

UNITED STATES DEPARTMENT OF AGRICULTURE BEFORE
THE SECRETARY OF AGRICULTURE

In re:)	
)	FMIA Docket No. 21-J-0014
Pudliner Packing, 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.*) and the applicable rules of practice (7 C.F.R. § 1.130 *et seq.*, 9 C.F.R. § 500.1 *et seq.*) to indefinitely suspend and permanently withdraw Federal inspection services for meat slaughter from Pudliner Packing, LLC. 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), alleging that Respondent has not provided satisfactory assurances to FSIS that all slaughtering and handling of livestock will be conducted humanely, as required under Section 3(b) of the FMIA (21 U.S.C. § 603(b)), the Humane Methods of Slaughter Act (HMSA) (7 U.S.C. § 1901 *et seq.*), and the regulations promulgated thereunder (9 C.F.R. Part 313) The parties have agreed that this proceeding should be terminated by entry of the Consent Decision and Order set forth below pursuant to the Consent Decision provisions of the Rules of Practice (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 waives oral hearing and further procedure, and waives any rights to seek judicial review or otherwise challenge or contest the validity of this Consent Decision and Order, including waiving challenges to the Administrative Law Judge's authority to enter this Consent Decision and Order under the Administrative

Procedure Act and the Constitution of the United States. Respondent waives any action under the Equal Access to Justice Act of 1980 (5 U.S.C. § 504 *et seq.*) for fees and expenses incurred by Respondent in connection with this proceeding, and any other action against USDA or any USDA employee in connection with the events that gave rise to this proceeding.

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

Findings of Fact

1. Respondent is now, and at all times material herein was, a limited liability company organized and existing under the laws of the State of Pennsylvania. Respondent's physical and mailing address is 167 Norton Road, Johnstown, Pennsylvania, 15906
2. Respondent is a recipient of federal meat inspection services at its facility in Johnstown, Pennsylvania, and is designated as Official Establishment No. M/P-4999.
3. Since 2018, on five different dates, the most recent date being November 16, 2020, FSIS withheld the marks of inspection and suspended the assignment of inspectors for the meat slaughter process at Respondent's establishment, following violations of the humane handling and slaughter requirements under the FMIA, HMSA and 9 C.F.R. Part 313.
4. Additionally, FSIS withheld the marks of inspection and suspended the assignment of inspectors for the meat slaughter and processing HACCP processes at Respondent's establishment for Sanitation Performance Standards (SPS) violations under the FMIA and 9 CFR Part 416.

Conclusion

4. Respondent having admitted the jurisdictional facts, and the parties having agreed to the entry of this Consent Decision and Order, the Consent Decision and Order will be entered.

Order

5. Federal inspection services under the FMIA are indefinitely suspended and permanently withdrawn from Respondent and its owners, officers, directors, partners, successors, affiliates and assigns, directly or through any business or other device, beginning on the effective date of this Consent Decision and Order; provided, however, the indefinite suspension and permanent withdrawal of inspection services shall be held in abeyance, and inspection services shall be provided to Respondent pursuant to a conditional grant of inspection, for so long as the terms and conditions of this Consent Decision and Order, in addition to all the statutory and regulatory requirements for inspection services under the FMIA, are met and maintained. This Consent Decision and Order will expire three (3) years from the date on which Respondent's federal meat inspection services resume.

Conditions To Be Met Prior to Resumption of Inspection Services

6. Respondent will not resume federal meat operations until Respondent demonstrates, subject to verification by FSIS, that all the conditions in paragraphs 7 through 25 of this Consent Decision and Order have been met.

Updated Application for Federal Inspection

7. Within 15 days of entry of this Consent Decision and Order by the Administrative Law Judge, Respondent will submit to the District Manager, FSIS, Office of Field Operations,

Philadelphia District Office (hereafter “District Manager”), an updated Application For Federal Inspection (FSIS Form 5200-2). The application shall include all required information, including, but not limited to, applicant information, establishment information, types of operations (identifying all HACCP categories and associated products intended to be slaughtered, processed, and otherwise produced), and responsible persons information (identifying name, title, contact information, and any prior convictions) for all management officials required by this Consent Decision and Order and for all other partners, officers, holders or owners of 10 percent or more of voting stock of Respondent, and any other employees in a managerial or executive capacity.

Humane Handling Coordinator

8. Prior to resumption of inspection services, and subject to verification by FSIS, Respondent will hire a new employee or appoint a current employee to serve as Humane Handling Coordinator. Respondent also may designate an Alternate to act only when the Humane Handling Coordinator is unavailable. The Humane Handling Coordinator and any designated Alternate must each have at least two years of experience in the management of livestock slaughter at a federally inspected establishment and have taken training in humane handling and slaughter from a qualified, independent third-party organization or will complete such training prior to resumption of inspection services.

9. Prior to resumption of inspection services, Respondent will provide in writing to the FSIS Enforcement Operations Branch (EOB) Branch Chief (Chief), for review and concurrence, the name of the Humane Handling Coordinator and any designated Alternate, and provide documentation of their education and work experience.

10. The Humane Handling Coordinator will be responsible for the overall implementation, coordination, monitoring, documentation, recordkeeping, evaluation, and maintenance of Respondent's "Humane Handling and Slaughtering Program" established under paragraphs 20 through 22 of this Consent Decision and Order. The Humane Handling Coordinator shall be present at all times during the handling of livestock and the slaughter of livestock.

11. In the absence of the Humane Handling Coordinator or Alternate, Respondent agrees not to slaughter livestock on its premises.

12. Within fifteen (15) calendar days of the Humane Handling Coordinator vacating the assigned role, Respondent is responsible for assigning a new Humane Handling Coordinator who meets all qualifications as detailed above and notifying the Chief, in writing, receives concurrence by the Chief. Respondent may submit a request to the Chief for an extension of time if the Respondent is unable to fill the role within the allotted time.

Initial Assessment and Review

13. Prior to the resumption of inspection services, and subject to verification by FSIS, Respondent will contract a qualified, independent third party to conduct an initial assessment of Respondent's facility, operations, practices, and controls for humane slaughter and handling. Respondent will submit to the Chief, for review and concurrence, the name and credentials of the individual, prior to conducting the initial assessment.

14. The assessment will, at a minimum:

- a. list and provide an analysis of all incidents of regulatory noncompliance related to the humane handling and slaughter requirements at Respondent's facility, including

Noncompliance Records (NRs), Notices of Intended Enforcement, Notices of Suspension, or as otherwise documented by FSIS from 07/31/2018 to 11/16/2020;

b. analyze Respondent's past livestock handling and stunning practices and describe how those practices and/or other factors contributed to the regulatory violations noted in part (a) above;

c. recommend corrective actions and preventative measures, based on its analysis, for adoption by Respondent that will prevent the recurrence of noncompliance. These corrective actions include, but are not limited to, any structural changes or repairs, management changes, employee training, and new humane handling methodologies or programs.

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

a. a description of the corrective actions taken in response to the assessment recommendations; and

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

16. Prior to the resumption of services, Respondent will submit a copy of the third-party initial assessment and the Respondent's written response to the Chief for review and concurrence.

Physical Conditions of Facilities and Humane Handling and Slaughter Equipment

17. Prior to resumption of inspection services, Respondent will provide the Chief documentation demonstrating that all stunning devices, restraining equipment, and any other equipment used in livestock handling and slaughter have been tested for functionality and, as applicable, have received service from the manufacturing company or otherwise in accordance with the manufacturer's guidelines.

18. Prior to resumption of inspection services, Respondent will provide the Chief documentation demonstrating that all facilities, structures, and areas in which live animals are held have received evaluation and repair as needed to meet the requirements of 9 C.F.R. 313.1.

19. Prior to the resumption of inspection services, and subject to verification by FSIS, Respondent will demonstrate that the structural and physical conditions of the establishment comply with the FMIA, HMSA, and the regulations under 9 C.F.R. 313.

Humane Handling and Slaughter Program

20. Prior to resumption of inspection services, and subject to verification by FSIS, Respondent will develop a written Humane Handling and Slaughter Program to ensure that any slaughter of livestock or any handling of livestock in connection with slaughter at Respondent's establishment complies with the FMIA, HMSA, and 9 C.F.R. 313.

21. Respondent's written Humane Handling procedures will at a minimum:

a. detail procedures for the construction, maintenance, and monitoring of pens, driveways, ramps, and stunning areas so that: (i) they are kept in good repair, (ii) they are free from sharp or protruding objects; (iii) the floors of livestock pens, driveways, and ramps are

constructed and maintained in a manner to provide slip resistant surfaces; and (iv) the facilities are monitored and preventative actions are taken in a timely manner to prevent pain and injury to any animal;

b. identify procedures to be implemented and monitored by Respondent for the unloading, driving, and holding of livestock that will prevent or minimize discomfort, stress, and excitement;

c. identify the implements and aids to be used by employees during the unloading and driving of animals and the acceptable procedures and limitations for the use of the implements and aids to be implemented and monitored;

d. address procedures to be implemented and monitored to ensure: (i) that pen structures are appropriate to the size of the animals to avoid overcrowding; (ii) that livestock are placed in holding pens that provide functioning watering systems and systems are monitored as frequently as necessary to ensure continuous access to potable water at all times and at all ambient temperatures; and (iii) that all animals that are held overnight are provided adequate quantities of formula or feed, appropriate for the species and age of the animal, and clean potable water at all times;

e. address procedures to be implemented and monitored for the arrival and unloading of animals into holding areas, to be conducted only during the approved hours of federal inspection.

f. address procedures to be implemented and monitored to ensure that suspect, ambulatory disabled, and non-ambulatory disabled animals will be immediately identified, segregated into separate and distinct holding areas, and handled using humane methods;

g. address procedures to be implemented and monitored to ensure that all livestock destined for slaughter under the custom exemption are adequately identified, segregated into separate and distinct holding areas from animals destined for inspected slaughter, and handled using humane methods and in compliance with 9 C.F.R. 313.1 and 313.2.

h. address procedures to be implemented and monitored for the prompt administration, monitoring, and documentation of animal euthanasia to ensure minimal animal suffering;

i. ensure that the monitoring and documentation of all handling procedures are conducted on a daily and on-going basis, or as applicable, to ensure that livestock are treated in a humane manner prior to slaughter; and

j. ensure that corrective actions are implemented and recorded in a timely manner to prevent recurrence of noncompliance.

22. Respondent's written Humane Slaughter procedures will at a minimum:

a. identify the systems and procedures which will account for variations in animal size and strength, for the restraint of animals prior to the application of a stun that are appropriate for each species, and ensure that animal movement is limited to allow accurate and effective stunning and slaughter procedures in a manner that minimizes pain and excitement;

b. identify specific stunning devices and projectiles that will provide adequate force to ensure animals are unconscious after a single application. Stunning devices and projectiles must be appropriate for the type, size, and age of the animal to be stunned;

c. identify the anatomical locations for the placement of the stunning device, per species and per stunning method, to ensure that animals will be rendered immediately unconscious and remain unconscious throughout shackling, hoisting, sticking, and bleeding.

d. address procedures to be implemented and monitored that ensure all backup devices, parts, and projectiles are readily accessible to the stunning employee(s);

e. address procedures to be implemented and monitored that ensure storage and maintenance of all stunning equipment, parts, and projectiles, including backup equipment, are done under appropriate conditions;

g. address procedures to be implemented and monitored for assessing signs of consciousness in each animal after the application of a stun and throughout shackling, hoisting, sticking, and bleeding;

h. address the specific actions to be taken by employees in the event of an ineffective stun or a return to consciousness after the application of a stun;

i. address procedures to be implemented and monitored for the daily maintenance and testing of all slaughter equipment, including restraint devices and primary and backup stunning devices. Daily maintenance and equipment testing procedures must be recorded every slaughter day;

j. address procedures for routine service of slaughter equipment, including restraint devices and primary and backup stunning devices, to ensure that equipment is kept in good repair. The frequency of service will be per the manufacturer's recommendations or other supporting documentation. Records of equipment service are maintained with the written program and are available for review by inspection personnel;

k. ensure that the monitoring and documentation of all slaughter procedures are conducted on each slaughter day and on an on-going basis, as applicable; and

l. ensure that corrective actions are implemented and recorded in a timely manner.

Establishment Management and Personnel Training

23. Prior to resumption of inspection services, and subject to verification by FSIS, Respondent will ensure:

a. training for Respondent's management, supervisors, and employees working in the live animal areas, in all aspects of the humane handling and slaughtering requirements set forth in the HMSA (7 U.S.C. § 1901 et. seq.), the FMIA (21 U.S.C. §§ 603 and 610), and the regulations promulgated thereunder (9 C.F.R. Part 313). This training will be conducted under the direction of the Humane Handling Coordinator and will ensure, at a minimum, that such personnel are trained and qualified in: (i) livestock handling practices; (ii) restraint and stunning techniques; (iii) signs of consciousness and unconsciousness; and (iv) the regulations in 9 C.F.R. Part 313.

b. additional training for employees conducting stunning procedures to ensure that employees are trained in all aspects of humane handling and slaughtering requirements set forth in the HMSA (7 U.S.C. § 1901 et. seq.), the FMIA (21 U.S.C. §§ 603 and 610), and the regulations promulgated thereunder (9 C.F.R. Part 313). This training will be conducted under the direction of the Humane Handling Coordinator and will ensure, at a minimum, that employees are trained and qualified in: (i) the selection of the appropriate stunning device and projectile for each animal class, size, and type; (ii) the routine testing and monitoring of restraining and stunning equipment, including back-up devices, to ensure functionality; and (iii) actions to take in the event of an ineffective stun or a return to consciousness.

24. Prior to resumption of inspection services, Respondent will submit to the Chief, for review and concurrence, a copy of all training and educational program materials, including

training records, test results, and any other materials and records, for the training described in paragraph 23.

25. Respondent will make all training and education materials, training records, test results, and other materials and records of the initial training of employees and management personnel available to FSIS for review and/or copying upon request by FSIS, in a timeframe consistent with FSIS requirements.

FSIS Compliance Verification

26. Respondent will prepare and submit to the Chief for review and concurrence all written programs and documentation described in paragraphs 7 through 25 within 120 days of entry of this Consent Decision and Order by the Administrative Law Judge, unless other time periods are specified in those paragraphs. Respondent may submit such programs and documentation at any time during the 120-day period.

27. Upon completion of the written submissions required by paragraphs 7 through 25, Respondent may make a written request to the Chief for on-site verification of compliance with 9 C.F.R. Part 313.

28. If FSIS determines that any written program or documentation submitted by Respondent, or any portion thereof, does not meet regulatory requirements, FSIS will notify the Respondent. Respondent may thereafter resubmit the relevant program, documentation, or portion thereof, for concurrence by FSIS. If, after 180 days from entry of this Consent Decision and Order by the Administrative Law Judge, Respondent is unable to bring the programs and documentation required by this Consent Decision and Order into compliance to the satisfaction of FSIS, FSIS may summarily withdraw inspection services in accordance with paragraph 46.

Terms to Be Met Upon and After Resumption of Federal Inspection Services

Humane Handling and Slaughter Program

29. Upon resumption of inspection services, and subject to verification by FSIS, Respondent shall implement and maintain, on every slaughter day, its Humane Handling and Slaughter Program, as provided in this Consent Decision and Order.

30. Respondent shall document and maintain a written record of the implementation, monitoring, and maintenance of its Humane Handling and Slaughter Program for the duration of this Consent Decision and Order and make these records available to FSIS personnel for review and/or copying upon request by FSIS, in a timeframe consistent with FSIS requirements.

Reassessments of the Humane Handling and Slaughter Program

31. Upon resumption of inspection services, and subject to verification by FSIS, Respondent will ensure that the Humane Handling Coordinator will periodically reassess its Humane Handling and Slaughter Program to determine the program's effectiveness in complying with this Consent Decision and Order and FSIS's statutory and regulatory requirements. This reassessment will be conducted and documented by the Humane Handling Coordinator every ninety (90) days from the date of resumption of inspection services. Further, if an enforcement action is taken under 9 C.F.R. 500.3(b) related to humane handling, such a reassessment shall also be made prior to resuming inspection services subsequent to such action.

32. Each reassessment will include, at a minimum:

a. an evaluation of all records associated with humane handling and slaughter program implementation generated during the prior ninety (90) day period;

b. a summary of any failures to implement the humane handling and slaughter program, any NRs for 9 C.F.R. Part 313 violations, and any actions taken by FSIS related to humane handling during the prior ninety (90) day period;

c. a summary of any corrective actions taken as a result of any humane handling and slaughter program deviations, NRs, and FSIS actions during the prior ninety (90) day period;

d. an assessment of the adequacy of the humane handling and slaughter program and its effectiveness in maintaining compliance with this Consent Decision and Order and FSIS statutory and regulatory requirements; and

e. a summary of any actions taken as a result of the reassessment, including changes to the humane handling and slaughter program, personnel, facilities, or equipment.

33. Upon resumption of inspection services, Respondent will submit records of each reassessment to the Chief, for review, within 15 days after the reassessment is conducted, and prior to FSIS resuming inspection services after taking an action related to humane handling under 9 C.F.R. 500.3(b).

Third-Party Audits

34. Upon resumption of inspection services, and subject to verification by FSIS, Respondent will cause to be made, by a qualified and independent third party, written audits of Respondent's implementation, monitoring, and maintenance of the humane handling and slaughter program required by paragraphs 20 through 22 of this Consent Decision and Order. The independent third-party auditor shall be subject to the approval of the Chief prior to conducting this audit.

35. The audits will be conducted at least as frequently as follows:

- a. within sixty (60) calendar days from the resumption of inspection services; and
- b. every (180) calendar days thereafter for the duration of this Consent Decision and Order.

36. Respondent will prepare, for each audit conducted, a written response to the audit findings and recommendations. Respondent's written response shall identify:

- a. any modifications to the Humane Handling and Slaughter Program and any other programs reviewed by the auditor;
- b. any corrective actions or any other actions implemented or planned in response to the audit findings and recommendations; and
- c. supportable information and reasoning for any decision by Respondent to not implement any audit recommendation.

37. Respondent will submit a copy of each third-party audit, a copy of Respondent's written response to the audit, or other documents related to the audit to the Chief within thirty (30) calendar days after each audit is completed.

38. An independent third party shall be a person, entity, or corporation free from bias or any conflict of interest with the Respondent. Specifically, the person, entity or corporation conducting a third-party audit shall not be a current or former officer, Director, employee, affiliate, representative, or agent of. If the Chief has good cause to believe that an audit was conducted by a person, entity, or corporation currently or formerly employed by or affiliated with Respondent, or with a bias or a conflict of interest, the Chief may determine that any written

audit and report of the audit are disqualified for the purposes of complying with this Consent Decision and Order.

Ongoing Training

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

a. train and educate any new manager, supervisor, and employee working in live animal areas prior to starting work duties, consistent with the requirements of paragraph 23 of this Consent Decision and Order; and

b. conduct annual training for all employees, current and new, working in live animal areas consistent with the requirements of this Consent Decision and Order.

40. Respondent will make all training and education materials, training records, test results, and other materials and records of the initial and annual training of current and new employees and management personnel available to FSIS personnel for review and/or copying upon such request by FSIS, in a timeframe consistent with FSIS requirements.

Recordkeeping

41. Respondent will keep and maintain full, complete and accurate copies of (a) all written records of all of its practices under its Humane Handling and Slaughtering Program, and (b) all other written records required by this Consent Decision and Order. Respondent will make all such records available to FSIS representatives for review and/or copying upon request, in a time frame consistent with FSIS requirements.

42. Respondent will notify the Chief of any changes or modifications to Respondent's humane handling and slaughter program, including changes and modifications to all related record-keeping forms.

General Provisions

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

a. violate any section of the FMIA, the regulations promulgated thereunder, or any Federal, State, or local statute or regulation involving the preparation, sale, transportation, distribution or attempted distribution of any adulterated, non-inspected, misbranded or deceptively packaged meat, or 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 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 the 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 the Respondent's business; or

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.

44. Respondent will maintain compliance with statutory and regulatory requirements for sanitation, food safety programs, process controls, humane slaughter and handling, and all other applicable requirements, including, but not limited to, Sanitation Performance Standards (SPS), Sanitary Standard Operating Procedures (SSOP), Hazard Analysis and Critical Control Point (HACCP), and all other requirements as specified in 9 C.F.R. Parts 310, 313, 416, 417, and 418 as applicable.

Enforcement

45. Respondent will fully and completely cooperate with any FSIS investigation, inquiry, review, or examination of Respondent's compliance with this Consent Decision and Order.


46. The FSIS Administrator will have the right to summarily withdraw inspection services upon a determination by the Chief, or his or her designee, that Respondent has violated one or more terms of this Consent Decision and Order. It is acknowledged that Respondent retains the right to request an expedited hearing in accordance with the applicable Rules of Practice (7 C.F.R. § 1.130 et seq. and 9 C.F.R. Part 500) concerning any violation alleged as the basis for a summary withdrawal of inspection services. This does not affect Complainant's right to suspend operations in accordance with the Rules of Practice, 9 C.F.R. Part 500.


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

48. If any provision of this Consent Decision and Order is declared invalid, such declaration will not affect the validity of any other provision herein. This Consent Decision and Order will be considered entered and effective on the date of signature by an Administrative Law Judge.

49. This Consent Decision and Order will expire three (3) years from the date on which the Respondent's federal inspection services resume under this Consent Decision and Order.

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


Andrew Pudliner, Sr., Owner, for
Pudliner Packing, LLC.
Branch


Scott C. Safian
Chief, Enforcement Operations
Food Safety and Inspection Service
U.S. Department of Agriculture


Tracey Manoff
Attorney for Complainant
United States Department of Agriculture
Office of the General Counsel

Issued this 11th day of February 2021

in Washington, D.C.


Chief ADMINISTRATIVE LAW JUDGE
Channing D. Strother