

UNITED STATES DEPARTMENT OF AGRICULTURE
BEFORE THE SECRETARY OF AGRICULTURE

In re:)
) FMIA/PPIA Docket No. **21-J-0016**
Harry Herpe, DBA Nob Hill Pizza,)
) Consent Decision and Order
Respondent.)

REC'D - USDA/OALJ/OHC
2021 FEB 19 AM 8:30

This proceeding was instituted under the Federal Meat Inspection Act (FMIA), as amended (21 U.S.C. § 601 *et seq.*), the Poultry Products Inspection Act (PPIA), as amended (21 U.S.C. § 451 *et seq.*), the applicable Rules of Practice (9 C.F.R. §§ 500.6 and 500.7), and the Uniform Rules of Practice (7 C.F.R. § 1.130 *et seq.*), to refuse and withdraw federal inspection services indefinitely from Harry Herpe, DBA Nob Hill Pizza (Respondent), based on multiple instances of egregious insanitary conditions observed and documented in Respondent's establishment whereby products produced at the facility may have been rendered adulterated in violation of the FMIA (21 U.S.C. §§ 608 and 621), the PPIA (21 U.S.C. §§ 456 and 463), and the regulations promulgated thereunder (9 C.F.R. Part 416). 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 the same date as the filing of this Consent Decision and Order.

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

Respondent admits the findings of fact set forth herein and specifically admits that the Secretary has jurisdiction in this matter. Respondent waives oral hearing and further procedure,

and waives any rights to seek judicial review or otherwise challenge or contest the validity of this Consent Decision and Order, including waiving any challenges to the Administrative Law Judge's authority to enter this Consent Decision and Order under the Administrative Procedure Act and the Constitution of the United States. Respondent waives any action under the Equal Access to Justice Act of 1980 (5 U.S.C. § 504 *et seq.*) and waives any other action against USDA or any USDA employees in connection with this proceeding and the facts and events that gave rise to this proceeding.

Complainant agrees to the entry of this Consent Decision and Order.

FINDINGS OF FACT

1. Respondent Harry Herpe is a sole proprietor doing business as Nob Hill Pizza. The physical address for Nob Hill Pizza is 155 South Boulevard, San Mateo, California 94402. The mailing address for service of Mr. Herpe is a private residence and will be provided to the Office of the Hearing Clerk separately from this Consent Decision and Order to protect the privacy interests of Mr. Herpe.

2. Respondent was issued a conditional Grant of Inspection pursuant to the FMIA and PPIA on or about September 9, 2014, and was assigned Official Establishment Number M/P 40118. Under its conditional Grant of Inspection, Respondent has received federal inspection services for meat and poultry products produced under its Hazard Analysis and Critical Control Point (HACCP) plans for Fully Cooked Not Shelf Stable and Heat Treated Not Fully Cooked Not Shelf Stable products.

3. Since 2018, FSIS has documented multiple violations of the FMIA, PPIA, and the regulations promulgated thereunder, based on observations of rodent droppings and conditions allowing for the entry of rodents and other pests in and around Respondent's establishment. On

or about September 26, 2018, the FSIS Alameda District Office suspended inspection services and issued a Notice of Suspension (NOS) following FSIS inspection program personnel's observation of rodent droppings at Respondent's establishment. The NOS was held in abeyance on or about October 18, 2018, based on corrective and preventive actions proffered by Respondent. The FSIS Alameda Office reinstated the suspension of inspection services at Respondent's establishment based on observations of rodent droppings and additional evidence of pest harborage on or about December 17, 2018, April 9, 2019, and January 24, 2020. Each of those Notices of Reinstatement of Suspension were held in abeyance by the Alameda District Office based on corrective and preventive measures proffered by Respondent.

4. On or about April 20, 2020, the FSIS Enforcement Operations Branch (EOB) issued a warning letter to the Respondent, notifying the Respondent of potential action by FSIS should the establishment be unable to maintain sanitary conditions in compliance with statutory and regulatory requirements.

5. On or about August 27, 2020, the Alameda District Office issued another Notice of Reinstatement Of Suspension to Respondent based on the observation of rodent droppings in or around the production room and warehouse of Respondent's establishment, indicating Respondent's failure to effectively implement corrective actions and measures to prevent pest harborage. Inspection services remain suspended as of the filing of the Complaint initiating this administrative proceeding.

CONCLUSION

6. Respondent having admitted jurisdiction and the findings of facts herein, and the parties having agree to the entry of this Consent Decision and Order, the Consent Decision and Order will be entered.

ORDER

7. Federal inspection services under the FMIA and PPIA are refused and withdrawn from Respondent, its owners, officers, directors, partners, successors, affiliates, successors, and/or assigns, directly or indirectly through any business or other device, beginning on the effective date of this Consent Decision and Order. Provided, however, that the refusal and withdrawal of 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 Respondent complies with the terms and conditions of this Consent Decision and Order, as well as the statutory and regulatory requirements for receiving inspection services under the FMIA and PPIA.

Terms to be completed prior to the resumption of Federal inspection services

8. Prior to the resumption of federal inspection services, and subject to verification by FSIS, Respondent shall submit to the Alameda District Office an Application for Federal Inspection, in accordance with FSIS regulations and consistent with this Consent Decision and Order, updating ownership and management information to reflect all individuals responsibly connected to the Respondent. FSIS will review the application and verify that the responsibly connected individuals are eligible to receive federal inspection services. Throughout the duration of this Consent Decision and Order, Respondent shall submit updated Applications for Federal Inspection, as needed to accurately reflect current ownership, management, and operational information.

9. Prior to the resumption of federal inspection services, and subject to verification by FSIS, Respondent shall demonstrate compliance with all applicable FMIA and PPIA statutory and regulatory requirements, based upon FSIS's review and examination of:

- a. Respondent's Hazard and Critical Control Point (HACCP) system, Sanitation Performance Standards (SPS), Sanitation Standard Operating Procedures (SSOP), pest management program, sampling and testing provisions in accordance with 9 C.F.R. Part 430, and any other food safety or sanitation programs; and
- b. the physical and sanitary conditions of the Respondent's establishment.

Food Safety Coordinator

10. Prior to resumption of federal inspection services, Respondent shall hire or appoint a Food Safety Coordinator who will be responsible for the overall implementation, coordination, documentation, monitoring, recordkeeping, review, and maintenance of the Respondent's food safety or sanitation programs (including its HACCP program, SPS, SSOP, pest management program, sampling and testing procedures, and any other food safety or sanitation programs) and other written programs, in accordance with applicable statutory and regulatory requirements and this Consent Decision and Order. Respondent will provide to the EOB Chief, for review and concurrence, the name of the proposed Food Safety Coordinator and documentation of their education and work experience. The Food Safety Coordinator:

- a. shall have completed, prior to resumption of inspection services, a course of instruction in the seven principles of HACCP and SSOP, and shall have at least two years of work experience in food safety, quality assurance, and FSIS regulations;
- b. shall be present at all times when operations requiring federal inspection are conducted; and
- c. shall not be a current or former owner, manager, or supervisor at Respondent's establishment.

11. Respondent shall not conduct any processing operations requiring federal inspection in the absence of the Food Safety Coordinator. The Food Safety Coordinator shall have the authority to slow production, stop production, remove product from production, and/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.

12. Should the Food Safety Coordinator vacate their role during the period of this Consent Decision and Order, Respondent shall immediately notify the EOB Chief and shall hire or appoint a new Food Safety Coordinator within ten (10) calendar days, subject to the concurrence of the EOB Chief. Any replacement Food Safety Coordinator must meet the qualifications in paragraph 10. Respondent may submit a request to the EOB Chief for an extension of time if the Respondent is unable to fill the role within the allotted time.

Initial Assessment

13. Prior to the resumption of federal inspection services, Respondent will contract a qualified, independent third party to conduct an initial assessment of the Respondent's facility, operations, and food safety or sanitation programs (including its, SPS, SSOP, pest management program, sampling and testing procedures, and any other food safety or sanitation programs). The qualified, independent third party must be certified by an accredited HACCP certifying organization. Respondent must submit to the EOB Chief, for review and concurrence, the name and credentials of the proposed qualified, independent third party, prior to their conducting the initial assessment. For the purposes of this Consent Decision and Order, an independent third party shall be a person, entity, or corporation free from bias or conflict of interest with respect to the Respondent. Specifically, the person or entity conducting the initial assessment shall not be a

current or former officer, director, employee, affiliate, representative or agent of Respondent. If the EOB Chief has reason to believe that the initial assessment was conducted by a person or entity affiliated with Respondent, or with a present bias or a conflict of interest, any assessment and report of the assessment shall be deemed disqualified for the purpose of complying with this Consent Decision and Order.

14. The initial assessment will, at a minimum:
 - a. include an on-site review and evaluation of the Respondent's facility and equipment used in processing operations;
 - b. review the Respondent's SSOP, SPS, pest management program, sampling/testing procedures, and any other food safety or sanitation programs;
 - c. list and provide an analysis of the incidents of regulatory noncompliance with the SSOP, and SPS requirements at Respondent's facility documented in Noncompliance Records (NRs), Notices of Suspension, or as otherwise documented by FSIS;
 - d. analyze Respondent's facilities, food safety procedures, programs, and past practices and describe how they contributed, in addition to other related factors, to the regulatory violations noted in subsection (c) above; and
 - e. recommend corrective actions and preventative measures for adoption by Respondent that will address and prevent recurrence of noncompliance. These corrective actions shall include, but are not limited to, structural and facility changes and repairs, reassessment and revision of the Respondent's food safety or sanitation programs and procedures, management changes, and management and employee training.

15. Respondent will prepare a written response to the third-party initial assessment. The written response will include, at a minimum:

a. a description of the corrective actions taken in response to the assessment's recommendations or an explanation for why specific recommendations are not being considered for action; and

b. documentation demonstrating implementation of corrective actions, including new or revised written programs and procedures, invoices and photographs of facilities and equipment, and/or any other relevant supporting documents that prove corrective actions were taken.

16. Prior to the resumption of federal inspection services, Respondent will submit a copy of the third-party initial assessment and the Respondent's written response and any other relevant supporting documents proving corrective actions were taken to the EOB Chief for review and concurrence.

Sanitation Performance Standards

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

a. develop and implement written procedures, including monitoring, corrective action, and recordkeeping procedures, to operate and maintain its establishment, including its premises, facility, equipment, and outside premises, in a manner sufficient to:

i. prevent the creation of insanitary conditions and practices, and to preclude harborage and breeding of pests;

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

iii. ensure that meat and meat food products, and poultry and poultry food products, that are prepared, packed, and stored at the Respondent's facility, are not adulterated or misbranded;

b. address and correct any premises, facility, and/or equipment noncompliance issues previously identified by FSIS or identified by FSIS at the time of the physical plant review conducted pursuant to paragraph 9(b) of this Consent Decision and Order; and

c. develop additional written procedures for grounds and pest control, including monitoring, corrective action, and recordkeeping procedures, that Respondent will implement to prevent and address the harborage and breeding of pests within the facility and on its grounds consistent with 9 C.F.R. § 416.2. This program, at a minimum, shall ensure:

i. at least daily examination, on the days of operation, of the facilities and structure for potential pest entry ways, attractants, and evidence of harborage and breeding;

ii. at least monthly service by an independent contracted pest control service to audit the facility and grounds and recommend corrective actions and preventive measures to be implemented by the Respondent or by the contracted pest control service at the direction of the Respondent; and

iii. the review and maintenance of records associated with the program implementation, including the contracted pest service findings, reports, and corrective actions taken by the Respondent or at the direction of the Respondent, to be available for review by FSIS.

Management and Employee Training

18. Prior to the resumption of federal inspection services, and subject to verification by FSIS, Respondent shall provide training for Respondent's management, supervisors, and employees involved in the preparation, processing, and/or production of meat and poultry food products, in all aspects of food safety measures and statutory and regulatory requirements. This training will be conducted by a qualified, independent third party and will include, at a minimum, the requirements of the establishment's HACCP plan, SPS, SSOP, pest management program, and other sanitation procedures, process controls, corrective actions, and record keeping procedures relevant to each employee's position.

19. Prior to resumption of inspection services, Respondent will submit to the EOB Chief, for review and concurrence, a copy of all training and educational program materials, including training records, test results, and any other materials and records for the training described in this Consent Decision and Order.

20. Respondent shall train and educate any new employee(s), consistent with the requirements of this Consent Decision and Order, within thirty (30) calendar days of their first date(s) of employment.

21. Respondent shall provide annual training for all employees and management personnel involved in the preparation, processing, and /or production of meat and poultry food products, consistent with all applicable FMIA and PPIA statutory and regulatory requirements and the requirements of this Consent Decision and Order.

22. Respondent shall document and maintain all training and educational materials, certifications, training records, test results, and other materials for all training required by

paragraphs 18 through 21 of this Consent Decision and Order and make these records available to FSIS personnel for review and/or copying immediately upon request.

Terms to be met upon resumption of Federal inspection services

Implementation of SPS and Pest Management Program

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

a. implement and maintain its SPS and pest management program provided for in paragraph 17 of this Consent Decision and Order;

b. continuously assess its SPS and pest control procedures to evaluate their effectiveness and make necessary improvements, corrections, and repairs to the buildings, structures, rooms, and compartments to ensure that they are kept in good repair and they are of 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

c. maintain records associated with implementation of its pest management program, including the contracted pest service's findings, reports, and corrective actions taken.

Third Party Audits

24. 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 food safety or sanitation programs (including its HACCP program, SPS, SSOP, pest management program, sampling and testing procedures, and any other sanitation programs);

b. the effectiveness of Respondent's food safety or sanitation programs (including its HACCP program, SPS, SSOP, pest management program, sampling and testing procedures, and any other sanitation programs);

c. Respondent's compliance with FMIA and PPIA statutory and regulatory requirements; and

d. Respondent's compliance with the terms of this Consent Decision and Order.

25. The frequency of the third-party audits shall be as follows:

a. the first audit shall be conducted within one hundred eighty (180) calendar days from the effective date of this Order; and

b. subsequent audits shall be conducted annually thereafter for the duration of this Consent Decision and Order.

26. Respondent shall submit a copy of each third-party audit and Respondent's written response to each audit to the EOB Chief, for review and concurrence, within 30 calendar days after each audit is complete.

Recordkeeping

27. Upon resumption of federal inspection services, and subject to verification by FSIS, Respondent will keep and maintain full, complete, and accurate copies of:

a. written records required by the FMIA, PPIA, the regulations promulgated thereunder, and all applicable State or local statutes; and

b. written records of its HACCP plans, SPS, SSOP, pest management program, sampling and testing procedures, other food safety or sanitation programs, and any other written records required by this Consent Decision and Order.

28. Respondent shall immediately submit to the EOB Chief any modifications to its HACCP plans, SPS, SSOP, pest management program, sampling and testing procedures, and/or any other food safety or sanitation programs required by applicable statute, regulation or this Consent Decision and Order, and all associated recordkeeping forms.

29. Respondent shall make all records regarding its federally inspected establishment and any other regulated activities at the establishment available to FSIS personnel for review and/or copying upon request by FSIS.

General Provisions

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

a. violate any section of the FMIA, PPIA, or regulations promulgated thereunder, or any State or local statute involving the preparation, sale, transportation, or attempted distribution of any adulterated, non-inspected, misbranded, or deceptively packaged meat, poultry, meat food products or poultry food products;

b. commit any felony or more than one violation of any law, other than a felony, based upon the acquiring, handling, or distributing of unwholesome, mislabeled, or deceptively packaged food or upon fraud in connection with transactions in food, or commit any violation of law involving fraud, bribery, extortion, or any other act or circumstances indicating a lack of the integrity needed for the conduct of operations affecting public health;

c. knowingly 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 Consent Decision and Order; neglect or fail to make full, true, and correct entries in any such accounts, records, reports, or memoranda; or 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 FSIS employee in the performance of his or her official duties under the FMIA, PPIA, or the regulations promulgated thereunder; or

e. conduct any operation requiring federal inspection outside Respondent's official hours of operation without first submitting a request to and receiving written approval from FSIS.

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

32. FSIS will have the right to summarily refuse and withdraw federal inspection services upon a determination by the EOB Chief, or their designee, that one or more of the provisions set forth in this Consent Decision and Order have been violated. Respondent retains the right, after any summary refusal or withdrawal of inspection services, to request an expedited hearing, pursuant to the applicable Rules of Practice (7 C.F.R. Part 1, subpart H and 9 C.F.R. Part 500), concerning any violation alleged as the basis for a summary refusal or withdrawal of inspection services. This does not affect the Complainant's right to suspend operations or take any other enforcement action in accordance with the applicable Rules of Practice.

33. Nothing in this Consent Decision and Order will preclude FSIS from referring any violation of law to the U.S. Department of Justice for possible criminal or civil proceedings, or preclude FSIS from taking other appropriate administrative action under the FMIA, PPIA, and the regulations promulgated thereunder.

34. If any provision of this Consent Decision and Order is declared invalid, such declaration will not affect the validity of any other provision herein.

35. This Consent Decision and Order will become effective upon issuance by an Administrative Law Judge.

36. The provisions of this Consent Decision and Order will remain in effect for a period of three (3) years from the date of issuance by the Administrative Law Judge.

Copies of this Consent Decision and Order shall be served upon the parties.

[Redacted]

Harry Herpe, DBA Nob Hill Pizza
Respondent

[Redacted]

Scott Safian
Chief, Enforcement Operations Branch
FSIS

[Redacted]

Tracy McGowan
Attorney for Complainant

Issued this 19th day of February, 2021

[Redacted]

Chief Administrative Law Judge
Channing D. Strother