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UNITED STATES DEPARTMENT OF AGRICULTURE

BEFORE THE SECRETARY OF AGRICULTURE

In re:	}
	} FMIA Docket No. 16-0182
	} PPIA Docket No.
California Qi Li's Braised Chicken LLC,	}
	}
	}
	} **Consent Decision and Order**
	}
Respondent	}

This proceeding was instituted under the Federal Meat Inspection Act ("FMIA"), as amended (21 U.S.C. § 601 *et seq.*), and the Poultry Products Inspection Act ("PPIA"), as amended (21 U.S.C. § 451 *et seq.*), 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 California Qi Li's Braised Chicken LLC, (hereinafter referred to as Respondent). This proceeding was commenced by a complaint filed by the Administrator of the Food Safety and Inspection Service (FSIS), United States Department of Agriculture (USDA), on September 16, 2016.

The parties have agreed that this proceeding should be terminated by entry of this Consent Decision and Order (Order) set forth below pursuant to the consent decision provisions of the Rules of Practice (7 C.F.R. § 1.138).

The Respondent admits the findings of jurisdictional fact as set forth herein. The Respondent neither admits nor denies the remaining allegations and waives oral hearing and further procedure. Respondent and its owners, officers, directors, partners, successors, assigns, and affiliates waive any claim against complainant under the Equal Access to Justice Act of 1980 (5 U.S.C. § 504 *et seq.*) and waive other action against USDA or its employees in connection

with this proceeding and the facts and events that give rise to this proceeding. Respondent consents and agrees, for the purpose of settling this proceeding and for such purpose only, to entry of this decision.

Findings of Fact

1. Respondent is now, and at all times material herein was, a meat and poultry processing plant that has a business and mailing address of 44250 Old Warm Springs Boulevard, Fremont, California 94518.

2. Respondent received a grant of federal inspection services on February 27, 2012, and was designated Official Establishment No, 40286 M/P.

3. On March 28, 2012, February 26, 2013, August 27, 2013, September 27, 2013, and August 26, 2013, FSIS issued Respondent Notices of Suspension, whereby FSIS withheld the marks of inspection and suspended the assignment of inspectors to respondent's facility, because FSIS inspection personnel observed various sanitation and food safety violations at the facility on those dates. Each suspension of respondent's inspection services was subsequently held in abeyance following Respondent's submittal of acceptable corrective actions and preventive measures.

4. On April 25, 2016, FSIS issued Respondent a Reinstatement of Notice of Suspension whereby FSIS withheld the marks of inspection and suspended the assignment of inspectors to the facility for continued insanitary conditions due to rodent droppings and other insects in and around the establishments Fully Cooked, Not Shelf Stable areas, including the processing room, equipment storage, employee and USDA office areas, restrooms and plant vestibule.

Conclusion

The parties having admitted the jurisdictional facts and the parties having agreed to entry of this decision, this decision will be entered.

Order

Federal meat and poultry inspection services under Title I of the FMIA and the PPIA are withdrawn from Respondent, its owners, officers, directors, partners, successors, affiliates or assigns, directly or indirectly or through any corporate device, for a period of three (3) years, beginning on the effective date of this Order. Provided, however, the withdrawal of Federal meat and poultry inspection services shall be held in abeyance, and inspection services shall be provided to Respondent, pursuant to a conditional grant of inspection, for so long as the statutory and regulatory requirements for inspection services under the FMIA and PPIA are met, in addition to all terms and conditions of this Order as set forth below.

Conditions

1. Prior to the resumption of inspection services, and subject to verification by FSIS, Respondent shall demonstrate compliance with all applicable FSIS statutory and regulatory requirements, including but not limited to 9 C.F.R. §§ 416, 417, 418, and 430, upon a review and examination of:

(a) Respondent's Sanitation Performance Standards (SPS), Sanitation Standard Operating Procedures (SSOPs), Hazard Analysis and Critical Control Point (HACCP) plan, *Listeria monocytogenes ("Lm")* sampling and testing program, Recall of Meat and Poultry Products Plan, Pest Management Program, Planned Improvement Program, Allergen Control Program, other

written sanitation programs, process controls, corrective actions, and sampling and testing programs, and any other related food safety programs; and

(b) the physical and sanitary conditions of Respondent's establishment.

2. During the period of this Order, within its discretion, FSIS may conduct examinations of records, Intensified Verification Testing , and other verification and monitoring activities to ensure Respondent's compliance with, and the implementation, and effectiveness of, its SPS, SSOPs, HACCP plan, *Lm* sampling and testing program, and other systems, plans, and records required by the FMIA and PPIA, the regulations, and this Order.

Sanitation Performance Standards (SPS)

3. Prior to resumption of inspection services, and subject to verification by FSIS, Respondent shall:

(a) develop and implement written procedures for monitoring and identifying noncompliance, taking corrective and preventive actions, and recordkeeping; and for operating and maintaining its establishment, including its premises, facilities, equipment, and outside premises in a manner sufficient to: (i) prevent the creation of insanitary conditions and practices; (ii) preclude harborage and breeding of pests; (iii) comply with the requirements of the SPS regulations (9 C.F.R. § 416.1 to § 416.5); and (iv) ensure that meat and meat food products, and poultry and poultry products that are prepared, packed, and stored at Respondent's facility are not adulterated or misbranded;

(b) ensure that its SPS includes specific, written instructions addressing, at a minimum, the following procedures: (i) re-conditioning of contaminated product; and (ii) employee hygienic practices; and

(c) address and correct any premises, facility and equipment noncompliance issues previously identified by FSIS, or identified by FSIS at the time of the physical plant review conducted pursuant to paragraph 1(b) of this Order.

4. Upon the resumption of inspection services, and subject to verification by FSIS, Respondent shall:

(a) comply with the requirements of the SPS regulations (9 C.F.R. § 416.1 to § 416.5);

(b) operate and maintain, at all times, its establishment, including its interior premises, facilities, equipment, and outside premises, in a manner sufficient to prevent the creation of insanitary conditions and practices, and to preclude harborage and breeding of pests;

(c) ensure that meat and meat food products, and poultry and poultry food products, are not adulterated;

(d) assess its written SPS procedures to evaluate their effectiveness, and make necessary improvements, corrections, and repairs to the establishment buildings, structures, rooms, and compartments to ensure that they are kept in good repair and have sufficient size to allow for processing, handling, and storage of product in a manner to ensure and maintain sanitary conditions, and to preclude harborage and breeding of pests; and

(e) implement and maintain the SPS written procedures for the duration of this Order.

Allergen Control Program

5. Prior to the resumption of inspection services, and subject to verification by FSIS, Respondent shall:

(a) develop a written allergen program for allergenic ingredients, including monitoring, verification, corrective and preventive actions, and recordkeeping that it will

implement, conduct, and maintain, on a daily and ongoing basis, to ensure that all inspected meat and poultry food products do not become adulterated, contaminated, or misbranded. This control program shall include, at a minimum, provisions to (i) process, handle, store, and label product with an allergenic ingredient or ingredient of public health concern and (ii) ensure monitoring, verification, and recordkeeping activities.

(b) ensure written recall procedures are in place to effectively recall potentially adulterated or misbranded products because of the presence of undeclared allergens produced or processed by Respondent when found within distribution channels.

6. Upon the resumption of inspection services, and subject to verification by FSIS, Respondent shall implement, conduct, and maintain, on a daily and ongoing basis, its written allergen control program.

Planned Improvement Program

7. Prior to resumption of inspection services, and subject to verification by FSIS, Respondent shall develop a "Planned Improvement Program" (PIP) designed to identify and correct noncompliance and to ensure that the entire structure of the facility, to include its rooms and compartments, is of sound construction and that all equipment is maintained in proper working order and kept in good repair.

8. Upon the resumption of inspection services, and subject to verification by FSIS, Respondent shall implement and maintain its PIP as required in this Order, and document any findings and corrective actions to address structural and/or mechanical repairs and/or improvements to its facility and make these records available to FSIS for review and/or copying upon request.

Pest Management Program

9. Prior to the resumption of inspection services, and subject to verification by FSIS, Respondent shall develop, implement and maintain a written pest management program,

based on the recommendation and findings of an assessment conducted by an independent third party company, to prevent the harborage and breeding of pests within the facility and on its grounds consistent with 9 C.F.R. § 416.2(a) and (b). This program shall ensure that:

(a) the pest control service reviews and services Respondent's facility and grounds on at least a bi-weekly basis; and

(b) the pest control service provides Respondent written reports detailing its findings and recommendations.

10. Upon resumption of inspection services, and subject to verification by FSIS, Respondent shall implement and maintain its pest management program in a manner sufficient to prevent the creation of insanitary conditions and practices, to prevent the harborage and breeding of pests, and to ensure that meat and poultry products stored, prepared, and packed are not contaminated or adulterated.

Sanitation Standard Operating Procedures (SSOPs)

11. Prior to the resumption of inspection services, and subject to verification by FSIS, Respondent shall:

(a) develop written sanitation standard operating procedures (SSOPs) to describe the monitoring activities, recordkeeping, and other procedures that Respondent will implement, conduct, and maintain, on a daily and ongoing basis, before, during, and after operations, in accordance with this Order and the regulatory requirements (9 C.F.R. § 416.11 to § 416.16) to ensure sanitary conditions and prevent product adulteration; and

(b) ensure that its SSOPs include specific, written instructions addressing, at a minimum, the following procedures: (i) cleaning and sanitizing of food contact surfaces of facilities, equipment and utensils; (ii) using and cleaning complex equipment; (iii) proper handling, storage, denaturing, and disposal of inedible products; (iv) re-conditioning of

contaminated product; and (v) employee hygienic practices. These written instructions shall specify the frequency of each aforementioned procedure.

12. Upon the resumption of inspection services, and subject to verification by FSIS, Respondent shall:

(a) implement and maintain, on a daily and ongoing basis, its SSOP system as provided in this Order and the regulatory requirements of 9 C.F.R. § 416.11 to § 416.16 to ensure sanitary conditions and prevent product adulteration; and

(b) implement and document all corrective and preventive actions, as required by 9 C.F.R. § 416.15; routinely evaluate the effectiveness of its SSOPs; and implement necessary modifications as required by 9 C.F.R. § 416.14 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.

Hazard Analysis and Critical Control Points (HACCP) Systems and Plans

13. Prior to the resumption of inspection services, and subject to verification by FSIS, Respondent shall:

(a) reassess its HACCP systems and plans to describe each system of process controls and procedures that Respondent will implement, conduct, and maintain on a daily and on-going basis to control and prevent the introduction of food safety hazards in its meat or poultry food products. These plans shall address specific process controls and procedures within Respondent's HACCP system(s) and plans and *Lm* sampling and testing program, including but not limited to, the following: (i) measures to identify the biological, chemical, and physical food safety hazards reasonably likely to occur at each process step, and to eliminate such hazards or reduce them to undetectable levels; (ii) measures to address *Lm* as a hazard in the process; and (iii) measures to

eliminate or reduce and control the level of *Lm* to prevent contamination of respondent's finished product, food contact surfaces, and non-contact environmental surfaces; and

(b) retain all decision-making documents for its HACCP systems and 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).

14. Upon the resumption of inspection services, and subject to verification by FSIS, Respondent shall:

(a) implement, validate and maintain on a daily and on-going basis its HACCP system(s) and plan(s), in accordance with the regulatory requirements of 9 C.F.R. § 417 and as provided in this Order;

(b) implement timely and appropriate corrective and preventive actions and reassess and modify its HACCP system(s) and plan(s) 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. § 417; and

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

Listeria monocytogenes (Lm) Program Provisions

15. Prior to the resumption of inspection services, and subject to verification by FSIS, Respondent shall develop a written *Lm* sampling and testing program for its ready-to-eat (RTE) products in accordance with 9 C.F.R. § 430 and, at a minimum, shall:

(a) include Alternative 3 for the production of post-lethality exposed RTE product based on its control program for *Lm;*

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

(c) describe the conditions under which the establishment will implement hold and test procedures following a positive test of a food-contact surface for *Lm* or an indicator organism;

(d) state the frequency of the testing;

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

(f) include an explanation of why the testing frequency is sufficient to ensure that effective control of *Lm* or of an indicator organism is maintained.

16. Respondent shall document and maintain sample laboratory results and records regarding the implementation and monitoring of its *Lm* program, and corrective actions and preventive measures in accordance with 9 C.F.R. § 417.5.

17. In the event of any positive *Lm* test result for food contact surfaces, non-contact surfaces, or RTE products, Respondent shall;

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

(b) take appropriate action to identify and eliminate the source of the *Lm* contamination;

(c) reassess its *Lm* program, SSOPs, and HACCP plan or other prerequisite programs; and

(d) monitor and verify the effectiveness of the corrective actions and preventive measures identified and implemented.

18. Upon the resumption of inspection services, and subject to verification by FSIS, Respondent shall implement, conduct, and maintain, on a daily and on-going basis, its written *Lm* sampling and testing program for the duration of this Order, and comply with 9 C.F.R. § 430.

Establishment Management and Personnel

19. Prior to the resumption of inspection services, and subject to verification by FSIS, Respondent shall:

(a) designate, in writing, two full-time employees, one as a principal and the other as an alternate, who shall be responsible for the overall implementation, coordination, documentation, monitoring, recordkeeping, review and maintenance of the facility's SPS, PIP, SSOPs, and HACCP plans, *Lm* sampling and testing program, Pest Management Program, Allergen Control Program, and all other requirements of this Order. (i) The designated principal and alternate shall have completed, prior to the resumption of inspection services, a course of instruction in the seven principles of HACCP, and SSOP, and be trained in the *Lm* sampling and testing procedures; and (ii) either the principal or the alternate shall be present at all times when operations requiring inspection are conducted.

(b) provide a detailed summary of the authority and responsibilities that the designated principal and alternate are granted with respect to actions taken in the establishment.

20. Upon resumption of inspection services, Respondent shall not conduct any processing operations in the absence of said designated principal or alternate. The designated principal and alternate shall have authority to hold up production, stop production, remove

product from production, or take positive control of any products produced, processed, packed, or stored at the establishment that are or are believed to be adulterated or misbranded, or when facility sanitation or production deficiencies are observed. Respondent may name a new designated principal and alternate employee or employees upon written notification to the Director, Enforcement and Litigation Division (ELD).

Management and Employee Training

21. Prior to the resumption of inspection services, and subject to verification by FSIS, Respondent shall develop a training program for all current employees and future hires involved in the preparation, processing, and/or production of meat and meat food products, and poultry and poultry products, to ensure that employees are trained in all aspects of food safety measures and regulatory requirements, including the requirements of its SPS and SSOP programs, HACCP plan, *Lm* sampling and testing program, Pest Management program, Planned Improvement Program, Allergen control program, recordkeeping procedures, and Good Manufacturing Practices, relevant to each employee's position. Respondent shall provide copies of all training materials to FSIS for review and evaluation prior to training employees.

22. Respondent shall, within thirty (30) days from the effective date of this Order, and subject to verification by FSIS, train all current employees consistent with the requirements of paragraph 21 of this Order.

23. Upon resumption of inspection services Respondent shall train and educate any new employee(s), consistent with the requirements of this Order, within thirty (30) calendar days of the first date(s) of employment.

24. Upon resumption of inspection services Respondent shall conduct annual training for all employees and management personnel, current and new, involved in the preparation, processing, and/or production of meat and meat products, and poultry and poultry products, consistent with statutory and regulatory requirements 9 C.F.R. §§ 416, 417, 418, and 430, and the requirements of this Order.

25. Respondent shall document and maintain all training and education materials, certifications, training records, test results, and other materials for all training required by paragraphs 21 through 24 of this Order and make these records available to FSIS personnel for review and/or copying immediately upon request.

Third Party Audits Provisions

26. Respondent shall, upon resumption of Federal inspection services, cause to be made, by a qualified, independent third-party, written audits of: (a) Respondent's implementation, monitoring, and maintenance of its sanitation, SSOP, HACCP plans, other process controls and other programs; (b) the effectiveness of Respondent's sanitation program, SSOPs, HACCP plans, other process controls and other programs to ensure food safety; (c) Respondent's compliance with FSIS statutory and regulatory requirements; (d) Respondent's compliance with the terms of this Order; and (e) any other findings and recommendations of the independent third-party.

27. Respondent shall prepare, for each audit conducted, a written response to the audit findings and recommendations. Respondent's written response shall identify: (i) any modifications to its SSOPs, HACCP plan, *Lm* sampling and testing program, Pest Management Program, Planned Improvement Program, Allergen Control Program, or other programs or plans; (ii) any corrective actions implemented or planned in response to the

audit; and (iii) information in support of any decision by Respondent not to implement any audit recommendation.

28. Respondent shall submit a copy of each third-party audit report, a copy of Respondent's written response, or other documents related to the audit to the Director, ELD, for review and concurrence within (30) calendar days after each audit is completed.

29. The frequency of the aforementioned audits shall be as follows:

(a) the first audit shall be conducted within ninety (90) calendar days from the effective date of this Order; and

(b) subsequent audits shall be conducted every (180) calendar days thereafter for the duration of the Order.

30. Prior to any audits being conducted, Respondent shall submit the name and qualifications of the independent third-party auditor to the Director, ELD, for concurrence. The Director, ELD, shall not withhold concurrence, absent good cause.

31. For the purposes of paragraphs 26 through 30 and this paragraph, an independent third- party shall be a person, entity, or corporation free from bias and absent from a conflict of interest with the Respondent. Specifically, the person, entity, or corporation conducting an audit (a) shall not be a current or former officer, director, employee, affiliate, contractor, representative, or agent of Respondent and (b) shall serve the Respondent only in the limited capacity of executing the audit duties detailed in paragraphs 26 through 30. If the Director, ELD, has good cause to believe that an audit was conducted by a person, entity, or corporation otherwise employed by or affiliated with Respondent or with a present bias or a conflict of interest, any written audit and report of the audit shall be deemed disqualified for the purposes of complying with this Order.

Record Keeping Provisions

32. Upon resumption of inspection Respondent shall:

(a) maintain full, complete, and accurate copies of all written records required to be maintained by the FMIA, PPIA, and the regulations;

(b) maintain all records required under applicable Federal, State, and local statutes; and

(c) all plans and records of its SPS and SSOP programs, HACCP plan, *Lm* sampling and testing program, Pest Management Program, Planned Improvement Program, Allergen Control Program, or other systems, programs, or plans required by the FMIA, PPIA, and the regulations of this Order.

33. Upon resumption of inspection Respondent shall immediately notify FSIS program personnel of any changes or modifications to its SSOPs, HACCP plan, *Lm* sampling and testing program, Pest Management Program, Allergen Control Program, or other systems, programs, or plans required by regulation or by this Order, and all associated recordkeeping forms.

34. Respondent shall make all records regarding its federally inspected establishment or other regulated business activities at said establishment available to FSIS personnel for review and/or copying immediately upon such request by FSIS.

General Provisions

35. Respondent and its owners, directors, managers, partners, employees, agents, affiliates, successors or assigns, shall not:

(a) violate any section of the FMIA, PPIA or regulations promulgated thereunder, any state or local statute involving the preparation, sale, transportation, or attempted distribution

of any adulterated, non-inspected, misbranded or deceptively packaged meat, or poultry food products;

(b) commit any felony or fraudulent act or other criminal act involving fraud, conspiracy, bribery, or any other act or circumstances indicating a lack of integrity needed for the conduct of operations affecting public health;

(c) willfully make or cause to be made any false entry into any accounts, records, reports, or memoranda kept by respondent in compliance with Federal, State or local statutes or regulations or this Order; neglect or fail to make full, true, and correct entries in such accounts, records, reports or memoranda; and fail to keep such accounts, records, reports, or memoranda that fully and correctly disclose all transactions in respondent's business;

(d) assault, intimidate, impede, threaten or interfere with any program employee in the performance of his or her official duties under the FMIA, PPIA, or regulations promulgated thereunder; and

(e) conduct any operation requiring Federal inspection outside respondent's official hours of operations without first submitting a written request to, and receiving written approval from FSIS.

36. Respondent shall fully and completely cooperate with any FSIS investigation, inquiry, review, or examination of respondent's compliance with the FMIA, PPIA or this Order.

Enforcement Provisions

37. The Administrator, FSIS, may summarily withdraw Respondent's grant of federal inspection services under the FMIA and PPIA upon a determination by the Director, ELD, that Respondent has committed an act in violation of, or has otherwise failed to comply with, any requirement of this Order. Such summary withdrawal shall become effective immediately, without further proceeding, upon FSIS's service of a Notice of Summary Withdrawal to

Respondent. Respondent shall retain the right, after any summary withdrawal of its grant of federal inspection services, to request an expedited hearing to contest the summary withdrawal. Such request for an expedited hearing must be submitted to the Director, ELD within twenty (20) calendar days of FSIS' service of a Notice of Summary Withdrawal. Failure to submit a request for an expedited hearing within this twenty (20) day period shall be construed as a waiver of Respondent's right to request a hearing to contest the withdrawal.

Miscellaneous Provisions

38. Nothing in this Order shall preclude (a) any 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 C.F.R. § 500) or (b) the referral of any matter to any agency for possible criminal, civil, or administrative proceedings.

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

40. The provisions of this Order shall be applicable for a period of three (3) years from the effective date of this Order.

41. This Order shall become effective upon issuance by the Administrative Law Judge. The provisions of this Order shall be applicable for a period of three (3) years from the date of resumption of operations.

BY: [redacted]
Qing Yu Li, owner
California Qi Li's Braised Chicken.

[redacted]
Scott C. Safian, Director
Enforcement and Litigation Division
Food Safety and Inspection Service
U.S. Department of Agriculture

[redacted]
Tom Bolick
Attorney for Complainant
U.S. Department of Agriculture
Office of the General Counsel

Issued this 19th day of Sept 2016

at Washington, D.C.

[redacted]
Administrative Law Judge