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UNITED STATES DEPARTMENT OF AGRICULTURE
BEFORE THE SECRETARY OF AGRICULTURE

In re:	)	FMIA Docket No. 14-0180 PPIA Docket No. 14-0180
Tri-Town Packing Corp.	)	
Respondent	)	**Consent Decision and Order**

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 Tri-Town Packing Corp., (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 August 28, 2014.

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, and specifically admits that the Secretary has jurisdiction in this matter. 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 the Complainant under the Equal Access to Justice Act of 1980 (5 U.S.C.

§ 504 *et seq.*) and waive any other action against USDA or its employees in connection with this proceeding and the facts and events that gave rise to this proceeding. The Respondent consents and agrees, for the purpose of settling this proceeding and for such purpose only, to the entry of this decision and that this decision is the final resolution of all facts and events that gave rise to this proceeding.

Findings of Fact

1. Respondent is now, and was at all times material herein, a corporation organized and existing under the laws of the State of New York, operating a slaughtering and meat and poultry processing facility at 922 County Road 53, Brasher Falls, New York 13613.

2. Respondent was at all times material herein, a recipient of Federal inspection services at its place of business in Brasher Falls, NY, and designated as official Establishment Number 4499M/P-4499.

3. From January 21, 2014 through March 18, 2014, FSIS performed a Comprehensive Food Safety Assessment (CFSA) of Respondent's establishment and operations. Based on the results of the CFSA, on March 20, 2014, the Food Safety and Inspection Service (FSIS) issued Respondent a Notice of Intended Enforcement (NOIE) informing Respondent of its intent to withhold marks of inspection and suspend the assignment of FSIS inspection program personnel. Based on Respondent's response to the NOIE, including corrective actions, FSIS deferred further enforcement action.

4. On June 17, 2014, FSIS issued Respondent a Notice of Suspension (NOS) whereby FSIS withheld the marks of inspection and suspended the assignment of inspectors to the facility. Based upon proffered corrective actions and written assurances from Respondent, the NOS was

held in abeyance pending verification by FSIS personnel that proposed corrective actions and preventive measures had been effectively implemented.

5. On July 17, 2014, FSIS issued Respondent a Notice of Suspension (NOS) whereby FSIS withheld the marks of federal inspection and suspended the assignment of federal inspectors to the facility.

Conclusion

The Respondent having admitted the jurisdictional facts and the parties having agreed to the entry of this decision, this Order 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 and assigns, directly or through any business or other device, for a period of five (5) years, beginning on the effective date of this Order; Provided, however, said withdrawal of inspection services shall be held in abeyance, and Federal meat inspection services shall be provided to Respondent, pursuant to a conditional grant of inspection, for so long as the statutory and regulatory requirements for applicable inspection services and all terms and conditions of this Order set forth below are met and maintained. Federal poultry inspection services are permanently withdrawn in accordance with the Application for Inspection (FSIS Form 5200-2) that Respondent will submit as set forth below.

Conditions

1. Prior to the resumption of inspection services, pursuant to this Order, Respondents shall submit a new Application for Inspection (FSIS Form 5200-2) reflecting required information and

any changes of its business operations, including that Tri-Town will no longer conduct poultry operations.

2. 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. Parts § 307, 309, 310, 313, 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) system, Recall of Meat Products Plan, *E. coli* Biotype sampling and testing programs, *Listeria monocytogenes* ("*Lm*") sampling and testing program, Pest Management Program, Planned Improvement Program (PIP), other written sanitation, process controls, corrective actions, and sampling or testing programs required by regulation or this Order;

b. The physical and sanitary conditions of Respondent's establishment.

3. During the period of this Order, within its discretion, FSIS may conduct examinations of records, Intensified Verification Testing (IVT), and other verification and monitoring activities to ensure the Respondent's compliance, implementation, and the effectiveness of its SPS, SSOP, HACCP, and other systems, plans, and records required by the FMIA, the regulations, and this Order.

Sanitation Performance Standards (SPS)

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

a. Develop written procedures, including monitoring, corrective action, and recordkeeping procedures that Respondent will implement to operate and maintain its establishment, including its premises, facilities, 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 SPS regulations (9 C.F.R. § 416.1 to § 416.5); and (iii) ensure that meat and meat food 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) proper handling, storage, denaturing, and disposal of inedible products; (ii) re-conditioning of contaminated product; and (iii) employee hygienic practices;

c. Address specific process controls and procedures for *E.coli* Biotype I; and

d. 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.

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

a. 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, comply with the requirements of the SPS regulations (9 C.F.R. § 416.1 to § 416.5), and to preclude harborage and breeding of pests;

b. Ensure that meat and meat food products are not adulterated;

c. 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

d. Implement and maintain the SPS written procedures for the duration of this Order.

Planned Improvement Program

6. Prior to the resumption of Federal 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, including its rooms and compartments, is of sound construction and that all equipment is maintained in proper working order and kept in good repair.

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

Pest Management Program

8. Prior to the resumption of Federal inspection services, and subject to verification by FSIS, Respondent shall develop a written pest management program, to be implemented and maintained by an independent pest control service, 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) to ensure that:

a. The pest control service reviews and services Respondent's facility and grounds at least monthly; and

b. The pest control service provides Respondents written reports detailing its findings and recommendations of its review.

9. Upon resumption of inspection service, and subject to verification by FSIS, Respondent shall implement and maintain their 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 products stored, prepared, and packed are not contaminated or adulterated.

Sanitation Standard Operating Procedures (SSOPs)

10. Prior to the resumption of Federal 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 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; and (ii) complex equipment use and

methods of cleaning. These written instructions shall specify the frequency of each aforementioned procedure.

11. 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 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, not adulterated, and properly labeled products in commerce are met.

Hazard Analysis and Critical Control Points (HACCP) System

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

a. Reassess its HACCP system and plans to describe each system of process controls and procedures that Respondent will implement, conduct, and maintain on a daily and ongoing basis to control and prevent the introduction of food safety hazards in its meat food products. These plans shall address specific process controls and procedures within Respondent's HACCP system for *E. coli* O157:H7 sampling and testing, 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 *E. coli* as hazards in the process; and (iii) measures to eliminate or reduce and control the level of *E. coli* to prevent contamination of Respondent's finished product; and

b. Retain all decision-making documents for its HACCP system and plans, including its hazard analysis or analyses, validation protocols, and all parameters used in said protocols, and data to support the food safety systems.

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

a. Implement, validate and maintain on a daily and ongoing basis the HACCP system and plans, in accordance with the regulatory requirements of 9 C.F.R. Part 417 and as provided in this Order;

b. Conduct initial in-plant validation during the first ninety (90) days of resumed operations, in accordance with 9 C.F.R. §§ 304.3(b) and 417.4;

c. Implement timely and appropriate corrective and preventive actions and reassess and modify its HACCP system 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; and

d. 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 the HACCP system and plans, to ensure that

Respondent's food safety systems remain validated over time, as required by 9 C.F.R. Part 417.

***Listeria monocytogenes (Lm)* Program Provisions**

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

a. Include Alternative 2 for the production of post-lethality exposed ready-to-eat 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. Address specific process controls and procedures for *Lm* sampling and testing, 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 hazards 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;

d. 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;

e. State the frequency for which the testing will be done;

f. Identify the size and location of the sites that will be sampled; and

g. Include an explanation of why the testing frequency is sufficient to ensure that effective control of *Lm* or of an indicator organism is maintained.

15. 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. § 416.15 or 417.5.

16. 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 preventative actions;

b. Take appropriate action to identify and eliminate the source of the *Lm* contamination;

c. Reassess its *Lm* program, SSOP, and HACCP or other prerequisite programs; and

d. Monitor and verify the effectiveness of the corrective actions and preventative measures identified and implemented.

17. 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 Lm sampling and testing program for the duration of this Order, and comply with 9 C.F.R. § 430.

Establishment Management and Personnel

18. Prior to the resumption of Federal 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, SSOPs, and HACCP plans, Recall of Meat Products Plan, *E. coli* Biotype and *E. coli* O157:H7 sampling and testing programs, *Lm* sampling and testing program, Pest Management Program, Planned Improvement Program (PIP), other written sanitation, process controls, corrective actions, and sampling or testing programs required by regulation or this Order. 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, SSOP, and shall be present at all times when operations requiring inspection are conducted; and

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.

19. 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 FSIS.

Management and Employee Training

20. 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 to ensure that employees are trained in all aspects of food safety measures and regulatory

requirements applicable to their job responsibilities, including the requirements of the SPS and SSOP programs, HACCP plans, Recall of Meat Products Plan, *E. coli* Biotype and *E. coli* O157:H7 sampling and testing programs, *Lm* sampling and testing program, Pest Management Program, Planned Improvement Program (PIP), other written sanitation, process controls, corrective actions, and sampling or testing programs, and recordkeeping procedures relevant to each employee's position. Respondent will provide copies of all training materials to FSIS for review and evaluation prior to training employees.

21. Respondent shall, within thirty (30) days from the effective date of this Order, and subject to verification by FSIS, train all such current employees consistent with the requirements of paragraph 19 of this Order.

22. 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.

23. 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, consistent with statutory and regulatory requirements 9 C.F.R. § 307, 309, 310, 313, 416 and 417, 418, 430, and the requirements of this Order.

24. Respondent shall document and maintain all training and education materials, certifications, training records, test results, and other materials for all training required by paragraphs 19 through 22 of this Order and make these records available to FSIS personnel for review and/or copying immediately upon request.

Third Party Audit Provisions

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

26. The audits shall be conducted, at least as frequently, as follows: (a) the first audit shall be conducted within ninety (90) calendar days from the effective date of this Order; (b) subsequent audits shall be conducted every (180) calendar days thereafter for the duration of this Order.

27. The Respondent shall prepare, for each audit conducted, a written response to the audit findings and recommendations. The Respondent's written response shall identify: (a) any modifications to its SSOPs, HACCP plans, other process controls and other programs or plans; (b) any corrective actions implemented; (c) any other actions implemented or planned in response; and (d) supportable information for any decision by Respondent to not implement any audit recommendation

28. Respondent shall submit a copy of each third-party audit, 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.

Record Keeping Provisions

29. Respondent shall maintain full, complete, and accurate copies of (a) all records required to be maintained by the FMIA, and the regulations; (b) all records required to be maintained under applicable Federal, State, and local statutes; and (c) all plans and records of its SPS and SSOP programs, HACCP plans, Recall of Meat Products Plan, E. coli Biotype and E. coli O157:H7 sampling and testing programs, Lm sampling and testing program, Pest Management Program, Planned Improvement Program (PIP), other written sanitation, process controls, corrective actions, and sampling or testing programs or other systems, programs, or plans required by the FMIA, and the regulations of this Order.

30. Respondent shall immediately notify FSIS program personnel of any changes or modifications to its SSOPs, HACCP plans, other systems, programs, or plans required by regulation or by this Order, and all associated recordkeeping forms.

31. Respondent shall make all records regarding its operations available to FSIS personnel for review and/or copying, in accordance with the applicable statutes and regulations.

General Provisions

32. Respondent and any of its owners, officers, directors, partners, employees, agents, successors, affiliates, or assigns shall not:

a. Violate any section of the FMIA 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 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 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.

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

Enforcement Provisions

34. The Administrator, FSIS, may summarily withdraw the grant of Federal inspection from Respondent upon a determination by the Director, ELD, or his her designee, that one or more conditions set forth in paragraphs 1 through 32 of this Order have been violated. It is acknowledged that the Respondent retains the rights to request an expedited hearing pursuant to the rules of practice concerning any violation alleged as the basis for a summary withdrawal of

Federal inspection services. Nothing contained in these provisions prevents the right of the Respondent to appeal the decision of an FSIS employee to his/her immediate supervisor pursuant to 9 C.F.R. § 306.5.

Miscellaneous Provisions

35. 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. Part § 500), or (b) the referral of any matter to any agency for possible criminal, civil, or administrative proceedings.

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

37. This Order shall become effective upon issuance by the Administrative Law Judge. The provisions of this Order shall be applicable for a period of five (5) years from the date of resumption of operations.

Tri-Town Packing Corporation,
Respondent

[redacted]

Representative
Tri-Town Packing Corp.

[redacted]

Roger B. Linden
Attorney for Respondent

Food Safety Inspection Service (FSIS),
Complainant

[redacted]

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

[redacted]

Lauren C. Axley
Attorney for Complainant
Office of the General Counsel
U.S. Department of Agriculture

[redacted]

Elizabeth M. Kruman
Attorney for Complainant
Office of the General Counsel
U.S. Department of Agriculture

Issued this 19th day of MAY, 2015
at Washington, D.C.

[redacted]

Administrative Law Judge
JANICE K. BULLARD