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UNITED STATES DEPARTMENT OF AGRICULTURE

BEFORE THE SECRETARY OF AGRICULTURE

In re:	}	Docket No. _____ (FMIA and PPIA) 16-0030
Westminster Meats, LLC,	}	
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.), 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 Westminster Meats, LLC, hereafter referred to as Respondent, for its meat and poultry products produced under its Hazard Analysis and Critical Control Point (HACCP) systems for Poultry Slaughter, Red Meat Slaughter, Raw Meat Intact, and Raw Meat Non-Intact. 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), 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 this Consent Decision and Order (Order) set forth below pursuant to the rules of practice applicable to this proceeding (7 C.F.R. § 1.138).

Respondent admits the findings of fact, as set forth herein, and specifically admits that the Secretary has jurisdiction in this matter. 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. section 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 the proceeding. 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, and at all times material herein was, a limited liability company organized and existing under the laws of the State of Vermont. Respondent slaughters and processes all species of livestock and poultry at its facility located at 52 Seafood Lane, Westminster Station, Vermont 05159.

2. Respondent is, and at all times material herein was, a recipient of federal meat and poultry inspection services at its facility in Westminster Station, Vermont, designated as Official Establishment No. 40091/P-40091.

3. On September 28, 2015, marks of inspection were withheld and the assignment of FSIS inspectors was suspended for products produced under Respondent's HACCP systems for Poultry Slaughter, Red Meat Slaughter, Raw Meat Intact, and Raw Meat Non-Intact.

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 for its meat and poultry products produced under its (HACCP systems for Poultry Slaughter, Red Meat Slaughter, Raw Meat Intact, and Raw Meat Non-Intact 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 three (3) years, beginning on the effective date of this Order; Provided, however, said withdrawal of inspection services shall be held in abeyance, and Federal meat and poultry inspection services shall be provided to Respondent for so long as the statutory and regulatory requirements for applicable inspection services, are met and all terms and conditions of this Order set forth below are met and maintained.

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, based upon a review and examination of:

(a) Respondent's Sanitation Performance Standards (SPS), Sanitation Standard Operating Procedures (SSOPs), HACCP systems, Recall of Meat and Poultry Products Plan, *Escherichia coli* (*E. coli*) Biotype I and *E. coli* O157:H7 sampling and testing programs, *Salmonella* sampling and testing programs, Pest Management Program, Planned Improvement Program (PIP), and any other written sanitation programs, process controls, corrective actions, and sampling or testing programs required by regulation or this Order; and

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

2. During the period of this Order, within its discretion, FSIS may examine records and conduct other verification and monitoring activities to ensure Respondent's implementation and

the effectiveness of, and compliance with, its SPS, SSOP, HACCP, and other systems, plans, and records required by the FMIA, PPIA, the regulations, and this Order.

Sanitation Performance Standards (SPS)

3. 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, 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 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 products that are prepared, packed, and stored at Respondent's facility are not adulterated or misbranded;

(b) ensure that its SPS include specific, written instructions addressing, at a minimum, the following procedures: (i) proper handling, storage, denaturing, and disposal of inedible products; (ii) reconditioning of contaminated product, and (iii) 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) 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, and poultry and poultry 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 (i) 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 (ii) preclude harborage and breeding of pests; and

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

Planned Improvement Program

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

6. 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.

7. Respondent's written PIP procedures, as required in paragraphs 5- 6 of this Section, shall, at a minimum, include:

(a) daily procedures for the monitoring of facility ceiling leaks;

(b) appropriate facility repairs to eliminate any ceiling leaks that are found;

(c) if leaks are found, the cessation of production operations within the affected areas until corrective actions are taken; the corrective actions taken to restore sanitary conditions; and documentation of all findings and corrective actions, which shall be made available to FSIS for review and/or copying within twenty-four (24) hours of such request by FSIS;

(d) procedures for the detection and prevention of roof areas vulnerable to future leaks, and procedures to prevent product and product contact surface adulteration in the event of future roof leaks; and

(e) ongoing inspection of the roof structure and assessment of potential vulnerabilities, conducted at least quarterly, beginning within three (3) months from the effective date of the Order.

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). This program, at a minimum, shall ensure that:

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

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

9. 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)

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

(a) develop written 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 slaughter and processing operations, in accordance with 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) 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) methods of cleaning complex equipment; 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 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, not adulterated, and properly labeled products in commerce are met.

Hazard Analysis and Critical Control Points (HACCP) Systems

12. 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 ongoing basis to control and prevent the introduction of food safety hazards in its meat or poultry food products. These systems and plans shall address specific process controls and procedures within Respondent's HACCP system for *E. coli* O157:H7 sampling and testing programs, 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 O157:H7* as a hazard in the process; and (iii) measures to eliminate or reduce and control the level of *E. coli* O157:H7 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 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 its HACCP systems 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 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; 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 its HACCP systems and plans, to ensure that Respondent's food safety systems remain validated over time, as required by 9 C.F.R. Part 417.

***E. coli* Sampling and Testing Program**

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

(a) develop, implement and maintain written *E.coli* Biotype I sampling and testing programs to describe the procedures for sampling of products, sampling methodologies, frequencies, analyses, and recordings that the Respondent will conduct as part of its process control system; and

(b) provide a copy of its written *E. coli* sampling and testing programs and any supporting documentation and associated records.

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

(a) implement and maintain its written *E. coli* sampling and testing procedures, as provided in paragraph 14; and

(b) collect samples, test for *E coli* Biotype I and record and analyze sample results in accordance with 9 C.F.R. § 310.25.

16. The Respondent shall make its written *E. coli* Biotype I sampling and testing programs and all records associated with the sampling and testing programs, including supporting information, data or other decision making documents, available to FSIS personnel for review and/or copying immediately upon such request by FSIS.

***Salmonella* Sampling and Testing Program**

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

(a) develop, implement and maintain written *Salmonella* sampling and testing programs to describe the procedures for sampling of products, sampling methodologies, frequencies, analyses, and recordings that the Respondent will conduct as part of its process control system; and

(b) provide a copy of its written Salmonella sampling and testing programs and any supporting documentation and associated records.

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

(a) implement and maintain its written *Salmonella* sampling and testing procedures, as provided in paragraph 17; and

(b) collect samples, test for *Salmonella*, and record and analyze sample results.

19. The Respondent shall make its written *Salmonella* sampling and testing programs and all records associated with the sampling and testing programs, including supporting information, data or other decision making documents, available to FSIS personnel for review and/or copying immediately upon such request by FSIS.

Establishment Management and Personnel

20. 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 and Poultry Products Plan, *E. coli* Biotype 1 and *E. coli* O157:H7 sampling and testing programs, *Salmonella* sampling and testing programs, Pest Management Program, PIP, and any other written sanitation programs, 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 and SSOP, and either the

designated principal or the alternate 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.

21. 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

22. 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 the SPS and SSOP programs, HACCP plans, Recall of Meat and Poultry Products Plan, *E. coli* Biotype 1 and *E. coli* O157:H7 sampling and testing programs, *Salmonella* sampling and testing program, Pest Management Program, PIP, and any other written sanitation programs, process controls, corrective actions, and sampling or testing programs, and recordkeeping procedures relevant to each employee's position. Respondent shall provide copies of all training materials to FSIS for review and evaluation prior to training employees.

23. 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 22 of this Order.

24. 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.

25. 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 all applicable FSIS statutory and regulatory requirements and the requirements of this Order.

26. Respondent shall document and maintain all training and education materials, certifications, training records, test results, and other materials for all training required by paragraphs 22 through 25 of this Order and make these records available to FSIS personnel for review and/or copying immediately upon request.

Third Party Audit Provisions

27. 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 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) Respondent's compliance with FSIS statutory and regulatory requirements, (d) its compliance with the terms of this Order; and (d) any other findings and recommendations of the independent third-party.

28. The audits shall be conducted at least as frequently as follows: (a) the first audit

shall be conducted within hundred and eighty (180) 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.

29. Respondent shall prepare, for each audit conducted, a written response to the audit findings and recommendations. 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 not to implement any audit recommendation.

30. 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, Enforcement and Litigation Division (ELD), for review and concurrence within (30) calendar days after each audit is completed.

Record Keeping Provisions

31. Respondent shall maintain full, complete, and accurate copies of (a) all records required to be maintained by the FMIA, PPIA, and the regulations promulgated thereunder; (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 and Poultry Products Plan, *E. coli* Biotype 1 and *E. coli* O157:H7 sampling and testing programs, *Salmonella* sampling and testing program, Pest Management Program, PIP, and any other written sanitation programs, process controls, corrective actions, and sampling or testing programs or other systems, programs, or plans required by the FMIA, PPIA, the regulations promulgated thereunder, and this Order.

32.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.

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

General Provisions

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

(a) violate any section of the FMIA, PPIA or regulations promulgated thereunder, and 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 the 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.

35. Respondent shall fully and completely cooperate with any FSIS inquiry into or investigation, review, or examination of its compliance with the FMIA, PPIA or this Order.

Enforcement Provisions

36. The Administrator, FSIS, may summarily withdraw the grant of Federal inspection from Respondent upon a determination by the Director, ELD, or his or her designee, that one or more conditions set forth in paragraphs 1 through 35 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 Respondent to appeal the decision of an FSIS employee to his/her immediate supervisor pursuant to 9 C.F.R. § 306.5.

Miscellaneous Provisions

37. 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 procedure.

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

39. 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.

[redacted]

Daniel Mandich, Owner
For Westminster Meats, LLC

[redacted]

Scott C. Safian, Director
Enforcement and Litigation Division
Office of Investigation, Enforcement and Audit

[redacted]

for

Thomas N. Bolick
Attorney for Complainant
U.S Department of Agriculture
Office of the General Counsel

Issued this 18 day of Dec 2015
at Washington, D.C.

[redacted]

Administrative Law Judge
Jill S. Clifton