



UNITED STATES DEPARTMENT OF AGRICULTURE
BEFORE THE SECRETARY OF AGRICULTURE

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In re:)	
)	FMIA Docket No. 19-J-0063
Marks Meat, Inc.,)	
)	
Respondent.)	Consent Decision and Order

This proceeding was instituted under Title I of 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 under Title I of the FMIA from Marks Meat, Inc. This proceeding was commenced by a Complaint filed by the Administrator of the Food Safety and Inspection Service (FSIS), United States Department of Agriculture, alleging that Respondent has not provided 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, neither admits nor denies the remaining allegations, waives oral hearing and further procedure, waives all rights to seek judicial review and otherwise challenge or contest the validity of this decision, including waiving challenges to the Administrative Law Judge's authority to enter this Decision and Order under the Administrative Procedure Act and the Constitution of the United States, and waives any action against the United States Department of Agriculture under the Equal Access to Justice Act of 1980 (5 U.S.C. § 504 et seq.) for fees and other expenses incurred by Respondent in connection with this proceeding or any action against any USDA employee in their individual capacity.

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

Findings of Fact

1. Respondent, is a very small, all species slaughter and processing plant that is located at 10290 S. Mulino Road, Canby, OR 97013.
2. Respondent, is a recipient of federal meat inspection services at its facility in Canby, OR, designated as Official Establishment No. M9265.
3. Since 2018, on four different dates, with the most recent date of February 1, 2019, FSIS suspended the assignment of inspectors for the 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.

Conclusion

Respondent having admitted the jurisdictional facts and the parties having agreed to the entry of this consent decision, the consent decision will be entered.

Order

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 Order. 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 conditions set forth below, in addition to all other requirements of inspection, are met. This Order will expire three (3) years from the date on which Respondent's Federal inspection services resume pursuant to the terms of this Order.

Conditions

Conditions to be met prior to resuming inspection services

Respondent will not resume federal operations until Respondent demonstrates all provisions listed in paragraphs 1 through 22 of this Order have been met.

Prior to the resumption of inspection services, and subject to verification by FSIS, pursuant to this Order, Respondent shall:

1. Within 15 days of execution of this Order, Respondent shall submit to the District Manager, FSIS, Office of Field Operations, Denver District Office (hereafter "District Manager"), an updated application for Federal (meat, poultry, Siluriformes fish, egg products, and/or import) inspection (FSIS Form 5200-2). Said application shall update, as applicable, 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, prior convictions, and other required information) for all management officials required by this Order and for all other partners, officers, directors, holders, or owners of 10 percent or more voting stock, or employees in a managerial or executive capacity. Upon resumption of inspection services, Respondent shall submit an updated application for Federal (meat, poultry, Siluriformes fish, egg products, and/or import) inspection (FSIS Form 5200-2) to the District Manager within 15 days to reflect any changes to required information prescribed above.

2. Respondent shall provide to the Director, Enforcement and Litigation Division, Office of Investigation, Enforcement, and Audit (hereafter "Director") a written outline of the establishment's management structure, including the names of the management personnel designated to assigned roles and the specific duties and responsibilities associated with the role. Respondent shall immediately notify and provide in writing to the Director any changes in management personnel and/or the associated duties and responsibilities.

3. Prior to resumption of inspection services, Respondent will contract with Dr. R. Quinn Henley as the interim humane handling coordinator. Dr. Henley will serve as the interim human handling coordinator for the term specified in Schedule A of this Order. During this period, Respondent will designate and train two (2) alternate humane handling coordinators. The names of the two alternate humane handling coordinators will be provided to the Director.

4. Prior to resumption of inspection services, Respondent will provide in writing to the Director, for review and concurrence, documentation of Dr. Henley's education and work experience.

5. For the duration of his term as interim humane handling coordinator, Dr. Henley will be responsible for training, as well as the overall implementation, coordination, monitoring, documentation, recordkeeping, evaluation, and maintenance of the Respondent's "Humane Handling and Slaughtering Program" established under paragraphs 17 through 19 of this Order. Dr. Henley must be present during the handling of livestock and the slaughter of livestock as detailed in Schedule A of this Order.

6. Following Dr. Henley's term as interim humane handling coordinator, Respondent shall appoint one of the designated alternates as the primary humane handling coordinator. The primary humane handling coordinator will be responsible for the overall implementation, coordination, monitoring, documentation, recordkeeping, evaluation, and maintenance of the Respondent's "Humane Handling and Slaughter Program" established under paragraphs 17 through 19 of this Order.

7. In accordance with the terms of Schedule A, Dr. Henley must be present on site during the first forty-five (45) days during which slaughter operations are conducted. Following that time, in accordance with the terms of Schedule A and for the remainder of the Order, either Dr. Henley and/or one of the two designated alternates must be present during the handling and slaughter of livestock.

8. If Dr. Henley vacates the designated role of interim humane handling coordinator prior to the terms set forth in Schedule A, then Respondent shall suspend slaughter operations until Respondent hires or appoints a new interim humane handling coordinator who has received concurrence by the Director.

9. If someone other than the two designated alternates specifically named and trained in accordance with paragraph 3 is required to perform humane handling coordinator duties, then such individual must first be appointed by Respondent and will be subject to concurrence by the Director prior to performing such duties.

Initial Assessment and Review

10. Prior to the resumption of inspection services, and subject to verification by FSIS, Dr. Henley will conduct an initial assessment of Respondent's facility, operations, practices, and controls for humane slaughter and handling.

11. The assessment will, at a minimum:

a. list and provide an analysis of all incidents of regulatory noncompliance of the humane handling requirements, at Respondent's facility, documented by FSIS in Noncompliance Records (NR), Notices of Intended Enforcement, Notices of Suspension, or as otherwise documented by FSIS;

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 shall include, but are not limited to, any structural changes or repairs, management changes, employee training, and new humane handling methodologies or programs.

12. 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.

13. Prior to the resumption of services, Respondent will submit a copy of Dr. Henley's initial assessment and the Respondent's written response to the Director for review and concurrence.

Physical Conditions of Facilities and Humane Handling and Slaughter Equipment

14. Prior to resumption of inspection services, Respondent will provide the Director 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.

15. Prior to resumption of inspection services, Respondent will provide the Director 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.

16. 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. Part 313.

Humane Handling and Slaughter Program

17. 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. Part 313.

Humane Handling

18. 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;

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 for the prompt administration, monitoring, and documentation of animal euthanasia to ensure minimal animal suffering;

h. 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

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

Humane Slaughter

19. 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;

f. 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;

g. 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;

h. 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;

i. 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;

j. ensure that the monitoring and documentation of all slaughter procedures are conducted on a daily and on-going basis, or as applicable; and

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

Establishment Management and Personnel Training

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

a. training for Respondent's management, supervisors, and for employees working in the live animal areas, in all aspects of Respondent's Humane Handling and Slaughter Program, as well as 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 interim humane handling coordinator and will ensure, at a minimum, that management and supervisory personnel, as well as the designated humane handling coordinators, are trained and qualified in: (i) livestock handling practices; (ii) restraint and stunning; (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, as well as the designated humane handling coordinators, to ensure that said employees are trained in all aspects of Respondent's Humane Handling and Slaughter Program, as well as 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 interim 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.

21. Prior to resumption of inspection services, Respondent will submit to the Director, 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 20 (a) and (b) of this Order.

22. 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 personnel for review and/or copying upon such request by FSIS, in a timeframe consistent with FSIS requirements.

Terms to be met upon the resumption of Federal inspection services

Humane Handling and Slaughter Program

23. Upon resumption of inspection services, and subject to verification by FSIS, Respondent shall implement and maintain, on a daily basis, its Humane Handling and Slaughter Program, as provided in this Order.

24. 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 the 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.

Reassessment of the Humane Handling and Slaughter Program

25. Upon resumption of inspection services, and subject to verification by FSIS, Respondent will ensure that the humane handling coordinator will reassess the Humane Handling and Slaughter Program to determine the program's effectiveness in complying with this Order and the FSIS's statutory and regulatory requirements. This reassessment will be conducted and documented by the appointed humane handling coordinator every ninety (90) days from the effective date of this Order and prior to FSIS resuming inspection services after taking an action in accordance with 9 C.F.R. § 500.3(b).

26. Each reassessment will include, at a minimum:

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

b. a summary of any failures to implement the humane handling and slaughter program, as required by paragraphs 18 and 19 of this Order, NRs documented for 9 C.F.R. § 313 violations, and actions taken by FSIS in accordance with 9 C.F.R. § 500.3(b) documented during the ninety (90) day period;

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

d. an assessment on the adequacy of the program and its effectiveness in maintaining compliance with the Order and the FSIS statutory and regulatory requirements; and

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

27. Upon resumption of inspection services, Respondent will submit records of each reassessment to the Director, for review, within 15 days after the reassessment is conducted, and prior to FSIS resuming inspection services after taking an action in accordance with 9 C.F.R. 500.3(b).

Third Party Audits

28. Upon resumption of inspection services, and subject to verification by FSIS, Respondent shall cause to be made, by an independent third-party who is Professional Animal Auditor Certification Organization, Inc. (PAACO) certified, written audits of Respondent's effective implementation, monitoring, and maintenance of the humane handling and slaughter program required by paragraphs 17 through 19 of this Order.

29. The audits shall be conducted at least as frequently as follows within sixty (60) and one hundred eighty (180) calendar days from the resumption of inspection services; and annually thereafter for the duration of this Order.

30. 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 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.

31. 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 within thirty (30) calendar days after each audit is completed.

32. For the purposes of paragraphs 28 through 31, an independent third-party shall be a person, entity, or corporation free from bias and absent from a conflict of interest with the Respondent. Specifically, the person, entity or corporation conducting an audit shall not be a current or former officer, director, employee, affiliate, representative, or agent of Respondent. If the Director has good cause to believe that an audit was conducted by a person, entity, or corporation otherwise employed by or affiliated with Respondent, or with a present bias or a conflict of interest, any written audit and report of the audit shall be deemed disqualified for the purposes of complying with this Order. This person shall not be the person in paragraph 10, who conducted the initial assessment.

Ongoing Training

33. 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 paragraph 20 of this Order; and

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

34. 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

35. Respondent will keep and maintain full, complete and accurate copies of (a) all written records required by the FMIA, the regulations promulgated thereunder, and all applicable State or local statutes, (b) written records of all of its practices under its Humane Handling and Slaughtering Program, and (c) all other written records required by this Order. Respondent will make all such records available to FSIS representatives for review and/or copying upon request, in a timeframe consistent with FSIS requirements.

36. Respondent will notify the Director 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

37. Respondent and any of its owners, officers, directors, 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.

38. 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.

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

Enforcement Provisions

40. The Administrator, FSIS, will have the right to summarily withdraw inspection services upon a determination by the Director, or his or her designee, that one or more conditions set forth in paragraphs of this Order have been violated. It is acknowledged that Respondent retains the right to request an expedited hearing pursuant to the Rules of Practice, 9 C.F.R. 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 Rules of Practice, 9 C.F.R. 500.

41. Nothing in this 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 Administrator from taking other appropriate administrative action under the FMIA and the regulations promulgated thereunder.

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

43. This Order will expire three (3) years from the date on which the Respondent's Federal inspection services resume pursuant to the terms of this Order.

Copies of this decision and order shall be served upon the parties.

[Redacted]

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Marks Meat, Inc.

[Redacted]

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[Redacted]

Chief

ADMINISTRATIVE LAW JUDGE

Channing D. Strother