

UNITED STATES DEPARTMENT OF AGRICULTURE

2006 SEP -5 PM 3: 04

BEFORE THE SECRETARY OF AGRICULTURE

RECEIVED

In re:	}	
	}	FMIA Docket No. 05-0005
	}	PPIA Docket No. 05-0006
Trinh Company	}	
	}	
Respondent	}	Consent Decision
	}	
	}	

This is a proceeding under the Federal Meat Inspection Act, as amended (21 U.S.C. § 601 et seq.) ("FMIA") and the Poultry Products Inspection Act, as amended (21 U.S.C. § 451 et seq.) ("PPIA") and the applicable Rules of Practice (7 C.F.R. 1.130 et seq. and 9 C.F.R. § 500.1 et seq.) to withdraw Federal inspection services from Trinh Company, hereinafter referred to as Respondent. This proceeding was commenced by a complaint filed on May 24, 2005 by the Administrator of the Food Safety and Inspection Service (FSIS), United States Department of Agriculture (USDA), which is responsible for the administration of Federal inspection services for both meat and poultry. The parties have agreed that this proceeding should be terminated by entry of the Consent Decision set forth below and have agreed to the following stipulations:

1. For the purpose of this stipulation and the provisions of this Consent Decision only, Respondent admits all jurisdictional allegations of the complaint and waives:
 - (a) Any further procedural steps except as specified herein;
 - (b) Any requirement that the final decision in this proceeding contain any findings and conclusions with respect to all material issues of fact, law, or discretion, as well as the reasons or basis thereof; and

(c) Except as set forth herein, all rights to seek judicial review or to otherwise challenge or contest the validity of this decision.

2. This Stipulation and Consent Decision is for settlement purposes only and does not otherwise constitute an admission or denial by Respondent that Respondent violated the regulations or statutes involved.

3. Respondent waives any action against the USDA under the Equal Access to Justice Act of 1980 (5 U.S.C. § 504 et seq.) for fees and other expenses incurred by Respondent in connection with this proceeding.

4. Respondent, its owners, officers, directors, partners, successors, assigns, and affiliates waive, in addition to the action(s) waived in paragraph three above, any other action(s) against USDA or its employees in connection with these proceedings.

5. The parties agree that, in order to facilitate compliance with FSIS statutory and regulatory requirements and the terms and conditions of this Order:

(a) Respondent at its own expense shall completely translate the contents of this Order into Respondent's native language (Vietnamese) and shall maintain a copy of the original Order (English version) and its translation at Respondent's facility at all times.

(b) Within thirty (30) days of the effective date of this Order, Respondent shall participate with its legal representative and/or a translator in a meeting with FSIS officials to discuss all the terms, provisions and implications of this Order.

(c) Respondent shall seek translation services to facilitate communications in all instances where Respondent needs guidance in FSIS regulations and requirements.

Findings of Fact

1. Trinh Company is and was, at all times material herein, an unincorporated business located at 2485 Autumnvale Drive, Suite C, San Jose, California 95132.
2. Respondent was, at all times material herein, granted Federal inspection services under the FMIA and PPIA under Establishment number 6488/ P-6488.
3. Ms. "Linda" Mai Chen is and was, at all times material herein, the Owner of Trinh Company.
4. On January 6, 2004, FSIS reinstated the suspension of Federal inspection services issued to Respondent on February 28, 2003, based on Respondent's repetitive failures to meet Sanitation Standard Operating Procedures (SSOP), Pathogen Reduction/Hazard Analysis Critical Control Point (HACCP), and *Listeria monocytogenes* regulatory requirements of 9 C.F.R. Parts 416, 417 and 430.

Conclusion

Because the parties have agreed to the provisions set forth in the following Stipulation and Consent Decision in disposition of this proceeding, the following Order will be issued.

Order

Federal meat and poultry inspection services under the Title I of the FMIA and PPIA are withdrawn from Respondent Trinh Company, its owners, officers, directors, partners, successors, affiliates, or assigns, directly or through any corporate device, for a period of two (2) years beginning on the effective date of this Order; Provided, however, the withdrawal of inspection services shall be held in abeyance, and inspection services

shall be provided to Respondent for so long as the conditions set forth below, in addition to all other requirements for applicable inspection services, are met:

1. Prior to the resumption of inspection services, and subject to verification by FSIS, Respondent shall demonstrate compliance with FSIS statutory and regulatory requirements, including, but not limited to 9 C.F.R. Parts 416, 417 and 430, upon a review and examination of:

- (a) Respondent's Sanitation Standard Operating Procedures (SSOP), Hazard Analysis and Critical Control Point (HACCP) Plan, *Listeria monocytogenes (Lm)* Program, and other written sanitation, process controls, and sampling or testing programs; and
- (b) the physical and sanitary conditions of Respondent's establishment.

2. Upon the resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, Respondent shall at all times operate and maintain its establishment, including its facilities, equipment, and outside premises, in a manner sufficient to prevent the creation of unsanitary conditions and practices, and comply with the requirements of the Sanitation Performance Standards (SPS) regulations (9 C.F.R. §§ 416.1-416.6), to ensure that meat and poultry products prepared, stored and packaged at Respondent's establishment are not contaminated or adulterated.

3. **Sanitation Standard Operating Procedures.**

(a) Prior to the resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, Respondent shall develop revised written sanitation standard operating procedures (SSOP) to describe the monitoring activities, recordkeeping, and other procedures that Respondent will conduct, implement and maintain, on a daily and ongoing basis, before, during, and after operations, in

accordance with 9 C.F.R. §§ 416.11 to 416.16, to ensure sanitary conditions and prevent product adulteration.

(b) Upon the resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, Respondent shall:

(i) implement and maintain, on a daily and ongoing basis, its SSOP system as provided in paragraph 3(a) of this Order and the regulatory requirements of 9 C.F.R. 416 to ensure the prevention of unsanitary conditions and prevent product adulteration;

(ii) implement all corrective and preventive actions required by 9 C.F.R. 416.15, routinely evaluate the effectiveness of its SSOP, and implement all modifications required by 9 C.F.R. 416.14, as necessary, to ensure that regulatory requirements for the maintenance of sanitary conditions and the production and distribution of safe, wholesome, unadulterated, and properly labeled products in commerce are met; and

(iii) prepare and maintain records regarding the implementation and monitoring of its SSOP procedures and all corrective and/or preventive actions taken, as well as any decision-making documents regarding review and evaluation of its SSOP.

4. Hazard Analysis and Critical Control Point (HACCP) Plan.

(a) Prior to the resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, Respondent shall:

(i) develop HACCP Plans to describe each system of process controls and procedures that Respondent will implement and utilize on a daily and on-going basis to control and prevent the introduction of food safety hazards into meat, meat food products, poultry, and poultry products. These plans shall address specific process controls and procedures within Respondent's HACCP system(s) (i.e. *Listeria monocytogenes* in post

lethality process steps), including but not limited to the following:

(A) measures to identify the biological, chemical, and physical food safety hazards reasonably likely to occur at each critical control point in the Fully Cooked, Not Shelf Stable process, and to ensure the prevention or elimination of such hazards or their reduction to undetectable levels; and

(B) measures to eliminate or reduce and control the level of *L.*

monocytogenes to prevent contamination of Respondent's products and the environment.

(ii) Respondent's HACCP plan(s) shall include all decision making documents for the plan(s), including its hazard analysis or analyses, validation protocols and all parameters used in said protocols, and data to support the food safety system(s).

(b) Upon resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, Respondent shall:

(i) implement, validate and maintain its HACCP system(s) and plan(s), as provided in paragraph 4(a), in accordance with the requirements of 9 C.F.R. Part 417;

(ii) implement timely and appropriate corrective and preventive actions and reassess and modify its HACCP systems and plans as necessary to ensure that the regulatory requirements for the control and prevention of pathogens and the production and distribution of wholesome, unadulterated and properly labeled products in commerce are met, as required by and consistent with 9 C.F.R. Part 417;

(iii) conduct ongoing assessment, validation and testing of the adequacy of the critical control points, critical limits, monitoring and record-keeping procedures, and corrective actions set forth in the HACCP system(s) and plan(s), to ensure that the establishment's food safety systems remain validated over time, as required by 9 C.F.R. Part 417; and

(iv) complete its written validation documentation of the pork skin process in accordance with Respondent's validation procedures, and provide the validation documents to FSIS for review within thirty (30) days after the completed validation.

5. Listeria monocytogenes Program.

(a) Prior to resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, Respondent shall reevaluate and revise its *L. monocytogenes* sampling and testing program for its ready-to-eat (RTE) products, in accordance with 9 C.F.R. 430. Respondent's revised *L. monocytogenes* program shall, at the minimum:

(i) include one of the three alternatives for the production of post-lethality exposed RTE product based on its control program for *L. monocytogenes*;

(ii) include a testing program for food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;

(iii) state the frequency for which testing will be done;

(iv) identify the size and location of the sites that will be sampled;

(v) include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes*, or an indicator organism, is maintained;

(vi) include random sampling for all facility sites and production days that will give an equal opportunity of selection for all sites and times; and

(vii) describe the conditions under which the establishment will implement hold and test procedures following a positive test of a food contact surface for *L. monocytogenes* or an indicator organism.

(b) Upon resumption of inspection services Respondent shall document and maintain sample laboratory results and records regarding the implementation and monitoring of its *L. monocytogenes* program, and corrective actions and preventive measures in accordance with 9 C.F.R. 417.5. Respondent shall make its *L. monocytogenes* program, plant record(s), and regulatory record(s), including laboratory test results, regarding its *L. monocytogenes* program available to FSIS personnel for review and/or copying upon request. In the event of any positive *L. monocytogenes* test result for food contact surfaces, non-contact surfaces or RTE products, Respondent shall:

(i) document and implement appropriate corrective and preventive actions;

(ii) take appropriate action to identify and eliminate the source of the *L. monocytogenes* contamination;

(iii) reassess their *L. monocytogenes* program, SSOP, and HACCP programs; and

(iv) monitor and verify the effectiveness of the corrective actions and preventives measures identified and implemented.

6. Establishment Management and Employee Training.

(a) Prior to resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, Respondent shall designate in writing, one full-time person and one alternate person who shall be responsible for overall implementation, coordination, monitoring, verification, validation, reassessment, and record keeping for its SSOP and HACCP programs, and for conducting and maintaining its *L. monocytogenes* testing program, as required by and consistent with 9 C.F.R. Parts 416, 417 and 430 and the requirements of this Order.

(b) Prior to the resumption of inspection services, Respondent shall take all actions

necessary to ensure that the designee and alternate(s) have completed training in regulatory requirements regarding SSOP, HACCP, control of *Listeria monocytogenes* in the post-lethality process, *Listeria monocytogenes* sampling and testing procedures, good manufacturing practices and procedures, and record keeping, as well as the terms of this Order.

(c) Upon the resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, Respondent shall:

(i) train all current employees in regulatory requirements regarding SSOP, HACCP, control of *Listeria monocytogenes* in the post-lethality process, *Listeria monocytogenes* sampling and testing procedures, good manufacturing practices and procedures, and record keeping;

(ii) train any new employee, consistent with the requirements of this paragraph, within thirty (30) days of their employment;

(iii) conduct annual training for all employees, current and new, consistent with the requirements of this paragraph; and

(iv) document and maintain written records of the implementation and completion of the initial and annual training for current and new employees for the duration of this Order, and make these records available to FSIS personnel for review and/or copying immediately upon such request by FSIS.

7. **Recordkeeping.**

(a) Upon resumption of inspection services, and subject to verification by the FSIS District Manager and/or designees, Respondent shall:

(i) maintain full, complete and accurate copies of:

(A) all records required to be maintained by the FMIA, PPIA and the regulations;

(B) all records required to be maintained under applicable Federal, State and local statutes; and

(C) all SSOP, HACCP, *Listeria monocytogenes* programs, product sampling and testing plans, and all other systems, plans and records required by the FMIA, PPIA, the regulations or this Order.

(ii) notify the FSIS District Manager and/or designee of any changes or modifications to its SSOP, HACCP or other systems, programs or plans, and any recordkeeping forms that Respondent uses or intends to use in association with these systems, programs, and plans, as required by the regulations or this Order.

8. General Provisions.

(a) Respondents or any of its owners, officers, directors, partners, employees, agents, successors, affiliates, or assigns shall not:

(i) violate any section of the FMIA, the PPIA, State or local statutes involving the preparation, sale, transportation or attempted distribution of any adulterated or misbranded meat or poultry products;

(ii) willfully make, or cause to be made, any false entry in any account, record, or memorandum kept by Respondent in compliance with applicable Federal or State statutes or regulations; or willfully neglect or fail to make full, true and correct entries in such accounts, records or memoranda; or fail to keep such accounts, records or memoranda that fully and correctly disclose all transactions in Respondent's business;

(iii) commit any felony or fraudulent criminal act that results in a conviction; or

assault, intimidate, or interfere with; or threaten to assault, intimidate, or interfere with any program employee in the performance of his or her official duties under the FMIA and PPIA; or

(iv) knowingly hire or add any new individual who has been convicted, in any Federal or State court, of any felony, or more than one misdemeanor based upon the acquiring, handling, or distributing of unwholesome, mislabeled or deceptively packaged food, or fraud in connection with transaction in food; and shall immediately terminate its connection with any such individual when that individual's conviction becomes known to Respondent.

(b) Respondent shall not conduct any operations requiring federal inspection outside the official hours of operation without first submitting a written request and receiving approval from FSIS program personnel.

9. Enforcement Provisions.

(a) The Administrator, FSIS, shall have the right to summarily withdraw inspection services from Respondent upon a determination by the Administrator, or his or her designee, that one or more conditions set forth in paragraphs 1 through 8 of this Order have been violated. It is acknowledged that Respondent retains the right to request an expedited hearing pursuant to the Rules of Practice concerning any violation alleged as the basis for a summary withdrawal of inspection services. Nothing contained in these provisions prevents the right of Respondent to appeal the decision of an FSIS employee to his/her immediate supervisor pursuant to 9 C.F.R. § 306.5 and 381.35.

(b) Nothing in this Order shall preclude:

(i) any pending or future criminal, civil, regulatory or administrative action

authorized by law, regulation or otherwise, including, but not limited to any action under the FSIS Rules of Practice (9 CFR Part 500) or

(ii) the referral of any matter to any agency for possible criminal, civil, or administrative proceedings.

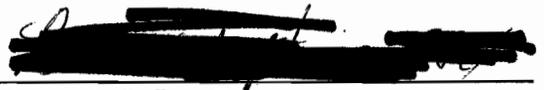
(c) If any provision of this Order is declared invalid, such declaration shall not affect the validity of any other provision herein.

10. This Order shall become effective upon issuance by the Administrative Law Judge.

11. This Consent Decision shall be effective for a period of two (2) years upon issuance by the Administrative Law Judge.



"Linda" Mai Chen, Owner
for Trinh Company

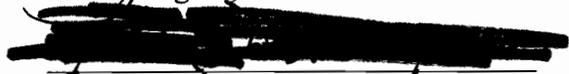


Scott C. Safian, Director
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Thomas N. Bolick, Esq.
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United States Department of Agriculture
Office of the General Counsel

Issued this 5th day of Sept 2006
at Washington, D.C.



ADMINISTRATIVE LAW JUDGE
PETER M. DAVENPORT