusted pipes with oil paint flakes. The enterprise management is already in a program to correct this inadequacy. 416.4."

Chinese side evaluation and response: On December 11, the enterprise conducted maintenance, anti-rust and oil painting of the workroom's rusted structures all in the same day and strengthened daily maintenance efforts.

-- Attachment 2: "46/51 Found that during review of preprocessing hygienic operations, from the ceiling to the floor, oil paint flakes were found in several locations in the carving room used on the work platform for food-use products. Enterprise management is already in a program to correct this inadequacy. 416.4."

Chinese side evaluation and response: On December 11, the enterprise conducted maintenance of the ceiling and awning. Exposed paint on the ceiling was eliminated that day.

-- Attachment 2: "55/51 There was no enterprise employee to inspect the pre-cooling pond and the post-cooling pond. In terms of the previously described inspection implementation inadequacy and lack of testing, enterprise control management is already in a correction program. 381.76."

Chinese side evaluation and response: The Chinese is now arranging improved CIQ and enterprise study and understanding of U.S. 381.76 regulations. The enterprise has already completed corrections in accordance with U.S. 381.76 regulations and formulated pre-cooling and post-cooling inspection operation procedures (SOP), completed December 9, 2004.

7. 3700/03373 Shandong Zhucheng Foreign Trade Cold Storage Company, Workroom Two (review date December 6, 2004)

FSIS on-site review found no items of non-compliance.