UNITED STATES DEPARTMENT OF AGRICULTURE
BEFORE THE SECRETARY OF AGRICULTURE

In re: Berry Packing, Inc.
and
James B. Davis;
Respondents.

FMIA Docket No. 308-0105
PPIA Docket No.

Consent Decision and Order

These proceedings were initiated pursuant to the Rules of Practice governing formal adjudicatory proceedings instituted by the Secretary under various statutes (7 C.F.R. §1.130 et seq.) and the Supplemental Rules of Practice (9 C.F.R. § 500 et seq.) to deny federal inspection services from Berry Packing, Inc. and James B. Davis, by the filing of a complaint on August 21st, 2006 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 meat and poultry inspection services. That complaint alleged that Respondents were unfit to engage in any business requiring inspection services under Title I of the Federal Meat Inspection Act, as amended (FMIA)(21 U.S.C. § 601 et seq.) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. § 456). The parties have now agreed that this proceeding should be terminated by entry of the Consent Decision and Order set forth below and have agreed to the following stipulations:
(1) For the purpose of this Consent Decision only, Respondents admit all the jurisdictional allegations of the complaint, and waive:

   a) Any further procedural steps;
   
   b) Any requirement that the final decision in this proceeding contain any findings and conclusions with respect to all material issues of fact, law, or discretion, as well as the reasons or bases thereof; and
   
   c) All rights to seek judicial review or to otherwise challenge or contest the validity of this decision.

(2) This Consent Decision is for settlement in these proceedings only and does not otherwise constitute an admission or denial by Respondents that Respondents violated the regulations or statutes involved.

(3) Respondents waive any action against the USDA under the Equal Access to Justice Act of 1980 (5 U.S.C. § 504 et seq.) for fees and other expenses incurred by the respondents in connection with this proceeding.

(4) Respondent Berry Packing, Inc., its owners, officers, directors, partners, successors, assigns, and affiliates and Respondent James B. Davis, waive, in addition to the action waived in paragraph three above, any other action against USDA or its employees in connection with these proceedings.
Findings of Fact

(1) The Respondent Berry Packing, Incorporated, is now, and at all times material herein was, a corporation, organized and existing under the laws of the State of Arkansas, operating as a meat slaughter and meat and poultry processing operation at its establishment located at 415 Binns Loop Road, Crossett, Arkansas 71635.

(2) The Respondent James B. Davis, is now, and at all times material herein, was the Owner and/or President of Respondent Berry Packing, Inc., with a business address of 415 Binns Loop Road, Crossett, Arkansas 71635.

II.

(3) The Respondents were granted federal inspection, pursuant to the FMIA (21 U.S.C. § 601 et seq.) and the PPIA (21 U.S.C. § 451 et seq.), on or about March 28, 2002, at the above named establishment that was designated as Official Establishment Number 2325/P2325.

(4) On September 21, 2005, the Administrator of the Food Safety and Inspection Service (FSIS) filed a Complaint for Suspension of Federal Meat and Poultry Inspection Services against Respondent Berry Packing, Inc. due to various alleged violations of the FMIA and PPIA. The alleged facts and violations against Respondent Berry Packing, Inc. included:

(a) On or about April 12, 2005, a Food Safety and Inspection Service (FSIS) inspector observed Respondent’s inhumane handling of swine, including the kicking and pulling of an ambulatory animal during the off-loading process at the Respondent’s federal establishment.

(b) On or about April 13, 2005, FSIS issued a Notice of Suspension (NOS) suspending federal inspection at the Respondent’s meat and poultry facility due to the act of inhumane
handling that occurred on April 12, 2005. After a review of the violation, FSIS determined that the Respondent was not in compliance with the Humane Methods of Slaughter Act (7 U.S.C. § 1901 et seq.), and the FMIA (21 U.S.C. § 603), and the regulations promulgated thereunder (9 C.F.R. §§ 313.1(a), 313.1(b), 313.2(a), 313.2(b), 313.2(d), and 313.2(e)).

(c) On or about August 29, 2005, FSIS conducted a Food Safety Assessment (FSA) and Intensified Verification Testing (IVT) at Respondent’s establishment. The assessment revealed that Respondent failed to effectively implement and execute its proposed corrective actions for humane methods of slaughter. In addition, the assessment disclosed that the Respondent had violated the FMIA and the PPIA by maintaining insanitary conditions and operations and by failure to comply with the Sanitation Performance Standards (SPS) requirements (9 C.F.R. Part 416), Sanitation Standard Operating Procedures (SSOP) requirements (9 C.F.R. Part 416), and Hazard Analysis and Critical Control Point (HACCP) (9 C.F.R. Part 417) requirements.

(d) On or about September 26, 2003, FSIs testing of ready-to-eat (RTE) product at Respondent’s establishment indicated positive presence of Listeria monocytogenes (Lm).

(e) On or about October 6, 2004 and June 23, 2005, FSIS testing of ready-to-eat (RTE) product at Respondent’s establishment indicated positive presence of Lm; and on January 17, 2004 and January 12, 2005, FSIS testing of RTE product contact and non-product contact surface areas at Respondent’s establishment indicated Lm in Respondent’s establishment.

(f) On or about October 11, 14, 20, and 25, 2004, and March 24, 2005, Respondent’s laboratory reports for Lm sampling indicated continued Lm positive results in samples taken from Respondent’s establishment.
(g) On or about August 30, 2005, FSIS submitted 35 samples from Respondent’s establishment, which laboratory reports indicated that a sample taken was confirmed positive for *Lm*. Such continued positive findings of *Lm* within the establishment’s RTE area failed to meet the sanitation requirements under 9 C.F.R. § 416.4(b), and the regulatory *Lm* requirements under 9 C.F.R. Part 430, and demonstrated that Respondent was continuing to fail to maintain facilities in a manner sufficient to prevent insanitary conditions and ensure that meat and poultry products were not adulterated.

(5) On or about October 3, 2005, Respondent Berry Packing, Inc. requested voluntary withdrawal of its grant of federal inspection for meat and poultry.

(6) On October 17, 2005, the FSIS withdrew federal inspection services at the Respondent Berry Packing, Inc. establishment.

(7) On or about November 30, 2005, due to Respondent’s voluntary withdrawal of its grant of inspection, the Administrator of FSIS filed to withdraw its complaint against the Respondent Berry Packing, Inc., which was granted by the Administrative Law Judge.

(8) On or about January 16, 2008, Respondents submitted an application for a federal grant of inspection service under the FMIA and PPIA for processing of meat and poultry products.

**Conclusion**

The respondents having admitted the jurisdictional facts and the parties having agreed to the entry of this Agreement, this Agreement will be issued.
Order

Inspection services under the FMIA and PPIA are denied to Respondent Berry Packing, Inc., and its owners, officers, directors, partners, successors, affiliates and assigns, and are being denied to Respondent James B. Davis, for a period of two (2) years, beginning on the effective date the conditional grant of inspection is issued to Respondents; Provided, however, the denial of inspection service shall be held in abeyance, and inspection service shall be provided to Respondents pursuant to a conditional grant of inspection for so long as, in addition to all other requirements of inspection, the additional conditions set forth herein below are met.

Conditions

(1) Prior to the Food Safety and Inspection Service (FSIS) issuing a conditional grant of federal inspection service, Respondents shall develop effective food safety control systems to ensure sanitary conditions and prevent product contamination and/or adulteration, and demonstrate their ability to operate the applicant establishment in compliance with the Sanitation Performance Standards (SPS) in 9 C.F.R. §§ 416.1 to 416.6, Standard Sanitation Operating Procedures (SSOP) in 9 C.F.R. §§ 416.11 to 416.16, and Hazard Analysis Critical Control Points (HACCP) in 9 C.F.R. Part 417.

Sanitation Performance Standards (SPS).

(2) Respondents shall have developed written procedures for sanitation performance standards (hereinafter, “SPS”) and shall implement the procedures immediately upon receiving its conditional grant of inspection service.
(3) Respondents shall operate, and maintain their premises, facilities, equipment and outside premises in a manner sufficient to prevent the creation of insanitary conditions and practices, and to preclude harborage and breeding of pests.

(4) Respondents shall comply with the requirements of SPS regulations 9 C. F. R. §§ 416.1 to 416.6, and ensure that meat and poultry products stored, prepared and packed are not contaminated or adulterated.

(5) Respondents shall make facility repairs and/or improvements necessary to ensure sanitary conditions, as required by 9 C.F.R. §§ 416.1 to 416.6 are met, including but not limited to:

(a) repairing or replacing walls, floors, ceilings, doors, windows, or other outside openings to prevent access of flying and crawling pests and the entrance of vermin, such as flies and rodents;

(b) maintaining a ventilation system adequate to control vapors and condensation to prevent product adulteration and insanitary conditions;

(c) maintaining overhead structures, including ceilings, hoists, and rails in a manner to prevent the presence of algae, mold, flaking paint, rust or other foreign material;

(d) maintaining all sinks, toilets, and other plumbing fixtures in proper functioning order, to include an adequate supply of potable hot and cold running water, knee or foot controls for hand wash sinks, and properly connected drain/sewage plumbing;

(e) maintaining a constant supply of hand soap and clean drying materials adjacent to all hand wash stations; and

(f) providing effective floor drainage in all areas where floors are subject to discharge water or other liquid waste on the floor.
(6) Respondents have submitted documentation, including photographs, that show the facility repairs and/or improvements that Respondents have made to applicant facility to ensure sanitary conditions, in accordance with 9 C.F.R. Part 416, and paragraph 5 of this Agreement. FSIS shall verify that the facility repairs and/or improvements have been made during an on-site review of the applicant establishment premise.

(7) Respondents shall develop, prior to the conditional grant of inspection, written pest control procedures consistent with the requirements of 9 C.F.R. § 416.2(a) and (b). Respondents shall implement and maintain said procedures for in-plant and outside premises to ensure sanitary conditions, prevent conditions that may adulterate product, and prevent the harborage and breeding of pests within the establishment and the surrounding grounds.

(8) Respondents shall, upon receipt of the conditional grant of inspection, (a) implement written pest control procedures; (b) monitor daily in-plant premises (bait stations and/or traps) for rodent activity; (c) document findings on a daily basis, and (d) implement immediate corrective and preventive actions.

(9) Respondents shall develop a written pest management program, 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). Respondents shall assure that: (a) the pest control service reviews and services Respondents’ facility and grounds on at least a twice monthly basis; (b) written reports are provided by the pest control service to Respondents detailing its findings and recommendations of its review; (c) reported recommendations are implemented in a timely fashion; and (d) Respondents’ pest management
program and servicing firm's written findings, recommendations, and reports are made available to FSIS personnel for review and for copying immediately upon request.

(10) Respondents shall monitor the soundness of the structural integrity of their facility, the proper functioning of their mechanical equipment, etc., to ensure a sanitary facility in compliance with 9 C.F.R. Part 416.

(11) Respondents shall document findings and corrective actions to address structural and/or mechanical repairs and/or improvements to their facility under a "Planned Improvement Program" (PIP) to ensure the entire structure of the facility, to include its rooms and compartments are of sound construction, and that all equipment is maintained in proper working order and kept in good repair. Respondents shall make these PIP records available to FSIS for review and/or copying immediately upon request.

(12) Respondents shall implement and maintain the SPS written procedures for the duration of this Order.

**Sanitation Standard Operating Procedures (SSOP)**

(13) Respondents shall have developed a written SSOP in compliance with regulatory requirements specified in 9 C.F.R. §§ 416.11 to 416.16 to describe its procedures, to include pre-operational and operational sanitation, monitoring activities, and recordkeeping. Respondents will conduct, implement and maintain on a daily and on-going basis, before, during and after operations, sufficient to prevent direct contamination or adulteration of products.

(14) Respondents shall implement and maintain said written procedures for the duration of this Agreement.
Hazard Analysis and Critical Control Point (HACCP).

(15) Respondents shall develop, prior to the issuance of a conditional grant of inspection, written HACCP plans to describe the process controls and procedures respondents will conduct, implement and maintain on a daily and ongoing basis to control and prevent the introduction of food safety hazards in meat and meat food products and poultry and poultry products. These plans shall address specific process controls and procedures within Respondents’ HACCP plans (i.e. Listeria monocytogenes (Lm)) in post lethality process steps, including, but not limited to the following:

(a) measures to identify the biological, chemical, and physical food safety hazards reasonably likely to occur at each critical control point in Respondents’ HACCP processes, and to ensure the prevention or elimination of such hazards or their reduction to undetectable levels; and

(b) measures to eliminate or reduce and control the level of Lm to prevent contamination of Respondents’ products and the environment.

(16) Respondents’ HACCP plan(s) shall include all decision making documents for the plan(s), including their hazard analysis or analyses, validation protocols and all parameters used in said protocols, and data to support the food safety system(s).

(17) Upon receiving the conditional grant of inspection, and subject to verification by the FSIS District Manager and/or designees, Respondents shall;

(a) implement, validate and maintain their HACCP plans in accordance with the requirements of 9 C.F.R. Part 417;
(b) implement timely and appropriate corrective and preventive actions and reassess and modify their HACCP 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 and consistent with 9 C. F. R. Part 417; and

(c) conduct ongoing assessment, 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 plans to ensure that the establishment’s food safety programs remain validated over time, as required by 9 C.F.R. Part 417.

Listeria monocytogenes (Lm) Program

(18) Respondents shall implement their Lm sampling and testing program for their ready-to-eat (RTE) products in accordance with 9 C. F. R. Part 430. For the duration of this Order, Respondents’ Lm program shall, at a minimum;

(a) Require the use of Alternative 1 for the production of post-lethality exposed RTE product based on its control program for Lm;

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

(c) State the frequency for which testing will be done;

(d) Identify the size and location of the sites that will be sampled;

(e) Include an explanation of why the testing frequency is sufficient to ensure that
effective control of *Lm*, or an indicator organism, is maintained;

(f) Include science based sampling for any area where post lethality exposed RTE product, is produced, packed, or held that will give an equal opportunity of selection for all sites and times; and

(g) 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.

(19) Respondents shall document and maintain sample laboratory results and records regarding the implementation and monitoring of their *Lm* program, and corrective actions and preventive measures in accordance with 9 C. F. R. § 417.5.

(20) Respondents shall make their *Lm* program, plant records, and regulatory records, including laboratory test results, regarding its *Lm* program available to FSIS personnel for review an/or copying immediately upon request.

(21) In the event of any positive *Lm* test result for food contact surfaces, non-contact surfaces or RTE products, Respondents shall;

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

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

(c) reassess its *Lm* program, SSOP, and HACCP programs; and

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

(22) For the duration of this Order, Respondents operations shall not include the handling or slaughter of livestock.

Custom Exemption

(23) For the duration of this Order, Respondents operations shall not include custom exempt operations.

Recordkeeping

(24) Respondents shall record and maintain full, complete and accurate written records of (a) all records required by the FMIA and PPIA or the regulations promulgated thereunder, (b) all applicable State or local statutes, and (c) all records of its SPS, SSOP, Lm Testing Program, PIP, product sampling and testing plans, Pest Control Programs and all those records otherwise required by this Order. Respondents shall make all such records available to FSIS representatives for review an/or copying immediately upon request.

Establishment Management and Personnel

(25) Respondents shall have provided to the FSIS, Evaluation and Enforcement Division, Director, (hereinafter "Director") the identity, in writing, of 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 SSOP, HACCP plans, Lm Testing program, Pest Control Programs, and all other requirements of this
Order. Said designee(s) shall be present whenever Respondents’ establishment conducts any processing operations, and Respondents shall not conduct any processing operations in the absence of said designee(s). Respondents may name a new designated official(s) upon written notification to the Director.

Training and Education

(26) Respondent James B. Davis, and all managers and all employees of Respondent Berry Packing, Inc. shall participate in a training/educational program encompassing food safety measures and regulatory requirements, including the Respondents’ SPS, SSOP, HACCP and \( Lm \) testing program. All employees, at a minimum, shall be trained and educated in job elements relevant to their required duties and responsibilities. Respondents shall record and maintain records regarding the completion of the training for the duration of the Order.

(27) Respondents shall train and educate any new employee(s) consistent with the requirements of paragraph 26 within five (5) working days of employment and make records of the training available to FSIS representatives for review and/or copying immediately upon request.

(28) Respondents, prior to the FSIS issuance of a conditional grant of inspection, shall submit name(s) in writing, for the concurrence of the Director, of the instructor(s) who shall be responsible for the training and education of Respondents’ proposed/current employees required by paragraphs 26 and 27 of this Order. The proposed instructor(s) shall have completed a course of instruction in the application of the subject course content for which
he/she is proposing to instruct. Respondents shall provide, along with the proposed name of
the instructor(s), documentation that said proposed instructor(s) have completed a course on
the subject course content.

(29) Respondents shall, within thirty (30) days from the effective date of this Order,
develop, implement, and maintain written training programs for managers and all employees,
including newly hired employees, in food safety regulatory requirements and the programs
and written procedures included in this Order. Respondents shall maintain the training and
educational program records and make them available to FSIS personnel for review and/or
copying immediately upon request.

Access and Examination

(30) Respondents shall fully and completely cooperate with any USDA, FSIS investigation,
inquiry, review or examination of respondents’ (a) facility, product, inventory or business
records, (b) compliance with the FMIA, PPIA and the regulations issued under these Acts, and
(c) compliance with the requirements in this Order.

General Provisions

(31) Respondents shall not (i) commit any felony or criminal act under the FMIA or PPIA; or
(ii) violate any section of the FMIA, PPIA, Federal, State, or local statute or regulation involving
the preparation, sale, transportation, distribution or attempted distribution of any adulterated or
misbranded meat or poultry product; or (iii) assault, intimidate, impede, or interfere with, or
threaten to assault, intimidate, impede, or interfere with any representative or designee of the Secretary of Agriculture.

(32) The Administrator, FSIS, may summarily withdraw federal inspection service from Respondents’ establishment upon a determination by the Director, Evaluation and Enforcement Division, Office of Program Evaluation, Enforcement and Review, FSIS, that one or more conditions set forth in this Order have been violated. It is acknowledged that Respondents retain the right to request an expedited hearing pursuant to the Rules of Practice concerning any violation alleged as the basis for the withdrawal of inspection services. Nothing contained in these provisions prevents the right of Respondents to appeal the decision of an FSIS employee to his/her immediate supervisor pursuant to 9 C. F. R. §§ 306.5 or 381.35.

(33) Nothing in this Order shall preclude any regulatory or administrative action authorized by law, regulation or otherwise, including, but not limited to the referral of any matter to any agency for possible criminal or civil proceedings.

The provisions of this Order shall become effective when signed by the Administrative Law Judge, and upon issuance of a conditional grant of federal inspection service by the FSIS Springdale District office.

James B. Davis, Corporate President
Berry Packing, Inc.

Scott C. Safian, Director
Evaluation and Enforcement Division
OPEER, FSIS
James B. Davis, individual

Margaret Burns Rath, Esq.
Attorney for Complainant
Office of the General Counsel

Issued this 6 day of May, 2008
at Washington, D.C.

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Administrative Law Judge

Jill S. Clifton

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