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Docket #: FMIA/PPIA-10-0395

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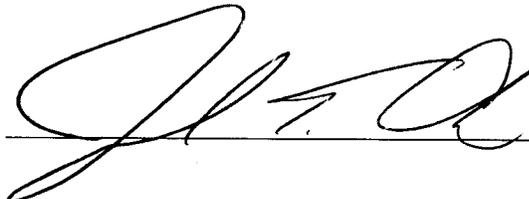
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UNITED STATES DEPARTMENT OF AGRICULTURE

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BEFORE THE SECRETARY OF AGRICULTURE

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In re:)	FMIA Docket No. 10-0395
)	PPIA Docket No. 10-0395
Jerry Hayes Meats, Inc.,)	
)	CONSENT DECISION
Respondent.)	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 Jerry Hayes Meats, Inc., hereinafter referred to as Respondent. This proceeding was commenced by a complaint filed on August 27, 2010, by the Administrator of the Food Safety and Inspection Service (FSIS), United States Department of Agriculture (USDA).

The parties have agreed that this proceeding should be terminated by entry of this Consent Decision and 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 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 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 was at all times material herein, a business organized and existing under the laws of the State of New York, operating a meat slaughter facility at RD 1, Stratton Road, Newark Valley, New York 13811.

2. Respondent is now, and was at all times material herein, a recipient of Federal inspection services at its place of business in Newark Valley, NY, and designated as official Establishment Number 04488/04488P.

3. Jerome A. Hayes, who resides at 829 Taylor Drive, Binghamton, New York 13904, is, and at all times herein was, the president of Jerry Hayes Meats, Inc.

4. During the period of May 29 - July 23, 2010, FSIS documented numerous Hazard Analysis and Critical Control Point System ("HACCP"), Sanitation, and *E. coli* testing non-compliance issues. The most egregious of these issues included the accumulation of fat and blood on equipment; blood and maggots on walls; and fecal matter, hair, and ingesta on carcasses. FSIS also documented repetitive failures with respect to the identification and segregation of cattle over 30 months of age; Specified Risk Material ("SRM") removal and documentation of such removal; generic *E. coli* testing and documentation; pre-shipment documentation; and general facility maintenance.

5. Based upon the repetitive trend and multiple and continuing non-compliance issues, on July 26, 2010, FSIS issued a Notice of Reinstatement of Suspension.

6. Prior to the abovementioned suspension, from the period of January 17, 2010 – May 7, 2010, Jerry Hayes Meats had been suspended on three other occasions for numerous HACCP, Sanitation, and *E. coli* testing non-compliance issues.

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 inspection services under the FMIA and the PPIA are withdrawn from Respondent, its owners, officers, directors, partners, successors, affiliates or assigns, directly or through any corporate device, for a period of five (5) years beginning on the effective date of this Order. Provided, however, the withdrawal of inspection services shall be held in abeyance, and inspection services shall be provided to Respondent for so long as the statutory and regulatory requirements for applicable inspection services are met, in addition to all terms and conditions of this Consent Decision and Order set forth below.

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. Parts 309, 310, 416 and 417, upon a review and examination of (a) Respondent's Sanitation Performance Standards (SPS), Sanitation Standard Operating Procedures (SSOP), Hazard Analysis

and Critical Control Point (HACCP) system, *Escherichia coli* (*E coli*) Biotype I and *E.coli* 0157:H7 sampling and testing program, specified risk material (SRM) program, and other written sanitation, process controls, corrective actions, sampling and testing programs, and any other related food safety programs and (b) of the physical and sanitary conditions of the establishment.

2. Prior to the resumption of inspection services, and subject to verification by FSIS, Respondent shall address and answer all open non-compliance reports for violation of the SPS, SSOP, HACCP, SRM or humane slaughter or handling requirements.

Sanitation Performance Standards

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

(a) develop written procedures for monitoring and identifying non-compliance, corrective and preventive actions, and recordkeeping that Respondent will conduct, and implement, to operate and maintain its premises, facilities, equipment, and outside premises, in a manner sufficient to: (i) prevent the creation of insanitary conditions and practices; and (ii) ensure that meat and meat food products, and poultry and poultry products, stored, prepared, and packed are not adulterated; and

(b) address and repair any premises, facility and/or equipment non-compliance issues previously identified by FSIS, and/or identified by FSIS at the time of the physical plant review conducted pursuant to paragraph 1 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);

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

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

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

Planned Improvement Program

5. 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 non-compliance 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.

6. 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

7. Prior to the resumption of inspection service, 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 on at least a monthly frequency; and

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

8. 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 and poultry products stored, prepared, and packed are not contaminated or adulterated.

Sanitation Standard Operating Procedures

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

(a) develop written sanitation standard operating procedures (SSOP) to describe the monitoring activities, recordkeeping, and other procedures Respondent will conduct, implement, and maintain, on a daily and ongoing basis, before, during, and after

operations, in accordance with 9 C.F.R. part 416, and this Order, to ensure sanitary conditions and prevent product adulteration; and

(b) ensure specific written instructions within its SSOP, including, at a minimum, the following: (i) cleaning and sanitizing of food contact surfaces of facilities equipment and utensils; (ii) proper handling, storage, denaturing, and disposal of inedible products; (iii) re-conditioning of contaminated product; (iv) employee hygienic practices; (v) specify the frequency of procedures.

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

(a) comply with the requirements of the SSOP regulations (9 C.F.R. 416.11 to 416.16); 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 SSOP, 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) Plan

11. 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 conduct, implement and maintain on a daily and on-going basis to control and prevent the introduction of food safety hazards in their

meat or poultry products. These plans shall address specific process controls and procedures for *Escherichia coli* Biotype I and *E.coli* 0157: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, or elimination of such hazards, or their reduction to undetectable levels; (ii) measures to address *Escherichia coli* as a hazard reasonably likely to occur; and (iii) measures to eliminate or reduce and control the level of *Escherichia coli* to prevent contamination of Respondent's finished product, and food contact surfaces; and

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

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

(a) comply with the requirements of the HACCP regulations (9 C.F.R 417.1 to 417.8);

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

(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 the 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. Part 417.

Humane Handling and Slaughter

13. Respondent shall ensure that any beef, veal, sheep, or goats slaughtered or handled in connection with slaughter at their facility comply with the Humane Methods of Slaughter Act (HMSA) of August 27, 1958 (7 U.S.C. 1901-1906), 9 C.F.R. Part 313, and any Federal, state, or local laws regarding the humane treatment of animals.

Specified Risk Material Program

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

(a) develop a written hazard control program for SRM's, including monitoring, verification, corrective and preventive actions, and recordkeeping that it will conduct, implement and maintain, on a daily and on-going basis, to ensure the control of SRM's and regulatory compliance with 9 C.F.R. Parts 309, 310, 311 and 314; and

(b) address specific procedures within its SRM program, including, but not limited to the following: (i) identification of animals; (ii) determination of the age of cattle; (iii) receiving and holding controls; (iv) removal, segregation and control of SRM's from cattle slaughtered at the establishment; (v) ensuring no cross contamination with edible products; and (vi) ensuring monitoring, verification and recordkeeping activities.

15. Upon resumption of inspection services, and subject to verification by FSIS, Respondent shall conduct, implement and maintain, on a daily and on-going basis, its written SRM removal program, and comply with the requirements of the SRM regulations (9 C.F.R 310.22).

Establishment Management and Personnel

16. Prior to the resumption of inspection services, and subject to verification by FSIS, Respondent shall identify in writing, one full-time person designee and one alternate designee who shall be responsible for the overall implementation, coordination, documentation, monitoring, recordkeeping, review and maintenance of the facility's SPS, PIP, SSOP, HACCP plans, *Escherichia coli* (*E.coli*) Biotype I and *Escherichia coli* (*E.coli*) 0157:H7 sampling and testing programs, SRM program, Pest Control Programs, and all other requirements of this Order. Prior to the resumption of inspection services, Respondent shall provide a detailed summary of the authority and responsibilities the designee is granted with respect to actions taken in the establishment. Respondent may name new designated official(s) upon written notification to the FSIS. Said designee(s) shall be present whenever Respondents' establishment conducts any slaughter and/or processing operations, and Respondent shall not conduct any slaughter and/or processing operations in the absence of said designee(s).

Management and Employee Training

17. 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 aspects of food safety measures and regulatory requirements, including the requirements of the SPS, SSOP, HACCP, *E. coli* Biotype I and *E. coli* 0157:H7 sampling and testing, SRM controls, recordkeeping procedures, and Good Manufacturing Practices (GMP's), relevant to each employee's position. Respondent will provide copies of all training materials to FSIS for review and evaluation prior to training employees.

18. Prior to the resumption of inspection services and the effective date of this Order and subject to verification by FSIS, Respondent shall train all such current employees consistent with the requirements of paragraph 17 of this Order.

19. Respondent shall train and educate any new employee(s), consistent with the requirements of this Order, within thirty (30) calendar days of employment.

20. Respondent shall conduct annual training for all employees and management personnel, current and new, involved in the preparation, slaughter, processing, and/or production, of meat and meat products, and poultry and poultry products, consistent with statutory and regulatory requirements 9 C.F.R. 303, 310, 311, 314, 416 and 417, and the requirements of this Order.

21. Respondent shall document and maintain all training and education materials, training records, test results, and other materials for all training required by paragraphs 17 thru 20 of this Order and make these records available to FSIS personnel for review and/or copying immediately upon request.

Third Party Audits

22. Respondent shall, upon resumption of inspection services, cause to be made, by qualified, independent third-party, written audits of;

(a) Respondent's implementation, monitoring, documentation, records and maintenance of its sanitation, SSOP, HACCP and *E.coli* Biotype I and *E.coli* 0157:H7 sampling and testing, SRM controls, and other programs;

(b) the effectiveness of Respondent's sanitation, SSOP, HACCP, and other process control, *E.coli* Biotype I and *E.coli* 0157:H7 sampling and testing, SRM, and other programs to ensure food safety;

(c) Respondent's compliance with FSIS statutory and regulatory requirements; and the terms of this Order.

23. 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 SSOP, HACCP, *E.coli* Biotype I, *E.coli* O157:H7, SRM, or other programs or plans; (ii) any corrective actions implemented or planned in response to the audit; and (iii) supportable information for any decision by Respondent to not implement any audit recommendation.

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

25. 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; and

(b) subsequent audits shall be conducted every (120) calendar days for the first year, and then every 180 calendar days thereafter for the duration of this Order.

26. Prior to the resumption of inspection services, Respondent shall name in writing, with the concurrence of the Director EED, the individual(s) responsible for performing the audits. Said auditors must have completed a course of instruction in the application of HACCP, in accordance with 9 C.F.R. 417.7, and provide a copy of such certification to the Director EED. Respondent may name a new independent third party auditor, at any time, with prior notification to and the written concurrence of the Director EED.

Recordkeeping

27. Respondent shall document and maintain complete and accurate written records of (a) all records required to be maintained by the FMIA, PPIA and the regulations; and (b) all records required by this Order available to FSIS personnel for review and/or copying immediately upon such request by FSIS.

28. Respondent shall notify the FSIS District Manager and/or designee of any changes or modifications to its SSOP, HACCP, *E.coli* Biotype I and *E.coli* O157:H7 sampling and testing program, SRM, or other systems, programs or plans, and all associated recordkeeping forms as required by the regulations or this Order, Said changes will be submitted for review and evaluation prior to their implementation.

General Provisions

29. Respondent, its officers, partners, employees, agents or affiliates shall not:

(a) be convicted of any felony or fraudulent act; (b) violate any section of the FMIA the PPIA, State or local laws involving the preparation, sale, transportation, distribution or attempted distribution of any adulterated or misbranded meat, poultry or food product or article; (c) assault, intimidate, impede, threaten, or interfere with, or threaten to assault, intimidate, impede, or interfere with any USDA or FSIS employee(s) in the performance of his/her official duties; (d) supply labeling materials bearing Respondent's official mark for unauthorized use; or, (e) conduct any operations requiring federal inspection outside the official hours of operation without obtaining prior written approval from FSIS.

Enforcement Provisions

30. The Administrator, FSIS, may summarily withdraw the grant of federal inspection from Respondent upon a determination by the Director EED that Respondent has committed an act in violation of, or failed to comply with any requirement of this Order. The withdrawal of Respondent's grant of federal inspection shall become effective immediately upon FSIS's service of a Notice of Summary Withdrawal to Respondent, without further proceeding. Respondent shall retain the right, after any summary withdrawal of Respondent's grant of federal inspection, to request within twenty days 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). Such request for an expedited hearing must be submitted within twenty (20) calendar days of FSIS' service of a Notice of Summary Withdrawal.

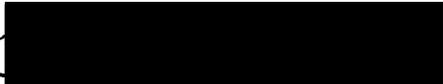
Miscellaneous Provisions

31. 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.

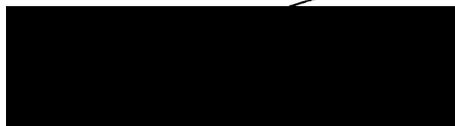
32. If any provision of this Order is declared invalid, such declaration shall not affect the validity of any other provisions herein.

33. The provisions of this Order shall be applicable for a period of five (5) years from the effective date of this Order.

34. This Consent Decision and Order shall become effective upon issuance by the Administrative Law Judge.


Jerome A. Hayes, President
Jerry Hayes Meats, Inc.


Wayne M. Chariff
Attorney for Respondent


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


Carlynnne Cockrum
Attorney for Complainant
U.S. Department of Agriculture
Office of the General Counsel

Issued this 23rd day of December, 2010
at Washington, D.C.


Administrative Law Judge

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